

## THE STARK LAW AND THE COMPLIANCE PROFESSIONAL

Larry Vernaglia, JD, MPH, Partner, Foley & Lardner LLP  
Lisa Ohrin Wilson, JD, Senior Technical Advisor, Centers for Medicare & Medicaid Services

*Today's Most Vexing Problems*

---

---

---

---

---

---

---

---

### Disclaimers

- The opinions expressed today are the personal opinions of the speakers and not the official position of any governmental or law enforcement agency or any individual client

---

---

---

---

---

---

---

---

### Today's Presentation

- Top 3 Vexing Stark Law Problems for Compliance Professionals
  - "Ministerial" noncompliance
  - Leasing arrangements
  - Payments to physicians in leadership roles
- Disclosing noncompliance with the Stark Law to the government
- What's new and what's on the horizon

---

---

---

---

---

---

---

---

### Top 3 Vexing Stark Law Problems for Compliance Professionals



---

---

---

---

---

---

---

---

### The Stark Law's Prohibitions

- Unless an exception applies and its requirements are satisfied, a *physician* may not refer:
  - Medicare beneficiaries
  - For designated health services (DHS)
  - To an entity with which the physician or an immediate family member has
  - A financial relationship
- Unless an exception applies and its requirements are satisfied, an entity may not submit a claim to the Medicare program for DHS furnished pursuant to a prohibited referral

---

---

---

---

---

---

---

---

### Common Elements Necessary for Compliance with the Stark Law

- Arrangement must be in writing and signed by the parties
- Arrangements must have a 1-year duration
- Compensation must be set in advance and fair market value
- Compensation must not be determined in a manner that varies with or takes into account the volume or value of referrals or other business generated between the parties
- Arrangements must be commercially reasonable, even in the absence of referrals
- This list is not exclusive, and not all requirements exist in every exception to the Stark Law

---

---

---

---

---

---

---

---

### Ministerial Noncompliance



---

---

---

---

---

---

---

---

### What is Ministerial Noncompliance?

- Missing signatures
- Insufficient writing
  - Is this really "ministerial" or is it substantive noncompliance?
- Holdovers beyond what is permitted by the Stark Law



---

---

---

---

---

---

---

---

### CY 2016 Physician Fee Schedule Revisions to Stark Regulations

- Purpose of the updates to the Stark regulations in the Medicare Physician Fee Schedule (PFS) for CY 2016 (the "Final Rule"):
  - Accommodate delivery and payment system reform
  - Reduce burden
  - Facilitate compliance
- 80 Fed. Reg. 70886 (Nov. 16, 2015)
- Correction Notice; 81 Fed. Reg. 12024 (Mar. 8, 2016)
  - Made minor typographical corrections and included inadvertently omitted word(s) in regulation text

---

---

---

---

---

---

---

---

### Significant Issues Addressed in CY 2016 PFS

- Clarifications
  - Existing policy
  - Additional explanation where it appears stakeholders would benefit from clarification
- New exceptions (effective January 1, 2016)
  - Assistance to a physician to compensate a non-physician practitioner
  - Timeshare arrangements
- Revisions to existing definitions, exceptions, and other rules (effective January 1, 2016)
  - Signature requirements
  - Holdover arrangements
  - Renewing arrangements that qualify for the exception for fair market value compensation

---

---

---

---

---

---

---

---

### The Writing Requirement

- **Standard:** “[T]he relevant inquiry is whether the available contemporaneous documents (that is, documents that are contemporaneous with the arrangement) would permit a reasonable person to verify compliance with the applicable exception at the time that a referral is made” (80 FR 71315)
- **Single “formal contract” not required:**
  - Collection of documents may satisfy the writing requirement
  - Collection of documents may include “contemporaneous documents evidencing the course of conduct between the parties” (80 FR 71315)
  - Note: Single signed written contract is the best practice and the best way to ensure compliance
- **Relationship of documents in a collection:**
  - Documents in the collection must clearly relate to one another
  - Document must clearly evidence one and the same arrangement between the parties

---

---

---

---

---

---

---

---

### The Writing Requirement (cont.)

- **Signature requirement, as applied to a collection of documents:**
  - Signature is required on a contemporaneous writing documenting the arrangement
- **Relation to State law**
  - State law principles are not dispositive in determining compliance with the writing and signature requirements of the physician self-referral law
  - Parties may look to state law to INFORM the analysis of whether an arrangement is in writing and signed by the parties
- **Clarification of existing policy**
  - Guidance regarding the writing requirement is a clarification of existing policy

---

---

---

---

---

---

---

---

### The 1-year Term Requirement

- **Clarification:**
  - Formal "term" provision in a contract not required to satisfy requirement
  - Arrangement with a duration of at least 1 year as a matter of fact satisfies the requirement
- **Written documentation of the term/duration:**
  - Contemporaneous documents establishing that the arrangement lasted for at least 1 year, or
  - If the arrangement is terminated during the 1st year, a party must be able to demonstrate that the parties did not enter into a new arrangement for the same space, equipment, or services during the 1st year

---

---

---

---

---

---

---

---

### Leasing Arrangements




---

---

---

---

---

---

---

---

### Office Space

- CMS policy: Office space is neither an "item" nor a "service."
  - Despite a contrary statement in Phase II, CMS later clarified that it does "not believe that the lease of office space is an 'item or service'"
  - Phase III; 72 Fed. Reg. 51012, 51059 (Sep. 5, 2007)
- CMS policy: Where control over office space is conferred on a party such as to give that party a "right against the world" (including a right against the owner or sub-lessor of the office space), the arrangement must qualify for the exception for the rental of office space at 42 CFR 411.357(a) in order not to run afoul of the physician self-referral law
  - CY 2016 PFS Final Rule; 80 Fed. Reg. at 71328
- CMS policy: Indirect compensation arrangements between a DHS entity and a physician for the rental of office space must satisfy the requirements of the exception at 42 CFR 411.357(p)

---

---

---

---

---

---

---

---

### Are Other Exceptions to the Stark Law Available to Protect the Lease of Office Space?

16

- “[W]e do not believe that Congress meant for the ‘items or services’ exception to cover a rental agreement as a service that a physician might purchase, when it has already included in the statute a specific rental exception, with specific standards, in section 1877(e)(1)”
  - 1998 Proposed Rule; 63 Fed. Reg. at 1703
- “In Phase III, we declined to permit office space leases to be eligible for the exceptions for fair market value compensation at § 411.357(l) and payments by a physician at § 411.357(i). . . . Our position regarding the availability of [these exceptions] for arrangements involving the rental of offices space has not changed”
  - CY 2016 PFS Final Rule; 80 Fed. Reg. at 71327

---

---

---

---

---

---

---

---

### Timeshare Arrangements

17

- Covers premises “use” arrangements only
- Does not cover traditional office space leases
- The arrangement may not convey a possessory leasehold interest in the office space that is the subject of the arrangement (42 CFR 411.357(y)(9))

---

---

---

---

---

---

---

---

### Non-office Space and the Stark Law

18

- Non-office space
  - Residential space
  - Storage space
  - Commercial space
- Which exceptions to the Stark Law are applicable?
  - Payments by a physician
  - Fair market value compensation
  - Indirect compensation arrangements
  - Timeshare arrangements

---

---

---

---

---

---

---

---

### Payments to Physicians in Leadership Roles



---

---

---

---

---

---

---

---

### Leadership Roles

- Medical Directors – old news
- Special one-offs (health fair, Football game physicians)
- Clinical Committees:
  - ACOs
  - EHR roll-out
  - Shared savings programs
- Board of directors
- And don't forget the "immediate family members" in those roles!

---

---

---

---

---

---

---

---

### Leadership Roles

- Options:
  - 1. What entity actually paid? Is financial relationship with a DHS entity?
  - 2. In scope of employment? (or other arrangement?)
  - 3. Available documentation to prove person services arrangement:
    - Letter agreements, offer letters, emails? (Some arrangements are longstanding)
    - Minutes, Bylaws, Charters, Website?
  - 4. Isolated Transaction
  - NOT for non-monetary compensation or medical staff incidental benefits

---

---

---

---

---

---

---

---

### Disclosing Noncompliance with the Stark Law to the Government



---

---

---

---

---

---

---

---

### Options for Self-disclosure

- CMS' Self-Referral Disclosure Protocol (SRDP)
  - Only available for violations of the Stark Law
    - Not available routine billing noncompliance
    - Not available where violations of anti-kickback statute are present
- OIG's Self-Disclosure Protocol (SDP)
  - Not available for Stark Law-only violations
  - Must have anti-kickback statute violation
- United States Attorney
- Medicare Administrative Contractors
  - Must refund 100% of the overpayment; no compromise authority with respect to Stark Law violations

---

---

---

---

---

---

---

---

### SRDP History and Timeline

- Affordable Care Act (March 23, 2010); §6409 provided authority for the compromising of overpayments resulting from noncompliance with the physician self-referral law and required the establishment of the SRDP
- September 23, 2011 – initial SRDP was posted and became effective
  - May 2, 2014 – CMS published in the Federal Register its intent to adopt an optional "expedited SRDP review process"
- August 26, 2014 – OMB approved a renewal of the existing "standard" SRDP and an expedited process
- December 23, 2014 – CMS updated the SRDP to require that submissions should be made electronically only
  - Exception: hard copies of signed certifications must be provided

---

---

---

---

---

---

---

---



### SRDP History and Timeline (cont.)

- March 2015 – CMS posted process for disclosures involving only noncompliance with the ACA requirement that a physician-owned hospital (POH) must disclose such physician ownership or investment on the hospital's website and in its advertising
- February 2016 – CMS issued final overpayment rule (effective March 14, 2016) requiring a 6-year lookback period
  - Current SRDP uses a timeframe that follows the prior reopening rules
  - Effectively, a 4-year lookback period
  - Existing OMB collection of information approval does not sync with final overpayment rule's 6-year lookback period
- March 16, 2016 – CMS posted an FAQ regarding disclosures on or after March 14, 2016 to address 6-year lookback period (web page currently under revision)
- March 27, 2017 – CMS posted the updated SRDP and forms for use in disclosing noncompliance under the physician self-referral law
  - Use of forms is mandatory for all disclosures submitted on or after June 1, 2017

---

---

---

---

---

---

---

---

---

---

### CMS Settlement Activity under the SRDP

Calendar Year	Number of Disclosures Settled	Range of Amounts of Settlements	Aggregate Amount of Settlements
2011	3	\$60 - \$579,000	\$709,060
2012	14	\$1,600 - \$584,700	\$1,236,200
2013	24	\$760 - \$317,620	\$2,468,348
2014	41	\$3,322 - \$463,473	\$5,175,168
2015	49	\$5,081 - \$815,405	\$6,706,458
2016	102	\$80 - \$1,195,763	\$6,913,988
<b>Totals</b>	<b>233</b>	<b>\$60-\$1,195,763</b>	<b>\$23,209,222</b>

NOTES:  
 As of December 31, 2016, an additional 92 disclosures to the SRDP were withdrawn, closed without settlement or settled by CMS' law enforcement partners.  
 Because disclosures of actual or potential violations of the physician self-referral law include proprietary, confidential, or otherwise nondisclosable information, we present settlement information on an aggregate basis.

---

---

---

---

---

---

---

---

---

---

### State of the SRDP

- As of July 31, 2017
  - Total disclosures received: 941
    - Includes 83 POH website and advertising disclosures
  - Total disclosures settled in SRDP: 263
  - Total disclosures withdrawn or closed without administrative resolution in the SRDP: 112
  - Total disclosures currently under active review: 139
    - Small number of disclosures (8) on hold
  - Percentage of disclosures settled, closed or withdrawn: 40.0%
  - Percentage of remaining disclosures under active review: 24.6%

---

---

---

---

---

---

---

---

---

---

### CY 2016 PFS Clarifications and Regulatory Revisions

#### Impact on SRDP submissions

- Parties considering submitting a disclosure to the SRDP for conduct that predates the proposed rule may rely on guidance provided in the proposed rule to determine compliance with the writing requirement
- Parties that have already submitted disclosures to the SRDP (but not yet settled the matter with CMS) may also rely on guidance provided in the proposed rule regarding the writing requirement; parties may amend or withdraw previously submitted disclosures as appropriate

---

---

---

---

---

---

---

---

### Self-Disclosure Protocol Lookback Period

- Q: . . . How does the 6-year lookback period apply to disclosures submitted to the SRDP?
- A: Self-referral overpayments reported to CMS in accordance with the SRDP prior to March 14, 2016 are not governed by the 6-year lookback period specified in the final overpayment rule. This includes both overpayments reported and returned (via compromise and settlement) as well as those reported and still in the process of being reviewed through the SRDP. Providers and suppliers that reported self-referral overpayments to the SRDP prior to March 14, 2016 are not expected to return overpayments from the fifth and sixth years.
- Providers and suppliers reporting overpayments to the SRDP on or after March 14, 2016 are subject to the 6-year lookback period specified in the final overpayment rule. However, at this time, CMS is only authorized under the Paperwork Reduction Act to collect financial analysis of overpayments that occurred during a 4-year time frame. In connection with the final overpayment rule, we are seeking authorization from the Office of Management and Budget (OMB) to collect financial information regarding overpayments using the 6-year lookback period. Until the revised collection is approved by OMB, providers and suppliers reporting overpayments to CMS in accordance with the SRDP have no duty to provide financial information from the fifth and sixth years, that is, the 2 years outside of the currently authorized 4-year time frame. Accordingly, until notification of changes to the SRDP, providers and suppliers submitting to the SRDP may voluntarily provide financial information from the fifth and sixth years or report and return overpayments from the fifth and sixth years through other means.

---

---

---

---

---

---

---

---

### What's New and What's on the Horizon




---

---

---

---

---

---

---

---

### Per-click Leases

- 31  CMS finalized per-click leasing limitations in the CY 2017 Physician Fee Schedule
  - ▣ 81 Fed. Reg. 80170, 80524-366 (November 15, 2016)
- The final regulations are identical to those effective October 1, 2009
  - ▣ 73 Fed. Reg. 48434, 48688-740 (Aug. 19, 2008)
- Regulations and rationale issued in response to Court Order in *Council for Urological Interests v. Burwell*, 790 F.3d 212 (D.C. Cir. 2015)

---

---

---

---

---

---

---

---

### Emanuele Summary Judgment Order

- 32  All violations of the Stark Law are material to the government's determination whether to pay a claim
- 

---

---

---

---

---

---

---

---

### Individual Liability

- 33  Former Tenet Healthcare executive, John Holland, is facing criminal charges for implementing a health care fraud scheme involving kickbacks in exchange for referrals and misleading federal authorities about the company's billing practices
  - ▣ Tenet Healthcare settled the allegations against the company for \$514M in 2016
- Former Tuomey Healthcare System CEO to pay \$1M to settle claims arising from his involvement in the hospital's violations of the Stark Law
  - ▣ Ralph Cox III will also be excluded from federal health care programs for 4 years
  - ▣ Government alleged that Cox caused the hospital to enter into arrangements with 19 physicians that violated the physician self-referral law

---

---

---

---

---

---

---

---

### Recent Settlements and Prosecutions of Stark Law and/or Anti-kickback Statute Violations

34

- University Behavioral Health of El Paso paid \$860K under a civil settlement to resolve allegations that the organization submitted false claims to Medicare that were tainted by the payment of kickbacks to a physician under the guise of a professional services agreement (entered into by previous owner) and that the payments were above fair market value or for services not furnished
- Tenet Healthcare Corporation and two of its Atlanta-area subsidiaries agreed to pay \$51.3M to resolve criminal charges and civil claims relating to a scheme to defraud the United States and pay kickbacks in exchange for patient referrals
  - The subsidiaries agreed to plead guilty to conspiracy to defraud the United States and to pay health care kickbacks and bribes in violation of the anti-kickback statute, and will forfeit \$1.45M to the United States (the amount paid to the two subsidiaries by the Medicare and Medicaid programs for services provided to patients as part of the scheme)
  - Tenet Healthcare Corporation will pay \$368M to resolve the civil claims originating in a whistleblower action
  - The government stated that this is the first case brought through the assistance of the DOJ Criminal Division's corporate health care fraud strike force and is one of a dozen active corporate investigations by the strike force

---

---

---

---

---

---

---

---

---

---

### Recent Settlements and Prosecutions of Stark Law and/or Anti-kickback Statute Violations

35

- Lexington Medical Center agreed to pay \$17M to resolve allegations of improper billings resulting from violations of the physician self-referral law related to its purchase of certain physician practices
  - Whistleblower and government alleged that the purchase prices took into account the volume or value of physician referrals, were not commercially reasonable, or provided compensation in excess of fair market value
- Dr. Asad Qamar and his medical practice, the Institute of Cardiovascular Excellence, agreed to pay \$5.3M to resolve allegations that they improperly billed federal health care programs
  - Allegations include billing for medically unnecessary and inadequately documented peripheral artery interventional services and related procedures
  - Allegations include paying kickbacks to patients by routinely and indiscriminately waiving Medicare copayments irrespective of the patient's financial need
  - Dr. Qamar will be excluded from participation in any federal health care program for 3 years, followed by a 3-year integrity agreement with OIG

---

---

---

---

---

---

---

---

---

---

### Recent Settlements and Prosecutions of Stark Law and/or Anti-kickback Statute Violations

36

- OURLab, OPKO Health and OPKO Lab together agreed to pay \$9.35M to resolve allegations that their donations toward electronic health records (EHR) systems purchased by their client physician practices violated the anti-kickback statute and the physician self-referral law
  - Government alleged that OURLab, OPKO Health and OPKO Lab directly considered the volume or value of referrals and business when determining whether to make an EHR donation and the amount of a donation; improperly considered the volume of Medicare business supplied by a physician practice when considering an EHR donation; and occasionally withheld previously agreed-upon donation payments until the lab(s) received a certain number of referrals from a physician's practice
  - *First precedent for abuse of the EHR safe harbor and physician self-referral law exception*

---

---

---

---

---

---

---

---

---

---

**Recent Settlements and Prosecutions of Stark Law  
and/or Anti-kickback Statute Violations**

- Following a self-disclosure to the United States Attorney Office, Tri-City Medical Center agreed to pay \$3.2M to settle allegations that it submitted false claims to the Medicare program because it violated the physician self-referral law by entering into certain arrangements with its former chief of staff that appeared not to fair market value for the services furnished or not commercially reasonable
  - The hospital also identified 92 financial relationships with community-based physicians that did not satisfy the requirements of an applicable exception, primarily due to expiration of the agreements or lack of written documentation of the arrangement

---

---

---

---

---

---

---

---