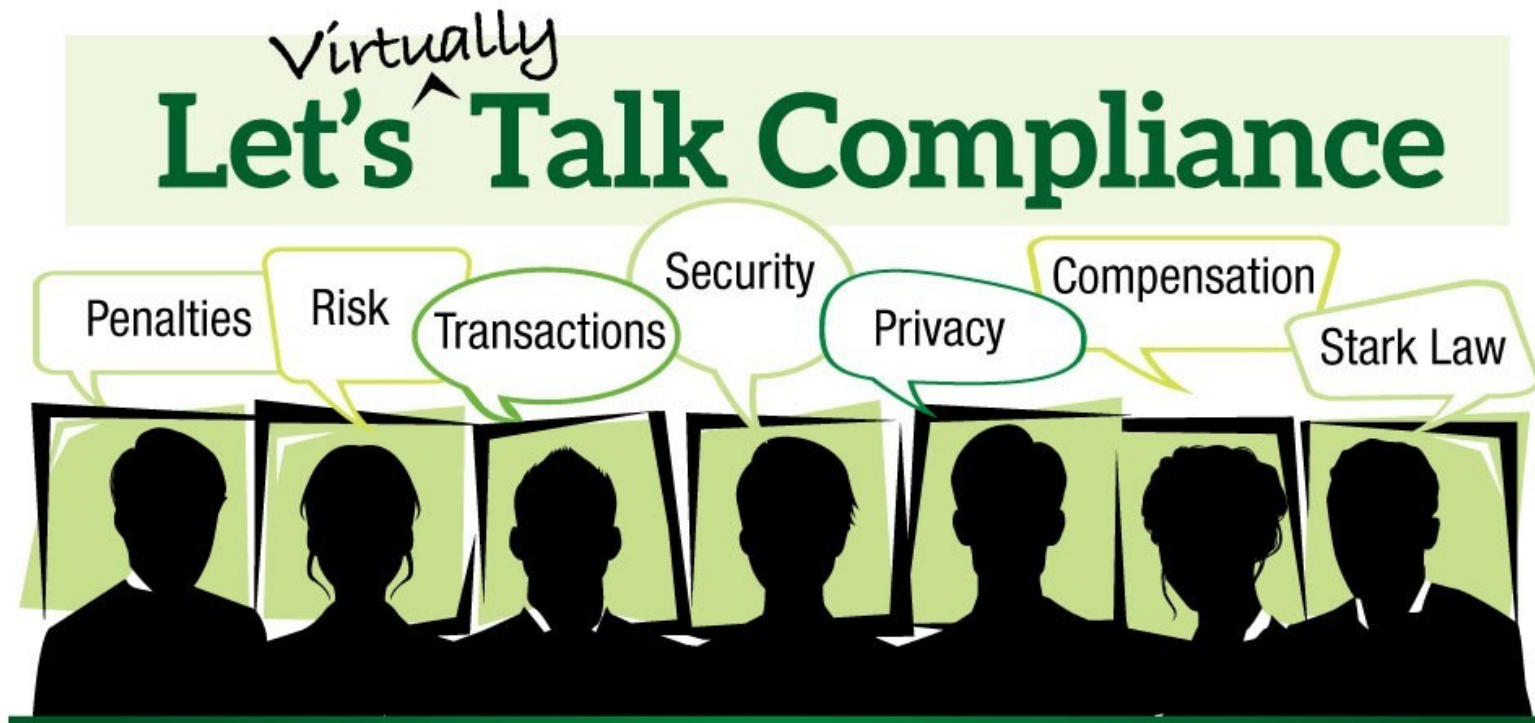


Let's Talk Compliance

One-Day Compliance Master Class



A group of professionals, including a man in a suit and a woman with glasses, are seated around a wooden table in a meeting. They are looking at documents and a laptop. There are coffee cups and a notebook on the table. The scene is brightly lit, suggesting an indoor setting with large windows.

SESSION #4

Physician Compensation: Hot Topics

Jana Kolarik & Angie Caldwell

Agenda

1. Regulatory Landscape Update

- Compliance risk for all healthcare organizations
- Stark Law
- Anti-Kickback Statute
- CMS Final Rules

2. Recent Settlements and Cases

- Problematic areas
- Comparison of conclusions under revised guidance



These Organizations Have Something In Common

- Texas Heart Hospital - \$48 million
- Medtronic - \$9.2 million
- Merit Medical Systems - \$18 million
- Wheeling Hospital - \$50 million
- Oklahoma Center for Orthopaedic and Multi-Specialty Surgery - \$72.3 million
- Novartis - \$642 million



Regulatory Guidance, Summarized

Law	Translation
False Claims Act	Don't lie to the government
Civil Monetary Penalties	Seriously, don't lie or do the other stuff below
Anti-kickback Statute	Don't get or give stuff in return for referring patients or for the purchase, order, lease or arranging for or recommending the purchase... (all FHCPs, criminal and applicable to all in the healthcare stream of commerce)
Stark Law	Don't give stuff in return for the referral of patients or the generation of business (Medicare, civil and physicians)

Stark Law Overview

- Prohibition:

The Stark Law provides that “a physician who has a direct or indirect financial relationship with [a Designated Health Service or ‘DHS’] entity, or who has an immediate family member who has a direct or indirect financial relationship with the DHS entity, may not make a referral for the furnishing of a DHS for which payment otherwise may be made under Medicare,” unless an exception applies.

- Further, an entity that furnishes DHS pursuant to a prohibited referral may not present or cause to be presented a claim or bill to the Medicare program or to any individual, third party payer, or other entity for the DHS performed pursuant to the prohibited referral, unless an exception applies.



Stark Law Overview (continued)

- Civil statute
- Strict liability (intent is irrelevant)
- Covers relationships with **physicians** (and physicians' immediate family members)
- If Stark is implicated, an exception must be met
- Potential penalties
 - Payment denial or recoupment
 - CMPs of up to \$15,000 per prohibited service (\$25,820 for 2020)
 - Exclusion
 - Circumvention scheme – Up to \$100,000 per claim (\$172,137 for 2020)
 - Liability under False Claims Act



Stark Law – What Changed in 2021?

- Formalization of the “Big 3”
 - Fair Market Value (FMV)
 - Commercial Reasonableness (CR)
 - Volume/Value (V/V)
- Value-Based Care Exceptions (3 options)
- Other Changes
 - New Limited Remuneration to a Physician Exception
 - New Cybersecurity Technology & Related Services Exception
 - Revisions to Indirect Compensation Arrangement Definition
 - Revisions to Group Practices Provisions (effective 1/1/2022)



Stark Law – What Changed in 2021?

- Other Changes (Continued)
 - Removal of the Period of Disallowance Provisions & New Special Rule for Reconciling Compensation Arrangements
 - Additional Revisions to Special Rules on Compensation
 - New Patient Choice & Directed Referrals Provision
 - Revisions to EHR exception
 - Revision to FMV Exception
 - Clarification of Office Space & Equipment Lease Exceptions (exclusive use concept)

Stark Law – The “Big 3”

CMS eliminated references to V/V in the definition of FMV, setting it apart as its own element of determining compliance with an exception.

- FMV – Did the calculation result in compensation that is FMV for an asset item, service, or rental property?
- CR – Does the arrangement make sense as means to accomplish the parties’ goals?
- V/V – How did the parties calculate the remuneration?



Stark Law – The “Big 3” – V/V

CMS developed a two-part test to determine whether an arrangement meets the V/V standard.

1 – Does a mathematical physician compensation formula exist that includes DHS referrals or other business generated as a variable?

2 – If the answer to #1 is yes, then does a physician’s compensation increase or decrease based on a positive or negative correlation with the physician’s referrals or other business generated?



Stark Law – Value-Based Care Exception

- Much anticipated
- But first, definitions:
 - Value-Based Enterprise (“VBE”), Value-Based Participant
 - Value-Based Arrangement
 - Target Patient Population (“TPP”)
 - Value-Based Purpose
 - Value-Based Activity



Stark Law – Value-Based Care Exception (continued)

- To meet exception, Option 1 –
 - Be at *Full Financial Risk* (or is contractually obligated to be a full financial risk within 12 months) – includes the cost of **all** patient care items and services covered by the applicable payer for each patient in the TPP
 - Payment is for results of Value-Based Activity for patients of the TPP
 - Payment is not an inducement to reduce or limit necessary items or services
 - Payment is not conditioned on referrals of patients *who are not part of* the TPP or business not covered by the Value-Based Arrangement



Stark Law – Value-Based Care Exception (continued)

- To meet exception –
 - If payment is conditioned on referrals of patients in the TPP, it must pass a 2-part test:
 - The requirement to make referrals (to a provider, practitioner, or supplier) is set out in writing and signed by the parties
 - The requirement to make referrals does not apply if the patient otherwise expresses a preference, the patient’s insurer determines the preference, or the referral is not in the patient’s best interest
 - Keep documentation supporting payments for a minimum of six years

Stark Law - Value-Based Care Exception (Continued)

- To meet exception, Option 2 –
 - Be at *Meaningful Downside Risk* during the entire duration of the VB arrangement – physician is responsible to repay or forgo no less than 10% of the total value of the payment the physician receives under the VB Arrangement
 - Downside risk is in writing
 - Methodology used to determine the payment is set in advance of the undertaking of VB Activities
 - All other requirements same as Full Financial Risk



Stark Law - Value-Based Care Exception (Continued)

- To meet exception, Option 3 – arrangement is set forth in writing and signed by the parties and includes a description of
 - A. the VB activities to be undertaken under the arrangement,
 - B. how those activities are expected to further the VB purposes of the VBE;
 - C. the target patient population for the arrangement;

Stark Law - Value-Based Care Exception (Continued)

- To meet exception, Option 3 – arrangement is set forth in writing and signed by the parties and includes a description of: (cont.)
- D. the type/nature of the (monetary or nonmonetary) remuneration;
- E. the methodology used to determine the remuneration; and
- F. the outcome measures against which the recipient of the remuneration is assessed (if any).

Value-Based Exception Option 3

- “Outcome measure” means a benchmark that quantifies:
 - A. Improvements in or maintenance of the quality of patient care; or
 - B. Reductions in the costs to or reductions in growth in expenditures of payors while maintaining or improving the quality of patient care.

A Word About Outcome Measures...

- To meet exception –
 - Outcome Measures must be:
 - Objective, measurable, and selected based on clinical evidence or credible medical support
 - Changes to the measures are made prospectively and in writing
 - Methodology for determining amount of payment is set in advance of the undertaking of Value-Based Activities
 - Remuneration is for results from Value-Based Activities of the physician for patients in the TPP
 - The arrangement is CR

A Word About Outcome Measures...

- To meet exception –
 - Outcome measures must be:
 - Monitored at least annually by the VBE, including
 - Did the parties provide the Value-Based Activities
 - If and how the continuation of the Value-Based Activities furthers the Value-Based Purpose(s) of the VBE
 - Progress was made toward achievement of the Outcome Measures
 - If monitoring indicates a Value-Based Activity is not expected to further the Value-Based Purpose(s), then the ineffective Value-Based Activity must be terminated (30 days to terminate; 90 days to modify).
 - If the Outcome Measure is unattainable, the parties must terminate or replace the Outcome Measure within 90 days.

Value-Based Exception – What is Missing?

- FMV
- V/V

However, this does not remove the requirement to “stack” value-based compensation in an employment (or other) arrangements.

Anti-Kickback Statute Overview

- The Anti-Kickback Statute (“AKS”)
 - provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit or receive remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in order to induce the referral OR the purchase, lease, order or arrangement for OR recommending the purchase, lease, order or arrangement for any good, facility, service or item paid in whole or in part under the Federal health care programs.
- Criminal statute
- Intent-based – “One purpose” test
- Covers all types of arrangements, not just physician arrangements

Anti-Kickback Statute Overview (continued)

- Statutory exceptions and regulatory safe harbors are voluntary
 - OIG Advisory Opinions, Special Fraud Alerts and Bulletins offer guidance
- Potential penalties
 - Maximum penalties increased in 2018 from \$25,000 to \$100,000
 - Maximum jail time doubled in 2018 from 5 Years to 10 Years
 - CMPs of up to \$15,000 per prohibited service
 - Exclusion
 - Liability under false claims act



Anti-Kickback Statute – What Changed in 2021?

- Value-Based Care Delivery Safe Harbors
 - Vary in terms of the type of remuneration that can be provided, the level of financial risk the parties assume (full, substantial downside & no risk), and the types of safeguards required.
 - Narrower than the Stark Law exceptions – e.g., no risk exception requires (1) remuneration exchanged be in-kind only and that participants must contribute 15% of the offeror's costs or the FMV of the remuneration and (2) one of the VB purposes of the VBE be coordination and management of the care of the TPP.
 - OIG prohibits the following entities from being able to rely on the VB safe harbors: (1) pharmaceutical manufacturers, distributors and wholesalers, (2) PBMs, (3) laboratories, (4) compounding pharmacies, and (5) medical device and supply distributors and wholesalers.



Anti-Kickback Statute – What Changed in 2021?

- Provided New Safe Harbors

- Patient engagement & support safe harbor to protect certain tools and support to patients in order to improve quality, health outcomes and efficiency.
 - This safe harbor is only available for VBE participants.
 - In-kind remuneration only with a \$500 annual cap (adjusted for inflation) among other requirements
- CMS-sponsored models safe harbor to protect certain remuneration in connection with CMS models, reducing the need for HHS to issue individualized fraud and abuse waiver for each model.

Anti-Kickback Statute – What Changed in 2021?

- Provided New Safe Harbors
 - Cybersecurity technology and services safe harbor
 - ACO Beneficiary Incentive Program – OIG codified the BBA of 2018 statutory exception for ACO Beneficiary Incentive programs for the Medicare Shared Savings Program.
 - Telehealth for In-Home Dialysis – OIG finalized its proposal to interpret and incorporate the BBA of 2018 statutory exception for furnishing telehealth technologies to certain in-home dialysis patients.



Anti-Kickback Statute – What Changed in 2021?

- Modified Safe Harbors

- **Personal services & management contracts safe harbor revisions removed the aggregate compensation set-in-advance requirement and the part-time schedule requirement. OIG also created at (d)(2) a new outcomes-based payments safe harbor to protect payments, outside of the VBE context, for the achievement of one or more legitimate outcomes measures that were selected based on clinical evidence or credible medical support to improve quality, reduce costs (but not solely internal costs) or both.



Anti-Kickback Statute – What Changed in 2021?

■ Modified Safe Harbors

- Local transportation safe harbor – distance extended to 75 miles in rural areas (from 50).
- EHR safe harbor – similar revisions as CMS.
- Warranties safe harbor – expanded to protect warranties covering a bundle of one or more items and related services. Bundled items and services must be reimbursed by the same FHCP and payment. Manufacturers can structure warranties to guaranty product performance in conjunction with services intended to enhance clinical effectiveness.



Stark Law v. Federal Anti-kickback Statute

Stark Law	Anti-kickback Statute
Regulated by CMS	Regulated by OIG
Prohibits referrals where a financial relationship exists	Prohibits payments intended to induce referrals/other business
Civil penalties only	Criminal and civil penalties
Strict liability	"Intent"
Applies only to physicians/physicians immediate family members	Applies to anyone who offers/gives, requests/accepts remuneration in exchange for a referral/other business
Mandatory exceptions	"Voluntary" safe harbors
Has a self-disclosure protocol	Has a self-disclosure protocol

2021 Medicare Physician Fee Schedule

- Reimbursement changes
- wRVU changes, resulting in compensation changes
 - Employment
 - Professional Services Agreements
- Items for organizational focus
 - Availability of contract provisions allowing changes to compensation due to payer reimbursement changes
 - Financial impacts
 - Documentation of commercial reasonableness



A Look Into Certain Cases

Wheeling Hospital

Oklahoma Center for Orthopaedic and
Multi-Specialty Surgery

Merit Medical Systems

Wheeling Hospital

- Claim: Wheeling Hospital and its management company (R&V Associates, Ltd.) inflated salaries of employed physicians to capture patient referrals
 - High physician compensation despite operating losses
 - Management team catered to physicians whose referrals were most lucrative to the Hospital, with internal communications describing the dollar value of downstream referrals to the Hospital alongside compensation determinations

Wheeling Hospital, continued

- Stark Law, AKS, and FCA implicated
- Wheeling Hospital settled for \$50 million
- Would this outcome change under the new Stark Law guidance?
 - Opportunity to reframe arguments around financial losses, but
 - Documentation linking referrals and compensation would be difficult to defend

Oklahoma Center for Orthopaedic and Multi-Specialty Surgery

- Claim: OCOM (and part-owner & management company (USP)) provided improper remuneration to the physician group (SOS) and certain of its physicians in exchange for referrals to OCOM
 - Free or below-FMV office space, employees, and supplies
 - Compensation in excess of FMV
 - Equity buyback provisions and payments that exceeded FMV
 - Preferential investment opportunities in connection with the provision of exclusive anesthesia services at OCOM, resulting in anesthesia company profits distributed to physician owners in a manner related to V/V



Oklahoma Center for Orthopaedic and Multi-Specialty Surgery (cont.)

- Stark Law, AKS, and state and federal FCA (Medicare, Medicaid and TRICARE) implicated
- Resolves allegations between 2006 and 2018 (12 years)
- USP paid \$60.86M to the United State, \$5M to Oklahoma and \$206K to Texas. SOS and 2 of its physicians paid \$5.7M to the United States and \$495,619 to Oklahoma.
- OCOM & SOS entered 5-year CIAs.
- Would this outcome change under the new Stark Law or AKS guidance? **No, linkage of referrals and compensation would be difficult to defend**



Merit Medical Systems

- **Claim:** MMS, a medical device maker, engaged in a kickback scheme to pay physicians, medical practices, and hospitals for use of MMS products
 - Provided remuneration in the form of millions of dollars of free advertising assistance, practice development and practice support, all-expense paid trips, and “educational grants” for over 6 years
 - To induce providers to purchase & use a variety of products including devices used for uterine fibroid embolization procedures.
 - Remuneration provided only to select providers to reward past sales, induce future sales, and block competitors
 - Organization ignored the warnings of its Chief Compliance Officer that conduct may violate the AKS



Merit Medical Systems, continued

- AKS and FCA implicated (Medicare, Medicaid & TRICARE)
- MMS settled for \$18 million (\$15.21M to the United States & \$2.79M to the various states) and a 5-year CIA
- Would this outcome change under the new Stark Law guidance?
 - No, linkage of referrals and remuneration would be difficult to defend

Thank you.

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Jana has worked with the spectrum of health care entities from academic medical centers (AMCs) to device and pharmaceutical manufacturers. She currently works with AMCs, health systems, community hospitals, large physician groups, physician and midlevel management and staffing companies, DME suppliers, orthotics suppliers and imaging companies, as well as investors in health care entities. Jana is a member of the Health Care Industry Team and the Government Enforcement Defense & Investigations Practice.





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Angie consults with physician practices and healthcare systems in the areas of fair market value compensation, commercial reasonableness, and contract compliance. She advises clients relative to physician/hospital economic alignment models and assists physician practices with strategic, financial, and operational issues. Angie also provides a full range of auditing and review services for various entities, including hospitals, health systems, community mental health centers, health insurance companies, employee benefit plans, and not-for-profit organizations. Angie serves as principal-in-charge of PYA's Tampa office.

Angie is a graduate of Marshall University with a Bachelor of Business Administration degree in Accounting (magna cum laude), and a graduate of the University of Tennessee, Knoxville with a Master of Business Administration (first in class). Angie is a Certified Public Accountant, licensed in Tennessee and West Virginia.

Angie is a member of Association of Healthcare Internal Auditors (AHIA), American Health Lawyers Association (AHLA), Florida Institute of Certified Public Accountants (FICPA), and American Institute of Certified Public Accountants (AICPA).

