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Stark Compliance Audits in Hospital-Physician Arrangements: Mitigating Provider Liability

Implementing Monitoring Processes to Avoid Penalties, Denial of Payment, and CMS Program Exclusion

TUESDAY, MARCH 31, 2020

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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Tuesday, March 31, 2020 | 1:00 P.M. Eastern

Stark Compliance Audits in Hospital-Physician Arrangements: Mitigating Provider Liability

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Today's Webinar

Webinar Agenda

I. Introduction

II. The Current Regulatory Standards and Health Reform

III. Conducting a Stark Audit

IV. Special Fair Market Value (FMV) Considerations

V. Questions

Part I: Introduction

Introduction

Why Audit????

- The regulatory environment is evolving and challenging. Auditing puts a health care organization in the best position to develop and improve its strategy for defensibility:

- Auditing ensures the **"Big 3"** below stand on their own:
  - **Fair Market Value ("FMV")**
  - **Commercial Reasonableness ("CR")**
  - **Total compensation cannot "Taking Into Account" a provider's referrals (e.g., inpatient/outpatient hospital revenues)**

- Auditing helps health care organizations police each physician contract's internal record, confirm calculations and ensure alignment with contracting best practices.

Introduction

A Moving Target?? Reform & The Pandemic

HALL RENDER KILLIAN HEATH & LYMAN

HEALTH LAW NEWS

OCTOBER 22, 2019

THREE WAYS THE CMS PROPOSED STARK LAW CHANGES AFFECT SPACE LEASES

HEALTH LAW NEWS

OCTOBER 10, 2019

EHR DONATIONS AND CYBERSECURITY TECHNOLOGY EXCEPTION INCLUDED IN NEW PROPOSED RULES FROM OIG, CMS

HEALTH LAW NEWS

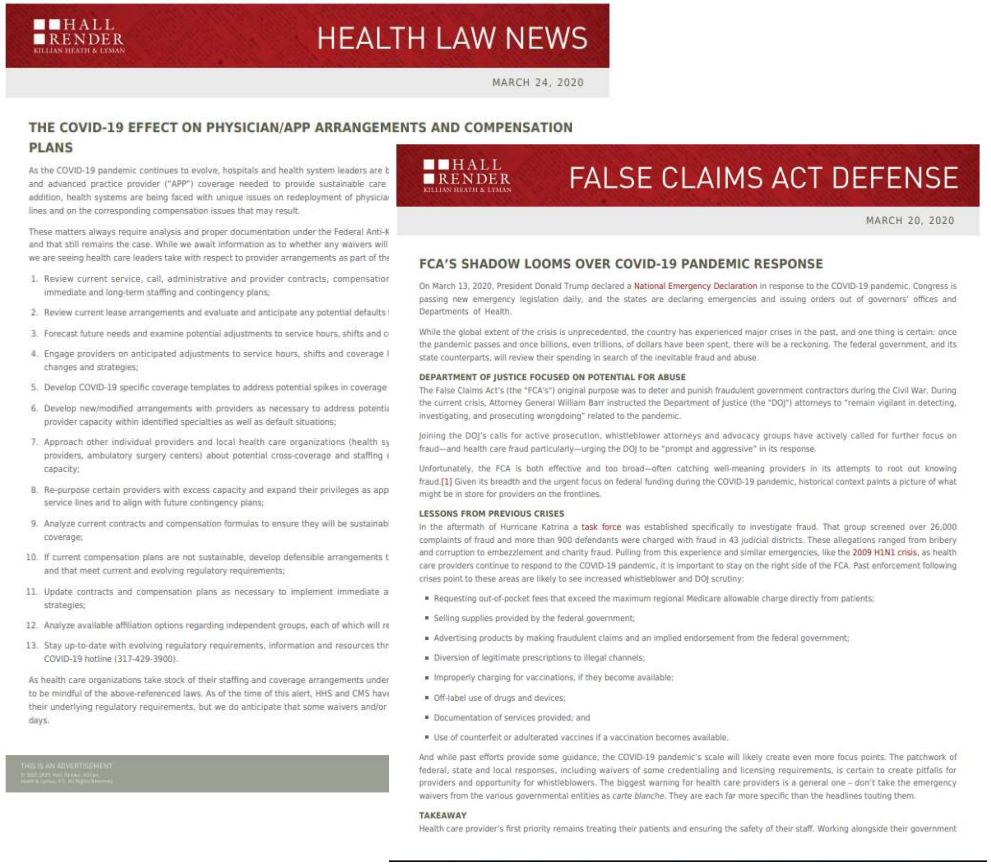
OCTOBER 10, 2019

CMS MAKES VALUE THE CENTERPIECE OF PROPOSED STARK RULES

HEALTH LAW NEWS

OCTOBER 09, 2019

SPRINTING TOWARD VALUE: OIG PROPOSES REGULATIONS BENEFITING PATIENTS AND PROVIDERS



HALL RENDER KILLIAN HEATH & LYMAN

HEALTH LAW NEWS

MARCH 24, 2020

THE COVID-19 EFFECT ON PHYSICIAN/APP ARRANGEMENTS AND COMPENSATION PLANS

FALSE CLAIMS ACT DEFENSE

MARCH 20, 2020

FCA'S SHADOW LOOMS OVER COVID-19 PANDEMIC RESPONSE

On March 13, 2020, President Donald Trump declared a National Emergency Declaration in response to the COVID-19 pandemic. Congress is passing new emergency legislation daily, and the states are declaring emergencies and issuing orders out of governors' offices and Departments of Health.

While the global extent of the crisis is unprecedented, the country has experienced major crises in the past, and one thing is certain: once the pandemic passes and once billions, even trillions, of dollars have been spent, there will be a reckoning. The federal government, and its state counterparts, will review their spending in search of the inevitable fraud and abuse.

DEPARTMENT OF JUSTICE FOCUSED ON POTENTIAL FOR ABUSE

The False Claims Act's (the "FCA's") original purpose was to deter and punish fraudulent government contractors during the Civil War. During the current crisis, Attorney General William Barr instructed the Department of Justice (the "DOJ") attorneys to "remain vigilant in detecting, investigating, and prosecuting wrongdoing" related to the pandemic.

Joining the DOJ's calls for active prosecution, whistleblower attorneys and advocacy groups have actively called for further focus on fraud—and health care fraud particularly—urging the DOJ to be "prompt and aggressive" in its response.

Unfortunately, the FCA is both effective and too broad—often catching well-meaning providers in its attempts to root out knowing fraud.[1] Given its breadth and the urgent focus on federal funding during the COVID-19 pandemic, historical context paints a picture of what might be in store for providers on the frontlines.

LESSONS FROM PREVIOUS CRISES

In the aftermath of Hurricane Katrina a task force was established specifically to investigate fraud. That group screened over 26,000 complaints of fraud and more than 900 defendants were charged with fraud in 43 judicial districts. These allegations ranged from bribery and corruption to embezzlement and charity fraud. Pulling from this experience and similar emergencies, like the 2009 H1N1 crisis, as health care providers continue to respond to the COVID-19 pandemic, it is important to stay on the right side of the FCA. Past enforcement following crises point to these areas are likely to see increased whistleblower and DOJ scrutiny:

- Requesting out-of-pocket fees that exceed the maximum regional Medicare allowable charge directly from patients;
- Selling supplies provided by the federal government;
- Advertising products by making fraudulent claims and an implied endorsement from the federal government;
- Diversion of legitimate prescriptions to illegal channels;
- Improperly charging for vaccinations, if they become available;
- Off-label use of drugs and devices;
- Documentation of services provided; and
- Use of counterfeit or adulterated vaccines if a vaccination becomes available.

And while past efforts provide some guidance, the COVID-19 pandemic's scale will likely create even more focus points. The patchwork of federal, state and local responses, including waivers of some credentialing and licensing requirements, is certain to create pitfalls for providers and opportunity for whistleblowers. The biggest warning for health care providers is a general one – don't take the emergency waivers from the various governmental entities as carte blanche. They are each far more specific than the headlines touting them.

TAKEAWAY

Health care provider's first priority remains treating their patients and ensuring the safety of their staff. Working alongside their government

Part II: The Current Regulatory Standards and Proposed Health Reform

The Current Regulatory Standards

The Fraud and Abuse Laws

The Anti-Kickback Statute (AKS)	The Stark Law	The False Claims Act
• Covers all Provider Contracts	• Covers all Physician Contracts	• Covers all claims reimbursed by the Government
• Total compensation must be consistent with FMV	• Total compensation must be consistent with FMV. Terms must be Commercially Reasonable	• Contracts must comply with AKS and Stark for an entity to receive reimbursement
• Contract and model should meet an AKS safe harbor	• Contract and model must meet a Stark exception	• Actions can be brought by whistleblowers

The Current Regulatory Standards

Stark Law = Strict Liability

- **If an <u>Entity</u> contracts with a <u>Physician</u>:**
  - The Physician **<u>may not make a Referral</u>** to the Entity for the furnishing of Designated Health Services ("**DHS**") for which payment may be made under Medicare; and
  - The Entity **<u>may not bill Medicare</u>**, an individual or another payor for the DHS performed pursuant to the prohibited referral…

  … unless the terms fit squarely within a <u>Stark exception</u>

- **Bottom Line.. all physician contracts <u>must</u> meet a Stark exception**
  - Strict liability – no intent required. Civil (non-criminal statute)
  - Triggered by "technical" violations, inadvertence and error

The Current Regulatory Standards

The Exceptions and Safe Harbors

Stark Exceptions

- Rental of Office Space
- Rental of Equipment
- Bona Fide Employment Relationships
- Personal Service Arrangements
- Physician Recruitment
- Isolated Transactions
- Non-Monetary Compensation
- Fair Market Value Compensation
- Medical Staff Incidental Benefits
- Indirect Compensation Arrangements
- Assistance to Compensate a Non-Physician Practitioner
- Timeshare Arrangements
- In-Office Ancillary Services (available for Stark Group Practices)

AKS Safe Harbors

- Investment Interests
- Space Rental
- Equipment Rental
- Personal Services and Management Contracts
- Sale of Practice
- Referral Services
- Warranties
- Discounts
- Employees
- Group Purchasing Organizations
- Practitioner Recruitment
- Ambulatory Surgery Centers
- Ambulance Replenishing

Proposed Health Reform

New Value-Based Framework

New Stark Exceptions

- ❑ Full financial risk
- ❑ Meaningful downside financial risk to the physician
- ❑ Value-based arrangements
- ❑ Indirect value-based arrangements

New AKS Safe Harbors

- ❑ Full financial risk
- ❑ Substantial downside financial risk (to the value-based enterprise)
- ❑ Care coordination to improve quality, health outcomes and efficiency
- ❑ Patient engagement and support

Proposed Health Reform

Proposed Changes to Stark

- New Limited Remuneration Exception
- New Cybersecurity Technology and Related Services Exception
- Limitations on the Isolated Financial Transaction Exception
- Deletion of the Period of Disallowance
- New 90 Day Rule for Preparing the Written Contract
- Revisions to the Definition of DHS
- Clarifications to FMV, Commercial Reasonableness and the Volume or Value Standards

The Regulatory Standards

Proposed Clarifications to Stark's "Big 3"

- Fair Market Value
- Commercial Reasonableness
- Can't "Take Into Account" DHS Referrals

Part III: Auditing Physician Contracts

Auditing Physician Contracts

The Employment Exception

- FMV remuneration required
- Compensation must not be determined in a manner that "takes into account" the volume or value of any DHS referrals by the referring physician.
- Agreement must be commercially reasonable "even if no referrals were made to the employer"
- No "in writing" requirement unless requiring or directing referrals

*Not all requirements listed.

Auditing Physician Contracts

The Rental Exceptions*

- The arrangement must be set out in a writing, and signed by the parties
- Duration of the lease arrangement must be at least 1 year
- Rental charges must be set in advance and be consistent with FMV
- Rental charges must not be determined in a manner that TIA the volume or value of any referrals or other business generated
- Space or equipment rented must be reasonable and necessary (CR)
- No per click or percentage-based formulas allowed
- Exclusive use required
- Special rules for allocating common area expenses
- If the lease arrangement expires after a term of at least 1 year, new writing clarification and/or indefinite holdover rules may apply

* Actually two exceptions. Not all requirements listed.

Auditing Physician Contracts

The Personal Services Exception

- The arrangement must be set out in a writing, and signed by the parties
- Duration of the arrangement must be at least 1 year
- Compensation must be set in advance and FMV
- Compensation must not be determined in a manner that TIA the volume or value of any referrals, or other business generated between the parties
- Aggregate services contracted for may not exceed those that are reasonable and necessary for legitimate business purposes (CR)
- Very similar to Stark's fair market value exception
- If the arrangement expires after a term of at least 1 year, new writing clarification and/or indefinite holdover rules may apply

*Not all requirements listed.

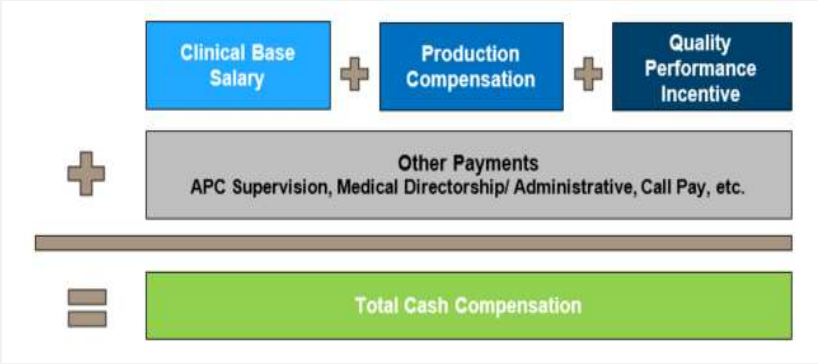
Auditing Physician Contracts

Applying the "Big 3" to Actual Models

Current Models

- ❑ Guarantee, Base, Hourly Rate or Draw
- ❑ Variable Production Compensation
- ❑ Supervision, Medical Directorship and/or Call Pay
- ❑ Performance Incentives (quality, patient satisfaction, structured as additive or at risk)
- ❑ **Understand <u>all</u> components and test total compensation against the "Big 3"**

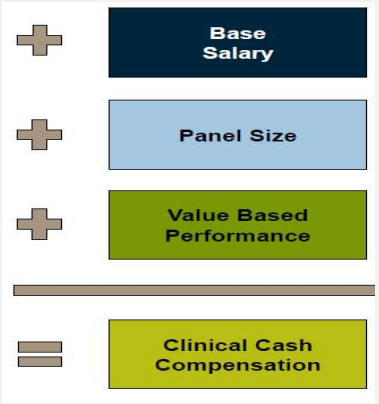
<u>Example</u>



Future Models

- ❑ More incentives for Quality and Value Based Performance?
  - ❑ Care Coordination, Cost Containment
  - ❑ Following Evidence-Based Medicine Guidelines
  - ❑ Outcomes
- ❑ **Understand <u>all</u> components and test total compensation against the "Big 3"**

<u>Example</u>



Auditing Physician Contracts

Managing Risk for Rockstars/Outliers

- Why is the physician highly compensated?
  - What credentials make the physician a Rockstar?
  - What metrics/inputs show that the physician is exceptionally productive?
  - Are there other contributing risk factors in addition to high compensation?
- Could a compliance review and FMV analysis help to mitigate risk?
- Common FMV Analysis Components:
  - Income, market and/or cost approach.
  - Market Approach: Benchmarking of (1) total compensation per FTE; (2) compensation to productivity; and/or (3) compensation to collections percentiles.
  - Commercial Reasonableness determined by multi-factor test.

Auditing Physician Contracts

Self-Disclosure Process, Challenges

- CMS Self-Referral Disclosure Protocol
  - ✓Actual or potential Stark violations only
- OIG Self-Disclosure Protocol
  - ✓Stark only conduct is not eligible
  - ✓Remuneration based multiplier (1.5)
  - ✓Much faster than CMS self-disclosure protocol
- Must analyze for the 6 year lookback period
  - ✓Not all appraisers have this capability
- Typically must reform/repair arrangement before disclosure:
  - ✓Reforming is often more challenging than self-disclosure
  - ✓Any retrospective FMV analysis must be in sync with the new terms

Auditing Physician Contracts

4 Questions – COVID-19 Contracting

1. How does the financial arrangement align with current and evolving regulatory requirements (e.g., applicable Stark exceptions, Anti-Kickback safe harbors, CMPs, in writing, set-in-advance, FMV, commercial reasonableness)?

2. Is the new financial arrangement (or modification or amendment to an existing arrangement) reasonably related to the national emergency and a COVID-19 response?

3. What documentation could be developed supporting: (i) the anticipated services that will be performed and their relationship to the response to the COVID-19 national emergency; and (ii) the payment amount/ formula and rationale for the financial terms and FMV?

4. Should the financial arrangement terminate at the end of the national emergency, soon after or in some other reasonable timeframe?

Part IV: Special Fair Market Value (FMV) Considerations

Planning The Audit

- Scope of audit depends on
  - Size and complexity of the company
  - Prior experience with the process under audit
  - Recent changes in the company or the company's operations
  - Previously recognized deficiencies
  - Other circumstances that occur during the audit
- Laws auditing for: Stark Law, Anti-Kickback Statute, Private Benefit

Auditing Process

- Compile a list of currently executed contract with physicians.
- Interview individuals commonly involved in physician relationships.
- Reconcile interviews to currently executed physician contracts.
- Reconcile physician payments to physician contracts.
- Review time sheets or other attestation forms for completeness and accuracy.
- Verify that fair market value and commercial reasonableness is documented for each agreement.
- Verify that other terms of agreement and necessary steps are performed in executing agreements.

Common Physician Arrangements

- Employment
- Call Coverage
- Medical Directorships
- Subsidy/Stipend Arrangements
- Equipment Lease/Other Services Agreements (e.g., lithotripsy, perfusion, and dialysis)
- Income Guarantees
- Real Estate Leases

Increasingly Common Arrangements

- Clinical co-management agreements and other quality based compensation arrangements
- Gainsharing and demand matching agreements
- Management and billing agreements
- Risk-sharing agreements

Interview Planning

- Employees generally involved in physician relationships:
  - Hospital and physician practice executive staff;
  - Department administrative staff; and
  - Development and recruiting staff.
- Understand the following processes:
  - Strategy;
  - Documentation;
  - Approval; and
  - Selection.

Reconciliation of Contracts

Most common issues include:

- Use of space, office equipment, and other items by physicians for professional or personal use.
  - U.S. ex rel. Kosenske v. Carlisle HMA
- Payment for services not provided.
  - U.S. v. Campbell

Verify Fair Market Value

- Fair market value means the value in arm's-length transactions, consistent with the general market value.
- General market value means ". . . the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party on the date of acquisition of the asset or at the time of the agreement." Stark II, Phase III Final Rule (42 CFR Section 411.351).

Using Benchmark Surveys

Specialty: General Cardiology		Compensation per wRVU				
		25th %ile = $46.30	50th %ile = $57.95	75th %ile = $74.77	90th %ile = $128.05	Reported Compensation
wRVUs	25th %ile = 4,710	$218,073	$272,945	$352,167	$603,116	$309,469
	50th %ile = 6,634	307,154	384,440	496,024	849,484	431,740
	75th %ile = 9,078	420,311	526,070	678,762	1,162,438	544,123
	90th %ile = 12,092	559,860	700,731	904,119	1,548,381	700,736

Commercial Reasonableness

- An arrangement will be considered 'commercially reasonable'… if the arrangement would make commercial sense if entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential designated health services ("DHS") referrals (69 Fed. Reg. 16093, March 26, 2004).
- Factors to consider:
  - Who is providing the services?
  - Why are the services required?
  - When are the services performed?
  - How are the services provided?
- Hebrew Homes Health Network Settlement

Other Terms and Necessary Steps

- Compensation Structure
  - U.S. ex rel. Elin Baklid-Kunz v. Halifax Hospital
  - U.S. ex rel. Drakeford v. Toumey Healthcare System, Inc.
- Length of fair market value opinion versus length of contract
- Compensation set in advance
- Agreements executed
- Expired agreements

Effective Compliance Program

- Implementing written policies and procedures
- Conducting effective training and education
- Developing effective lines of communication
- Conducting internal monitoring and auditing
- Enforcing standards through well-publicized disciplinary guidelines
- Responding promptly to detected problems and undertaking corrective action

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