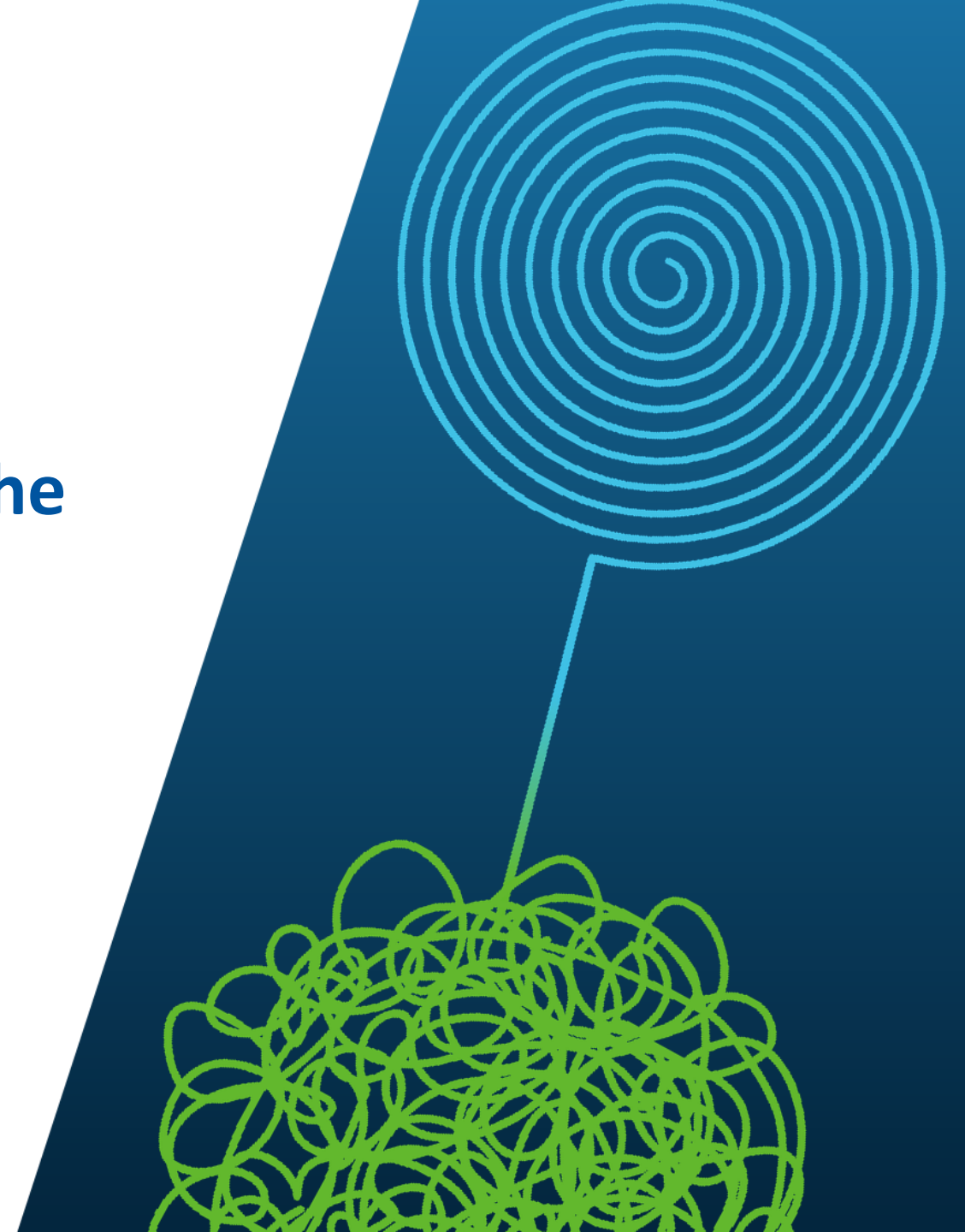




Healthcare Regulatory Roundup #120

Physician Arrangements Under the Microscope: Identifying Risk and Managing Compliance

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Introductions



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Today's Agenda



1. Why Physician Arrangements Remain Under Scrutiny
2. Regulatory Framework
3. Arrangement Lifecycle and Review Framework
4. Arrangement Review and Risk Identification
5. Governance, Auditing, and Monitoring

1. Why Physician Arrangements Remain Under Scrutiny

Why It Matters



FY 2025 Highlights

 **\$6.8B**

FCA Settlements and Judgments

 **\$5.7B**

Healthcare FCA Recoveries

 **1,227**

Qui Tam Lawsuits Filed
(record high)

- **\$345M – Community Health Network (2023)**
 - Fair Market Value (FMV) compensation tied to referrals
 - Largest False Claims Act (FCA)/Stark Settlement in DOJ history
- **\$31.5M – Fresno-Based Health System (2025)**
 - FCA settlement
- **\$6.8M – NY Presbyterian Hudson Valley (2026)**
 - Medical director payments with little documentation of services
- **Erlanger Health System (ongoing litigation)**
 - Allegations that physician compensation exceeded FMV
 - Stark Law and FCA allegations involving referral-based compensation

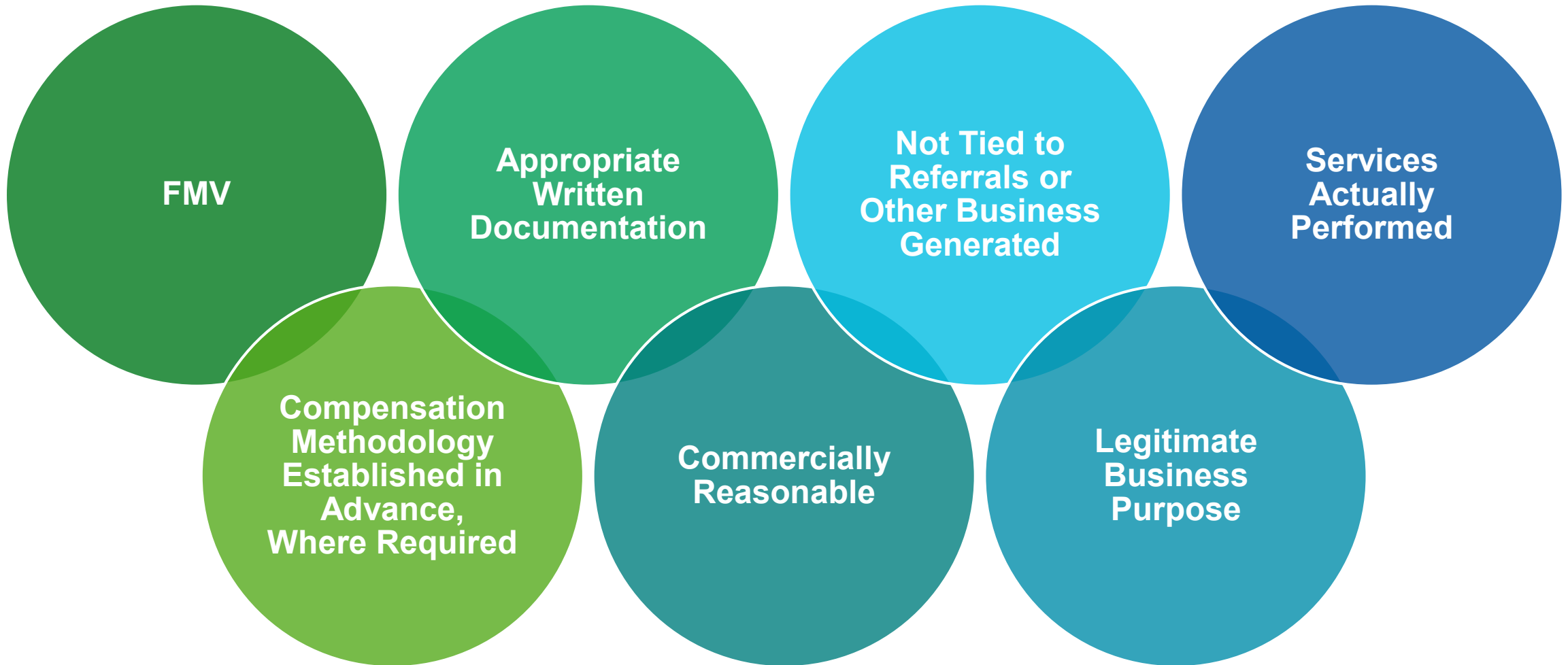
Lessons Learned from Enforcement Actions



1. Whistleblowers come from every level of employment
2. Missing or incomplete time and activity records can significantly weaken the organization's ability to support payments and services
3. Inconsistent practices across locations may create broader, systemic compliance concerns
4. Agreements should be reviewed, approved, and fully executed before services and payments begin
5. Aggregate compensation across all arrangements must be evaluated
6. Compensation above FMV with referral-generating physicians can create heightened Anti-Kickback Statute (AKS) and Stark risk
7. Changes in duties, locations, payment methodologies, or operational circumstances should trigger reassessment
8. Organizations should periodically document continued need, performance, compensation, and compliance with arrangement terms
9. Actual payments should be tested against the approved methodology
10. Written terms should be compared with actual services and operations
11. Renewals should not occur automatically without reassessing need, performance, compensation and legal requirements

2. Regulatory Framework

Common Compliance Principles Across Physician Arrangements



The Anti-Kickback Statute (AKS)



- Applies to remuneration intended to induce or reward referrals or other federal healthcare program business
- Illegal to offer, pay, solicit or receive anything of value to induce or reward referrals of federal healthcare program business
 - **Cash**
 - **Compensation/benefits exceeding the value of legitimate items or services**
 - **Free services**
 - **Gifts and meals**
 - **Free rent**
- Safe harbor protection is voluntary, and failure to satisfy a safe harbor does not automatically create an AKS violation
- The analysis should consider the parties' intent, the nature of the remuneration, and whether any purpose of the arrangement is to induce or reward referrals or other federal healthcare program business

Civil Monetary
Penalties

Exclusion

Incarceration

FCA Liability

The Stark Law



Stark generally prohibits a physician from referring Medicare patients 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.

The entity may not bill Medicare for services resulting from a prohibited referral.

- **Common compliance failures include:**

- ✓ Failure to identify whether there is a physician referral for DHS
- ✓ Failure to identify the nature of the financial relationship or the specific exception relied upon
- ✓ No written executed agreement on file
- ✓ Failure to follow contract terms (missing time logs)
- ✓ Compensation that is not consistent with FMV, where FMV is required by the applicable exception
- ✓ Space changes not reflected in lease
- ✓ Failure to test whether every applicable requirement was satisfied through the arrangement
- ✓ Failure to compare the written arrangement, actual payments and operational performance

Key Differences



Element	Anti-Kickback Statute	Stark Law
Standard	Intent-based (criminal)	Strict liability (no intent)
Scope	Any federal healthcare program	Medicare DHS referrals Medicaid when claims involve services also covered or payable under Medicare/through federal financial matching rules
Protection	Safe Harbors (Voluntary)	Exceptions (mandatory)
Penalty	Criminal, Civil, Exclusion	Civil
Missed Protection?	Heightened scrutiny Not automatic violation	If Stark applies, the financial relationship must satisfy an applicable exception
Common Themes	Intent; remuneration; referrals or federal healthcare program business; safe harbors (voluntary)	Physician referrals; DHS; financial relationship; all requirements of applicable exception satisfied; term longer than one year



State physician
self-referral laws



State anti-kickback
laws



Tax-exempt
organization
requirements



Corporate practice
of medicine
considerations



Organizational
policies and
approval
requirements

Other Considerations

Key Arrangement Compliance Concepts



FMV

- Compensation reflects arm's-length value

Commercial Reasonableness

- Arrangement supports a legitimate business purpose

Operational Compliance

- Services, payments, records, and actual practices remain consistent with approved terms

Documentation & Oversight

- Supporting records, approvals, monitoring and reassessments are maintained

Structured Arrangement Review Framework



Define	Define the parties to the arrangement
Identify	Identify the remuneration, referrals, DHS and applicable laws
Determine	Determine the applicable exception, safe harbor or other framework
Validate	Validate business purpose and organizational need
Evaluate	Evaluate compensation methodology, FMV, commercial reasonableness, documentation and operational compliance
Compare	Compare the written agreement to actual services, payments and operations
Confirm	Confirm required approvals and supporting documentation
Document	Document concerns, escalation, corrective action, and follow up

Compensation Valuation Considerations



- 1 Identify **provider qualifications, expected duties, time requirements, and anticipated outcomes of** the arrangement.
- 2 Identify **multiple objective compensation benchmarks and other relevant market data** to inform the valuation analysis.
- 3 Assess **operational, financial and compliance considerations** including existing resources, potential duplication of services, and other facts and circumstances affecting value.
- 4 Identify and apply **one or more valuation approaches** to determine fair market value compensation.
- 5 Document the **analysis, conclusions, approvals, and rationale** supporting the FMV determination.

Compensation Valuation Considerations *(continued)*



- Compensation review should be considered alongside documentation, operational compliance, governance, monitoring activities, and applicable legal requirements
 - Confirm business purpose and organizational need
 - Understand duties, responsibilities and expected effort
 - Evaluate compensation methodology and supporting data
 - Assess operational and compliance considerations
 - Document conclusions, approvals, and monitoring requirements



Stark Law Clarifications



Salary surveys, in and by themselves, do not constitute FMV.

*CMS clarified “...[W]e continue to believe that the fair market value of a transaction...may not always align with published valuation data compilations, such as salary surveys. In other words, **the rate of compensation set forth in a salary survey may not always be identical to the worth of a particular physician’s services.**”*

Compensation set at or below the 75th percentile is not always FMV.

CMS conjectured it is “...uncertain why the commenters believe that it is CMS policy that compensation set at or below the 75th percentile in a salary schedule is always appropriate, and that compensation set above the 75th percentile is suspect, if not presumed inappropriate. The commenters are incorrect that this is CMS policy.”

FMV is not the same as investment value.

“A hospital may not value a physician’s services at a higher rate than a private equity investor or another physician practice...we recognize that reliance on similar transactions in the marketplace could simplify the process of determining fair market value for purposes of the physician self-referral law, but adopting such a standard would allow parties to consider additional (or investment) value to certain types of entities, skewing the buyer-neutral fair market value.”

Source: 2021 Healthcare Transactions Resource Guide, © 2021 American Health Law Association, accessed on May 4, 2023, <https://www.americanhealthlaw.org/getmedia/4486d7f1-d51c-48a4-b355-17b7270e3e12/2021-Health-Care-Transactions-Resource-Guide-HSG.pdf>

Stark Law Clarifications (*continued*)



Arrangements can be CR even if they are not profitable.

CMS cites examples of non-profitable arrangements including those that meet community need, timely access to healthcare, fulfill licensure/regulatory obligations, charity care, and others. Profitability is still relevant – ***“We are not convinced that the profitability of an arrangement is completely irrelevant or always unrelated to the determination of CR.”***

Even when arrangements have a legitimate business purpose, they may not be CR.

CMS cited an example of the need for a medical director of a service line. So, if a second medical director for the same service line was added, the arrangement would not be CR because while a legitimate business need exists for a medical director, the fact that it was duplicative makes it commercially unreasonable.

Arrangements require re-evaluation after being initially established.

Arrangements may appear to further a legitimate business purpose at their onset but may not be CR over time. It is not good enough just to have a legitimate business purpose; the organization should periodically reassess whether the arrangement continues to further a legitimate business purpose and remains CR.

Source: 2021 Healthcare Transactions Resource Guide, © 2021 American Health Law Association, accessed on May 4, 2023, <https://www.americanhealthlaw.org/getmedia/4486d7f1-d51c-48a4-b355-17b7270e3e12/2021-Health-Care-Transactions-Resource-Guide-HSG.pdf>

Commercial Reasonableness Review Considerations



- Why is the arrangement needed?
- What organizational objective does it support?

Business Need & Strategy



- Does the provider have the qualifications and experience needed?

Provider Qualifications



- Are responsibilities clearly defined?
- Are expected outcomes measurable?

Duties & Deliverables



- Are duties duplicative of existing personnel?
- Are adequate organizational resources available?

Resources & Operational Alignment



- Are approvals, monitoring, reassessments, and accountability structures established?

Oversight & Monitoring



3. Arrangement Lifecycle and Review Framework

The Spectrum of Physician Arrangements



- **Employment and productivity-based compensation**
 - Base salary, productivity incentives, quality incentives, other compensation methodologies
 - Subject to FMV and commercial reasonableness
- **Medical directorships and administrative services**
 - Clinical leadership, medical director, management, and administrative service arrangements
 - Scope, duties, time requirements, and compensation should be clearly documented
- **Professional services agreements**
 - Coverage, consulting, teaching, and other contracted professional services
 - Requires demonstrable need and compensation supported by FMV
- **Space and equipment leases**
 - Office space, clinical space, equipment, and technology arrangements
 - Lease terms and compensation must reflect FMV and legitimate business use

The Spectrum of Physician Arrangements (*continued*)



- **Call coverage and co-management arrangements**
 - Coverage stipends and service line management incentives
 - Heightened scrutiny regarding need, performance metrics, and compensation structure
- **Recruitment and relocation arrangements**
 - Income guarantees, recruitment assistance, and relocation support
 - Governed by specific Stark exceptions and regulatory requirements
- **Joint venture and ownership interests**
 - Physician investment and co-ownership arrangements
 - Requires analysis of ownership structure, returns, control and referral implications
- **Non-monetary compensation and other benefits**
 - Meals, gifts, CME, technology travel, and other benefits
 - Subject to Stark nonmonetary compensation limits and AKS considerations

4. Arrangement Review and Risk Identification

Medical Directorships



Identify the Need

Document the business purpose and organizational need

Identify positions required by law, regulation, accreditation or operational need

Define expected duties, deliverables and anticipated benefit



Evaluate and Structure

Confirm physician qualifications and ability to perform services

Establish expected hours, level of effort, and compensation methodology

Review for duplicate or overlapping duties across arrangements

Ensure responsibilities are reasonable and support a legitimate business purpose



Document and Administer

Execute a written agreement before services begin

Maintain time and activity records

Obtain evidence that services were performed and completed

Review and approve supporting documentation before payment



Monitor and Reassess

Reconcile payments to approved services and contract terms

Review arrangements periodically for ongoing business need

Evaluate changes in duties, hours, compensation or operations

Perform renewal, reassessment and remediation activities as needed

Call Coverage, Co-Management, and Professional Services Arrangements



Call Coverage

Key Compliance Focus:

Compensation should be evaluated in light of **availability requirements, response burden, specialty considerations, coverage model, and other arrangement-specific facts and circumstances**

- ✓ Availability requirements should be clearly defined and documented
- ✓ Compensation should reflect the frequency and intensity of call responsibilities
- ✓ Consider actual response burden, including call-back and in-person coverage requirements
- ✓ Evaluate specialty-specific and geographic market factors
- ✓ Consider payer mix, patient acuity and uncompensated call burden
- ✓ Assess the impact of APPs, residents or other first-call coverage models
- ✓ Review concurrent clinical administrative or leadership responsibilities
- ✓ Compensation methodology should be supported by FMV and commercial reasonableness analysis

Call Coverage, Co-Management, and Professional Services Arrangements (*continued*)



Co-Management Arrangements

Key Compliance Focus:

Performance incentives should **reward measurable, operational, or quality improvements**, not referral generation or reductions in medically necessary care

- ✓ Establish clear, objective and measurable quality and operational metrics
- ✓ Document baseline performance methodology before incentives are earned
- ✓ Validate data used to measure performance and calculate incentives
- ✓ Maintain safeguards against rewarding referrals or inappropriate reductions in case
- ✓ Document achievement of performance metrics and supporting results
- ✓ Recalculate incentive payments based on actual performance outcomes
- ✓ Review aggregate compensation across all physician relationships
- ✓ Periodically reassess the arrangement for ongoing business need and effectiveness

Call Coverage, Co-Management, and Professional Services Arrangements (*continued*)



Professional Services Agreements

Key Compliance Focus:

Arrangements should **reflect actual operations**, and **payments should align with documented services performed and contract requirements**

- ✓ Clearly define services, responsibilities, personnel and deliverables
- ✓ Verify that contracted services were actually performed
- ✓ Compare invoices and supporting documentation to contractual requirements
- ✓ Perform invoice and payment testing periodically
- ✓ Review arrangements for duplicate or overlapping duties
- ✓ Evaluate related physician arrangements in the aggregate
- ✓ Monitor changes in duties, personnel, locations or operations
- ✓ Amend agreements when material changes occur

Physician Recruitment



Common Recruitment Tools

- Income guarantees
- Signing bonuses
- Relocation expenses
- Student loan repayment
- Practice overhead support

Selected Stark Recruitment Requirements

- Relocation
- Recruitment purpose
- Written agreement
- No referral linkage
- Community need and recruitment rationale
- Relocation requirements
- Existing local practice considerations
- Additional requirements when payments pass through an existing group
- Repayment and forgiveness terms
- Restrictions that may improperly condition referrals
- Post-recruitment monitoring
- Documentation confirming satisfaction of obligations

Risks

- Income guarantee payments extend beyond the Stark exception period
- Failure to confirm ongoing satisfaction of recruitment exception requirements
- Recruited physician was already practicing locally
- Guaranteed income through an existing physician group requires additional compliance analysis

Provider Needs Assessment and Recruitment Support



What?

- Evaluates provider supply, demand, and community need within a defined service area

Why?

- Supports strategic workforce planning and physician recruitment initiatives
- Assists with regulatory and compliance considerations

Methodology?

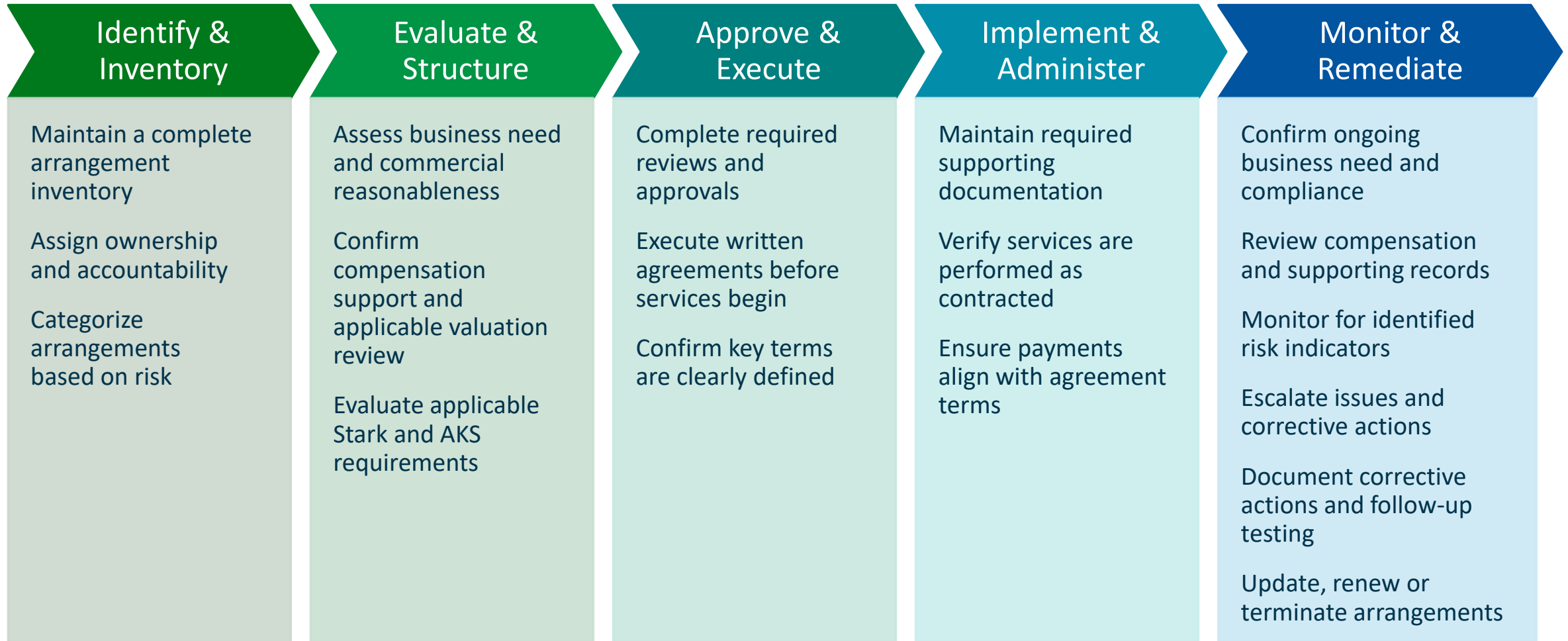
- Qualitative and quantitative analyses
- Specialty-specific supply and demand evaluation
- Consideration of physicians and advanced practice providers, as applicable

Application?

- Supports recruitment and expansion decisions
- Documents community need and recruitment rationale
- Informs arrangement review and compliance analysis
- Should be evaluated alongside recruitment facts, applicable Stark requirements, organizational strategy, and other supporting documentation

5. Governance, Auditing, and Monitoring

Effective Monitoring Programs



Risk-Based Monitoring Triggers

- Changes in compensation
- Changes in duties, time commitments or locations
- High or unusual aggregate compensation
- Significant practice losses
- Incomplete supporting documentation
- Payment calculation variances
- Expired or unsigned agreements
- Duplicate or overlapping duties
- Differences between contracted and actual activities



Productivity-Based Compensation



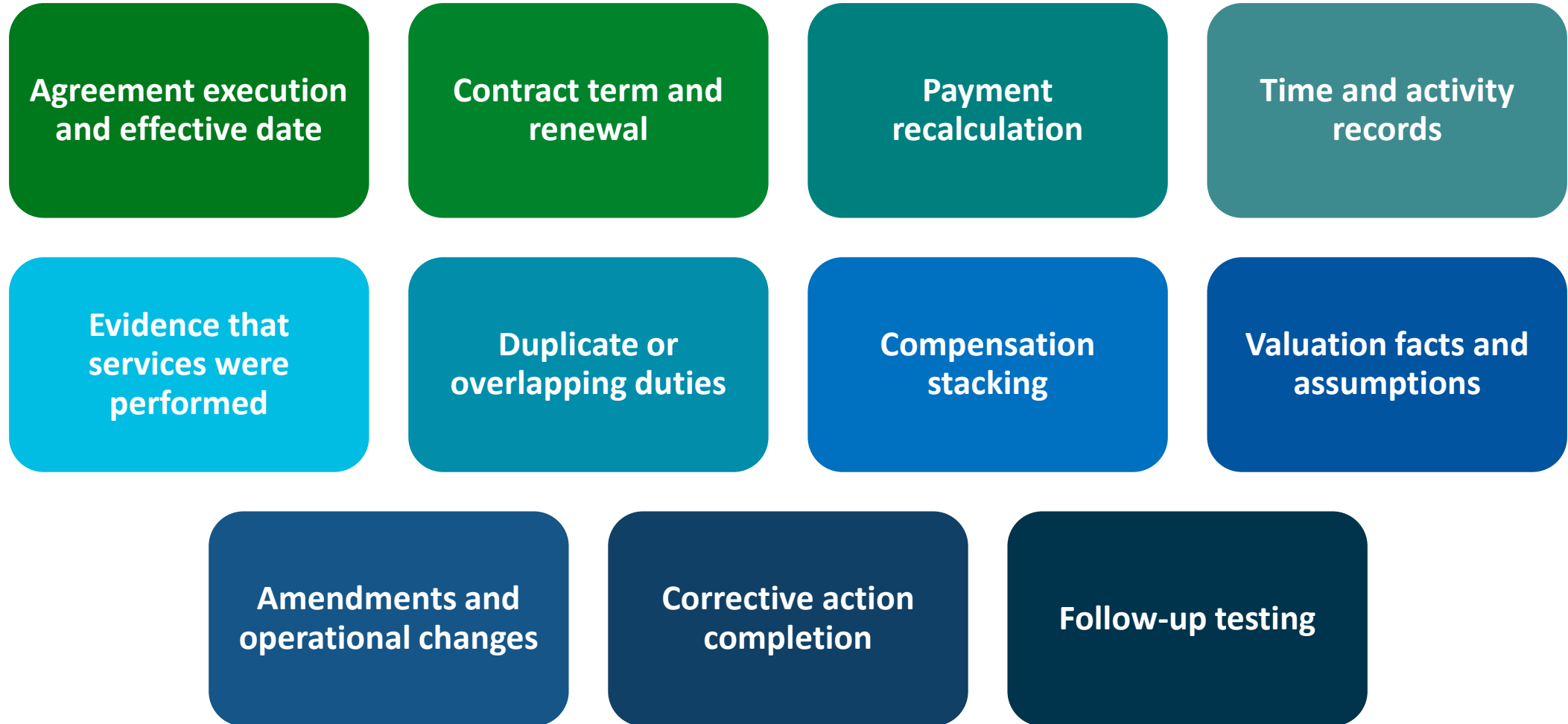
- wRVU methodology and conversion factors
 - Personally performed services
 - Coding and charge data integrity
 - Split/shared and team-based credit
 - Quality incentives
 - Caps, floors and thresholds
 - Changes to compensation methodology
 - Retrospective adjustments
- Payment recalculation
 - Aggregate compensation
 - Practice losses and business rationale
 - Documentation supporting productivity calculations
 - Internal review and approval of compensation adjustments
 - Monitoring for operational consistency with compensation plans

Governance and Accountability



Arrangement owners	Operational leadership	Compliance, legal, finance, human resources	Valuation support	Approval authority	Renewal and amendment responsibility	Defined escalation pathway and corrective action monitoring	Board and Compliance Committee reporting, as applicable
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Practical Auditing and Monitoring Procedures



- **Physician Contract Review Checklist**
 - <https://www.pyapc.com/insights/upgraded-tool-from-pya-physician-contract-review-checklist/>
- **Physician Contract Management System Checklist**
 - <https://www.pyapc.com/insights/pya-resource-physician-contract-management-system-checklist/>
- **Medical Director Needs Checklist**
 - <https://www.pyapc.com/insights/medical-director-needs-assessment-checklist-article/>
- **Commercial Reasonableness Assessment Tool**
 - <https://www.pyapc.com/insights/interactive-practice-aid-commercial-reasonableness-assessment-tool/>
- **PYA Overwatch Services**
 - <https://www.pyapc.com/overwatch/>



Our Next Webinars

Thursday, November 5; 12 pm – 1:00 pm ET

CPE Webinar

The Bottom Line #3

2026 Federal Tax Update: From Tax Law to Client Action

1 CPE credit in Taxes available to live attendees

Wednesday, November 11; 11:00 am – 12:00 pm ET

Healthcare Regulatory Roundup #121

FY 2027 Medicare Final Rules: Outpatient, Home Health, and ESRD

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