



Physician Arrangements – Update Regarding Stark and Anti-Kickback

Montana Hospital Association
Compliance Conference

October 28, 2021

Presented by:

Shannon Sumner, CPA, CHC®

Christopher Adelman, Attorney

Traci Waugh, CHC®, RHIA, CHPS

© 2021 PYA, P.C.

WE ARE AN INDEPENDENT MEMBER OF HLB—THE GLOBAL ADVISORY AND ACCOUNTING NETWORK

Agenda

1. Introductions
2. Stark Law and Anti-Kickback Statute Update
3. Auditing Physician Arrangements
4. Questions and Group Discussion

Speaker Introduction



Shannon Sumner

(800) 270-9629

ssumner@pyapc.com

Shannon manages PYA's Compliance Advisory Services and serves as the Firm's Compliance Officer.

A CPA certified in healthcare compliance, she has more than two decades' experience in healthcare internal auditing and compliance programs. She advises large health systems and legal counsel in strengthening their compliance programs, and aids in areas of Anti-Kickback Statute and Stark Law compliance. Shannon also assists health systems regarding compliance with Corporate Integrity Agreements (CIAs) and Non-Prosecution Agreements (NPAs), conducts health system merger/acquisition/divestiture due diligence activities, and advises health system governing boards on their roles and responsibilities for effective compliance oversight.

At the direction of the Department of Justice, Shannon has served as the healthcare compliance and internal audit subject-matter expert for the largest federal compliance co-monitorship of a health system in U.S. history.

Speaker Introduction



Christopher Adelman handles a broad range of health care issues including regulatory law and compliance by providing general counsel services to hospitals and other health care entities, including: hospital-physician relationships, medical staff bylaws and governance, credentialing, peer review and related hearings, corporate organization, compliance, patient care and consent issues, risk management and liability, fraud and abuse and Stark issues, HIPAA matters, employee issues, acting as bond counsel, drafting of employment, independent contractor and vendor agreements.

Chris Adelman

Attorney

Hall, Render, Killian, Health, & Lyman, P.C

970-945-6521

cadelman@hallrender.com

Speaker Introduction



Traci Waugh

(800) 270-9629

twaugh@pyapc.com

Traci has been immersed in the healthcare industry with an assortment of responsibilities. She started her career as the director of medical records and eagerly took on additional roles including utilization review, risk management, medical staff services, discharge planning, quality improvement, contracting, privacy, and compliance. Traci's enthusiasm as not subsided; she is always willing to help her peers and serve as a resource.

Along with her initial certification as Registered Health Information Administrator (RHIA), she obtained her Certification in Healthcare Privacy and Security (CHPS) and Certification in Healthcare Compliance (CHC).

Currently as the Director of Outreach Services and Compliance, Traci assists partner critical access hospitals with their compliance programs and provides customized compliance education to staff and board or directors. In addition, she serves as a liaison for other contracted services provided by Kalispell Regional Healthcare.



Stark Law and Anti-Kickback Statute Update

Anti-Kickback Statute (AKS)



- **42 U.S.C. §1320a-7b(b)**

- ✓ Designed to prevent certain payments in connection with the furnishing of services reimbursable under the Medicare and Medicaid programs as well as other governmental health care initiatives
- ✓ Prohibits knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in exchange for or to induce the referral of any item or service for which payment may be made in whole or in part under Medicare, Medicaid or other government health programs



- Violation is a felony, punishable by fines up to \$25,000 and up to 5 years imprisonment.
- Violation can also result in imposition of civil monetary penalties and/or exclusion from such government health care programs.
- **Safeguards:**
 - It is imperative that any arrangement not be pursued for the purpose to induce referrals.
 - It is always possible that a trier of fact, such as a judge or jury, could misconstrue the facts and find differently.
 - **Intent and structure of an arrangement are vital!**

Intent Test

- **Greber test**

- If one purpose of the arrangement or deal is to induce referrals, the AKS is violated. *U.S. v. Greber*, 760 F.2d 69 (3rd Cir. 1985)

- **The ACA test**

- There is no requirement of actual knowledge of or specific intent to commit a violation of the AKS.
- Be careful with communications to avoid risk that illegal intent could be misconstrued!



Compliance/Safe Harbors



- OIG has issued safe harbor regulations to protect certain arrangements.
- An arrangement must meet each element of a safe harbor in order to be safe from investigation or prosecution as a criminal offense or as a basis for exclusion from participating in the government health care programs.
- However, an arrangement does not necessarily violate the AKS if it does not satisfy a safe harbor. Such an arrangement is judged under the language of the AKS itself.

Safe Harbors



- ✓ Investment Interests (large entity, small entity, underserved area)
- ✓ Space Rental
- ✓ Equipment Rental
- ✓ Personal Services and Management Contracts
- ✓ Sale of Practice
- ✓ Practitioner Recruitment
- ✓ Waiver of Coinsurance/ Deductibles
- ✓ Price Reductions for Health Plans/Managed Care Organizations
- ✓ Referral Services
- ✓ Warranties
- ✓ Discounts
- ✓ Employees
- ✓ Group Purchasing Organizations
- ✓ Ambulatory Surgical Centers
- ✓ Group Practices
- ✓ Obstetrical Malpractice and Insurance Subsidies
- ✓ Referral Agreements for Specialty Services
- ✓ Ambulance Replenishing
- ✓ Health Centers
- ✓ Electronic Prescribing/Health Records

Stark Law (Stark)



- When a physician (or physician’s immediate family member) has a financial relationship with an entity (**unless an exception applies*), the federal Stark Law provides that:
 - Physician may not make referrals to the entity for “designated health services”; **and**
 - Entity may not present a claim or bill to the government, patient, or any other party for designated health services furnished pursuant to a prohibited referral.
 - **If Stark is implicated, an exception must be found.*

Designated Health Services



- Clinical laboratory services
- Physical therapy, occupational therapy and speech-language pathology services
- Radiology and certain other imaging services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment and supplies
- Prosthetics, orthotics and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services

Sanctions Are Severe



- OIG may impose a civil money penalty of up to \$15,000 against any person whom:
 - Has presented or caused to be presented a claim for a payment that such person knows, or should know, may not be made under Medicare or Medicaid; **or**
 - Against any person whom it determines has not refunded on a timely basis (within 60 days) amounts collected as a result of billing an individual, third-party payor, or other entity for a designated health service that was provided in accordance with a prohibited referral under Stark.
- Stark sanctions include exclusion from Medicare and Medicaid and fines of up to \$100,000 for circumvention schemes.
- Qui tam/false claim actions may also reference Stark violations.

Stark Exceptions



- Stark has numerous exceptions based on the type of financial relationship.
- Exceptions are in three categories:
 1. Both an ownership interest and compensation arrangement
 2. Only an ownership interest
 3. Only a compensation arrangement
- When reviewing a particular physician practice or other arrangement, it is imperative that the correct type of exception is used.

Compensation Arrangement Exceptions



- Rental of office space
- Rental of equipment
- Bona fide employment relationships
- Personal service arrangements
- Physician recruitment
- Isolated transactions
- Certain arrangements with a hospital unrelated to DHS
- Payments by a physician for items and services
- Obstetrical malpractice insurance subsidies
- Charitable donations
- Non-monetary compensation (up to \$385 annually)

Compensation Arrangement Exceptions



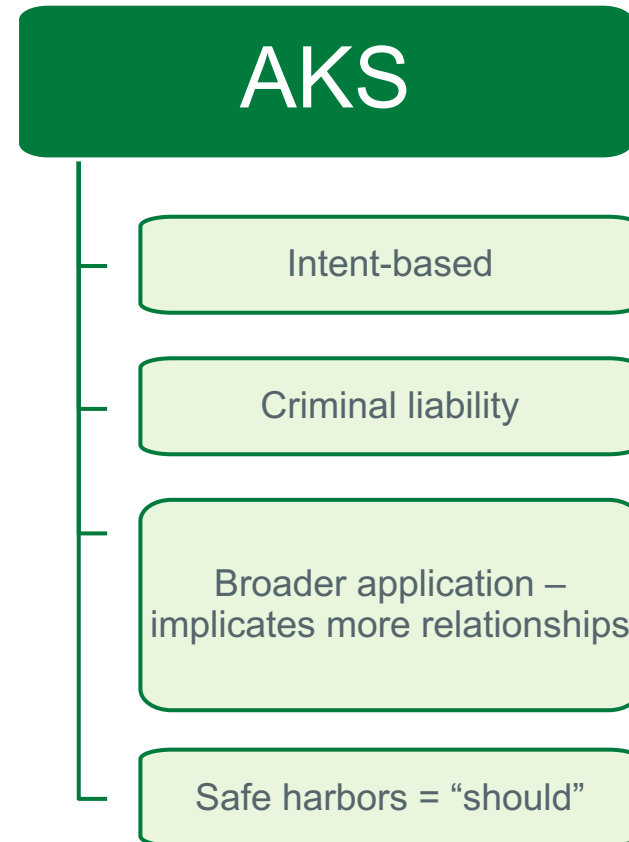
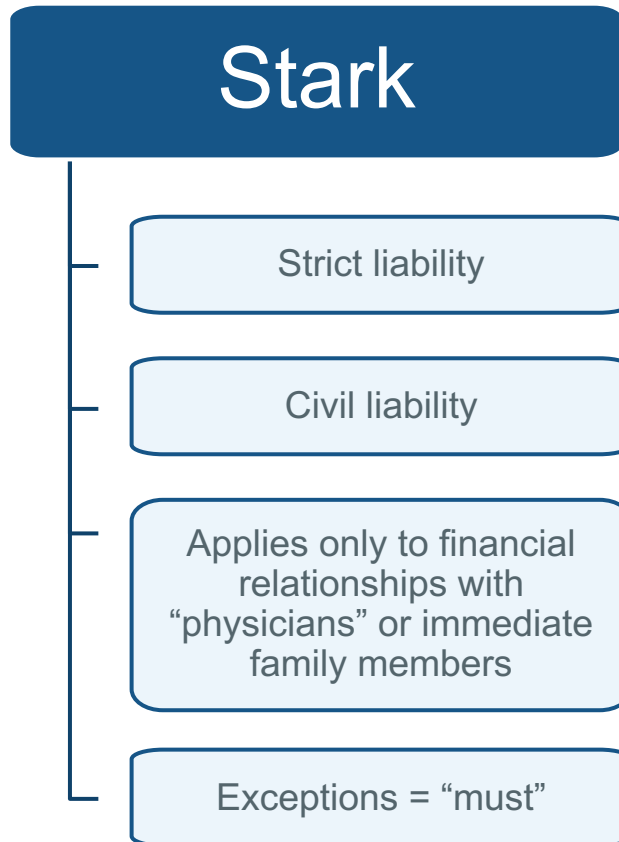
- Fair Market Value (FMV) compensation
- Medical staff incidental benefits
- Risk-sharing arrangements
- Compliance training
- Indirect compensation arrangements
- Referral services
- Professional courtesy
- Retention payments in underserved areas
- Community wide health information systems
- Electronic prescribing/health records

Common Elements of Stark Exceptions



- Agreement is set out in writing
- Agreement is signed by all parties (signatures should be obtained before the effective date)
- Agreement describes the specific items/services to be provided
- Amount of remuneration is consistent with FMV
- Remuneration does not take into account the volume or value of any referrals by the referring physician/entity
- Terms of the agreement are commercially reasonable

Differences Between Stark and AKS



Impact to Clients

- CMS and OIG are enforcing Stark and AKS laws with continued vigor.
- All agreements made with physicians – past, present and future – must be scrutinized for compliance with these laws.
- Failure to ensure compliance and make appropriate corrections in a prompt manner has severe consequences.





Auditing Physician Arrangements

What do these organizations have in common?



Settlements Due to Compliance Violations



| | |
|---|---|
| \$513M | Tenet Healthcare Corporation (North Fulton Medical Center and Atlanta Medical Center) October 2016 |
| \$237M judgment settled for \$72.4M | Tuomey Healthcare System Sumter, SC October 2015 (Hospital sold to third party) |
| \$84.5M | William Beaumont Hospital Detroit, MI August 2018 |
| \$69.5M | North Broward Hospital District Broward County, FL September 2015 |
| \$55M | Lancaster Regional Medical Center & Heart of Lancaster Medical Center (HMA) Lancaster, PA September 2018 |
| \$42M | Pacific Alliance Medical Center Los Angeles, California June 2017 |
| \$34M | Mercy Hospital Springfield, MO June 2015 |

| | |
|-----------------|---|
| \$30M | Detroit Medical Center Detroit, MI December 2010 |
| \$25M | Columbus Regional Healthcare System Columbus, GA September 2015 |
| \$24M | Kalispell Regional Healthcare System Kalispell, MT September 2018 |
| \$21.75M | Citizens Medical Center Victoria, TX April 2015 |
| \$20.75M | University of Pittsburgh Medical Center – Hamot Hamot, PA March 2018 |
| \$18M | Westchester Medical Center Valhalla, NY May 2015 |
| \$17M | Lexington Medical Center West Columbia, SC July 2016 |
| \$14.25M | Mercy Health Cincinnati, OH May 2018 |
| \$10M | Robinson Health System Portage County, OH March 2015 |

Shaded organizations either engaged PYA after settlement, or PYA was selected to serve a Federal Monitor post-settlement.

Key Themes in Government Settlements



- Breakdown in processes and key controls due to growth
- Reactive vs. proactive compliance program
- Relationships with referral sources
 - Employed physician compensation
 - Multiple medical directors in same specialty
 - “Stacking Arrangements”
 - Highly compensated physicians
 - Disparities in call coverage arrangements
 - Lack of commercial reasonableness
 - Real estate transactions
 - Paying for services above FMV
 - No evidence of FMV



10 Common Healthcare Compliance Concerns Related to Hospital/Physician Transactions

1
Healthcare Real Estate

Office space, ambulatory surgery centers (ASCs), timeshares, etc.

Common concerns and challenges include

- Hospital leases space to physicians at below fair market value (FMV) rates, or not under commercially reasonable (CR) terms (e.g., month-to-month lease term when there is sufficient demand for space under a long-term lease).
- Hospital leases space from physicians at above FMV rates or not under CR terms (e.g., 40-year lease term, but not a master lease).
- Terms are long-term in nature, so transactions are not easily discoverable.
- Different company names representing real estate LLCs are often utilized, as it is rare for physician practices to own real estate within the practice corporation.

2
Collections-Based Compensation Formula

Any compensation formula that pays physicians under a methodology based all, or in part, on collections (e.g., physicians under employment or professional services arrangements (PSAs)) can be prone to error.

Formulas based upon work relative value units (wRVUs) are commonplace but should be based on “personally performed wRVUs.” In other words, formulas generally should not include wRVUs from nurse practitioners, physician assistants, or other non-MDs, particularly if the physicians are not financially responsible for the mid-level providers’ costs. Applicable regulatory guidance includes Stark Law, Anti-Kickback Statute, IRS requirements.

Common concerns and challenges include

- Compensation per wRVU exceeds industry benchmarks by an excessive amount, and is not supported by high-commercial population percentage or other external factors.
- Absent valid environmental reasons, high compensation to physicians may result in steep penalties for physician practices.
- Lack of reasonable correlation of physician productivity to related compensation (e.g., absent other environmental factors such as excessive call coverage, physician is paid at 90th percentile for his/her specialty but produces wRVUs at the 25th percentile).
- Lack of governance approval/oversight for highly compensated physicians.

© 2019 PYA, P.C. 800.270.9629 | pyapc.com
WE ARE AN INDEPENDENT MEMBER OF HLB—THE GLOBAL ADVISORY AND ACCOUNTING NETWORK

Source: <https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019>



- What are the goals of a Physician Arrangement review?
 - Overview and oversight of organization-wide contracting practices
 - Uncover potentially non-compliant arrangements, and bring them to the attention of the compliance officer and legal services
 - Examine compensation to assure consistency with FMV and commercial reasonableness
 - Ensure all arrangements have necessary, accurate supporting documentation
 - Evaluate for duplicative services and agreements
 - Determine whether contract management system(s) are complete and appropriately maintained

Types of Physician Arrangements



- Employment
- Professional Services
- Income Guarantee/Support
- Loan Repayment
- Recruitment
- On-Call Pay
- Administrative
 - (e.g., Medical Director Services, Medical Staff Officer)
- Program Advisor
- Committee Work
- Co-Management
- Supervision
- Joint Venture
- Facility and Equipment Lease

Review Approach



- Identify the purpose
 - Compliance work plan
 - Reporting requirements
- Identify the scope of the review
 - Time period covered
 - Evergreen/non-evergreen arrangements
- Define the role of counsel (in-house and outside), compliance officer, consultants
- Utilize attorney-client privilege



Attributes to Be Evaluated



- Centralized tracking system
 - Current written agreement in place, fully executed with signatures
 - Parties to the agreement
 - Names and positions of individuals involved in negotiation, review and approval
 - Items, services, equipment, space is clearly noted in agreement
 - Amount of compensation
 - Effective Date
 - Expiration Date

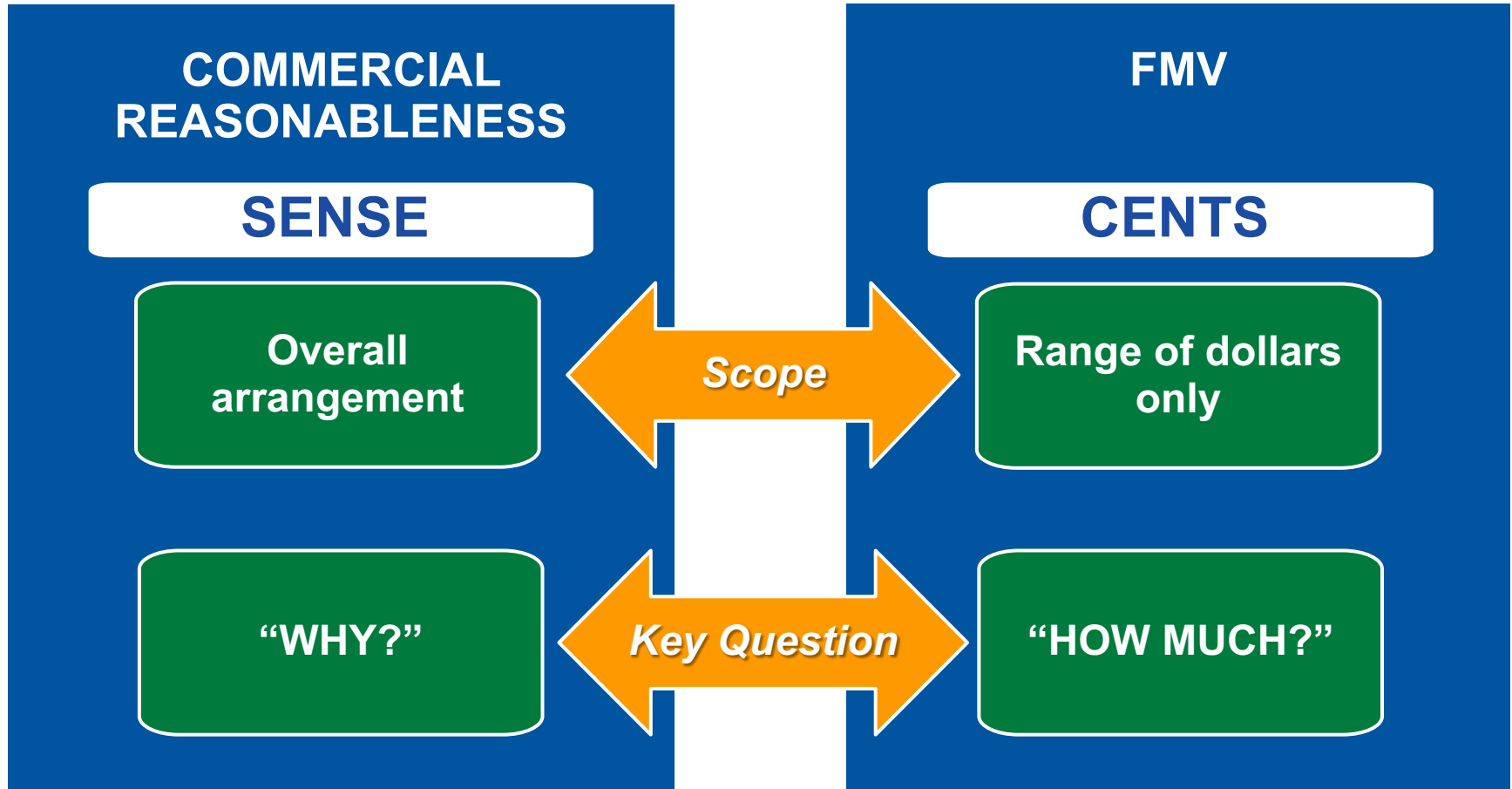
| Physician Contract Review Checklist | | |
|--|--|--|
| 1. Acquire the physician's contract. | | |
| Establish how the physician is classified – employee, independent contractor, other. | <input type="checkbox"/> | |
| Determine all of the duties the physician is providing – clinical services, medical director, professional services, on-call, administrative, teaching. | <input type="checkbox"/> | |
| Confirm that the physician and hospital/health system authority have both signed the contract in accordance with authority limits and applicable policies and procedures. | <input type="checkbox"/> | |
| Verify that hospital/health system legal counsel approves all contracts. | <input type="checkbox"/> | |
| Comments: <div style="border: 1px solid black; height: 20px; width: 100%;"></div> | | |
| 2. Review the process and controls for payment. | | |
| Establish that the contract describes the methodology for compensation. | <input type="checkbox"/> | |
| Determine whether a fair market value assessment has been completed for the arrangement and that it includes all sources of payment. | <input type="checkbox"/> | |
| Evaluate all types of supplemental compensation included in the contract. | | |
| Loans <input type="checkbox"/> | Practice support (equipment, staffing, stipend, etc.) <input type="checkbox"/> | Sign-On Bonus <input type="checkbox"/> |
| Grants <input type="checkbox"/> | Relocation Expenses <input type="checkbox"/> | Miscellaneous <input type="checkbox"/> |
| Determine whether a commercial reasonableness analysis (including a needs assessment) has been completed for the arrangement and documented in the file. | <input type="checkbox"/> | |
| Comments: <div style="border: 1px solid black; height: 20px; width: 100%;"></div> | | |
| 3. Identify the physician's duties. | | |
| Confirm that the contract defines the specific duties of the physician based on the type of arrangement, including any and/or all limitations for the provision of outside services or employment. | <input type="checkbox"/> | |
| Examine <u>all</u> contracts for each physician to determine whether there are duplicative duties for which the physician will be compensated. | <input type="checkbox"/> | |
| Determine whether the term of the contract is for at least one year, and whether it can be terminated without notice within one year. | <input type="checkbox"/> | |
| Review the contract for supervisory duties and the method for allocating compensation for supervised services. | <input type="checkbox"/> | |
| Comments: <div style="border: 1px solid black; height: 20px; width: 100%;"></div> | | |
| 800.270.9629 www.pyapc.com | | |

Attributes to Be Evaluated



- Performance under agreement (items, services are actually performed and/or provided)
- Legal and business review is performed and documented
- Remuneration is at FMV and documented (e.g., outside opinion where necessary)
- Remuneration is accurate in accordance with contract and within FMV
- Business need or rationale documented
- Service or activity log is complete and reviewed
- Leased space and/or other patient care items are monitored

Attributes to Be Evaluated



Corrective Actions, Ongoing Physician Contract Monitoring, and “Best Practices”



- Corrective action
 - Corrective action is required for non-compliance.
 - ✓ Termination or amendment of arrangements
 - ✓ Implementation of new arrangements
 - ✓ Consideration of potential refund or disclosure obligations
- Ongoing contract monitoring
 - Physician arrangements must be managed regularly to assure compliance.
 - Contract reviews must be a regular part of the compliance work plan.
- Best practices
 - Organizations must stay abreast of current regulations and have a process in place to receive updates.
 - Compensation must account for current payment methodologies (e.g., value-based purchasing, quality initiatives).



Questions and Group Discussion

Image Source: Shutterstock



Thank you!



Shannon Sumner

CPA, CHC

Principal, Chief Compliance Officer
ssumner@pyapc.com



Chris Adelman

Attorney; Hall, Render, Killian,
Heath & Lyman, P.C.
cadelman@hallrender.com



Traci Waugh

RHIA, CHPS, CHC

Senior Manager
twaugh@pyapc.com



pyapc.com
800.270.9629