Starting Right:
Compliance Considerations for Startups

April 8, 2025

About PYA

Founded in 1983, PYA is a **national accounting and healthcare advisory firm** providing consulting, audit, and tax services to clients in all 50 states.

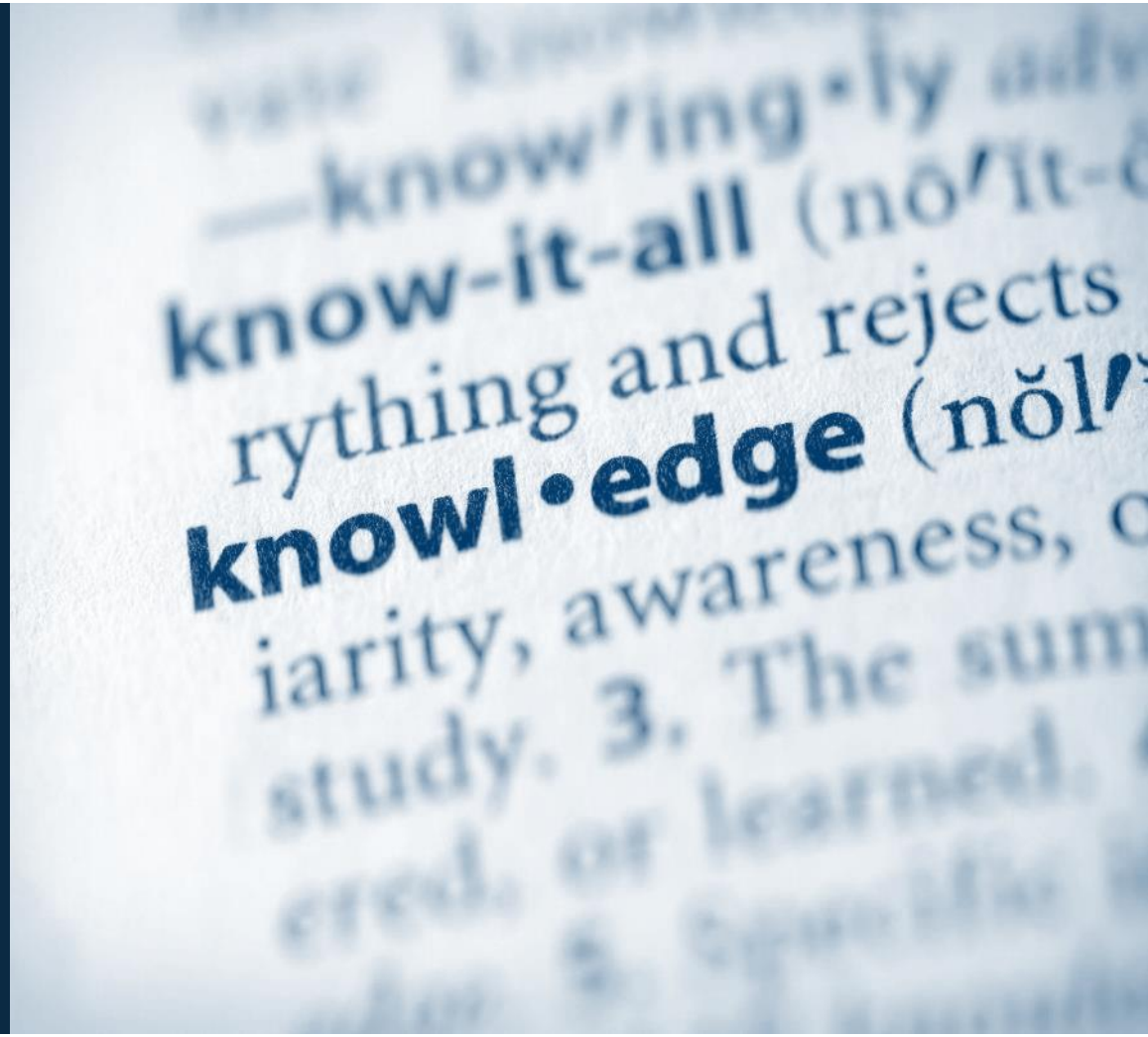
OFFICE LOCATIONS

Atlanta
Charlotte
Kansas City
Knoxville
Nashville
Tampa

- STRATEGY & TRANSACTION SOLUTIONS
- REVENUE & COMPLIANCE ADVISORY
- COMPENSATION VALUATION PLANNING & DESIGN
- LITIGATION SUPPORT
- TAX COMPLIANCE, ACCOUNTING, & PLANNING
- AUDIT & ASSURANCE

What Is Compliance?

- General definition of ***compliance***:
  - Meeting the expectations of others
- **Compliance for healthcare providers**
  - Activities that assist organizations and providers with conducting operations and activities ethically, with the highest level of integrity, and in compliance with legal and regulatory requirements
  - Helps prevent violations and reduce the risk and liability to the provider organization



Mandates for Compliance

Centers for Medicare & Medicaid Services (CMS)

- Compliance efforts designed to establish a culture that promotes prevention, detection and resolution of instances of conduct that do not conform to federal and state law or to federal healthcare programs

Affordable Care Act (ACA)

- Curb healthcare provider fraud and abuse
- Section 6401 mandates that ALL healthcare providers enrolled in Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) establish a compliance program as a condition of enrollment

Source: 42 U.S.C. § 1395cc(j)(8). Section 6401,Health and Human Services (HHS)

What Is Covered by “Compliance”?

False Claims Act (FCA): Fraud, waste, and abuse

Anti-Kickback Statute (AKS): Incentives and/or bribes

Stark Law: Physician self-referral

Civil Monetary Penalties (CMPs): Settlement agreements

HIPAA/HITECH: Protected Health Information (PHI) privacy and security

Equal Employment Opportunity Commission (EEOC): Employment discrimination

Harassment and Retaliation

Whistleblower/Qui Tam

Occupational Safety and Health Administration (OSHA): Employee safety

A host of **other federal and state laws and regulations**

Definitions of Fraud, Waste, and Abuse (FWA)

Fraud:

The intentional deception or misrepresentation that an individual knows, or should know, to be false, or does not believe to be true, and makes, knowing the deception could result in some unauthorized benefit to himself or some other person(s)

- To purposely bill for services that were never given or to bill for a service that has a higher reimbursement than the services produced

Waste:

Incurring unnecessary costs as a result of deficient management, practices, or controls

- Overutilization of services that result in unnecessary costs to the Medicaid program

Abuse:

Provider practices that are inconsistent with sound fiscal, business, or medical practices, and that result in an unnecessary cost to the Medicaid program; or in reimbursement for services that are not medically necessary or that fail to meet professionally recognized standards for healthcare

- Includes beneficiary practices that result in unnecessary cost to the Medicaid program
- Paying for items or services that are billed by mistake by providers, but should not be paid for by Medicare/Medicaid

Source: https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/Fraud-Abuse-MLN4649244.pdf

Examples of FWA

Coding

- Unbundling
- Upcoding/downcoding

Billing

- Unnecessary treatments/services not rendered
- Duplicate billing resulting in duplicate reimbursement

Referral Relationships

- Kickbacks and inducements

Excluded Providers

- Billing for services provided by excluded provider

Expectations for Compliance Oversight

- **U.S. Sentencing Commission *2023 Guidelines Manual Annotated*** (*November 2023*)
  - https://www.ussc.gov/guidelines/guidelines-archive/2023-guidelines-manual-annotated
- **DOJ Criminal Division *Evaluation of Corporate Compliance Programs*** (*September 2024*)
  - https://www.justice.gov/criminal/criminal-fraud/page/file/937501/dl
- **OIG (guidance, updates)**
  - https://oig.hhs.gov/
- **OIG *Compliance Guidance***
  - https://oig.hhs.gov/compliance/compliance-guidance/
- **OIG *General Compliance Program Guidance (GCPG)***
  - https://oig.hhs.gov/compliance/general-compliance-program-guidance/

7 Elements . . .

. . . of an Effective Compliance Program are identified in the 1991 Federal Sentencing Guidelines for Organizations, which are the primary indicators of the federal government's expectations for effective compliance activities.

Settlements Due to Compliance Violations

- DOJ settlements are wide-spread among healthcare companies for non-compliance with the False Claims Act (FCA) and Stark Law.
- Settlements range from $10,000 to $2.3 billion (Pfizer, 2009).
- **Some recent examples of non-compliance include:**
  - Failure to provide medically necessary services
  - Upcoding of services
  - Paying kickbacks to increase Medicare services
  - Beneficiary inducement/waiver of patient cost-share (co-payments)
  - Services provided by Medicare/Medicaid-excluded persons
- Many settlements include additional government oversight, such as a corporate integrity agreement.

Sources: https://oig.hhs.gov/fraud/enforcement/
https://www.oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp

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 fair market value
  - No evidence of fair market valuation

Source: https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023

Healthcare Fraud Is Big Business

Of the more than $2.68 billion in settlements and judgments recovered by the DOJ this past fiscal year…

- **$1.8 billion** relates to matters that involved the healthcare industry, including:
  - Telehealth
  - Medicare Advantage
  - Unlawful kickbacks
  - Unnecessary medical services
  - Procurement fraud
  - COVID-19-related fraud

- **Over $2.3 billion** arose from lawsuits filed under the *qui tam* provisions of the FCA
  - During the same period, the government paid out **millions** to the individuals who exposed fraud and false claims by filing these actions.

The amounts included in the $2.68 billion reflect only federal losses, but in many of these cases the department was instrumental in recovering additional millions of dollars for state Medicaid programs.

Source: https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-268-billion-fiscal-year-2023

Significant Settlements with Federal Government (Public Records Data)

Company	Settlement Amount	Year	Alleged Conduct
Innovasis	$12 million	2024	Kickbacks included excessive consulting fees, payments for intellectual property acquisitions and licensing, performance shares in the company, lavish dinners, and travel expenses for events at luxury ski resorts.
Pfizer	$60 million	2025	Its subsidiary, Biohaven Pharmaceuticals, engaged in unlawful kickback practices to promote the migraine medication Nurtec ODT
DePuy Synthes	$9.75 million	2023	Kickbacks: Payments to HCP to induce use of products
Bayer	$40 million	2022	Kickbacks and Off-label Promotion: Consulting arrangements, grants, gifts
Biogen	$900 million	2022	FCA and Kickbacks: Payment of HCPS to induce prescriptions through speaker programs, consulting fees, meals, and entertainment; declined qui tam
Biotronik	$12.95 million	2022	Kickbacks: Preceptorships/employee training programs, entertainment
Essilor	$16.4 million	2022	Kickbacks: Practice-building support, loyalty programs, and growth-based discounts/rebates
Arthrex	$16 million	2021	Kickbacks: Improper royalty payments
Kaleo	$12.7 million	2021	FCA: Arrangements with pharmacy that submitted false PA requests Kickbacks: Food and gifts to HCPs

Compliance Considerations For Engaging with KOLs and HCPs

- Sunshine Act and Open Payments Reporting

  Since the Physician Payments Sunshine Act took effect, physicians' payments from life sciences companies for speaking engagements and other promotional activity are published annually on the Open Payments website maintained by the Centers for Medicare and Medicaid Services.

  https://openpaymentsdata.cms.gov/

- **OIG Special Fraud Alert**

  https://oig.hhs.gov/documents/special-fraud-alerts/865/SpecialFraudAlertSpeakerPrograms.pdf

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

Special Fraud Alert: Speaker Programs

November 16, 2020

What May Be Compensated and How May Compensation be Structured?

What?

- Speaking Services
- Advisory Board Participation
- Consulting
- Travel Time

How?

- Hourly compensation
- *A*nnual or monthly stipend

Fair Market Value and Commercial Reasonableness

Start by Determining Commercial Reasonableness

Document the Following for Every KOL or HCP Arrangement

1. Business Purpose
2. Appropriateness of the Provider
3. Requirements and Limitations of the Arrangement and Location
4. Resources Available and Alternatives to the KOL or HCP
5. Oversight and Monitoring Plan

Then Evaluate FMV: Five-Step Approach

1. Identify the **background, relevant facts, and key assumptions** surrounding the arrangement.

2. Initiate an analysis by identifying **multiple objective benchmark compensation surveys** and/or other resources to help analyze the specific services.

3. Identify **all the factors and surrounding circumstances** that should be considered when determining fair market value compensation for a specific transaction.

4. Identify **one or more approaches** to determine fair market value compensation.

5. Reconcile the various approaches and **document conclusion** in writing.

Valuation Approaches – Definitions

- **Which ones do we use?**
  - All **three approaches must be considered** in a valuation – however, not all approaches must be used or developed. For each of these approaches, there are multiple valuation methods.
- **Market Approach - based on transaction data involving similar assets or services**
  - The Market Approach is a valuation approach in which **market data is analyzed** to determine what is actually being paid in the marketplace for comparable ownership interests or services. The data is gathered and analyzed, and a comparison is made between the facts of the subject being valued and the facts of the particular market from which the information is obtained.
- **Cost Approach - based on the anticipated cost to recreate, replace, or replicate the asset**
  - The Cost Approach is a general way of determining the value of an ownership interest or services using one or more methods based on the value of the underlying assets or resources. The Cost Approach often involves a **calculation of the cost to replace or replicate** an asset or resource.
- **Income Approach - based on the economic benefits anticipated to be derived from the asset**
  - The Income Approach is a forward-looking premise of value based on the assumption that the value of a service or ownership interest is equal to the sum of the present values of the **expected future benefits** of providing a service or owning that interest.

Checklist for Life Science Organizations

Engagement Process: Service Definition

At the beginning of each engagement with a KOL/HCP consider the following:

- What is pre-approval process?
- What are the required qualifications of the KOL/HCP?
- What is the business purpose of the arrangement?
- How much time and preparation is required of the KOL/HCP?
- Have budgets been developed?

Engagement Process: Documentation of Need

After the service has been defined, document the previous items but also consider:

- Document the expected outcomes and benefits
- Document why the outcomes and benefits make sense excluding income from referrals.
- Document the needed scientific/medical expertise, reputation, knowledge, and experience in a particular therapeutic area.
- Document safeguards.
- Document how the arrangement will be periodically reviewed

Determine Fair Market Value

After the need is determined and documented, consider FMV:

- How will FMV be determined (internally, externally, benchmarks, market data, etc.)?
- Does the compensation structure set forth criteria to be paid?
- Is the compensation structure applied uniformly applied?
- How will exceptions be handled?
- If exceptions to predetermined levels occur frequently, such levels may need to be evaluated to minimize the need for exceptions.

Speaker Program Factors

- Is the information available only available through the speaker program?
- Is the event held in a location that is conducive to learning
- Is this the first time the KOL/HCP has presented as a speaker for the product or device?
- Is the information presented relevant to the selected audience?
- Does the organization distinguish speaker program activities from continuing medical education activities?
- Does the organization monitor speaker programs for compliance with regulatory requirements (i.e., FDA)?

Advisory Board (Ad Board)

- Is the compensation structure for KOL/HCP participation in an Ad Board consistent with the market (e.g., per meeting, annual retainer, etc.)?
- Has the format of Ad Board participation been considered (e.g., in-person, virtual, hybrid)?
- Are the expectations required of Ad Board KOLs/HCPs well defined and documented?

Consulting

- Are KOLs/HCPs selected based on the qualifications or experience needed and not solely on recommendations from interested parties (e.g., sales and marketing representatives, business unit operators, etc.)?
- Can the organization demonstrate use of KOL/HCP's expertise, and is it documented?

Other

- Are relevant decision-makers (i.e., compliance, legal, etc.) involved in the contract review process?
- Does the organization have a policy for compensating KOLs/HCPs for travel?
- Does the organization conduct training (e.g., compliance) at regular intervals for company representatives who interact with HCPs/KOLs?
- Does the organization periodically (e.g., annually) monitor executed agreements with KOLs/HCPs?

Questions?

PYA is here to Help