Healthcare Focus Arrangements

Scrutinize referral source contracts

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Healthcare is based on symbiotic relationships. For example, physicians refer their patients to hospitals and health systems for needed care. The hospitals and health systems benefit economically from these referrals by payments for these services from various sources including government programs.

"In some industries, it is acceptable to reward those who refer business to you. However, in the Federal health care programs, paying for referrals is a crime."[1]

To safeguard against hospitals and health systems providing anything of value to entice referrals, laws and regulations prohibit gifts and other kickbacks to referral sources. Without a comprehensive audit plan for focus (referral source) arrangements, organizations are vulnerable to regulatory violations that can damage their finances and reputation.

A focus arrangement (FA), or referral source arrangement, encompasses any relationship between an individual or organization and any source of government-reimbursed product, service, or sale that involves, directly or indirectly, the offer, provision or payment of anything of value. A referral source is anyone, including their immediate family members, who has the capacity to refer or influence the flow of Medicare, Medicaid or other federal healthcare program business to another party.

According to the Office of Inspector General (OIG), an FA is any agreement that might implicate Stark Law or the Anti-Kickback Statute (AKS). In addition, FAs must be scrutinized considering the False Claims Act (FCA). FAs are also key provisions in many Corporate Integrity Agreements (CIAs).

The laws and regulations for focus arrangements are intended to prevent overutilization of services, increased program costs, corruption of medical decision making, patient steering and unfair competition.

Spectrum of FAs

FAs can exist across the full spectrum of a healthcare organization's operations and the individuals and entities with which they have relationships. Exhibit 1 provides examples of individuals and entities where FAs can exist. Compelling

Laws and regulations for FAs

Stark Law – This set of federal laws prohibits a physician who has financial relationships with a hospital from making referrals for certain services for Medicare or Medicaid patients to that hospital. In addition, the hospital cannot bill Medicare or Medicaid for those referred services unless an appropriate exception is met.

Under Stark Law, a financial relationship may be direct or indirect—and a physician may stand in the shoes of his physician group. Remuneration is considered anything of value (e.g., wages, cash, tickets, gift cards, and payment for a medical directorship).

Anti-Kickback Statute (AKS) – AKS prohibits knowingly and willfully soliciting, receiving, offering, or paying any remuneration—anything of value, cash, or in-kind—in exchange for a Medicare or Medicaid referral. Providers can be found guilty under the AKS if one purpose of remuneration is to induce future referrals—the Greber "One Purpose" Test.[2]

False Claims Act (FCA) – The FCA is a longstanding federal law that imposes liability on those who attempt to defraud the government. The law includes a *qui tam* provision that allows people who are not affiliated with the government (whistleblowers) to file actions

[1] Page 4, OIG, A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse
[2] www.falseclaimsact.com/wp-content/uploads/2018/02/MSR-DER-A-Practitioners-Primer-on-History-and-Use-of-Federal-Anti-kickback-Statute.pdf

on behalf of the government and receive up to 30 percent of the recovered funds. The FCA carries both civil and criminal penalties. The civil penalties include up to $22,927 per false claim and up to three times the amount of damages.

Corporate Integrity Agreements (CIAs) – CIAs are negotiated by the OIG with healthcare providers as part of the settlement of federal investigations arising from suspected FCA violations. Providers that agree to the terms of CIAs are not excluded from Medicare and Medicaid billing.

reasons to identify, monitor and audit FAs include increasing regulatory enforcement and stiffer penalties.

Red flags of referral sources

Referral source scenarios that might prove problematic include, but are not limited to:

- A hospital provides free office space to referral sources like private practice physicians.
- A hospital stocks an ambulance with supplies and provides transporters with free food and other benefits.
- A referring physician, or immediate family member, has an interest in a company that does business with the hospital, like a physician-owned supply distributor.
- A hospital pays a referring physician to be a medical director or to provide other administrative services.

Exhibit 1 – Relationships with possible FAs

Employed physicians	Contracted physicians	Medical staff members (both privileged and credentialed)
Ambulatory surgery centers	Referring physicians	Private physician practices
Hospices	Operating room or neurology monitoring services	Academic medical center affiliations
Reference labs	Locum tenens companies	Home health agencies
Emergency medical services companies	Psychiatric/behavioral health facilities	Durable medical equipment providers
Lithotripsy providers	Wound care providers	Third-party facility managers
Community hospitals	Independently licensed nonphysician providers	Dialysis providers
Pharmaceutical manufacturers or distributors	Physical, occupational, speech therapists	Skilled nursing facilities
Optometrists	Medical device manufacturers or distributors	Dentists, dental surgeons
Long-term acute care facilities	Chiropractors	Psychologists
Physician-owned entities	Podiatrists	Residential care facilities

A focus arrangement is any agreement that might implicate the Stark Law and/or AKS.

Aggressive watchdogs

In 2018 the Department of Justice (DOJ) recovered $2.9 billion in FCA cases, up from $2.5 billion in 2017 and $2.2 billion in 2016. The escalating magnitude of annual recoveries indicates a continued focus on cases involving a wide array of alleged kickbacks, fraudulent billing schemes, illegal opioid distribution and much more.

Some examples include:

- Four Houston-area hospitals agreed to pay $8.6 million in 2017 to settle allegations that they received kickbacks from several ambulance companies in exchange for Medicare and Medicaid transport referrals.[3]
- A physician was sentenced in 2017 to seven months in prison for his role in criminal healthcare fraud totaling nearly $3 million. The case involved the physician's undisclosed partial ownership of an implantable medical device distributorship. In exchange for a share in the company, the physician persuaded the hospital where he worked to purchase the devices.[4]
- A Pennsylvania-based operator of long-term care and rehabilitation hospitals entered into numerous physician-services contracts on behalf of its hospitals. The purpose of the contracts was ostensibly to retain physicians as medical directors or in other administrative or medical roles. However, the government alleged that the company's payments under these contracts were intended to persuade the physicians to refer patients to the organization's facilities. In 2018 the company agreed to pay more than $13 million to settle the allegations of kickbacks and improper physician relationships.[5]
- A California healthcare system in 2019 agreed to pay $30.5 million to the federal government to settle a whistleblower lawsuit. An executive accused the system of disbursing millions of dollars of payments to physicians. The suit claimed that the payments were for unlawful kickbacks, excessive compensation, free employees and other illegal incentives to physicians in exchange for patient referrals.[6]

Structure provides safeguards

Every organization needs to pay enough attention to FAs to ensure that every contract is thoroughly vetted for possible legal and regulatory violations. The lack of centralized contract tracking systems, and outdated or absent formal policies and procedures for contract review, approval and monitoring are common structural deficiencies. These conditions can be a recipe for disaster for both large and small healthcare organizations.

By contrast, some organizations have comprehensive contract management processes that require signatures before services start. These organizations know exactly where to find the documentation for their FAs and are aware of expiring agreements. While not completely insulated from FA concerns, the organizations are better positioned given their focus on key risk mitigation strategies.

Ideally, an organization should integrate contract approvals into its systemwide compliance plan and governance structure. In its relationships with employed and contracted physicians, an organization's human resources function should have consistent onboarding procedures and a recruitment process that understands compliance.

All appropriate staff members should receive training in the intricacies of managing FAs. Regular monitoring and auditing of such arrangements should identify potential issues before a regulatory body or potential whistleblower identifies them.

Regulatory compliance developments

Several notable developments related to FAs have occurred:

- The Granston Memo curbs meritless *qui tam* suits and gives DOJ attorneys broader discretion in dismissing them.
- The Brand Memo limits the use of guidance documents in litigation. The memo clearly indicates that guidance documents lack the force of law and emphasizes that DOJ lawyers should not consider them mandatory.
- A 2018 DOJ memorandum discouraged piling on, when one agency begins an investigation and other agencies seek punishment for the same alleged misconduct.
- In 2018, President Trump issued an executive order establishing a new working group to make recommendations about white-collar crime and corporate compliance. The working group is examining the strength of corporate compliance programs and the

[3] www.justice.gov/usao-sdtx/pr/four-area-hospitals-pay-millions-resolve-ambulance-swapping-allegations
[4] https://dakotafreepress.com/tag/wilson-asfora/
[5] www.justice.gov/opa/pr/post-acute-medical-agrees-pay-more-13-million-settle-allegations-kickbacks-and-improper
[6] www.justice.gov/opa/pr/california-health-system-and-surgical-group-agree-settle-claims-arising-improper-compensation

Exhibit 2 – CIAs include FA components

1. Hire a compliance officer, if that position does not already exist, and establish a compliance committee. The compliance officer must make an annual report to the committee.
2. Develop written standards and policies, including certifications that employees and contracted parties will not violate Stark Law or AKS.
3. Establish an FA approval process that clearly defines the individuals required to approve arrangements and ensures that legal counsel reviews each new and renewed contract.
4. Implement a comprehensive training program that includes employees, board members and all individuals covered by FAs.
5. Select an independent review organization (IRO) to conduct annual reviews.
6. Create an FA tracking system that monitors remuneration, services, leased space, medical supplies, medical devices and more.
7. Conduct randomly selected FA reviews to verify that arrangements have been approved internally, meet all compliance metrics and are properly documented.
8. Document greater involvement from the board of directors, including certification that the board has reviewed the annual IRO findings.
9. Implement effective responses for compliance violations, including disclosure of reportable events.
10. Provide an annual report to the OIG.

value of corporate cooperation in the context of investigations.

CIA requirements for FAs

FA requirements are typically included in CIAs. A comprehensive CIA between the OIG and a healthcare organization typically lasts five years. You should take heed in understanding CIA expectations and use the CIA components in Exhibit 2 as best practices in compliance planning.

Create an oversight process

Once your organization has identified all its FA agreements and supporting documentation, the following steps are critical to creating an effective auditing and monitoring program:

Establish an FA review committee – The committee overseeing referral source arrangements should be high-level, reporting to the organization's compliance committee.

Verify contract approval and execution – The FA committee should verify that the organization's legal counsel has approved all contracts. Also, the committee should confirm that referral sources and the organization have signed the contracts in accordance with applicable policies and procedures.

Verify value and reasonableness assessments – Determine whether a fair market value (FMV) assessment has been completed for the FA to include a review of all types and sources of payment. A commercial reasonableness (CR) analysis also should have been completed and documented.

Identify the referral source's duties – The contract should clearly define the referral source's specific duties. Check each contract for any duplicative duties for which the physician could be compensated. Determine whether the contract covers at least one year and whether the contract can be terminated without notice within that period. Also, review the contract for any supervisory duties and the method for determining compensation (i.e., advanced practice provider supervision, etc.).

Create a performance evaluation process – Every contract should include an annual performance evaluation to assess the referral source's professionalism and performance of contracted duties. Make sure the contract has functional

One red flag is a hospital providing free office space to referral sources.

The lack of a centralized contract tracking system is common structural deficiency.

metrics to ensure that care, treatment and services have been administered in a compliant manner.

Review contract documentation – Where appropriate and applicable, contracts should include documentation, or an alternative form of record, of all delivered services and the hours spent performing duties. Pursuant to an established compensation philosophy, contract files should include documentation of FMV and CR. Both often include supporting materials such as provider needs assessments and, more frequently, medical director needs assessments.

Review any supplemental compensation – Supplemental compensation, like signing and retention bonuses, recruitment arrangements and income guarantee payments, should meet the terms of the agreement in order to comply with the Stark Law. For instance, compensation should be terminated on the date defined in the contract. Reviewers should also determine whether a forgiveness or repayment plan is included in a recruitment agreement and confirm that the plan is carried out properly.

Review payment support and rates – The FA committee should periodically sample FA disbursement data, including payroll data, in order to ensure what is being paid is in accordance with the agreement. For example, if a medical director agreement indicates that submission of time sheets with documented service hours is required prior to payment, the audit should verify the submitted information.

You should confirm that accounts payable disbursement requests for contracted referral sources were verified using invoices, check requests and other supporting information. A review of all nonmonetary compensation, including gifts, gratuities, entertainment, and meals is also a prudent exercise.

Identify and prioritize FA risks – Know your biggest risks and allocate your resources accordingly. Exhibit 3 summarizes most common risks.

Exhibit 3 – FA risks

1. Stacked agreements where one referral source has multiple agreements that provide compensation
2. Unsigned contracts
3. Contracts that do not define accountability for monitoring the terms and conditions
4. Duties are submitted for compensation but are not included in the contract
5. Any implication that the referral source is compensated for volume or value of referrals
6. Remuneration rates that are inconsistent with FMV
7. Agreements that do not include an assessment of FMV
8. Longstanding evergreen contracts where FA terms have not been regularly reviewed

Summary

With healthcare organizations continuing to enter into focus or referral source arrangements, regulatory compliance must remain at the forefront when developing and implementing such contracts. By compliantly managing all focus arrangements with robust auditing and monitoring, your organization should avoid regulatory violations that could invoke significant financial harm and tarnish its prestige. **NP**

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