Navigating Harbors and Exceptions in Healthcare Contracting

by Andrew T. Wampler

Lawyers are well versed in contracts. Offer, acceptance, and consideration are usually straightforward. However, there can be many industry-specific issues, particularly in health care. Several laws place restrictions on arrangements between healthcare providers, some of which seem counterintuitive.

Providers face increasing difficulty structuring practices. There is a push to deliver quality care with decreasing reimbursement. As the largest payer of services, the government applies intense scrutiny.[1] Providers who treat Medicare or Medicaid patients have an obligation to prevent unnecessary billing. Regulators seek to ensure care based on medical decision-making rather than financial.

Myriad Restrictions

The maze of laws to prevent healthcare fraud creates traps for the unwary for what appear to be appropriate business decisions. When healthcare clients call, it is important to understand compliance hazards. Prohibited relationships are those that create incentives to bill services that should not be billed or pay for patient referrals.

Courts recognize the complexity providers face. In an appeal upholding a multi-million-dollar judgment, Judge Wynn of the Fourth Circuit wrote: "It seems as if, even for well-intentioned health-care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure — especially when coupled with the False Claims Act."[2]

The following federal laws impact providers: Physician Self-Referral Law ("Stark"), Anti-Kickback Statute (AKS), False Claims Act (FCA), Civil Monetary Penalties Law (CMPL), and Exclusion Authorities. Virginia has complimentary laws: Virginia Fee-Splitting Act, Virginia Practitioner Self-Referral Act, and Virginia Anti-Kickback Statute. This article does not discuss nuances of applicable laws, outline all exceptions and safe harbors to illegal relationships, or discuss all agreement types. There are treatises that do that. This article provides basic overview of some common situations to help practitioners spot issues and minimize risk.

Stark

The physician self-referral law, or Stark Law, prohibits referrals for designated health services (DHS) payable by Medicare to an entity with which the physician (or immediate family) has a financial relationship.[3] The statute prohibits DHS-furnishing entities from filing claims with Medicare for services referred by that physician. Financial relationships include direct or indirect ownership, investment, or compensation for services. The government is prohibited from paying claims that violate Stark. The law allows commercially reasonable arrangements when physicians are paid market value without considering value or volume of referrals.[4] Specific exceptions outline relationships deemed not to pose a risk to payment programs.

DHS includes many services patients need. When in question, providers can generally assume that services are included.[5] Originally, the law applied to laboratory services, but the legislature expanded to DHS and included Medicaid. Changes and phases of adoption require constant evaluation of current regulations and enforcement efforts.

Stark was created to provide "bright line" rules to "ensure compliance and minimize . . . costs."[6] It has provided anything but bright lines. Stark has strict liability, thus intent does not matter, and there is no defense for technical violations.

Anti-Kickback Statute

AKS is a criminal statute, prohibiting one from offering something of value to influence the referral of business.[7] Both parties can be liable, and conviction can include significant fines and imprisonment. AKS applies to anyone who "knowingly and willfully offers, pays, solicits, or receives remuneration in order to induce business reimbursed under the Medicare or Medicaid programs."[8] Induce referrals need be only one purpose of a transaction.

Safe harbors describe practices that are not treated as kickbacks. Regulations specify allowable "safe" financial relationships. Safe harbors exist for numerous arrangements, both common and uncommon, such as employment agreements, leases, electronic prescribing, warranties, investment interests, recruitment, and discount programs. Under AKS, transactions that do not have specific safe harbors are not automatically violations but are reviewed case-by-case for their effect on payment programs.[9]

False Claims Act

FCA imposes liability on those who "knowingly present[], or cause[] to be presented, a false or fraudulent claim for payment or approval."[10] Knowingly involves actual knowledge of falsity, deliberate ignorance, or reckless disregard.[11] This scienter requirement avoids punishing "honest mistakes" or "mere negligence."[12] One defense is good faith reliance on the advice of counsel.[13]

FCA's purpose is to indemnify the government against fraud. FCA is often a vehicle to assert Stark and AKS violations.

Civil Monetary Penalties Law & Exclusion Authorities

CMPL creates civil monetary penalties for fraud. Many acts can constitute violations from presenting a claim to including false statements on program applications to violating Medicare assignment provisions. The Office of Inspector General (OIG) has mandatory and permissive authority to exclude from program participation. The authorities arise under the Social Security Act.[14] CMPL is interconnected with the web of federal restrictions and used in conjunction with other laws. The OIG seeks different penalties depending on the conduct and which laws are implicated.

Virginia Laws

The Virginia Fee-Splitting Statute prohibits physicians from sharing "any professional fee received for the provision of health services … to a patient with another physician licensed to practice medicine … in return for such other

physician's making a referral … or [accepting] any portion of a professional fee paid to another physician"[15]

The Virginia Physician Self-Referral Statute prohibits patient referral to an entity outside the practitioner's practice if the practitioner (or immediate family) is an investor.[16] The statute applies to all services and all patients, whether the government is a payer. Virginia enforces the statute in a manner consistent with Stark. The Department of Health Professions provides advisory opinions on arrangements and maintains them on its website along with regulations.[17]

The Virginia Anti-Kickback Statute states that any person who "knowingly and willfully solicits or received any remuneration, including any kickback, bribe, or rebate, directly or indirectly, overtly or covertly, in cash or in-kind" for a referral or for "purchasing, leasing or ordering any goods, facility, service or item for which payment may be made in whole or in part under medical assistance" commits a felony.[18] Interpreted to be consistent with AKS, the statute does not prohibit disclosed discounts, bona-fide employment, or other AKS-permitted conduct.

Contract Compliance

Federal rules and regulations address arrangements that are deemed legal under the various restrictions. Many exceptions and safe harbors include specific drafting or procedure requirements. They differ from one type of arrangement to another. But there are general principles to keep in mind. Basic rules are that all payments be fair market value and services actually be needed and medically necessary. The question is whether payments are consistent with comparable arm's-length transactions and are commercially reasonable.

Of the many agreement types, service agreements and leases are two of the most common; while there is not room to discuss all provider arrangements, this article lists exceptions and safe harbors for these forms of agreements. Service agreements include employment and independent contractor agreements. Leases can cover space, equipment, or personnel.

Service Agreements

For employment agreements, Stark has an Employment exception. This exception requires fair market value compensation set in advance, but allows referrals in certain circumstances.[19] Productivity payments are based on personally performed services and cannot take into account facility fees.[20] For employees, there is also an In-Office Ancillary Services exception.

For Independent contractors, Stark has Personal Service Arrangement and Fair Market Value exceptions.[21] These exceptions apply to medical director, call coverage, professional service, and management services agreements. These agreements must be for a year or longer, and if terminated in the first year, a new agreement cannot be executed for the same services. They must pay fair market value and not take into account referrals or business between the parties.

For services agreements, AKS may also be implicated because AKS applies when one purpose of a payment could be to induce referrals. For employees, the OIG has established an Employee safe harbor which simply requires a bona-fide employment agreement.[22] OIG has more rigorous safe harbors such as Management Contracts and Personal Services, requiring aggregate compensation in a fixed amount.[23] Unlike strict compliance under Stark, the AKS analysis is intent based. Therefore, providers can aim to meet the majority of requirements since failure to comply completely does not establish a *per se* violation.

Leases

Stark has a Rental of Office Space exception, which requires a written arrangement with a one-year term.[24] There can be shared common areas, but clinical space must be exclusive. Rent must be fair market value set in advance, not based on business between the parties.

For equipment, Stark has Rental of Equipment and Fair Market Value exceptions.[25] There are documentation, term length, and fair market value requirements. The Rental exception requires exclusive use, and both prohibit percentage-based or per-unit payments.

Both Equipment and Space lease safe harbors require part-time use to be scheduled in advance and aggregate compensation to be set in advance.[26] As with other safe harbors, failure to meet all requirements does not necessarily indicate a violation.

Changes in 2016

Because enforcement, implementation, and interpretation of Stark has been fluid, proposed arrangements require review of current regulations. With the complexities and the possibility of running afoul of requirements, providers have called for more flexibility. As of 2016, a new Final Rule relaxes some Stark requirements.[27]

Historically, time-share leases have been extremely complicated. Under a new Time-Share License exception, a provider can use an office, including personnel, equipment, and furnishings, on a periodic, fluctuating basis. Exclusive use is required, but the license is flexible. Unlike a lease that transfers control, a license offers the privilege to access. This license must be signed, specifying location and services.

The rule also relaxed standards for a writing under various exceptions. Several exceptions now use the term "arrangement" rather than "agreement" or "contract." Document collections can show course of conduct to establish an arrangement.[28] Board minutes, communications, fee schedules, and time sheets are examples. Documents must be contemporaneous, and there is no grace period. Centers for Medicare and Medicaid Services (CMS) still states that "the surest and most straightforward means" to be compliant is to have a single writing.

The rule outlines a 90-day window to obtain signatures and relaxes some one-year-term requirements, provided the arrangement lasts for a year.

Suggestions

Many arrangements create some level of risk. These risks can be managed by an understanding of the concepts underlying the prohibitions. There are few strategies that help:

1. Be wary. Request prior legal reviews.
2. Identify pertinent aspects of the arrangement.
3. Consider fair market value.
4. Consider commercial reasonableness.
5. Document fair market value/commercial reasonableness.[29] Specific nature of relationship matters, not business in general.
6. Review all party arrangements. Aggregation can cause issues.
7. Specify services and compensation. Don't change them retroactively.
8. Check family members.
9. Get signed agreements, even if not mandatory. They provide the best protection.
10. Ensure services are necessary and performed. Conduct matters.

Healthcare contracting raises unique concerns that require care. Compliance with Stark and AKS is necessary, but numerous other issues need attention as well, from government audit requests to hazardous substance management to accrediting body standards to protected health information. Asking questions with a critical eye to regulations is an important first step representing providers who come calling for contract advice.

Endnotes:

1 Government has "strong interest" in preventing fraud because "[f]raudulent claims make the administration of Medicare more difficult, and widespread fraud would undermine public confidence in the system." *United States ex rel Drakeford v. Tuomey d/b/a Tuomey Healthcare System, Inc.*, No. 13-2219, 792 F.3d 364 (4th Cir. 2015).
2 *Id.* at 395 (Wynn, J., concurring).
3 42 U.S.C. § 1395nn.
4 42 C.F.R. § 411.357(p).
5 Following are DHS:
   1. Clinical laboratory services.
   2. Physical therapy services.
   3. Occupational therapy services.
   4. Outpatient speech-language pathology services.
   5. Radiology and certain other imaging services.
   6. Radiation therapy services and supplies.
   7. Durable medical equipment and supplies.
   8. Parenteral and enteral nutrients, equipment, and supplies.
   9. Prosthetics, orthotics, and prosthetic devices and supplies.
   10. Home health services.
   11. Outpatient prescription drugs.
   12. Inpatient and outpatient hospital services.
6 66 F.R. 856, 860 (Jan. 4, 2001).
7 42 U.S.C. § 1320a-7b.
8 Section 1128B(b), Social Security Act.
9 OIG Dept. HHS, Fact Sheet Nov. 1999, *Federal Anti-Kickback Laws and Regulatory Safe Harbors.*
10 31 U.S.C. § 3729(a)(1)(A).
11 *Id.* § 3729(b)(1).
12 *United States v. First Kuwaiti Gen. Trading & Contracting Co.*, 612 F.3d 724, 728 (4th Cir. 2010).
13 *United States v. Newport News Shipbuilding, Inc.*, 276 F. Supp. 2d 539, 565 (E.D. Va. 2003).
14 42 U.S.C. § 1320a-7. *See* https://oig.hhs.gov/exclusions/authorities.asp (accessed July 23, 2017).
15 Va. Code § 54.1-29.62.
16 Va. Code § 54.1-2411.
17 https://www.dhp.virginia.gov/bhp/bhp_PSR.htm (accessed July 23, 2017). Application procedure: http://law.lis.virginia.gov/admincode/title18/agency75/chapter20/section60 (accessed July 23, 2017). *See* 18 VAC 75-20-10 *et seq.*
18 Va. Code § 32.1-315.
19 42 C.F.R. § 411.354(d).
20 42 C.F.R. § 411.357(c).
21 42 C.F.R. § 411.355(b).
22 42 C.F.R. § 1001.952(i).
23 42 C.F.R. § 1.952(d).
24 42 C.F.R. § 411.357(a).
25 *Id.*
26 42 C.F.R. § 1001.952(b), (c).
27 80 F.R. 220 (Nov. 16, 2015).
28 *Id.* at 71314.
29 66 F.R. 856, 944-45 (Jan. 4, 2001). Cost attestations, price lists, and compensation surveys are options. Best practice is to obtain an independent valuation. Reports should be updated every two years.

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