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Valuation of Hospitals: Regulatory Environment

Hospitals face a range of complex, overlapping federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and transactions. Fraud and abuse laws, specifically those related to the federal Anti-Kickback Statute (AKS) and physician self-referral laws (the "Stark Law"), may have the greatest impact on the operations of hospitals. The third installment in this five-part series on the valuation of hospitals highlights some of the newer and more pressing statutes and regulations that comprise the regulatory environment in which hospitals operate.

Federal Fraud & Abuse Laws

The AKS and Stark Law are generally concerned with the same issue – the financial motivation behind patient referrals. However, while the AKS is broadly applied to payments between providers or suppliers in the healthcare industry and relates to any item or service that may be paid for under any federal healthcare program, the Stark Law specifically addresses the referrals from physicians to entities with which the physician has a financial relationship for the provision of defined services that are paid for by the Medicare program.[1] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[2]

Anti-Kickback Statute

Enacted in 1972, the federal AKS makes it a felony for any person to "*knowingly and willfully*" solicit or receive, or to offer or pay, any "*remuneration*", directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program,[3] even if only one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.[4] Notably, a person need not have actual knowledge of the AKS or specific intent to commit a violation of the AKS for the government to prove a kickback violation,[5] only an awareness that the conduct in question is "generally unlawful."[6] Further, a violation of the AKS is sufficient to state a claim under the *False Claims Act* (FCA).[7]

Criminal violations of the AKS are punishable by up to ten years in prison, criminal fines up to $100,000, or both, and civil violations can result in administrative penalties, including exclusion from federal healthcare programs, and civil monetary penalties plus treble damages (or three times the illegal remuneration).[8] In addition to the civil monetary penalties paid under the AKS, if the AKS violation triggers liability under the FCA, defendants can incur additional civil monetary penalties of $13,508 to $27,018 per violation, plus treble damages.[9]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[10] In response to these concerns, Congress created a number of statutory exceptions and delegated authority to HHS to protect certain business arrangements by means of promulgating several *safe harbors*.[11] These *safe harbors* set out regulatory criteria that, if met, shield an arrangement from regulatory liability, and are meant to protect transactional arrangements unlikely to result in fraud or abuse.[12] Failure to meet all of the requirements of a *safe harbor* does not necessarily render an arrangement illegal.[13] It should be noted that, in order for a payment to meet the requirements of many AKS safe harbors, the compensation must not exceed the range of fair market value.

The AKS was revised in December 2020, many of which revisions are similar to those made to the Stark Law, as discussed more fully below.[14] Among the more notable revisions are newly-established safe harbors for value-based arrangements (the safe harbor requirements for which arrangements lessen as the participants take on more financial risk) and revisions to existing safe harbors.[15]

Stark Law

The Stark Law prohibits physicians from referring Medicare patients to entities (such as hospitals) with which the physicians or their family members have a financial relationship for the provision of designated health services (DHS).[16] DHS include, but are not limited to, the following:

(1) Inpatient and outpatient hospital services;
(2) Radiology and certain other imaging services;
(3) Radiation therapy services and supplies;
(4) Certain therapy services, such as physical therapy;
(5) Durable medical equipment; and,
(6) Outpatient prescription drugs.[17]

Under the Stark Law, financial relationships include ownership interests through equity, debt, other means, and ownership interests in entities also have an ownership interest in the entity that provides DHS.[18] Additionally, financial relationships include compensation arrangements, which are defined as

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arrangements between physicians and entities involving any remuneration, directly or indirectly, in cash or in kind.[19]

Civil penalties under the Stark Law include overpayment or refund obligations, a potential civil monetary penalty of $15,000 for each service, plus treble damages, and exclusion from Medicare and Medicaid programs.[20] Further, similar to the AKS, violation of the Stark Law can also trigger a violation of the FCA.[21]

Notably, the Stark Law contains a large number of exceptions, which describe ownership interests, compensation arrangements, and forms of remuneration to which the Stark Law does not apply.[22] Similar to the AKS safe harbors, without these exceptions, the Stark Law may prohibit legitimate business arrangements. It must be noted that in order to meet the requirements of many exceptions related to compensation between physicians and other entities, compensation must: (1) not exceed the range of fair market value; (2) not take into account the volume or value of referrals generated by the compensated physician; and, (3) be commercially reasonable. Unlike the AKS safe harbors, an arrangement must fully fall within one of the exceptions in order to be shielded from enforcement of the Stark Law.[23]

As noted above, the Centers for Medicare & Medicaid Services (CMS) released a number of revisions to the Stark Law in December 2020, including:

(1) Revised definitions for Fair Market Value, General Market Value, and Commercial Reasonableness; and,
(2) New permanent exceptions for value-based arrangements.[24]

Importantly, the new value-based arrangements exceptions protect the following arrangements:

(1) Full Financial Risk Arrangements: Includes capitated payments and predetermined rates or a global budget;
(2) Value-Based Arrangements with Meaningful Downside Financial Risk: Where a physician pays no less than 25% of the value of the remuneration the physician receives when he or she does not meet pre-determined benchmarks; and,
(3) Value-Based Arrangements: Applies regardless of risk level to encourage physicians to enter value-based arrangements, even if they only assume upside risk.[25]

It is important to note that, the regulatory scrutiny of healthcare entities (especially with regard to fraud and abuse violations) has generally increased over the past decade. The Department of Justice (DOJ) recovered over $1.8 billion from healthcare fraud and abuse enforcement in 2023 alone.[26] These recoveries reflect the DOJ's focus on its current enforcement priorities, including violations of cybersecurity requirements in government-funded grants and contracts and fraud in pandemic relief programs.[27]

The Emergency Medical Treatment and Labor Act (EMTALA)

In April 1986, Congress passed the *Consolidated Omnibus Budget Reconciliation Act of 1985*, which included an amendment to the *Social Security Act* that created new requirements for hospitals that participate in the Medicare program.[28] Known today as EMTALA, this law requires Medicare-participating hospitals that operate an emergency department (ED) to provide "an appropriate medical screening examination" to any patients who present themselves to the ED.[29] Further, if the hospital determines that a patient is in active labor or is suffering from some other emergency condition, the hospital is required to provide treatment for the patient, regardless of the patient's ability to pay or insurance status.[30] If the hospital cannot provide appropriate treatment, or if the patient requests, the hospital must transfer the patient to a more suitable site.[31] Medicare-participating hospitals that fail to comply with EMTALA regulations may: (1) lose their status as a Medicare-participating hospital; (2) incur civil monetary penalties of up to $50,000; and/or (3) be liable for damages in civil actions brought by patients or other medical facilities that were harmed as a result of the violation of EMTALA.[32]

Price Transparency Act

One of the newer regulations that has targeted hospitals is price transparency. Beginning January 1, 2021, group and individual health plans and insurers were required by CMS to disclose cost-sharing information for certain covered items and services.[33] This information must be available online and in paper form, and aims to allow patients to estimate their own out-of-pocket expenses.[34] The Price Transparency Act requires the disclosure of negotiated rates, historically allowed amounts for out-of-network providers, and drug prices.[35] The goal of this final rule is to create better-informed consumers who can shop for services more efficiently and ultimately slow the rise of healthcare spending.[36] On November 2, 2023, CMS finalized changes to the hospital price transparency regulations; the updated rule requires hospitals to provide the pricing information in a standardized template and include a completeness and accuracy affirmation statement.[37] The updates, most of which took effect in 2024, are intended to expand transparency and streamline the enforcement process.[38]

Conclusion

Hospitals face many obstacles within the regulatory environment that can prohibit their formation, growth, and development. For example, fraud and abuse scrutiny has increased over the past two decades and continues to be a significant risk factor for hospitals. Moreover, new regulations, such as the Price Transparency Act, adds to a hospital's administrative burden, and can result in large fines if not complied with. Consequently, having a robust compliance program, to ensure a hospital stays within regulatory bounds, is integral to a hospital's success.[39] Another factor integral to the success of a hospital is the reimbursement environment. Consequently, the next installment in this series will discuss the reimbursement environment in which hospitals operate.

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