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Valuation of MSOs: Regulatory Environment

Management service organizations (MSOs) face a range of 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 healthcare providers. The last installment in this three-part series on the valuation of MSOs discusses the regulatory environment in which these organizations operate.

Federal Fraud and 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 and must be commercially reasonable.

Of note, in a December 2020 final rule, the Department of Health & Human Services Office of Inspector General (HHS OIG) released several revisions to the AKS, many of which are similar to those revisions to the Stark Law proposed by the Centers for Medicare & Medicaid Services (CMS), as discussed below.[14] Among the more notable revisions are new 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, including to the safe harbor for Personal Services and Management Contracts and Outcomes-Based Payment Arrangements.[15] Among other things, this safe harbor requires that the "[t]he methodology for determining the compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arm's-length transactions, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties…"[16] Notably, the OIG eliminated the requirement that *aggregate compensation* under these agreements be set in advance, instead requiring only that the *compensation methodology* be set in advance.[17]

The OIG regularly issues advisory opinions on the application of the AKS to certain business arrangements – either existing or proposed – on which a party has requested an opinion. An advisory opinion is the OIG's position on whether a certain business arrangement is in

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conflict with the AKS.[18] Over the years, a number of these advisory opinions have analyzed various management services arrangements. For example:

(1) A 1998 advisory opinion expressed concern regarding MSOs receiving payment from a physician group as a percentage of collections or revenue while performing marketing services.

(2) A 2006 advisory opinion reviewed payment to a dental marketing and management company.[19] While it ultimately found that the arrangement was in compliance with the AKS, the OIG noted that "Per patient, per unit-of-service, percentage, or similar variable compensation structures are particularly problematic under the statute, because they relate to the volume or value of business generated between parties."[20]

(3) A 2003 advisory opinion reviewed a proposed management fee, calculated on a per patient per day basis, to be paid to a company to develop inpatient rehab units in general acute care hospitals, to be in violation of the AKS.[21]

Stark Law

The Stark Law prohibits physicians from referring Medicare patients to entities with which the physicians or their family members have a financial relationship for the provision of designated health services (DHS).[22] Under the Stark Law, 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.[23]

If DHS is not included in the arrangement (which is not uncommon in management services arrangements, particularly those involving medical practices), the Stark Law would not apply.[24]

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.[25] Additionally, financial relationships include compensation arrangements, which are defined as arrangements between physicians and entities involving any remuneration, directly or indirectly, in cash or in kind.[26]

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.[27] Further, similar to the AKS, violation of the Stark Law can also trigger a violation of the FCA.[28]

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.[29] 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 Stark enforcement.[30]

As noted above, in December 2020, CMS released a number of revisions to the Stark Law in a final rule, including:

(1) Revised definitions for Fair Market Value, General Market Value, and Commercial Reasonableness; and,

(2) New permanent exceptions for value-based arrangements.[31]

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. Therefore, under current regulation, the severe penalties that may be levied against healthcare providers under the AKS, the Stark Law, and/or the FCA will likely raise investors' estimate of the risk related to a given management services arrangement.

Corporate Practice of Medicine Provisions

Almost all states have provisions against the *corporate practice of medicine* (CPOM), a doctrine first developed by the American Medical Association (AMA).[32] Although the regulated content of CPOM provisions vary across states, these laws generally prohibit unlicensed individuals or corporations from engaging in the practice of medicine by employing licensed physicians.[33] CPOM laws were established with the intent of ensuring that licensed physicians could practice medicine without pressure from a lay person or being "*subject to commercialization or exploitation.*"[34] CPOM laws relate directly to MSOs because they dictate what type of relationship healthcare entities may have with physicians (i.e., employment versus independent contractor).[35] While there are significant variations in regulation between states, most states have adopted all or some of the following measures in the four key areas addressed by the doctrine:

(1) Prohibiting business entities from employing physicians to provide medical care;

(2) Requiring that licensed medical doctors own and operate facilities providing medical services;

(3) Not allowing professional fee splitting between licensed practitioners and non-licensed individuals or entities; and,

(4) Mandating that management service agreements (MSAs) adhere to fair market value standards.[36]

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MSAs and MSOs have received increased regulatory scrutiny in recent years, in part because they allow outside (often non-healthcare) companies to manage medical practices or groups, including administration and operations.[37] In order to mitigate potential fraud and abuse issues, regulations require fees for these management services to be consistent with fair market value, and state laws and regulations create certain standards for decisions that must be made by a licensed physician and how much revenue that an MSO may receive from the practice.[38]

Conclusion

Considering the various competitive, reimbursement, technological, and regulatory trends discussed in this three-part series, MSOs may face some challenges in the coming years. As noted in the first installment, the scope of MSO services may also reflect the specific needs and concerns of the healthcare entity contracting with the MSO. For example, as fraud and abuse scrutiny increases and the claims submission process for reimbursement becomes significantly more complex, MSOs may choose to focus their services on coding, billing, and other revenue cycle management tasks. As noted in the second installment, MSOs that are positioned to adopt rapidly-advancing technology may be able to utilize technology to improve savings and the quality of care. As with most other healthcare organizations, MSOs will be required to efficiently provide services while maintaining compliance with regulations and remaining aware of government enforcement initiatives in order to survive.

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23 "Limitation on Certain Physician Referrals" 42 USC § 1395nn(a)(1)(B); "Definitions" 42 CFR § 411.351 (2015). Note the distinction in 42 CFR § 411.351 regarding what services are included as DHS: "Except as otherwise noted in this subpart, the term 'designated health services' or DHS means only DHS payable, in whole or in part, by Medicare. DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, SNF Part A payments or ASC services identified at §416.164(a)), except to the extent that services listed in paragraphs (1)(i) through (1)(x) of this definition are themselves payable through a composite rate (for example, all services provided as home health services or inpatient and outpatient hospital services are DHS)."
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26 42 USC § 1395nn (h)(1).
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