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Valuation of Senior Healthcare: Regulatory

As noted in the first installment of this five-part series, senior healthcare options have dramatically expanded in the past decade, and seniors have more healthcare service choices than ever before to meet varied care needs and income levels. These myriad options also have varying degrees of regulation, both at the federal and state level. This third installment in this five-part series on the valuation of senior healthcare will discuss the regulatory environment in which senior care facilities operate.

Federal Fraud and Abuse Laws

Healthcare organizations 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 most significant impact on the operations of healthcare providers.

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 receive funding from 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] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[4] Congress amended the original statute in 1987 with the passage of the *Medicare and Medicaid Patient & Program Protection Act* to include exclusion from the Medicare and Medicaid programs as an alternative civil remedy to criminal penalties.[5] Additionally, the *Balanced Budget Act of 1997* added a civil monetary penalty of treble damages, or three times the illegal remuneration, plus a fine of $50,000 per violation.[6] Additionally, interpretation and application of the AKS under case law have created a precedent for a regulatory hurdle known as the *one purpose test*. Under the *one purpose test*, healthcare providers violate the AKS if even one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.[7]

The *Patient Protection and Affordable Care Act* (ACA) made two noteworthy changes to the intent standards related to the AKS. First, the legislation amended the AKS by stating that a person need not have *actual knowledge* of the AKS or specific intent to violate the AKS for the government to prove a kickback violation.[8] However, the ACA did not remove the requirement that a person must "*knowingly and willfully*" offer or pay remuneration for referrals to violate the AKS.[9] Therefore, to prove a violation of the AKS, the government must show that the defendant was aware that the conduct in question was "*generally unlawful*," but not that the conduct specifically violated the AKS.[10] Second, the ACA provided that a violation of the AKS is sufficient to state a claim under the *False Claims Act* (FCA).[11] The amended AKS points out that liability under the FCA is *"[i]n addition to the penalties provided for in [the AKS]*…"[12] The amendment suggests that in addition to civil monetary penalties paid under the AKS, violation of the AKS would create additional liability under the FCA, which itself carries civil monetary penalties of over $21,500 plus treble damages.[13]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[14] In response to these concerns, Congress created several statutory exceptions and delegated authority to the *U.S. Department of Health & Human Services* (HHS) to protect specific business arrangements through the promulgation of several safe harbors.[15] 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.[16] Failure to comply with all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[17] Importantly, for a payment to meet the compliance of many AKS safe harbors, the compensation must not exceed the range of fair market value and must be commercially reasonable.[18]

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Of note, in October 2019, the HHS *Office of Inspector General* (OIG) proposed several revisions to the AKS, many of which are similar to those revisions to the Stark Law proposed by CMS. Additionally, the OIG proposed modifying some safe harbors currently established, such as personal services and management contracts and outcomes-based payment arrangements. These arrangements were changed to add more flexibility, e.g., by adding protections to certain outcomes-based payments.[19]

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).[20] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[21] Under the Stark Law, DHS include, but are not limited to, the following:

(1) Certain therapy services, such as physical therapy;
(2) Radiology and certain other imaging services;
(3) Radiation therapy services and supplies;
(4) Durable medical equipment;
(5) Outpatient prescription drugs; and,
(6) Inpatient and outpatient health services.[22]

Under the Stark Law, financial relationships include ownership interests through equity, debt, other means, and ownership interests in entities that also have an ownership interest in the entity that provides DHS.[23] 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*."[24]

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.[25] Similar to the AKS safe harbors, without these exceptions, the Stark Law may prohibit legitimate business arrangements. Unlike the AKS safe harbors, however, an arrangement must *entirely* fall within one of the exceptions to shield from enforcement of the Stark Law.[26]

Certificate of Need

Certificate of Need (CON) laws present market entry barriers for senior care providers. The rationale behind CON laws mainly originates from the belief that healthcare does not operate like other markets to correct excess supply, and that healthcare is plagued by market failures resulting in excess supply and needless duplication of some services, causing overall costs to rise.[27] However, the validity of CON programs has been contested by the *Department of Justice* (DOJ) and the *Federal Trade Commission* (FTC), which have found that CON laws create barriers to competition, increase costs for consumers, and do not stop unnecessary spending.[28]

Nursing homes and skilled nursing facilities are often specifically subject to state CON laws.[29] Currently, 11 states have some form of CON regulation on skilled nursing or nursing homes, and most states have a moratorium on the number of nursing facility beds allowed in a given region.[30] CON programs require a community need to be proven to state regulators in order to open or expand a service line in a region.[31] The healthcare facility may receive authorization to open if a set of criteria are met; many times however, CON laws set certain limitations on healthcare projects.[32] In states where CON laws exist for nursing homes, spending on nursing home care grows much faster than in states without CON laws on nursing homes.[33] Moreover, long-term care expenditures in CON states tend to be dominated by nursing homes, and there is much less diversification of (less costly) care.[34] CON laws and nursing home bed moratoria impose constraints on access to the market which, in turn, leaves seniors unable to access care.[35]

Licensure & Compliance

Generally, healthcare facility licensure, which is intended to ensure that patients receive high-quality healthcare,[36] is typically the domain of state governments because Medicare plays less of a role in senior care from a reimbursement perspective. However, there exists a *Catch-22* between state and federal government regulations pertaining to senior care licensure.[37] Most states require entities to meet certain practice standards set forth by Medicare as a condition of licensure, while Medicare requires state licensure as a condition of reimbursement.[38] Moreover, while the federal government may define licensure standards, it relies on state governments to physically assess and survey the facilities.[39]

All 50 states (as well as the District of Columbia) require nursing homes to be licensed.[40] To maintain licensure, facilities may need to meet certain building requirements, as well as comply with limits on the number of beds allowed in the facility.[41] While states and the federal government share regulatory responsibilities of long-term care (e.g., licensure), states usually control licensure and other standards for many residential care arrangements because there is no federal funding.[42]

Central components of long-term care regulation at a state and federal level include: (1) establishing quality standards; (2) designing a survey process to measure conditions of residents and assess compliance; and, (3) specifying remedies or sanctions for noncompliance.[43] Overall, federal government regulation of long-term care is aimed at protecting the residents' safety and holding facilities accountable for the use of public funds.[44] For example, the nursing home licensure reforms in the *Omnibus Reconciliation Act of 1987* (OBRA 87) require nursing homes to comply with standards such as patient rights relating to admission and discharge, the right to be free from abuse, and restraints, and the overall promotion of resident quality of life.[45] OBRA 87 places a focus on processes of care and resident outcomes.[46]

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The scope and enforcement of state regulations of many specific senior care services vary widely across the U.S. Although a 50-state survey is beyond the scope of this article, this does not render compliance with state regulations and guidance any less important, as compliance with these regulations may be a condition precedent to receiving Medicaid reimbursement.

Future Regulatory Trends

The COVID-19 pandemic has greatly affected senior healthcare services. For example, reporting requirements have increased, with the federal government requiring nursing homes to inform residents and their representatives of any COVID-19-related infections or deaths among nursing home staff or residents.[47] Such requirements have shined a spotlight on the failures of nursing homes to control infections, with providers under intense pressure from regulators to limit the spread of COVID-19 among residents. Nursing homes and other long-term care facilities are likely to face increased government enforcement post-COVID-19,[48] with providers that fail to take appropriate infection control measures likely to face government investigation.[49] However, many states have taken actions to shield nursing home operators from liability.[50] Nonetheless, federal regulatory scrutiny, such as from the *Office of Inspector General* (OIG) of *Health and Human Services* (HHS), has continually focused on oversight of nursing homes and other long-term care facilities,[51] and it is likely that federal regulatory oversight of senior care services will persist going forward.

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