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Valuation of Home Health Agencies: Regulatory Environment

Home healthcare in the U.S. is highly regulated, creating a complex system, especially for home health agencies (HHAs) that operate across multiple states. HHAs face a range of federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and ability to engage in transactions. The second installment of this home health valuation series will discuss the regulatory environment in which these organizations operate.

Certificate of Need

At its core, a state certificate of need (CON) program is one in which a government determines where, when, and how major capital expenditures (e.g., funds spent on public healthcare facilities, services, and key equipment) will be made.[1] The theory behind CON regulations is that, in an unregulated market, healthcare providers will provide the latest costly technology and equipment, regardless of duplication or need, resulting in increased costs for consumers.[2] For example, hospitals may raise prices to pay for underused services, equipment, or empty beds.[3] Proponents of this system argue that CON programs are necessary to limit healthcare spending because healthcare consumers are unable to "shop" for goods and services, as most of these are ordered by physicians.[4] Opponents of the system assert that restricting new entrants to the market may reduce competition, and encourage construction and other additional spending, all of which ultimately results in higher healthcare prices.[5] Ideally, though, CON programs would not prevent change in the healthcare market but merely provide a way for the public and stakeholders to give input and allow for an evaluation process.[6] This regulatory scheme may serve to distribute care to disadvantaged or underserved populations and block low-volume facilities, which may provide a lower quality of care.[7]

Currently, 35 states and Washington D.C. have a CON program in place, and most of those programs regulate HHAs.[8] Therefore, a prospective HHA operator must apply for and be granted a CON through the applicable state agency prior to commencing operations. The process for obtaining a CON varies from state to state.

Licensure & Accreditation

At their inception, HHAs must satisfy state licensing requirements in order to begin operation. In addition, HHAs must be certified by Medicare in order to receive reimbursement for services provided to patients who are Medicare or Medicaid beneficiaries. HHAs may meet the requisite Medicare certification requirements by obtaining accreditation through an accepted national accreditation organization such as: (1) the Joint Commission on Accreditation of Healthcare Organizations; (2) the Accreditation Commission for Home Care, Inc.; or, (3) the Community Health Accreditation Program.[9] Once operational, HHAs must also maintain compliance with applicable federal fraud and abuse laws, such as the Anti-Kickback Statute and the Stark Law.

Fraud & Abuse

Fraud and abuse laws, specifically those related to the federal Anti-Kickback Statute (AKS) and Stark Law, may have the greatest impact on the operations of HHAs. 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. Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.

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.[10] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[11] Congress amended the original statute in 1987 to include exclusion from the Medicare and Medicaid program as an alternative civil remedy to criminal penalties[12] and again in 1997 to add a civil monetary penalty of treble damages, or three times the illegal remuneration, plus a fine of $50,000 per violation.[13] Additionally, interpretation and application of the AKS under case law has created precedent for a regulatory hurdle known as the *one purpose* test. Under the *one purpose* test, healthcare providers violate the AKS if

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even one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.[14]

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 commit a violation of the AKS for the government to prove a kickback violation.[15] However, the ACA did not remove the requirement that a person must "*knowingly and willfully*" offer or pay remuneration for referrals in order to violate the AKS.[16] Therefore, in order 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.[17] Second, the ACA provided that a violation of the AKS is sufficient to state a claim under the False Claims Act (FCA).[18] The amended AKS points out that liability under the FCA is "*[i]n addition to the penalties provided for in [the AKS]…*"[19] This 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.[20]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[21] In response to these concerns, Congress created a number of statutory exceptions and delegated authority to the HHS to protect certain business arrangements by means of promulgating several *safe harbors*.[22] 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.[23] Failure to meet all of the requirements of a *safe harbor* does not necessarily render an arrangement illegal.[24] 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.

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).[25] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[26] Under the Stark Law, DHS include, but are not limited to:

(1) Home health services;
(2) Certain therapy services, such as physical, occupational, and outpatient speech-language pathology services;
(3) Durable medical equipment and supplies;
(4) Prosthetics, orthotics, and prosthetic devices and supplies;
(5) Inpatient and outpatient hospital services; and,
(6) Outpatient prescription drugs.[27]

Under the Stark Law, financial relationships include *ownership interests* through equity, debt, other means, and ownership interests in entities which then have an ownership interest in the entity that provides DHS.[28] 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.[29] 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.[30] 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.[31]

It is important to note that the regulatory scrutiny of healthcare entities (especially with regard to fraud and abuse violations) has generally increased in recent years. Therefore, the severe penalties that may be levied against healthcare providers under the AKS, the Stark Law, and/or the FCA will likely raise a hypothetical investor's estimate of the risk of investing in an HHA. For example, in September 2021, BAYADA Home Health Care Inc., BAYADA Health LLC, and BAYADA Home Care settled allegations they had violated the AKS for $17 million.[32] BAYADA was alleged to have paid kickbacks to a retirement home operator by purchasing two of its Arizona HHAs, and subsequently filing false claims to Medicare from 2014 to 2020.[33] Additionally, in November 2021, PruittHealth settled FCA claims for $4.2 million.[34] PruittHealth allegedly submitted claims to Medicare and Medicaid without conducting the requisite face-to-face certifications or plans of care or without documenting the patient's need for home health services.[35] The HHA also allegedly failed to refund overpayments received from CMS as reimbursement for other legitimate services provided.[36]

Conclusion

HHAs face many obstacles within the regulatory environment that can prohibit their formation, growth, and development. Understanding state CON and licensing laws as well as fraud and abuse laws, among other statutes and regulations, are integral to the success of an HHA. The next installment in this series will discuss the competitive environment in which HHAs operate.

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27 42 U.S.C. § 1395nn(h)(6). Note the distinction in 42 C.F.R. § 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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