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HEALTHCARE INSIGHTS

Valuation of Senior Healthcare (Part II of III)

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Elderly adults have more options than ever before when it comes to where and how to receive healthcare services. Many seniors who require healthcare services still desire some form of independent living; consequently, new models of senior care have developed. These models vary as to care level and reimbursement requirements to better meet the demands of this growing age cohort.

In this three-part series on the valuation of senior healthcare, we examine the "Four Pillars" of the industry: the reimbursement, regulatory, competitive, and technological environments affecting senior healthcare services and organizations. Part I[1] provided a brief overview of the various enterprises and services that make up the senior care industry. It also discussed the differing reimbursement levels and coverage for these enterprises and services, ranging from Medicare, Medicaid, and commercial insurance to no coverage at all (many long-term care options are paid for solely by the senior). In Part II, we discuss the regulatory environment in which senior care facilities operate.

Regulatory Environment

Federal Fraud and Abuse Laws

Healthcare organizations face a range of federal and state legal and regulatory constraints that 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 law (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 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.[2] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[3]

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.[4] Violations of the AKS are punishable by up to five years in prison, criminal fines up to $25,000, or both.[5] Congress amended the original statute in 1987 with the passage of the Medicare and Medicaid Patient and Program Protection Act to include exclusion from the Medicare and Medicaid programs as a civil alternative to criminal penalties.[6] Later, the Balanced

1 Todd Zigrang and Jessica Bailey-Wheaton, "Valuation of Senior Healthcare (Part I of III)," *The Value Examiner* (September/October 2020): 34–41.

2 Asha B. Scielzo, "Fundamentals of the Stark Law and Anti-Kickback Statute" (presentation, American Health Lawyers Association Fundamentals of Health Law Conference, Chicago, IL, November 13, 2014), 4–6, 17, 19, 42, https://docplayer.net/17313708-Ahla-fundamentals-of-the-stark-law-and-anti-kickback-statute-asha-b-scielzo-pillsbury-winthrop-shaw-pittman-llp-washington-dc.html.

3 Ibid., 42.

4 Criminal Penalties for Acts Involving Federal Health Care Programs, 42 U.S.C. § 1320a-7b(b)(1).

5 Ibid.

6 Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, § 2, 101 Stat. 680, 680–681 (1987).

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.[7] In addition, case law interpreting and applying the AKS has created a precedent for a regulatory hurdle known as the "one purpose test." Under this test, healthcare providers violate the AKS if even one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.[8]

The Affordable Care Act[9] (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.[10] 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.[11] Therefore, to prove a violation, 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.[12] Second, the ACA provided that a violation of the AKS is sufficient to state a claim under the False Claims Act (FCA).[13] The amended AKS points out that liability under the FCA is "[i]n addition to the penalties provided for in [the AKS]."[14] 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 up to $23,331 per violation, plus treble damages.[15]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[16] 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.[17] 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.[18] Failure to comply with all of the requirements of a safe harbor does not necessarily render an arrangement illegal.[19] Importantly, for a payment to comply with many AKS safe harbors, the compensation must not exceed the range of fair market value and must be commercially reasonable.[20]

Notably, on November 20, 2020, the HHS Office of Inspector General (OIG) finalized several revisions to the AKS, many of which are similar to revisions to the Stark Law proposed by the Centers for Medicare & Medicaid Services. The OIG also modified some safe harbors, such as personal services and management contracts, and outcomes-based payment arrangements. These arrangements were changed to add more flexibility, for example, by adding protections to certain outcomes-based payments.[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

7 The Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4304, 111 Stat. 251, 384 (1997).

8 "Re: OIG Advisory Opinion No. 15-10," letter from Gregory E. Demske, Chief Counsel to the Inspector General, to [name redacted] (July 28, 2015), 4–5, https://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-10.pdf; U.S. v. Greber, 760 F.2d 68, 69 (3d. Cir. 1985).

9 Patient Protection and Affordable Care Act, Pub. L. No. 111-148, §§ 6402, 10606, 124 Stat. 119, 759, 1008 (2010).

10 Ibid.

11 Jennifer A. Staman, Cong. Rsch. Serv., RS22743, Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview 5 (2014).

12 Ibid.

13 "Health Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enacted" (newsletter, McDermott Will & Emery, April 12, 2010), 3; Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402, 124 Stat. 119, 759 (2010).

14 Liability under subchapter III of chapter 37 of title 31, 42 U.S.C. § 1320a-7b(g).

15 False claims, 31 U.S.C. § 3729(a)(1).

16 "Re: OIG Advisory Opinion No. 15-10," 5 (*see* n. 8).

17 Ibid.

18 Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute; Final Rule, 64 Fed. Reg. 63518, 63520 (Nov. 19, 1999).

19 "Re: Malpractice Insurance Assistance," letter from Lewis Morris, Chief Counsel to the Inspector General, U.S. Department of Health & Human Services, to [Name redacted] (January 15, 2003), 1, https://oig.hhs.gov/fraud/docs/alertsandbulletins/malpracticeprogram.pdf.

20 Scielzo, "Fundamentals of the Stark Law and Anti-Kickback Statute," 9–13, 42 (*see* n. 2).

21 Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77684–77686 (December 2, 2020).

of designated health services (DHS).[22] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[23] 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
6. Inpatient and outpatient health services[24]

For purposes of the Stark Law, financial relationships include ownership interests through equity, debt, or other means, as well as ownership interests in entities that, in turn, have an ownership interest in an entity that provides DHS.[25] Financial relationships also include compensation arrangements, which are defined as arrangements between physicians and entities involving any remuneration, directly or indirectly, in cash or "in kind."[26]

Notably, the Stark Law contains a large number of exceptions—that is, ownership interests, compensation arrangements, and forms of remuneration to which the Stark Law does not apply.[27] Similar to the AKS safe harbors, absent these exceptions the Stark Law might prohibit legitimate business arrangements. Unlike the AKS safe harbors, however, an arrangement must fall entirely within one of the exceptions to shield it from enforcement of the Stark Law.[28]

Certificate of Need

Certificate of Need (CON) laws present market entry barriers for senior care providers. The rationale behind CON laws originates mainly 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.[29] However, the validity of CON programs has been contested by the Department of Justice and the Federal Trade Commission, which have found that CON laws create barriers to competition, increase costs for consumers, and do not stop unnecessary spending.[30]

Nursing homes and skilled nursing facilities (SNFs) are often specifically subject to state CON laws.[31] As of the end of 2019, 11 states had some form of CON regulation of nursing homes or SNFs, and most states have a moratorium on the number of nursing facility beds allowed in a given region.[32] CON programs require a community need to be proven to state regulators in order to open or expand a service line in a region.[33] 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.[34] In states where CON laws exist for nursing homes, spending on nursing home care grows much faster than in states without CON laws for nursing homes.[35] 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.[36] CON laws and nursing

22 Jennifer O'Sullivan, Cong. Rsch. Serv., RL32494, Medicare: Physician Self-Referral ("Stark I and II") (2004), available at https://www.policyarchive.org/handle/10207/2137; Limitation on certain physician referrals, 42 U.S.C. § 1395nn.

23 Ibid., § 1395nn(a)(1)(A).

24 Ibid., § 1395nn(a)(1)(B); Definitions, 42 C.F.R. § 411.351 (October 1, 2014). Note the distinction in 42 C.F.R. § 411.351 regarding which 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)."

25 Limitation on certain physician referrals, 42 U.S.C. § 1395nn (a)(2).

26 Ibid., § 1395nn (h)(1).

27 Ibid., § 1395nn.

28 Thomas S. Crane, "Federal Physician Self-Referral Restrictions," in *Health Care Fraud and Abuse: Practical Perspectives,* ed. Linda A. Baumann (Washington, DC: BNA Books, 2002), 106.

29 "Chapter 8: Miscellaneous Subjects," in *Improving Health Care: A Dose Of Competition,* a report by the Federal Trade Commission and the Department of Justice, updated June 25, 2015, https://www.justice.gov/atr/chapter-8-miscellaneous-subjects#1a.

30 Maureen K. Ohlhausen, "Certificate of Need Laws: A Prescription for Higher Costs," *Antitrust* 30, no. 1 (Fall 2015): 51, https://www.ftc.gov/system/files/documents/public_statements/896453/1512fall15-ohlhausenc.pdf.

31 Momotazur Rahman, et al., "The Impact of Certificate-of-Need Laws on Nursing Home and Home Health Care Expenditures," *Medical Care Research and Review* 73, no. 1 (February 2016): 85–105, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4916841/.

32 "CON—Certificate of Need State Laws," National Conference of State Legislatures, December 1, 2019, https://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx.

33 Ibid.

34 Ibid.

35 Rahman, et al., "The Impact of Certificate-of-Need Laws on Nursing Home and Home Health Care Expenditures" (*see* n. 30).

36 Ibid.

home bed moratoria impose constraints on access to the market which, in turn, leaves seniors unable to access care.[37]

Licensure and Compliance

Healthcare facility licensure, which is intended to ensure that patients receive high-quality healthcare,[38] 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.[39] 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.[40] Moreover, while the federal government may define licensure standards, it relies on state governments to physically assess and survey the facilities.[41]

All 50 states (as well as the District of Columbia) require nursing homes to be licensed.[42] To maintain licensure, facilities may need to meet certain building requirements and comply with limits on the number of beds allowed in the facility.[43] While states and the federal government share regulatory responsibilities with respect to long-term care (e.g., licensure), states usually control licensure and other standards for many residential care arrangements because there is no federal funding.[44]

37 David C. Grabowski, "A Longitudinal Study of Medicaid Payment, Private-Pay Price and Nursing Home Quality," *International Journal of Health Care Finance and Economics* 4, no. 1 (March 2004): 5–26.
38 "Improving Quality through External Oversight," in *Improving the Quality of Long-Term Care*, ed. Gooloo S. Wunderlich and Peter O. Kohler (Washington, DC: National Academies Press, 2001), https://www.ncbi.nlm.nih.gov/books/NBK224499/.
39 Ibid.
40 Ibid.
41 Ibid.
42 Ibid.
43 Ibid.
44 Ibid.

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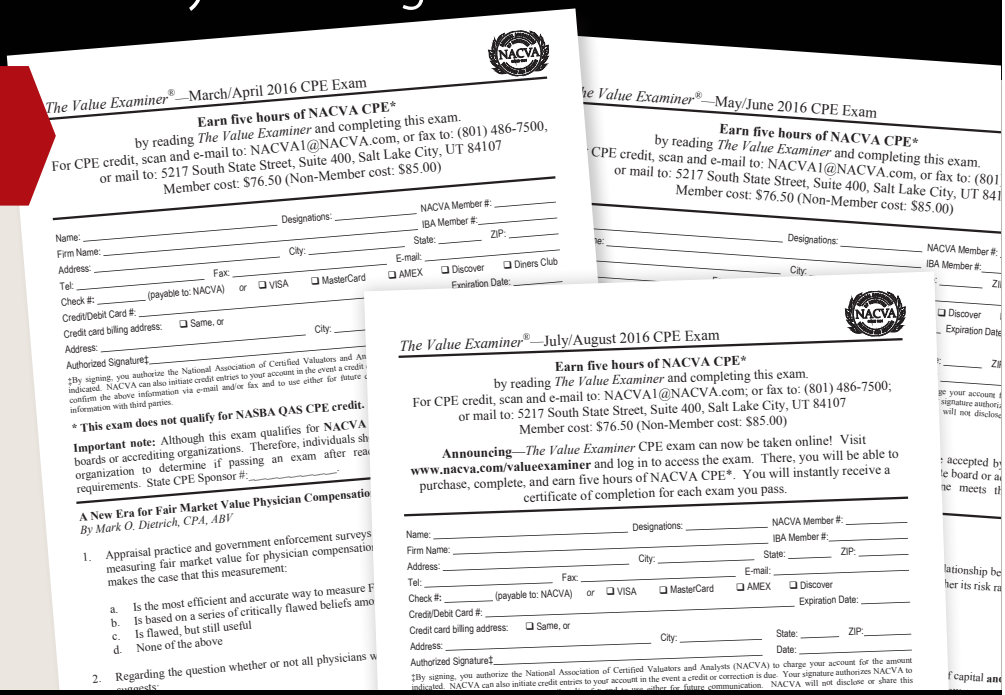
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Central components of long-term-care regulation at the state and federal level include: (1) establishing quality standards, (2) designing a survey process to measure conditions of residents and assess compliance, and (3) specifying remedies or sanctions for noncompliance.[45] 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.[46] 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.[47] OBRA 87 focuses on processes of care and resident outcomes.[48]

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 it may be a condition precedent to receiving Medicaid reimbursement.

Future Regulatory Trends

The COVID-19 pandemic has greatly affected senior healthcare services. For example, the federal government now requires nursing homes to inform residents and their representatives of any COVID-19-related infections or deaths among nursing home staff or residents.[49] These reporting requirements have shined a spotlight on the failures of nursing homes to control infections, intensifying pressure on providers 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,[50] and providers that fail to take appropriate infection control measures are likely to face government investigation.[51] However, many states have taken actions to shield nursing home operators from liability.[52] Nonetheless, federal regulatory scrutiny, such as from the OIG of HHS, has continually focused on oversight of nursing homes and other long-term care facilities,[53] and it is likely that federal regulatory oversight of senior care services will persist going forward.

Part III of this series will discuss the senior healthcare industry's competitive environment and technological advancements that affect senior healthcare services and organizations. VE

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45 Ibid.
46 Ibid.
47 Ibid.
48 Ibid.
49 "Upcoming Requirements for Notification of Confirmed COVID-19 (or COVID-19 Persons under Investigation) Among Residents and Staff in Nursing Homes," April 19, 2020, Centers for Medicare & Medicaid Services, https://www.cms.gov/files/document/qso-20-26-nh.pdf.
50 Brian K. French, Hannah Bornstein, and Adam R. Tarosky, "Nursing homes are likely to face increased government enforcement actions over COVID-19," Nixon Peabody, April 15, 2020, https://www.nixonpeabody.com/en/ideas/articles/2020/04/15/doj-investigations-of-nursing-facilities-during-coronavirus-covid-19?utm_medium=alert&utm_source=interaction&utm_campaign=government-investigation.
51 Ibid.
52 Lydia Wheeler and Valerie Bauman, "Coronavirus Liability Shields for Nursing Homes Only Go So Far," *Bloomberg Law* (April 24, 2020).
53 Active Work Plan Items, Office of Inspector General, U.S. Department of Health & Human Services, accessed December 17, 2020, https://oig.hhs.gov/reports-and-publications/workplan/active-item-table.asp.