

## Valuation of Dialysis Centers: Regulatory Environment

Healthcare organizations, including dialysis centers, face a range of federal and state legal and regulatory constraints, which affect their formation, operation, procedural coding and billing, and transactions. With existing federal and state regulations related to medical liability, licensure, accreditation, certificate of need, fraud and abuse, and antitrust laws, the expansive regulatory landscape of the U.S. healthcare industry greatly shapes the practice of medicine and the delivery of healthcare services. This fourth installment in the five-part series regarding dialysis centers will review the *regulatory environment* in which these enterprises operate.

Government regulators perceive many types of healthcare business arrangements, which in other industries are often regarded as typical motivations inherent in commercial relationships between parties, as exhibiting the potential for a significant risk of fraud. 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 organizations.

The federal 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 remuneration 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 healthcare 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.

### 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 to 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.<sup>1</sup> Violations of the AKS are punishable by up to five years in prison, criminal fines up to \$25,000, or both.<sup>2</sup> Congress amended the original statute in 1987 with the passage of the *Medicare and Medicaid Patient*

*& Program Protection Act of 1987* to include exclusion from the Medicare and Medicaid program as an alternative civil remedy to criminal penalties.<sup>3</sup> Further, 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.<sup>4</sup>

Subsequent interpretation and application of the AKS under case law has created a precedent for a regulatory hurdle known as the *one purpose test*. Under the *one purpose test*, healthcare providers will have violated the AKS if even one purpose of the arrangement in question is to offer illegal remuneration.<sup>5</sup> Additionally, 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.<sup>6</sup> 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.<sup>7</sup> Therefore, in order to show 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.<sup>8</sup> Second, the ACA provided that a violation of the AKS is sufficient to state a claim under the *False Claims Act (FCA)*.<sup>9</sup> The amended AKS is clear to point out that liability under the FCA is “[i]n addition to the penalties provided for in [the AKS]...”<sup>10</sup> 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.<sup>11</sup>

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.<sup>12</sup> In response to these concerns, Congress created a number of statutory exceptions and delegated authority to the *Department of Health and Human Services (HHS)* to protect certain business arrangements by means of promulgating several *safe harbors*.<sup>13</sup> These *safe harbors* set forth 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.<sup>14</sup> However, failure to meet all of the requirements of a *safe harbor* does not necessarily render an arrangement illegal.<sup>15</sup> 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*.<sup>16</sup>

### Stark Law

The Stark Law, originally passed as the *Ethics in Patient Referral Act of 1989*, as part of the *Omnibus Budget Reconciliation Act (OBRA) of 1989*, 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)*.<sup>17</sup> Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral. Under the Stark Law, DHS include:

- (1) Certain therapy services, such as physical therapy;
- (2) Radiology and certain other imaging services;
- (3) Radiation therapy services and supplies;
- (4) Outpatient prescription drugs; and,
- (5) Inpatient and outpatient hospital services.<sup>18</sup>

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.<sup>19</sup> 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.<sup>20</sup> Notably, the Stark Law contains a number of *exceptions*, which describe ownership interests, compensation arrangements, and forms of remuneration to which the Stark Law does not apply.<sup>21</sup> However, unlike the AKS *safe harbors*, an arrangement *must* fall within one of the *exceptions* in order to be legally permissible under the Stark Law.<sup>22</sup>

Of note, *erythropoietin (EPO)* and other dialysis-related drugs that meet the following conditions fall within an exception to the referral prohibition, related to both ownership/investment interests and compensation arrangements under the Stark Law:

- (1) *The EPO and other dialysis-related drugs are furnished in or by an ESRD facility. For purposes of this paragraph, "EPO and other dialysis-related drugs" means certain outpatient prescription drugs that are required for the efficacy of dialysis and identified as eligible for this exception on the List of [Current Procedural Terminology/ Healthcare Common Procedure Coding System] CPT/HCPCS Codes; and "furnished" means that the EPO or dialysis-related drugs are administered to a patient in the ESRD facility or, in the case of EPO or Aranesp (or equivalent drug identified on the List of CPT/HCPCS Codes) only, are dispensed by the ESRD facility for use at home.*

- (2) *The arrangement for the furnishing of the EPO and other dialysis-related drugs does not violate the anti-kickback statute....*
- (3) *All billing and claims submission for the EPO and other dialysis-related drugs does not violate any Federal or State law or regulation governing billing or claims submission.*
- (4) *The exception set forth in this paragraph does not apply to any financial relationship between the referring physician and any entity other than the ESRD facility that furnishes the EPO and other dialysis-related drugs to the patient.*<sup>23</sup>

The 2016 *Medicare Physician Fee Schedule (MPFS)* final rule, published by CMS on November 16, 2015, added two new exceptions to the Stark Law, an exception for certain timeshare arrangements, and included several alterations to existing provisions of the Stark Law, including:

- (1) A relaxation of the writing requirements of many exceptions, specifically that "*parties need not reduce the key terms of an arrangement to a single formal contract to satisfy the writing requirement of the compensation exceptions at § 411.357 that require a writing*";<sup>24</sup>
- (2) A relaxation of the *holdover* requirements found in some exceptions (i.e., the continuation of agreements that have expired) to allow for indefinite holdovers, so long as the arrangements "*continue on the same terms and conditions*" as the original arrangement and continue to comply with an exception;<sup>25</sup> and,
- (3) A revision to the *stand in the shoes* definition (i.e., the provision that physicians are treated as standing in the shoes of their physician organizations for the purposes of applying the rules regarding compensation arrangements), such that "*all physicians in a physician organization are considered parties to the compensation arrangement between the physician organization and the DHS entity*."<sup>26</sup>

### Continued Regulatory Scrutiny of Dialysis Services

Governmental scrutiny of dialysis services is likely to continue, of not increase, going forward. In June 2018, the *Office of Inspector General (OIG)* of HHS stated that it will review claims for Medicare Part B dialysis services provided to beneficiaries with ESRD to determine whether such services complied with Medicare requirements, as a result of identified unallowable Medicare payments.<sup>27</sup> The increase in federal regulatory scrutiny of dialysis centers is being mirrored on the state level in some cases as well. For example, California currently has a proposed bill to introduce more state regulations for dialysis centers, especially to improve staffing ratios, which currently averages one dialysis nurse for 12 patients, and is adversely affecting the quality of care provided to ESRD patients.<sup>28</sup>

## Certificate of Need (CON) Laws

*Certificate of Need* (CON) laws are one of the most significant market entrance barriers affecting the U.S. healthcare delivery system. A state CON program is one in which a government determines where, when, and how capital expenditures will be made for public healthcare facilities, services, and major equipment. CON requirements are based on the highly contested theory that in an unregulated market, healthcare providers will provide healthcare service using costly technology and equipment, regardless of duplication or need. Twelve state CON programs currently regulate renal failure and dialysis centers, which pose a significant barrier to entry for dialysis centers in these states.<sup>29</sup>

## Conclusion

The regulatory scrutiny of healthcare entities has significantly increased in recent years. Therefore, the severe penalties that may be levied against healthcare providers, including dialysis centers, under the AKS or the Stark Law will likely raise a hypothetical investor's estimate of the risk of investing in a Dialysis Center. There has been a continuous change and innovation in the *technological environment* of dialysis centers, which will be discussed in the fifth and final installment of the series.

1 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1) (2013).

2 *Ibid.*

3 "Medicare and Medicaid Patient and Program Protection Act of 1987" Pub. L. No. 100-93, § 2, 101 Stat. 680, 680-681 (August 18, 1987).

4 "The Balanced Budget Act of 1997" Pub. L. 105-33, § 4304, 111 Stat. 251, 384 (August 5, 1997).

5 "Re: OIG Advisory Opinion No. 15-10" By Gregory E. Demske, Chief Counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, <http://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-10.pdf> (Accessed 4/24/18), p. 4-5; "U.S. v. Greber" 760 F.2d 68, 72 (3d Cir. 1985).

6 "Health Care Reform: Substantial Fraud and Abuse and Program Integrity Measures Enacted" McDermott Will & Emery, April 12, 2010, p. 3; "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 6402, 119, 124 Stat. 119, 759 (March 23, 2010).

7 "Health Care Fraud and Abuse Laws Affecting Medicare and Medicaid: An Overview" By Jennifer A. Staman, Congressional Research Service, September 8, 2014, <https://www.fas.org/sgp/crs/misc/RS22743.pdf> (Accessed 12/10/18), p. 5.

8 *Ibid.*, p. 4-5.

9 McDermott Will & Emery, p. 3; "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, § 6402, 124 Stat. 119, 759 (March 23, 2010).

10 "Liability under subchapter III of chapter 37 of title 31" 42 U.S.C. § 1320a-7b(g) (2013).

11 "Civil Monetary Penalties Inflation Adjustment for 2017" Federal Register Vol. 82, No. 22 (February 3, 2017) p. 9133.

12 Demske, p. 5.

13 *Ibid.*

14 "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" Federal Register Vol. 64, No. 223 (November 19, 1999) p. 63518 and 63520.

15 "Re: Malpractice Insurance Assistance" By Lewis Morris, Chief Counsel to the Inspector General, U.S. Department of Health and Human Services, Letter to [Name redacted], January 15, 2003, <http://oig.hhs.gov/fraud/docs/alertsandbulletins/MalpracticeProgram.pdf> (Accessed 3/28/18), p. 1.

16 "Exceptions" 42 C.F.R. §1001.952 (October 1, 2017).

17 "CRS Report for Congress: Medicare: Physician Self-Referral ("Stark I and II")" By Jennifer O'Sullivan, Congressional Research Service, The Library of Congress, July 27, 2004, <http://www.policyarchive.org/handle/10207/bitstreams/2137.pdf> (Accessed 7/2/12), p. 15; "Limitation on certain physician

referrals" 42 U.S.C. §1395nn (2013); "Avoiding self-referral: Understanding the Stark laws" Medical Economics, April 1, 2015, <http://www.medicaleconomics.com/practice-management/avoiding-self-referral-understanding-stark-laws> (Accessed 1/22/18).

18 42 U.S.C. § 1395nn(a)(1)(B) (2013); "Definitions" 42 C.F.R. § 411.351 (October 1, 2014).

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)."

19 42 U.S.C. § 1395nn (a)(2) (2013).

20 42 U.S.C. §1395nn (h)(1) (2013).

21 42 U.S.C. §1395nn (2013).

22 Baumann, p. 106.

23 "General exceptions to the referral prohibition related to both ownership/investment and compensation" 42 C.F.R. 411.355 (g) (1-4) (2010).

24 "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule" Federal Register Vol. 80, No. 220 (November 16, 2015) p. 71315.

25 *Ibid.*, p. 71318.

26 *Ibid.*, p. 71322.

27 "OIG Work Plan: 2018 Year in Review and a New Approach for 2019 – Hospitals" Office of Inspector General, December 11, 2018, [https://www.hcca-info.org/Portals/0/PDFs/Resources/Conference\\_Handouts/webConferences/december11attendecopy.pdf?ver=2018-12-05-140938-057](https://www.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/webConferences/december11attendecopy.pdf?ver=2018-12-05-140938-057) (Accessed 1/21/19), p.12.

28 "California proposes bill to regulate dialysis clinics" By Maria Castellucci, Modern Healthcare, March 30, 2017, <https://www.modernhealthcare.com/article/20170330/NEWS/170339996> (Accessed 1/21/19); "Mandating Staffing Ratios in Hemodialysis Facilities" By Anjay Rastogi and Glenn M. Chertow, Clinical Journal of American Society of Nephrology, Vol. 13, No. 7 (July 2018), p. 1110-1112.

29 "CON-Certificate of Need State Laws" National Conference of State Legislatures, August 17, 2018, available at: <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (Accessed 1/23/19).





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