HEALTH CAPITAL Topics
Volume 16
Issue 2
February 2023
Jessica L. Bailey-Wheaton, Esq., Editor
Todd A. Zigrang, MBA, MHA, FACHE, CVA, ASA, ABV, Publisher

Valuation of Clinical Laboratories: Regulatory Environment

Clinical laboratories 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 laws (the "*Stark Law*"), may have the greatest impact on the operations of healthcare providers. Further, clinical labs must adhere to regulations mandating minimum quality control standards, most notably federal requirements under the Clinical Laboratory Improvement Amendments (CLIA). The last installment in this three-part series on the valuation of clinical labs will discuss 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 the U.S. Department of Health & Human Services (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 HHS Office of Inspector General (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.[15]

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).[16] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[17] For the purposes of this article, DHS include, but are not limited to, clinical lab services and inpatient and outpatient hospital services.[18]

Under the Stark Law, financial relationships include ownership interests through equity, debt, other means, and ownership interests in entities also have an

(Continued on next page)

ownership interest in the entity that provides DHS.[19] 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.[20]

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.[21] Further, similar to the AKS, violation of the Stark Law can also trigger a violation of the FCA.[22]

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.[23] 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.[24]

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.[25]

Importantly, the new value-based arrangements exceptions protect the following arrangements:

(1) Full Financial Risk Arrangements: Includes capitated payments and predetermined rates or a global budget;
(2) Value-Based Arrangements with Meaningful Downside Financial Risk: Where a physician pays no less than 25% of the value of the remuneration the physician receives when he or she does not meet pre-determined benchmarks; and,
(3) Value-Based Arrangements: Applies regardless of risk level to encourage physicians to enter value-based arrangements, even if they only assume upside risk.[26]

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 two decades. 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 a hypothetical investor's estimate of the risk related to clinical lab services.

Clinical lab Improvement Amendments (CLIA)

Prior to 1988, only independent and hospital laboratories were subject to federal regulation under the *Medicare, Medicaid, and Clinical labs Improvement Act of 1967*.[27] Following a public outcry after numerous reports of inaccurate Pap smear results, Congress passed the *Clinical lab Improvement Amendments* (CLIA), and its subsequent amendments, in order to improve the quality of laboratory test results.[28] Three agencies – CMS, the Food & Drug Administration (FDA), and the U.S. Centers for Disease Control and Prevention (CDC) – possess regulatory authority over clinical labs under CLIA.[29] CMS is charged with regulating healthcare providers who perform laboratory testing on patient specimens in order to ensure accurate and reliable test results.[30] Laboratory testing performed for forensic purposes; on human specimens without patient specific results; or, drug testing by *Substance Abuse and Mental Health Service Administration* (SAMHSA) laboratories are exempted from CLIA's requirements.[31]

CLIA regulations categorize laboratory testing procedures by complexity, assigning each test to a waived, moderate, or high level.[32] A test's category is determined by assessing its complexity, on a scale of 1 to 3, based on seven distinct areas:

(1) The level of scientific and technical knowledge required to perform the test;
(2) The level of training and experience required for the three pre-analytic, peri-analytic, and post-analytic phases of the test;
(3) The stability and reliability of the materials needed for the test;
(4) The relative ease or difficulty of each step of the testing process;
(5) The calibration, control, and proficiency of the testing materials;
(6) The relative ease or difficulty of maintaining or troubleshooting the testing system; and,
(7) The amount of interpretation and judgment needed during the three phases of the test.[33]

Laboratories only performing the lowest level complexity tests, known as "*waived tests*," must enroll in CLIA, pay applicable fees, and follow specific manufacturing instructions as well as standards related to cytology tests.[34] Laboratories performing moderate and high level complexity tests are subject to more stringent rules that set minimum qualifications for individuals who perform or supervise testing procedures. Laboratories performing moderate and high level complexity tests must satisfy quality standards related to: (1) proficiency testing; (2) patient test management; (3) quality control; and, (4) personnel training.[35] Penalties for non-compliance include: *"(A) Use of intermediate sanctions; (B) Suspension, limitation, or revocation of the certificate of a laboratory that is out of compliance with one or more requirements for a certificate; and, (C) Civil suit to enjoin any laboratory activity that constitutes a significant hazard to the public health."*[36]

(Continued on next page)

COVID-19 Testing Enforcement

During 2020, the first year of the COVID-19 pandemic in which COVID-19 tests were available, Medicare spent approximately $1.5 billion on COVID-19 tests alone.[37] The federal government also issued a number of regulatory "flexibilities" to ease provider burden during the public health emergency (PHE). For example, during the PHE, Medicare beneficiaries may obtain their first COVID-19 test without a physician/practitioner order, but must obtain an order for subsequent tests. Additionally, some documentation and recordkeeping requirements for COVID-19 test orders were removed. However, CMS has made clear that "After the PHE, Medicare will require all COVID-19 and related testing that is performed by a laboratory to be ordered by a physician or other practitioner."[38] Further, in order to ensure proper government spending occurred for these tests, the OIG announced in December 2021 its plans to audit tests, "looking more closely at which lab tests had declines in volume in 2020….[as well as] monitor annual payments for lab tests, including COVID-19 tests."[39]

Conclusion

Considering the various competitive, reimbursement, technological, and regulatory trends discussed in this three-part series, clinical labs may face some challenges in the coming years. As noted in the first installment, the growth in the Baby Boomer population, a significant portion of whom have one or more chronic conditions, may create significant demand that greatly benefit clinical labs. However, a clinical lab's ability to meet this demand may be tempered by the shortage of pathologists and other laboratory professionals. Therefore, as discussed in this second installment, clinical labs that are positioned to adopt rapidly-advancing technology may be able to utilize technology to automate some manual work in order to thwart any workforce shortage. Further, in some industries, a gap between supply and demand may lead to increased prices, but with the U.S. healthcare system's third-party payor system, in which the government has an outsized influence, the typical supply-demand dynamic does not affect prices. In fact, Medicare reimbursement is expected to stay stagnant (if not decrease) in the next couple of years. This will require clinical labs to be clinically efficient – while remaining compliant with regulations and keeping clear of government enforcement initiatives – in order to survive.

1 "Comparison of the Anti-Kickback Statute and Stark Law" Health Care Fraud Prevention and Enforcement Action Team (HEAT) Office of Inspector General (OIG), https://oig.hhs.gov/documents/provider-compliance-training/939/StarkandAKSChartHandout508.pdf (Accessed 2/21/23).
2 Health Care Fraud Prevention and Enforcement Action Team (HEAT) Office of Inspector General (OIG), (Accessed 2/21/23).
3 "Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b)(1).
4 "Re: OIG Advisory Opinion No. 15-10" By Gregory E. Demske, Chief Counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, https://oig.hhs.gov/fraud/docs/advisoryopinions/2015/AdvOpn15-10.pdf (Accessed 5/13/22), p. 4-5; "U.S. v. Greber" 760 F.2d 68, 69 (3d. Cir. 1985).
5 "Patient Protection and Affordable Care Act" Pub. L. No. 111-148, §§ 6402, 10606, 124 Stat. 119, 759, 1008 (March 23, 2010).
6 "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 5/13/22), p. 5.
7 "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, 124 Stat. 119, 759 (March 23, 2010).
8 42 U.S.C. § 1320a-7b(b)(1); "Civil Monetary Penalties" 42 U.S.C. § 1320a-7a(a).
9 "False claims" 31 U.S.C. § 3729(a)(1)(G); "Civil Monetary Penalties Inflation Adjustments for 2023" Federal Register, Vol. 88, No. 19 (January 30, 2023), p. 5777.
10 Demske, Chief Counsel to the Inspector General, Letter to [Name Redacted], July 28, 2015, p. 5.
11 *Ibid.*
12 "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, 63520.
13 "Re: Malpractice Insurance Assistance" By Lewis Morris, Chief Counsel to the Inspector General, United States Department of Health and Human Services, Letter to [Name redacted], January 15, 2003, https://oig.hhs.gov/fraud/docs/alertsandbulletins/malpracticeprogram.pdf (Accessed 5/13/22), p. 1.
14 "Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements" Federal Register, December 2, 2020, Vol. 85, No. 232, p. 77814-77815.
15 *Ibid*.
16 "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, available at: http://www.policyarchive.org/handle/10207/bitstreams/2137.pdf (Accessed 5/13/22); "Limitation on certain physician referrals" 42 U.S.C. § 1395nn.
17 *Ibid*, (a)(1)(A).
18 *Ibid*, (a)(1)(B); "Definitions" 42 C.F.R. § 411.351 (2015).
19 "Limitation on certain physician referrals" 42 U.S.C. § 1395nn (a)(2).
20 *Ibid*, (h)(1).
21 *Ibid*, (g).
22 Health Care Fraud Prevention and Enforcement Action Team (HEAT) Office of Inspector General (OIG), (Accessed 2/21/23).
23 42 U.S.C. § 1395nn.
24 Health Care Fraud Prevention and Enforcement Action Team (HEAT) Office of Inspector General (OIG), (Accessed 2/21/23).
25 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77492.
26 *Ibid*, 77510-77528.
27 "Medicare, Medicaid, and Clinical Laboratories Improvement Act" Pub. Law 90-174, 81 Stat. 536 (December 5, 1967), p. 536, 538.
28 "Basis and Scope" 42 C.F.R. § 493.1 (2016); "Clinical Laboratory Improvement Amendments (CLIA)" Centers for Medicare and Medicaid Services, April 5, 2017, https://www.cms.gov/regulations-and-guidance/legislation/clia (Accessed 11/16/22).
29 U.S. Food and Drug Administration, April 16, 2014.
30 "CLIA Overview" Centers for Medicare and Medicaid Services, October 22, 2013, https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/ldt-and-clia_faqs.pdf (Accessed 11/16/22).
31 "Applicability" 42 C.F.R. § 493.3(b) (2016).
32 "Categories of Tests by Complexity" 42 C.F.R. § 493.5(a) (2016).
33 "Test Categorization" 42 C.F.R. § 493.17(a) (2016).
34 "Program Descriptions/Projects" Centers for Medicare and Medicaid Services, December 1, 2021, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Program_Descriptions_Projects.html (Accessed 11/16/22).
35 *Ibid.*
36 "Laboratory Requirements – Enforcement Procedures: Basis and Scope" 42 C.F.R. § 493.1800(a) (2) (iii) (2016).
37 "COVID-19 Tests Drove an Increase in Total Medicare Part B Spending on Lab Tests in 2020, While Use of Non-COVID-19 Tests Decreased Significantly" Office of Inspector General, OEI-09-21-00240, December 2021, https://oig.hhs.gov/oei/reports/OEI-09-21-00240.pdf (Accessed 11/16/22).
38 "Laboratories: CMS Flexibilities to Fight COVID-19, Centers for Medicare & Medicaid Services, https://www.cms.gov/files/document/laboratories-cms-flexibilities-fight-covid-19.pdf (Accessed 11/17/22).
39 Office of Inspector General, OEI-09-21-00240, December 2021.

(Continued on next page)

HEALTH CAPITAL CONSULTANTS

(800) FYI -VALU

Providing Solutions in an Era of Healthcare Reform

- Valuation Consulting
- Commercial Reasonableness Opinions
- Commercial Payor Reimbursement Benchmarking
- Litigation Support & Expert Witness
- Financial Feasibility Analysis & Modeling
- Intermediary Services
- Certificate of Need
- ACO Value Metrics & Capital Formation
- Strategic Planning
- Industry Research

LEADERSHIP

Todd A. Zigrang, MBA, MHA, FACHE, CVA, ASA, ABV, is the President of **HEALTH CAPITAL CONSULTANTS** (HCC), where he focuses on the areas of valuation and financial analysis for hospitals, physician practices, and other healthcare enterprises. Mr. Zigrang has over 25 years of experience providing valuation, financial, transaction and strategic advisory services nationwide in over 2,000 transactions and joint ventures. Mr. Zigrang is also considered an expert in the field of healthcare compensation for physicians, executives and other professionals.

Mr. Zigrang is the co-author of "*The Adviser's Guide to Healthcare - 2nd Edition*" [AICPA - 2015], numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: *The Guide to Valuing Physician Compensation and Healthcare Service Arrangements* (BVR/AHLA); *The Accountant's Business Manual* (AICPA); V*aluing Professional Practices and Licenses* (Aspen Publishers); *Valuation Strategies; Business Appraisal Practice*; and, *NACVA QuickRead*. Additionally, Mr. Zigrang has served as faculty before professional and trade associations such as the American Society of Appraisers (ASA); the National Association of Certified Valuators and Analysts (NACVA); the American Health Lawyers Association (AHLA); the American Bar Association (ABA); the Association of International Certified Professional Accountants (AICPA); the Physician Hospitals of America (PHA); the Institute of Business Appraisers (IBA); the Healthcare Financial Management Association (HFMA); and, the CPA Leadership Institute.

Mr. Zigrang holds a Master of Science in Health Administration (MHA) and a Master of Business Administration (MBA) from the University of Missouri at Columbia. He is a Fellow of the American College of Healthcare Executives (FACHE) and holds the Certified Valuation Analyst (CVA) designation from NACVA. Mr. Zigrang also holds the Accredited Senior Appraiser (ASA) designation from the American Society of Appraisers, where he has served as President of the St. Louis Chapter. He is also a member of the America Association of Provider Compensation Professionals (AAPCP), AHLA, AICPA, NACVA, NSCHBC, and, the Society of OMS Administrators (SOMSA).

Jessica L. Bailey-Wheaton, Esq., is Senior Vice President and General Counsel of HCC. Her work focuses on the areas of Certificate of Need (CON) preparation and consulting, as well as project management and consulting services related to the impact of both federal and state regulations on healthcare transactions. In that role, Ms. Bailey-Wheaton provides research services necessary to support certified opinions of value related to the Fair Market Value and Commercial Reasonableness of transactions related to healthcare enterprises, assets, and services.

Additionally, Ms. Bailey-Wheaton heads HCC's CON and regulatory consulting service line. In this role, she prepares CON applications, including providing services such as: health planning; researching, developing, documenting, and reporting the market utilization demand and "need" for the proposed services in the subject market service area(s); researching and assisting legal counsel in meeting regulatory requirements relating to licensing and CON application development; and, providing any requested support services required in litigation challenging rules or decisions promulgated by a state agency. Ms. Bailey-Wheaton has also been engaged by both state government agencies and CON applicants to conduct an independent review of one or more CON applications and provide opinions on a variety of areas related to healthcare planning. She has been certified as an expert in healthcare planning in the State of Alabama.

Ms. Bailey-Wheaton is the co-author of numerous peer-reviewed and industry articles in publications such as: The Health Lawyer; Physician Leadership Journal; The Journal of Vascular Surgery; St. Louis Metropolitan Medicine; Chicago Medicine; The Value Examiner; and QuickRead. She has previously presented before the ABA, the NACVA, and the NSCHBC. She serves on the editorial boards of NACVA's QuickRead and AHLA's Journal of Health & Life Sciences Law.

Janvi R. Shah, MBA, MSF, serves as Senior Financial Analyst of HCC. Mrs. Shah holds a M.S. in Finance from Washington University Saint Louis. She develops fair market value and commercial reasonableness opinions related to healthcare enterprises, assets, and services. In addition she prepares, reviews and analyzes forecasted and pro forma financial statements to determine the most probable future net economic benefit related to healthcare enterprises, assets, and services and applies utilization demand and reimbursement trends to project professional medical revenue streams and ancillary services and technical component (ASTC) revenue streams.

For more information please visit: www.healthcapital.com