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Jessica L. Bailey-Wheaton, Esq., Editor
Todd A. Zigrang, MBA, MHA, FACHE, CVA, ASA, ABV, Publisher

Valuation of Accountable Care Organizations: Regulatory Environment

Because of the federal government's preference for, and reliance on the success of, accountable care organizations (ACOs), some ACOs assume their legal status shields the organization from legal scrutiny on all issues. However, since the 2010 advent of ACOs, the law has adapted uniquely to these organizations. This fourth installment of a five-part series on the valuation of ACOs will discuss this unique regulatory environment in which ACOs operate.

MSSP ACO Eligibility

Qualification for ACO contract participation with MSSP, the most popular ACO program, requires:

(1) General eligibility requirements;
(2) Being an eligible provider and supplier;
(3) Meeting minimum participation levels required of primary care providers;
(4) Reporting on qualities and costs;
(5) Care coordination capabilities; and,
(6) The governance structure of the ACO vests decision-making control in ACO participants.[1]

Additionally, ACOs must meet certain governance and leadership structure requirements:

(1) "*The ACO's governing body has made and duly authorized a bona fide determination… that the arrangement is reasonably related to the purposes of the Shared Savings Program*;
(2) "*Both the arrangement and its authorization by the governing body are documented*;" and,
(3) "*The description of the arrangement is publicly disclosed at a time and in a place and manner established in guidance issued by*" HHS.[2]

ACOs must have at least 5,000 assigned beneficiaries for the lower levels of MSSP participation.[3] An ACO's clinical management must be managed by a board-certified physician that is a senior-level medical director.[4]

ACOs are required to maintain documentation for 10 years on:

(1) "*A description of the arrangement, including all parties to the arrangement*;"
(2) "*[The] date of the arrangement*;"
(3) "*The purpose of the arrangement*;"
(4) "*The items, services, facilities, and/or goods covered by the arrangement (including non-medical items, services, facilities, or goods)*;" and,
(5) "*The financial or economic terms of the arrangement*."[5]

Finally, ACOs require extensive quality measures and patient satisfaction reporting.[6]

Antitrust Law

The formation of ACOs has often been criticized for facilitating the increased consolidation of market power in healthcare. Legal implications can arise from anticompetitive behavior on the part of ACOs, as antitrust laws still apply to ACOs and the Department of Health and Human Services (HHS) is not authorized to waive the applicability of antitrust laws to ACO formation and operation.[7] The lack of authorization leaves ACOs in a precarious position because ACO actions can be interpreted as anticompetitive. However, the Federal Trade Commission (FTC) and the Department of Justice (DOJ) had originally allowed for certain exceptions to be made for ACOs participating in MSSP.[8] The goal of this FTC/DOJ policy was to prevent ACOs from enhancing or entrenching market power.[9] Further, the FTC and DOJ wanted to encourage the development of a competitive ACO marketplace.[10] However, the DOJ announced the withdrawal of this statement on February 6, 2023, classifying it as outdated and not reflecting the realities of the current market.[11] The withdrawal was seen as consistent with the Biden Administration's priorities on being more aggressive with the enforcement of antitrust issues.[12] The withdrawal of this FTC/DOJ policy signals a potential increase in the scrutiny of ACO antitrust actions, among other networks of organizations and providers.[13]

Federal Fraud & Abuse Laws

Additionally, healthcare provider 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 greatest 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

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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.[14] Additionally, while violation of the Stark Law carries only civil penalties, violation of the AKS carries both criminal and civil penalties.[15]

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,[16] even if only one purpose of the arrangement in question is to offer remuneration deemed illegal under the AKS.[17] 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,[18] only an awareness that the conduct in question is "*generally unlawful*."[19] Further, a violation of the AKS is sufficient to state a claim under the *False Claims Act* (FCA).[20]

Due to the broad nature of the AKS, legitimate business arrangements may appear to be prohibited.[21] In response, AKS *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.[22] Failure to meet all of the requirements of a *safe harbor* does not necessarily render an arrangement illegal.[23] 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 CMS, as discussed below.[24] 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).[25]

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).[26] Further, when a prohibited referral occurs, entities may not bill for services resulting from the prohibited referral.[27] Under the Stark Law, DHS include, but are not limited to, the following:

(1) Inpatient and outpatient hospital services;

(2) Radiology and certain other imaging services;

(3) Radiation therapy services and supplies;

(4) Certain therapy services, such as physical therapy;

(5) Durable medical equipment; and,

(6) Outpatient prescription drugs.[28]

Under the Stark Law, financial relationships include ownership interests through equity, debt, other means, and ownership interests in entities also have an ownership interest in the entity that provides DHS.[29] 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.[30] 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.[31] Similar to the AKS safe harbors, without these exceptions, the Stark Law may prohibit legitimate business arrangements.

As noted above, in December 2020, CMS released a number of revisions to the Stark Law in a final rule, including new permanent exceptions for value-based arrangements.[32] These new 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.[33]

ACO Fraud & Abuse Waivers

ACO formation may have a variety of legal risks. To encourage participation in MSSP, CMS and the OIG have created *waivers* to shield participating ACOs from legal risks related to fraud and abuse.[34] There are five waivers available:

(1) The *Pre-Participation Waiver* allows ACO participants to fund ACO development for the overall benefit of the ACO participants;[35]

(2) The *Participation Waiver*, applies broadly to ACO-related arrangements and is similar to the *Pre-Participation Waiver* in that it protects ACO activities required to sustain the business, such as investment and operating agreements.[36]

(3) The *Shared Savings Waiver* protects arrangements related to, and allows for the distribution and use of, shared savings payments earned from the MSSP.[37]

(4) The *Compliance with Stark Law Waiver* allows the ACO to pursue arrangements that may otherwise implicate the AKS;[38] and

(5) The *Patient Incentive Waiver* offers protection from fraud and abuse laws when an ACO, ACO participant, or ACO provider provides medically-related incentives to MSSP beneficiaries, e.g., free or below-fair market value items and services that advance the goals of preventative care, adherence to medications/treatment, or management of chronic diseases/conditions.[39]

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Importantly, the waivers must be reasonably related to the MSSP to shield an ACO from fraud and abuse implications.[40] Arrangements that are unrelated to the MSSP (even if they have similar underlying purposes) are not shielded from fraud and abuse law by ACO waivers.[41]

Conclusion

ACOs face many obstacles within the regulatory environment that can prohibit their formation, growth, and development. Understanding fraud and abuse laws, among other statutes and regulations, are integral to the success of an ACO. Another factor integral to the success of an ACO is their health information technology infrastructure. Consequently, the final installment in this series will discuss the technological environment in which ACOs operate.

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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); *Valuing 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.

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