HEALTH CAPITAL Topics
Volume 14
Issue 1
January 2021
Jessica L. Bailey-Wheaton, Esq., Editor
Todd A. Zigrang MBA, MHA, CVA, ASA, FACHE, Publisher

Stark & Anti-Kickback Revisions Finalized: New Safe Harbors

On November 20, 2020, the *Centers for Medicare & Medicaid Services* (CMS) and the *Office of Inspector General* (OIG) of the *Department of Health and Human Services* (HHS) issued two final rules to modernize and clarify the *Stark Law* and the *Anti-Kickback Statute* (AKS).[1] This is the third installment in a *Health Capital Topics* series examining these final rules and their impact on healthcare valuation going forward. The first article provided an overview of the Stark Law and summarized the law's final rule as relates to "The Big Three" Requirements – Commercial Reasonableness, the Volume or Value Standard and the Other Business Generated Standard, and Fair Market Value.[2] The second article summarized the new Stark Law exceptions finalized by CMS, particularly those related to *value-based arrangements* (VBAs).[3] This third article will summarize the new AKS Safe Harbors finalized by the OIG.

Similarity to, and Distinction from, Stark Exceptions

Similar to CMS, OIG finalized a number of new, permanent AKS safe harbors, most notably for VBAs. As part of the new safe harbors, OIG established several new definitions, including those for value-based activity, VBA, value-based enterprise (VBE), value-based purpose, VBE participant, and target patient population. Note that these terms have been color-coded herein to highlight the interconnectedness of these terms.

It is critical to note that not all of the AKS safe harbors are the same as the Stark Law exceptions for VBAs. Consequently, this article will note those safe harbors that are identical to their sister Stark Law exceptions, and expand on those safe harbors that diverge from their sister exceptions.

New Value-Based Safe Harbors

Definitions

OIG finalized the definition of **value-based activity** as "*any of the following activities, provided that the activity is reasonably designed to achieve at least one **value-based purpose** of the **value-based enterprise**: (1) The provision of an item or service; (2) The taking of an action; or (3) The refraining from taking an action*."[4] This definition is identical to the Stark Law definition of the term, and similar to the Stark Law, referrals may not be considered value-based activities.[5]

OIG finalized the definition of **value-based arrangement** as "*an arrangement for the provision of at least one **value-based activity** for a **target patient population** to which the only parties are: (1) The **value-based enterprise** and one or more of its **VBE participants**; or (2) **VBE participants** in the same **value-based enterprise***."[6] [Emphasis added.] Just like CMS, OIG finalized the emphasized language in this definition instead of its proposed language, "*between or among*," to "*clarify that that only the value-based enterprise and one or more of its VBE participants, or VBE participants in the same value-based enterprise, may be parties to a value-based arrangement*."[7] While this definition is identical to the Stark Law definition of the term, the application of the definition necessarily differs – while Stark VBAs are limited to physicians and entities as well as to designated health services, the AKS version of the definition does not have such limitations.[8]

OIG finalized the definition of **value-based enterprise (VBE)** to mean "*two or more **VBE participants**: (i) Collaborating to achieve at least one **value-based purpose**; (ii) each of which is a party to a **value-based arrangement** with the other or at least one other **VBE participant** in the **value-based enterprise**; (iii) that have an accountable body or person responsible for the financial and operational oversight of the **value-based enterprise**; and (iv) that have a governing document that describes the **value-based enterprise** and how the **VBE participants** intend to achieve its **value-based purpose(s)***."[9] This definition is identical to the Stark Law definition of the term.[10]

OIG finalized the definition of **VBE participant** to mean "*an individual or entity that engages in at least one **value-based activity** as part of a **value-based enterprise**, other than a patient acting in their capacity as a patient*."[11] This definition generally aligns with the CMS definition, but is not verbatim.[12] Where the OIG's interpretation of VBE participant does differ from CMS is in its application. While the definition itself does not exclude certain entity types, the various value-based safe harbors (discussed below) identify certain entities that are ineligible for a given safe harbor (e.g., pharmaceutical manufacturers, distributors, and wholesalers; pharmacy benefit managers, laboratory companies; compounding pharmacies; medical device/supply manufacturers; entities/individuals that

(Continued on next page)

sell/rent DMEPOS (other than a pharmacy or a provider); and, medical device distributors/wholesalers.[13]

OIG finalized the definition of ***value-based purpose*** as "*(i) Coordinating and managing the care of a **target patient population**; (ii) improving the quality of care for a **target patient population**; (iii) appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a **target patient population**; or (iv) transitioning from health care delivery and payment mechanisms based on the volume of items and services provided to mechanisms based on the quality of care and control of costs of care for a **target patient population***."[14] This definition is identical to the Stark Law definition of the term.

OIG finalized the definition of **target patient population** to mean "*an identified patient population selected by the **VBE** or its **VBE participants** using legitimate and verifiable criteria that: (i) Are set out in writing in advance of the commencement of the **value-based arrangement**; and (ii) further the **value-based enterprise**'s **value-based purpose(s)***."[15] This definition is identical to the Stark Law definition of the term.

Exceptions

OIG finalized new safe harbors for three types of value-based arrangements:

(1) Value-Based Arrangements with Full Financial Risk;

(2) Value-Based Arrangements with Substantial Downside Financial Risk; and,

(3) Care Coordination Arrangements.

In general, OIG "*sought to align value-based terminology and safe harbor conditions with those [Stark Law exceptions] being adopted by CMS…wherever possible….However, complete alignment is not feasible because of fundamental differences in statutory structures and sanctions across the two laws…the [AKS] is an intent-based, criminal statute that covers all referrals of Federal health care program business…In contrast, the [Stark Law] is a civil, strict-liability statute that prohibits payment by CMS for a more limited set of services referred by physicians who have certain financial relationships with the entity furnishing the services. As a result, the value-based exceptions adopted by CMS do not need to contemplate the broad range of conduct that implicates the [AKS]*."[16]

Each of these arrangements are discussed in turn below.

Full Financial Risk Arrangements[17]

OIG finalized the safe harbor for full financial risk arrangements to be those where "*the VBE is financially responsible on a prospective basis for the cost of all items and services covered by the applicable payor for each patient in the target patient population for a term of at least 1 year*."[18] This definition is largely in alignment with its sister Stark Law exception – similar to CMS, OIG extended the "*pre-risk period*" (the time prior to the commencement of the arrangement) for such arrangements from 6 to 12 months.[19] However, there are a couple of differences in the wording of the definition itself. For example, OIG differed on the characterization of the "*items and services*" at issue – CMS specified these as "*patient care items and services*,"[20] while OIG made no such stipulation. Additionally, instead of simply stating that the term must be a "*specified period of time*," as CMS did,[21] OIG quantified the term as being at least one year in length.

Substantial Downside Financial Risk Arrangements[22]

In the final rule, OIG finalized its "*substantial downside financial risk*" safe harbor to apply to a VBE if it falls under one of three methodologies:

"*(A) Financial risk equal to at least 30 percent of any loss, where losses and savings are calculated by comparing current expenditures for all items and services that are covered by the applicable payor and furnished to the target patient population to a bona fide benchmark designed to approximate the expected total cost of such care;*

(B) Financial risk equal to at least 20 percent of any loss, where:

(1) Losses and savings are calculated by comparing current expenditures for all items and services furnished to the target patient population pursuant to a defined clinical episode of care that are covered by the applicable payor to a bona fide benchmark designed to approximate the expected total cost of such care for the defined clinical episode of care; and

(2) The parties design the clinical episode of care to cover items and services collectively furnished in more than one care setting; or

(C) The VBE receives from the payor a prospective, per-patient payment that is:

(1) Designed to produce material savings; and

(2) Paid on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed to approximate the expected total cost of expenditures for the predefined set of items and services."[23] [Emphasis added.]

Further, under this safe harbor, VBE participants (unless they are the payor undertaking the risk) must be at risk for "*a meaningful share*" of the VBE's substantial downside financial risk. OIG defined "*meaningful share*" to mean:

"*the VBE participant:*

(A) Assumes two-sided risk for at least 5 percent of the losses and savings, as applicable, realized by the VBE pursuant to its assumption of substantial downside financial risk; or

(B) Receives from the VBE a prospective, per-patient payment on a monthly, quarterly, or annual basis for a predefined set of items and services furnished to the target patient population, designed

(Continued on next page)

to approximate the expected total cost of expenditures for the predefined set of items and services, and does not claim payment in any form from the payor for the predefined items and services."[24] [Emphasis added.]

This is significantly different from the Stark Law's Value-Based Arrangements with Meaningful Downside Risk exception,[25] which only requires "*that the physician is responsible to repay or forgo no less than 10 percent of the total value of the remuneration the physician receives under the value-based arrangement*."[26]

Care Coordination Arrangements[27]

The Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency safe harbor allows for certain remuneration provided if 13 factors are met. Notably, the safe harbor only protects certain in-kind (but not monetary) remuneration (a departure from the comparable Stark Law exception, which covers both monetary and in-kind compensation[28]); the arrangement must be "*commercially reasonable, considering both the arrangement itself and all value-based arrangements within the VBE*"; and, the recipient of the remuneration must pay "*15 percent of the offer's cost or 15 percent of the fair market value of the remuneration*" (also a departure from the comparable Stark Law exception, which does not include a contribution requirement).[29]

Of note, unlike CMS, OIG defined the term "*coordination and management of care*," stating it means "*the deliberate organization of patient care activities and sharing of information between two or more VBE participants, one or more VBE participants and the VBE, or one or more VBE participants and patients, that is designed to achieve safer, more effective, or more efficient care to improve the health outcomes of the target patient population*."[30]

Other New Safe Harbors

CMS-Sponsored Models

OIG established a new safe harbor related to remuneration exchanged among CMS-sponsored model participants and to CMS beneficiaries treated under the model (i.e., patient incentives). Importantly, CMS must affirmatively determine that this safe harbor applies to a given CMS-sponsored model.[31] There are several criteria that must be satisfied for both remuneration among participants and remuneration to patients;[32] notably, the arrangement must be memorialized in advance in a signed writing, which must include, "*at a minimum the activities to be undertaken by the CMS-sponsored model parties and the nature of the remuneration to be exchanged under the CMS-sponsored model arrangement*."[33]

Patient Engagement and Support

Another new safe harbor established by OIG protects arrangements for patient engagement and support to improve quality, health outcomes, and efficiency. Specifically, remuneration by way of tools and supports furnished by VBE participants to those in a target patient population would be protected, provided that, among other things, no more than $500 worth of in-kind (i.e., nonmonetary) remuneration is provided to a given patient in a year.[34] This safe harbor is only available to VBE participants – pharmaceutical manufacturers, distributors, and wholesalers; pharmacy benefit managers; laboratories; compounding pharmacies; physician-owned medical device and supply manufacturers; medical device distributors and wholesalers; and sellers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), are not eligible for this safe harbor.[35]

Cybersecurity Technology and Services

OIG also finalized a new safe harbor for donations of cybersecurity technology and related services donation, similar to the Stark Law's new exception,[36] "*to protect nonmonetary donations of certain cybersecurity technology and related services to help improve the cybersecurity posture of the health care industry*."[37] For the safe harbor to apply, a number of conditions must be met, including that: (1) the volume or value of referrals not be considered; and, (2) the receipt of such technology may not be a condition of future referrals.[38] Importantly, OIG included in the finalized safe harbor protection for certain cybersecurity hardware, which had previously been omitted in the proposed safe harbor.[39]

Conclusion

While some modifications were made to the various new AKS safe harbors, the overall intent behind these safe harbors remain the same – to catch up to the rapidly changing healthcare system, and accelerate the transformation of the healthcare system into one that better pays for value and promotes care coordination. However, because of the novelty of these safe harbors, as well as their interplay with the Stark Law exceptions, putting these arrangements into practice may raise a number of questions that will need to be subsequently addressed by OIG. Either way, given the high number of new healthcare fraud and abuse enforcement actions over the past decade, the enforcement of AKS will likely continue in its intensity going forward.

(Continued on next page)

1 "HHS Makes Stark Law and Anti-Kickback Statute Reforms to Support Coordinated, Value-Based Care" U.S. Department of Health & Human Services, November 20, 2020, https://www.hhs.gov/about/news/2020/11/20/hhs-makes-stark-law-and-anti-kickback-statute-reforms-support-coordinated-value-based-care.html (Accessed 11/24/20).
2 "Stark & Anti-Kickback Revisions Finalized: Changes to Stark's Big Three Provisions" Health Capital Topics, Vol. 13, Issue 11 (November 2020), https://www.healthcapital.com/hcc/newsletter/11_20/HTML/STARK/convert_stark-aks-final-rules-11.24.20a.php (Accessed 12/4/20).
3 "Stark & Anti-Kickback Revisions Finalized: New Stark Exceptions Established" Health Capital Topics, Vol. 13, Issue 12 (December 2020), https://www.healthcapital.com/hcc/newsletter/12_20/HTML/STARK/convert_stark-aks-final-rules---new-exceptions-12.18.20.php (Accessed 1/8/21).
4 "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: Final rule" Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77703.
5 *Ibid*.
6 *Ibid*, p. 77700.
7 *Ibid*.
8 *Ibid*, p. 77695.
9 *Ibid*, p. 77705-77706.
10 *Ibid*, p. 77697.
11 *Ibid*, p. 77706.
12 The CMS definition of VBE participant is: "*a person or entity that engages in at least one value*-based activity as part of a value-based enterprise." [Emphasis added.] The emphasized language differs from the OIG definition of the term. "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77497.
13 Federal Register, Vol. 85, No. 232, p. 77706.
14 *Ibid*, p. 77720.
15 *Ibid*, p. 77702.
16 *Ibid*, p. 77689.
17 42 C.F.R. § 1001.952(gg).
18 42 C.F.R. § 1001.952(gg)(10)(i). Federal Register, Vol. 85, No. 232, p. 77770-77771.
19 Federal Register, Vol. 85, No. 232, p. 77771.
20 *Ibid*, p. 77510.
21 *Ibid*.
22 42 C.F.R. § 1001.952(ee).
23 42 C.F.R. § 1001.952(ee)(i).
24 42 C.F.R. § 1001.952(ee)(ii).
25 42 C.F.R. § 411.357(aa)(2).
26 Federal Register, Vol. 85, No. 232, p. 77515.
27 42 C.F.R. § 1001.952(ee).
28 *Ibid*.
29 Federal Register, Vol. 85, No. 232, p. 77724, 77731.
30 *Ibid*, p. 77748.
31 42 C.F.R. § 1001.952(ii)(1)(i).
32 Federal Register, Vol. 85, No. 232, p. 77809.
33 42 C.F.R. § 1001.952(ii)(1)(iv).
34 Federal Register, Vol. 85, No. 232, p. 77781.
35 42 C.F.R. § 1001.952(hh)(1).
36 Federal Register, Vol. 85, No. 232, p. 77630.
37 *Ibid*, p. 77814-77815.
38 42 C.F.R. § 1001.952(jj)(1).
39 Federal Register, Vol. 85, No. 232, p. 77814-77815.

(Continued on next page)

HEALTH CAPITAL CONSULTANTS

(800)FYI - VALU

Providing Solutions in the Era of Healthcare Reform

Founded in 1993, HCC is a nationally recognized healthcare economic financial consulting firm

- HCC Home
- Firm Profile
- HCC Services
- HCC Experts
- Clients & Projects
- HCC News
- Upcoming Events
- Contact Us
- Email Us

HCC Services

- 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 Consulting
- Industry Research Services

Todd A. Zigrang, MBA, MHA, CVA, ASA, FACHE, 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*" [2015 – AICPA], numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: *The Accountant's Business Manual* (AICPA); *Valuing Professional Practices and Licenses* (Aspen Publishers); *Valuation Strategies; Business Appraisal Practice*; and, *NACVA QuickRead*. In addition to his contributions as an author, Mr. Zigrang has served as faculty before professional and trade associations such as the American Society of Appraisers (ASA); American Health Lawyers Associate (AHLA); the American Bar Association (ABA); the National Association of Certified Valuators and Analysts (NACVA); 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 Accredited Senior Appraiser (ASA) designation from the American Society of Appraisers, where he has served as President of the St. Louis Chapter, and is current Chair of the ASA Healthcare Special Interest Group (HSIG).

Jessica L. Bailey-Wheaton, Esq., is Senior Vice President and General Counsel of HCC, where she conducts project management and consulting services related to the impact of both federal and state regulations on healthcare exempt organization transactions, and 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.

She serves on the editorial boards of NACVA's The Value Examiner and of the American Health Lawyers Association's (AHLA's) Journal of Health & Life Sciences Law. Additionally, she is the current Chair of the American Bar Association's (ABA) Young Lawyers Division (YLD) Health Law Committee and the YLD Liaison for the ABA Health Law Section's Membership Committee. She has previously presented before the ABA, NACVA, and the National Society of Certified Healthcare Business Consultants (NSCHBC).

Ms. Bailey-Wheaton is a member of the Missouri and Illinois Bars and holds a J.D., with a concentration in Health Law, from Saint Louis University School of Law, where she served as Fall Managing Editor for the Journal of Health Law & Policy.

Daniel J. Chen, MSF, CVA, focuses on developing Fair Market Value and Commercial Reasonableness opinions related to healthcare enterprises, assets, and services. In addition he 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. Mr. Chen holds the Certified Valuation Analyst (CVA) designation from NACVA.