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

Stark & Anti-Kickback Revisions Finalized: New Stark Exceptions Established

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 second 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] This second article will summarize the new Stark Law exceptions finalized by CMS.

New Value-Based Exceptions

CMS finalized a number of new, permanent exceptions to the Stark Law, most notably for *value-based arrangements* (VBAs).[3] As part of the new exceptions, CMS introduced a number of new definitions, including those for value-based activity, VBA, value-based enterprise (VBE), value-based purpose, VBE participant, and target patient population.[4] Note that these terms have been color-coded herein to highlight the interconnectedness of these terms.

Definitions

CMS 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*."[5] CMS made some revisions to this definition from the proposed rule, based on commenter suggestions. Notably, CMS did not finalize its proposed statement that the making of a referral is not a value-based activity, in response to commenters' concern that referrals are "*an integral part of a value-based health care delivery and payment system, especially with respect to care planning*."[6] Specifically, CMS stated that "*[c]are planning activities that meet the definition of 'referral'…will qualify as 'the taking of an action' for purposes of applying the definition of 'value-based activity.'*"[7] Despite commenter requests, CMS declined to "*provide a list of items or services, actions, and ways to refrain from taking an action that qualify as value-based activities*" so as not to limit potential activities.[8] On the topic of whether a value-based activity is "*reasonably designed to achieve at least one value-based purpose*," CMS stated that such a determination is fact specific – "*[p]arties must have a good faith belief that the value-based activity will achieve or lead to the achievement of at least one value-based purpose...*"[9] [Emphasis added.] This does not mean, however, that the value-based purpose(s) must actually be achieved in order for the value-based arrangement to fall within an exception.[10] As to how to adequately memorialize value-based activities, CMS noted "*that contemporaneous documentation is a best practice, and we encourage parties to follow this practice*."[11] Further, CMS reminded stakeholders that the burden of proof to show compliance with an exception is on the parties asserting such an exception (i.e., those engaging in a value-based activity.[12]

CMS finalized the definition of **value-based arrangement** to mean "*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***."[13] [Emphasis added.] Notably, CMS finalized the emphasized language in this definition instead of its proposed language, "*between or among*," to clarify "*that all parties to the value-based arrangement must be VBE participants in the same VBE*."[14] Additionally, while CMS requested comment on requiring "*care coordination and management in order to qualify as a value-based arrangement*," the agency ultimately declined to include that requirement.[15] As to whom may participate in a value-based arrangement, CMS asserted that "*effectively, the parties to a value-based arrangement must include an entity…and a physician; otherwise the [Stark Law's] prohibitions would not be implicated*."[16] Further, "*…the value-based arrangement must be a compensation arrangement and not another type of financial arrangement…*"[17]

CMS finalized the definition of **value-based enterprise (VBE)** to mean "*two or more **VBE participants**— (1) Collaborating to achieve at least one **value-based purpose**; (2) 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**; (3) That have an accountable body or person responsible for the*

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financial and operational oversight of the ***value-based enterprise****; and (4) That have a governing document that describes the* ***value-based enterprise*** *and how the* ***VBE participants*** *intend to achieve its* ***value-based purpose(s)***."[18] Put another way, "*a value-based enterprise is a network of individuals and entities that are collaborating to achieve one or more value-based purposes of the value-based enterprise*."[19] Further, "*[i]f a value-based enterprise is comprised of only two VBE participants, they must have at least one value-based arrangement with each other…*"[20] VBEs can have multiple parties, or add parties later, to a contract, but CMS emphasized that "*each of the financial relationships that results from the contract must be analyzed separately under*" the Stark Law, as they are "*separate and distinct compensation arrangement[s] that must be analyzed for compliance with an applicable exception*."[21] While a number of commenters urged CMS to not finalize the requirement that a VBE have "*an accountable body or person that is responsible for the financial and operational oversight of the enterprise*," CMS declined to remove the requirement, finalized the requirement as proposed, and "*maintain[ed] the requirement that the enterprise must have a governing document that describes the value-based enterprise and how its VBE participants intend to achieve its value-based purpose(s).*"[22] The agency assured stakeholders that it was not "*dictating particular legal or other structural requirements for a value-based enterprise; rather, the final regulations accommodate both formal and informal value-based enterprises.*"[23] Consequently, "*the written agreements and contracts that parties enter into in the normal course of their business dealings could serve as the documentation required under the new exception for value-based arrangements.*"[24]

CMS finalized the definition of **VBE participant** to mean "*a person or entity that engages in at least one* ***value-based activity*** *as part of a* ***value-based enterprise***."[25] [Emphasis added.] In a departure from its proposed definition, CMS added "*person*" to the definition of VBE participant so as to: (1) bring the definition in line with that set forth in the AKS final rule; and, (2) not exclude any specific persons, entities, or organizations from the definition.[26] In adding this word, CMS noted that it intended for the phrase "*person or entity*" to refer to both natural and non-natural persons.[27] In making this change, CMS acknowledged commenters' assertions that "*laboratories and [Durable Medical Equipment, Prosthetics, Orthotics, and Supplies] DMEPOS suppliers may play a beneficial role in the delivery of value-based health care*."[28]

CMS finalized the definition of ***value-based purpose*** as "*any of the following: (1) Coordinating and managing the care of a* ***target patient population****; (2) Improving the quality of care for a* ***target patient population****; (3) Appropriately reducing the costs to or growth in expenditures of payors without reducing the quality of care for a* ***target patient population****; or (4) 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***."[29] Similar to the *value-based arrangement* definition, CMS did not finalize a definition for "*coordinating and managing care*," as that phrase is used in the first goal in the definition.[30] In discussing the "*four core goals related to a target patient population*,"[31] the agency agreed "*that [the 4th] value-based purpose shares certain aspects of the pre-participation waiver under the Shared Savings Program*"; however, CMS noted that the existing *accountable care organization* (ACO) fraud and abuse waivers will "*remain in place and are not affected by the existence of the value-based exceptions*."[32]

CMS finalized the definition of **target patient population** to mean "*an identified patient population selected by a* ***value-based enterprise*** *or its* ***VBE participants*** *based on legitimate and verifiable criteria that— (1) Are set out in writing in advance of the commencement of the* ***value-based arrangement****; and (2) Further the* ***value-based enterprise****'s* ***value-based purpose(s)***."[33] While this definition was finalized by CMS as it was proposed,[34] CMS did seek comment on (but ultimately did not finalize) whether this definition should "*incorporate a requirement that patients in the target patient population have at least one chronic condition in order to align with [the Office of Inspector General's] OIG's proposals…*"[35] In its discussion of this term, CMS discussed instances "*…where a target patient population is ascribed to the value-based enterprise (or the VBE participants that are parties to the specific value-based arrangement) by the payor*" and noted that VBEs and VBE participants are still ultimately responsible for "*ensur[ing] that the requirements of the definition of 'target patient population' are satisfied.*"[36] CMS further stated that "*[i]t is not sufficient for the [VBE] or its VBE participants to merely state that the selection criteria will be determined by another party (in this case, the payor)…[they] may need to collaborate with the payor to ensure that the patient population attributed meets the definition of 'target patient population.'*"[37]

Exceptions

CMS finalized new exceptions for three types of value-based arrangements:

(1) Full Financial Risk Arrangements;
(2) Value-Based Arrangements with Meaningful Downside Risk; and,
(3) Other Value-Based Arrangements.

In general, CMS stated that all three arrangements are "*aligned in nearly all respects with OIG's final value-based definitions*" in the AKS final rule.[38] Further, CMS finalized its proposal to *not* require that remuneration associated with a value-based arrangement: (1) be consistent with *Fair Market Value*; or, (2) not take into account the volume or value of a physician's referrals or the other business generated by the physician for the entity.[39] However, CMS is requiring that the compensation arrangements under these exceptions be commercially reasonable (although the agency noted that

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these arrangements are "*likely commercially reasonable*").[40]

Each of these arrangements are discussed in turn below.

Full Financial Risk Arrangements[41]

CMS finalized the exception for full financial risk arrangements, wherein "*the value-based enterprise is financially responsible on a prospective basis for the cost of all patient care items and services covered by the applicable payor for each patient in the target patient population for a specified period of time*," with one modification – the agency extended the "*pre-risk period* (the time prior to the commencement of the arrangement),[42] from 6 months to 12 months.[43] These arrangements do not have documentation requirements,[44] but a VBE's financial risk must be prospective.[45]

CMS discussed at length what remuneration under these arrangements may, or may not, include. As to what full financial risk arrangements *may* include, CMS noted that they may include "*risk mitigation terms such as risk corridors, global risk adjustments, reinsurance, or stop-loss provisions to protect against significant and catastrophic losses*,"[46] meaning that payors may make payments "*to offset losses incurred by the enterprise above those prospectively agreed to by the parties. The payment of shared savings or other incentive payments for achieving quality, performance, or other benchmarks are also not prohibited*."[47] The exception requires the remuneration to be for, or result from, value-based activities, which is intended "*to be an objective standard; that is, the remuneration must, in fact, be for or result from value-based activities…*"[48] Additionally, "*if remuneration paid to the physician is conditioned on the physician's referrals to a particular provider, practitioner, or supplier, the value-based arrangement [must] compl[y] with both of the following conditions:*

(A) *The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties; and*

(B) *the requirement to make referrals to a particular provider, practitioner, or supplier does not apply if the patient expresses a preference for a different provider, practitioner, or supplier; the patient's insurer determines the provider, practitioner, or supplier; or the referral is not in the patient's best medical interests in the physician's judgment*."[49]

Notably, "*[t]he final exception does not protect arrangements where one or both parties have made referrals or other business not covered by the value-based arrangement a condition of the remuneration*."[50] For example, "*the exception will not protect a value-based arrangement related to knee replacement services furnished to Medicare beneficiaries if the arrangement requires that the physician perform all his or her other orthopedic surgeries at the hospital*."[51]

Value-Based Arrangements with Meaningful Downside Risk[52]

In the final rule, CMS revised the definition of "*meaningful downside financial risk*" to mean "*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*," as opposed to the 25 percent that was proposed.[53] This change was in response to commenters who, in making this request, referenced "*a 2018 Deloitte Survey of U.S. physicians that surveyed 624 primary care and specialty physicians practicing in a variety of health care settings and found that most physicians are willing to tie approximately 10 percent of their compensation to quality and cost measures*."[54]

Similar to full financial risk arrangements, value-based arrangements with meaningful downside risk remuneration only relates to remuneration from an entity to a physician,[55] and may include *"[w]ithholds, repayment requirements, or incentive pay tied to meeting goals or outcome measures…provided that the physician's downside financial risk is tied to the achievement of the value-based purpose(s) of the value-based enterprise and not the goals of the parties or the arrangement (unless the parties alone comprise the value-based enterprise)*."[56]

However, unlike full financial risk arrangements, value-based arrangements with meaningful downside risk must set forth, in writing, the "*nature and extent of the physician's financial risk*,"[57] "*in advance of the undertaking of value-based activities for which the remuneration is paid*;"[58] however, "*[p]arties need not know the ultimate amount of remuneration under the value-based arrangement*."[59] [Emphasis added.]

Lastly, CMS specifically noted that this exception is not parallel with the substantial downside financial risk safe harbor under the AKS final rule.[60]

Other Value-Based Arrangements[61]

Other value-based arrangements, the definition of which is discussed above, included a number of additional requirements in order to fit within this exception. In the proposed rule, CMS required, among other things, that "*…the performance or quality standards against which the recipient of the remuneration will be measured, if any, are objective and measurable…*"[62] [Emphasis added.] However, "*[b]ecause commenters expressed concern regarding the term 'performance or quality standards,' and in an effort to reduce burden on stakeholders by aligning our terminology with OIG*" CMS removed the "*performance or quality standards*" language and replaced it with "*outcome measures*."[63] CMS defined "*outcome measure*" as "*a benchmark that quantifies:*

(A) *Improvements in or maintenance of the quality of patient care; or*

(B) *reductions in the costs to or reductions in growth in expenditures of payors while*

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maintaining or improving the quality of patient care."[64]

CMS did note that "*…outcome measures may not be applicable to all value-based arrangements…*"[65] but, if "*the value-based arrangement does include outcome measures…[they] must be determined in advance of their implementation*."[66] [Emphasis added.] CMS considered "*whether to require that outcome measures be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery*," but ultimately declined to include this requirement.[67] CMS did make clear that outcome measures may be replaced or substituted, so long as those changes are set forth in writing and made prospectively.[68]

CMS also included an explicit monitoring requirement, wherein "*[p]arties…must monitor the value-based arrangement no less frequently than annually…to determine whether the parties have furnished the value-based activities required under the arrangement, and whether and how continuation of the value-based activities is expected to further the value-based purpose(s) of the value-based enterprise.*"[69] If the parties' monitoring "*indicates that a value-based activity is not expected to further the value-based purpose(s) of the value-based enterprise, the parties must terminate the ineffective value-based activity*."[70] CMS did make clear that if a value-based arrangement is found to be ineffective, it will still be "*deemed to be reasonably designed to achieve at least one value-based purpose of the value-based enterprise during the entire period during which it was undertaken by the parties*," i.e., so long as the parties monitor their activities, catch an ineffective activity, and timely (i.e., within 90 days) cease that activity, they will not run afoul of the Stark Law.[71]

The other change CMS made to this exception in the final rule was its expansion of the proposed requirement that remuneration not be "*conditioned on the volume or value of referrals of any patients, including patients in the target patient population, to the entity or the volume or value of any other business generated, including business covered by the value-based arrangement, by the physician for the entity*."[72] [Emphasis added.] The proposed rule spoke only to patients *not* part of target patient population or business *not* covered by the value-based arrangement.[73] In expanding this requirement, CMS reminded "*readers that the value-based purpose of the arrangement must relate to the value-based enterprise as a whole…the exception will not protect a 'side' arrangement between two VBE participants that is unrelated to the goals and objectives (that is, the value-based purposes) of the value-based enterprise…*"[74]

Significantly, similar to the Value-Based Arrangements with Meaningful Downside Risk exception, CMS changed the Other Value-Based Arrangements exception's contribution requirement for physicians. In the proposed rule, CMS "*considered whether to require the recipient of any nonmonetary remuneration under a value-based arrangement to contribute at least 15 percent of the donor's cost of the nonmonetary remuneration*."[75] For the final rule, CMS declined to include any contribution requirement for this exception.[76]

Further, CMS chose not to limit this exception to nonmonetary remuneration only.[77] Consequently, the other value-based arrangements exception may cover both monetary and nonmonetary compensation.[78]

Of note, this exception does require the arrangement to be set forth in writing (and signed by the parties) and include "*a description of the value-based activities to be undertaken under the arrangement; how the value-based activities are expected to further the value-based purpose(s) of the value-based enterprise; the target patient population for the arrangement; the type or nature of the remuneration; the methodology used to determine the amount of the remuneration; and the performance or quality standards against which the recipient of the remuneration will be measured, if any*."[79]

Other New and Revised Exceptions

Indirect Compensation Arrangements

The definition of an indirect compensation arrangement was revised to include value-based arrangements, and was finalized so that "*…an unbroken chain of financial relationships that includes a value-based arrangement could form an 'indirect compensation arrangement' for purposes of*" the Stark Law, provided that certain factors are met.[80] This definition was updated "*[t]o avoid a blanket prohibition on indirect compensation arrangements that enhance value-based health care delivery and payment…[and] to make additional exceptions available to certain indirect compensation arrangements that include a value-based arrangement in the unbroken chain of financial relationships*."[81] CMS clarified that "*the link closest to the physician may not be an ownership interest; it must be a compensation arrangement that meets the definition of value-based arrangement*."[82]

Limited Remuneration to a Physician

In its proposed rule, CMS suggested a new exception for limited remuneration to a physician (without documentation) for items or services actually provided by the physician, on an "*infrequent or short-term basis*," in an aggregate amount not exceeding $3,500 per calendar year (as adjusted by inflation) if:

(1) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the physician;
(2) The compensation does not exceed the *Fair Market Value* of the items or services; and,
(3) Arrangements for the rental or use of office space or equipment do not violate the prohibitions on per-click and percentage-based compensation formulas.[83]

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The final rule made multiple changes to this new exception:

(1) The annual aggregate remuneration limit was raised from $3,500 to $5,000 (as adjusted by inflation);[84]

(2) Physicians are allowed to provide these services or items through employees whom were hired for the purpose of providing these services or items; and,

(3) The arrangement must be commercially reasonable.[85]

Notably, as set forth in the proposed rule, this exception operates on a calendar year basis, and not on a trailing twelve month basis from the start/end of the arrangement.[86]

Cybersecurity Donations

CMS also proposed the establishment of a new exception for donations of cybersecurity technology and related services that are "*necessary to implement, maintain, or reestablish security*."[87] For the exception to apply, a number of conditions must be met, including that: (1) the volume or value of referrals not be considered;[88] and, (2) the receipt of such technology may not be a condition of doing business with the donor.[89] CMS believes that the cybersecurity exception will be widely used by physicians because it helps address the growing threat of cyberattacks on data systems and health records.[90] CMS also proposed allowing for the donation of cybersecurity hardware, but only if that hardware was determined to be "*reasonably necessary*" based on the donor's risk assessments of its organization, as well as of the potential donee.[91]

The final rule remained generally the same as proposed, but with one notable exception. In finalizing this exception, CMS included hardware in the category of "*cybersecurity technology*"; the proposed definition had specifically omitted hardware, and the final rule removed that explicit omission.[92]

Conclusion

While some modifications were made to the various new Stark exceptions, the overall intent behind these new exceptions 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 new exceptions, putting these arrangements into practice may raise a number of questions that will need to be subsequently addressed by CMS. Either way, given the high number of new healthcare fraud and abuse enforcement actions over the past decade, the enforcement of the Stark Law will likely continue in its intensity going forward.

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5 "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations: Final rule" Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77497.
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9 *Ibid*.
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22 *Ibid*, p. 77502.
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30 *Ibid*, p. 77499.
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34 *Ibid*, p. 77499.
35 *Ibid*, p. 77505.
36 *Ibid*.
37 *Ibid*.
38 *Ibid*, p. 77508.
39 "Medicare 55777; Modernizing and Clarifying the Physician Self-Referral Regulations" Federal Register Vol. 84, No. 201 (October 17, 2019), p. 55829; "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations: Final rule" Federal Register, Vol. 85, No. 232 (December 2, 2020), p. 77510.
40 Federal Register, Vol. 85, No. 232, p. 77509.
41 42 C.F.R. § 411.357(aa)(1).
42 42 C.F.R. § 411.357(aa)(1)(vii).
43 Federal Register, Vol. 85, No. 232, p. 77510.
44 *Ibid*, p. 77512.
45 *Ibid*, p. 77511.
46 *Ibid*, p. 77513.
47 *Ibid*, p. 77512.
48 *Ibid*, p. 77511.
49 *Ibid*, p. 77514.
50 *Ibid*, p. 77512.
51 *Ibid*.
52 42 C.F.R. § 411.357(aa)(2)
53 Federal Register, Vol. 85, No. 232, p. 77515.

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56 *Ibid*, p. 77517.
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59 *Ibid*, p. 77518.
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61 42 C.F.R. § 411.357(aa)(3).
62 Federal Register Vol. 84, No. 201, p. 55784.
63 Federal Register, Vol. 85, No. 232, p. 77519.
64 *Ibid*, p. 77519.
65 *Ibid*.
66 *Ibid*.
67 *Ibid*, p. 77519-77520.
68 *Ibid*, p. 77525.
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75 *Ibid*, p. 77521.
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84 Federal Register, Vol. 85, No. 232, p. 77624.
85 *Ibid*.
86 *Ibid*, p. 77627.
87 Federal Register Vol. 84, No. 201, p. 55835.
88 *Ibid*, p. 55847.
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90 *Ibid*, p. 55839.
91 *Ibid*, p. 55834.
92 Federal Register, Vol. 85, No. 232, p. 77639.

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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.