

Importance of a Commercial Reasonableness Opinion for ACO Waivers (Part Two of a Three-Part Series)

The application of the federal healthcare fraud and abuse laws to *Accountable Care Organizations* (ACOs) is fraught with uncertainty and confusion. The *Centers for Medicare and Medicaid Services* (CMS), along with the *Office of Inspector General* (OIG) of the *U.S. Department of Health and Human Services* (HHS), released waivers of certain fraud and abuse laws for ACO participants in the federal *Medicare Shared Savings Program* (MSSP) in November 2011, and extended these waivers in its October 2014 interim rule.¹ However, as discussed in Part 1 of this Health Capital Topics series, entitled “*Definitions of Commercial Reasonableness and ACOs*,” these waivers have never been adopted in finalized regulations, resulting in uncertainty relating to the ongoing permissibility of these waivers.² In addition to these varying perspectives, both the OIG and, more recently, the *U.S. Department of Justice* (DOJ), are intensifying their regulatory scrutiny toward individual corporate executives for corporate regulatory violations, which may force individual executives to pay fines or face time in prison.³

For the reasons listed above, maintaining compliance with federal healthcare fraud and abuse laws is becoming an even more pressing issue for ACOs. Healthcare executives and ACO board members may be well-served to monitor the compensation arrangements, joint ventures, and acquisitions within the ACO to verify that they comply with certain regulatory thresholds, particularly the threshold of *commercial reasonableness* (CR). This second installment of the three-part Health Capital Topics series will address the uncertainty surrounding the continued viability of the fraud and abuse waivers going forward, as well as the need for a CR opinion related to ACOs to protect both the health system and the board of directors in today’s heightened regulatory environment.

As introduced above, CMS and OIG released waivers of certain fraud and abuse laws for ACO participants in November 2011, and extended these waivers in its October 2014 interim rule.⁴ There are five types of waivers; the broadest of these waivers are the ACO *Pre-Participation* and ACO *Participation* waivers.⁵ The ACO *Participation* and *Pre-Participation* waivers remove the requirements of the *Stark Law* and *Anti-Kickback Statute*, including the requirement of CR

found many *Stark Law* exceptions, as well as the gainsharing *civil monetary penalties* for those ACOs:

- (1) That have entered, or are acting with the good faith intent, to participate in the MSSP;
- (2) That meet certain requirements regarding governance, leadership, and management;
- (3) Whose governing body has made a bona fide determination that the arrangement with an ACO Participant reasonably relates to the purposes of the MSSP, such as:
 - (a) The promotion of accountability for the quality, cost, and overall care for a Medicare patient population;
 - (b) Managing and coordinating care for Medicare *fee-for-service* (FFS) beneficiaries through an ACO;
 - (c) Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients, including Medicare beneficiaries; and,
- (4) That document the arrangement and its authorization by the ACO governing body.⁶

Although the ACO fraud and abuse waivers may potentially place many arrangements outside the scope of the *Stark Law*, *Anti-Kickback Statute*, and *civil monetary penalties*, sole reliance on the waivers for compliance with these regulations may be unwise. First, both CMS and the OIG have indicated that these waivers may be narrowed in the future, potentially forcing providers who relied on these waivers to restructure their original arrangements.⁷ Additionally, ACO decision makers should note that the extension of the fraud and abuse waivers are set to expire on November 2, 2015, unless a final waiver rule (or additional extension) becomes effective on an earlier date.⁸ Owing to this uncertainty regarding the continuation of the protections provided by the waivers, ACO participants may be well served to ensure that any arrangements relying on an ACO fraud and abuse waiver to retain legal validity also receive the added protection afforded by satisfying the regulatory thresholds required under the federal healthcare fraud and abuse laws, including CR threshold, to which an ACO may become exposed should the waivers be allowed to expire.

Additionally, ACO participants and/or outside investors who invest capital in an ACO will likely expect a return on their investment. Such an arrangement between an ACO and its investors may better withstand regulatory scrutiny if the arrangement meets the thresholds of *fair market value* (FMV) and CR to avoid potential regulatory sanctions. The valuation consulting assignment that is commonly requested by legal counsel for an ACO client is the development and reporting of a certified opinion related to whether certain transactional elements involved in ACO capital formation activities, e.g., integration, affiliation, acquisition, and/or divestiture, of the various healthcare enterprises, assets, and services, meet the separate and distinct thresholds of FMV and CR.

In developing a certified opinion of FMV and CR, certain financial analyses may be required, including, e.g., the development of:

- (1) Requisite due diligence;
- (2) Economic and demographic analyses and trend reports;
- (3) Patient utilization demand forecasts;
- (4) Reimbursement yield and payor mix reports;
- (5) Forecasts, budgets, and provider income/shared savings distribution plans; and,
- (6) Financial projections and pro forma reports.

In light of recent regulatory trends and uncertainty surrounding the ongoing permissibility of the ACO waivers, including the growing willingness of the *U.S. Department of Justice* (DOJ) to target both the corporate owner of a health system but also the individual executives for corporate civil and criminal violations,⁹ a certified opinion, prepared in compliance with professional standards by an independent, credentialed valuation professional, and supported by adequate documentation that each of the proposed elements of the transaction are within the range of FMV and are *commercially reasonable*, will significantly enhance the likelihood of the ACO establishing a risk averse,

defensible position that the ACO, and its individual corporate executives, can withstand regulatory scrutiny, even in the absence of ACO waivers.

The third and final article in this three-part Health Capital Topics series will discuss the responsibilities of the board members of an ACO and participating hospitals in determining whether or not a proposed arrangement is *commercially reasonable*.

-
- 1 “Medicare Program; Final Waivers in Connection with the Shared Savings Program; Interim Final Rule” Federal Register Vol. 76, No. 212 (Nov. 2, 2011), p. 67992; “Medicare Program; Final Waivers in Connection with the Shared Savings Program; Continuation of Effectiveness and Extension of Timeline for Publication of Final Rule” Federal Register Vol. 79, No. 201 (Oct. 17, 2014), p. 62356.
 - 2 “Medicare Program; Final Waivers in Connection with the Shared Savings Program; Continuation of Effectiveness and Extension of Timeline for Publication of Final Rule,” October 17, 2014, p. 62357; “Definitions of Commercial Reasonableness and ACOs” Health Capital Topics, Vol. 8, No. 8, August 2015, p. 1.
 - 3 “Practical Guidance for Health Care Governing Boards on Compliance Oversight” Office of Inspector General et al., April 20, 2015, <http://oig.hhs.gov/compliance/compliance-guidance/docs/Practical-Guidance-for-Health-Care-Boards-on-Compliance-Oversight.pdf> (Accessed 9/10/15); “Individual Accountability for Corporate Wrongdoing” By Sally Quillian Yates, Deputy Attorney General, Letter to All United States Attorneys, September 9, 2015, p. 1.
 - 4 “Medicare Program; Final Waivers in Connection with the Shared Savings Program; Interim Final Rule,” Nov. 2, 2011, p. 67992; “Medicare Program; Final Waivers in Connection with the Shared Savings Program; Continuation of Effectiveness and Extension of Timeline for Publication of Final Rule,” Oct. 17, 2014, p. 62356.
 - 5 “Medicare Program; Final Waivers in Connection with the Shared Savings Program; Interim Final Rule,” Nov. 2, 2011, p. 68000-01.
 - 6 *Ibid.*
 - 7 *Ibid.*, p. 68008.
 - 8 “Medicare Program; Final Waivers in Connection with the Shared Savings Program; Continuation of Effectiveness and Extension of Timeline for Publication of Final Rule,” October 17, 2014, p. 62357.
 - 9 Yates, September 9, 2015, p. 2.



(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](#)

HEALTH CAPITAL CONSULTANTS (HCC) is an established, nationally recognized healthcare financial and economic consulting firm headquartered in St. Louis, Missouri, with regional personnel nationwide. Founded in 1993, HCC has served clients in over 45 states, in providing services including: valuation in all healthcare sectors; financial analysis, including the development of forecasts, budgets and income distribution plans; healthcare provider related intermediary services, including integration, affiliation, acquisition and divestiture; Certificate of Need (CON) and regulatory consulting; litigation support and expert witness services; and, industry research services for healthcare providers and their advisors. HCC's accredited professionals are supported by an experienced research and library support staff to maintain a thorough and extensive knowledge of the healthcare reimbursement, regulatory, technological and competitive environment.



Robert James Cimasi, MHA, ASA, FRICS, MCBA, CVA, CM&AA, serves as Chief Executive Officer of **HEALTH CAPITAL CONSULTANTS (HCC)**, a nationally recognized healthcare financial and economic consulting firm headquartered in St. Louis, MO, serving clients in 49 states since 1993. Mr. Cimasi has over thirty years of experience in serving clients, with a professional focus on the financial and economic aspects of healthcare service sector entities including: valuation consulting and capital formation services; healthcare industry transactions including joint ventures, mergers, acquisitions, and divestitures; litigation support & expert testimony; and, certificate-of-need and other regulatory and policy planning consulting.

Mr. Cimasi holds a Master in Health Administration from the University of Maryland, as well as several professional designations: Accredited Senior Appraiser (ASA – American Society of Appraisers); Fellow Royal Institution of Chartered Surveyors (FRICS – Royal Institution of Chartered Surveyors); Master Certified Business Appraiser (MCBA – Institute of Business Appraisers); Accredited Valuation Analyst (AVA – National Association of Certified Valuators and Analysts); and, Certified Merger & Acquisition Advisor (CM&AA – Alliance of Merger & Acquisition Advisors). He has served as an expert witness on cases in numerous courts, and has provided testimony before federal and state legislative committees. He is a nationally known speaker on healthcare industry topics, the author of several books, the latest of which include: “*Accountable Care Organizations: Value Metrics and Capital Formation*” [2013 - Taylor & Francis, a division of CRC Press], “*The Adviser’s Guide to Healthcare*” – Vols. I, II & III [2010 – AICPA], and “*The U.S. Healthcare Certificate of Need Sourcebook*” [2005 - Beard Books]; and, “*Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services*” was published by John Wiley & Sons in 2014. Mr. Cimasi is the co-author of the soon-to-be released “*Adviser’s Guide to Healthcare – 2nd Edition*” [2015 – AICPA].

Mr. Cimasi is the author of numerous additional chapters in anthologies; books, and legal treatises; published articles in peer reviewed and industry trade journals; research papers and case studies; and, is often quoted by healthcare industry press. In 2006, Mr. Cimasi was honored with the prestigious “*Shannon Pratt Award in Business Valuation*” conferred by the Institute of Business Appraisers. Mr. Cimasi serves on the Editorial Board of the Business Appraisals Practice of the Institute of Business Appraisers, of which he is a member of the College of Fellows. In 2011, he was named a Fellow of the Royal Institution of Chartered Surveyors (RICS).



Todd A. Zigrang, MBA, MHA, 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 20 years of experience providing valuation, financial, transaction and strategic advisory services nationwide in over 1,000 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 soon-to-be released “*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*. 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); 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).



John R. Chwarzinski, MSF, MAE, is Senior Vice President of **HEALTH CAPITAL CONSULTANTS (HCC)**. Mr. Chwarzinski holds a Master’s Degree in Economics from the University of Missouri – St. Louis, as well as, a Master’s Degree in Finance from the John M. Olin School of Business at Washington University in St. Louis. Mr. Chwarzinski’s areas of expertise include advanced statistical analysis, econometric modeling, as well as, economic and financial analysis.



Jonathan T. Wixom, MBA, is Vice President of **HEALTH CAPITAL CONSULTANTS (HCC)**. Mr. Wixom holds a Master of Business Administration degree from Washington University, a Bachelor of Arts in Economics from St. Louis University, and a Bachelor of Science in Business Administration from St. Louis University. Mr. Wixom’s areas of expertise include valuation consulting, financial analysis, due diligence, and financial modeling. He is a member of the St. Louis Chapter of the American Society of Appraisers, as well as a Level III Candidate in the Chartered Financial Analyst Program.



Jessica L. Bailey-Wheaton, Esq., is Senior Counsel of **HEALTH CAPITAL CONSULTANTS (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. Ms. Bailey 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*.



Kenneth J. Farris, Esq., is a Research Associate at **HEALTH CAPITAL CONSULTANTS (HCC)**, where he 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, and tracks impact of federal and state regulations on healthcare exempt organization transactions. Mr. Farris is a member of the Missouri Bar and holds a J.D. from Saint Louis University School of Law, where she served as the 2014-2015 Footnotes Managing Editor for the *Journal of Health Law & Policy*.