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

CMS to Review Stark Law Relevance Once Again

On June 25, 2018, the *Centers for Medicare & Medicaid Services* (CMS) issued a Request for Information (RFI) related to the regulatory burden of the *physician self-referral law* (known as the *Stark Law*), on both providers and the overall healthcare industry.[1] The aim of this request is to determine whether revision(s) of healthcare fraud and abuse laws is needed in order to remove any regulatory impediments to the accelerating shift toward *value-based reimbursement* (VBR) and coordinated care, and further innovation in the U.S. healthcare delivery system.

Government regulators perceive many types of healthcare business arrangements, which in other industries are often seen as typical motivations in commercial relationships, as exhibiting the potential for a significant risk of fraud. For example, referral relationships, which in other industries are lawful and exhibit the potential for increased profit, may violate federal fraud and abuse laws, such as the Stark Law, when existing between healthcare providers. However, there is an inherent conflict between fraud and abuse laws and VBR, as the pursuit of VBR and coordinated care by providers has driven the pursuit of closer relationships between hospitals (that are seeking to amass the various specialties needed to provide a full continuum of care in a cost-effective manner) and physicians (who are experiencing tightening reimbursement at the same time that they are being required to heavily invest in healthcare information technology for quality reporting purposes), through various alignment strategies, e.g., practice acquisitions, direct employment, *provider services agreements* (PSAs), co-management, and joint venture arrangements.[2]

One result of provider alignment in pursuit of VBR goals, particularly when aligning through employment arrangements with hospitals and health systems, may be that hospitals or health systems sustain *practice losses*.[3] This may be due to a number of reasons, including: (1) encountering a more adverse payor mix in a hospital setting; (2) needing to pay more competitive salaries to employed providers; and, (3) the treatment of ancillary services by the hospital or health system (i.e., treating vertically integrated physician practices as stand-alone economic enterprises, which, when stripped of their ancillary service and technical component (ASTC) revenue, and relying solely on professional services, i.e., *work relative value unit* [wRVU] related revenue, and paying physicians at FMV, are almost certain to generate "*book financial losses*").[4] Corresponding with this increased provider alignment, there has been enhanced federal, state, and local regulatory oversight regarding the legal permissibility of these arrangements.[5] Most notably, there has been more intense regulatory scrutiny related to the Anti-Kickback Statute and the Stark Law, especially as these fraud and abuse laws relate to potential liability under the *False Claims Act* (FCA).[6]

The 2018 CMS RFI specifically seeks input on the undue regulatory impact that the Stark Law has placed on VBR and coordinated care, and strategies to reduce this burden.[7] This request is part of the *U.S. Department of Health and Human Services* (HHS) initiative, *Regulatory Sprint to Coordinated Care*, which is in line with their goal to transform the U.S. healthcare industry from a *volume-based* to a *value-based* reimbursement system, with care coordination being a key aspect of this shift.[8] The list of information sought from healthcare industry stakeholders is extensive, but it includes requests on topics involving *alternative payment models* (APMs), additional exceptions to the Stark Law to facilitate innovation, changes to the current provisions of Stark Law, changes to existing compensation formulas, and exceptions necessary to protect *accountable care organizations* (ACOs) and bundled payment models.[9]

On July 17, 2018, the House Committee on Ways and Means hosted a hearing to gain insight from relevant stakeholders on modernizing the Stark Law to ensure a successful transition from *volume* to *value*-based Medicare reimbursement.[10] Of note, HHS Deputy Secretary, Eric Hagan, emphasized during the hearing the agency's interest in regulatory reforms for *both* Stark Law and the *Anti-Kickback Statute* (AKS); Hagan stated both laws could be stifling innovative arrangements, and thus, hindering better patient outcomes.[11] To address this, HHS plans to issue a separate RFI on AKS reforms imminently.[12]

The hearing also made apparent that HHS plans to make these modifications to Stark Law administratively (i.e., not through Congress), which it will seek to accomplish by creating a proposal to address the comments that CMS receives and other efforts to streamline coordination of care.[13] Also, as discernable from the comments of the panel of healthcare professionals, the Stark Law acts as a barrier to innovation, specifically in implementing APMs; the professionals note their desire to have the

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fraud and abuse waivers enjoyed by ACOs (which are a type of APM) be extended to all APMs.[14] Regarding the panelists' comments, panelist Michael Lappin, Chief Integration Officer for Advocate Aurora Health, stated his desire to have Congress involved in any reforms, specifically to define key terms such as *Fair Market Value* and other terms that would offer physicians bright-line guidance to ensure proper compliance.[15] However, panelist Claire Sylvia, a healthcare attorney, advised lawmakers to proceed with caution, because paying for value and/or coordinated care does not completely eliminate the financial motive for physicians to "*overlook*" a patient's best interests.[16] Ms. Sylvia's concern is in line with that of Representative Sander Levin (D-MI9), who argued that this move to VBR may potentially weaken "*important tools for protecting Medicare beneficiaries from inappropriate referrals and overutilization of care*."[17]

This is not the first time that Congress has sought information regarding the inherent conflict between the shift toward VBR and the enforcement of the Stark Law. In December 2015,[18] the U.S. Senate Finance Committee, along with the House Committee on Ways and Means, invited federal prosecutors, former CMS officials, and healthcare attorneys to take part in a roundtable discussion regarding significant potential changes to the Stark Law.[19] These participants were asked to identify two main issues: "*(1) changes to the Stark Law to implement health care reform, specifically [the Medicare Access and CHIP Reauthorization Act of 2015] MACRA, and (2) the distinction between technical and substantive violations*."[20] Beyond these two main categories, the comments received by the Finance Committee addressed other "*non-MACRA*" issues; most notable among these topics were changes to Stark Law definitions, such as *fair market value*, taking into account the volume or value of referrals, and *commercial reasonableness*.[21] On June 30, 2016, the Committee published a white paper recapping the meeting, which included discussions of the two issues specifically identified by the Finance Committee, as well as the other "*non-MACRA*" issues identified by the roundtable participants and outside commenters.[22]

In addition to the white paper, in July 2016, the Committee listened to testimony from healthcare attorneys and hospital executives suggesting desired changes to the Stark Law.[23] Similar to the December 2015 roundtable discussion, the hearing offered industry stakeholders an opportunity to:

> "*[G]ive members of the Committee the opportunity to hear how the Stark Law works in practice for today's healthcare providers and what reforms are needed to streamline the law to make it work for providers, patients and taxpayers*."[24]

At the end of the July 2016 hearing, Senator Orrin Hatch (R-UT), chairman of the Committee, noted that the Committee would "*try to do something about this before the end of the year*,"[25] but nothing ever came of the hearings.

This 2018 CMS RFI and hearing could be an important opportunity for providers and the healthcare industry to again express their experiences and challenges with the Stark Law to CMS, and has the potential to shape how the Stark Law (as well as the Anti-Kickback Statute) is implemented in the future.[26] As CMS Administrator, Seema Verma, stated, "*We are looking for information and bold ideas on how to change the existing regulations to reduce provider burden and put patients in the driver's seat*."[27] The public examinations into the scope and utility of the Stark Law over the past few years demonstrate an increased focus on reforming this regulatory scheme in light of the healthcare industry's continued transition from *volume* to *value*.[28] With the Stark Law not only serving as a significant driver of spending of healthcare compliance, but also as a potential impediment to the implementation of VBR strategies such as APMs,[29] many industry stakeholders have urged for some type of modification to this scheme.[30]

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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 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).

John R. Chwarzinski, MSF, MAE, is Senior Vice President of **HEALTH CAPITAL CONSULTANTS** (HCC). Mr. Chwarzinski's areas of expertise include advanced statistical analysis, econometric modeling, as well as, economic and financial analysis. Mr. Chwarzinski is the co-author of peer-reviewed and industry articles published in *Business Valuation Review* and *NACVA QuickRead*, and he has spoken before the Virginia Medical Group Management Association (VMGMA) and the Midwest Accountable Care Organization Expo. 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. He is a member of the St. Louis Chapter of the American Society of Appraisers, as well as a candidate for the Accredited Senior Appraiser designation from the American Society of Appraisers.

Jessica L. Bailey-Wheaton, Esq., is Vice President and General 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-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, is a Senior Financial Analyst at **HEALTH CAPITAL CONSULTANTS** (HCC), where he develops fair market value and commercial reasonableness opinions related to healthcare enterprises, assets, and services. In addition, Mr. Chen 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, as well as ancillary services and technical component (ASTC) revenue streams. Mr. Chen has a Master of Science in Finance from Washington University St. Louis.