

Stark Law Reform Debated by Senate Committee

During the summer of 2016, the *U.S. Senate Finance Committee* (Committee) has debated changing the standard of *fair market value* and the threshold of *commercial reasonableness* as part of a larger discussion of potential modifications to the Stark Law. Through releasing a whitepaper and administering a committee hearing on the issue, certain members of the Senate have publicized their intention to explore the efficacy and composition of the Stark Law, particularly in light of the impending implementation of the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA).¹ Ranging from complete repeal of the Stark Law, to the creation and/or expansion of waivers and exceptions to the law, the suggested changes discussed by the Senate may have a significant impact on regulatory compliance efforts by healthcare organizations.² Due to the prominent role held by valuation professionals to determine *fair market value* and *commercial reasonableness* for many arrangements within the healthcare industry,³ changes to these thresholds may have a noteworthy impact on the work of these experts. This *Health Capital Topics* article will discuss the suggested changes to the Stark Law highlighted by the Committee, as well as examine the significance of the Committee’s interest in changing the law and the implications that these potentially major changes may have on industry stakeholders, including valuation professionals.

The Committee’s public discussion of potential modifications to the Stark Law reflects a months-long initial deliberation on this important topic in healthcare operations. On December 10, 2015,⁴ the Committee, along with the House Committee on Ways and Means, invited federal prosecutors, former officials from the *Centers for Medicare and Medicaid Services* (CMS), and health law attorneys to take part in a round table discussion regarding major changes related to the Stark Law.⁵ These participants were asked to identify two main issues: “(1) changes to the Stark Law to implement health care reform, specifically MACRA, and (2) the distinction between technical and substantive violations.”⁶ However, beyond these two main categories, the comments received by the Committee addressed other “non-MACRA” issues; most notable among these topics are changes to Stark Law definitions, such as *fair market value*, taking into account the volume or value of

referrals, and *commercial reasonableness*.⁷ On June 30, 2016, the Committee published a white paper recapping the meeting, which included discussions of the two issues specifically identified by the Committee, as well as other “non-MACRA” issues identified by the round table participants and outside commenters.⁸ In addition to the whitepaper, on July 12, 2016, the Committee listened to testimony from healthcare attorneys and hospital executives suggesting desired changes to the Stark Law.⁹ Similar to the December 2015 round table 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.”¹⁰

Within this discussion, commenters recommended further clarification of three key terms in Stark Law compensation arrangement exceptions:

- (1) “Fair Market Value”;
- (2) “[T]akes into account’ the ‘volume or value’ of referrals;” and,
- (3) “[C]ommercially reasonable.”¹¹

According to the Committee whitepaper discussing the hearing, many commenters felt that any changes to the Stark Law should address these three key terms.¹²

In regards to *fair market value*, commenters addressed “concerns about the difficulty of establishing and documenting FMV.”¹³ In his submitted testimony, Peter B. Mancino, Esq., Deputy General Counsel for The Johns Hopkins Health System Corporation, testified that even though he has over twenty years of experience as a health law attorney, “no matter how much time, money or effort is expended in analyzing the issues, I have often had the unpleasant duty of informing a client that there are no clear or 100% safe answers.”¹⁴ Mr. Mancino argued that the ambiguities surrounding *fair market value* run contrary to the goal of the Stark Law upon its passage, which he states “was to create a bright line test to address the overutilization of health care services resulting from inappropriate physician referrals.”¹⁵ Additionally, the Committee received testimony arguing that the statutory definition of *fair market value*¹⁶ does not require

consideration of the “*volume or value*” of referrals between the parties, and that CMS added the standard to this definition.¹⁷

Commenters and the Committee also noted concerns regarding the definition of “*commercial reasonableness*” and recommended certain clarifications and alterations to the term. In his submitted testimony to the Committee, Troy A. Barsky, Esq., a noted private healthcare attorney who previously served as the Director of the Division of Technical Payment Policy at CMS for four of his eleven years at working at the U.S. Department of Health and Human Services (HHS), testified that Congress should amend the Stark Law to specifically define *commercial reasonableness*, stating:

“While a number of important exceptions have a requirement that the arrangement be commercially reasonable without taking into account Medicare referrals, the term ‘commercial reasonableness’ is not clearly defined anywhere. Under current law, there is confusion over whether a hospital’s subsidy of a physician’s practice is commercially reasonable even where the physician’s compensation is in the range of FMV. I recommend either that this standard be removed completely or that the statute be amended to add a definition of commercial reasonableness e.g., that the items or services are of the kind and type of items or services purchased or contracted for by similarly situated entities and are used in the purchaser’s business, regardless of whether the purchased items or services are profitable on a standalone basis.”¹⁸ [Emphasis Added]

The Committee echoed Mr. Barsky’s statement regarding the profitability of “*purchased items or services*” by an entity providing “*designated health services*” (DHS) (a requirement for applicability of the Stark Law), noting other commenters suggested Congress “*clarify that operating losses in DHS entity-owned physician practices are not commercially unreasonable.*”¹⁹ As discussed in a June 2016 *Health Capital Topics* article, entitled “*Practice Loss Postulate (PLP) Regulatory Trend Misapplies Economic Theory to Healthcare*

Integration,” government regulators have challenged certain vertical integration transactions on the premise that the acquisition of a physician practice, which then operates at a “*book financial loss,*” is, in and of itself, dispositive evidence of the hospital’s payment of consideration based on the volume and/or value of referrals.²⁰

At the end of the July 12, 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;*”²¹ however, the totality of the changes that will be made to the Stark Law remains to be seen, if any at all.²² Nevertheless, the recent public examinations into the scope and utility of the Stark Law by members of the U.S. Senate demonstrates an increased focus into reforming this regulatory scheme in light of the healthcare industry’s continued transition from volume to value-based reimbursement.²³ 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 *alternative payment methods* (APM),²⁴ many industry stakeholders are urging some type of modification to this scheme.²⁵

These modifications may have a significant impact on the work of valuation professionals providing a certified opinion that each of the proposed elements of a healthcare transaction are within the range of *fair market value* and are *commercially reasonable*. For example, changes regarding the definition of *fair market value* under the Stark Law may impact the *standard of value* employed in the valuation opinion of a healthcare enterprise, asset, or service, at a time of increasing government scrutiny regarding this standard. Additionally, changes to the definition of *commercial reasonableness* may provide further clarity to this threshold, particularly if recommendations regarding the profitability of vertically integrated physician practices are finalized. Healthcare industry stakeholders and valuation professionals may find it prudent to monitor deliberations closely in the coming months in order to best prepare for potential changes, in whatever form those changes are finalized.

1 “Health Care Delivery Reform: Senate Committee on Finance Holds Hearings on Stark Law” By Stuart Silverman, The National Law Review, July 14, 2016, <http://www.natlawreview.com/article/health-care-delivery-reform-senate-committee-on-finance-holds-hearings-stark-law> (Accessed 7/20/2016), p. 1.

2 “Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models” By Chairman Orrin Hatch (R-Utah), Senate Committee on Finance, June 30, 2016, p. 3-4; “Senate Finance Hearing To Focus Stark Self-Referral Law Exceptions” By Sue Darcey, Medtech Insight, July 7, 2016, <https://medtech.pharmamedtechbi.com/MT038419/Senate-Finance-Hearing-To-Focus-Stark-SelfReferral-Law-Exceptions> (Accessed 7/18/2016).

3 “Healthcare Valuation: The Financial Appraisal of Enterprises, Assets, and Services” By Robert James Cimasi, MHA, ASA,

FRICS, MCBA, AVA, CM&AA, Hoboken, New Jersey: John Wiley & Sons, Inc., 2014, p. 927.

4 Senate Committee on Finance, “Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models,” June 30, 2016, p. 1.

5 *Ibid.*; “This Week in Washington: Brought to You by Hall Render” Hall, Render, Killian, Heath, and Lyman, December 11, 2015, <http://www.hallrender.com/resources/article/2407/> (Accessed 7/21/16).

6 Senate Committee on Finance, “Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models,” June 30, 2016, p. 3.

7 *Ibid.*

8 *Ibid.*, p. 4-7; “Roundtable Discussion Results in Senate Committee White Paper on Stark Law Reform” By Amanda Enyeart, et al., McDermott Will & Emery, July 13, 2016,

<https://www.mwe.com/en/thought-leadership/publications/2016/07/senate-committee-white-paper-on-stark-law-reform> (Accessed 7/18/2016).

- 9 "Hatch to Hold Finance Hearing on Stark Law" By Aaron Forbes and Julia Lawless, United States Senate Committee on Finance, July 5, 2016, <http://www.finance.senate.gov/chairmans-news/hatch-to-hold-finance-hearing-on-stark-law> (Accessed 7/18/2016).
- 10 *Ibid.*
- 11 Senate Committee on Finance, "Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models," June 30, 2016, p. 15.
- 12 *Ibid.*
- 13 *Ibid.*
- 14 "Testimony for the Record Submitted to the United States Senate Committee on Finance for the Hearing Entitled 'Examining the Stark Law: Current Issues and Opportunities'" By Peter B. Mancino, Esq., The Johns Hopkins Health System Corporation, July 12, 2016, <http://www.finance.senate.gov/imo/media/doc/12jul2016Mancino.pdf> (Accessed 8/24/16) p. 2.
- 15 *Ibid.*
- 16 Under the Stark Law, "fair market value" is defined as: "the value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes (not taking into account its intended use) and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee."
"Limitation on Certain Physician Referrals" 42 U.S.C. § 1395nn(h)(3) (2014).
- 17 Senate Committee on Finance, "Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models," June 30, 2016, p. 15.
- 18 "Testimony Before the Committee on Finance" Troy A. Barsky, Esq., Crowell & Moring LLP, July 12, 2016, <http://www.finance.senate.gov/imo/media/doc/12jul2016Barsky.pdf> (Accessed 7/20/2016).
- 19 Senate Committee on Finance, "Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models," June 30, 2016, p. 16.
- 20 "United States ex rel. Drakeford v. Tuomey Healthcare System, Inc." 675 F.3d 394, 407 (4th Cir. 2012); "United States ex rel.

- Parikh v. Citizens Medical Center" Case No. 6:10-cv-00064, (S.D. TX. September 20, 2013), Memorandum and Order, p. 27-28; "United States ex rel. Reilly v. North Broward Hospital District, et al.," Case No. 10-60590-CV (S.D.Fla. September 11, 2012), Relator's Third Amended Complaint Under Federal False Claims Act, p. 31; "United States ex rel. Payne et al. v. Adventist Health System et al.," Case No. 3:12cv856-W (W.D.N.C. February 13, 2013), Relator's Amended Complaint, p. 56; "Health System Practice 'Losses' Make Headlines, Plaintiffs Make New Stark 'Law'" By Eric B. Gordon and Daniel H. Melvin, BNA's Health Care Fraud Report, Bloomberg BNA, November 25, 2015, <http://www.mwe.com/files/Publication/a1a5d17c-3c79-4380-baef-0d11822334a1/Presentation/PublicationAttachment/5bb1e6ca-6491-4907-9a57-1049c2f3ecec6/Gordan-Melvin.pdf> (Accessed 12/15/15).
- 21 Hearing entitled "Examining the Stark Law: Current Issues and Opportunities" Mr. Hatch makes statement at 1:34:31, located at <http://www.finance.senate.gov/hearings/examining-the-stark-law-current-issues-and-opportunities> (Accessed 7/19/2016).
- 22 *Ibid.*
- 23 "Senate Finance Committee Publishes Report on Stark Law Reform – Are Changes to the Stark Law on the Way?" By William D. Ezzell, Polsinelli, July 7, 2016, <http://www.polsinellifca.com/blog/2016/7/7/senate-finance-committee-publishes-report-on-stark-law-reform-are-changes-to-the-stark-law-on-the-way> (Accessed 7/19/2016).
- 24 Barsky, July 12, 2016, p. 2; "Senate Finance Committee Examines Repeal of the Stark Law" By Albert W. Shay and Kathleen McDermott, The National Law Review, July 6, 2016, <http://www.natlawreview.com/article/senate-finance-committee-examines-repeal-stark-law> (Accessed 7/20/2016); Enyeart, et al., July 13, 2016.
- 25 "Health systems urge Senate to revamp or repeal Stark Law" By Virgil Dickson, Modern Healthcare, July 12, 2016, <http://www.modernhealthcare.com/article/20160712/NEWS/160719972/health-systems-urge-senate-to-revamp-or-repeal-stark-law> (Accessed 7/20/2016); "Statement of the American Hospital Association before the Committee on Finance of the United States Senate" American Hospital Association, July 12, 2016, <http://www.aha.org/advocacy-issues/testimony/2016/160712-statement-stark.pdf> (Accessed 7/20/2016); "Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them" American Hospital Association, July 5, 2016, <http://www.aha.org/content/16/barriertocare-full.pdf> (Accessed 7/20/2016).

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