

**Completely Unreasonable: The “Practice Losses” Theory
as a Basis for Stark Violations in the Era of
Value-Based Reimbursement**

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I. ABSTRACT

With the passage of the Affordable Care Act and the Medicare Access and CHIP Reauthorization Act, the U.S. government has signaled a policy shift towards value-based physician reimbursement. To infuse more value into the provision of health care services, providers will need to consider various alignment strategies, such as whether to enter into employment arrangements with hospitals or health systems. While employment arrangements add clinical integration between the employed entity and a hospital or health system, the hospital or health system typically incurs substantial and continuing losses on the employment arrangement. However, the Stark Law's employment exception, with its requirement that the employment arrangement's compensation terms be of fair market value and commercially reasonable, have called these types of arrangements into question. Recent Stark enforcement actions have suggested that the presence of practice losses could amount to a Stark violation, as the presence of substantial practice losses could amount to the arrangement being deemed commercially unreasonable. This interpretation of commercial reasonableness within the context of Stark presents significant barriers to the complete transformation to value-based reimbursement from fee-for-service reimbursement. Without significant and fundamental changes to the Stark Law, both in terms of requirements of the statute as well as how the statute is enforced by government officials and *qui tam* relators, the transformation from a fee-for-service reimbursement to one of value-based reimbursement will falter, leaving the U.S. health care system as one of the most costly and inaccessible health care systems in the world.

II. INTRODUCTION

The Patient Protection and Affordable Care Act of 2009 ("ACA") was enacted with the hopes of achieving three goals: "[improve] the individual experience of care, [improve] the health of populations, and [reduce] the per capita costs of care for populations."¹ Before the passage of the ACA, most physicians were paid on a volume basis, i.e., the physician's compensation was tied to how many procedures he or she performed.² Because there was no independent evaluation as to whether the performed procedures were in the best interests of that particular patient, fee-for-service reimbursement is believed to have significantly contributed to a culture wherein physicians provided services with no real consideration of the cost or the value those services provided to the patient. In fact, because the physician's compensation was tied to the number of procedures the physician performed, this reimbursement environment led to some doctors recommending their patients undergo nonessential procedures. While the physician

¹ Donald Berwick, Thomas Nola & John Whittington, *The Triple Aim: Care, Health, and Costs*, 27 HEALTH AFF. 760, 760 (2008).

² Julie Barnes, *Moving Away From Fee-For-Service*, THE ATLANTIC, (May 7, 2012), <http://www.theatlantic.com/health/archive/2012/05/moving-away-from-fee-for-service/256755/>.

received more compensation, these additional procedures allegedly inflicted further pain and even resulted in the deaths of some patients.³

As a result of fee-for-service reimbursement, the cost of health care increased, which resulted in fewer individuals having the ability to pay for health care services. The increased costs for health care services led to the overall reduction of access to such services in the U.S. when compared to other western European countries.^{4, 5} Perhaps the worst consequence of a strictly fee-for-service reimbursement model was that it did not provide Americans with better health care: the United States consistently performed worse than most other developed countries in the areas of preventable deaths and life expectancy.⁶ Because of these concerns, legislators and other policy makers began to look for alternative methods to reimburse physicians.

After many failed attempts by the U.S. government, health reform was realized with the passage of the ACA. While many provisions of the law sought to increase access to health insurance, the law also ushered in the era of value-based reimbursement. Instead of compensating providers based on the number of procedures performed, value-based reimbursement examines the cost and effectiveness of treatment provided to a patient by his or her physician. Under value-based reimbursement, providers receive more compensation if they provide more positive health outcomes at the lowest possible price (value).

One payment reform created by the ACA was the implementation of accountable care organizations (“ACO”).⁷ “An ACO is a network of doctors and hospitals that share financial and medical responsibilities for providing coordinated care to patients in hopes of limiting unnecessary spending.”⁸ “These groups (ACOs) are intended to allow doctors to better coordinate patient care and improve the quality, help prevent disease and illness and reduce unnecessary hospital admissions.”⁹

Providers within the ACO accomplish the goal of providing more value to their patients by referring their patients to other providers within the ACO.¹⁰ If providers within the ACO meet

³ The Editorial Board, *Fee-for-service rewards volume: Our view*, USA TODAY, (6:04 PM EDT July 7, 2013), <http://www.usatoday.com/story/opinion/2013/07/07/fee-for-service-unnecessary-surgeries-editorials-debates/2497213/>.

⁴ Due to not being able to pay for high-priced healthcare services, access to healthcare is limited for those that do not have health insurance. “In the U.S., costs for office visits, lab tests, medical procedures, hospital stays, and prescription drugs are often much higher than in other countries. For example, the average cost for a day in a U.S. hospital is \$4,287; in France, its \$853. The total price for a normal birth is nearly \$10,000 in the U.S.; in the United Kingdom, its \$2,641.” *Better Care at Lower Cost: Is it Possible*, THE COMMONWEALTH FUND, (last visited August 12, 2016), <http://www.commonwealthfund.org/publications/health-reform-and-you/better-care-at-lower-cost>.

⁵ Some estimate that approximately \$750 billion is wasted each year on medical expenditures. Brian Fung, *How the U.S. Health-Care System Wastes \$750 Billion Annually*, THE ATLANTIC, (September 7, 2012), <http://www.theatlantic.com/health/archive/2012/09/how-the-us-health-care-system-wastes-750-billion-annually/262106/>.

⁶ *Id.*

⁷ See Patient Protection and Affordable Care Act of 2009, 111 Pub. L. 148, § 3022, 124 Stat 119 (2009).

⁸ Jenny Gold, *Accountable Care Organizations, Explained*, KAISER HEALTH NEWS, (September 14, 2015), <http://khn.org/news/aco-accountable-care-organization-faq/>

⁹ *Key Features of the Affordable Care Act by Year*, U.S. DEP’T HEALTH HUM. SERV., (August 12, 2016) <http://www.hhs.gov/healthcare/facts-and-features/key-features-of-aca-by-year/index.html#>.

¹⁰ Gold, *supra* note 8.

certain cost and quality of care benchmarks, they receive additional compensation from the Centers for Medicare and Medicaid Services (“CMS”), the governmental arm responsible for administering the Medicare program.¹¹ Failure to adequately reduce costs could require the ACO to pay a penalty to CMS.¹² To achieve savings, the providers within the network must work together to coordinate a patient’s care by sharing patient information, avoiding unnecessary tests and procedures and working as a team in treating the patient’s illness.¹³

Other reforms included within the ACA are the Value-Based Purchasing Program, which sought to link Medicare payments to quality patient outcomes,¹⁴ and the creation of the Bundled Care Payment Initiative.¹⁵ “Under payment ‘bundling,’ hospitals, doctors, and providers are paid a flat rate for an episode of care rather than the current fragmented system where each service or test or bundles of items or services are billed separately to Medicare.”^{16, 17} Bundled payments help to control the cost of care as providers and health systems receive a flat payment for an illness (such as a total knee replacement or a hip replacement) regardless of the amount of procedures performed or the length of the patient’s stay in a facility. By reducing the annual increases to Medicare’s Physician Fee Schedule, and by factoring in quality and cost of a patient’s care into the physician’s Medicare Part B payments, the Medicare Access and CHIP Reauthorization Act of 2015 (“MACRA”) furthered the move towards value-based reimbursement.^{18, 19}

With the ACA’s emphasis on value-based payments, the need to define and quantify “value” became apparent. Value in the health care arena is defined as “health outcomes achieved per dollar spent.”²⁰ In other words, value in health care focuses on the intersection between the highest quality results for the lowest possible price. Value-based reimbursement aligns the interests of many different types of providers in hopes of achieving the ultimate goal of providing positive health outcomes for patients.^{21, 22}

¹¹ *Id.*

¹² *Id.*

¹³ *Id.*

¹⁴ *Key Features of the Affordable Care Act by Year, supra note 9.*

¹⁵ Patient Protection and Affordable Care Act § 2704, *supra note 7.*

¹⁶ *Key Features of the Affordable Care Act by Year, supra note 9.*

¹⁷ The Bundled Payment Care Initiative has four tracks. In Model 1, “Medicare pays the hospital a discounted amount based on the payment rates established under the Inpatient Prospective Payment System. Medicare continues to pay physicians separately for their services under the Medicare Physician Fee Schedule. Models 2 and 3 entail an arrangement “where actual expenditures are reconciled against a target price for an episode of care.” “In Model 4, CMS makes a single, prospectively determined bundled payment to the hospital that encompasses all services furnished by the hospital, physicians, and other practitioners during the episode of care, which lasts the entire inpatient stay.” *Bundled Payments for Care Improvement (BCPI) Initiative: General Information*, CTRS. MEDICARE & MEDICAID SERV., (last accessed August 12, 2016), <https://innovation.cms.gov/initiatives/bundled-payments/>.

¹⁸ *Medicare Access and CHIP Reauthorization Act of 2015: What You Need to Know*, AM. C. OF CARDIOLOGY, (April 28, 2015), <https://www.acc.org/latest-in-cardiology/articles/2015/04/28/15/59/medicare-access-and-chip-reauthorization-act-of-2015-what-you-need-to-know>.

¹⁹ While providers who participate in an ACO or a bundled payment program still bill on a fee-for-service basis, these methods of payment are considered value-based payments since both models take into account quality and cost reduction measures when determining final payment. *See generally infra note 20.*

²⁰ Michael Porter, *What is Value in Health Care?*, 363 *NEW ENG. J. MED.* 2477, 2477 (2010); PORTER ME, TESIBERG EO, *Redefining health care: creating value-based competition on results* (HARV. BUS. SCH. PRESS, 2006).

²¹ *What is Value in Health Care, supra note 20.*

To ensure that a provider's care provides the most value to their patients, the spectrum of providers involved in a patient's treatment must take responsibility for the care they provide (by striving to provide the patient with positive health outcomes at the lowest possible price).²³ For this reason, coordination of care becomes necessary. To coordinate a patient's plan of treatment, physicians must align with one another and work together as a team during the patient's treatment in a manner that reduces costs while providing the most effective treatment possible. To coordinate and provide this team-based approach to health care services, providers can align to form ACOs, clinically integrated networks ("CIN")²⁴, professional services agreements ("PSA")²⁵, as well as enter into employment arrangements with hospitals and health systems.²⁶

As stated above, the goal of these alignment vehicles is to facilitate team-based care for the patient instead of acting as independent entities that are only responsible for one part of a patient's care. Even though the government has signaled a preference to shift to value-based reimbursement, as explained in the remainder of this thesis, the Stark law²⁷ presents significant hurdles to this transformation.

From 2009 – 2015, the Department of Justice recovered \$16.5 billion as a result of settlements and judgments arising from health care fraud litigation.²⁸ One of the most frequently used tools for healthcare fraud enforcement is the Physician Self-Referral Law ("Stark" and/or "Stark Law"). Stark prohibits physician referrals for designated healthcare services²⁹ to organizations to which that provider has a qualified financial relationship.³⁰ Because the text of the Stark Law

²² "Care for a medical condition for a patient population usually involves multiple specialties and numerous interventions." *Id.* at 2478.

²³ *Id.*

²⁴ The Federal Trade Commission has defined a clinically integrated network as a "provider network [that] implements an active and ongoing program to evaluate and modify practice patterns by the network's physician participants and create[s] a high degree of interdependence and cooperation among the physicians to control costs and ensure quality." U.S. Fed. Trade Commission, NORMAN PHO ADVISORY OPINION (Feb. 13, 2013) (regarding whether Norman's PHO violates antitrust laws).

²⁵ A PSA is "a formal contract between a hospital and a physician or group of physicians to render professional services at a location or number of locations operated by the hospital. In a PSA, the physician is considered an independent contractor and not a W-2 employee." *Professional Services Agreements Primer*, HEALTHCARE STRATEGY GROUP, (last accessed August 12, 2016), <http://www.healthcarestrategygroup.com/client-services/independent-physician-alignment-services/professional-services-agreements/professional-services-agreements-primer/>

²⁶ An acquisition of a practice group could also be considered a merger between the purchasing organization, typically a hospital or health system, and the physician group. Marti Cox, MLIS, *Physician-hospital alignment models: An evolving lexicon*, MED. GROUP MGM'T ASS'N, (April 4, 2016), <http://www.mgma.com/practice-resources/mgma-connection-plus/online-only/2016/april/physician-hospital-alignment-models-an-evolving-lexicon>.

²⁷ 42 U.S.C.S. § 1395nn (LEXIS through P.L. 144-165).

²⁸ *Justice Department Recovers Over \$3.5 Billion from False Claims Act Cases in Fiscal Year 2015*, U.S. DEP'T JUST., (Thursday, December 3, 2015), <https://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015>.

²⁹ Designated health care services include "clinical laboratory services; physical therapy services; occupational therapy services; outpatient speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services." § 1395nn(h)(6) (LEXIS).

³⁰ *Id.* at § 1395nn(a)(1)(a-b) (LEXIS).

would prohibit nearly every sort of financial transaction by a health system or hospital, Congress created several exceptions for a variety of transactions that do not violate Stark, including the exception for the bona fide employment of physicians, provided the arrangement meets a number of requirements.^{31, 32}

As stated above, providing value in health care often means aligning various providers to ensure that a patient's care is integrated. Such alignment arrangements, particularly employment arrangements between a health system and a physician or physician practice, often result in the health system needing to contract with the employed provider at a loss ("practice losses"). This is due to the significant costs incurred by the health system when entering into employment arrangements, such as increased overhead, human resources, billing, legal expenses, as well the employed entity providing care for a more adverse payer mix of patients than was experienced in private practice. Numerous recent cases and settlements have called into question the legality of these particular types of arrangements due to sustained "practice losses."

Most significantly, following, and no doubt in reaction to the 2015 Fourth Circuit Court of Appeals decision of *U.S. ex. rel. Drakeford v. Tuomey*, 732 F.3d 364, 395 (4th Cir. 2015), numerous health care organizations have tended to settle Stark allegations based primarily on the fact that the physician contracts at issue resulted in practice losses to the contracting organization.³³ The *Tuomey* court upheld the jury's verdict that Tuomey Healthcare System violated Stark Law due in part to the conclusion that its physician compensation contracts failed to meet the "commercially reasonable" requirement of the bona fide employment exception, based on the fact that Tuomey was losing money on their employed physician contracts.^{34, 35} "The government estimated that Tuomey was losing \$1 to \$2 million per year based on the amount it was paying the physicians more than the revenue generated from their personal services. At trial, the government argued that no hospital would enter into such an arrangement unless it were [doing so] to secure the revenue stream based on referrals [from the employed provider]," an alleged arrangement that Stark prohibits³⁶

Some legal commentators believe that the government's pursuit of Dr. Drakeford's³⁷ allegation that Tuomey's compensation arrangements were commercially unreasonable based solely on the practice losses has encouraged other *qui tam* relators³⁸ to pursue alleged Stark violations - and

³¹ *Id.* at § 1395nn(e)(2) (LEXIS); see Exceptions to the referral prohibition related to compensation arrangements, 42 C.R.R. § 411.357(c) (2016); See Exceptions, 42 C.F.R. § 1001.952(d) (2016).

³² However, to fit within an exception, an arrangement or agreement must meet each and every requirement of the exception. Failure to meet each part of an exception results in a Stark Law violation.

³³ Gary McRay, *Is Losing Money by Employing Physicians a Stark Violation?*, FOSTER SWIFT COLLINGS & SMITH, (March 8, 2016), <http://www.healthlawyersblog.com/losing-money-employing-physicians-stark>.

³⁴ *U.S. ex. rel. Drakeford v. Tuomey*, 732 F.3d 364, 395 (4th Cir. 2015).

³⁵ McRay, *supra* note 33.

³⁶ *Id.*

³⁷ Dr. Drakeford alerted the Department of Justice to Tuomey's potential Stark and False Claims Act violations by filing a *qui tam* lawsuit against Tuomey.

³⁸ Because a Stark violation is considered an unlawful and false claim, False Claims Act infringements are typically alleged concurrently with any Stark Law allegations. Because the False Claims Act permits private citizens to prosecute allegations in place of the government, Stark cases are often initiated by private citizens, known as *qui tam* relators, who are later entitled to a portion of any recovered damages. See 31 U.S.C.S. § 3730(b) (LEXIS current through P.L. 114-195).

that such claims are incompatible with the emerging value-based reimbursement environment.³⁹ “At a very basic level, this theory [that practice losses equate to a commercially unreasonable compensation arrangement] is destructive [sic] with health-care policy, and with the accepted practice of the vast majority of integrated delivery systems.”⁴⁰ Further, the “practice losses” theory poses significant compliance problems for those organizations seeking to align with other health care providers as a method of achieving more value and meeting the articulated goals of the ACA and MACRA. Without significant legislative and regulatory reforms to the Stark Law, both in what Stark allows and how the government enforces Stark, the U.S. healthcare system will fail in its attempted transformation towards value-based reimbursement and will ultimately remain the most expensive, inaccessible, and ineffective health care delivery system in the world.

One solution to this problem would be to adopt regulations similar to that employed by the Internal Revenue Service when analyzing whether an excess benefit transaction occurred in a non-profit organization. This rule as applied to the Stark Law would establish a rebuttable presumption that an arrangement is commercially reasonable and of fair market value if (1) the organization's governing body approves the employment agreement (and its compensation terms) between the physician/private practice and the hospital or health system; (2) the organization has sufficient documentation supporting the agreement's fair market value and commercial reasonableness from an independent party; and (3) the governing body documents the process for approving the transaction.⁴¹ This presumption would give providers on all levels the needed clarity about which arrangements are of fair market value and commercially reasonable.

Another solution would be to change the intent standard for Stark violations from that of strict liability to that of willful and intentional, as is required for Anti-Kickback Statute violations.⁴² Increasing the intent standard to that of “willful”⁴³ would conserve government resources by requiring that government and *qui tam* relators would only be able to prosecute willful violators instead of those organizations attempting to provide more value to their patients while incidentally violating Stark.

First, to understand how the U.S. healthcare system arrived at this problem, this paper will examine the fee-for-service reimbursement system and the impact it has had on those seeking healthcare treatment in the United States. Next, this article will detail the move from fee-for-service payments to that of value-based reimbursements, as well as explain some of the critical physician reimbursement provisions of the ACA and MACRA. Third, this article will examine

³⁹ Michael W. Peregrine, *The ‘Practice Losses’ Theory as an Enterprise List*, BNA INSIGHTS: HEALTH LAW RESOURCE CENTER ISSN 2160-8547, (December 9, 2015).

⁴⁰ *Id.*

⁴¹ *Cf.* Rebuttable presumption that a transaction is not an excess benefit transaction, 26 C.F.R. § 53.4958-6(c) (2016).

⁴² “Whoever knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program...shall be guilty of a felony and upon conviction thereof fined not more than \$25,000 or imprisoned not more than five years or both [emphasis added].” 42 U.S.C.S. § 1320(a)-7b(a)(1),(i) (LEXIS current through P.L. 114-195).

⁴³ Willful misconduct is defined as “Deliberate disobedience of the law, inclusive of acts of omission as well as acts of commission. The intentional doing, or omitting to do something, either with the knowledge that such act or omission is likely to result in harm or with a wanton and reckless disregard of the consequences.” *Wilful misconduct*, BALLENTINE’S LAW DICTIONARY (LEXIS 2010), citing *Gulf, M. & O. R. Co. v. Freund*, 183 F.2d 1005 (8th. Cir. 1950), cert. denied, 340 U.S. 904, 71 S.Ct. 280, 95 L. Ed. 654 (1950).

how health care providers can provide value, and what alignment arrangements are necessary to transform a physician reimbursement scheme from one that is based on volume to one that is based on the value provided to patients. Within this factual context, this paper will examine the Stark Law, the restrictions it places on various alignment arrangements and recent health care fraud settlements and judgments that cast doubt on the legality of different alignment methods based primarily on the fact that the arrangement resulted in practice losses for the health system. Finally, this article will recommend changes to the Stark Law that will allow healthcare organizations to transform from volume-based reimbursement to that of value-based reimbursement.

III. FEE-FOR-SERVICE AND THE PROBLEMS IT PRESENTS

A. History of Health Insurance

Beginning in the 1920s and continuing to the present day, the United States government has constantly examined the cost of medical care and how this care can be accessed by the populace. Modern health insurance has undergone many changes (including the most recent shift towards value-based reimbursement) within the past 100 years, and each of these changes to health insurance and how physicians are paid was done with the goal of reducing costs and providing more access to necessary medical services. To understand how we arrived at value-based reimbursement reforms through the ACA and MACRA, it is important to understand the evolution of modern health insurance.

Modern health insurance started in 1929 when a number of school teachers “contract[ed] with Baylor Hospital to provide 21 days of hospitalization for \$6 per year.”⁴⁴ Physicians supported this form of insurance mainly because they feared that if they did not, compulsory insurance would be enacted, hospitals would offer health insurance for doctors’ services, and consequently, insurance concerns would trump physicians’ medical decision-making.⁴⁵ Shortly thereafter, the American Medical Association established ten principles that allowed health insurance to apply to physician services.⁴⁶ Because these plans were offered by private-sector employers, the popularity of these plans grew.⁴⁷

In 1965, with the election of President Kennedy, congressional Democrats pushed to enact a form of compulsory health insurance.⁴⁸ Responding to pressures from the American Medical Association, Congress limited this type of insurance, later known as Medicare and Medicaid, to the elderly (over the age of 65) and the indigent (those who are unemployed and who could not

⁴⁴ John T. Preskitt, *Health care reimbursement: Clemens to Clinton*, 21 SOC’Y OF BAYLOR SURGEONS MEETING 41, 41 (July 4, 2016), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2190551/pdf/bumc0021-0040.pdf>

⁴⁵ Physicians believed that if hospitals provided health insurance their medical decision-making would be dictated by insurance concerns rather than what was in the best interests of the patient. Melissa Thompson, *Health Insurance in the United States*, E. HIST. ASS’N, (last accessed August 12, 2016), <https://eh.net/encyclopedia/health-insurance-in-the-united-states/>

⁴⁶ Preskitt, *supra* note 44.

⁴⁷ *Id.*

⁴⁸ Medicare was composed of two parts: “Part A represented the compulsory hospital insurance program the aged were automatically enrolled in upon reaching age 65. Part B provided supplemental medical insurance, or subsidized insurance for physicians’ services.” Thompson, *supra* note 45.

afford insurance).⁴⁹ Under this system, physicians and providers were only paid to treat the sick; preventative medicine was not compensated.⁵⁰

In response to the inflated costs this system produced, Congress passed the first form of managed care, the Health Maintenance Organization (HMO) Act of 1973.^{51, 52} Under an HMO plan, the patient paid a monthly premium and was charged a set dollar amount (co-pay) for a visit to a primary care provider who was within the HMO network.⁵³ HMOs reduced costs by allowing primary care providers and the HMO plan to act as a gatekeeper for their patient's care since the primary care provider and the HMO plan had to approve of any referrals to a specialist before that specialist treated the patient.⁵⁴ If the primary care provider kept costs below set target levels, that provider would receive increased compensation from the HMO.⁵⁵ While HMOs cut costs, many criticized the plans as denying necessary care.⁵⁶

In the 1980s and 1990s, HMOs began to be replaced by variations of Preferred Provider Organizations ("PPO") and Point of Service Organizations ("POS"). "A PPO is a group of doctors and/or hospitals that provide medical service only to a particular group or association...Rather than pre-paying for medical care [as in an HMO], PPO members pay for services as they are rendered."⁵⁷ POSs are "a type of managed healthcare system that combines characteristics of the HMO and the PPO. If the patient stays in-network, the POS functions like an HMO. If a patient goes out-of-network, the POS works like a PPO."⁵⁸

B. Problems Associated with Fee-for-Service Reimbursement

As stated above, before the passage of the ACA, physicians were primarily reimbursed under the fee-for-service model. "Fee-for-service payment[s] typically ha[ve] meant that a provider, usually a physician, receive[s] a set fee for a particular service – such as performing a physical exam or administering an inoculation – either directly from the patient, private insurer or other payer. Thus, fee-for-service payments are driven by the volume of services produced."⁵⁹

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*; *Health Insurance: HMOs, PPO & POS Plans*, (last accessed August 12, 2016),

<http://www.agencyinfo.net/iv/medical/types/hmo-ppo-pos.htm>

⁵² Due to Medicare having to reimburse physicians based on a fee schedule as opposed to the physician's "usual and customary rates," Medicare costs rose sharply in the 1970s. *Health Insurance in the United States*, *supra* note 45.

⁵³ *How Medicare Health Maintenance Organizations (HMOs) Work*, MEDICAREINTERACTIVE.ORG, (last accessed August 12, 2016), <http://www.medicareinteractive.org/get-answers/types-of-medicare-advantage-plans-hmos-ppos-and-more/medicare-hmos/how-medicare-health-maintenance-organizations-hmos-work>

⁵⁴ A referral by a person's primary care physician was also required if care was sought that exceeded the scope of the original referral. *How HMO Works – The Referral Process*, BLUE CROSS BLUE SHIELD, (last accessed August 12, 2016), <https://connect.bcbstx.com/understanding-benefits/b/weblog/archive/2015/02/17/how-hmo-works-the-referral-process>.

⁵⁵ *How Medical Health Maintenance Organizations (HMOs) Work*, *supra* note 53.

⁵⁶ Holcomb Noble, *HMO or No?*, N.Y. TIMES, (April 30, 1995),

<http://www.nytimes.com/1995/04/30/nyregion/hmo-or-no.html?pagewanted=all>

⁵⁷ *Health Insurance: HMOs, PPO & POS Plans*, *supra* note 51.

⁵⁸ *Id.*

⁵⁹ Paul Ginsburg, *Fee-for-Service Will Remain a Feature of Major Payment Reforms, Requiring More Changes in Medicare Physician Payment*, HEALTH AFF., (2012),

<http://content.healthaffairs.org/content/31/9/1977.full?ikey=Fo/gU/Tuuua1.&keytype=ref&siteid=healthaff>

Medical necessity and performance of the service were the only requirements for payment under the fee-for-service system; the quality or efficacy of the procedure did not factor into the reimbursement amount.

Because under the fee-for-service reimbursement scheme payers based payment upon medical necessity and whether or not a provider performed a service, and because there was no correlation between the value of the service and the amount the physician received as compensation, there was a strong incentive for the providers to increase the prices for said services.⁶⁰ As a result, the fee-for-service reimbursement scheme significantly contributed to the U.S. greatly outpacing the rest of the world in health care spending.⁶¹ Further, this increased spending did not increase the quality of healthcare services provided in the U.S. compared to other industrialized countries.

When analyzing the quality of health care services, the United States ranks lower than United Kingdom, France, and Germany.⁶² High prices and lack of universal coverage led to the decrease in quality of services provided in the United States.⁶³ “A recent comparison of factors underlying difference in mortality rates from the leading amenable causes of death in the United States and the United Kingdom showed that many Americans failed to obtain recommended treatment for common chronic conditions and to secure regular, *affordable* treatment (emphasis added).”⁶⁴

Further, medicine has evolved to where providers can more effectively treat certain conditions when there is coordination of care among a patient’s providers; however, under the fee-for-service reimbursement model, providers did not have an incentive to coordinate a patient’s care.⁶⁵ Because the only requirements for payment under the fee-for-service model were medical necessity and performance of the procedure, physicians were only compensated when they provided the service they were asked to provide (assuming the service was medically necessary). Those payments were not tied in any way to the value of the care the patient received from other providers for the same underlying condition. For these reasons, legislators, administrators and other policymakers within the U.S. government sought to reform the volume-based payment model to one that factors in the value said physicians and provider organizations provide to

⁶⁰ *Cracking the Code on Health Care Costs: A Report by the State Health Care Cost Containment Commission*, U. OF VIRGINIA MILLER CTR. 12 (January 2014), available at <http://web1.millercenter.org/commissions/healthcare/HealthcareCommission-Report.pdf>

⁶¹ “Physician spending per capita in the United States is much higher than in other countries. In 2008 per capita spending on physician services in the United States was \$1,599, while per person spending for these services across all other Organization for Economic Cooperation and Development (OECD) countries averaged just \$310 per person (in US dollars, adjusted for purchasing power parities) – 81 percent below the US figure.” Miriam J. Laugesen and Sherry A. Glied, *Higher Fees Paid to U.S. Physicians Drive Higher Spending for Physician Services Compared to Other Countries*, 30 HEALTH AFF. 1647, 1647 (Sept. 2011), available at <http://content.healthaffairs.org/content/30/9/1647.full.pdf+html>.

⁶² Ellen Nolte and C. Martin McKee, *In Amenable Mortality – Deaths Avoidable Through Health Care – Progress in the US Lags That of Three European Counties*, 31 HEALTH AFFAIRS 2114, 2114 (2012).

⁶³ *Id.* at 2120.

⁶⁴ This study focused on the amenable mortality rates, or deaths that are preventable assuming the patient timely seeks medical treatment, in the United States, United Kingdom, Germany and France. *Id.*

⁶⁵ Richard Amerling and Paul Ginsburg, *Should the U.S. Move Away From Fee-For Service Medicine*, WALL STREET J., (March 22, 2015), <http://www.wsj.com/articles/should-the-u-s-move-away-from-fee-for-service-medicine-1427079653>.

patients in the administration of their health care services. The passage of the ACA and MACRA drove these physician reimbursement reforms.

IV. VALUE-BASED REIMBURSEMENT REFORMS

A. ACA Reforms

While also expanding health insurance coverage through the creation of state and federally-run health insurance exchanges, the ACA alters how providers are paid by “testing new delivery models and spreading successful ones, encouraging the shift toward payment based on the value of care provided, and developing resources for system-wide improvement.”⁶⁶ One such reform established by the ACA is the Medicare Shared Savings Program, which allows for value-based reimbursement to those providers who deliver health care services through an ACO.⁶⁷

Value-based reimbursement for ACOs differs from a purely volume-based reimbursement model in that the ACO receives greater compensation if it achieves cost savings below predetermined levels set by CMS. In other words, CMS financially rewards ACOs for reducing the cost of treatment. Specifically, the ACO will be able to keep one-half of any achieved cost savings as compared with CMS-established cost benchmarks, with the other one-half of the savings being retained by CMS.⁶⁸ Along with the creation of ACOs, the ACA reduces annual rate increases in the Medicare Physician Fee Schedule, and the ACA mandates that CMS implement several reimbursement pilot programs such as the Bundled Care Payment Initiative.

As stated above, the ACA “lower[s] [the] annual increases in Medicare payment rates for hospitals and other facilities and explicitly set [sic] an expectation for providers to become more efficient over time.”⁶⁹ For example, hospitals that have a high rate of hospital-acquired illnesses are required to pay a penalty to CMS.⁷⁰ Along with seeking to increase quality in hospital-provided care, the ACA ties certain hospital-related payments to the quality of the services provided by the hospital through the Value-Based Purchasing Program.⁷¹ This program provides reimbursement to hospitals for inpatient services “based on the quality of care, not just quantity of the services they provide.”⁷² Submission of certain quality-related data is the basis for these payments by the hospital to CMS.⁷³

⁶⁶ *The Affordable Care Act’s Payment and Delivery System Reforms: A Progress Report at Five Years*, COMMONWEALTH FUND, (last accessed August 12, 2016), <http://www.commonwealthfund.org/publications/issue-briefs/2015/may/aca-payment-and-delivery-system-reforms-at-5-years>.

⁶⁷ For a description on how ACOs function, see *supra* note 8.

⁶⁸ Out of 400 ACOs in 2015, “52 were able to meet quality-of-care benchmarks and keep spending below budget targets; these ACOs generated \$700 million in total savings and roughly \$315 million in shared-savings bonuses.” *The Affordable Care Act’s Payment and Delivery System Reforms: A Progress Report at Five Years*, *supra* note 66.

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ The Value-Based Purchasing Program does not involve providers or CMS purchasing an asset; rather, the Program purchases quality care provided by hospital providers.

⁷² *Hospital Value-Based Purchasing*, CTRS. MEDICARE & MEDICAID SERV., (last accessed August 12, 2016), <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/>

⁷³ This program is paid for by CMS reducing Diagnosis Related Group (“DRG”) payments by 1.75%. CMS believes the incentive offered by the Value-Based Incentive Program can be greater than the reduction to the DRG payments. *Id.*

The ACA mandated the initiation of various pilot projects that test alternative payments systems such as the implementation of bundled payments. One pilot project governed by CMS is the Bundled Care Payment Initiative (“BCPI”). The BCPI currently offers four tracks for the provider to receive bundled payments. “One model focuses on care provided during the hospital stay, while the other three models include post-acute care provided once the hospital discharges the patient.”⁷⁴ CMS hopes that like other forms of value-based payments, the bundled payments will incentivize providers to coordinate with one another to provide more value to the patient receiving care instead of focusing on the number of procedures performed during a patient’s course of treatment.⁷⁵

Regarding payment under the bundled payment model, cost benchmarks are set for various episodes of care (such as knee or hip replacements), and if the provider(s) costs are below the benchmark, any savings achieved are kept by the provider(s).⁷⁶ Bundled payments function in the following manner:

Under these bundled payment arrangements, the contracting entity and its providers will be paid fee-for-service (FFS) for all services rendered. A target price will be established for each condition based on the entity’s historic spending minus an agreed-upon discount. CMS will conduct periodic retrospective reconciliations to compare actual FFS payments with the target price. If, during the period, aggregate FFS payments are higher than the agreed-upon target amount, the entity must repay Medicare. If payments are less, the entity is paid the difference (which may then be shared among participating providers). CMS will also monitor aggregate Medicare Part A and Part B FFS spending for the 30 days after the bundle period; if spending is higher than historic spending plus a risk threshold, the entity owes CMS the difference.⁷⁷

Model 1 pays hospitals “a discounted rate based on the IPPS⁷⁸ payment amount. Others who care for the patient during the inpatient stay, such as physicians, are paid the standard Medicare rates under the physician fee schedule.”⁷⁹ For Models 2 and 3, a provider can choose a risk track (how much risk the provider is willing to incur) for each episode of care it wishes to include in the models, and any savings achieved by the providers, as compared to established

⁷⁴ *Health Policy Brief*, HEALTH AFF. 1, (November 23, 2015), available at http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_148.pdf

⁷⁵ “More than 1,500 providers are participating as episode initiators, and more than 300 organizations have agreed to take on the financial risk of participation.” *Id.* at 2.

⁷⁶ *Id.* at 3.

⁷⁷ *Approaches to bundling payment for post-acute care*, MEDPAC 66, (last accessed August 12, 2016), http://www.medpac.gov/documents/reports/jun13_ch03.pdf?sfvrsn=0.

⁷⁸ The Acute Care Hospital Inpatient Prospective Payment System is a system that details the payment rates established by CMS that hospitals provide to Medicare patients who receive inpatient services. This payment is derived from the patient’s illness as opposed to which procedures were performed, as is the case for the provision of Medicare Part B services. *Acute Care Hospital Inpatient Prospective Payment System*, CTRS. MEDICARE & MEDICAID SERV. 1, (February 2016), available at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/AcutePaymtSysfctst.pdf>

⁷⁹ The hospitals can share the bundled payments with individual physicians. *Id.*

benchmarks, will be kept by the providers.⁸⁰ Model 4 allows participating hospitals to be “paid a prospectively set bundled rate for both the hospital services that would be paid under the IPPS and the physician services provided during the hospital stay that would be paid under the physician fee schedule.”⁸¹ “Historical claims data for each hospital participating as an episode initiator” is the basis for the final payment amount.⁸²

Providers that participate in Model 2 can choose “one or more of the 48 episodes [of care] and select a length of each episode (30, 60, or 90 days).”⁸³ Episodes begin when there is an inpatient admission for a DRG-related to an episode selected by the participant provider. Payment under Model 2 covers “related care covered under Medicare Part A and Part B within 30, 60, or 90 days following discharge from acute care hospital.”⁸⁴ The total payment amount to a participant is “reconciled against a bundled payment amount predetermined by CMS.”⁸⁵

Like Model 2 participants, Model 3 participants can choose 48 episodes of care for 30, 60, or 90 days.⁸⁶ However, Model 3 episodes begin at “initiation of post-acute services with a participating skilled nursing facility, inpatient rehabilitation facility, long-term care hospital, or home health agency following an acute care hospital stay for an anchor DRG or the initiation of post-acute care services where a member physician of a participating physician group was the attending or operating physician for the beneficiary’s inpatient stay.”⁸⁷ These services must start within thirty days of discharge “and either a minimum of 30, 60, or 90 days after the initiation of the episode.”⁸⁸ This model allows for the payment of both Medicare Part A and B services within the designated timelines.⁸⁹

Finally, Model 4 is similar to Models 2-3 in that participants can choose between 48 episodes of care.⁹⁰ The episode begins when a patient is admitted to an inpatient hospital for a DRG associated with one of the 48 episodes of care.⁹¹ The bundled payment includes “all Medicare Part A and Part B covered services furnished during the inpatient stay by the hospital, physicians, and non-physician practitioners, as well as any related readmissions that occur within 30 days after discharge.”⁹² CMS will make the bundled payment to the hospital instead of to the IPPS.⁹³ Much of the payment reforms enacted by the ACA are through CMS pilot programs, and it is unclear the impact these pilot programs will ultimately have.⁹⁴ Regardless of these

⁸⁰ Cases with extreme high or low costs are excluded from target calculations. *Id.*

⁸¹ *Id.* at 3-4.

⁸² *Id.* at 4.

⁸³ *Bundled Payments for Care Improvement: Overview and Basic Parameters*, CNTRS. MEDICARE & MEDICAID SERV. 10, (March 11, 2014), available at <https://innovation.cms.gov/Files/slides/BPCI-Overview2-4.pdf>.

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *Id.* at 13.

⁸⁷ *Id.* .

⁸⁸ *Id.*

⁸⁹ *Id.*

⁹⁰ *Id.* at 15.

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

⁹⁴ *The Affordable Care Act’s Payment and Delivery System Reforms: A Progress Report at Five Years*, *supra* note 66.

programs' particular effectiveness, along with the payment reforms introduced by the ACA and MACRA, it is clear that the U.S. government is determined to factor in value when determining physician reimbursement.

B. MACRA Reforms

MACRA enjoyed vast support among both political parties in Congress, and the President signed it into law on April 16, 2015.⁹⁵ MACRA introduced many payment reforms, including the elimination of the Sustainable Growth Rate (“SGR”) formula, which avoided a 21.2% cut in the Medicare Physician Fee Schedule.^{96, 97} MACRA also slows the Medicare Physician Fee Schedule’s annual increases pursuant to the following schedule: annual increases by 0.5% from July 2015 – 2019; no increases thereafter until 2025; 0.75% annual increases for advanced Alternative Payment Model (“APM”) participants.⁹⁸ MACRA established the Medicare Incentive Payment System (“MIPS”) and the APM payment incentives. The APM participants and MIPS participants receive 0.25% annual increases for each year after 2025.⁹⁹ As stated earlier, along with slowing annual increases to the Medicare Physician Fee Schedule, MACRA established, as detailed *infra*, the MIPS and APM payment incentives.

MACRA¹⁰⁰ established MIPS, which scores providers on various quality and cost-based categories. MIPS provides for payment adjustments to physicians’ Medicare Part B payments, either by awarding bonuses or by requiring providers to remit payment to CMS, depending on how each provider compares to his or her peers in providing value to his or her patients.¹⁰¹ “Performance and ‘composite scores’ under MIPS will be based upon four categories: quality

⁹⁵ Any hope by providers that a Republican-controlled executive and legislative branch would repeal the ACA and its value-based reimbursement reforms was dashed by the passage of MACRA, as it was passed by a margin of 392 to 32 in the House of Representatives and 92 to 8 in the Senate. *Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)*, H.R. 2, Pub. Law 114-10, AM. MED. ASS’N 1, (May 7, 2015).

⁹⁶ *Id.*

⁹⁷ The SGR was designed to limit spending on Medicare Part B physician payments. The goal of the SGR was for Medicare payments to not exceed the growth of the Gross National Product. For several years, Congress passed legislation that avoided the yearly cuts. However, without a repeal of the formula, the percentage of cuts grew to an expected 21.2% in 2015. With a repeal of this formula, providers are no longer in danger of receiving truly massive cuts in the Medicare Physician Fee Schedule. Eric Cragun, *The most important details in the SGR repeal law*, ADVISORY BOARD, (April 20, 2015), <https://www.advisory.com/research/health-care-advisory-board/blogs/at-the-helm/2015/04/sgr-repeal>; Jacob Goldstein, *Why Medicare Pay Cuts for Doctors Will Be Back*, WALL STREET J., (July 10, 2008), <http://blogs.wsj.com/health/2008/07/10/why-medicare-pay-cuts-for-doctors-will-be-back/>.

⁹⁸ In order to qualify as an advanced APM participant, the payments received by the provider must be based on quality-related factors, the provider must utilize certified electronic health record technology, and the provider must either “bear more than nominal financial risk for monetary losses or be a medical home model expanded under CMMI authority.” *The Medicare Access & CHIP Reauthorization Act of 2015 Path to Value*, CTRS. MEDICARE & MEDICAID SERV. 13, (last accessed August 12, 2016), available at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-LAN-PPT.pdf>

⁹⁹ *Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)*, H.R. 2, Pub. Law 114-10, *supra* note 95.

¹⁰⁰ MACRA payments will be received in 2019. However, 2019 payments will be based on 2017 reporting data. Generally, MACRA only applies to those receiving Medicare Part B payments. MACRA does not apply to providers receiving less than or equal to \$10,000 in Medicare Part B payments or those participating in their first year of Medicare Part B. *The Medicare Access & CHIP Reauthorization Act of 2015 Path to Value*, *supra* note 98, at 17.

¹⁰¹ *Id.* at 9.

(50 percent); resource use (10 percent); meaningful use (25 percent); and clinical practice improvement activities (15 percent).¹⁰² For those providers that score well against their peers, CMS will award up to a 4% payment increase in 2019, and up to a 9% payment increase in their Medicare Part B payments in 2022.¹⁰³ Because these payments must be budget-neutral, underperforming providers will be subject to a 4% reduction in 2019, and up to a 9% reduction in their Medicare Part B payments in 2022.¹⁰⁴

For providers participating in certain demonstration and pilot programs administered by CMS or otherwise authorized by federal law, MACRA allows for reimbursement other than what is provided by MIPS. Specifically, providers who participate in the “SMC Innovation Center Model, the Medicare Shared Savings Program, any demonstration under the Health Care Quality Demonstration Program or otherwise authorized by federal law” will qualify as an APM.¹⁰⁵ Most of the providers that participate in APMs will still need to report data to the MIPS program, but those participants will receive only favorable adjustments to their MIPS scores.¹⁰⁶ Select providers will qualify as advanced APM participants. Advanced APM participants will receive a 5% payment bonus annually, and will not be required to participate in MIPS reporting.¹⁰⁷ Those providers who participate in advanced APMs will also receive higher annual increases in their Medicare Physician Fee Schedule.¹⁰⁸ While the government is seeking to factor in value to physicians’ reimbursement, it is important to examine the operational transformation that providers will need to undergo in order to take advantage of the payment reforms instituted by the ACA and MACRA.

V. VALUE-BASED REIMBURSEMENT NECESSITATES ALIGNMENT AMONG PROVIDERS

A. Transformation from Fee-For-Service Reimbursement to Value-Based Reimbursement

One of the central tenants of value-based payments is that providers will be held more accountable for the cost and value of their patients’ care. In a fee-for-service reimbursement model, providers’ financial incentives were not necessarily united with the patient’s goal of having the underlying condition treated at the lowest possible cost. To have accountability, a group of providers must have a common goal in providing positive health outcomes while at the same time lowering the costs of treatment.¹⁰⁹ The goals and shared interests among providers differ depending upon the type of care that is being sought by the patient:

¹⁰² Effective in 2019, MIPS consolidates the Physician Quality Reporting System, Electronic Health Records/Meaningful Use, and the Value-Based Payment Modifier programs into one quality and cost-reduction reporting score. *Id.* at 8.

¹⁰³ *Id.* at 9.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.*

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* at 17.

¹⁰⁹ *What is Value in Health Care?*, *supra* note 20, at 2477.

For primary and preventive care, value should be measured for defined patient groups with similar needs. Patient populations requiring different bundles of primary and preventive care services might include, for example, healthy children, healthy adults, patients with a single chronic disease, frail elderly people, and patients with multiple chronic conditions. Care for a medical condition (or a patient population) usually involves multiple specialties and numerous interventions. Value for the patient is created by providers' combined efforts over the full cycle of care. The benefits of any one intervention for ultimate outcomes will depend on the effectiveness of other interventions throughout the care cycle.¹¹⁰

Patient outcomes are usually not achieved immediately; rather, they are obtained after the patient has undergone a prolonged recovery process, multiple interventions, or complications arising from treatment.¹¹¹ To measure outcomes, integration and alignment strategies among providers are necessary.

Providers will need to align and/or merge with one another to take advantage of the value-based payment reforms. This due to a number of factors, the first of which is because standalone providers have difficulty measuring patient outcomes.¹¹² Most providers only can measure what they can control, which is usually a single portion of a patient's treatment.¹¹³ Such individual measurements are too narrow because small or solo providers do not possess the necessary IT infrastructure to measure patient outcomes.^{114, 115} Small practices can measure the charges billed to a particular patient; however, charges do not indicate patient outcomes.¹¹⁶ Charges at a single practice also do not take into account the amount of charges the patient incurs from other providers for the treatment of other aspects of the underlying condition. Additionally, physicians at small practices tend to shy away from being held responsible for outside events they cannot control such as the care the patient received from other providers.¹¹⁷ Recognizing the infrastructure and alignment realities of value-based reimbursement, many small practices believe the passage of MACRA will result in the end of their current practice model.¹¹⁸

¹¹⁰ *Id* at 2478.

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ *Id.*

¹¹⁴ *Id.*

¹¹⁵ "Patient Reported Outcomes are also used at the University of Pittsburgh Medical Center. Patients visiting the center's outpatient primary care clinic fill out the SF-36 on tablet computers before seeing a physician. The tool has helped clinicians identify patients with depression and older adults with mobility limitations. In a health system such as UPMC, PROMs data could also help improve care coordination, says Rachel Hess, M.D., assistant professor of medicine, epidemiology, and clinical and translational science at the University of Pittsburgh. "One of the things we talked about across the medical center is that as patients transition from primary care practice to different specialty practices for particular conditions, it would be helpful to have that same sort of standardized data across time so that we know how the condition has evolved and responded to different treatments," Hess says." Martha Hostetter and Sarah Klein, *Using Patient-Reported Outcomes to Improve Health Care Quality*, COMMONWEALTH FUND, (December 2011/January 2012), <http://www.commonwealthfund.org/publications/newsletters/quality-matters/2011/december-january-2012/in-focus>.

¹¹⁶ *What is Value in Health Care?*, *supra* note 20, at 2478.

¹¹⁷ *Id.*

¹¹⁸ "Despite small practice education, training and technical assistance programs promised from the Centers for Medicare and Medicaid Services to help physicians with the MACRA programs, 89 percent of the remaining solo

To begin the transformation from fee-for-service reimbursement to value-based reimbursement, the method of healthcare delivery must change. One way to begin this transformation is for providers to form Integrated Practice Units (“IPU”) or other CINs.¹¹⁹ While the members of the networks may be located in many geographical locations and while the providers may specialize in many different areas of care, the members of the Units or CIN work as a team to treat the patient’s condition.¹²⁰ For example, data has shown that an IPU that treats back pain has resulted in its patients missing four fewer days of work and requiring four fewer physical therapy visits.¹²¹ IPUs can function as primary care teams; however, this often requires multiple teams specializing in various areas of care since the range of patients is much larger.^{122, 123}

As stated earlier, to ensure that providers are providing value in the provision of their care, it is vital to be able to track healthcare outcomes. Practices that aren’t integrated often do not have the ability to measure quality; their measurements center on legal compliance and practice guidelines.¹²⁴ However, to measure quality, the measurements should fall into three tiers. Tier one measures a patient’s achieved health status – not just mortality rates but also activities patients can perform through the different stages of their recovery.¹²⁵ Measurements in the second tier relate to the patient’s care cycle and recovery.¹²⁶ These measures include emergency room readmissions, the amount of pain experienced during the recovery process, and when a patient can resume regular activities.¹²⁷ The last tier of criteria relates to how long a person can expect to remain healthy or whether they will need subsequent procedures to maintain their ideal level of functionality.¹²⁸ These tiers cannot adequately be measured if a provider acts as a

practices expect to minimize Medicare volumes so they're not required to submit reports for the quality and clinical practice improvement activities, or report in the cost performance category. Seventy-seven percent of small practices identified themselves as financially struggling due to physician staffing losses directly to larger group practices and hospital integrated delivery networks, the survey found. Seventy-two percent also blame their underperforming billing technology and compounding payment issues for their troubles.” Jeff Lagasse, *Most Small medical practices expect MACRA to spell the end of their model, Blackbook says*, HEALTHCARE FIN., (last accessed August 12, 2016), <http://www.healthcarefinancenews.com/news/most-small-medical-practices-expect-macra-spell-end-their-model-blackbook-says>

¹¹⁹ “In an IPU, a dedicated team made up of both clinical and nonclinical personnel provides the full care cycle for the patient’s condition. IPUs treat not only a disease but also the related conditions, complications, and circumstances that commonly occur along with it – such as kidney and eye disorders for patients with diabetes, or palliative care for those with metastatic cancer.” Michael Porter and Thomas Lee, *The Strategy That Will Fix Health Care*, HARV. BUS. REV., (October 2013), <https://hbr.org/2013/10/the-strategy-that-will-fix-health-care>

¹²⁰ *Id.*

¹²¹ *Id.*

¹²² Primary care physicians typically see a wide variety of patients from young, non-sick adults to older patients with many chronic conditions. As such, the range of illnesses that are treated by primary care physicians vary widely.

Id.

¹²³ Providers can also form ACOs, CINs, patient-centered medical homes or IPAs. The providers can also seek employment with an already established health system. Whichever model is chosen, the steps outlined in the transformation process must occur in order to be prepared to provide care in such a manner that maximizes the opportunities for revenue under the ACA and MACRA.

¹²⁴ Porter, *supra* note 119.

¹²⁵ *What is Value in Health Care?*, *supra* note 20, at 2479.

¹²⁶ *Id.*

¹²⁷ *Id.*

¹²⁸ *Id.*

standalone entity; rather, many providers must work as a team to have access to the type of information necessary to adequately measure value.

Next, a provider must be able to adequately measure costs relative to the treatment of the patient's underlying condition.¹²⁹ Many providers struggle with being able to measure costs relative to conditions since most hospital accounting systems are based on a particular department and not on a patient's full cycle of care.¹³⁰ Further, most patient record systems measure charges and not the resources used to provide a full cycle of care for each patient.¹³¹ Current patient record systems prevalent in small medical practices focus on the charges incurred for a particular procedure, and are thus problematic in a value-based reimbursement environment since fee-for-service payments are continually decreasing.¹³² One possibility is for providers to transition to a time-driven activity-based costing system.¹³³ Time-driven activity-based costing involves "managers directly estimat[ing] the resource demands imposed by each transaction, product, or customer rather than assign resource costs first to activities and then to products or customers."¹³⁴ This requires two measurements: "the cost per time unit of supplying resource capacity and the unit times of consumption of resource capacity by products, services, and customers."¹³⁵ Not knowing the amount of resources used when providing care for an underlying condition prevents an accurate determination of the amount of value the patient receives during their course of treatment.

Another important step in the transition from fee-for-service reimbursement to value-based reimbursement is integrating care among a multitude of providers.¹³⁶ Integrated systems must accomplish four tasks: "define the scope of services, concentrate volume in fewer locations, choose the right location for each service line, and integrate care for patients across numerous provider sites."¹³⁷

Many provider networks do not integrate their care with other providers; rather, the providers in these networks operate as standalone providers that offer many of the same services in different locations.¹³⁸ Providing the maximum amount of value requires integrated networks to eliminate or narrow the scope of services that networks offer their patients, as the offering of multiple service lines typically results in an inefficient use of resources when providing treatment to the patient.¹³⁹ Further, it is important for networks to decide which conditions they want to treat. "Providers with significant experience in treating a given condition have better outcomes along

¹²⁹ Porter, *supra* note 119.

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² *Id.*

¹³³ "For example, Virginia Mason, a group practice consisting of more than 400 doctors, found that it costs \$4 per minute for an orthopedic surgeon or other procedural specialist to perform a service, \$2 for a general internist, and \$1 or less for a nurse practitioner or physical therapist. In light of those cost differences, focusing the time of the most expensive staff members on work that utilizes their full skill set is hugely important." *Id.*

¹³⁴ Steven Anderson and Robert Kaplan, *Time-Driven Activity-Based Costing*, HARV. BUS. REV., (November 2004), <https://hbr.org/2004/11/time-driven-activity-based-costing>.

¹³⁵ *Id.*

¹³⁶ Porter, *supra* note 119.

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

with a reduction in costs.”¹⁴⁰ When a network removes service lines that are duplicated across multiple locations, the network increases the volume of the relevant cases to a few locations.¹⁴¹ To integrate care, it is important for the central entity to coordinate the patient’s care across multiple network sites.¹⁴² “Integrating mechanisms, such as assigning a single physician team captain for each patient and adopting standard scheduling and other protocols, help ensure that well-coordinated multidisciplinary care is delivered in a cost-effective and convenient way.”¹⁴³

Besides forming and executing the integration plan, one of the most onerous obstacles in transitioning to value-based reimbursement is obtaining the necessary IT processes. Most IT systems in small practices, assuming the practice has an IT system, concentrate data by “department, location, type of service, and type of data.”¹⁴⁴ However, to adequately capture value, the IT system must have many components.

First, the system must have the data centered on the patient.¹⁴⁵ The IT system also must be able to capture varying types of information, including “physician notes, images, chemotherapy orders, lab tests, and other data that is stored in a single place” so that all providers across different locations can have access to the necessary information when providing care to the patient.¹⁴⁶ The system should have templates that allow for easy entry of the data.¹⁴⁷ These information systems identify the processes of care for that condition as well as identify risks the patient will encounter during treatment.¹⁴⁸ Finally, the system must allow for an easy extraction of the data.¹⁴⁹ As healthcare transitions from a volume-based reimbursement model to a value-based model, it will be necessary for smaller practices to form and execute an alignment strategy that best fits that clinician’s goals and needs.

B. Alignment Is Likely to Cause “Practice Losses.”

Since the passage of the ACA, hospitals have been purchasing, acquiring, and employing physician practices as part of their integration strategy.¹⁵⁰ Some hospitals are also hoping that “by acquiring practices, especially in specialties that drive hospital admissions, hospital beds will remain full during the transition [from fee-for-service reimbursement to value-based reimbursement].”¹⁵¹ However, this strategy has resulted in substantial and continuing financial losses to the hospital or health system. The economic realities of hospital-based employment almost always lead to the hospital operating the practice at a loss when comparing the expenses paid by the hospital or health system versus the professional net revenue received from the

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ Beth Kutscher, *Making Physicians Pay Off: Hospitals Struggle to Balance Current Costs with Future Benefits of Employing Docs*, MODERN HEALTHCARE, (February 22, 2014), <http://www.modernhealthcare.com/article/20140222/MAGAZINE/302229986>

¹⁵¹ *Id.*

practice. An illustration of the changing economics from a private practice model to a hospital-employed practice model is helpful.

In a private practice setting, the doctor provides medical services to the patient and either bills the patient or submits a claim for reimbursement to the payer. The bill or claim is for the overall charges for the procedure (gross charges). If the provider submits a claim to a payer, the payer will reduce the amount of gross charges by an agreed upon amount. Because it is exceedingly rare for physicians and payers to not have contracts detailing the agreed-upon fee schedules, the agreed upon amounts are generally stated in the contract between the physician and the payer. The payer will pay a specific amount of the contracted-for charges, and then the provider is left to collect the remainder from the patient, excluding the contractual losses.¹⁵² After the private practice pays operating expenses such as occupancy, employment taxes, and malpractice insurance expenses, any remaining revenue is considered to be income for the practice.

However, when a provider joins a hospital or health system, the physician or the acquired practice's bottom line is subject to more adverse economic conditions common to hospital reimbursement. While the hospital or health system may have better contractual rates with the commercial payers, the payer mix in a hospital or health system is typically worse than that experienced in private practice.¹⁵³ "The percentage of Medicare charges is approximately the same, but integrated delivery system-owned multispecialty groups have twice the percentage of Medicaid charges, five times the charity care and 10% less commercial insurance."¹⁵⁴ The adverse payer mix yields less reimbursement than private practice physicians who perform the same amount of work.¹⁵⁵ The new adverse payer mix is due to a private practice being able to control their payer mix while non-profit hospitals are required to treat every type of patient, regardless of the patient's health insurance plan. Along with an adverse payer mix, hospital billing offices are typically not as efficient as private practice billing offices (due in part to the hospital's payer mix) in collecting outstanding amounts owed by patients.^{156, 157} This results in less revenue for the employed practice.

Practice losses can also stem from the hospital being required to upgrade its IT infrastructure, "pay comprehensive benefits packages and assume the costs of maintaining office space,

¹⁵² The amount received from the payer and the patient is known as a provider's net collections.

¹⁵³ A provider's payer mix is a percentage breakdown of the amount of patients that are covered by Medicare, Medicaid, commercial insurance, and those patients that are self-pay. Providers typically receive more reimbursement from commercial payers than Medicare, who typically pay more than Medicaid, who typically pay more than self-pay patients.

¹⁵⁴ David Gans, *Why Hospital-Owned Medical Groups Lose Money*, MED. GROUP MGMT. ASS'N 2, (April 2012), available at <http://www.mgma.com/Libraries/Assets/Practice%20Resources/Publications/MGMA%20Connexion/2012/Data-Mine-Why-hospital-owned-medical-groups-lose-money---MGMA-Connexion-magazine-April-2012.pdf>

¹⁵⁵ *Id.*

¹⁵⁶ "A recent study found that hospitals collect from only 35 percent of patients at the point of service which represents just 19.8 percent of patient-owed fees." *Maximize patient collections at the point of service*, AVAILITY, (last accessed August 12, 2016), <https://www.availity.com/business-challenges/hospitals-and-health-systems/improving-patient-collections>.

¹⁵⁷ The average collections recovery rate for hospitals is 15.3% while the average rate for non-hospitals is 21.8%. *Healthcare Collection Statistics*, ACA INT'L, (last accessed August 12, 2016), <http://www.acainternational.org/products-healthcare-collection-statistics-5434.aspx>.

equipment, and staff. The health system may also pay certain practice group overhead expenses such as HR, legal services, and accounting.”¹⁵⁸ Additionally, the market may dictate that certain physicians receive a higher amount of compensation than other physicians. “A study by the American Hospital Association projects a shortage of 56,000 Primary Care physicians and 7,000 Orthopedic Surgeons by 2015. Shortages in these specialties have resulted in higher salaries paid by hospitals than these physicians can make in private practice.”¹⁵⁹

As stated above, hospitals and health systems are forced to offer lucrative benefit and compensation packages to recruit high-quality physicians. First, many benefit packages allow for six weeks of vacation and ten days of continuing medical education seminars. Such benefit packages typically do not exist in private practice. Second, the median salary is usually higher in an employment setting than in a private practice setting. For example, the average amount of compensation for a primary care physician (excluding obstetricians) in a physician-owned practice is approximately \$215,000 per year according to the 2015 MGMA physician compensation report.¹⁶⁰ Conversely, the average salary for a hospital-owned practice is approximately \$226,000.¹⁶¹ The salaries only increase for rural hospitals since those hospitals usually must offer higher salaries to recruit physicians to practice in rural areas.¹⁶² Failure to provide these salaries and benefit packages could result in the hospital failing to provide a particular service line to the community due to that hospital failing to recruit physicians that offer that line of service. This failure then negatively impacts the ability of the hospital to provide value to its patients.

Similarly, changes in hospital financial reporting make it appear that the practice is losing money when compared with how the practice performed before the acquisition. For example, when employed by a hospital provider, a physician’s “ancillary revenues for services (e.g., lab tests) that previously were billed by the practice are billed through the hospital. The result is lower income for the practice, making it appear to perform worse than it had historically performed.”¹⁶³

Another reason for practice losses is that once a hospital or health system enters into an employment arrangement with a physician or practice group, that physician or practice group must begin the process of becoming credentialed under the hospital or health system’s commercial payer contracts.¹⁶⁴ This process can take anywhere from 90 to 180 days.¹⁶⁵ During

¹⁵⁸ David Miller, *Can you Explain Practice Losses to Your Board?*, HEALTHCARE STRATEGY GROUP, (last accessed August 12, 2016), <http://www.healthcarestrategygroup.com/thought-leadership/articles/can-explain-practice-losses-board/>

¹⁵⁹ *Id.*

¹⁶⁰ Medical Group Management Association, *2015 Provider Compensation Survey*, MED. GROUP MGMT. ASS’N, (last accessed August 16, 2016), <https://www.mgma.com/my-account/my-dashboard>.

¹⁶¹ *Id.*

¹⁶² Susan Morse, *How Much Money do Doctors Make? Way More in Rural Areas, Report Says*, HEALTHCARE FIN., (Jan. 30, 2015), <http://www.healthcarefinancenews.com/news/how-much-money-do-doctors-make-way-more-rural-areas-report-says>.

¹⁶³ Luke Sullivan and Conor McCaw, *Evaluating Reasons for Physician Practice Losses*, HEALTHCARE FIN. MGMT. ASS’N, (Monday, December 8, 2014), <http://www.hfma.org/Content.aspx?id=26345>

¹⁶⁴ “Provider credentialing is a verification of [a provider’s] experience, expertise, interest and willingness to provide medical care. Without successful credentialing, provider reimbursement for medical services can be delayed and, even, denied.” *Provider Credentialing: Steps for Success*, MEDTRONIC, (September 9, 2013),

this time, any services provided by the un-credentialed provider will not be compensated by commercial payers; rather, these services will be deemed to be losses to the hospital or health system.¹⁶⁶ Once the provider becomes credentialed, the commercial payer will not reimburse the provider for services performed while the provider was not credentialed.

Employing practice groups and physicians results in “hospitals los[ing] \$150,000 to \$250,000 per year over the first 3 years...owing in part to a slow ramp-up period as physicians establish themselves or transition their practices and adapt to management changes.”¹⁶⁷ In fact, to break even, recently-employed providers “must generate at least 30% more visits, and new specialists must generate 25% [more] referrals than they do at the outset. After three years, hospitals expect to begin making money on employed physicians when they account for the value of all care, tests, and referrals.”¹⁶⁸ However, this accounting of downstream revenue when entering into employment arrangements between hospitals and physicians is met with suspicion from the Department of Justice.¹⁶⁹

Even though the hospitals are feeling the impact of the losses, many hospital leaders see this as a necessary first step in the transition towards realizing the value-based payment incentives created by the ACA and MACRA.¹⁷⁰ However, it is unlikely the losses can be seen as initial ramp-up costs that will decrease the longer the employment arrangement remains in place, since in the case of some hospitals, these losses have grown larger the longer the hospital employs the physician(s).¹⁷¹ Further, most of the factors responsible for these losses are long-term and are not likely to be eradicated after the initial ramp-up period.

While the health system or hospital may experience practice losses when analyzing their total losses from all employed physicians, doctors who specialize in “hematology/oncology, cardiology, cardiac/thoracic surgery, general surgery, neurosurgery, and orthopedics” generate practice gains.¹⁷² Further, hospitals that track downstream revenue¹⁷³ show that “overall

<https://professional.medtronic.com/rm/pmr/business-clinical-operations/NHCP-PM-PROVIDER-CRED-BCO#.V55IBzXYnHE>

¹⁶⁵ *High Cost of Credentialing Delays*, E-MDs, (last accessed August 16, 2016), <http://www.e-mds.com/high-cost-credentialing-delays-1>.

¹⁶⁶ *Id.*

¹⁶⁷ Robert Kocher and Nikhil Sahni, *Hospitals’ Race to Employ Physicians – The Logic Behind a Money Losing Proposition*, 364 N. ENGL. J. MED. 1790, 1790 (2011), available at <http://www.nejm.org/doi/pdf/10.1056/NEJMp1101959>.

¹⁶⁸ *Id.* at 1790-91.

¹⁶⁹ *See generally infra* note 226.

¹⁷⁰ “You have to bring them [other practice groups] in – and then you have to bring them in as efficiently as you can,” said Dr. Alan Kaplan, president and CEO of UnityPoint, the physician arm of UnityPoint Health, a 12-hospital system based in West Des Moines, Iowa. “It’s really a strategic asset that requires investment.” Kutscher, *supra* note 150.

¹⁷¹ *The Challenges of Integrating Physician Group Operations: 2014 Kentucky Healthcare Industry Study*, DEAN DORTON ALLEN FORD, PLLC 4, (2014), available at <http://deandorton.com/wp-content/uploads/2015/09/The-Challenges-of-Integrating-Physician-Group-Operations-web.pdf>

¹⁷² *Id.* at 11.

¹⁷³ Downstream revenue includes “referrals to specialists within the health system, ancillary services such as lab and radiology, and inpatient admissions.” Brad Boyd, *Downstream Revenue: Evaluating the Financial Return of Clinical Alignment Tactics*, CULBERT HEALTHCARE SOLUTIONS, (September 21, 2015), <http://culberthealth.com/blog/?p=738>

financial results were breakeven or profitable when taking downstream contribution margins into account.”¹⁷⁴ While hospitals primarily seek to employ practice groups to position themselves better for value-based reimbursement models, all parties – health systems and individual providers – must be cautious of the Stark Law prohibitions when entering into an employment or alignment arrangement.

VI. HEALTHCARE FRAUD AND ABUSE STATUTES

Healthcare fraud is a significant problem in the United States. Recently, the FBI arrested 243 individuals for fraudulently billing Medicare “for \$712 million worth of patient care that was never given or [was] unnecessary.”¹⁷⁵ This scheme included many fraudulent acts, including providers allowing criminals to access patient information for the providers to bill Medicare for care that providers did not perform.¹⁷⁶ “Sometimes fraudsters, known to the Feds as ‘patient recruiters,’ will go to places like homeless shelters and soup kitchens and offer money to those who would share their Medicare patient numbers.”¹⁷⁷ Because federal tax dollars fund Medicare and other federal healthcare programs, and because the fraudulent provision of healthcare procedures may cause unnecessary pain, suffering, and even death, the U.S. government prosecutes those who commit fraud on their patients and the federal healthcare programs. One of the most frequently used anti-fraud enforcement statutes is the Stark Law.

The Stark Law states if “a physician [who] has a financial relationship with an entity specified in paragraph (2), then the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made ...and the entity may not present or cause to be presented a claim...or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).”¹⁷⁸ A financial relationship is “a compensation arrangement...between the physician (or an immediate family member of such physician and the entity).”¹⁷⁹

Because nearly every healthcare-related financial arrangement potentially violates the Stark Law (*e.g.*, employment arrangements between hospitals and physicians), Congress enacted many exceptions to the Stark Law including one for bona fide employment relationships. This exception provides:

- (2) Bona fide employment relationships. Any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for the provision of services if--
 - (A) the employment is for identifiable services,
 - (B) the amount of the remuneration under the employment--

¹⁷⁴ *The Challenges of Integrating Physician Group Operations: 2014 Kentucky Healthcare Industry Study*, *supra* note 171, at 10.

¹⁷⁵ Katie Lobosco, *Doctors and nurses busted for \$712 million Medicare Fraud*, CNN, (June 21, 2015 2:50 PM ET), <http://money.cnn.com/2015/06/19/pf/medicare-fraud-doctors/>.

¹⁷⁶ *Id.*

¹⁷⁷ *Id.*

¹⁷⁸ 42 U.S.C.S. § 1395nn(a)(1)(a-b) (LEXIS current through P.L. 114-195).

¹⁷⁹ *Id.* at §1395nn(a)(2)(B) (LEXIS).

- (i) *is consistent with the fair market value of the services, and*
 - (ii) *is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician,*
 - (C) *the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer, and*
 - (D) *the employment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.*
- Subparagraph (B)(ii) shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or an immediate family member of such physician).¹⁸⁰

There has been much uncertainty surrounding which arrangements are deemed to be of fair market value. Stark states, in relevant part, that fair market value is “the value in arm’s 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).”¹⁸¹ On January 4, 2001, CMS stated they will accept a number of different methods of compensation provided it is “commercially reasonable and [the provider] provides us with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm’s-length transactions who are not in a position to refer to one another.”¹⁸² Despite this additional guidance, CMS failed to elaborate on the type and amount of documentation that would be appropriate, nor did they state a preferred method on how to structure compensation arrangements so that they do not run afoul of the employment exception.¹⁸³

Because the Stark definition of fair market value takes into consideration the general market value of services or items, it is important to understand that CMS defines general market value as “the price that an asset would bring as the result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.”¹⁸⁴ Due to the draconian nature of the Stark and False Claims Act penalties, (described hereafter), many providers have decided to settle claims brought by *qui tam* relators and the U.S. government instead of taking their case to trial. As a result, there has been limited case law that elaborates as to what is, and is not, fair market value compensation.

¹⁸⁰ *Id.* at § 1395nn(e)(1)(2) (LEXIS) (emphasis added).

¹⁸¹ *Id.* at § 1395nn(h)(3) (LEXIS).

¹⁸² Medicare and Medicaid Programs; Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships; Final Rule, 66 Fed. Reg. 944 (January 4, 2001) (to be codified at 42 C.F.R. Parts 411 and 424).

¹⁸³ Timothy Smith and Mark Dietrich, *Fair Market Value Issues in Physician Practice Acquisition and Employment Deals by Health Systems*, AICPA 10 (last accessed August 16, 2016), available at http://www.healthcareappraisers.com/presentations/FMV_Issues_in_Physician_Acquisition_Smith_Dietrich_11-10.pdf

¹⁸⁴ 42 C.F.R. § 411.351 (2016).

Regarding the commercial reasonableness requirement of a compensation arrangement, CMS believes an arrangement to be commercially reasonable if “in the absence of referrals [the arrangement was] entered into by a reasonable entity of similar type and size and a reasonable physician (or family member or group practice) of similar scope and specialty, even if there were no potential DHS (Designated Health Services) referrals.”¹⁸⁵ This guidance makes it clear that the hospital or health system must analyze the entire arrangement and not simply any one part of the agreement in isolation.¹⁸⁶ Because guidance on how to determine commercial reasonableness is relatively sparse, the U.S. government typically relies on expert witnesses to determine whether to prosecute a hospital based upon the commercial reasonableness of the agreement.¹⁸⁷

In determining the commercial reasonableness of a particular transaction, it is helpful to consider a number of factors: (1) whether the services provided by the physician or practice group is essential to the many goals and strategies of the hospital or health system; (2) whether the “arrangement makes rational sense from a general business perspective;” (3) whether the proposed arrangement will develop a service line of the hospital or health system; and (4) whether there will be a duplication in another service line provided by the hospital or health system.¹⁸⁸

Stark is especially dangerous for health care providers due to it being a strict liability statute.¹⁸⁹ Providers who violate this law are subject to a penalty of \$15,000 per unlawful claim along with being required to refund any monies that were paid by a federal healthcare program for unlawful claims.¹⁹⁰ Stark violations that were performed with willful and intentional intent also create liability under the False Claims Act¹⁹¹ since a claim that violates Stark is considered to be a false claim. False Claims Act violations carry with it triple damages.¹⁹² For example, if a federal healthcare program pays a provider \$1,000 on a claim that is deemed to have violated Stark and

¹⁸⁵ Medicare Program; Physicians’ Referrals to Health Entities With Which They Have Financial Relationships (Phase II); Interim Final Rule, Fed. Reg. 16093 (March 26, 2004) (to be codified at 42 C.F.R. 411 and 424).

¹⁸⁶ *Analysis of the Interconnectivity between Fair Market Value and Commercial Reasonableness*, ELLIOT DAVIS DECOSIMO 3, (last accessed August 12, 2016), available at <http://www.elliottdavis.com/assets/Analysis-of-the-Interconnectivity-between-Fair-Market-Value-and-Commercial-Reasonableness.pdf>

¹⁸⁷ “As a result, under the Stark Law, the factors to take into account to determine commercial reasonableness and FMV (fair market value) are likely to be ultimately established by the government’s expert witnesses’ reports in FCA (False Claims Act) litigation (where the government is seeking treble damages and substantial civil penalties) rather than by notice and comment rulemaking by the specialized agency charged with developing the regulations.” Robert Salcido, *Minimizing Exposure to Stark Law Liability in False Claims Act Cases by Isolating Those Who Determine Fair Market Value from Those Who Measure Contribution Margin or Other Similar Operational Data*, AKIN GROUP 3, (October 28, 2015), available at <https://www.akingump.com/images/content/3/8/v2/38744/The-Salcido-Report-Minimizing-Exposure-to-Stark-Law-Liability.pdf>

¹⁸⁸ *Analysis of the Interconnectivity between Fair Market Value and Commercial Reasonableness*, *supra* note 186, at 2-3.

¹⁸⁹ Unlike the Anti-Kickback Statute, a heightened level of intent is not required for a Stark violation. Unintentional violations are punished the same as willful and intentional violations.

¹⁹⁰ 42 U.S.C.S. §1395nn(g)(2-3) (LEXIS current through P.L. 114-195).

¹⁹¹ The False Claims Act states, “Any person who knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval or knowingly makes, uses, or cause to be made or used, a false record or statement material to a false or fraudulent claim. . . is liable to the United States Government for a civil penalty of not less than \$5,000 and not more than \$10,000. . . plus 3 times the amount of damages which the Government sustains because of the act of that person.” 31 U.S.C.S. § 3729 (LEXIS current through PL 114-183).

¹⁹² *Id.*

the False Claims Act, the provider will be liable to the government for \$18,000 (\$15,000 statutory Stark penalty plus \$3,000 False Claims Act treble damages). When thousands of claims are at issue, the penalties can become crippling to a healthcare organization.

Due to Stark violations having the ability to also be considered False Claims Act violations, private citizens, known as *qui tam* relators, may investigate and pursue alleged False Claims Act and Stark violations in court.¹⁹³ If the DOJ decides to subsequently intervene and prosecute the matter, the *qui tam* Relator will receive at least fifteen percent (15%) of any monies collected.¹⁹⁴ If the DOJ does not intervene and the Relator is successful with his or her Stark and False Claims Act violation claims, the Relator will be entitled to at least twenty-five percent (25%) of any funds collected.¹⁹⁵ With Stark judgments reaching into the millions of dollars, there is a strong financial incentive for *qui tam* relators to look for Stark violations and bring those actions to the attention of the U.S. government.

As discussed in Section V(A), *supra*, to achieve the goals and financial rewards of the ACA and MACRA, many providers have merged and/or aligned with one another by forming clinically integrated networks, ACOs, or by entering into various employment arrangements with hospitals or health systems. Since these providers are dependent on one another for payment from CMS, and because these providers refer patients to one another during their treatment of a patient's episode of care, there is a sufficient financial relationship between the providers to implicate Stark. However, for certain payment models, CMS has instituted "waivers" that allow organizations to align and integrate without violating the healthcare fraud and abuse statutes.¹⁹⁶

The fraud and abuse waivers established by CMS only apply to the "Pioneer Accountable Care Organization (ACO) Model, the Bundled Payment for Care Improvement (BCPI) Models, the Health Care Innovation Awards (HCIA) Round Two Model, the Comprehensive ESRD Care (CEC) Model, the Comprehensive Care for Joint Replacement (CJR) Model, the Next Generation ACO Model, the Oncology Care Model (OCM), and the Medicare Shared Savings Plan Program."¹⁹⁷ The CMS waivers do not apply to arrangements that are not governed by the previously mentioned models but still seek to take advantage of the MACRA reimbursement reforms.

The government and *qui tam* relators have consistently prosecuted those who have fraudulently billed Medicare for unnecessary and non-performed healthcare services. Recently, the government and *qui tam* relators have alleged Stark violations for physician compensation arrangements paid to physicians by hospitals and health systems due to the arrangements not being commercially reasonable and/or exceeding fair market value based on allegations that the

¹⁹³ *Id.* at § 3730(b)(1) (LEXIS).

¹⁹⁴ *Id.* at § 3730(d)(1) (LEXIS).

¹⁹⁵ *Id.* at § 3730(d)(2) (LEXIS).

¹⁹⁶ The ACO pre-participation waiver states, "Pursuant to section 1899(f) of the Act, section 1877(a) of the Act (relating to the physician self-referral law) and sections 1128B(b)(1) and (2) of the Act (relating to the Federal anti-kickback statute) are waived with respect to start-up arrangements that pre-date an ACO's participation agreement, provided all of the following requirements are met..." Medicare Program; Final Waivers in Connection with the Shared Savings Program; Final Rule, 80 Fed. Reg. 66742 (Oct. 29, 2015) (to be codified at 42 C.F.R. Chapter V).

¹⁹⁷ *Fraud and Abuse Waivers*, CTRS. MEDICARE & MEDICAID SERV., (last accessed August 12, 2016), <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html>

acquired physician or practice group's net income is less than the practice group's or physicians' expenses to the hospital or health system.

VII. "PRACTICE LOSSES" AS A BASIS FOR STARK VIOLATIONS

Many *qui tam* relators are pursuing alleged Stark violations based upon the "practice losses" theory. The reasoning behind this approach is relatively straightforward: it makes little economic sense to employ a provider whose expenses and compensation exceed his or her net professional services collections.¹⁹⁸ Therefore, since there must be another reason for employing the provider, the hospital or health system must be employing the provider for its anticipated volume or value of referrals – an alleged arrangement that is prohibited by Stark.¹⁹⁹ This theory was alleged in *United States ex rel. Drakeford v. Tuomey*, 792 F.3d 364 (4th Cir. 2015).

Tuomey was a non-profit hospital in a rural and underserved area in South Carolina.²⁰⁰ In 2000, after experiencing losses from physicians performing outpatient surgical procedures at offsite locations instead of at the hospital, Tuomey negotiated part-time employment agreements with various doctors.²⁰¹ During the negotiations, Tuomey sought numerous opinions from valuation experts regarding whether the arrangements violated Stark.²⁰² The terms of the arrangements consisted of a guaranteed portion of the salary as well as the physicians receiving a large productivity bonus based upon the physician's previous year's collections.²⁰³ Tuomey also paid the physicians' billing and collection costs, malpractice insurance and the physicians' share of employment taxes.²⁰⁴ Dr. Drakeford, who brought the initial *qui tam* suit against Tuomey, rejected Tuomey's employment offer, claiming that the agreements violated Stark due to the group's compensation exceeding their net collections.²⁰⁵ The jury found that Tuomey's employment contracts only violated Stark and not the False Claims Act, and the trial court ordered Tuomey to pay approximately \$39 million in damages to the U.S. government.²⁰⁶ Believing Tuomey had also violated the False Claims Act as well as the Stark Law, the government appealed the jury's verdict.

The 4th Circuit panel found that "Stark's volume or value standard can be implicated when aggregate compensation varies with the volume or value of referrals or otherwise takes into account the volume or value of referrals."²⁰⁷ Because the physician's base salary is adjusted each year depending upon the previous year's collections, and because the employed physicians received a vast majority of their salary by way of a productivity bonus, the court found that the employment arrangement unlawfully factored in the volume and value of the employed

¹⁹⁸ *Why Providers Must Address the Practice Losses Argument During Fraud and Abuse Legal Proceedings*, ADVISORY BOARD, (10:22 AM – December 11, 2015), <https://www.advisory.com/daily-briefing/2015/12/11/why-providers-must-address-the-practice-losses-argument>

¹⁹⁹ *Id.*

²⁰⁰ *U.S. ex rel. Drakeford v. Tuomey*, 792 F.3d 364, 370 (4th Cir. 2015).

²⁰¹ *Id.* at 370-371.

²⁰² *Id.*

²⁰³ *Id.*

²⁰⁴ *Id.*

²⁰⁵ *Id.*

²⁰⁶ *Id.* at 373.

²⁰⁷ *Id.* at 379, *citing* 42 C.F.R. § 411.354(c)(2)(ii).

physicians' referrals.²⁰⁸ Because of this, the court found that Tuomey's compensation arrangements violated Stark and the False Claims Act, and ordered Tuomey to pay \$237,454,195 to the government for its unlawful employment arrangement.²⁰⁹

As stated earlier, in his *qui tam* suit, Dr. Drakeford alleged the physician compensation arrangements were commercially unreasonable due to the physicians' compensation exceeding the group's net collections. While Drakeford asserted this claim, the Department of Justice used an expert witness at trial to advocate that "practice losses" can be a basis for determining that a compensation arrangement is commercially unreasonable.²¹⁰ Specifically, during the second trial, the Department of Justice's ("DOJ") expert witness, Ms. McNamara, testified to the following:

A. [Referring to Plaintiff's Exhibit 576] This is the amount of money Tuomey is losing on these practices from the beginning of the contract starting in 2005. So through 2005 and 2008 they lost \$4.4 million on these financial arrangements. And if you project that out to the term of the contract for those ten years they would lose approximately \$14 million. And the way the financial – the way that this is modeled, the compensation model is set up, they can never, ever make any money on these contracts. They will always lose money every single year for all ten years.

Q. How did that information impact your opinions on commercial reasonableness?

A. It was just one of the issues that I took into account when evaluating my commercial reasonableness. Are they protecting the financial interests of the hospital by entering into these arrangements? That – these material losses along with some other issues I had made me determine that the arrangements were not commercially reasonable.²¹¹

Further, Ms. McNamara stated:

A. [Regarding Plaintiff's Exhibit 577 which demonstrated the financial impact of the employment arrangements] So mathematically, no matter how efficient Tuomey was at managing the physician practices they would never, ever be able to make money. And on the average, it averaged anywhere from 171 percent to 231

²⁰⁸ "In sum, the more procedures the physicians performed at the hospital, the more facility fees Tuomey collected, and the more compensation the physicians received in the form of increased base salaries and productivity bonuses." *Drakeford, supra* note 200.

²⁰⁹ *Id.* at 389.

²¹⁰ Michael Peregrine, *The 'Practice Losses' Theory as an Enterprise Risk*, BNA INSIGHTS, 19 HFRA 924, (July 10, 2016). Transcript of Record at 975-81, *U.S. ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, No. 3:05-CV-02858-MJP (D.S.C.); David Pursell, *Commercial Reasonableness: The New Target*, J. OF HEALTH CARE COMPLIANCE 74, (March – April 2011); T. Reed Stephens and Tony Maida, *A Post-Tuomey Future: Huge Stark Law Hospital Settlements*, LAW360, (October 7, 2015).

²¹¹ Transcript for April 23, 2013 at 1155-1156, *U.S. ex rel. Drakeford v. Tuomey*, 976 F. Supp. 2d 776 (D. S.C. 2013), *aff'd*, 792 F.3d 364 (4th Cir. 2015).

percent of collections. So, again, absent those referrals one would have to question why a hospital would enter into this type of arrangement.²¹²

When cross-examined regarding what Ms. McNamara considers to be a commercially unreasonable compensation arrangement, she stated:

Q. Well, so then I understand that the compensation agreements do not have to be structured such that the hospital is guaranteed to make a profit to be considered commercially reasonable?

A. I believe that if a compensation arrangement is structured that the hospital is guaranteed to lose money then given the particular – in this case given these particular facts and circumstances I would say is not commercially reasonable. Now there are situations whereby the hospital owns and operates a free clinic, obviously, they need to enter an arrangement with the physician, and that's pretty much guaranteed to lose money. So there are different circumstances, where, yes, it's okay for a hospital to lose money on their physician practice, that's why each one is evaluated separately.²¹³

While the *Tuomey* court did not affirm the jury's verdict on the basis of the "practice losses" theory, one federal court has given credence to the theory. In *United States v. ex rel. Parikh v. Citizens Medical Center*, 977 F. Supp. 2d 654 (S.D. Tex. 2013), Drs. Dakshesh Parikh, Harish Chandna, and Ajay Gaalla alleged that Citizens Medical Center violated the Stark and Anti-Kickback Statute (and consequently, the False Claims Act) by "implementing bonus and fee-sharing programs for emergency room physicians working at the hospital who referred patients for cardiology treatment at Citizens, employing cardiologists at above-market salaries and providing them discounted office space, and demanding that Relators refer all their surgical patients to the hospital's exclusive cardiac surgeon, Dr. Yusuke Yahagi."²¹⁴

In denying Citizens' request to dismiss a particular Anti-Kickback Statute allegation, the court stated, "Even if the cardiologists were making less than the national median salary for their profession, the allegations that they began making substantially more money once they were employed by Citizens is sufficient to allow an inference that they were receiving improper remuneration. *This inference is particularly strong given that it would make little apparent economic sense for Citizens to employ the cardiologists at a loss unless it were doing so for some ulterior motive—a motive Relators identify as a desire to induce referrals* [emphasis added]."²¹⁵

After *Tuomey*, there was an increase in the *qui tam* suits alleging Stark violations based primarily on the "practice losses" theory. On September 4, 2015, Columbus Regional Medical Center entered into a settlement agreement where they agreed to pay \$35 million regarding various

²¹² *Id.* at 1159.

²¹³ Transcript for April 24, 2013 at 1220-1221, *U.S. ex rel. Drakeford v. Tuomey*, 976 F. Supp. 2d 776 (D. S.C. 2013), *aff'd*, 792 F.3d 364 (4th Cir. 2015).

²¹⁴ *U.S. ex rel. Parikh v. Citizens Medical Center*, 977 F.Supp.2d 654, 660 (S.D. Tex. 2013).

²¹⁵ *Id.* at 671.

Stark and False Claim Act allegations.²¹⁶ The *qui tam* relator in this matter filed two complaints. In his first *qui tam* complaint, the Relator’s primary allegation was that Columbus up-coded its claims.²¹⁷ The government did not intervene in the Relator’s first complaint.²¹⁸ The Relator then filed a second *qui tam* complaint in which he alleged that Columbus’s physician compensation agreements were neither commercially reasonable nor were they of fair market value due to the employed physician’s compensation exceeding its net collections.²¹⁹ The government intervened in this matter, and instead of suffering a fate similar to Tuomey, Columbus opted to settle the case for \$35 million.²²⁰

Another settlement that involved the “practice losses” theory was that of North Broward Hospital District. In this matter, “the relator alleged that the compensation was [in] excess of fair market value and was commercially unreasonable because it was over the 90th percentile of total cash compensation as published in physician compensation surveys and generated substantial practice losses for Broward.”²²¹ It is unclear from the settlement agreement on exactly which allegations the DOJ’s violations were based; however, as stated above, the DOJ has in the past argued that the presence of practice losses indicates that a compensation arrangement is commercially unreasonable.²²² Similar to Columbus Regional Medical Center, the risk presented by Stark and the False Claims Act was too high to proceed to trial, and on September 11, 2015, Broward opted to settle the allegations for \$69.5 million.²²³

Finally, in the largest settlement in healthcare fraud litigation history, on September 21, 2015, Adventist Health System “agreed to pay \$118.7 million to resolve allegations that it violated the False Claims Act by submitting claims in violation of the Stark Law and by miscoding claims.”²²⁴ Two complaints were filed by *qui tam* relators alleging numerous Stark violations, including that “compensation paid to physicians and non-physician practitioners was above fair market value, as evidenced by consistent physician practice losses.”^{225, 226} The Department of

²¹⁶ Tony Maida, *Huge Stark Law Hospital Settlements and Physician Culpability – The New Normal Post-Tuomey*, MCDERMOTT WILL & EMERY, (September 25, 2015), <https://www.mwe.com/en/thought-leadership/publications/2015/09/huge-stark>

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ *Id.*

²²⁰ *Id.*

²²¹ The *qui tam* relator made other allegations such as stating that the arrangement would only be self-sustaining if one took into account the hospital facility fees, and that “Broward pressured physicians to limit charity care, even though Broward is a public entity.” *Id.*

²²² *Id.*

²²³ *Id.*

²²⁴ Linda Baumann and Samula Cohen, *Stark Law is Coming: Adventist Health System Pays \$118.7 Million in Third Large September Settlement*, HEALTH CARE COUNSEL, (October 2, 2015), <http://healthcarecounselblog.com/articles/stark-law-coming-adventist-health-system-pays-1187-million-third-large-september-settlement>

²²⁵ *Id.*

²²⁶ “The Adventist hospitals kept careful track of the value of the referrals the physician employees made to the hospitals, according to the complaint. Losses suffered by the hospitals were due in large part to overcompensation of physicians, the complaint said. For instance, one doctor at Park Ridge was marked in Adventist financial records as a “recurring issue” because he needed to bring in approximately \$70,000 per month in billings for the hospital to break even on the compensation Adventist paid him, but he was bringing in only about \$57,000 per month.” *Adventist Health System’s 118.7 million settlement stated with Phillips & Cohen’s whistleblower lawsuit*, PHILLIPS

Justice indicated its intention to continue prosecuting providers based upon the “practice losses” theory by stating:

Would-be violators should take notice that my office will use the False Claims Act to prevent and pursue health care providers that threaten the integrity of our healthcare system and waste taxpayer dollars. Companies that financially reward physicians in exchange for patient referrals – as the government contended in this case [Adventist Health System] – undermine the physicians’ impartial medical judgment at the expense of patients and taxpayers, said Special Agent in Charge Derrick L. Jackson of the U.S. Department of Health and Human Services Office of Inspector General (HHS-OIG) in Atlanta. We will continue to investigate such wasteful business arrangements.²²⁷

It is very concerning that the government and at least one federal court, who assumedly are quite familiar with health system income statements, and consequently the reasons these income statements are often in the negative as it pertains to employed physicians, would endorse the “practice losses” theory.²²⁸ As stated earlier, there are many legitimate business reasons hospitals and health systems incur losses when employing physicians, such as the hospital or health system being required to pay competitive salaries, benefits, and other ancillary costs such as malpractice insurance and the acquired practice’s employment taxes.²²⁹ If the health system did not pay these amounts, the hospital or health system would have difficulty recruiting quality physicians.²³⁰

Endorsing the “practice losses” theory is also very misguided. By stating that it does not make economic sense to employ a physician practice group at a loss, the DOJ and the *Parikh* court demonstrate a fundamental misunderstanding of the health care industry and its governing reimbursement statutes (such as the ACA and MACRA). The DOJ is treating the healthcare industry like any other industry in the U.S. economy when in reality the healthcare industry is incredibly unique, as demonstrated in Section V(B), *supra*.

In no other industry does the government heavily scrutinize how an entity receives payment for its services, nor do organizations in other industries receive payment from a few select sources (health insurance and governmental payers such as Medicare), all of whom have different rules

& COHEN, LLP, (September 21, 2015), <http://www.phillipsandcohen.com/2015/Adventist-Health-System-s-118-7-million-settlement-started-with-Phillips-Cohen-s-whistleblower-lawsuit.shtml>.

²²⁷ *Adventist Health System Agrees to Pay \$115 Million to Settle False Claims Act Allegations*, U.S. DEPT. JUST., (September 21, 2015), <https://www.justice.gov/opa/pr/adventist-health-system-agrees-pay-115-million-settle-false-claims-act-allegations>

²²⁸ While the government’s expert witness testified it may be acceptable for a hospital or health system to lose money on its employed physician practice, it is clear from Ms. McNamara’s testimony that those circumstances would only be acceptable if the hospital were operating a free clinic or were otherwise devoting that practice to predominantly serve the indigent. Ms. McNamara failed to take into account the economic realities shared by all employed physician practices as discussed in Section V(B), *supra*. See *supra* note 213.

²²⁹ “State-owned hospitals have to pay employees state benefits, which can rise to 50% of compensation.” *Controversy Over Losses on MDs Heats Up as Adventist Settles FCA Case for \$115M*, AIS HEALTH, (September 28, 2015), <https://aishealth.com/archive/rmc092815-03>.

²³⁰ It has been estimated that only 20% of hospital-employed physician practices are profitable based upon their professional collected fees. *Id.*

regarding how and by what amount the providers are reimbursed for services provided to patients. Part of the reason that practice losses occur for hospital providers is due to adverse payer rates in hospitals and health systems as opposed to small private practices. Unlike other industries who directly control how much money is received for their products or services, the hospital or health system cannot influence how much reimbursement it receives from its various payers, especially payment received from Medicare and Medicaid since those reimbursement rates are set by the U.S. government as well as the individual states.

Perhaps the biggest concern with the “practice losses” theory is that it is predicated on a volume-based reimbursement model.²³¹ Providers are no longer being paid strictly on the number of procedures they perform. Their payments are derived from the effectiveness and cost-efficiency of their treatment. As stated earlier, this requires alignment among various providers, many of whom would not be employed by hospitals and health systems if not for the competitive salary and benefits offered by the hospitals or health systems.²³² Section V(B), *supra*, demonstrates that employing physicians almost always results in the hospital or health system incurring a practice loss.

Further, as demonstrated in Section V(A), *supra*, providers cannot provide value-based care by operating as single entities. There must be alignment and integrated care with other providers to monitor health outcomes, reduce costs and provide value-based care. In reality, a hospital or health system may employ a physician or practice group because that practice group will help the hospital or health system develop a service line that serves a charitable mission of the hospital or health system. While the arrangement may not be commercially reasonable when considered in a vacuum, the employment arrangements could be considered commercially reasonable when considering the hospital or health system’s charitable mission to provide various types of medical care to the community, especially if the charitable mission requires the provider to provide charity or low-cost care to those in the community.²³³ This interpretation is in line with CMS’ own guidance on commercial reasonableness in the context of Stark, since this guidance implies that the entire transaction must be considered when evaluating commercial reasonableness.²³⁴ The “practice losses” theory may have been viable under a fee-for-service reimbursement model, but the “practice losses” theory is now incompatible with the policy goals and the expected alignment necessities of a value-based reimbursement scheme.

²³¹ Eric Gordon and Daniel Melvin, *Health System Practice ‘Losses’ Make Headlines, Plaintiffs Make New Stark ‘Law,’* BNA’S HEALTH FRAUD REPORT 5, (November 25, 2015), available at <https://www.mwe.com/~media/files/experience/health-care-resource-center/topical-analysis/healthsystempracticelossesmakeheadlines.pdf>

²³² “Where the purpose of physician employment is to create an integrated delivery system designed with an eye toward the triple aim and evolving payment structures that contemplate close collaboration between health system and physicians, employment that generates ‘losses’ may nevertheless be commercially reasonable apart from referrals.” *Id.* at 4.

²³³ See *The Threshold of Commercial Reasonableness*, QUICKREAD, (June 25, 2014), <http://quickreadbuzz.com/2014/06/25/threshold-commercial-reasonableness/>.

²³⁴ See *supra* notes 185 - 186.

VIII. PROPOSED CHANGES TO THE STARK LAW

In light of *Tuomey*, the Columbus Regional Medical Center settlement, the North Broward Hospital District settlement and the Adventist Health System settlement, it is clear that changes to Stark are necessary. First and foremost, Congress should amend Stark to require that in order to violate Stark, one must act in a willful and intentional manner. Originally, Stark was meant to guard against only those “with bad intentions who are soliciting referrals, and offering kickbacks and special rates,” according to Fortney ‘Pete’ Stark, the statute’s sponsoring congressman.²³⁵ However, since Stark is a strict liability statute, those that structure compensation arrangements in a manner that does not intend to violate Stark are just as guilty as those who are intentionally attempting to solicit unlawful referrals. Amending the intent requirement would help restore the law to its original purpose: protecting the public from those providers who are actively seeking to defraud the Medicare program.

The second proposed change regards the fraud and abuse waivers instituted by CMS. These waivers only apply to particular CMS-regulated programs such as the BCPI and the MSSP. However, as discussed in Section V(A), *supra*, to take advantage of the physician reimbursement reforms in MACRA, providers will need to align, merge, and otherwise integrate their care with one another. If these alignment vehicles do not fall within one of the models protected by the CMS-regulated programs, the aligned-providers will be at risk for violating Stark. To protect providers who are trying to align and provide more value to their patients, CMS should expand the waivers to those providers who are merging, aligning or otherwise integrating their care with other providers in attempts to take advantage of the payment reforms initiated by the ACA and MACRA. Expanding these waivers would demonstrate that the government is placing more importance on achieving the ACA’s triple aim goals rather than prosecuting providers for minor Stark violations that result in the payment of millions of dollars in penalties.

The third proposed change that should occur involves the Stark exceptions. Congress should add an exception that permits those forming an integrated care arrangement to do so as long as the provider implements the following process in regards to their physician compensation package: “(1) the authorized body of the organization composed entirely of individuals who do not have a conflict of interest with respect to the compensation arrangement approves of the agreement in advance of its implementation”;²³⁶ (2) an assessment as to the commercial reasonableness and fair market value of the agreement is performed by an independent third party; and (3) “the authorized body adequately documents the basis for its determination concurrently with making said decision.”²³⁷ Further, the exception should state that the “practice losses” theory cannot be a basis for a Stark violation, given the preceding analysis demonstrating that practice losses in and of themselves are not indicative of a hospital or health system entering into a commercially unreasonable employment arrangement.

²³⁵ Joe Carlson, *Pete Stark: Repeal the Stark Law*, MODERN HEALTHCARE, (August 2, 2013), <http://www.modernhealthcare.com/article/20130802/blog/308029995>

²³⁶ While a similar rule is already in place for non-profit hospitals, providing a similar application of the rule for other hospitals would be beneficial. See *e.g.*, 26 C.F.R. § 4958-6(a)(1) (2016).

²³⁷ *Id.* at § 4958-6(a)(3) (2016).

Implementation of this process would create a rebuttable presumption that the compensation is of fair market value and is commercially reasonable. The presumption could be rebutted by CMS, the Office of Inspector General, DOJ, or other *qui tam* relators by demonstrating by clear and convincing evidence that the compensation terms are not of fair market value and/or that the terms are not commercially reasonable.²³⁸ This process should also be added to Stark's employment exception so as to guard against outcomes similar to Columbus and Broward. This solution is not perfect; not every organization will be willing to pay an independent party to perform a fair market value and commercial reasonableness evaluation. There could also be questions as to whether an assessment was carried out by a party that was truly independent.

Undoubtedly, this will allow some minor fraudulent arrangements to continue. However, the risks associated with this option are significantly outweighed by the benefits. Given CMS's unwillingness to expound upon and give meaningful guidance as to which arrangements are of fair market value or are commercially reasonable, this option would assist providers by allowing them to determine whether a compensation arrangement is compliant with Stark. This option would not act as a get-out-of-jail-free card since relators could rebut the presumption of fair market value and commercial reasonableness by clear and convincing evidence.

Finally, prohibiting the "practice losses" theory from being the primary basis for a Stark violation would not hinder investigations into whether an employment agreement is of fair market value or commercial reasonableness. The DOJ and *qui tam* relators can demonstrate an agreement is not of fair market value by analyzing a provider's work RVU^{239, 240} and compensation data with similar data provided by the three major productivity and compensation surveys.²⁴¹

Commercial reasonableness can also be analyzed by determining whether the arrangement makes general business sense in light of the mission of the hospital and the goals of the ACA and MACRA- *i.e.*, whether the services provided are essential to the aims and strategies of the hospital or health system, whether the arrangement will develop a service line of the hospital or health system, and whether this arrangement will duplicate service lines across the hospital or

²³⁸ Clear and convincing evidence is defined as "Evidence that leaves you with a firm belief or conviction that it is highly probable that the factual contentions of the claim or defense are true. This is a higher standard of proof than proof by a preponderance of the evidence, but it does not require proof beyond a reasonable doubt." *1.4 Burden of Proof – Clear and Convincing Evidence*, U.S. Ct. 9TH. CIR., (last accessed August 12, 2015), <http://www3.ce9.uscourts.gov/jury-instructions/node/48>.

²³⁹ "Relative Value Units ("RVU") were developed by [CMS] to establish a value for each physician service categorized by current procedural terminology code." Charles Kentros and Charles Barbato, *Using Normalized RVU Reporting to Evaluate Physician Productivity*, HEALTHCARE FIN. MGMT. ASS'N, (Thursday, August 1, 2013), <http://www.hfma.org/Content.aspx?id=18548>. The goal of the RVU is to measure the amount of resources used when performing procedures. RVUs help drive Medicare Part B reimbursement.

²⁴⁰ RVUs are split into three components: "work RVU, practice expense RVU, and the malpractice expense RVU." The work RVU is one of the better known measurements of physician productivity. The work RVU "is calculated based on an estimate of time and effort expended by a provider in performing the procedure or delivering the service associated to the specific procedure code to which the RVU values are assigned." Frank Cohen, *The Basics of Making RVUs Work for Your Medical Practice*, PHYSICIANS PRACTICE, (July 1, 2014), <http://www.physicianspractice.com/rvu/basics-making-rvus-work-your-medical-practice>.

²⁴¹ Each year compensation and productivity surveys are produced by the Medical Group Management Association ("MGMA"), the American Medical Group Association ("AMGA"), and Sullivan & Cotter Associates which analyze various provider compensation and productivity data.

health system. *Qui tam* relators and government officials can still prosecute Stark violators with an equal amount of fervor without taking into account the amount of practice losses a health system incurs through its employment arrangements.

IX. CONCLUSION

With the passage of the ACA and MACRA, the transition from a reimbursement model based on the number of procedures performed to a value-based payment model is underway. Small practices and solo practitioners will need to consider various integration and alignment options, including IPU, CINs, ACOs, and other integrated care models to be able to monitor health outcomes adequately and provide value-based care. However, despite the U.S. government's clear policy shift towards a value-based reimbursement model, providers who attempt to form or align with integrated care models are at risk for violating Stark because at least at the outset (and likely for the duration of the arrangement), these arrangements will more than likely not be profitable. The government's inclination to pursue hospital and health system providers on the basis of practice losses demonstrates an outdated understanding of the healthcare industry in this new era of value-based reimbursement.

Prosecuting organizations for violating Stark based solely upon practice losses is incompatible with the policy goals enunciated in the ACA and MACRA. To be able to transition fully from a reimbursement model based on the number of procedures performed to a value-based payment model, CMS should implement a documentation and valuation method that allows providers to establish a presumption that their physician compensation arrangements are commercially reasonable and that they are of fair market value. Failure to implement this and other changes discussed above will prevent the U.S. healthcare system from fully transitioning to the value-based reimbursement model.

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