Testimony Before the Committee on Finance

United States Senate

Examining the Stark Law: Current Issues and Opportunities

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Mr. Chairman, Ranking Member Wyden, and members of this distinguished Committee, it is an honor for me to participate in this hearing and to provide my thoughts and insights regarding the Stark Law. I am a partner at the law firm of Crowell and Moring, where I provide advice and counsel to health care entities engaged in new health care delivery models. Prior to joining Crowell & Moring, I spent 11 years working at the U.S. Department of Health & Human Services ("HHS"). I served as the Director of the Division of Technical Payment Policy at CMS for my last four years at HHS where I was responsible for Stark Law policy and other Medicare payment issues, including those related to the implementation and creation of new value-based payment models created by the Patient Protection and Affordable Care Act of 2010 ("ACA").[1] I am here today in my own capacity and not on behalf of my firm. My views do not represent those of any client or other organization.

I. Stark Law Reform Is Overdue and Necessary

The fundamental question at issue here is whether the Stark Law as it is currently drafted is precisely tailored to minimize unwarranted utilization resulting from certain financial relationships and is a net positive to patients/taxpayers. And if not, what reform is necessary to

[1] My full biography may be found at https://www.crowell.com/Professionals/troy-barsky.

remove extraneous aspects that unnecessarily drive up health care industry, and ultimately, patient costs. As I will discuss in greater detail below, the Stark Law has evolved from the simple objective of removing certain financial incentives from medical decision-making into a tortured web of confusing standards, ambiguous and conflicting definitions, and volumes of regulations that require countless lawyers and valuation experts to ensure compliance.

Compliance then is not only excessively costly, but unachievable as a practical matter. And because Stark is a strict liability statute, there is no need to intend to violate the law. If you fail to meet any of its technical requirements even inadvertently, a health care entity is subject to millions or tens of millions of dollars in payments and penalties, program exclusion, and False Claims Act ("FCA") [2] liability. And yet compliance with many of the elements of the Stark Law – such as requiring a signature on every written arrangement – have nothing to do with fraud, high quality service for patients, or protection of the Medicare program.

With the passage of the ACA[3] and the Medicare Access and CHIP Reauthorization Act of 2015[4] ("MACRA"), the Stark Law is now also an obstacle to the implementation of health care delivery and reimbursement reform. The goals of new payment models emanating from the ACA and MACRA are diametrically opposed to the requirements of the Stark Law. New health care payment models are designed to integrate providers clinically and financially and compensate physicians on value and quality care, while the Stark Law is intended to keep parties financially

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[2] 31 U.S.C. § 3729-3733; *see, e.g., United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc*., No. 13-2219 (4th Cir. July 2, 2015); U.S. Department of Justice Settlement Announcement (Oct. 16, 2015): https://www.justice.gov/opa/pr/united-states-resolves-237-million-false-claims-act-judgment-against-south-carolina-hospital; *United States ex rel. Baklid-Kunz v. Halifax Hospital Medical Center, et al.,* No. 09-cv-1002 (M.D. Fla.); U.S. Department of Justice Settlement Announcement (March 11, 2014): https://www.justice.gov/opa/pr/florida-hospital-system-agrees-pay-government-85-million-settle-allegations-improper.

[3] The Patient Protection and Affordable Care Act (Pub. L. No. 111–148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152) are collectively known as the "Affordable Care Act."

[4] Pub. L. No. 114-10.

separated. Further, this shift from volume-based (fee-for-service) to value-based payment systems reduces the underlying financial incentives believed to negatively impact medical decision-making for which the Stark Law was initially enacted to combat. As we move away from the fee-for-service world, the need and utility of the Stark Law continues to diminish. Therefore, Congress should consider repealing, in whole or in part, and replacing the law. For example, a balance of harms analysis would support keeping the ownership prohibition, but removing the compensation prohibition.

Absent repeal, there are common sense reforms that should be implemented to minimize the Stark Law's unjustified, onerous burden. First, the overwhelming vast majority of providers want to comply with the law, but struggle because of ambiguous critical terms. Making bright line rules that providers can follow and expanding CMS's authority to provide guidance through advisory opinions will greatly assist providers in complying. Second, limit the consequences of purely technical violations of the Stark Law. Either remove the technical requirements completely, or ascribe only a monetary penalty for technical violations rather than conditioning Medicare payment and exposing providers to FCA liability based on mere technicalities. Third, lower CMS's heightened standard of "no program or patient abuse" for promulgating new regulatory exceptions to the general prohibition.

Stark Law reform is also necessary to remove barriers to implementing health care reform. The ACA allowed for broad Stark exceptions under the law. Give greater authority to the Secretary to expand this waiver authority in a unified manner to allow for more innovative payment models as opposed to the piecemeal, constrained approach that is now developing. Additionally, Congress should amend the statute to limit loophole exceptions that are contrary to health care reform efforts. For example, the in-office ancillary services exception continues to

allow for in-office referrals and overutilization making it less likely these practices will move to an integrated care model. I recommend closing this exception to incent providers to move to value-based payment models. The Stark Law will continue to be a barrier if we do not modernize the law to reasonably protect against patient and program abuse while allowing for innovation.

II. The Basic Construction and History of the Stark Law

A. Broad Prohibition on Referrals

The Physician Self-Referral Law, or the Stark Law, found in Section 1877 of the Social Security Act,[5], consists of a 30-year series of statutory and regulatory enactments reflecting the complexity of the area for which it applies. Unless an exception applies, the Stark Law provides that if (1) a physician (or an immediate family member of a physician) has a direct or indirect financial relationship with an entity, the physician may not make a referral to the entity for the furnishing of designated health services ("DHS") for which payment may be made under Medicare, and (2) the entity may not present (or cause to be presented) a claim to the federal health care program or bill to any individual or entity for DHS furnished pursuant to a prohibited referral.[6]

The Stark Law is applicable when each of the following are involved: a physician (or a family member of a physician), a "financial relationship," and a "referral." Determining the existence of a "financial relationship" or a "referral" are complex inquiries. A financial relationship is defined as any direct or indirect (a) ownership or investment interest or (b) compensation arrangement by or between a physician (or an immediate family member of the

[5] Section 1877 of the Social Security Act.

[6] *See* Section 1877(a)(1) of the Social Security Act; 42 C.F.R. §411.353(a).

physician) in the entity providing the DHS.[7] Indirect ownership, for example, brings entire chains of ownership into the province of Stark.

B. Exceptions to the Broad Prohibition

There are numerous statutory and regulatory exceptions to this general prohibition, which can be grouped into the following general categories:

- General Exceptions to the Ownership and Compensation Arrangements Prohibitions[8]
- Permitted Ownership and Investment Interests[9]
- Permitted Compensation Arrangements[10]
- The Innocent Entity Exceptions and Related State-of-Mind Issues[11]
- Waivers for Accountable Care Organizations ("ACOs") in connection with Shared Savings Program[12] and other Center for Medicare and Medicaid Innovation ("CMMI") Models[13]

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[7] Section 1877(a)(2) of the Social Security Act.

[8] Several exceptions apply to both ownership or investment arrangements and compensation arrangements, *e.g.,* physicians' services provided by a physician in the same group practice as the referring physician are exempted by Section 1877(b)(1) of the Social Security Act.

[9] For example, ownership of investment securities purchased on terms available to the general public and listed on certain recognized exchanges, and exceed a specific level of average shareholder equity over 3 fiscal years are exempted under Section 1877(b)(2) of the Social Security Act.

[10] For example, rental of equipment under certain circumstances is exempted by Section 1877(e)(1)(B) of the Social Security Act.

[11] For example, an exception applies when the entity did not have actual knowledge or act in reckless disregard of deliberate ignorance of the identity of the referring physician, and the claim complies with all other federal and state laws under 42 C.F.R. § 411.353(e).

[12] For example, waivers under the Patient Protection and Affordable Care Act apply to arrangements within "accountable care organizations." *See* 80 Fed. Reg. 66726.

[13] All available fraud and abuse waivers for CMS models and programs, including those administered by CMMI, are listed here: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html. To date, the HHS Secretary has established waivers for the following programs:

•Pioneer Accountable Care Organization ("ACO") Model;

(Continued...)

C. The Stark Law Was Enacted to Address Possible Overutilization Due to Financial Interests

At its core, the Stark Law was intended to address the concern that physicians paid on a fee-for-service basis will perform or refer more or unnecessary services to earn more income. [14] The impetus behind the Stark Law was a documented positive correlation between physicians' financial ties and increased utilization of services.[15] As such, Congress sought to prohibit referrals to entities with which physicians or physicians' family members had a financial relationship in order to minimize or remove the possible impact of a financial incentive.

As the issue of physician self-referral was gaining attention in the 1980s, the HHS Office of Inspector General ("OIG") and the Government Accountability Office ("GAO") engaged in separate studies examining the relationship between physician ownership and referrals. Both the OIG and GAO studies examined the occurrence of self-referral involving various types of medical services, and both agencies determined that physician self-referral most significantly increased utilization of clinical laboratory services.[16] Congress concluded that such

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•Bundled Payment for Care Improvement ("BPCI") Models;

•Health Care Innovation Awards ("HCIA") Round Two;

•Comprehensive ESRD Care Model;

•Comprehensive Care for Joint Replacement ("CJR") Model;

•Next Generation ACO Modell

•Oncology Care Model; and

•Medicare Shared Savings Program ("MSSP").

[14] 66 Fed. Reg. 856, 859 (January 4, 2001) (describing the correlation found between financial ties and increased utilization as the basis for the Stark Law).

[15] *See* 66 Fed. Reg. 856, 859 (January 4, 2001).

[16] The OIG surveyed utilization patterns of physician owners of independent clinical laboratories, independent physiological laboratories, and durable medical equipment suppliers. The OIG found that physician self-referral related to laboratory tests was associated with a 45% increase in utilization, though the increased utilization with the other entity types was less significant. OIG-Office of Analysis and Inspections, *Report to Congress, Financial Arrangements Between Physicians and Health Care Businesses* 3 (1989). The GAO found that physician owners tended to order more, and more costly, laboratory services while ordering fewer, but more costly,
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overutilization was undesired, though neither agency's study examined the medical necessity, or lack thereof, of the specific tests ordered.[17]

1. Stark I Only Addressed Financial Relationships with Clinical Laboratory Services' Entities

In response, Stark I was created by the Omnibus Budget Reconciliation Act of 1989,[18] which became effective January 1, 1992. Stark I prohibited a physician (or an immediate family member) who had a financial relationship with a clinical laboratory services entity from referring Medicare beneficiaries to the entity, unless an exception applied. In addition, it prohibited the lab from billing for any services furnished pursuant to such referrals.

Congress actively decided[19] against applying the ban of physician self-referral beyond clinical laboratory services to a broad array of medical services for which there was no evidence of overutilization resulting from self-referral.[20] Since the agency reports indicated overutilization of only clinical laboratory services, this first legislative enactment targeted financial relationships with only those entities.

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imaging services. *Medicare, Referring Physicians' Ownership of Laboratories and Imaging Centers*, *Hearings on H.R. 939 before the Subcomm. on Health of the H. Comm. on Ways & Means*, 101st Cong. 9 (1989).

17 OIG-Office of Analysis and Inspections, *Report to Congress, Financial Arrangements Between Physicians and Health Care Businesses* 3 (1989); *Medicare, Referring Physicians' Ownership of Laboratories and Imaging Centers, Hearings on H.R. 939 before the Subcomm. on Health of the H. Comm. on Ways & Means*, 101st Cong. 9 (1989).

18 Pub. L. No. 101-239, 103 Stat. 2106 (1989) (Stark I was enacted in the Ethics in Patient Referrals Act).

19 The original federal bill prohibiting self-referrals would have applied to a broad array of health-related goods and services. H.R. 5198, § 2(a) 100th Cong., 2d Sess. (1988). The bill was introduced by Representative Fortney (Pete) Stark (D-Cal.). *Id*.

20 *Physician Ownership/Renewal Arrangements, Hearing before the Subcomm. on Health and the Subcomm. on Oversight, H. Comm. on Ways & Means*, 102nd Cong. 6 (1991) (statement of Rep. Pete Stark, Chariman, Subcomm. on Health, H. Comm. on Ways & Means).

2. Stark II's Statutory Amendments Broadened the Self-Referral Ban to a Wide-Array of Health Services

Only a few years later, in the second legislative enactment[21] Congress expanded the clinical laboratory prohibition to a number of "designated health services" (DHS). This expansion was based on the latest studies which associated overutilization of several additional services with self-referral[22] as well as Former Representative Pete Stark's ongoing efforts to prevent "turning a physician's decision to refer a patient into a marketable commodity."[23]

Stark II, as part of the Omnibus Budget Reconciliation Act of 1993,[24] expanded the physician self-referral ban to the following DHS:[25]

- Clinical laboratory services (Stark I);
- Physical therapy services;
- Occupational therapy services;
- Radiology or other diagnostic services, including MRI, CAT scans, and ultrasound services;
- Radiation therapy services;
- Durable medical equipment;
- Parenteral and enteral nutrients, equipment, and supplies;

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21 Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 312 (1993).

22 *See, e.g.*, Jean M. Mitchell & Elton Scott, *Physician Ownership of Physical Therapy Services*, 268 Journal of the Am. Med. Ass'n 2055 (1992); Jean M. Mitchell & Jonathan Sunshine, *Consequences of Physicians' Ownership of Health Care Facilities — Joint Ventures in Radiation Therapy*, 327 The New England Journal of Med. (1992).

23 *See Physician Ownership and Referral Arrangements And H.R. 345, "The Comprehensive Physician Ownership and Referral Act of 1993", Hearings before the Subcomm. On Health, H. Comm. on Ways & Means* , 103rd Cong. (1993); *Physician Ownership/Renewal Arrangements, Hearing before the Subcomm. on Health and the Subcomm. on Oversight, H. Comm. on Ways & Means*, 102nd Cong. 6 (1991).

24 Pub. L. No. 103-66, 107 Stat. 312 (1993).

25 Section 1877(h)(6) of the Social Security Act.

- Prosthetics, orthotics, and prosthetic devices;
- Home health services;
- Outpatient prescription drugs;
- Inpatient and outpatient hospital services.

3. CMS has Created a Complex and Ever-Growing Body of Regulations to Implement the Stark Law

The Centers for Medicare and Medicaid Services (CMS) is responsible for interpreting the Stark Law and issuing regulations and other guidance. The regulatory definition and exception framework and interpretation thereof is ever-changing. The final rules are codified at 42 C.F.R. § 411.350–411.389.[26] Below, we provide a list of the most substantive regulatory promulgations, but there are many others. All of these regulatory and other preamble guidance must be read, studied, and understood in order to comply with the Stark Law.

- Stark I regulations, August 14, 1995. [27] The first round of regulations was promulgated in connection with Stark I. However, since Stark II maintained the same general prohibitions and some of the exceptions of Stark I, the regulations implementing Stark I were applied by CMS to the other DHS subject to Stark II.
- Stark II Phase I regulations, January 9, 1998 (proposed rule).[28] These proposed regulations focused on applying many of the existing provisions of the 1995 rule to additional DHS as well as updating others in accordance with the changes to the Stark Law enacted in the Omnibus Budget Reconciliation Act of 1993 and the Social Security Act amendments from 1994. It also provided additional

[26] *See* Significant Regulatory History, Physician Self-Referral, Centers of Medicare and Medicaid Services, https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Significant-Regulatory-History.html.

[27] 60 Fed. Reg. 41914, 41916 (Aug. 14, 1995).

[28] 63 Fed. Reg. 1659 (January 1, 1998).

explanation of CMS's views on the appropriate application of the various exceptions and the scope of the referral prohibition.

- Stark II Phase I regulations, January 4, 2001 (interim final rule). [29] These regulations specifically interpreted and implemented Stark II and offered guidance concerning its interpretation and application to a wide range of arrangements and relationships. Because the 1998 proposed rules introduced restrictive interpretations, the 1998 proposed rules were received critically and received extensive comments that CMS interpretation was too conservative. These regulations provided guidance regarding the service-based exceptions that apply to both the ownership or investment interests and compensation arrangements, like the in-office ancillary services exception.
- Stark II Phase II regulations, March 26, 2004 (interim final rule). [30] This regulation addressed remaining portions of the statute not covered under Phase I, including reporting requirements and sanctions. CMS attempted to clarify the exceptions to compensation arrangements and added additional exceptions for financial relationships that posed no risk of fraud and abuse. In particular, CMS added a "fair market value" exception.
- Stark II Phase III regulations, September 5, 2007. [31] Phase III regulations interpreted provisions relating to direct and indirect compensation arrangements.

[29] 66 Fed. Reg. 856 (January 4, 2001).

[30] 69 Fed. Reg. 16054 (March 26, 2004).

[31] 72 Fed. Reg. 51012 (Sept. 5, 2007).

CMS indicated that all three phases of Stark II regulations "are intended to be read together as a unified whole."

- Stark II, Inpatient Prospective Payment System ("IPPS") regulations, August 19, 2008. [32] These regulations expanded the definition of the term "entity" to include those actors that "perform" services billed as DHS. Further, the regulations limited the ability of entities to utilize percentage and per-click compensation formulas for equipment and space lease arrangements.
- Stark II, IPPS regulations, October 30, 2015.[33] These regulations clarified the definition of "remuneration" and the writing requirements of compensation exceptions. Furthermore, CMS created an exception for timeshare leases.

Despite the amount of time and money that goes into development, interpretation, implementation, and verifying compliance with the exceptions, sometimes it remains unclear whether the intended purpose of an exception was achieved, *e.g.*, the "whole hospital" exception. The "whole hospital" exception, since Stark I's passage, exempted arrangements where physicians have an interest in an entire hospital – whether a general acute care or specialty hospital.[34] Since DHS includes inpatient and outpatient hospital services, absent an exception, referrals by a physician retaining an interest in a hospital would be prohibited. Over many years, some constituents sought to restrict this particularly broad exception, especially given a perception that specialty hospitals appropriate high-margin surgeries from general acute care hospitals. As a result of such efforts, in 2003, Congress imposed an 18-month moratorium

[32] 73 Fed. Reg. 48434 (Aug. 19, 2008).

[33] 80 Fed. Reg. 70885 (Oct. 30, 2015).

[34] Section 1877(d)(3)(A) of the Social Security Act; 42 C.F.R. § 411.356(c). The exception requires (1) the ownership or investment interest must be in the hospital itself and not merely in a "subdivision" of the hospital; (2) the referring physician must be "authorized" to perform services at the hospital.

prohibiting physicians from referring a Medicare patient to any specialty hospital in which the physician had an ownership interest. Later, the ACA limited the whole hospital exception's application to only those hospitals that are "grandfathered" in, *i.e.*, hospitals with physician ownership and an effective Medicare provider number before December 31, 2010.[35] Further, to avoid circumvention by increasing physician-ownership of exempted hospitals, the law and the regulations strictly limit the expansion of space or service of any grandfathered hospitals.[36] And still, constituents on both sides of this issue continue to debate whether this exception and the imposed limitations on the exception effectively achieve their intended goals.

C. Strict Liability for Stark Law Violations Creates Staggering Consequences

Any proposed arrangement that involves a financial relationship with a physician who refers DHS that are payable by Medicare must be evaluated for compliance with every aspect of an exception to ensure the referral complies with Stark. Most exceptions have very detailed and technical requirements, including signatures on agreements and written contracts. Failure to comply with any of these requirements means an automatic violation of the Stark Law. Given the difficult and lengthy processes necessary to make a Stark Law compliance determination compared with the practical demands and structure of the health care industry, non-compliance is inevitable even for the best intentioned providers. This is troublesome for a number of reasons, such as the steep consequences for non-compliance.

The Stark Law is a condition of Medicare payment: failure to comply with the Stark Law means a denial of Medicare payment for any claims submitted pursuant to the prohibited referral. In addition, sanctions, including civil monetary penalties and potential program exclusion, may

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[35] ACA § 6001(a)(3) added section 1877(i)(1) of the Social Security Act which sets out conditions that a facility must meet to continue to use the whole hospital exception.

[36] 42 C.F.R. §411.362 (b)(2).

be imposed against any person that submits or causes such claims to be submitted or fails to make a timely refund of any amounts collected. It is now well-established that a violation of the Stark Law can lead to FCA liability. This liability for submitting a false claim or causing a person or entity to submit a false claim is the most significant risk that health care providers face under the Stark Law. A violation of the FCA results in potential treble damages and civil penalties for every "tainted" claim.

The penalties under the Stark Law can be much higher than the penalties for other billing issues resulting in a Medicare overpayment. To illustrate, if a hospital has a non-compliant financial arrangement with a physician, all Medicare payments for all inpatient or outpatient services referred by that physician are overpayments and must be returned, regardless of the nature and the amount of the tainted transaction.[37] This impact is further compounded because the Stark Law is also a strict liability statute. So if a physician and hospital violate the Stark Law, the entity must refund the payment amount, is subject to civil monetary penalties, and potential FCA liability even if there was no intent to unlawfully incent the referral and the referral was, in fact, warranted and medically necessary.

III. Stark Law Deficiencies and Recommended Resolutions

A. The Stark Law Creates Unnecessary Impediments to Healthcare Reform

1. Overview of Reforms Creating Value-Based Payment Models and Incentives

The ACA encourages a fundamental shift away from traditional Fee-for-Service ("FFS") payment models that reward providers based on the quantity of services administered to patients – to value-based and population-based payment models that reward providers based on the

[37] Senate Committee on Finance, "Why Stark, Why Now? Suggestions to Improve the Stark Law to Encourage Innovative Payment Models" 5 n.10 (June 30, 2016) (using this example to illustrate the higher penalties for a Stark violation.)

quality and efficiency of care delivered. Value-based payment models significantly and, in many cases, entirely eliminate the risk of health care resource overutilization, which is the risk the Stark Law was designed to address. When health care providers earn their margin not by the volume of services they provide, but by the efficiency of their services and the excellence of the treatment outcomes, their economic self-interest aligns with the interest of law enforcement seeking to protect patients from unnecessary services. This is especially critical in an environment where health systems are earning an ever-increasing proportion of their income (Medicare and otherwise) outside FFS.

The ACA chiefly promotes the use of value-based payment models through the creation of integrated care delivery models. Under the ACA's authority, the Center for Medicare and Medicaid Innovation ("CMMI") has created and continues to oversee a number of demonstration projects under Section 1115A of the Social Security Act that are changing health care payment and delivery by offering value-based and population-based payments to providers.[38] Similarly, the Centers for Medicare & Medicaid Services ("CMS") administers the Medicare Shared Savings Program ("MSSP"),[39] which is the permanent ACO program for CMS. Of note, the MSSP offers financial incentives under which ACOs – groups of doctors, hospitals, and other health care providers who come together voluntarily to provide coordinated care to their Medicare patients – can share a percentage of their achieved savings with Medicare, if the ACOs meet quality and savings requirements.[40]

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[38] CMMI, https://innovation.cms.gov/. Three of these models include the BPCI, the CJR, the Pioneer ACO Model, and the Next Generation ACO Model.

[39] Section 1899 of the Social Security Act.

[40] As of January 2016, when accounting for participating providers in the MSSP, the Next Generation ACO Model, Pioneer ACO Model, and the Comprehensive ESRD Care Model administered by CMS and CMMI, nearly 8.9 million Medicare beneficiaries are served through a total of 477 ACOs, 64 of which utilize two-sided risk-bearing models. CMS, *Press Release*, "New Hospitals and Health Care Providers Join Successful, Cutting-Edge (Continued...)

Building upon innovative payment models promoted under the ACA, Congress created a new framework to incent physicians to continue to engage in collaborative relationships to provide coordinated care to patients by enacting MACRA. MACRA ended the Sustainable Growth Rate ("SGR") formula that previously dictated payment amounts for physicians enrolled as Medicare providers. In its stead, MACRA establishes the new Merit-Based Incentive Payment System ("MIPS") that uses a combination of existing health care quality reporting programs to provide positive or negative payment adjustments based on value-based metrics. In addition, MACRA gave CMS the authority to provide incentive payments to clinicians who engaged in certain Alternative Payment Models ("APMs").

APMs are defined under MACRA as: (1) section 1115A models being tested by CMMI (except health care innovation awards); (2) the MSSP; (3) a demonstration under section 1866C of the Social Security Act (establishing the Health Care Quality Demonstration Program); and (4) other demonstrations "required by Federal law."[41] According to the law and CMS's proposed rule implementing MACRA, beginning in 2019, if an "eligible clinician" participates in what CMS has deemed an "Advanced APM"[42] and receives a certain percentage of payments set

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Federal Initiative that Cuts Costs and Puts Patients at the Center of Their Care," (Jan. 11, 2016) *available at* http://www.hhs.gov/about/news/2016/01/11/new-hospitals-and-health-care-providers-join-successful-cutting-edge-federal-initiative.html; *see also* CMS, "Accountable Care Innovation Models," *available at* https://innovation.cms.gov/initiatives/index.html#views=models&key=accountable care (last visited July 11, 2016).

[41] *Id*. 81 Fed. Reg. 28161. According to the MACRA proposed rule, CMS would impose three criteria for the fourth category, including that: (1) the demonstration must be compulsory under the statute, not just a provision of statute that gives the agency authority, but one that requires the agency to undertake a demonstration; (2) there must be some "demonstration" thesis that is being evaluated; and (3) the demonstration must require that there are entities participating in the demonstration under an agreement with CMS or under a statute or regulation

[42] As further explained in the MACRA proposed rule from CMS, an APM must meet all three of the following criteria defined under section 1833(z)(3)(D) of the Social Security Act to be deemed an "Advanced APM:"

1. require participants to use certified electronic health records technology ("CEHRT");
2. provide for payment for covered professional services based on quality measures comparable to those in the quality performance category under MIPS; and

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in advance by CMS from delivering care to certain classes of Medicare beneficiaries through the Advanced APM, these clinicians may become "Qualifying APM Participants" ("QPs") and be eligible for incentive payments from CMS equal to five percent of their prior year's payments from Medicare Part B as well as higher payment updates under the annually issued Physician Fee Schedule ("PFS"). Starting in 2021, eligible clinicians may also become QPs by participating in a combination of Advanced APMs and APMs with other payers, including commercial payers (defined as "Other Payer Advanced APMs").[43] By 2024, the incentive payments will phase out, and the same will occur with the enhanced PFS updates. Overall, the incentives for participation in Advanced APMs and Other Payer Advanced APMs are intended to accelerate the transition from Medicare fee-for-service payments to value-based models.

2. The Incomplete Protection of Existing Waivers for Innovative Payment Models

Both the ACA and MACRA premise health care reform on the coordination of multiple health care providers to provide better care at lower cost. In other words, one of the main goals of the ACA and MACRA is to drive health care entities together, both clinically and financially. Yet, the goals of the Stark Law are diametrically opposed to this goal, having been designed to keep health care entities financially apart.

a. The Fraud and Abuse Waivers Under the ACA

In enacting the ACA, Congress recognized Federal "fraud and abuse" laws are increasingly incompatible with these innovative payment and integrated care models. Thus, the ACA authorized the Department of Health and Human Services ("HHS") Secretary to issue

3. either require that participating APM Entities bear risk for monetary losses of a more than nominal amount under the APM, or be a Medical Home Model expanded under section 1115A(c) of the Act. 81 Fed. Reg. 28297.

[43] Section 1833(z)(2)(B)(ii) of the Social Security Act.

regulatory waivers for innovative payment and service delivery models under MSSP, CMMI's authority, and the Health Care Quality Demonstration Program.[44] Using that authority, the Secretary issued waivers from the requirements of the Stark Law as well as other fraud and abuse laws for participants in the MSSP,[45] and has exercised that authority as well for participants in the BPCI, the CJR and other demonstration programs at CMMI. Because of these waivers, providers can meaningfully participate in innovative payment models without being subject to the Stark Law. However, the waivers under the MSSP and under the CMMI programs operate very differently and provide incomplete protection, as described below.

(i) The MSSP Waivers Are Broad, But May Be Out of Reach for Commercial Entities

Under the MSSP, CMS and OIG collaborated to create five waivers that would provide collective protection from enforcement under the Stark Law as well as from other selected anti-fraud and abuse statutes.[46] The broadest waivers available under the MSSP protect arrangements protect "start-up" and continuing the operations of an ACO as well as distributions and uses of shared savings payments earned under the MSSP.[47]

All of the waivers provide simple requirements regarding the parties eligible for the waivers, the arrangements to which the waivers could apply, the terms during which the arrangements would receive protection under the waiver, and requirements for parties' governing bodies to fulfill in order to memorialize the adoption of the waivers at their respective

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[44] Section 1899 of the Social Security Act (42 U.S.C. 1395jjj); Section 1115A of the Social Security Act (42 U.S.C. 1315a); and Section 1866C of the Social Security Act (42 U.S.C. 1395cc-3).

[45] CMS and OIG, "Final Waivers in Connection with the Shared Savings Program," 80 Fed. Reg. 66726 (Oct. 29, 2015).

[46] *Id*.

[47] *Id.* (specifically, the ACO Pre-Participation Waiver, the ACO Participation Waiver, and the ACO Shared Savings Distribution Waiver).

organizations. Most importantly, however, these waivers are generally available to participants in the MSSP as well as entities that arrange to provide items or services that support the MSSP participants, so long as the governing boards have determined that the arrangements are "reasonably related" to the MSSP. The MSSP waivers have allowed health care systems to engage in innovative care coordination and payment arrangements and ACOs find them relatively easy to adopt and apply to their operations. But despite these benefits, the MSSP waivers are not broad enough to protect arrangements that may involve commercial arrangements that still trigger the Stark Law, as I describe in Section III.A.3 below.

(ii) The CMMI Waivers Are Too Narrow and Time-Limited for Long-Term Results

In contrast, the waivers applicable to CMMI initiatives are extremely program-specific. As CMMI implements more models, the waiver requirements have gotten more prescriptive and extremely narrow. These waivers are too program-specific and too numerous to keep track of to facilitate continued progress toward health reform, especially when a health care entity or system is participating in multiple programs simultaneously. More importantly, however, the waivers related to CMMI's programs offer only temporary protection for participants because they are only available during the time they are being tested by CMMI. Thus, once the program related to the specific waiver is over, there is little incentive to continue the arrangement it previously protected because the parties to the arrangement would have to make it comply with applicable exceptions and safe harbors under the fraud and abuse laws. More likely than not, this means that an arrangement that could have immense cost-efficiencies for the health care system would have to end with the termination of the CMMI program. And given the short-term nature of the CMMI programs (they generally last for three to five years), many health systems will not want to invest

in infrastructure redesign only to have to unwind such arrangements to comply with existing Stark Law restrictions.

b. New APMs Under MACRA

Similarly, MACRA is a landmark shift toward value-based payment systems in the U.S. health care system, but falls short in addressing the still-existing barriers presented by the fraud and abuse laws, including the Stark Law, that were not remedied in the ACA. Although Congress established the HHS Secretary's authority to waive certain requirements including the payment-related requirements imposed by the Stark Law within specific provisions of the ACA, no such authority exists in MACRA. Thus, providers must rely on the authorities granted in the ACA to find relief from the fraud and abuse laws, even though MACRA opened the door to the creation of additional government-based and non-government based programs to support the transition to value-based payment for services to Medicare beneficiaries.[48] But having to "bootstrap" the waivers available under the ACA to new programs under MACRA still provides incomplete protection from the fraud and abuse laws in the following situations:

- in CMMI programs where the HHS Secretary elects to not create waivers from the fraud and abuse laws;
- in APMs from the "demonstration programs required by federal law" category where Congress did not provide the HHS Secretary authority to establish waivers; or

[48] Of note, however, Congress has requested a report "with options for amending existing fraud and abuse laws in, and regulations . . . through exceptions, safe harbors, or other narrowly targeted provisions, to permit . . . arrangements between physicians and hospitals [] that improve care while reducing waste and increasing efficiency." MACRA § 512(b). I welcome the opportunity to respond and provide comment to this report whenever it is available to the public.

- in APMs that are not specified in MACRA, such as Other Payer APMs and Other Payer Advanced APMs.

3. Examples of the Incomplete Nature of Fraud and Abuse Waivers

Currently, in order to use the waivers from fraud and abuse laws, particularly the Stark Law, health care providers or payers must undergo the following steps: (1) choose to participate in a program where a potential waiver exists, (2) examine the requirements of the waiver established by the HHS Secretary to determine the requirements, and (3) fulfill the requirements of the waiver, sometimes without certainty that the waiver provides complete protection against potential enforcement under the Stark Law. As a result, the health care system requires providers and payers to engage in a piecemeal, patchwork approach to conforming to the requirements of the fraud and abuse laws, and prevents a centralized approach to fraud and abuse compliance. Where waivers from the fraud and abuse laws are available only in certain programs, in the absence of a mechanism to allow for application of similar waivers to multiple programs, health care providers are deterred because they do not have the time, money, or staff resources to structure arrangements to address the requirements of each and every program's waivers.

Finally, while the Stark Law is an impediment to the full success of MACRA, it is also a significant barrier to those providers who engage in innovative payment models outside of the MSSP ACOs, CMMI models, and APMs. These arrangements, often found in the commercial market, create the same financial relationships found in Medicare innovative payment models and therefore trigger the Stark Law's application. While some of these relationships will fit within existing Stark Law exceptions, many others do not. It is not clear how broadly HHS has exercised its waiver authority to protect these commercial arrangements, and it has failed to provide definitive guidance on the application of their waivers to these new relationships. This

issue is vitally important to the success of MACRA and other CMS innovative payment models, because many of these new non-Medicare models are an "on-ramp" towards more sophisticated payment arrangements. In other words, as physicians and health care providers move towards new payment arrangements, some are not ready to move immediately into a Medicare model. Instead, they are moving at a slower pace, with the intention of moving towards these new models within the next few years. Without specific protection from the Stark Law's application to these intermediate models, these health care providers will never be able to move to more sophisticated models that are being offered by CMS. Removing the Stark Law as a barrier to these partially integrated entities will allow them to leave behind the fee-for-service payment model and begin accepting value based payment without the risk of Stark Law enforcement.

4. Recommendations For Removing Barriers to Reform

For the reasons set forth above, unfortunately, the following quote from Timothy Jost and Ezekiel Emanuel's article 2008 still applies: "[t]he current legal environment has created major barriers to delivery system innovation. Innovation will not occur if each novel way to organize and pay for care needs to be adjudicated case-by-case or is threatened with legal proceedings."[49] Thus, without Congressional intervention, the fraud and abuse laws will still prevent providers from pursuing collaborative, non-abusive relationships that would support value-based payment.

CMS's most recent attempt at such a comprehensive approach occurred eight years ago, when it proposed a new "Exception for Incentive Payment and Shared Savings Programs" to the Stark Law in the proposed 2009 PFS Rule.[50] It was intended to permit incentive payments

[49] Timothy S. Jost and Ezekiel J. Emanuel, *Legal Reforms Necessary to Promote Delivery System Reform Innovation*, 299 JAMA 2561, 2561 (2008).

[50] CMS, "Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009; and Revisions to the Amendment of the E-Prescribing Exemption for Computer generated Facsimile Transmissions; Proposed Rule," 73 Fed. Reg. 38502, 38548-38558 (July 7, 2008).

between physicians and entities furnishing DHS, conditioned on the fulfillment of sixteen conditions. Similar to the issue raised in the prior section, this exception would protect all incentive-based payment arrangements regardless of whether they exclusively focused on Medicare patients. CMS never finalized the exception, but the enactment of ACA and MACRA has accelerated the growth of these models to a point where it is necessary to explore the possibility of a global exception once again. Rather than take the prescriptive, element-by-element approach that CMS attempted in the proposed Stark Law exception, however, I would recommend that Congress provide broad waiver authority for the HHS Secretary to use the same approach employed to establish waivers for the MSSP.

As described above in Section III.A.2.a(i), CMS and OIG's joint waivers provide collective protection from enforcement under the Stark Law as well as from other selected anti-fraud and abuse statutes.[51] These waivers are generally available so long as the arrangements at issue are "reasonably related" to the MSSP. Congress should legislatively provide the framework for CMS to employ a similarly flexible approach for any arrangement that is "reasonably related" to APMs under MACRA, and make it clear that CMS can permit health care entities that operate in the commercial marketplace to enjoy waiver protection as well, as long as they are engaged in integrated delivery models paid through a value-based payment methodology. As noted above, while it is clear that CMS needs broader waiver authority for MACRA to succeed, equally as important is waiver authority or a broader statutory exception that allows for innovative payment models that operate outside of the ACA and MACRA, but still violate the Stark Law.

[51] CMS and OIG, "Final Waivers in Connection with the Shared Savings Program," 80 Fed. Reg. 66726 (Oct. 29, 2015).

I recommend that in addition to modeling any new exception after the MSSP waivers, that the Committee also review and use portions of the managed care safe harbors under the Anti-Kickback Statute ("AKS") that provide fraud and abuse protection.[52]

B. Penalties for Technical Non-Compliance Far Exceed Possible Harm

The Stark Law has a strict liability penalty scheme, in which even inadvertent violations can trigger enormous repayment obligations. Compensation arrangements between a referring physician and a DHS entity are typically considered to be "substantive" Stark Law violations if the compensation (1) is not Fair Market Value ("FMV"); (2) takes into account the value or volume of referrals or other business generated; or (3) is commercially unreasonable.

In addition to these substantive rules, the Stark Law requires compliance with a number of technical, non-substantive requirements. For example, to qualify under the commonly used "fair market value compensation" exception, compensation resulting from an arrangement between an entity and a physician for the provision of items or services is excepted under the law, if the arrangement meets certain substantive requirements and is "in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in writing."[53] The writing must specify the timeframe of the arrangement and the compensation to be provided.[54] Under Stark Law's strict liability scheme, any missing element – such as a signature by one of the parties to the agreement – pulls the entire arrangement out of compliance. The compensation could be set at fair market value, not determined in a manner that takes into

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52 *See* Section 1128B(b) of the Social Security Act and 42 C.F.R. § 1001.952(t) and (u).

53 42 C.F.R. 411.357(l)(1).

54 *Id*.

account the volume or value of referrals or other business generated by the referring physician, and be commercially reasonable – yet still violate Stark Law due to a technical error.

Under the Stark Law, all Medicare payments for DHS furnished pursuant to a prohibited referral are disallowed.[55] In the above example, failure to include a required signature could result in the disallowance of Medicare payments for DHS, requiring a hospital to repay tens of millions of dollars, depending on the size of the hospital and the length of the unsigned agreement – an enormously disproportionate penalty given the triviality of the violation and lack of resulting harm to patients or to the Medicare program.

There is a general consensus in the industry and among regulators that the unintentional failures to satisfy such documentation requirements are "technical" and do not impact the proclivity of providers to make referrals. Compliance with the law's technical requirements does not reduce the overutilization of medical items and services. Likewise, failure to comply with the technical requirements does not increase the overutilization of medical items and services.

The technical requirements were designed as a means for parties to evidence adherence to the substantive requirements of the Stark Law. For example, signatures provide proof that two parties mutually entered an agreement – a premise necessary to establish that an arrangement is commercially reasonable, set at fair market value, and does not take into account the volume or value of referrals. However, a signature is only *one* means to evidence mutual assent. The rendering of services, invoices, and a payment trail are other means by which by both mutual assent and compliance with the substantive requirements can be shown.

Recognizing some of the challenges posed by the technical requirements, CMS recently clarified aspects of the technical elements (e.g., allowable duration of noncompliance with the

[55] 42 C.F.R. 411. 353 (c).

signature requirement").[56] While the clarification provided by CMS relaxes the technical requirements to a degree, it does not provide reprieve from the severe penalties for technical noncompliance. Further, because these technical requirements are based in statute, CMS does not have the authority to revise or remove these requirements. Congress must do so. The technical requirements under Stark Law are unnecessary and result in both high compliance costs and excessive penalties for hospitals and providers. Congress could eliminate these technical requirements with no harm to patients or to Medicare.

If Congress chooses not to eliminate the technical requirements under Stark Law, I recommend removing compliance with technical requirements as a condition of Medicare payment and granting authority to CMS to impose a simple monetary penalty per arrangement. Currently, CMS has the authority to reduce the amount due and owing under the Stark Law through its Medicare self-referral disclosure protocol ("SRDP"), a process by which health care entities can voluntarily disclose actual or potential violations of the Stark Law. Yet, CMS does not have clear Congressional authority to settle such cases on a per-penalty basis. As part of the disclosure, entities must provide copious amounts of referral data to CMS – which is often extremely time and resource intensive for both the health care entity in its data collection efforts and for CMS in its review and assessment of the data to determine the overpayment amount. Providing specific legislative direction to settle these technical non-compliance matters on a per-penalty basis would remove any doubt as to the limited importance of technical violations and would provide for greater efficiency in administration of the Stark Law.

[56] CMS, "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016," 80 Fed. Reg. 70885, 71300-71341 (Nov. 16, 2015).

C. The Stark Law's Complexity and Lack of Clarity Raises Costs and Yields Inconsistent Application in the Health Care Industry

The Stark Law was intended to provide a bright line test limiting physician self-referral. As applied, the Law's structure, breadth, and complexity have yielded few bright lines, in part, due to unclear and ambiguous critical terms: "fair market value," "taking into account the volume or value of referrals," and "commercial reasonableness." For example, despite the general lack of case law interpreting the Stark Law, the determination of fair market value has reached judicial review several times.[57] As a result, the health care industry incurs significant costs for legal interpretation from counsel, which, in turn, yields a myriad of differing and sometimes conflicting opinions. Thus, depending on the interpretation adhered to by an entity, an arrangement deemed non-compliant by one institution may be deemed compliant by another.

To achieve greater clarity and certainty, I recommend the following changes to the statute: (1) modify the definitions of the terms identified pursuant to the criteria below, and (2) expand CMS's authority to issue advisory opinions and regulatory exceptions.

1. Define Critical Terms in an Objectively Verifiable Manner

Fair Market Value.[58] Determining what constitutes fair market value is not clear under existing CMS guidance. Further, recent case law has conflated and combined the definition of fair market value and the volume or value standard. To remedy this confusion, I recommend that Congress set forth a clear statutory standard. At the very least, I recommend the establishment of a "safe harbor" for compensation to a physician from a DHS entity that is at or anywhere below the 75th percentile for national compensation for physicians in the same specialty in any national

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[57] *See United States ex rel. Kosenske v. Carlisle HMA Inc.*, 554 F.3d 88 (3d Cir. 2009); *United States ex rel. Goodstein v. McLaren Reg'l Med. Ctr.*, 202 F. Supp. 2d 671 (E.D. Mich. 2002); *United States ex rel. Singh v. Bradford Reg'l Med. Ctr.*, 752 F. Supp. 2d 602 (W.D. Pa., 2010).

[58] 42 C.F.R. § 411.351.

survey designated by the Secretary. The 75th percentile is considered fair market value according to the valuation expert relied on by the government in several recently litigated cases. This "safe harbor" approach builds on a proposal by CMS raised in the Stark II rulemaking that was not adopted. This safe harbor approach should be revisited. While it would not address all physician arrangements, it would provide certainty on the FMV standard in the vast majority of them.

Taking Into Account Volume or Value of Referrals.[59] Under current law, there is confusion over whether the "takes into account the volume or value of referrals" is an objective standard (*i.e.,* did the compensation actually vary based on referrals) or a subjective standard (*i.e.*, did the entity think about potential referrals even if it did not set the compensation using them). I recommend a "safe harbor" for all compensation arrangements that are initially established at a fair market value rate and do not change or vary during the term of the arrangement based on the value or volume of referrals (or other business generated where applicable). This is similar to the approach taken by CMS with respect to only certain per unit of service payments. Because the Stark Law is a strict liability statute, examining a party's intent or frame of mind should be irrelevant. Instead, only an objective, verifiable standard should be applied.

[59] This phrase is used in fair market value definition cited above, as well as the definitions of "remuneration" and the special rules on compensation relationships defined at 42 C.F.R. § 411.354(d), and the regulatory exceptions at 42 C.F.R. § 411.355(e)(academic medical centers), 42 C.F.R. § 411.357(a)(rental of office space), (b)(rental of equipment), (c)(bona fide employment), (d)(personal service arrangements), (e)(physician recruitment), (f)(isolated transactions), (g)(certain arrangements with hospitals), (h)(group practice arrangements), (j)(charitable donations by a physician), (l)(fair market value compensation), (m)(medical staff incidental benefits), (p)(indirect compensation arrangements), (r)(obstetrical malpractice arrangements), (s)(professional courtesy), (t)(retention payments in underserved areas), (v)(electronic prescribing items and services), (w) electronic health records items and services), (x)(assistance to compensate a nonphysician practitioner), and (y)(timeshare arrangements).

Commercial Reasonableness.[60] While a number of important exceptions have a requirement that the arrangement be commercially reasonable without taking into account Medicare referrals, the term "commercial reasonableness" is not clearly defined anywhere. Under current law, there is confusion over whether a hospital's subsidy of a physician's practice is commercially reasonable even where the physician's compensation is in the range of FMV. I recommend either that this standard be removed completely or that the statute be amended to add a definition of commercial reasonableness *e.g.*, that the items or services are of the kind and type of items or services purchased or contracted for by similarly situated entities and are used in the purchaser's business, regardless of whether the purchased items or services are profitable on a standalone basis.

2. Expand CMS's Advisory Opinion Authority

While the Stark Law authorizes CMS to issue advisory opinions to the industry,[61] CMS's advisory opinion regulations are unduly restrictive.[62] CMS modeled its advisory opinion regulations on the OIG's advisory opinion regulations for the federal health care programs' AKS.[63] For example, CMS regulations prohibit CMS from issuing advisory opinions to a party if the same or similar arrangement is under investigation by another government agency, and prohibit advisory opinions on hypothetical arrangements. While these restrictions may be appropriate for advisory opinions addressing a criminal statute, they are inappropriate where the regulated community needs to know how to comply as a condition of payment. The Stark Law is

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[60] This term is used in the exceptions at 42 C.F.R. § 411.357(a)(rental of office space), (b)(rental of equipment), (c)(bona fide employment), (e)(physician recruitment), (f)(isolated transactions), (l)(fair market value compensation), (n)(risk-sharing arrangements), and (y)(timeshare arrangements).

[61] Section 1877(g)(6) of the Social Security Act.

[62] 42 C.F.R. §§ 411.370-411.389.

[63] 42 C.F.R. Part 1008; *see also* OIG, "Advisory Opinions," https://oig.hhs.gov/compliance/advisory-opinions/index.asp (last visited July 10, 2016).

a strict liability statute where the regulations are complex, technical, and ambiguous in crucial areas. The regulated community is entitled to clear, timely guidance on how to structure such arrangements in order to qualify for Medicare reimbursement.

I recommend that CMS advisory opinion authority be modified to expressly (a) permit CMS to advise on existing, proposed, or hypothetical compensation or ownership arrangements; and (b) prohibit the agency from declining to issue an opinion on the grounds that a similar arrangement between other parties is under investigation or the subject of a proceeding involving another government agency.

3. Relax the Standard for CMS to Promulgate New Regulatory Exceptions

The Secretary may only create additional exceptions where she determines an arrangement "does not pose a risk of program or patient abuse."[64] CMS has interpreted this language to constrain its ability to create exceptions if there is any theoretical risk, however small. This stance is significantly more restrictive than the Secretary's ability to create safe harbors to the AKS.[65]

The constraint prevents CMS from creating exceptions for arrangements that pose small or minimal risks. For example, it significantly affected efforts by CMS to create a value-based or innovative payment exception. It also requires CMS to impose more safeguards than necessary, which limits the usefulness of the exceptions it does create. For example, each of the Stark Law's regulatory exceptions included a requirement that the arrangement not violate the AKS. Since compliance with the AKS depends on intent and requires a case-by-case investigation,

64 Section 1877(b)(4) of the Social Security Act.

65 Section 1128D(a)(2) of the Social Security Act.

compliance with the Stark exception will also require an investigation into intent and the specific facts. Such limitations are unworkable and unnecessary for a payment regulation.

I recommend that the statute be modified, at a minimum, to allow CMS to create new exceptions to the self-referral prohibition so long as the Secretary determines the exception does not pose a significant risk of program or patient abuse.

D. Abuse of the In-Office Ancillary Exception is Contrary to the Stark Law's Intent

Since its enactment in 1989, the Stark Law has provided a statutory exception for "in-office ancillary services" ("IOAS"),[66] supplemented by requirements in subsequent regulations.[67] Despite its early adoption and incorporation into the law's regulatory framework, many stakeholders have singled out the IOAS exception as one of the most abused in the law, because it ultimately promotes the very conduct that the Stark Law was intended to prevent – overutilization of services and unnecessary self-referrals of health care services.

1. Background of the IOAS

The IOAS exception was adopted under the guise of promoting patient convenience by allowing physicians to self-refer patients for services that could be provided by other practitioners in the same group practice. The original intent was to allow for limited diagnostic testing such as lab services and x-rays to assist in determining the proper course of treatment.

But over the years, it has become clear that the IOAS exception is being used and abused well beyond its original intent. For example, as evidenced by GAO reports, the use of the IOAS exception has increased dramatically with specific service lines, including radiation therapy, advanced imaging, clinical laboratory services, and physical and occupational therapy.

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66 Section 1877(b)(2) of the Social Security Act.

67 42 C.F.R. § 411.355(b).

Specifically, "[p]hysician self-referral of ancillary services leads to higher volume when combined with fee-for-service payment systems, which reward higher volume, and the mispricing of individual services, which makes some services more profitable than others."[68] A GAO report determined that "[s]elf-referring providers in 2010 generally referred more anatomic pathology services on average than those providers who did not self-refer these services, even after accounting for differences in specialty, number of Medicare FFS beneficiaries seen, patient characteristics, or geography."[69] In addition, a 2013 GAO report focusing on a high-cost prostate cancer radiation therapy found that "[s]elf-referring providers referred approximately 52 percent of their patients who were newly diagnosed with prostate cancer in 2009" for that therapy, in contrast with the 34 percent of patients referred for the same procedure by non self-referring providers.[70] The self-referring providers were also less likely to refer patients for other, potentially less costly treatments.[71]

2. Remedying the Incompatibility of IOAS with Health Reform

As stated by the Medicare Payment Advisory Commission, "under an alternative payment structure in which providers are rewarded for constraining volume growth while improving the quality of care, the volume-increasing effects of self-referral would be mitigated."[72] Yet, until we move to a fully integrated payment system, the incentives to abuse the IOAS exception remains. Further, because of the significant financial incentives that the IOAS

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68 Medicare Payment Advisory Commission ("MedPAC"), "Report to the Congress: Medicare and the Health Care Delivery System," 27 (June 2011) (hereafter, "MedPAC Report").

69 GAO, GAO-13-445 "Action Needed to Address Higher Use of Anatomic Pathology Services by Providers Who Self-Refer," (Jun 24, 2013).

70 GAO, GAO-13-525 "Higher Use of Costly Prostate Cancer Treatment by Providers Who Self-Refer Warrants Scrutiny," (July 19, 2013).

71 *Id.*

72 MedPAC Report at 27.

exception affords, providers engaged in in-office referrals have less incentive to shift to innovative payment models. While some providers have argued that the IOAS exception is a type of integrated delivery, referring from one service line to a second service line is not integrated care as the concept is defined under the ACA and MACRA.

Because of the statutory structure of the exception, CMS cannot reform the IOAS exception by regulation to solve this problem. Instead, Congress must provide additional authority. Thus, in order to promote and support the goals of health care reform, I recommend limiting certain service lines from the IOAS exception's protection that have a history of abuse. Yet, in order to further the goals of health reform, I also recommend allowing the IOAS to continue to apply to those group practices that are participating in APMs under MACRA and other value-based payment systems. By doing so, Congress would stop the increasing rate of unnecessary utilization due to IOAS and promote value-focused arrangements among providers that further the goals of higher quality health care at lower cost and better patient outcomes.

IV. Conclusion

The Stark Law issues I have outlined above are not exhaustive but are issues for which I believe there is the most pressing need to address. Once these concerns are addressed, Medicare patients and the Medicare program will be better off than under the current system.

Thank you again for this opportunity to testify on the Stark Law and recommended reforms. I am happy to answer any questions that the Committee has.