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1100 East Woodfield Road
Suite 350
Schaumburg, IL 60613
www.lugpa.org

January 29, 2016

BY ELECTRONIC SUBMISSION

The Honorable Orrin G. Hatch
Chairman
Committee on Finance
U.S. Senate
219 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
U.S. House of Representatives
102 Longworth HOB
Washington, DC 20515

RE: Modernizing the Stark Law

Dear Chairman Hatch and Chairman Brady:

On behalf of LUGPA, we thank you for undertaking a fundamental re-examination of the Physician Self-Referral Law (commonly known as the “Stark Law”),¹ with a goal of modernizing the statute to reflect the integrated delivery of health care by physician practices. We welcome the chance to share the perspective of more than 2,000 urologists and other physician specialists who struggle every day to comply with a law that has not matched the pace of innovation in the American healthcare system. We greatly appreciate your Committees’ interest in exploring responsible ways to modernize the Stark Law for the benefit of millions of Medicare beneficiaries and taxpayers who support the program.

Respectfully, the Stark Law is an anachronism that ill serves a healthcare system that is rapidly transitioning away from fee-for-service reimbursement. This law was first passed in 1989, and substantially amended in 1993.² At the time, Congress intended to limit potential incentives for overutilization and unnecessary care present in a fee-for-service payment system. But in more than 25 years since its passage, the law has become one of the most significant sources of regulatory burden on physicians and, ultimately, for Medicare beneficiaries. The Stark Law’s system of strict liability coupled with extremely narrow and technical exceptions means that every healthcare transaction, partnership, and initiative carries significant legal and operational risk. The net effect of these restrictions has been to make it more difficult for independent physician practices to coordinate care, creating a competitive advantage for large hospital systems. This has fueled provider consolidation, enabling such systems to acquire independent physician practices, while

¹ 42 U.S.C. § 1395nn *et seq.*

² See Omnibus Budget Reconciliation Act of 1989 § 6204 (Pub. L. 101-239) and Omnibus Budget Reconciliation Act of 1993 § 13624 (Pub. L. 103-66).



stifling competition and increasing costs.³ We urge your Committees to consider several simple, common-sense changes that will bring the Stark Law into the twenty-first century.

The need to modernize the Stark Law is even more pronounced in light of recent Congressional action encouraging physicians to shift to “value-based payment” models. The payment system created by the Patient Protection and Affordable Care Act (“ACA”)⁴ and, more substantially, by the Medicare Access and CHIP Reauthorization Act (“MACRA”)⁵ requires new forms of collaboration between physicians, group practices, hospitals, and other providers to improve patient care while managing system costs. These new payment models, however, conflict with the Stark Law’s prohibitions on payments based on the “volume or value of referrals or other business generated.”⁶ This conflict is particularly great for the more than 2,000 physicians who care for patients in LUGPA’s member practices and are committed to an independent and integrated model of healthcare delivery. Our members are caught between recent Congressional directives to embrace new payment models and fraud and abuse laws that were created a generation ago for fundamentally different payment schemes.

This comment letter will be divided into four sections. Part I is a brief introduction of LUGPA. Part II reviews the history of the Stark Law and provides an overview of the extensive and complex regulatory regime created by the Centers for Medicare and Medicaid Services (“CMS”). Part III discusses specific problems posed by the Stark Law for value-based payment systems, and Part IV lays out a set of simple legislative changes to the Stark Law that would modernize the statute consistent with the dictates of the bi-partisan MACRA legislation.

In brief, our fundamental proposals for Stark Law reform are as follows:

- Congress should extend language consistent with the waivers of the Stark Law for Accountable Care Organizations (“ACOs”) participating in the Medicare Shared Savings Program (“MSSP”) to cover relationships necessary to participate in an Alternative Payment Model (“APM”) or private equivalent under MACRA.
- Congress should modify CMS’s authority to create new exceptions and other regulatory changes to the scope of the Stark Law to require the Agency to proactively support Congressional payment reform.

³ Xu T, Wu AW, Makary MA. The Potential Hazards of Hospital Consolidation: Implications for Quality, Access, and Price. JAMA. 2015 Oct 6;314(13):1337-8.

⁴ Pub. L. 111-148, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152).

⁵ Pub. L. 114-10.

⁶ This language is present in a number of Stark Law exceptions and definitions. See e.g., the “group practice” definition at 42 U.S.C. § 1395nn(h)(4)(A)(iv); the “lease of space” exception at 42 U.S.C. § 1395nn(e)(1)(A)(iv); and the personal services exception at 42 U.S.C. § 1395nn(e)(3)(A)(v).

- Congress should clarify that the definition of “fair market value” in section 42 U.S.C. § 1395nn(h)(3) of the Stark Law is not intended to prohibit healthcare practices regulated under the law from paying compensation to incentivize high-quality, cost-efficient care, even if such compensation takes into account “the volume or value of referrals.”
- Congress should revise the definition of “group practice” to clarify that members of group practices may be paid on the basis of furnishing high-quality care without running afoul of the Stark Law.

I. LUGPA

In 2008, when physician leaders of large urology group practices began to recognize the need for a formal association to help meet the challenges of the future, LUGPA was initially established with the purpose of enhancing communication between large urology groups, allowing for benchmarking of operations, promoting quality clinical outcomes, developing new business opportunities, and improving advocacy and communication in the legislative and regulatory arenas. Since that time, LUGPA has expanded its mission to include smaller group practices that are equally committed to providing integrated, comprehensive services to patients suffering from genitourinary disease. LUGPA currently represents 118 urology group practices in the United States, with more than 2,000 physicians who, collectively, provide approximately 30% of the nation’s urology services.⁷

Integrated urology practices are able to monitor health care outcomes and seek out medical “best practice” in an era increasingly focused on medical quality and the cost-effective delivery of medical services, as well as better meet the economic and administrative obstacles to successful practice. LUGPA practices often include other specialists, such as pathologists and radiation oncologists, who work as teams with urologists to coordinate and deliver care through a one-stop shop for the patient. LUGPA’s mission is to provide urological surgeons committed to providing integrated, comprehensive care the means to access resources, technology, and management tools that will enable them to provide all services needed to care for patients with acute and chronic illnesses of the genitourinary system, including men with prostate cancer, in an efficient, cost-effective, and clinically superior manner, while using data collection to create parameters that demonstrate quality and value to patients, vendors, third party payors, regulatory agencies, and legislative bodies.

II. The Basic Structure of the Stark Law Conflicts With the Modern, Post-Fee-For-Service Payment System.

Enacted more than 25 years ago to respond to the potential risk of overutilization of health care services in a fee-for-service world, the Stark Law now serves as a barrier to

⁷ Centers for Medicare and Medicaid Services, *Medicare Provider Utilization and Payment Data: Physician and Other Supplier*, available at: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html>.

the types of clinical and financial integration contemplated by the ACA and MACRA and crucial to healthcare delivery in the twenty-first century. More significantly, the barriers to innovation posed by the Stark Law fall squarely on those physician specialists who have chosen to continue caring for patients in the high quality, cost-efficient independent practice setting. Without fundamental changes to the Stark Law, the trend of physicians being driven out of independent practice and into the higher-cost hospital setting will continue and, almost certainly, worsen. Having created a new payment system that directly incorporates value-based care and moves away from fee-for-service models, Congress now has a responsibility to modernize the Stark Law to ensure that independent physicians can fully participate in these new models.

In short, the Stark Law prohibits a physician from making a referral to a healthcare entity for the furnishing of a “designated health service,” if the physician (or a member of his or her immediate family) has any financial relationship with that healthcare entity.⁸ If this rule is violated, the healthcare entity may not submit any claims for payment for designated health services (“DHS”) furnished pursuant to this referral. The list of DHS generally includes inpatient and outpatient hospital services as well as imaging, laboratory (including clinical and anatomic pathology services), durable medical equipment, home health, radiation therapy services, and physical, occupational, and speech therapy services.⁹

Notably, unlike other laws that regulate the provision of healthcare services, the Stark Law does not require any showing of intentional offers of remuneration to induce referrals, or any risk of patient harm.¹⁰ Rather, it is a strict liability statute that automatically applies unless a financial relationship meets each and every element of an applicable exception. Because the terms of this prohibition would eliminate many common relationships that are essential to the healthcare system, Congress authorized a number of statutory exceptions.¹¹

Although the key provisions of the Stark Law have not been updated by Congress in any significant way in more than a generation, the Centers for Medicare and Medicaid Services (“CMS”) has issued a series of detailed regulations under the law. Although a full description of those regulations is outside the scope of this comment letter, it is important to note that CMS has issued several major rules implementing and interpreting provisions of the statute—sometimes in very restrictive ways.¹² In addition to this

⁸ 42 U.S.C. § 1395nn(a)(1).

⁹ *Id.* at 1395nn(h)(6). This list is not comprehensive; CMS maintains a list of specific procedures that are designated health services at: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html.

¹⁰ Other federal healthcare fraud and abuse laws also cover these concepts, including the Anti-Kickback Statute (42 U.S.C. § 1320a-7b) and Civil Monetary Penalty Law (42 U.S.C. § 1320a-7a). In addition, many Medicare payment rules include patient protections as a condition of payment.

¹¹ 42 U.S.C. §§ 1395nn(b)-(e).

¹² See e.g., the “Phase 1” Regulation at 66 Fed. Reg. 856, 856 (January 4, 2001); the “Phase 2” Regulation at 69 Fed. Reg. 16054, 16054 (March 3, 2004); the “Phase 3” Regulations at 72 Fed. Reg. 51012, 51012 (September 5, 2007). CMS has also made a number of important changes to the Stark Law in yearly payment rules covering the Inpatient Prospective Payment System, Outpatient Prospective Payment System, and Physician Fee Schedule. A full list of applicable regulations is available at:

extensive regulatory history, the Agency has numerous publications guiding providers, including frequently asked question (“FAQ”) documents, protocols, and advisory opinions.¹³ CMS and other federal agencies frequently refer to specific elements of the preamble discussion and additional guidance as binding law. It is therefore necessary for providers to understand an enormous body of complicated material to assure compliance.

At a high level, the Stark Law establishes separate regulatory regimes based on whether the physician has an “**ownership**” or “**compensation**” relationship with the healthcare entity. There are fewer exceptions for ownership, and these are subject to a higher number of restrictions. In the context of independent physician practices, these exceptions are mainly restricted to entities that qualify as a “group practice” (as discussed further below). There are significantly more exceptions covering various types of compensation relationships; however, most of these exceptions also restrict collaboration to achieve value-based payment goals by limiting payments that take into account the “volume or value of referrals or other business generated.”

In fact, restrictions on remuneration that “take into account the volume or value of referrals” are encoded in one of the most important elements of the Stark Law: the very definition of “fair market value.” Almost all of the Stark exceptions require compensation to be “fair market value.” CMS defines the term, in relevant part, as “**the value in arm's-length transactions, consistent with the general market value.**”¹⁴ CMS goes on to say that, “[u]sually, the fair market price is the price at which *bona fide* sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in *bona fide* service agreements with comparable terms at the time of the agreement, **where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals.**”¹⁵

Congress also provided HHS with limited ability to craft new Stark Law exceptions “in the case of any other financial relationship which the Secretary determines, and specifies in regulations, does not pose a risk of program or patient abuse.”¹⁶ CMS has used this authority to craft new exceptions in the past.¹⁷ However, this standard has often required CMS to create highly technical, restrictive exceptions that limit innovation in health care delivery.

Finally, the Stark Law creates enormous challenges for integrated, value-based care arrangements like those contemplated by MACRA. Previously, in the ACA, Congress recognized this challenge and granted HHS the ability to waive Medicare requirements

<https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Significant-Regulatory-History.html>.

¹³ Most of this material is available at: <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html>. (Last updated on January 5, 2015.)

¹⁴ 42 C.F.R. § 411.351, “Fair Market Value” (emphasis added).

¹⁵ *Id.* (emphasis added). CMS’s definition also includes less relevant information specifically addressing rentals and leases.

¹⁶ 42 U.S.C. § 1395nn(b)(4).

¹⁷ See *e.g.*, 42 C.F.R. §§ 411.357(j)-(y).

(including fraud and abuse provisions) “as may be necessary to carry out the provisions” of the Medicare Shared Savings Program and demonstrations under the Center for Medicare and Medicaid Innovation.¹⁸ However, these waivers are only available to participants in these voluntary models. As such, the waivers do not apply uniformly to all physician practices. MACRA did not grant CMS comparable regulatory authority with regard to the Merit-Based Incentive Payment System or even Alternative Payment Models, which inherently envision more coordinated delivery through bundling, capitation or other such arrangements.

III. The Stark Law Prevents Independent Physician Practices From Fully Participating in New Integrated, Value-Based Care Models.

Protecting the independent practice model is critical to the continued viability of our healthcare system, generally, and the Medicare program, in particular, for a number of reasons.

- 1) Physicians in LUGPA’s member practices and other physician specialty practices provide high-quality, cost-efficient care to millions of patients, including in underserved and rural communities.
- 2) Independent practices such as LUGPA member practices reduce healthcare costs and represent competition to increasingly-consolidated hospital systems,¹⁹ as evidenced by data demonstrating that healthcare costs increase significantly when physician groups are acquired by hospitals and even more dramatically when physician groups are acquired by hospital systems.²⁰
- 3) Perhaps most relevant to future payment paradigms, independent physician groups have been shown to provide higher quality at lower cost in Medicare risk-sharing arrangements. Large independent groups are particularly well-suited to reduce costs while delivering high-quality care. For example, one comparison found that hospital-based groups were associated with an average of \$849 in increased total per-beneficiary spending and 1.3% higher total hospital readmissions.²¹ By contrast, per-beneficiary spending was similar for small, medium, and large independent groups.²²

¹⁸ 42 U.S.C. §§ 1395jjj(f) and 1315a(d)(1). We refer to “HHS” rather than “CMS” in connection with these waivers, because the waivers are issued jointly by CMS and the HHS Office of the Inspector General (“OIG”).

¹⁹ See e.g., David M. Cutler, Ph.D. and Fiona Scott Morton, Ph.D., Hospitals, Market Share, and Consolidation, 310(18) JAMA 1964 (November 13, 2013). McWilliams JM, Chernew ME, Zaslavsky AM, et al., Delivery system integration and health care spending and quality for Medicare beneficiaries. (2013) JAMA internal medicine, 173(15), 1447-1456.

²⁰ Robinson JC, Kelly Miller K. Total expenditures per patient in hospital-owned and physician-owned physician organizations in California. JAMA 312.16 (2014): 1663-1669.

²¹ McWilliams JM, Chernew ME, Zaslavsky AM, et al., Delivery system integration and health care spending and quality for Medicare beneficiaries. (2013) JAMA internal medicine, 173(15), 1447-1456.

²² Id.

However, the continued viability of independent physician practice is increasingly threatened in the current regulatory system. Each of LUGPA's member practices is a business that must perform a variety of basic commercial functions, including employing or contracting with physicians, other healthcare providers and staff, leasing space and equipment, and distributing profits. The Stark Law adds significant complexity to each of these functions. For example, the "group practice" definition places strict limits on the ways that a practice may distribute profits to its owners.²³ Similarly, agreements with physician contractors must satisfy seven different regulatory subsections, which make them vulnerable to purely technical non-compliance.²⁴

Further, the Stark Law makes collaboration with other entities to manage patient care extremely risky. If an entity (including a physician practice) has a prohibited financial relationship with a physician, that entity may not submit Medicare claims for referrals of DHS received from a physician, unless an exception applies.²⁵ This means that even minor, technical non-compliance can lead to significant liability. In addition, the Affordable Care Act requires a refund of any claims of this nature within sixty days, and failure to do so can trigger liability under the False Claims Act.²⁶

In an era where cost savings and value-based care are increasingly vital considerations, one might predict that physician specialty practices would be at the heart of innovative care models. Unfortunately, this is not the case, with ACOs and other integrated care systems lagging in their inclusion of physician specialists.²⁷

A. Congress's Actions to Shift Away from Fee-For-Service Payment Structures Must be Supported by Stark Law Reform.

The bipartisan passage of MACRA signaled Congress' clear intention to move away from a fee-for-service payment system by ending the flawed "sustainable growth rate" formula and by providing a specific timeline transitioning Medicare Part B payments to one of two systems:

- 1) The Merit-Based Incentive Payment System ("MIPS"), a modified fee-for-service system in which payments to physician practices may be increased or decreased on the relative basis of various quality, resource and system improvement metrics.
- 2) Alternative Payment Models ("APMs"), which represent wholly new payment systems in which each physician practice may take on the risk for managing the care of a patient or population.

²³ 42 C.F.R. § 411.352(g) and (i).

²⁴ 42 C.F.R. § 411.357(d).

²⁵ 42 U.S.C. § 1395nn(a)(1)(B).

²⁶ 42 U.S.C. § 1320a-7k(d).

²⁷ John W. Peabody and Xiaoyan Huang, A Role for Specialists in Resuscitating Accountable Care Organizations, Harvard Business Review (November 5, 2013), available at: <https://hbr.org/2013/11/specialists-can-help-resuscitate-accountable-care-organizations/>.

i. The MIPS

The MIPS combines the three existing incentive payment programs into a single composite metric used to adjust Medicare payments. These programs are: 1) the Patient Quality Reporting System; 2) the Value-based Modifier; and 3) Medicare electronic health record incentives.²⁸ Providers paid under the MIPS will receive certain annual incentive payments or reductions based on their attainment of specific quality goals.²⁹ Specifically, each provider who submits bills to Medicare Part B will receive a composite score on the basis of four factors: 1) quality; 2) resource use; 3) meaningful use of certified EHR technology; and 4) clinical practice improvement activities.³⁰ CMS will then increase or decrease each professional's Part B reimbursement on the basis of this composite score.³¹

We are concerned that the Stark Law poses a significant barrier to aligning incentives in the manner contemplated by the MIPS. Most importantly, group practices must be able to incentivize high-quality care among the physicians in their practices. However, the definition of “group practice” prohibits compensation that varies on the basis of the volume or value of the physician’s referrals.³² This could raise concerns in situations where a group practice attempts to incentivize its members to achieve certain quality goals—particularly where this is ultimately linked to greater overall compensation at the group level.

The Stark Law contains certain exceptions to this “volume or value” standard. The two exceptions to this rule are: 1) profit shares, so long as they are not determined in a manner that is directly related to the volume or value of the physician’s referrals for DHS; and 2) a productivity bonus based on the physician’s personally performed services *and/or* those provided “incident to” his or her services (so long as this bonus does not itself relate to the volume or value of the physician’s referrals of DHS).³³ CMS deems certain kinds of profit shares and productivity bonuses as not relating to the volume or value of referrals, but these provisions largely focus on payments based on non-DHS revenues and the physician’s personally performed services.³⁴ In general, these flexibilities focus on incentives to increase *volume*, such that the distribution of *quality*-based, incentive-based compensation may not be fully protected.

²⁸ <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html>.

²⁹ See generally 42 U.S.C. § 1395w-4(q).

³⁰ *Id.* at § 1395w-4(q)(2)(A).

³¹ *Id.* at § 1395w-4(q)(1)(A).

³² 42 U.S.C. § 1395nn(h)(4)(A)(iv).

³³ *Id.* at § 1395nn(h)(4)(B)(i).

³⁴ 42 C.F.R. § 411.352(i).

ii. Background of APMs

Although the MIPS creates potential challenges, we are more concerned about the ability of physicians in independent practices to participate in APMs. Physicians who participate in APMs receive a guaranteed five percent reimbursement increase for several years and the opportunity to earn higher reimbursement if they achieve quality and shared savings goals. LUGPA practices include the most innovative independent urology practices in the country and are eager to participate in innovative delivery arrangements that enable them to manage a patient's full urological health needs or urological diseases, such as prostate cancer. Therefore, we anticipate that many of our members will gravitate toward this kind of model. Unfortunately, we also believe that this model raises the most significant concerns under the Stark Law. As a result, the remainder of this Section will focus on the APMs.

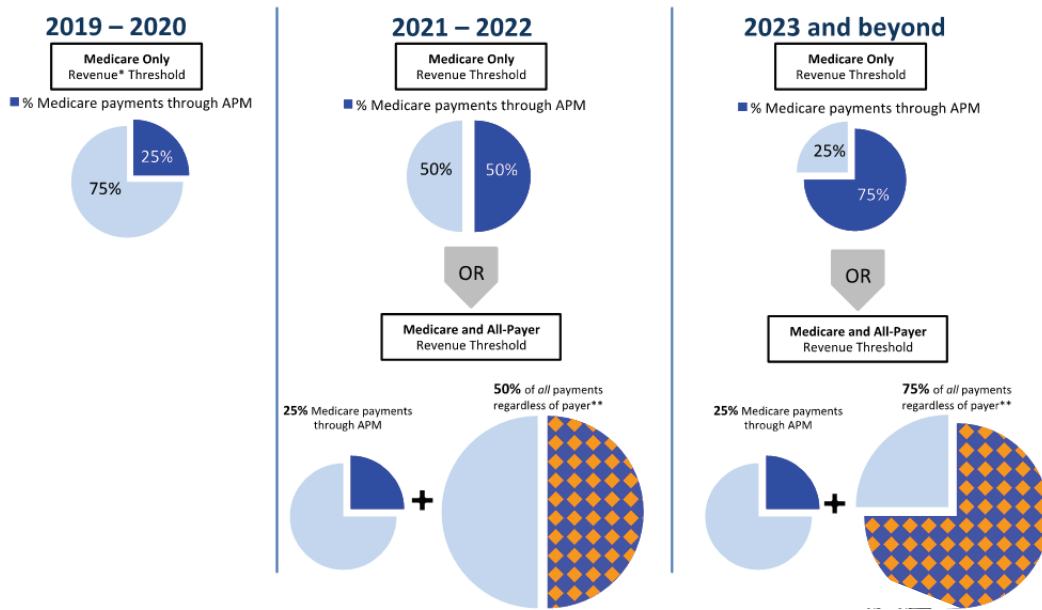
MACRA created significant incentives for professionals to move to APMs. At the most basic level, each "qualifying APM participant" will automatically receive an automatic five percent bonus for participation in this program.³⁵ An eligible professional is a "qualifying APM participant" if he or she receives a certain percentage of payments for professional services on a non-fee-for-service ("FFS") basis.³⁶ Beginning in 2021, this will either require that *at least 50 percent of a provider's Medicare payments* be through an "alternative payment entity," or that *at least 50 percent of a provider's all-payer reimbursement* be on a non-FFS basis.³⁷ **In other words, for the first time, Congress has established a legal framework in which a provider's Medicare payments may explicitly depend on the provider's participation in *private* non-FFS models.** Parameters for APM qualification are illustrated in the following:

³⁵ 42 U.S.C. § 1395L(z)(1). This amount will be equal to five percent of the estimated aggregate payment amounts for the professional's services in the prior year, or the equivalent as determined by HHS when the provider's payments are made to an alternative payment entity, or where the professional is paid on a non-FFS basis.

³⁶ 42 U.S.C. § 1395L(z)(2).

³⁷ Id.

Qualifying APM Practice



* Threshold could be based on number of patients in lieu of revenue if Secretary deems appropriate

**The % of payments must be based on quality measures comparable to MIPS, bear financial risk and EHR use

| Years | Medicare-only Requirement | All-Payer Requirement |
|----------------|--|---|
| 2019 & 2020 | At least 25% of Part B payments made through an alternative payment entity. | N/A |
| 2021 & 2022 | At least 50% of Part B payments made through a Medicare alternative payment entity | At least 50% of all-payer payments made through Medicare alternative payment entities <i>or</i> qualifying private arrangements |
| 2023 and later | At least 75% of payments made through a Medicare alternative payment entity | At least 75% of all-payer payments made through Medicare alternative payment entities <i>or</i> qualifying private arrangements |

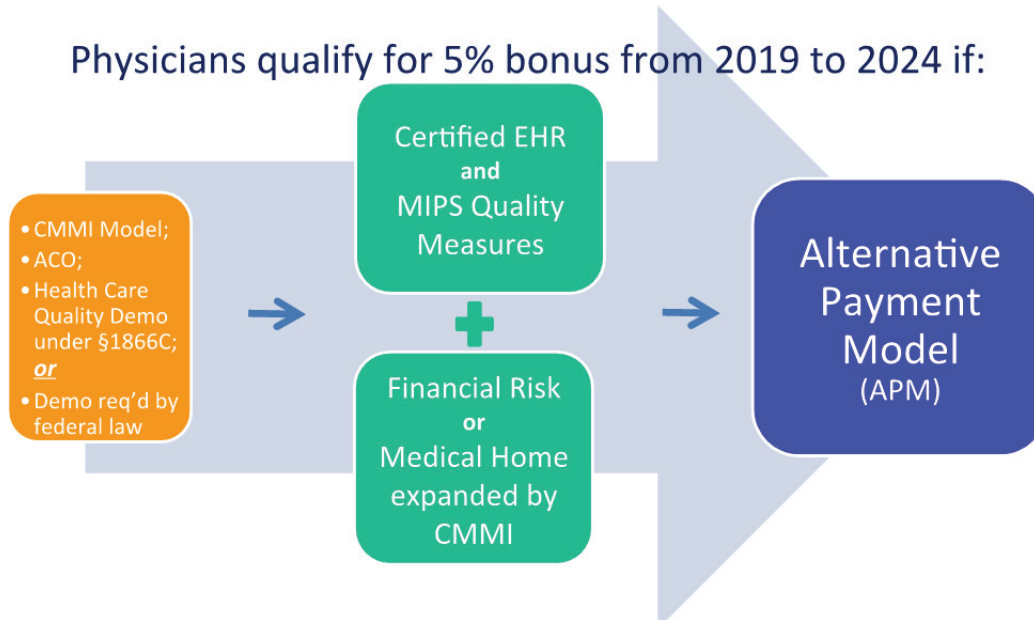
Table 1: MACRA Options for APM Eligibility

A provider can meet these goals either by participating in a Medicare APM with an “eligible alternative payment entity” or by participating in a qualifying arrangement with a non-Medicare entity. The following table lays out the relevant standards for each:

Alternative Payment Model (APM)

The Medicare Access and CHIP Reauthorization Act (MACRA)

Physicians qualify for 5% bonus from 2019 to 2024 if:



| Medicare Alternative Payment Entity ³⁸ | Non-Medicare Qualifying Arrangement ³⁹ |
|--|---|
| <ul style="list-style-type: none"> • Participates in an APM that: <ul style="list-style-type: none"> ○ Requires participants to use certified EHR technology; ○ Bases payment on quality measures comparable to the MIPS; • Bears financial risk for monetary losses in excess of a nominal amount; • <i>Or</i> is a medical home. | <ul style="list-style-type: none"> • No requirement to be an official “APM”; • Quality measures comparable to the MIPS apply; • Certified EHR technology is used; • The entity: <ul style="list-style-type: none"> ○ Bears more than nominal financial risk if actual aggregate expenditures exceed expected aggregate collections; ○ <i>Or</i> is a medical home. |

Table 2: Qualifying vs. Non-Qualifying APM Arrangements

The statute defines an APM to include the following types of models:⁴⁰

- Medicare Shared Savings Program ACOs;
- A model tested by the Center for Medicare & Medicaid Innovation (“CMMI”);
- The Healthcare Quality Demonstration Program; or
- Other demonstrations required by federal law.

³⁸ 42 U.S.C. § 1395L(z)(3)(D).

³⁹ 42 U.S.C. § 1395L(z)(2)(B)(iii) and (C)(iii).

⁴⁰ 42 U.S.C. § 1395L(z)(3)(C).

Notably, all of these programs are existing **voluntary** initiatives. Although ACOs have grown in popularity, the fee-for-service system is still the dominant payment system for Medicare providers. MACRA reflects an intent on the part of Congress to move substantially more care into these payment models. As a result, Congress should consider the barriers that currently prevent providers from entering these voluntary programs. In our view, the Stark Law, as presently written, is one of the most significant barriers to physician practice participation in APMs.

iii. The Stark Law Poses Significant Barriers for Physician Practice Participation in APMs

As is evident from the descriptions above, APMs are complex arrangements that can take a wide array of forms. Arrangements operating under this model may be public or private, may be operated by CMS through regulations or by payors through contracts, and may structure compensation in a myriad of different ways. The only required commonalities are that: 1) payment is linked to quality measures; 2) certified EHR technology should be used; and 3) the entity bears more than nominal “downside risk” of loss. But all of the models foresee tremendous coordination between physicians that can be impaired by outdated provisions of the Stark Law.

With that said, there is some useful precedent in the ongoing implementation of Accountable Care Organizations (ACOs). From an experimental beginning in 2011, ACOs have grown to the point that over 420 Medicare ACOs have been established, and Medicare ACOs now serve 7.8 million Americans.⁴¹ The growth in the non-Medicare market has also been strong, to the point that nearly 750 Medicare and non-Medicare ACOs now serve nearly 30 million Americans.⁴² CMS has relied on this growth as a key part of its strategy to transform the healthcare payment system, with bold goals of moving 50% of its payments to alternative models by 2018 and by incorporating value-based metrics into 90% of its payments by 2018.⁴³

CMS now has four separate ACO programs in place—two under the Medicare Shared Savings Program and two under CMMI. These programs vary based on the presence of downside risk, the potential magnitude of available shared savings, and certain programmatic rules. For example, a Track One ACO does not require any assumption of downside risk. By contrast, a “Next-Generation” ACO offers the potential for much higher shared savings, but requires the entities that make up the ACO to bear the risk of a loss.

⁴¹ David Muhlestein, Growth And Dispersion Of Accountable Care Organizations In 2015, Health Affairs Blog (March 31, 2015) available at: <http://healthaffairs.org/blog/2015/03/31/growth-and-dispersion-of-accountable-care-organizations-in-2015-2/>.

⁴² Id.

⁴³ Centers for Medicare and Medicaid Services, Fact Sheet: Better Care. Smarter Spending. Healthier People: Paying Providers for Value, Not Volume (January 26, 2015), available at: <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-01-26-3.html>.

The experience of ACOs in navigating the Stark Law illustrates many of the significant problems that APMs may face. These entities exist to encourage separate, independent healthcare providers to collaborate in order to manage the care of a patient population. This approach directly conflicts with the Stark Law's inherent suspicion of coordination between physicians and the entities to which they refer. In particular, the distribution of shared savings incentives could arguably be characterized as a payment that takes into account the "volume or value" of referrals, given that the overall magnitude of the ACO's incentive payment reflects the effective management of care. Moreover, the various entities that make up an ACO may need to provide one another with remuneration to achieve the goals of the ACO. For example, a hospital may provide its partners with EHR software to assure interoperability, or multiple physician groups may share the overhead costs of a nurse providing care coordination services.

Separately, CMMI has developed a range of other programs to coordinate care. In addition to the ACO programs listed above, CMMI has created a set of bundled payment programs and episode-based payment initiatives. Although the details of these programs vary, they generally provide an incentive payment covering the provision of all care associated with a given condition or population.⁴⁴ It is then the responsibility of the providers to allocate this payment fairly to manage the care of the applicable patients. CMMI is also empowered to create other programs in the future to "test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles."⁴⁵

And yet, these coordinated care programs raise significant compliance concerns for independent physicians under the Stark Law. As discussed further below, **the current set of waivers, exceptions, and flexibilities primarily benefit hospitals and a limited set of primary care physicians, but largely leave independent specialty practices unprotected.** This lack of protection for physicians in independent specialty practices becomes increasingly troubling as we transition into an era in which value-based, coordinated care is no longer an experiment, but rather the predominant form of payment. We believe the Stark Law's exception at 42 U.S.C. § 1395nn(b) could be significantly modernized by adding additional provisions covering care coordination and by broadening CMS's regulatory authority to create new exceptions.

In particular, MACRA's requirement that APM's must take on risk is more stringent than even certain ACO agreements under the Medicare Shared Savings Program. This has led at least one national body representing ACO's to opine that even Track One ACOs (which share savings without taking on "downside" risk) would not qualify as APMs.⁴⁶ **However, Track One ACOs would continue to benefit from waivers of the Stark Law under the terms of the MSSP waivers.** This situation illustrates the fact that

⁴⁴ A full list of CMMI models is available at: <https://innovation.cms.gov/initiatives/index.html#views=models>.

⁴⁵ 42 U.S.C. § 1315a(a)(1).

⁴⁶ National Association of ACOs, Summary of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (May 4, 2015), available at: <https://www.naacos.com/pdf/MACRASummary050415.pdf>.

Congress must broaden existing waivers and exceptions to provide truly universal protection for innovative payment arrangements.

The exceptions to the Stark Law generally benefit single and/or related entities that provide the full spectrum of care over coordination by multiple independent, specialized clinical providers. For example, the Stark Law contains a specific exception for academic medical centers that allows enormous flexibility in structuring ownership or compensation relationships across multiple types of providers, as long as the referring physician is an employee meeting the standards of the exception.⁴⁷ In addition, the compensation exception covering bona fide physician employment is one of the most flexible of all exceptions.⁴⁸

The Stark Law poses a number of serious challenges for independent specialty medical practices that wish to partner with hospitals or other entities providing “designated health services.” The “volume or value” standard present in many of the compensation exceptions could be interpreted to prohibit physician compensation arrangements that incentivize physicians to *reduce* utilization or the overall cost of care. Hospitals have significantly more flexibility to classify such incentive plans with employee physicians as “productivity bonuses”;⁴⁹ such leeway does not exist with independent physician groups seeking to coordinate care with individual hospitals or hospital systems.

The Stark law also impedes care coordination *outside* of Medicare—a key avenue to qualify for an APM under MACRA—due to the “other business generated” requirement of several compensation exceptions.⁵⁰ To its credit, CMS recognizes that much of the activity on innovative payment models is occurring in the private sector through programs like the Blue Cross and Blue Shield Alternative Quality Contract.⁵¹ Unfortunately, payment based on the volume or value of “other business generated” frequently causes a compensation relationship to fall out of compliance with a Stark Law compensation exception. This means that a *private plan’s* program to provide a global incentive payment to both a hospital and physician practice for cooperating to achieve quality goals or cost reductions could taint all of the practice’s referrals to the hospital—even if the parties fully comply with the Stark Law as to Medicare business.

The application of the “other business generated” standard is particularly concerning in light of MACRA’s escalating requirements for payment on the basis of value-based care. In order to remain eligible for the APM bonus, providers will ultimately need to show that either 75% of their *Medicare* reimbursement or 75% of *all* reimbursement is paid through an APM or qualifying private arrangement.⁵² However, the Stark Law protections for participation in non-Medicare value-based plans are extremely limited.

⁴⁷ 42 C.F.R. 411.355(e).

⁴⁸ 42 C.F.R. 411.357(c).

⁴⁹ 42 C.F.R. § 411.357(c)(4).

⁵⁰ See *e.g.*, the lease exceptions at 42 C.F.R. §§ 411.357(a) & (b), the personal services exception at 42 C.F.R. § 411.357(d), the non-monetary compensation exception at 42 C.F.R. § 411.357(k), and the fair market value compensation exception at 42 C.F.R. § 411.357(l).

⁵¹ 80 Fed. Reg. at 41928.

⁵² 42 U.S.C. § 1395L(z)(2)(C).

B. Existing Stark Law Provisions are Insufficient.

For all of the foregoing reasons, CMS has recognized that the structure of the current exceptions to the Stark Law does not account for the new imperative for hospitals and physician practices to collaborate and coordinate patient care. Efforts to address this to date have been piecemeal and generally exclude independent specialty practices because CMS is constrained by an antiquated law that no longer reflects modern healthcare delivery.

i. Existing Exceptions

A number of Stark exceptions protect certain kinds of incentive-based payments. However, we believe that these provisions are too narrow to protect the diverse array of arrangements contemplated by APMs.

The Stark compensation exceptions include two avenues for quality-based incentive compensation. First, personal service arrangements may be paid under a “physician incentive plan.”⁵³ Second, there is a broad exception for payments under a “risk-sharing arrangement.”⁵⁴ Neither avenue provides the kind of broad-based flexibility that providers realistically need to achieve APM goals.

The “physician incentive plan” is limited to payments made to physicians under personal service contracts. This means it is not available to cover compensation to employees or between entities.⁵⁵ A “physician incentive plan” is defined as any compensation arrangement between an entity (or downstream contractor) and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals “enrolled” with the entity.⁵⁶ In addition, CMS regulations require that no “specific” payment be made as an “inducement to reduce or limit medically necessary services furnished with respect to a specific individual enrolled with the entity.”⁵⁷

This exception is an awkward fit for many value-based payment arrangements—arrangements that were not even conceived of at the time Congress enacted the Stark Law more than a generation ago. First, ACOs and other value-based arrangements often involve management of a population of beneficiaries attributed by CMS or a plan to the provider (or entity). It is unclear whether these patients would be considered “enrollees” in the entity providing the remuneration. For example, if a hospital provided remuneration to physician partners in an ACO, it is unlikely that any patients would be classified as “enrollees.” Second, this provision’s limitation on payment to induce the limitation of medically necessary services is counterproductive. In many cases, multiple

⁵³ 42 C.F.R. § 411.357(d)(1)(v) and (d)(2).

⁵⁴ 42 C.F.R. § 411.357(n).

⁵⁵ However, the employment exception prohibits payment based on the volume or value of a physician’s referrals, except in the case of a productivity bonus based on the physician’s own personally performed services. See 42 C.F.R. § 411.357(c)(4).

⁵⁶ 42 C.F.R. § 411.351, “Physician incentive plan.”

⁵⁷ 42 C.F.R. § 411.357(d)(2)(i).

modes of treatment may arguably be “medically necessary” for a given patient, but a provider could be vulnerable to penalties for choosing one form of medical intervention over another even though it may be more efficient and optimal for patient outcomes. One of the most important tasks of value-based payment models is to align incentives such that providers choose the mode that is most efficient from a cost and quality perspective. This element of the physician incentive plan exception would seem to frustrate that goal.

The “risk-sharing exception” is even more limited. By its terms, this exception only applies to compensation pursuant to a risk-sharing arrangement between a Managed Care Organization or an Independent Practice Association and a physician for services provided to enrollees of a health plan.⁵⁸ Although there are a wide range of compensation arrangements protected by this exception, it only applies in narrow circumstances. For example, the terms “Managed Care Organization” and “Independent Practice Association” are not defined in either regulation or statute, and value-based payment entities like ACOs or the entities that bear risk and receive payments under bundled payment programs are unlikely to fit this definition. Therefore, the flexibility provided by this exception is not sufficient to support all necessary relationships.

Finally, even HHS has previously made a determination that a waiver was necessary to protect payments under the MSSP.⁵⁹ By definition, this is an admission that **current exceptions do not provide sufficient flexibility to implement this program.**

ii. ACO Waivers:

CMS’s most comprehensive effort to address the problematic nature of the Stark exceptions is the set of waivers produced for Accountable Care Organizations.⁶⁰ As discussed below, these waivers provide genuine, broad-based protections to those entities that qualify for their protection. However, the implementation of these waivers reveals tension between Congress’s broad grant of authority and HHS’s approach to rulemaking.

Congress’s statutory grant of authority is clear and unambiguous: “The Secretary may waive such requirements of sections 1128A and 1128B and title XVIII of this Act as may be necessary to carry out the provisions of [the MSSP].”⁶¹ But HHS’s rulemaking approach is significantly more complex. The waivers were issued in an Interim Final Rule with Comment Period jointly published by CMS and the HHS Office of Inspector General (“HHS-OIG”) in 2011.⁶² At the time, CMS and the HHS-OIG warned that they would carefully monitor new ACOs to determine whether the waiver led to increased fraud and abuse.⁶³ Indeed, the initial waiver notice stated that these waivers **would be**

⁵⁸ 42 C.F.R. § 411.357(n). In addition, the arrangement must not violate the Anti-Kickback Statute or any federal or state law or regulation governing billing or claims submission,

⁵⁹ 76 Fed. Reg. 67992, 67993 (November 2, 2011), “Based on stakeholder input and other factors, the Secretary has found that it is necessary to waive these fraud and abuse laws in order to carry out the Shared Savings Program.”

⁶⁰ 76 Fed. Reg. 67992 and 79 Fed. Reg. 62356.

⁶¹ 42 U.S.C. § 1395jjj(f).

⁶² 76 Fed. Reg. at 67992.

⁶³ See *id.* at 68008.

narrowed “unless the Secretary determines that information . . . suggests that such waivers have not had the unintended effect of shielding abusive arrangements.”⁶⁴ Although CMS has not narrowed the reach of these waivers, this standard was reiterated in the final rule codifying the waivers in 2015.⁶⁵

The content of the waivers is generally broad, and represents a significant departure from the exacting provisions of the current Stark exceptions. Simply stated, the waivers protect physicians and entities that are participating (or intend to participate) in the MSSP or in certain initiatives proposed by CMMI. CMS proposed a set of flexible waivers covering ACOs’ operations (the “participation” waiver) *and* the activities of the physicians and entities preparing to join or create an ACO (the “pre-participation” waiver).⁶⁶ CMS also believed it was necessary to waive each ACO’s distribution of shared savings to entities inside and outside the ACO (as long as formal requirements are met, and the payments are used for activities reasonably related to the purposes of the MSSP).⁶⁷

The waivers, however, are of limited utility to independent physician specialty practices attempting to participate in APMs under MACRA. Because the statutory provision is limited to waivers necessary to carry out the MSSP, CMS is not able to extend these protections in important ways. **Most importantly, these waivers will not apply to APMs created under authorities other than the MSSP or through CMMI, and the waivers will not protect participation in private initiatives.**

Moreover, participation in the MSSP by physicians in independent physician specialty practices is not viable because the MSSP is heavily weighted towards primary care. For example, beneficiary assignment to an MSSP ACO is determined based on where the beneficiary receives a plurality of his or her primary care services, with a preference for “primary care physicians” defined as internal medicine, general practice, family practice, and geriatric medicine.⁶⁸ Other specialties are considered only where a beneficiary has *no* primary care services furnished by any other primary care physician—whether inside or outside the ACO.⁶⁹ In addition, the set of 33 quality metrics identified for MSSP ACOs is heavily weighted toward primary care case management.⁷⁰ Moreover, a specialty practice that *does* serve as the basis for beneficiary assignment is forbidden from participating in another ACO.⁷¹ Although CMS attempted to solve the latter problem in this year’s revised MSSP regulations, the solution it applied was to exclude

⁶⁴ *Id.*

⁶⁵ 80 Fed. Reg. at 66741 (October 29, 2015).

⁶⁶ 76 Fed. Reg. 67992, 68000.

⁶⁷ *Id.* at 68001.

⁶⁸ See 42 C.F.R. § 425.402 and definition of “primary care physician” and “primary care services” at 42 C.F.R. § 425.20.

⁶⁹ *Id.*

⁷⁰ Centers for Medicare and Medicaid Services, “ACO Quality Metrics,” available at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharesavingsprogram/Downloads/ACO-Shared-Savings-Program-Quality-Measures.pdf>.

⁷¹ See 42 C.F.R. §§ 425.402 and 425.306(b) and associated discussion in 80 Fed. Reg. 32692, 32750-32755.

certain specialties entirely from involvement in beneficiary assignment.⁷² As a result, most independent specialty practices are unable to benefit from the ACO waivers authorized under the MSSP statutory authority at 42 U.S.C. § 1395jjj(f).

In addition, the implementation of these waivers represents a significant departure from Congress's broad waiver authorization. In contrast to the strict limitations of the Stark Law exception authority, Congress granted HHS the ability to waive any element of Medicare payment rules as necessary to implement program goals. Although the waivers developed by CMS and the HHS-OIG are significantly more flexible than existing Stark exceptions, these waivers are still limited in comparison to the extraordinarily broad waiver authority provided by Congress. The agencies effectively communicated that providers could assume significant risk by entering into these arrangements, but warned waiver recipients that they would be subject to additional fraud monitoring, and that waivers could be revoked at any time. This naturally has had a chilling effect on innovation and provides little utility to most specialty practices.

A similar pattern is present with regard to the CMMI initiatives. Congress authorized broad waivers for CMMI demonstrations, using similar language as for the MSSP.⁷³ However, in the case of CMMI demonstrations, most of the waivers were not initially published. Instead, HHS selectively released the waivers as confidential addenda to the participation agreements of entities accepted into each initiative. To its credit, HHS now makes value-based payment waivers issued by CMS and the HHS-OIG available on a publicly accessible website.⁷⁴ However, this kind of initial secrecy was not conducive to wide-scale participation in these initiatives. Moreover, these waivers consistently fail to protect value-based arrangements with *private* payors.⁷⁵ As discussed below, we believe Congress should take this history of implementation into account as it explores new ways to support MACRA. Furthermore, we do not believe that a new waiver will be sufficient here; rather, Congress should include clear statutory language **requiring** HHS to protect all relationships necessary to achieve APM goals—including relationships under private payor models that are incorporated into the “all payer” standards.

iii. New Exceptions

CMS is also statutorily empowered to create Stark Law exceptions that protect any financial relationship that the Agency determines “does not pose a risk of program or patient abuse,”⁷⁶ but CMS has been unable to use this statutory authority to protect innovative payment arrangements.

⁷² Id.

⁷³ 42 U.S.C. § 1315a(d)(1).

⁷⁴ <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html>.

⁷⁵ See e.g., OIG and CMS's statement regarding waivers for the Next Generation ACO program: “We are aware that ACOs may have questions regarding protection for the distribution of Shared Savings earned by the ACO under a comparable program sponsored by a commercial health plan. As with the MSSP, we are not including in this Notice specific waiver protection for such arrangements. We are not persuaded that a specific waiver is necessary for such payments to carry out the Next Generation ACO Model.” <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/Next-Generation-ACO-Model-Waiver.pdf>.

⁷⁶ 42 U.S.C. § 1395nn(b)(4).

CMS attempted to exercise this authority to propose a gainsharing exception in the 2009 MPFS Rule.⁷⁷ However, this attempt was hampered by the need to incorporate extremely rigid and precise elements in order to meet the high bar of “no risk of program or patient abuse.” The proposed gainsharing exception only protected incentive payments and shared savings programs offered by hospitals, only cash (or cash equivalent) payments, and only those payments to physicians who directly achieved savings (rather than to their groups), and were on the hospital’s medical staff, and even then only in “pools” of five or more.⁷⁸ The proposed rule also included requirements for an applicable gainsharing program’s quality metrics, performance goals, prior review by CMS or an accrediting body (and annual reviews thereafter), and other complex administrative requirements.⁷⁹ Despite enormous interest and active public comment, CMS never finalized this exception.⁸⁰ As CMS stated at the time, **“the majority of commenters urged [the Agency] to finalize such an exception or exceptions only if substantial modifications were made to the conditions proposed.”**⁸¹ The commenters’ reaction underscores the fact that the extremely technical approach of traditional Stark Law exceptions, which effectively channels healthcare transactions into a limited number of government-approved pathways, is inappropriate in the world of innovative, coordinated care models.

IV. Congress Should Modernize the Stark Law to Ensure that Independent Physician Practices Can Fully Participate in New Integrated, Value-Based Care Models.

A. Congress Should Incorporate the ACO Waivers Into Statute.

As stated above, HHS was able to use the increased flexibility provided by the MSSP and CMMI waivers to create significant new protections that produced some of the most flexible, program-focused protections associated with the Stark Law. However, this regulatory approach is inherently problematic and creates unpredictable compliance risk. First, the waivers came with concerning caveats that expose providers who used the waivers to additional monitoring and provided for limited notice of waiver termination. Second, by excluding private payors and being limited to formal ACO programs, these waivers do not encourage innovation by independent specialty practices. We are concerned that the implementation of these waivers does not come close to fully implementing Congress’s vision of a post-fee-for-service payment system; therefore, new statutory protection is necessary and warranted.

These waivers have now been in place for nearly five years in the ACO program, with no evidence of increased fraud and abuse risk. Congress should act to ensure that this well-understood methodology is now available to all APM participants. In particular, it is critical that physician specialty practices have adequate statutory protection to enter into relationships in preparation for a formal APM (analogous to the ACO “pre-participation”

⁷⁷ 73 Fed. Reg. 38502, 38548.

⁷⁸ *Id.* at 38552-38558.

⁷⁹ *Id.*

⁸⁰ 73 Fed. Reg. 69726, 69793.

⁸¹ *Id.* (emphasis added).

waiver) without concern of running afoul of the Stark Law. To provide true clarity to APM participants, Congress should incorporate into the Stark Law the terms of the waivers created by CMS. Therefore, **we request that Congress add language into the Stark Law exception section at 42 U.S.C. § 1395nn(b) specifying that pre-participation, participation, and post-participation compensation to APM participants do not violate the Stark Law if the waivers' standards are satisfied.**

B. Congress Should Expand CMS's Authority to Create New Exceptions.

Congress has delegated an enormous number of policymaking decisions to CMS as part of the implementation of MACRA. The Agency is responsible for defining quality metrics, developing a methodology for the composite MIPS score, developing APMs, and implementing a wide variety of other elements of the law. CMS is expected to exercise an enormous degree of judgment and policymaking authority as it effectively designs a new payment system for healthcare professionals across the country.

And, yet, CMS's current authority to create regulatory exceptions to the Stark Law is limited to those that "do[] not pose a risk of program or patient abuse"—a standard that, as a practical matter, hamstringing the Agency from modernizing the Stark Law. It is extremely difficult to identify any policy change that creates "no risk." Although we share CMS's interest in preventing any harm to patients or abuse of the Medicare program, we also believe that the Agency is best positioned to balance that risk with other program goals. As a result, we urge Congress to modify the exception authority to provide CMS with additional discretion to craft exceptions. Congress should amend 42 U.S.C. § 1395nn(b)(4) to allow CMS the authority to create new exceptions that evolve along with Congress's changes to the physician payment system. Specifically **we recommend that Congress amend the Agency's authority at 42 U.S.C. § 1395nn(b)(4) to state that the Agency may protect "any other financial relationship which the Secretary determines, and specifies in regulations, would promote the goals of the Medicare Part B payment system (42 U.S.C. Chapter 7, Subchapter 18, Part B)." Consistent with this change, Congress should also amend the statute to ensure that CMS, through its regulatory authority, shall not be permitted to impose new requirements that impede the adoption of the MIPS (42 U.S.C. § 1395w-4(q)) or APMs (42 U.S.C. § 1395L(z)).**

C. Congress Should Amend the Stark Law to Ensure that Group Practices Are Permitted To Compensate Physicians Based on Quality and Resource Use.

One of the Stark Law's most significant barriers to implementation of MACRA and the development of innovative payment structures is the prohibition on a group practice's distributions to physicians that "take into account the volume or value of referrals." As explained above, virtually all legal methods to distribute funds to physician members of a group practice are explicitly or implicitly linked to volume-based productivity measures. If quality metrics and overall population management are to be incorporated into the basic payment system for physicians (as they are under the MIPS and APMs), group practices need a mechanism to incentivize this kind of care delivery. **Congress should**

amend this section of the group practice definition to remove the restriction on compensation “tak[ing] into account the volume or value of referrals.”⁸² Note that virtually all of the commonly used *exceptions* continue to impose this standard. However, its inclusion in the group practice *definition* creates enormous confusion and opportunities for technical non-compliance. This risk will only grow as physicians’ compensation under Medicare Part B increasingly reflects the “value” of their services and referrals.

D. Congress Should Remove or Modify the “Volume or Value” Standard that CMS Imposed on the Statutory Definition of “Fair Market Value.”

The statutory definition of “fair market value” does not include any reference to the volume or value of referrals.⁸³ Rather, the definition created by Congress simply reflects the clear rule that arrangements must reflect arm’s length bargaining. The “volume or value” standard was a regulatory addition created by CMS.⁸⁴ Unfortunately, the addition of this phrase has created serious challenges for value-based payment models. By incorporating the “volume or value” standard into the definition of “fair market value,” CMS has muddied the clear interpretation of the standard Congress created. Indeed, the inclusion of this phrase creates significant problems for many value-based care arrangements. As such, any incentive payment that increases or decreases based on a physician’s contribution towards value-based payment goals could be viewed as violating the “fair market value” standard. This is particularly serious from a compliance perspective because failure to meet the “fair market value” standard tends to be a significant indicator of non-compliance.

In order to preserve the necessary flexibility to design meaningful value-based care arrangements, Congress should modify this language by amending the Stark Law. For example, **Congress could include a new subsection under the definition of “fair market value” in the Stark Law clarifying that payments made to achieve the goals of an APM are deemed not to take into account the volume or value of the physician’s referrals.**

V. Request for Action

Consistent with our comments above and the steps Congress has already taken to shift our healthcare system away from a fee-for-service payment system and towards value-based payment models, LUGPA respectfully requests that Congress take the following actions in order to modernize the Stark Law:

- Congress should extend the protections of the HHS waivers for Accountable Care Organizations to the MACRA payment reforms. This can be done by adding a new subsection to 42 U.S.C. § 1395nn(b) specifying that remuneration does not trigger the Stark Law’s prohibition

⁸² 42 U.S.C. § 1395nn(h)(4)(A)(iv)

⁸³ 42 U.S.C. § 1395nn(h)(3). The sole reference in the statute is that lease payments must not be adjusted to reflect the additional value the lessee would attribute to the proximity or convenience to the lessor where the lessor is a potential source of referrals.

⁸⁴ 42 C.F.R. § 411.351, “Fair Market Value.”

- if it meets the standards of a “pre-participation,” “participation,” or “distribution of shared savings” arrangement established by HHS in the Medicare Shared Savings Program waivers at (80 Fed. Reg. 66726, 66742-43), if this remuneration is provided to a qualifying APM participant (as defined at 42 U.S.C. § 1395L(z)(2)), or to a MIPS eligible professional for the purpose of improving the eligible professional’s composite performance score (as established at 42 U.S.C. § 1395w-4(q)).
- Congress should revise CMS’s regulatory exception authority to provide the Agency with flexibility to create additional exceptions necessary to promote non-fee-for-service payment structures. Specifically, Congress should amend the language of 42 U.S.C. § 1395nn(b)(4) to establish that “other permissible exceptions” include “any other financial relationship which the Secretary determines, and specifies in regulations, promotes the goals of 42 U.S.C. Chapter 7, Subchapter 18, Part B.”
 - At the same time, Congress should amend the Stark Law to ensure that CMS action does not frustrate Congress’s clear policy goal of moving the country towards value-based payment structures. Specifically, in those instances in which current Stark Law definitions or exceptions call on the Agency to impose new restrictions to “protect against patient and program abuse,” Congress should add language stating that “the Secretary shall not impose new requirements that impede the adoption of MIPS (42 U.S.C. 1395w-4(q)) or APMs (42 U.S.C. 1395L(z)).”
 - Congress should amend the “group practice” definition to remove the “volume or value” language at 42 U.S.C. § 1395nn(h)(4)(A)(iv). This standard is not needed because it is already built into the most commonly used exceptions; it should not be part of the crucial threshold determination of whether an entity qualifies as a “group practice.”
 - Congress should amend 42 U.S.C. § 1395nn(h)(3) to establish that “fair market value” under the Stark Law does not prohibit compensation that varies with the volume or value of referrals, if such compensation is necessary to achieve the goals of APMs (42 U.S.C. 1395L(z)) or MIPS (42 U.S.C. 1395w-4(q)).

On behalf of LUGPA, we would like to thank your Committees for providing us with this important opportunity to comment on how best to modernize the Stark Law to keep pace with the Congressionally-led innovation of our healthcare system. Please feel free to contact John McManus at (202) 546-6040 or jmcmamus@mcmanusgrp.com, Tracy Spicer at (202) 347-8725 or tspicer@dcavenuesolutions.com, or Howard Rubin at (202) 625-3534 or howard.rubin@kattenlaw.com, if you have any questions or if LUGPA can provide additional information to assist your Committees as they consider these issues.

Respectfully submitted,



Gary M. Kirsh, M.D.
President



Deepak A. Kapoor, M.D.
Chairman, Health Policy

cc: Celeste Kirschner, Chief Executive Officer, LUGPA
John McManus, The McManus Group
Tracey Spicer, Avenue Solutions
Howard Rubin, Esq., Katten Muchin Rosenman LLP