DIGESTIVE HEALTH
PHYSICIANS ASSOCIATION

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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: Stark Law Reform

Dear Chairman Hatch and Chairman Brady:

On behalf of the Digestive Health Physicians Association ("DHPA") and the more than 1,300 gastroenterologists and other physician specialists who care for millions of Americans in DHPA's member medical practices, we thank you for the opportunity to comment on potential revisions to the Physician Self-Referral Law (commonly known as the "Stark Law").[1] DHPA is grateful for the leadership your Committees showed last year as Congress enacted the Medicare Access and CHIP Reauthorization Act ("MACRA")—a critically important step in reforming our healthcare payment system.[2] Your recent request for comment on ways to modernize the Stark Law reflects an understanding of the fact that we will not be able to achieve MACRA's goals without bringing the Stark Law—created more than a generation ago to address a wholly different payment system—into the twenty-first century.

Through passage of MACRA, Congress took a bold step to place value-based care at the center of our healthcare system. MACRA effectively requires all Medicare Part B payments to incorporate value-based standards by 2019. Yet, when the Stark Law was created in the late 1980s and early 1990s, Medicare operated in a fee-for-service system with virtually no reliance on "value-based payment models" and "risk sharing arrangements." And over the last 25 years, the Stark Law has become one of the most significant sources of regulatory policy imposed on physicians and, ultimately, Medicare beneficiaries. Moreover, the ways in which physicians and non-physician providers deliver care has markedly changed in that period. The Stark Law's system of strict liability coupled with extremely narrow and technical exceptions means that virtually every

[1] 42 U.S.C. § 1395nn et seq.
[2] Pub. L. 114-10.

healthcare transaction, partnership, and initiative carries significant legal and operational risk.

And, of even greater concern in light of Congress's passage of MACRA is the fact that the Stark Law places significant restrictions on coordinated care that are fundamentally at odds with a value-based payment system. The new payment system created by the Patient Protection and Affordable Care Act ("ACA")[3] and MACRA requires new forms of collaboration between physicians, group practices, hospitals, and other providers to improve patient care while managing system costs. These new mandates, however, conflict with the Stark Law's prohibitions on payments based on the "volume and value of referrals or other business generated."[4] This conflict is particularly acute for physicians who care for Medicare beneficiaries in independent medical group practices, but are caught between Congressional directives to embrace new payment models and fraud and abuse laws that were created a generation ago for a fundamentally different payment structure. **We applaud your Committees' efforts to modernize the Stark Law consistent with the bold steps Congress has already taken to shift away from a fee-for-service payment system.**

Following a brief introduction about DHPA, we divide this comment letter into two sections. Part I focuses on the ways in which the Stark Law conflicts with Congress's goals in enacting MACRA as well as the particular Stark Law provisions that inhibit DHPA's member medical practices from participating in new payment models. Part II proposes a discrete set of legislative changes to the Stark Law that would modernize the statute consistent with the dictates of the bipartisan MACRA legislation.

As we discuss in more detail below, DHPA proposes the following reforms of the Stark Law:

- Independent GI and other physician specialty practices need the ability to incentivize high-quality care on the same basis as hospitals or health care systems. Accordingly, **Congress should revise the Stark Law's 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.

- CMS has interpreted the phrase "fair market value" in a way that could harm efforts to distribute incentive payments. **Congress should amend the definition of "fair market value" in section 42 U.S.C. § 1395nn(h)(3)** to clarify that it is not intended to prohibit incentive payments to improve quality, even if such compensation partially reflects the "volume or value" of a physician's referrals.

- Congress provided the Department of Health and Human Services ("HHS") with broad authority to waive Medicare rules as necessary to

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

[4] 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).

implement Accountable Care Organizations ("ACOs"). However, this language does not align with the Alternative Payment Model ("APM") provisions of MACRA. Because hospitals have dominated ACO relationships, these waivers represent an unintentional advantage for hospitals over independent practices in achieving the goals of APMs. **Congress should create a new exception under 42 U.S.C. § 1395nn to establish that the terms of the HHS ACO waivers apply to remuneration related to a relationship covered under 42 U.S.C. § 1395L(z).**

- When Congress enacted the Stark Law more than a generation ago, it provided CMS with extremely limited authority to create new exceptions. The Agency may only create new exceptions that "do[] not pose a risk of program or patient abuse."[5] This exception authority has become the only meaningful method to protect new financial arrangements from liability under the Stark Law in the fast-evolving healthcare market. Unfortunately, the "no risk" standard means that new exceptions are highly restrictive and technical. **Congress should modernize CMS's exception authority to allow the Agency greater flexibility to design exceptions to the Stark Law that balance healthcare innovation with adequate patient protections.**

DHPA

DHPA formed in early 2014 to promote and protect the high quality, cost-effective and coordinated care furnished in independent gastroenterology (GI) practices. It is the only national medical association that exclusively represents the voices of those gastroenterologists who have chosen to care for patients in the independent practice setting. DHPA practices typically employ pathologists and other specialists who work in a team setting with gastroenterologists in order to provide comprehensive GI care to our patients. In less than two years, DHPA has grown to include 58 member GI practices from 29 states in every region of the country. Our more than 1,300 physicians provide care to more than 2.5 million patients annually in approximately 3.5 to 4 million distinct patient encounters.

DHPA member practices are committed to exploring new care models. For example, we recently surveyed our 58 member practices to collect information regarding the ways in which our member practices are currently engaged in—or are seeking to develop—various alternative payment models.[6] The overwhelming majority (over 80%) of respondents who were not ACO participants were interested in joining one in the future;[7] nearly 80% of respondents would be interested in a GI-specific initiative under the Center for Medicare and Medicaid Innovation ("CMMI").[8] But despite this strong interest, fewer than half of our member practices currently participate in an ACO. And, as we now show in Part I of this comment letter, the Stark Law is in need of reform to ensure

[5] 42 U.S.C. § 1395nn(b)(4).
[6] Digestive Health Physician Association Member Practice Survey – Alternative Payment Models.
[7] Id.
[8] Id.

that independent GI and other physician specialty practices are able to participate in value-based payment models such as those contemplated by MACRA.

I. The Stark Law Needs to Be Modernized To Support the Implementation and Success of MACRA.

The Stark Law is a relic—a law that was created more than 25 years ago to address concerns of potential overutilization of physician services in a strictly fee-for-service payment system while maintaining patient access to high-quality care. That law, and the labyrinth of restrictions imposed on physicians (particularly those caring for patients in independent medical group practices), needs to be revisited in light of the bold steps Congress has taken to move us toward new payment models including episode-based care, bundling, and capitation.

MACRA mandates that, starting in 2019, all Medicare Part B payments will incorporate quality-based metrics. This will be done through two models:

- The Merit-Based Incentive Payment System ("MIPS"), a modified fee-for-service system in which payments may be increased or decreased on the basis of various quality and system improvement metrics.

- Alternative Payment Models ("APMs"), which represent wholly new payment systems in which each provider (or entity) takes on the downside risk of losses while managing the care of a patient or population.

The MIPS effectively replaces the basic fee-for-service system that is the foundation of Medicare Part B professional payments (and was the foundation for the creation of the Stark Law more than 25 years ago). As a result, the MIPS will impact virtually *all* of DHPA's member practices, even those that are not yet participating in ACOs or other Alternative Payment Models ("APMs"). The MIPS collapses existing Medicare quality incentive programs: (i) the Patient Quality Reporting System; (ii) the Value-Based Payment Modifier; and (iii) Medicare electronic health record incentives.[9] Providers paid under the MIPS will receive certain annual incentive payments or reductions based on their attainment of specific quality goals.[10] Specifically, each MIPS eligible professional who submits bills to Medicare will receive a composite score on the basis of four factors: (a) quality; (b) resource use; (c) meaningful use of certified EHR technology; and (d) clinical practice improvement activities.[11] CMS will then increase or decrease each provider's Part B reimbursement on the basis of this composite score.[12] The incentive pool starts at four percent in 2019 and grows to nine percent by 2021.[13]

By providing a 5% bonus for five years, and larger updates thereafter for those physicians who engage in APMs, it is clear that Congress clearly wants physician practices to

[9] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MACRA-MIPS-and-APMs.html.
[10] See generally 42 U.S.C. § 1395w-4(q).
[11] Id. at § 1395w-4(q)(2)(A). Quality scores will be assigned at the group practice level. See id. at § 1395w-4 (q)(1)(d).
[12] Id. at § 1395w-4(q)(1)(A).
[13] Id. at § 1305w-4(q)(6)(B).

engage in APMs.[14] An APM may include ACOs or other innovative care arrangements that require an entity to assume risk.[15] A physician may also receive greater overall compensation under the APM rules depending on his or her performance. But, in order to qualify, a physician must demonstrate that an increasing number of Medicare *or* all-payer reimbursement is paid through an alternative payment model. This represents Medicare's most significant attempt to incentivize participation in *private* value-based arrangements. However, existing Medicare rules do not provide adequate protection for independent member practices (or their physician members) entities to participate in APMs because of the antiquated Stark Law.

Finally, MACRA also calls for a set of new "Physician-Focused Payment Models."[16] DHPA supports these models, but Congress provided limited details as to the structure and function of such models and left it to CMS to design these new structures. However, CMS was not provided with specific authority to modify the Stark Law in order to facilitate implementation of the new physician-focused payment models. As a result, we are concerned that any new model designed under this provision will create compliance risks under the Stark Law and thereby undermine a key policy goal of MACRA.

Even HHS has acknowledged that existing Stark Law exceptions do not adequately protect value-based payment arrangements. This is evidenced by the Stark Law waivers that have been issued for the Medicare Shared Savings Program and other CMMI programs. As HHS explained while issuing waivers for ACOs, "[b]ased 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."[17] Unfortunately, the waiver programs that have been established effectively provide more protection to hospitals than to independent practices, because they do not take into account unique constraints that the Stark Law imposes on independent physician specialty practices such as DHPA's member practices.

A. The Group Practice Definition

Many of the Stark Law exceptions require a physician's medical practice to qualify as a "group practice."[18] The statutory definition itself is complex, and CMS has prescribed an additional set of standards to determine whether an entity meets this standard.[19] The most onerous element of the definition of "group practice" is its prohibition on compensation that varies on the basis of the volume or value of the physician's referrals.[20] 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 designated health services ("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).[21] CMS deems certain kinds of profit shares and

[14] 42 U.S.C. § 1395L(z)(1)(A).
[15] 42 U.S.C. § 1395L(z)(3)(C).
[16] 42 U.S.C. § 1395ee(c).
[17] 76 Fed. Reg. 67992, 67993 (November 2, 2011).
[18] See e.g., the in-office ancillary services exception at 42 U.S.C. § 1395nn(b)(2).
[19] 42 U.S.C. § 1395nn(h)(4); 42 C.F.R. § 411.352.
[20] 42 U.S.C. § 1395nn(h)(4)(A)(iv).
[21] Id. at § 1395nn(h)(4)(B).

productivity bonuses not to relate 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.[22] 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. The focus on volume in the current Stark law is at odds with the fundamental nature of an APM – capitation or other risk-bearing mechanisms that place the provider, not the Medicare program, at risk for any potential overutilization.

We are concerned that the complex nature of the group practice definition, coupled with the volume-based flexibilities, will impede efforts to incentivize high-quality care under MACRA. For example, it is not clear that the current definition would allow an incentive payment based on a physician's contribution to achieving certain group-level quality goals. Such a payment could be characterized as a payment reflecting the "volume or value" of the physician's referrals, that may lie outside existing flexibilities under Stark.

This is particularly challenging for *independent group practices* that do not benefit from the flexibility that the Stark Law provides to *hospitals and academic medical centers* in how they may compensate their employed physicians. For example, Stark contains a specific exception for academic medical centers that allows a variety of potential arrangements between related entities as long as services are provided by a physician employed by an entity that is a "component" of an academic medical center.[23] In addition, the exception covering "bona fide" employment arrangements is one of the most flexible arrangements, and actually includes provisions allowing an employer to *require* an employed physician to refer within a defined network of preferred providers (subject to certain limits).[24] Hospitals therefore enjoy substantial flexibility that creates an uneven playing field as compared to independent practices, in a manner at odds with MACRA's policy goals. Simply put, the Stark Law's restraints on care delivery by group practices more than a generation ago need to be revisited in a post-MACRA world, which seeks to enhance care coordination between physicians and other entities.

B. The Fair Market Value Standard

Virtually all of the Stark Law exceptions require payments to be "fair market value,"[25] which Congress defined as "the value in arm's length transactions, consistent with the general market value."[26] However, CMS greatly expanded upon this language through regulation by requiring that "fair market value" compensation not "vary with the volume or value of referrals."[27]

This regulatory overlay poses a significant threat to independent practices' ability to participate in incentive-based compensation arrangements. A prohibition of distributions based on the "volume or value" of referrals may have the effect of blocking payments to incentivize appropriate changes to a physician's practice. There is a risk that a payment based on the reduction of costly services, or to incentivize more-effective and efficient

[22] See 42 C.F.R. § 411.352(i).
[23] 42 C.F.R. § 411.355(e).
[24] 42 C.F.R. § 411.354(d)(4).
[25] See e.g., the lease of space exception at 42 U.S.C. § 1395nn(e)(1)(A); employment exception at 42 U.S.C. § 1395nn(e)(2); personal service arrangements exception at 42 U.S.C. § 1395nn(e)(3).
[26] 42 U.S.C. § 1395nn(h)(3). This definition also provides special rules for leases of space.
[27] 42 C.F.R. § 411.351, "Fair Market Value."

care, could be seen as a payment based on the "volume or value of referrals." As a result, Congress should clarify its intent that the "fair market value" was not intended to limit incentive-based compensation under the MIPS, APMs, or physician-focused payment models.

C. Implementation of APMs

The APM provisions represent a more fundamental break with traditional Medicare fee-for-service payment policy. Eligible alternative payment entities under this program must incorporate quality measures comparable to the MIPS, use certified EHR technology, and bear more than nominal financial risk if actual aggregate expenditures exceed expected aggregate collections.[28]

Although the MIPS represents an important shift towards value-based care, the APM system will ultimately require participating providers to receive the majority of their payments through formal value-based models. Critically, these models explicitly require payment through an alternative payment entity that accepts risk of loss.[29] In addition, participating providers must receive *Medicare* payments through: (i) a Medicare Shared Savings Program ACO; (ii) another CMMI program; (iii) the Healthcare Quality Demonstration Program; or (iv) another federal government demonstration.[30]

Alternatively, a provider can also meet this goal by showing it received reimbursement from all payers, *including private payers*, if these models: (a) incorporate quality measures comparable to the MIPS; (b) mandate the use of certified EHR technology; and (c) the entity receiving payment bears more than nominal financial risk if actual aggregate expenditures exceed expected aggregate collections.[31] This strategy is particularly meaningful to DHPA; our recent survey of member practices indicated a high level of interest in being able to engage in value-based payment arrangements with private payers.[32]

HHS has acknowledged that flexibility outside of the boundaries of the Stark Law statute and regulations is necessary to implement existing value-based payment models. For example, in 2011 it issued a set of extremely flexible waivers to facilitate the creation and operation of ACOs.[33] These take the form of (i) a pre-participation waiver covering expenses associated with the start-up of an ACO; (ii) a participation waiver covering remuneration necessary to achieve ACO program goals (for example, payments associated with the bona fide operations of the ACO); (iii) a waiver covering the distribution of shared savings earned by the ACO in a given program year; and

[28] See 42 U.S.C. § 1395L(z)(2)(B)(iii) and (C)(iii). Alternatively, payments from a medical home also qualify.
[29] 42 U.S.C. § 1395L(z)(2)(B) and (C).
[30] 42 U.S.C. § 1395L(z)(3)(D).
[31] See 42 U.S.C. § 1395L(z)(2)(B)(iii) and (C)(iii). Alternatively, payments from a medical home also qualify.
[32] Digestive Health Physician Association Member Practice Survey – Alternative Payment Models.
[33] 76 Fed. Reg. 67992, 67992 (November 2, 2011).

(iv) financial relationships associated with unwinding an ACO.[34] These waivers have been in place for years and were recently re-authorized by HHS.[35]

Unfortunately, the waiver mechanism—as currently constructed—contains significant limitations that are at odds with the APM model developed by MACRA. First, broad waivers only exist for the Medicare Shared Savings Program.[36] Second, CMS has consistently refused to expand its waivers to cover arrangements with private payors.[37] And, in any event, private pay ACO (or other value-based) arrangements may raise compliance risks under the Stark Law because many exceptions prohibit payment based on "other business generated," such that incentives jointly earned by entities under a private, value-based payment program may place Medicare payments at risk.[38] Since Congress clearly envisioned physician-led APMs being permitted to contract with private payors, it is critical that the Stark Law be modernized to allow this to happen.

The method used by HHS to develop these waivers illustrates why Congress should incorporate them into the Stark Law. Although Congress authorized HHS to craft broad waivers "as may be necessary" to facilitate the creation and functioning of ACOs, HHS expressed significant concern regarding the use of this authority. HHS warned that entities and providers who used the waivers would be subject to heightened monitoring,[39] and warned that it might revoke the waivers at any time.[40] These warnings appeared again in the final rule issued by HHS last year reauthorizing the same waivers.[41]

Consistent with MACRA's aim of encouraging providers to adopts APMs, Congress can offer much-needed clarity by extending the ACO waivers set forth at 80 Fed. Reg. 66726 to payments made to qualifying APM participants. This could be done by creating a new Stark Law exception at 42 U.S.C. § 1395nn(b).

D. Congress Should Expand CMS Exception Authority

The authority Congress granted to HHS with respect to ACO waivers represents an important step in the right direction, but it is only a first step. As explained above, the waiver authority is limited to ACO programs and CMMI initiatives. And, not surprisingly, the regulatory authority that Congress granted to CMS under the Stark Law to create additional exceptions is inadequate to ensure effective implementation of MACRA.[42]

That exception authority—created a generation ago—does not take into account the enormous responsibility Congress has placed on CMS to implement MACRA and

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[34] Id.
[35] 80 Fed. Reg. 66726, 66726 (October 29, 2015).
[36] 76 Fed. Reg. at 67992. CMS has developed other waivers for specific CMMI programs, but those tend to be less suited to general applicability. A full list of CMMI waivers is available here: https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html. The majority of these provide that the Participation Agreement with CMMI may limit the application of the waiver.
[37] 80 Fed. Reg. at 66738.
[38] See e.g., the lease of space exception at 42 C.F.R. § 411.357(a)(5)(i).
[39] 76 Fed. Reg. at 68008.
[40] Id.
[41] 80 Fed. Reg. at 66738.
[42] 42 U.S.C. § 1395nn(b)(4).

numerous decisions yet unforeseen that CMS must make in order to optimize MACRA implementation. Under current law, CMS only has the authority to craft new Stark Law exceptions if the Agency can guarantee such exceptions "do not pose a risk of patient or program abuse."[43] We need to strike a better balance—one that eliminates overly restrictive, arcane policies placed upon independent physician practices while still maintaining important consumer and patient protections.

The restrictive nature of this standard—and the limitations it places on innovation—is readily seen in the proposed gainsharing exception. The concept of "gainsharing" is the predecessor to the shared savings mechanisms currently in place under the Medicare Shared Savings Program. This payment methodology would have allowed providers to be compensated by hospitals or payors on the basis of the *savings* they achieved.[44] This is now one of the key mechanisms of the Medicare Shared Savings Program and other ACO initiatives. Notably, there was enough interest in such a methodology that CMS proposed a gainsharing exception in 2008—years before the Affordable Care Act specifically endorsed these same payment models. [45]

But this effort was limited because of the restrictive nature of CMS's exception authority. The Agency found it was required to incorporate unworkable restrictions to meet the high bar of "no risk of program or patient abuse". The proposed gainsharing exception contained strict limits on the type and source of payments, the kinds of physicians who could receive payments, and the safeguards that would apply.[46] Despite enormous interest and active public comment, CMS never finalized this exception.[47] 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."[48] The commenters' reaction underscores the fact that the extremely technical approach of traditional Stark Law exceptions, which effectively channel healthcare transactions into a limited number of government-approved pathways, is inappropriate in a post-MACRA world seeking to promote innovative, coordinated care models across sites of service.

This important revision is necessary in recognition of the fact that policymakers cannot divine how health care delivery will change in the future. Since it has been more than two decades since the major set of Stark Law exceptions (and the exception authority) was designed, the current law is too circumscribed to provide necessary flexibility. Congress should consider the implications of CMS's narrow exception authority when it takes steps in 2016 to modernize the Stark Law to support the implementation and success of MACRA.

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[43] Id.
[44] See e.g., CMS Report to Congress: Medicare Gainsharing Demonstration: Report to Congress on Quality Improvement and Savings, https://innovation.cms.gov/Files/reports/DRA5007-Report-to-Congress.pdf.
[45] 2009 Medicare Physician Fee Schedule, 73 Fed. Reg. 38502, 38548 (July 7, 2008).
[46] Id. at 38552-38558.
[47] 73 Fed. Reg. 69726, 69793 (November 19, 2008).
[48] Id.

II. Congress Can Modernize the Stark Law Through a Small Number of Important Changes.

The Stark Law needs to be modernized to keep pace with the innovation that is at heart of MACRA. Congress can amend the Stark Law in several discrete ways that will provide physicians who care for patients in independent GI and other physician specialty practices with the flexibility and clarity to participate in value-based payment models. Respectfully, DHPA believes that these modifications to the Stark Law are compelled by MACRA.

A. Group Practice Definition Under Stark Law

The group practice definition is a fundamental element of many Stark Law exceptions.[49] Virtually all of these exceptions contain a requirement that external compensation must not be paid in a manner that takes into account the volume or value of referrals. The complex nature of the group practice definition means that practices can fail to meet this standard for compensation paid *within* the group. Congress can greatly lessen the burden on group practices and make APMs more workable by simply deleting the phrase "volume or value" from the group practice definition at 42 U.S.C. § 1395nn(h)(4).

Congress should acknowledge that limitations on the "volume or value of referrals" are properly handled in the exceptions set forth in the Stark statute and regulations, rather than in the definition of the term "group practice." The threshold question of whether a physician entity qualifies as a "group practice" should be simple and easy to understand for independent practices. This issue will only become harder to navigate as reimbursement is more commonly based on the overall "value" of a physician's care. **As a result, we request that Congress delete the phrase "volume or value" from the definition at 42 U.S.C. § 1395nn(h)(4).**

B. Fair Market Value

CMS's inclusion of the phrase "volume or value" in the regulatory definition of fair market value creates significant, unnecessary complexity with respect to value-based payment arrangements. **Congress can address this issue by modifying the statutory definition of fair market value at 42 U.S.C. § 1395nn(h)(3) to affirmatively state that compensation may vary with the volume or value of referrals if necessary to implement MACRA payment reforms.**

For example, one of the most important elements of the MIPS is that fee-for-service reimbursement will be adjusted based on the objective "value" of an individual physician's care. For the first time, two similarly situated physicians performing the same service might receive *substantially different reimbursement*. Physician practices must be able to structure compensation that reflects this kind of differential value.

The incorporation of the "volume or value" standard into the "fair market value" definition may have had some merit in a pre-MACRA, fee-for-service payment system. CMS was concerned about compensation methodologies that made a physician's

[49] See e.g., the in-office ancillary service exception at 42 U.S.C. § 1395nn(b)(2).

payment contingent on his or her referrals to the entity.[50] The policy rationale was that a physician would be more likely to increase referrals for unnecessary services (or direct referrals to a lower-quality provider) due to this incentive. This is because, under a fee-for-service payment system, an entity's overall revenue was primarily based on volume. As a result, a physician's high-quality care would not carry any direct financial benefit to the entity. Now, in a post-MACRA world, the quality of a physician's services (and the metrics developed to measure that quality) are highly relevant to payment structures. This is also true for other elements of the MIPS composite score—particularly resource use—for which practices will want to incentivize better performance.

DHPA's member practices need the clarity to ensure that they can compensate physician members to properly reflect the performance of each physician. In the payment system created by the MIPS, this means payment based on quality or resource use. However, it is possible to see this kind of compensation methodology as taking into account the "value" of a physician's referrals or other business generated. This is particularly true when the group obtains an overall quality bonus due to the performance of its physician members. In this case, a regulator could see an incentive payment as a payment to incentivize referrals, which could violate the "fair market value" standard.

C. Waivers

The ACO waivers provide significant flexibility to facilitate integrated, coordinated care. There is no reason why this kind of flexibility should not be extended to cover the new processes designed by Congress and embodied in MACRA. Unfortunately, the waivers currently contain two major deficiencies: (i) they only apply to Shared Savings Program ACOs, but not to other value-based care arrangements; and (ii) they do not extend to private payor arrangements.

Congress can readily address this gap by incorporating the standards of the ACO waivers into 42 U.S.C. § 1395nn(b) as a new exception that applies to the MIPS, physician-focused payment models, and payments associated with APMs.

D. CMS Exception Authority

As discussed in Part I(D), the current CMS exception authority presents serious obstacles to innovation. The Agency cannot create new exceptions unless it demonstrates that the exception does not pose a risk of patient or program abuse.[51] This high bar effectively means that any new change in the business of healthcare must go through a needlessly restrictive rulemaking process. This is particularly concerning given the sheer breadth of rulemaking discretion that Congress delegated to CMS in MACRA. If CMS enjoys the power to establish basic policies like the definition of high-quality care, the use of reporting systems, and the creation of physician-focused payment models, it should also be granted the authority to design a meaningful fraud and abuse system that gives providers equal opportunity—whether they are caring for Medicare beneficiaries in hospitals, academic medical centers or independent medical group practices—to achieve program goals. **Therefore, Congress should take this opportunity to broaden the CMS exception authority at 42 U.S.C. § 1395nn(b)(4) to empower the Agency to**

[50] 66 Fed. Reg. 856, 944 (January 4, 2001).
[51] 42 U.S.C. § 13955nn(b)(4).

establish new exceptions covering financial relationships that promote the evolving goals of Medicare Part B (42 U.S.C. Chapter 7, Subchapter 18, Part B).

DHPA greatly appreciates the opportunity that your Committees have provided us to share our thoughts on the reforms that should be made to the Stark Law in order to support the implementation and success of MACRA. Please reach out with any questions to John McManus (jmcmanus@mcmanusgrp.com) at (202) 546-6040, Tracy Spicer (tspicer@dcavenuesolutions.com) at (202) 347-8725, or Howard Rubin (howard.rubin@kattenlaw.com) at (202) 625-3534.

Sincerely,

Scott Ketover, M.D.
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