DIGESTIVE HEALTH
PHYSICIANS ASSOCIATION®

12510 PROSPERITY DRIVE | SUITE 200 | SILVER SPRING, MD 20904

August 24, 2018

BY ELECTRONIC SUBMISSION

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Comments to CMS-1720-NC

Dear Administrator Verma:

On behalf of the Digestive Health Physicians Association ("DHPA"), we thank you for the opportunity to respond to the Medicare Program Request for Information ("RFI") Regarding the Physician Self-Referral ("Stark") Law.[1] As the voice of the nation's leading independent gastroenterology practices, DHPA is committed to ensuring that independent GI practices across the country are able to participate in alternative payment models ("APMs") and other novel financial arrangements that deliver better and more coordinated care for Medicare beneficiaries and other patients. Unfortunately, our ability to achieve these goals is hampered by the lack of protection under the Stark Law for physicians seeking to participate in these new value-based payment arrangements.

We appreciate the Administration's recognition of the fact that we cannot "transform the health care system into one that pays for value"[2] —the core principle behind the bipartisan Medicare Access and CHIP Reauthorization Act ("MACRA")[3]—without modernizing the Stark Law. As we explain in this comment letter, we believe that the effort to reform Stark will require collaboration by Congress, HHS and CMS in striking a balance between statutory changes that will need to be made through legislative action and regulatory changes that can be made by CMS through its existing regulatory authority.

[1] 83 Fed. Reg. 29524 (June 25, 2018).
[2] *Id*. at 29524
[3] Pub. L. 114-10, enacted April 16, 2015.

We divide our comment letter into three sections. First, we describe two specific examples of APMs that our member practices were instrumental in developing but have been blocked, in significant part, from being implemented for the benefit of Medicare beneficiaries by the challenges posed by the Stark Law. Second, we focus on significant ways in which CMS, through its existing regulatory authority, can create greater flexibility under the Stark Law to enable independent gastroenterology (and other specialty) practices to participate more fully in value-based payment models. Third, because it is important to take a holistic approach to modernizing the Stark Law, we describe—and seek CMS's support for—three modifications to the Stark statute that are at the heart of the bipartisan Medicare Care Coordination Improvement Act pending in Congress.[4]

Digestive Health Physicians Association

DHPA formed in early 2014 to promote and protect the high quality, cost-effective and coordinated care furnished in independent gastroenterology practices. DHPA 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 has grown to include 78 member gastroenterology practices from 36 states in every region of the country. Our more than 1,800 physicians provide care to approximately 2.5 million patients annually in more than four million distinct patient encounters. Physicians in DHPA member practices are on the front lines of providing innovative treatments for serious diseases and chronic conditions such as colorectal cancer, Crohn's disease, and Ulcerative Colitis.

DHPA member practices are also committed to exploring new, coordinated care models for the benefit of our patients. We recently surveyed our member practices to collect information regarding the ways in which our member practices are currently engaged in—or are seeking to develop—APMs and other novel financial arrangements.[5] The overwhelming majority (over 80%) of respondents who were not ACO participants were interested in joining one in the future;[6] nearly 80% of respondents were interested in developing a GI-specific initiative under the Center for Medicare and Medicaid Innovation ("CMMI").[7] But despite this strong interest, fewer than half of our member practices currently participate in an ACO. And, as we show below, the Stark Law is in need of reform to ensure that independent gastroenterology and other physician specialty practices are able to participate in APMs and other value-based payment models such as those contemplated by MACRA.

[4] S. 2051 & H.R. 4206, 115th Congress (2017-2018).
[5] Digestive Health Physician Association Member Practice Survey – Alternative Payment Models.
[6] *Id.*
[7] *Id.*

In response to the Stark Law posing such serious barriers to coordinated care, DHPA has been a leader in developing responsible proposals for modernizing the 30-year-old statute and its accompanying regulations. In January 2016, we submitted comments to Congress in which we identified those aspects of the Stark Law that we believe need to be modified through legislative action.[8] Later that year, we urged CMS to exercise its existing regulatory authority to make targeted changes to the Stark Law to enable independent gastroenterology (and other specialty) practices to participate fully and successfully in the MIPS and Advanced APMs.[9] And, over the last year, we have actively supported the bipartisan Medicare Care Coordination Improvement Act of 2017 (S. 2051/H.R. 4206) that seeks to expand the Secretary's waiver authority and the Agency's authority to create additional exceptions to the Stark Law for purposes of promoting physician participation in APMs.[10] DHPA has led a coalition of 25 physician organizations, representing over 500,000 physicians, that have supported the bill's introduction and growing support in Congress.

I. The Need for Stark Reform Has Serious, Practical Implications for the Delivery of Value-Based Care to Medicare Beneficiaries.

Independent gastroenterology practices have been at the forefront of developing APMs and other novel financial arrangements for the benefit of Medicare beneficiaries and other patients. In fact, DHPA member practices were responsible for developing two of the first five Advanced APM proposals submitted to the Physician-Focused Payment Model Technical Advisory Committee ("PTAC"). A brief discussion of each of those proposals will provide CMS with concrete examples of the kind of value-based payment models being developed by independent gastroenterology practices that are in need of protection under the Stark Law.

Project Sonar is a care management program developed to improve the management of patients with high-beta chronic diseases, where outcome and cost are highly variable.[11,12] It

[8] Comment Letter from DHPA President Scott Ketover, M.D. and Health Policy Chair Michael Weinstein, M.D. to The Honorable Orrin G. Hatch, Chairman, U.S. Senate Committee on Finance, and The Honorable Kevin Brady, Chairman, U.S. House of Representatives Committee on Ways and Means, "Stark Law Reform," (Jan. 29, 2016).

[9] Comment Letter from DHPA President Fred Rosenberg, M.D. and Health Policy Chair Lawrence Kim, M.D. to CMS Acting Administrator Andrew Slavitt, CMS-5517-P (June 27, 2016) pp. 3-5.

[10] See Letter from DHPA and 23 other national medical societies to The Honorable Robert J. Porman and The Honorable Michael F. Bennett in Support of S. 2051 (Nov 1. 2017); Letter from DHPA and 23 other national medical societies to The Honorable Larry Buschon, M.D., The Honorable Raul Ruiz, M.D., The Honorable Kenny Marchant, The Honorable Ron Kind in Support of H.R. 4206 (Nov 1. 2017).

[11] See Project Sonar Advanced APM submitted by the Illinois Gastroenterology Group and SonarMD, LLC to the Physician-Focused Payment Model Technical Advisory Committee (Dec. 21, 2016)

is a critically important Advanced APM for our physicians who are on the front lines diagnosing and caring for the millions of patients who suffer with these diseases. In gastroenterology, the main high-beta diseases are the Inflammatory Bowel Diseases ("IBD")—Crohn's Disease and Ulcerative Colitis, which affect upwards of 1.5 million Americans.[13] And, in the Medicare population, IBD is responsible for 2.5 times the per capita cost of care.[14]

The key to Project Sonar, which has been deployed, to date, only in the commercial setting, is the combined use of evidence-based medicine coordinated with proactive patient engagement. Project Sonar enables us to

- decrease the cost of care for our patients with IBD by decreasing the complication rate through enhanced patient engagement;
- identify the high-risk patient with IBD before complications ensue;
- channel care of patients to those healthcare professionals in our practices who have the most knowledge, experience and expertise to address the specific patient's needs; and
- better engage our patients so that early warning signs can routinely be assessed even before the patients realize they need intervention.

In short, Project Sonar's enhanced patient engagement represents a powerful tool that improves the quality of life of our patients and decreases costs by reducing potentially avoidable complications, emergency department visits, and inpatient admissions. It fosters a

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("Project Sonar Submission"), *available at* https://aspe.hhs.gov/system/files/pdf/253406/ProjectSonarSonarMD.pdf p. iv (last accessed Aug. 23, 2018).

[12] Clinical Gastroenterology and Hepatology 2016;14:1751–1752.

[13] An analysis in the peer-reviewed literature estimates that annual, IBD-associated treatment costs in the United States are $6.3 billion ($3.6 billion for Crohn's disease, $2.7 billion for ulcerative colitis). See Kappelman, MD, et al., "Direct Health Care Costs of Crohn's Disease and Ulcerative Colitis in United States Children and Adults," Gastroenterology 2008 Dec; 135(6): 1907-1913, *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2613430/, (last accessed Aug. 18, 2017).

[14] See Presentation to PTAC by Dr. Paul Casale, Preliminary Review Team ("PRT") assigned to Project Sonar, *available at* https://www.youtube.com/watch?v=Eb2nd4jhIfk&list=PLrl7E8KABz1GhfgKO2KNvwVT59K-wYSw0&index=1, at 16:53 (April 19, 2017) (noting that in 2015, the data reviewed by the PRT showed that approximately 0.48 percent of the Medicare fee-for-service population had inflammatory bowel disease, and this accounted for 1.25 percent of fee-for-service spending") (last accessed August 19, 2018).

true partnership between us as clinicians and our patients—with a documented patient engagement rate of 75-80% maintained over a 24-month study period.[15] Moreover, Project Sonar shifts the management and care of patients with IBD and other high-beta diseases from a reactive to proactive model, inducing the transformation of the practice from fee-for-service reimbursement to a value-based payment model.

PTAC approved Project Sonar on a pilot basis. Yet, there was no mechanism under the Stark Law to test Project Sonar in the Medicare population prior to submission to PTAC and, ultimately, the submission was not approved by CMS (much like every other Advanced APM proposal submitted to PTAC). Given its success in the commercial markets, this was a missed opportunity, because adoption of the Project Sonar Advanced APM would have allowed specialists to participate in value-based care outside of an ACO/MSSP model and to do so in connection with chronic diseases and conditions that are not triggered by a surgical procedure on an inpatient or outpatient basis. Ultimately, Project Sonar was about improving patient outcomes and creating shared savings for Medicare and providers.

For its part, the Comprehensive Colonoscopy Advanced APM for Colorectal Screening, Diagnosis and Surveillance ("Colonoscopy Advanced APM"), was developed as a comprehensive, prospective bundled payment with retrospective reconciliation to encourage practitioners from multiple specialties to collaborate and coordinate care across settings to more effectively manage patients who require colonoscopy for colorectal cancer ("CRC") screening, diagnosis, and surveillance, and for other diagnostic purposes.[16] Given the critical nature of early CRC screening as a tool in fighting colon cancer, and the serious deficiencies in screening rates that continue to exist in eligible U.S. adults age 50 to 75, the Colonoscopy Advanced APM presented a perfect opportunity to close the gaps in CRC screening, improving detection of CRC at early stages, decreasing the rate of CRC, and improving survival for this disease.[17] Importantly, the Colonoscopy Advanced APM would have addressed a substantial problem with Medicare's current, fee-for-service reimbursement structure, which unnecessarily pays hospitals twice as much as independent ambulatory surgery centers for the facility fee in connection with identical colonoscopy procedures. As was the case with Project Sonar, in light of the roadblocks created by the Stark Law, there was no mechanism for testing the Colonoscopy Advanced APM in the Medicare population prior to submission.

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[15] Project Sonar Submission p. 4.

[16] See Colonoscopy Advanced APM submitted by the Digestive Health Network, Inc. to PTAC (Dec. 28, 2016), *available at* https://aspe.hhs.gov/system/files/pdf/253406/PFPM.pdf (last accessed Aug. 23, 2018).

[17] Public Comment from Digestive Health Physicians Association to PTAC, p.2 (Jan. 5, 2017) re: Colonoscopy Advanced APM ("DHPA Comment on Colonoscopy Advanced APM"), *available at* https://aspe.hhs.gov/system/files/pdf/255731/ComprehensiveColonoscopyAAPMPublicCommentsUpdated.pdf (last accessed Aug. 23, 2018).

DHPA supported both proposals, because we believed (and continue to believe) that Project Sonar and the Colonoscopy Advanced APM are the types of innovative care models that ensure high quality, cost-efficient, coordinated care in the Medicare program.[18] And, yet, Medicare beneficiaries are not benefitting from either of these Advanced APMs due, in large measure, to Stark Law prohibitions created 30 years ago for a fee-for-service payment model that did not contemplate such value-based care delivery models. Limited changes to the Stark Law—including the ability of group practices to test care delivery models such as Project Sonar and the Colonoscopy Advanced APM in "real world" clinical practice for the benefit of Medicare beneficiaries while awaiting Agency action—will unlock innovation and enable HHS to realize its goal of transforming the healthcare system into one that pays for value.

[18] Public Comment from Digestive Health Physicians Association to PTAC (Jan. 20, 2017) re: Project Sonar Advanced APM, *available at* https://aspe.hhs.gov/system/files/pdf/255731/ProjectSonarPublicComments.pdf (last accessed Aug. 23, 2018); DHPA Comment on Colonoscopy Advanced APM.

II. CMS Can Exercise Its Existing Regulatory Authority to Modify the Stark Law In Order to Achieve the Goals of MACRA.

Administrator Verma hit the proverbial "nail on the head" when she explained that, in modernizing the Stark Law, we must "leave in place the law's important protections for our beneficiaries—and for the trust fund—while not penalizing providers who are taking brave steps away from fee-for-service."[19] It is next-to-impossible for physicians in independent gastroenterology (and other specialty) practices to take those "brave steps away from fee-for-service" and towards value-based care, thereby achieving MACRA's policy objectives, in the face of Stark Law provisions that inhibit coordination between providers in a fee-for-service system. In order for MACRA to succeed, CMS must develop new flexibilities within the Stark Law to allow physicians to better coordinate care, work as teams (often across specialties such as gastroenterology and pathology) and participate in a broad range of APMs. At the same time, the success of independent specialty practices under MACRA depends in part on the use of existing provisions of the Stark Law, including the in-office ancillary services exception, that ensure the delivery of comprehensive, integrated care demanded by MACRA.

MACRA makes physician group practices much more accountable for the overall healthcare status and resource use of their patients—whether or not these measures are driven by services provided by the group itself. As but one example, the MIPS resource use metric, and the measures of spending used by each of CMS's approved Advanced APMs, are largely based on the *total cost* of each attributed patient's care under Medicare Part A and Part B.[20] The total cost of care will necessarily capture spending for services outside the domain of the independent practice itself, such as hospitalization, prescription drugs and post-acute care.

Under MACRA, physicians share responsibility for the quality and cost of care provided to patients, whether or not providers across sites of service have any formal relationship. As such, physicians in independent practice need options to structure relationships with hospitals and other community providers to ensure patients are receiving care from high-quality, cost-efficient providers on a coordinated basis. Moreover, physicians need assurance that they may move to formal APMs to redesign the model of care offered to patients without violating the strict liability terms of the Stark Law.

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[19] Excerpt from Remarks by CMS Administrator Seema Verma at American Hospital Association Annual Membership Meeting, May 7, 2018, Washington, DC, *available at* https://www.cms.gov/newsroom/fact-sheets/speech-remarks-cms-administrator-seema-verma-american-hospital-association-annual-membership-meeting (last accessed Aug. 23, 2018) ("Administrator Verma Remarks to AHA").

[20] 81 Fed. Reg. at 28198.

CMS should utilize its existing authority to create new exceptions, which create "no risk for program or patient abuse."[21] The Agency has exercised this authority in the past to protect a number of essential commercial relationships.[22] CMS last attempted to use this authority to protect gainsharing arrangements prior to enactment of the Affordable Care Act.[23] The result was an extremely limited, technical proposal that CMS chose not to finalize after it failed to attract significant support.[24]

The landscape of risk-based arrangements has changed dramatically since CMS's gainsharing proposal. Notably, the Affordable Care Act created the MSSP and CMMI and provided CMS with the ability to develop waivers to support these programs.[25] Since then, the Agency has established a broad waiver of the Stark Law for MSSP ACOs, and has issued certain tailored waivers for CMMI demonstrations.[26] The waivers have now been in place for many years without creating fraud and abuse risks while encouraging more coordinated care with the aim of improving patient outcomes.

However, those limited waivers are generally not relevant to independent gastroenterology (or other specialty) practices that seek to participate meaningfully in APMs. The existing waivers are limited to ACOs operating under the MSSP, or models under the CMMI demonstration authority.[27] The waivers cannot extend to APMs operating under Medicaid or commercial payer arrangements, including those that qualify as "Other Payer Advanced APMs." CMS should address this deficiency since MACRA provides an avenue to becoming a QP through participation in Advanced APM models with commercial payers under the all-payer metric.[28] Without CMS protection, gainsharing payments or other distributions in an Other Payer APM would create "financial relationships" between participants in the APM,[29] and all Medicare referrals between these participants could be prohibited.

Independent gastroenterology practices need a new Stark Law exception protecting our members' participation in any type of *bona fide* APM—whether it is operated by Medicare or

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[21] 42 U.S.C. § 1395nn(b)(4).
[22] See e.g., 42 C.F.R. § 411.357(l) (exception for fair market value relationships).
[23] See 73 Fed. Reg. 38502, 38548.
[24] *Id*.
[25] 42 U.S.C. §§ 1395jjj(f) and 1315a(d)(1).
[26] See the list of CMS and HHS-OIG fraud and abuse waivers for these programs *available at* https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html (last accessed Aug. 20, 2018).
[27] 42 U.S.C. §§ 1395jjj(f) and 1315a(d)(1).
[28] 42 U.S.C. § 1395L(z)(2)(B).
[29] Note that this would be true for any non-Medicare model that is operating as an APM, whether or not it meets the criteria for an "Advanced" APM.

another payer. We do not believe that Congress or CMS intended to create an artificial distinction between how physicians who participate in the MSSP or CMMI models treat Medicare patients as contrasted with patients who are covered by other payers. For now, though, waivers apply *only* to arrangements with MSSP ACOs and entities participating in CMMI programs, but no waivers or other Stark Law exceptions apply to equivalent entities in a non-Medicare context. Existing Stark Law exceptions for compensation relationships frequently do not protect non-Medicare value-based arrangements because these exceptions prohibit payments that vary with the volume or value of "other business generated."[30] Thus, financial relationships between a physician and a DHS entity created as a result of participation in a Medicare program are protected from Stark liability (assuming that providers can overcome the practical challenge of PTAC not approving Advanced APM proposals), but the same financial relationships created under a non-Medicare program could violate the Stark Law. As a result, current Stark Law exceptions arguably force a physician and DHS entity to establish entirely different care models for treating non-Medicare patients. This is becoming increasingly unworkable as MACRA transforms the entire payment system—public and private.

We ask CMS to use its current authority to create a new regulatory exception under the Stark Law for participation in Medicare *and* non-Medicare APMs. This exception should be consistent with the structure of the waivers issued by CMS for existing MSSP and CMMI ACO models. Such a new exception—coupled with the Stark Law's existing in-office ancillary services exception that fosters care models that deliver integrated, comprehensive care—is needed to ensure that independent gastroenterology (and other specialty) practices can participate in a full complement of APMs. This will go a long way toward promoting better, more integrated care under MACRA and to achieving the mission of HHS's Regulatory Sprint to Coordinated Care.

[30] See *e.g.*, 42 C.F.R. § 411.357(l)(3) (the exception for fair market value arrangements). Although this exception might protect the financial relationship created between an entity and a physician as a result of non-Medicare shared savings earned collectively by both entities, the fact that such savings would potentially reflect the referral patterns of the physician to the entity could arguably "take into account the volume or value of . . . other business generated by the referring physician."

III. CMS Should Support the Medicare Care Coordination Improvement Act as a Complement to Stark Reform that the Agency Can Make Under Its Existing Regulatory Authority While Also Protecting Coordinated Care Through the Stark Law's In-Office Ancillary Services Exception.

The Stark Law is implemented through statute and regulation. And, while we recognize that this RFI "focuse[s] on identifying *regulatory* requirements or prohibitions that may act as barriers to coordinated care,"[31] we believe it is critical to examine, holistically, the challenges the Stark Law poses so that CMS and Congress can determine which modifications can be made through the Agency's existing regulatory authority and which modifications require changes to the statute.

For the last year, DHPA and a coalition of two dozen specialty physician organizations have been working closely with Congressional staff on legislation to modernize those aspects of the Stark statute that pose barriers to participation and care coordination in APMs. Those efforts resulted in the introduction in the Senate and House of the bipartisan Medicare Care Coordination Improvement Act of 2017 (S. 2051 & H.R. 4206), which is gaining support and was the focus of a recent hearing in the House Ways and Means Committee.[32]

The guiding principle behind the legislation—consistent with the goals Administrator Verma recently articulated[33]—is to ensure that efforts to modernize Stark to permit greater participation in APMs and other novel financial arrangements do no harm to the original intent of the Stark law as a mechanism for regulating improper incentives that could lead to increased utilization. The bill accomplishes this by amending the Stark statute in three ways:

(a) Waivers to Promote Care Coordination by Facilitating Participation in APMs

This subsection permits the Secretary to waive the Anti-Kickback Statute and Civil Monetary Penalties Law provisions that are barriers to participation in all types of APMs.[34] This waiver

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[31] 83 Fed. Reg. at 29524.
[32] Hearing before the U.S. House of Representatives Ways and Means Subcommittee on Health, "Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program" (July 17, 2018).
[33] See Administrator Verma Remarks to AHA, n.19 *supra*.
[34] See § 2(a), S. 2051 & H.R. 4206, 115th Congress (2017-2018), available at https://www.congress.gov/bill/115th-congress/senate-bill/2051?q=%7B%22search%22%3A%5B%22s.+2051%22%5D%7D&r=1 & https://www.congress.gov/bill/115th-congress/house-bill/4206/text (last accessed Aug. 14, 2018).

authority mirrors the current waiver authority set forth in section 1899jjj(f) of the Social Security Act to facilitate participation in the Medicare Shared Savings Program.

(b) Promotion of Care Coordination through Expansion of Administrative Authority to Provide Exceptions to the Stark Law's Physician Ownership and Compensation Arrangement Prohibitions

This subsection gives CMS broader authority than under current law to create exceptions to the Stark law that do not pose a significant risk of program or patient abuse, including those that would promote care coordination, quality improvement or resource conservation.[35] The provision also ensures that CMS will not interpret the Stark Law to impose requirements (even under current exceptions) that could adversely affect physician care coordination in the MIPS or participation in APMs under the Medicare program.[36]

(c) New Statutory Exception to the Stark Law to Facilitate the Development and Operation of APMs

This new statutory exception (to be codified at 42 U.S.C. § 1395nn(b)(6)) is designed to protect arrangements that are entered into for the purpose of developing or operating an APM (including, Advanced APMs, MIPS APMs, and other APMs specified by the Secretary) and are in writing and signed by parties to the arrangement.[37] For purposes of the new exception, items and services must be subject to fair market value except the Secretary may not take into account the volume or value of referrals in determining such fair market value.[38] The arrangement must meet other requirements as the Secretary may impose by regulation as needed to protect against significant risk of program or patient abuse. This provision recognizes the protections needed for practices striving to qualify for any type of APM under a written agreement with the Secretary and for those operating approved APMs.

This reform is critical to the successful testing and operation of APMs (such as Project Sonar and the Colonoscopy Advanced APM), particularly those provided by physician specialty practices, because a substantial portion of practice revenue is derived from designated health services, which are presently tightly regulated by the Stark statute. If practices cannot reward or penalize their physicians monetarily for abiding by best practices and exemplary treatment

[35] *Id.* § 2(b)(1).
[36] *Id.* § 2(b)(2).
[37] *Id.* § 2(c).
[38] *Id.*

pathways, we have little ability to deliver more coordinated care that can improve health outcomes and restrain costs.

Our comments have focused on the discrete regulatory and statutory changes to the Stark Law that are needed to promote care coordination, but it is equally important that CMS not alter—or support altering through legislation—the in-office ancillary services exception ("IOASE") to the Stark Law. That provision provides a bulwark protection for physicians in independent practices to provide comprehensive, coordinated care to their patients at a lower cost to Medicare and seniors than if those same services (e.g., advanced imaging, anatomic pathology) continue to migrate into the more expensive hospital inpatient and outpatient settings. And, yet, the President's Budget proposes to establish a targeted prior authorization program for certain in-office ancillary services.

Simply put, there is no basis for changing the application or scope of the IOASE, particularly when Medicare data shows that utilization of designated health services is growing faster in hospitals than in physician offices. Two different studies by Milliman—separately commissioned by the American Medical Association ("AMA") and DHPA—showed that utilization of ancillary services in physician practices is a small percentage of total spending on ancillary services and is declining or growing more slowly than in hospital settings.[39,40] As the AMA noted with respect to the Milliman study it commissioned, "the data simply do not support the contention that self-referral causes over utilization or increased Medicare spending." [41] Any narrowing of protections under the IOASE would undermine the Administration's efforts to enhance care coordination and promote value-based payment models.

V. Request for Action

DHPA looks forward to working with HHS and CMS to transform the healthcare system into one that pays for value. Congress began that process three years ago by enacting MACRA, but the job cannot be completed without discrete modifications to the Stark Law. CMS has the regulatory authority to make certain of the needed changes; others will require action by Congress. As the agency charged with administering the Stark Law, we believe CMS will play a critical role with respect to all aspects of Stark modernization.

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[39] American Medical Association, Milliman Study, March 2015, *available at* https://www.ama-assn.org/practice-management/medicare-office-ancillary-services-exception (last accessed Aug, 21, 2018).

[40] Digestive Health Physicians Association, Milliman Study, February 2015, *available at* http://cqrcengage.com/dhpa/file/Mqq6fLiKQM1/03-2009-2013 Medicare Utilization Analysis.pdf (last accessed Aug. 21, 2018).

[41] See https://www.ama-assn.org/practice-management/medicare-office-ancillary-services-exception (last accessed Aug, 21, 2018).

To that end, we respectfully request that CMS take the following steps to ensure that, post-MACRA value-based payment arrangements work well for all physicians, including those of us who care for patients in the independent practice setting:

- Exercise the Agency's existing regulatory authority to create a new exception to the Stark Law that is consistent with the structure of existing MSSP and CMMI waivers for ACO models, while maintaining other existing protections for integrated care, so that independent gastroenterology (and other specialty) practices can participate in a full complement of APMs.

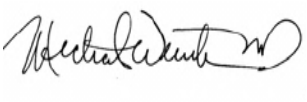
- Exercise the Agency's existing regulatory authority to extend the protections of the ACO waivers to physicians and DHS entities that participate in Other Payer APMs.

- Support passage of—and provide technical assistance in connection with—the bipartisan Medicare Care Coordination Improvement Act of 2017 (S. 2051 & H.R. 4206) as a mechanism for making those changes to the Stark Law that the Agency cannot achieve through regulation.

- Oppose changes to the Stark Law's in-office ancillary services exception, which has been critical to the delivery of cost-effective, integrated care to Medicare beneficiaries in the independent practice setting.

Please reach out with any questions to DHPA's Chair of Health Policy, Dr. Naresh Gunaratnam (gunaratnamn@hurongastro.com, 734-714-0455), or to DHPA's legal counsel, Howard Rubin (Howard.Rubin@kattenlaw.com, 202-625-3534).

Sincerely,



Michael Weinstein, M.D.
President

Naresh Gunaratnam, M.D.
Chair, Health Policy

cc: Kevin Harlen, DHPA Executive Director
Howard Rubin, Esq., Katten Muchin Rosenman LLP