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October 26, 2018

BY ELECTRONIC SUBMISSION

Susan Edwards
Office of Inspector General
Department of Health and Human Services
Room 5512, Cohen Building
330 Independence Avenue, SW
Washington DC 20201

RE: Comments to OIG-0803-N

Dear Ms. Edwards:

On behalf of the Digestive Health Physicians Association ("DHPA"), we thank you for the opportunity to respond to HHS-OIG's Request for Information ("RFI") regarding the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalty.[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 Anti-Kickback Statute ("AKS")—as well as other laws such as the federal physician self-referral ("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 AKS and Stark Law. As HHS Deputy Secretary Hargan put it in recent Congressional testimony, it is critical that health care fraud and abuse laws "aren't strangling innovation and new models of care that will be for the

[1] 83 Fed. Reg. 43607 (Aug. 27, 2018).
[2] *Id*. at 43608.
[3] Pub. L. 114-10, enacted April 16, 2015.

benefit of the American people."[4] For our part, DHPA believes that the effort to reform the AKS and Stark Law will require collaboration by Congress, HHS, OIG and CMS in striking a balance between statutory changes that will need to be made through legislative action and changes that can be made by OIG and CMS through their existing regulatory authority. Most relevant for purposes of our response to this RFI, we believe that OIG can make significant reform to the AKS, while protecting the Medicare programs and beneficiaries, in order to aid in the transition from a fee-for-service to value-based payment structure.

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 AKS and Stark Law. Second, we focus on significant ways in which OIG, through its existing regulatory authority, can create greater flexibility under the AKS 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 health care fraud and abuse laws, we describe—and seek OIG's support for—the bipartisan Medicare Care Coordination Improvement Act that continues to gain support in Congress.[5]

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.[6] The overwhelming

[4] See Testimony of HHS Deputy Secretary Eric Hargan, 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).
[5] S. 2051 & H.R. 4206, 115th Congress (2017-2018).
[6] Digestive Health Physician Association Member Practice Survey – Alternative Payment Models.

majority (over 80%) of respondents who were not ACO participants were interested in joining one in the future;[7] nearly 80% of respondents were interested in developing 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 show below, the AKS (much like 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.

In response to current health care fraud and abuse laws posing such serious barriers to coordinated care, DHPA has been a leader in developing responsible proposals for modernizing these statutes and accompanying regulations. In January 2016, we submitted comments to Congress on the topic,[9] and 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.[10] And, over the last year, we have led a coalition of 25 physician organizations, representing over 500,000 physicians, actively supporting the bipartisan Medicare Care Coordination Improvement Act of 2017 (S. 2051/H.R. 4206).[11] Most recently, we submitted comments to CMS in response to its RFI seeking input on reform of the Stark Law[12] and testified before the House Energy and Commerce Subcommittee on Health on the very topic that it the subject of this RFI—the importance of removing barriers that impede the development of APMs and other value-based care delivery models.[13]

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[7] *Id.*
[8] *Id.*
[9] 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).
[10] 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.
[11] 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).
[12] Comment Letter from DHPA President Michael L. Weinstein, M.D. and Health Policy Chair Naresh Gunaratnam, M.D. to CMS Administrator Seema Verma, CMS-1720-NC (Aug. 24, 2018).
[13] Testimony of Michael L. Weinstein, M.D., DHPA President, Hearing Before the U.S. House of Representatives Energy and Commerce Subcommittee on Health, "Examining Barriers to Expanding Innovative, Value-Based Care in Medicare," (Sept. 13, 2018) ("DHPA Cong. Testimony").

I. The Need for Reform of the Anti-Kickback Statute 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 OIG 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 AKS and 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.[14,15] It 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.[16] And, in the Medicare population, IBD is responsible for 2.5 times the per capita cost of care.[17]

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 do the following:

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[14] 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) ("Project Sonar Submission"), *available at* https://aspe.hhs.gov/system/files/pdf/253406/ProjectSonarSonarMD.pdf p. iv.

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

[16] 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/.

[17] 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").

- 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 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.[18] 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 federal health care fraud and abuse laws to test Project Sonar in the Medicare population prior to submission to PTAC and, ultimately, the submission was not approved (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")

[18] Project Sonar Submission p. 4.

screening, diagnosis, and surveillance, and for other diagnostic purposes.[19] 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.[20] 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 AKS and Stark Law, there was no mechanism for testing the Colonoscopy Advanced APM in the Medicare population prior to submission.

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.[21] And, yet, Medicare beneficiaries are not benefitting from either of these Advanced APMs due, in large measure, to decades-old prohibitions in the AKS and Stark Law created for a fee-for-service payment model that did not contemplate such value-based care delivery models. Limited changes to the AKS and 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.

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[19] 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.

[20] 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.

[21] 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; DHPA Comment on Colonoscopy Advanced APM.

II. OIG Can Exercise Its Existing Regulatory Authority to Modify the Anti-Kickback Statute In Order to Achieve the Goals of MACRA.

Administrator Verma hit the proverbial "nail on the head" when she explained, in connection with the need to modernize the Stark Law, that 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."[22] Administrator Verma's statement applies doubly with respect to the AKS, given the criminal liability and potentially bankrupting damages and penalties, including under the False Claims Act, that attach to AKS violations.[23] 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 AKS provisions that inhibit coordination between providers in a fee-for-service system. In order for MACRA to succeed, OIG must develop new flexibilities within the AKS 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.

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.[24] 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 AKS.

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[22] 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 ("Administrator Verma Remarks to AHA").

[23] 42 U.S.C. § 1320a-7b(b); *id.* § 1320a-7a(a); 31 U.S.C. § 3729(a)(1).

[24] 81 Fed. Reg. at 28198.

The central purpose of MACRA is to transform our health care system from a fee-for-service model in which physicians furnish care in silos to a value-based payment model in which physicians collaborate across specialties and sites of service and take on risk with the aim of delivering high quality, cost-efficient care. But no physician (or other individual or entity) reasonably can be expected to take on the risk of crushing civil and criminal liability that attaches to violations of the AKS. This creates the proverbial Catch-22 in which MACRA expects independent gastroenterology (and other specialty) practices to share resources and coordinate care across sites of service, but it is that very collaboration that triggers the prospect of civil and criminal liability under the AKS and False Claims Act.

HHS recognized and addressed the potential paralysis of such a situation through the grant of broad waivers for primary care physicians and hospitals. Unfortunately, the most typical Medicare APMs are ACOs through which gastroenterologists and other physician specialists are unable to participate in any meaningful way given that, by definition, a specialist (unlike a primary care physician) is unable to manage a patient population's full spectrum of care. As we showed in Part I above, DHPA and its member practices have been developing potential APM models and other novel financial arrangements that would provide meaningful opportunities for gastroenterologists and other physicians to collaborate across sites of service in order to improve care delivery and reduce expenditures.

The waivers put into effect for ACOs, beginning in 2011, are significant departures from the exacting provisions of the AKS and Stark Law. Those waivers provide broad protection to physicians and entities who are participating (or intend to participate) in the Medicare Shared Savings Program ("MSSP") or certain initiatives proposed by the Center for Medicare and Medicaid Innovation ("CMMI"). HHS also believed it was necessary to waive each ACO's distribution of shared savings to entities inside and outside the ACO (as long as they are used for activities reasonably related to the purposes of the ACO). Those waivers, which have been in effect for seven years, are now part of the fabric of federal health care fraud and abuse law's in the post-MACRA era.

The protections of those waivers should be extended to value-based care models developed by independent gastroenterology (and other specialty) practices. We see no reason why OIG could not take this step in order to facilitate the kind of far-reaching, change contemplated by Congress in MACRA applicable to all physicians, regardless of specialty or site of service. We ask OIG to create a single, comprehensive waiver of the AKS for participants in any bona fide APM.

OIG can also exercise its regulatory authority to establish a new safe harbor for those seeking to develop and participate in APMs and other value-based payment arrangements that would shield them from liability under the AKS. Although a new safe harbor to be applied on a case-by-case basis would not be as effective (or efficient) in removing barriers to coordinated care as a broader waiver of the AKS, a new safe harbor focused on protecting participants in APMs would 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.

III. OIG Should Support the Medicare Care Coordination Improvement Act as Part of the Overall Effort to Modernize Health Care Fraud and Abuse Laws to Promote Coordinated, Value-Based Care.

Although we recognize that this RFI focuses on the ways in which the AKS acts as a barrier to coordinate care and the steps that OIG might be able to take, through regulation, to address that concern, OIG acknowledged in the RFI the "intersection" that exists between the AKS and Stark Law and sought feedback on how exceptions to the Stark Law and safe harbors to the AKS "should align for purposes of the goals of this RFI."[25] We share OIG's view that it is important to examine, holistically, the challenges the AKS and Stark Law pose so that OIG, CMS and Congress can determine which modifications can be made through existing regulatory authority and which modifications require changes to statutes.

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 federal health care fraud and abuse laws set forth in 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 recent hearings in the House Ways and Means Committee as well as in the House Energy and Commerce Committee.[26]

The guiding principle behind the legislation—much like our proposals outlined in this comment letter with respect to modernizing the AKS—is to ensure that efforts to modernize

[25] 83 Fed. Reg. at 43611.

[26] 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); Hearing before the U.S. House of Representatives Energy and Commerce Subcommittee on Health, "Examining Barriers to Expanding Innovative, Value-Based Care in Medicare," (Sept. 13, 2018).

health care fraud and abuse laws to permit greater participation in APMs and other novel financial arrangements do no harm to the original intent of those laws law as mechanisms for regulating improper incentives that could lead to increased utilization and cost. The legislation accomplishes this 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.[27] This waiver 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.[28] 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.[29]

(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.[30] For purposes of the new exception, items and services must be subject to fair market value except the Secretary may not take

[27] 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.
[28] *Id*. § 2(b)(1).
[29] *Id*. § 2(b)(2).
[30] *Id*. § 2(c).

into account the volume or value of referrals in determining such fair market value.[31] 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 pathways, we have little ability to deliver more coordinated care that can improve health outcomes and restrain costs. Likewise, if distinct health care entities—whether it be multiple independent medical practices working together or a medical practice and hospital coordinating care—are unable to distribute shared savings across entities to reward the delivery of high quality, cost-efficient care without risking violation of the AKS—then MACRA's goal of shifting the Medicare program from a fee-for-service to value-based payment system will not be realized.

IV. Request for Action

DHPA looks forward to working with OIG 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 Anti-Kickback Statute and Stark Law. OIG and CMS have the regulatory authority to make certain of the needed changes; others will require action by Congress. With its enforcement authority under the AKS, we believe OIG will play a critical role with respect to the modernizing of federal health care fraud and abuse laws.

To that end, we respectfully request that OIG 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 existing regulatory to create a comprehensive waiver of the AKS for participants in bona fide APMs so that independent gastroenterology (and other specialty) practices can participate in a full complement of APMs.

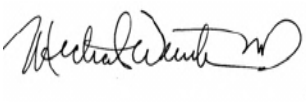
[31] *Id.*

- Create a new safe harbor under the AKS to encourage development and operation of APMs and other value-based care delivery models.

- Support passage of the bipartisan Medicare Care Coordination Improvement Act of 2017 (S. 2051 & H.R. 4206) as a mechanism for making those changes to health care fraud and abuse laws that cannot be achieved through regulation.

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