DIGESTIVE HEALTH PHYSICIANS ASSOCIATION®



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December 31, 2019

**BY ELECTRONIC SUBMISSION**

Joanne Chiedi, Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Room 5521, Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

RE: Comments to OIG-0936-AA10-P

Dear Ms. Chiedi:

The Digestive Health Physicians Association ("DHPA") submits these comments in response to the Proposed Rule Regarding Revisions to Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements ("AKS Proposed Rule").[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 value-based arrangements ("VBAs") that deliver high quality, coordinated care for Medicare beneficiaries and other patients. The Office of Inspector General ("OIG") has appropriately recognized that our ability to participate in VBAs is hampered by the lack of protection afforded valued-based care delivery and payment models under the Anti-Kickback Statute ("AKS") and other health care fraud and abuse laws such as the federal physician self-referral law ("Stark Law").

We appreciate the Administration's recognition of the fact that we cannot "transform[]our 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 observed in 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] 84 Fed. Reg. 55694 (Oct. 17, 2019).
[2] *Id*. at 55694.
[3] Pub. L. 114-10, enacted April 16, 2015.

benefit of the American people."[4] DHPA appreciates the steps that OIG and CMS are taking, through their respective regulatory authority, to address this very real concern. In this comment letter (and in comments being submitted contemporaneously to CMS), we endorse various of the proposals that OIG and CMS have made to modernize the AKS and Stark Law to aid in the transition from a fee-for-service to a value-based payment system.

We recognize and appreciate the effort involved in developing such bold changes to the AKS and Stark Law and in coordinating those efforts across OIG and CMS. We also recognize that OIG and CMS have significant work ahead in studying the hundreds, if not thousands, of comments submitted in response to the AKS and Stark Proposed Rules from across the health care industry. With that said, we cannot overstate the importance of OIG and CMS finalizing their respective proposals as soon as possible. Ever since passage of MACRA in 2015, independent gastroenterology (and other specialty) practices have been unable to participate fully in the development and operation of value-based care delivery models out of fear of running afoul of the criminal liability that attaches to violations of the AKS and the civil liability that attaches to violations of the Stark Law. The innovation that the Administration seeks to unlock will not occur without OIG and CMS finalizing and putting into effect their proposals to modernize the AKS and Stark Law.

We divide our comment letter into four sections. First, we offer concrete examples of the types of innovative care models for which protection under the AKS is needed to ensure access to these models for Medicare beneficiaries. Second, we explain the importance of finalizing the newly proposed safe harbors to ensure that value-based care models can be implemented in the independent practice setting. Third, we offer comments on the terminology that OIG has proposed as the foundation for the new AKS safe harbors. Fourth, we provide comments on (i) the proposed Care Coordination Safe Harbor, (ii) the proposed safe harbors that require assumption of risk, and (iii) the proposed Patient Engagement and Support Safe Harbor.

## 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 89 member gastroenterology practices from 38 states in every region of the country. Our more than 2,000 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

[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).

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. In response to OIG's Request for Information ("RFI") regarding the AKS last year, we surveyed our member practices to collect information regarding the ways in which our member practices are participating in or are seeking to develop VBAs.[5] Nearly 80% of respondents were interested in developing a GI-specific initiative under the Center for Medicare and Medicaid Innovation ("CMMI") or in otherwise developing and operationalizing VBAs.[6] Despite this strong interest, only a small percentage of our member practices are participating in VBAs and even fewer in VBAs aimed at delivering care to Medicare beneficiaries.

In response to the barriers that current health care fraud and abuse laws pose 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,[7] 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.[8] Last year, we testified before the House Energy and Commerce Subcommittee on Health on the very topic that is the subject of the AKS and Stark Proposed Rules—the importance of removing barriers that impede the development and operation of value-based care delivery models.[9] DHPA is leading a coalition of 25 physician organizations, representing over 500,000 physicians, actively supporting the bipartisan and bicameral Medicare Care Coordination Improvement Act of 2019. (S. 966/H.R. 2282). Finally, and most relevant to this current rulemaking process, we submitted comments last year to OIG and CMS in response to their respective RFIs seeking input on reform of the AKS and Stark Law.[10]

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[5] Digestive Health Physician Association Member Practice Survey – Alternative Payment Models.
[6] *Id.*
[7] 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).
[8] 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.
[9] 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").
[10] Comment Letter from DHPA President Michael L. Weinstein, M.D. and Health Policy Chair Naresh Gunaratnam, M.D. to Susan Edwards, Office of Inspector General, Department of Health and Human Services, OIG-0803-N (Oct. 26, 2018); Comment Letter from DHPA President Michael L.

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

The AKS, as currently constructed, does not work in an era of value-based care delivery and payment models in which providers need to coordinate care across specialties and sites of service. Reforming the AKS will have impactful consequences for independent gastroenterology practices and the patients we serve.

DHPA's member practices have been at the forefront of developing value-based 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, submitted to PTAC on December 21, 2016, is a care coordination program developed to improve the outcomes of patients with high-beta chronic diseases, where costs are highly variable.[11,12] It is a critically important tool 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] In the Medicare population, IBD is responsible for 2.5 times the per capita cost of care.[14]

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Weinstein, M.D. and Health Policy Chair Naresh Gunaratnam, M.D. to CMS Administrator Seema Verma, CMS-1720-NC (Aug. 24, 2018).

[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) ("Project Sonar Submission"), *available at* https://aspe.hhs.gov/system/files/pdf/253406/ProjectSonarSonarMD.pdf p. iv (last accessed Dec. 14, 2019).

[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 Dec. 14, 2019).

[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

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:

- 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 warning signs of early deterioration can routinely be assessed even before the patients realize they need intervention.

In short, Project Sonar's enhanced patient engagement and care coordination 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.[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 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 the overwhelming majority of Advanced APM proposals submitted to PTAC). Given its success in the commercial markets, this was a missed opportunity, because adoption of the Project Sonar Advanced APM in the Medicare population 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.

Independent gastroenterology practices developed the Comprehensive Colonoscopy Advanced APM for Colorectal Screening, Diagnosis and Surveillance ("Colonoscopy

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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 Dec. 14, 2019).

[15] Project Sonar Submission p. 4.

Advanced APM"), as a comprehensive, prospective bundled payment with retrospective reconciliation to encourage practitioners from multiple specialties to collaborate and coordinate care to manage patients more effectively 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, improve detection of CRC at early stages, decrease the rate of CRC, and improve 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 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, value-based 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 decades-old prohibitions in the AKS and Stark Law created for a fee-for-service payment system that did not contemplate such value-based care delivery models.

CMMI has not approved these PTAC-submitted APMs nor any other of the 16 APMs PTAC has recommended for implementation or testing. The APM approval process at CMMI is totally dysfunctional and has resulted in the resignation of two long-standing PTAC members who declared such on November 19, 2019. In resigning, Harold Miller, president and CEO of the Center for Healthcare Quality and Payment Reform, stated, "[s]adly, not a single one

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[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 Dec. 14, 2019).

[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 Dec. 14, 2019).

[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; DHPA Comment on Colonoscopy Advanced APM.

of the proposals we have recommended is being implemented or tested by the Department of Health and Human Services, and the Secretary has stated that none of them will be."[19]

This is why it is imperative for OIG and CMS to finalize the AKS and Stark Proposed Rules as soon as possible. We cannot wait for CMMI approval of submitted and PTAC-recommended APMs that may never be forthcoming. And the key strength of the AKS Proposed Rule is that it does not rely on CMMI approval of an APM to impart the protections that facilitate value-based care delivery. Rather, the proposals, once finalized, will protect physicians and health care entities complying with the new value-based arrangement requirements.

With respect to the AKS, in particular, the proposed Care Coordination Safe Harbor, Substantial Downside Financial Risk and Full Financial Risk Safe Harbors, and Patient Engagement and Support Safe Harbor, create mechanisms through which VBA participants can avoid the threat of criminal liability under the AKS without going through a burdensome—and, heretofore, ineffective—process for securing protection from CMMI. The narrowly defined, proposed safe harbors, once finalized, will afford group practices the ability 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, thereby unlocking innovation and enabling HHS to realize its goal of transforming the healthcare system into one that pays for value.

## II. The Reforms Proposed by OIG Are Particularly Needed to Ensure that Value-Based Care Models Can be Implemented in the Independent Practice Setting.

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."[20] 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.[21] It is next-to-impossible for physicians in independent 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

[19] "PTAC Members Resign, Say Congress Needs To Step In And Fix Process," Inside Health Policy (Nov. 20, 2019), *available at* https://insidehealthpolicy.com/daily-news/ptac-members-resign-say-congress-needs-step-and-fix-process (last accessed Dec. 17, 2019).
[20] 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 Dec. 14, 2019).
[21] 42 U.S.C. § 1320a-7b(b); *id*. § 1320a-7a(a); 31 U.S.C. § 3729(a)(1).

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 VBAs.

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.[22] 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 the flexibility under our health care fraud and abuse laws 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. That cannot happen without the addition of the newly proposed AKS safe harbors.

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 within practices, 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 that very collaboration triggers the prospect of 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 value-based models 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.

[22] 81 Fed. Reg. at 28198.

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 MSSP or certain initiatives proposed by 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 eight years, are now part of the fabric of federal health care fraud and abuse law's in the post-MACRA era. Yet, until now, independent gastroenterology (and other specialty) practices have been left behind, hamstringing their ability to develop and operate VBAs for the benefit of their patients. OIG's and CMS's proposed changes to the AKS and Stark Law, once finalized, will level the playing field so that independent specialty practices can meaningfully participate in VBAs.

## III. OIG Should Finalize the Key Terminology that Will Govern the New AKS Safe Harbors in a Manner that Provides Maximum Flexibility for the Development of and Participation in Value-Based Arrangements.

DHPA urges OIG to continue working closely with CMS to ensure that the key terms that serve as the foundation for the new AKS safe harbors and new Stark exceptions track one another across the two sets of regulations. The coordination of our health care fraud and abuse laws is critical to unlocking the coordination of care across medical specialties and sites of service. Accordingly, our comments regarding certain definitions in the AKS Proposed Rule apply equally to the Stark Proposed Rule (and will be reflected in our comments to CMS).

We believe it is imperative that OIG maintain maximum flexibility in its definitions of the terms "value-based" and "value-based arrangements" in the AKS Final Rule.[23] OIG suggested in the Proposed Rule that it might revise—and, potentially, limit—the definition of the term "value-based" to refer to financial arrangements under Advanced APMs.[24] In our view, it is preferable for OIG to finalize its proposed, "non-technical" definition "to signal value produced through improved care coordination, improved health outcomes, lower costs or reduced growth of costs for patients and payors, and improved efficiencies in the delivery of care."[25] Likewise, OIG's definition of "value-based arrangement" recognizes that VBAs might be designed to be as small as encompassing a single value-based activity between two individual physicians or two independent medical practices for the benefit of a target population.[26] The terminology OIG is creating in coordination with CMS needs to serve all potential VBA participants, regardless of size, and needs to encompass value-based care furnished in more than just Advanced APMs.

[23] 84 Fed. Reg. at 55700-02.
[24] See *id.*
[25] *Id*. at 55700.
[26] *Id*. at 55702.

We ask that OIG not narrow the definition of "target population" to include only patients with a shared disease state or chronic condition.[27] To be sure, DHPA's independent gastroenterology practices are on the front lines treating patients with serious gastrointestinal diseases and conditions such as Crohn's and Ulcerative Colitis, but we also are immersed in preventive care such as colorectal cancer screening and innovative efforts to address obesity. One could readily imagine multi-disciplinary VBAs that bring together gastroenterologists, psychologists, bariatric endocrinologists, and others for the purpose of managing obesity in a target patient population of adults with a body mass index greater than 40. Likewise, VBAs could be designed to coordinate and manage care for target populations of patients with histories of smoking or drug use as well as target populations for patients in need of genetic screening. OIG should make clear in the final definition of "target population" that VBAs directed at patient populations in need of preventive care or health care management—selected though the use of legitimate and verifiable criteria—are equally appropriate candidates for safe harbor protection.

We support the flexible definition that OIG has proposed for the term "value-based purpose." As proposed, it is a legitimate value-based purpose to *maintain* the quality of care for a target population while *reducing* payors' costs for that care.[28] The newly proposed safe harbors should safeguard VBA participants who seek to deliver high quality care more efficiently. In our view, it would be too limiting to define "value-based purpose," as OIG is considering, to encompass only those instances in which costs to, or growth in expenditures of, payors is reduced commensurate with an *improvement* in patient quality of care.[29] Maintaining high quality care while furnishing that care more efficiently is an equally valid "value-based purpose."

## IV. With Limited Modifications, OIG Should Finalize the Newly Proposed Safe Harbors to Unlock Innovative Care Delivery Models in the Independent Medical Practice Setting.

We focus our comments on the four newly proposed safe harbors that we believe will have the greatest impact on the ability of independent gastroenterology (and other specialty) practices to develop and implement value-based care delivery and payment models. In general, we believe OIG has struck an appropriate balance between maintaining the AKS's protections for Medicare beneficiaries and ensuring that providers are not discouraged from pursuing VBAs.

[27] See *id.* at 55702-03.
[28] *Id*. at 55706-07
[29] *Id*. at 55707.

### A. Care Coordination Safe Harbor

We agree with OIG's decision to propose a safe harbor to protect care coordination efforts across health care entities that does not require an assumption of financial risk.[30] Many such VBAs can improve quality, health outcomes, and efficiency in care delivery and are worthy of safe harbor protection separate and apart from the Substantial Downside Risk and Full Financial Risk Safe Harbors. To encourage care coordination efforts, we believe it is important that protection under the Care Coordination Safe Harbor be available not only when remuneration is used *exclusively* to engage in value-based activities directly connected to coordination and management of care of the target population, but when such remuneration is used *primarily* in furtherance of such activities. We fully expect that in-kind remuneration in furtherance of value-based activities will have "spillover benefits" outside the target population.[31] Those benefits should not jeopardize safe harbor protection; thus, OIG should not finalize an alternative approach that would require remuneration be limited to VBAs that *only* benefit the target patient population.

Nor should OIG revise the proposed Care Coordination Safe Harbor to deny safe harbor protection when aggregate compensation paid by the offeror is determined in a manner that takes into account the volume or value of referrals or business generated between the parties for which payment may be made by a Federal health program. As OIG articulated in the Proposed Rule, imposing such a limitation could undermine the goal of the AKS Proposed Rule—"to remove barriers to improved care coordination and to promote value-driven care."[32] As currently formulated, the proposed safe harbor provides adequate protection insofar as it prohibits the offeror of the remuneration from taking into account the volume or value of, or conditioning an offer of remuneration on, (i) referrals of patients that are not part of the VBA's target patient population, or (ii) business not covered under the VBA.[33]

With our health care system still in the early days of the transition from fee-for-service to value-based care delivery and payment models, we think it is important for OIG to build into the Care Coordination Safe Harbor a period in which VBA participants can seek to remediate deficiencies before having to terminate the VBA or risk violation of the AKS. It should not be that termination is the only option for VBA participants when they determine that the VBA is unlikely to further coordination and management of care for the target patient population, has resulted in material deficiencies in quality of care, or is unlikely to achieve the evidence-based, valid outcome measures.[34] The proposal of a 60-day window to

[30] *Id*. at 55708-16.
[31] *Id*. at 55710.
[32] *Id*. at 55711.
[33] *Id*.
[34] *Id*. at 55713.

terminate the VBA should take effect only after VBA participants have been permitted to make a good faith effort at remediation during a 120-day period.

### B. Substantial Downside Financial Risk and Full Financial Risk Safe Harbors

The Substantial Downside Risk and Full Financial Risk Safe Harbors will provide important flexibility to independent medical practices that seek to build VBAs that include in-kind and monetary remuneration. Our comments are similar with respect to both safe harbors and focus on ways in which the two safe harbors should be modified to ensure they are of practical utility for independent medical practices and not only hospitals and health systems that have far greater resources and infrastructure to employ in developing VBAs.

It is critical that OIG build into the Substantial Downside Financial Risk and Full Financial Risk Safe Harbors protection for a substantial period prior to the date by which the value-based entity ("VBE") must assume substantial (or full) financial risk. The proposed 6-month period might be adequate for larger health care entities,[35] but it is critical that smaller provider entities, including independent specialty practices, be encouraged to develop VBAs without concern that they might violate the AKS and trigger potential criminal liability under the statute. Providing safe harbor protection for 12 months before a VBE must assume financial risk will incentivize smaller health care provider entities to create VBAs.

With respect to the Substantial Downside Financial Risk Safe Harbor, we believe it is important for OIG to provide added flexibility to new or small VBEs to establish baselines against which to measure losses or payments that will serve as the basis for calculating the repayment obligations required to meet the safe harbor.[36] Accordingly, OIG should finalize the proposal that would permit new or small VBEs, including those created by independent medical practices, to have 12 months from the start of operations to establish the necessary baselines against which performance is measured.

Finally, with respect to the Full Financial Risk Safe Harbor, we believe OIG should modify its proposal to protect remuneration that passes from a VBE participant to a downstream contractor.[37] OIG created the Full Financial Risk Safe Harbor to provide maximum flexibility to those providers seeking to develop innovative, coordinated care delivery models. Many of those models will invariably seek to coordinate care with downstream contractors that may or may not assume financial risk. OIG should not limit care coordination opportunities by denying safe harbor protection to downstream contractors.

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[35] *Id.* at 55717, 55720.
[36] *Id.*
[37] *Id.* at 55721.

### C. The Patient Engagement and Support Safe Harbor

A successful transition to a health care delivery system that pays for value—while driving high quality health care outcomes in a cost-efficient manner—must include engagement of our patients in that endeavor. DHPA member practices have been innovators in patient engagement as Project Sonar discussed in Part I above demonstrates. Such innovation is just beginning and will increase in the coming years—whether in the form of apps for weight management and monitoring diet, secure chat rooms for patients with specific chronic conditions, and home monitoring devices such as medication reminder devices, blood testing for anticoagulation assessment, electrolytes and glucose, and measuring chronic liver disease parameters such as ammonia levels. We welcome OIG's proposal of a new Patient Engagement and Support Safe Harbor to protect independent medical practices and other providers that seek to offer patients tools and supports designed to enhance patient engagement with their care and adherence to care protocols.[38]

It is so critical to include the patient in care coordination efforts that we believe safe harbor protection should be granted to all health care provider entities seeking to provide patient engagement tools and supports that would advance coordination and management of care for a patient.[39] Such protection should not be limited to VBE participants, nor should protection be limited to Federal health care program beneficiaries. Just as value-based activities are expected to have spillover benefits outside a target population without jeopardizing protection under the Care Coordination Safe Harbor, so too should patient engagement tools and supports be available when the target population is defined without regard to payor type. Safe harbor protection should be available as long as the tools and supports primarily address needs of the target population and the tools and supports have a direct connection to the coordination and management of care for the patient.[40]

## V. 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 four years ago by enacting the bipartisan MACRA legislation but, as OIG recognizes, the evolution from fee-for-service to value-based care delivery and payment models demands discrete modifications to the Anti-Kickback Statute. To that end, we respectfully request that OIG promptly finalize the newly proposed safe harbors—subject to the modifications we outlined above—to ensure that value-based payment arrangements work well for all physicians, including those of us who care for Medicare beneficiaries and other patients in the independent practice setting.

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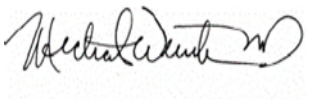
[38] *Id*. at 55722.
[39] *Id*.
[40] *Id*. at 55723.

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@katten.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