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

December 31, 2019

BY ELECTRONIC SUBMISSION

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

RE: Comments to CMS-1720-P

Dear Administrator Verma:

The Digestive Health Physicians Association ("DHPA") submits these comments in response to the Proposed Rule to modernize the Physician Self-Referral Law ("Stark 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 Centers for Medicare and Medicaid Services ("CMS") 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 Stark law and other health care fraud and abuse laws such as the Anti-Kickback Statute ("AKS").

We appreciate the Administration's recognition of the fact that we cannot "transform[]our health care system into one that better pays for value"[2]—the core principle behind the bipartisan Medicare Access and CHIP Reauthorization Act ("MACRA")[3]—without modernizing the Stark Law and AKS. 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. 55766 (Oct. 17, 2019).
[2] *Id*. at 55768.
[3] Pub. L. 114-10, enacted April 16, 2015.

benefit of the American people."[4] DHPA appreciates the steps that CMS and the US Department of Health and Human Services Office of Inspector General ("OIG") are taking, through their respective regulatory authority, to address this very real concern. In this comment letter (and in comments being submitted contemporaneously to OIG), we endorse various of the proposals that CMS and OIG have made to modernize the Stark Law and AKS 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 Stark Law and AKS and in coordinating those efforts across CMS and OIG. We also recognize that CMS and OIG have significant work ahead in studying the hundreds, if not thousands, of comments submitted in response to the Stark and AKS Proposed Rules from across the health care industry. With that said, we cannot overstate the importance of CMS and OIG 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 civil liability that attaches to violations of the Stark Law and the criminal liability that attaches to violations of the AKS. The innovation that the Administration seeks to unlock will not occur without CMS and OIG finalizing and putting into effect their proposals to modernize the Stark Law and AKS.

We divide our comment letter into six sections. First, we offer concrete examples of the types of innovative care models for which protection under the Stark Law 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 explain the importance of finalizing, with limited modifications, the key value-based terminology that CMS and OIG have proposed that will be central to the functioning of the new exceptions under the Stark Law and the new safe harbors under the AKS. Fourth, we provide comments on the three newly proposed exceptions for VBAs to ensure that independent gastroenterology (and other specialty) practices can successfully develop and implement value-based care models. Fifth, we comment on the proposed changes to key terminology that CMS has proposed that are critical to simplifying the Stark Law even outside the context of value-based care delivery and payment models—the definition of "commercially reasonable," the volume or value and other business generated standards, and the definition of "fair market value." Finally, we emphasize the importance of the Stark Law's in-office ancillary services exception ("IOASE") as a critical component of physicians delivering comprehensive, coordinated care in the independent practice setting and urge CMS to reject the call by some stakeholders, who seek to create monopolies over the furnishing of certain ancillary services, to narrow the application of the IOASE.

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[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).

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 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 CMS's Request for Information ("RFI") regarding the Stark Law 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 medical 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 Stark and AKS Proposed Rules—the importance of removing

[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.

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 CMS and OIG in response to their respective RFIs seeking input on reform of the Stark Law and AKS.[10]

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

The Stark Law, as currently framed, 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 Stark Law 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 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 and AKS.

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

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[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).

[10] 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); 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).

[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.

("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]

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 clinicians and 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.

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[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 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.

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 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 Stark Law and AKS, 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]

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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*

And, yet, Medicare beneficiaries are not benefitting from either of these Advanced APMs due, in large measure, to decades-old prohibitions in the Stark Law and AKS 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 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 CMS and OIG to finalize the Stark and AKS 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 Stark 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 Stark Law, in particular, the Full Financial Risk, Meaningful Downside Financial Risk to Physicians, and Value-Based Arrangement Exceptions create mechanisms through which parties to value-based entities and participants in VBAs can avoid the threat of financial penalties under the Stark Law and liability under the False Claims Act without going through a burdensome—and, heretofore, ineffective—process for securing protection from CMMI. The exceptions, 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 CMS 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

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https://aspe.hhs.gov/system/files/pdf/255731/ProjectSonarPublicComments.pdf; DHPA Comment on Colonoscopy Advanced APM.

[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).

protections for our beneficiaries—and for the trust fund—while not penalizing providers who are taking brave steps away from fee-for-service."[20] 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 provisions in the Stark Law that inhibit coordination between providers in a fee-for-service system and the potentially bankrupting damages and penalties under the False Claims Act that can attach to Stark Law violations.[21] 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 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 Stark Law exceptions.

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 liability that attaches to violations of the Stark Law. 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 Stark Law and False Claims Act.

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[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] 31 U.S.C. § 3729(a)(1).
[22] 81 Fed. Reg. at 28198.

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.

The waivers put into effect for ACOs, beginning in 2011, are significant departures from the exacting provisions of the Stark Law and AKS. 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 laws 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. CMS's and OIG's proposed changes to the Stark Law and AKS, once finalized, will level the playing field so that independent specialty practices can meaningfully participate in VBAs.

III. CMS Should Finalize the Key Terminology that Will Govern the New Stark Exceptions in a Manner that Provides Maximum Flexibility for the Development of, and Participation in, Value-Based Arrangements.

DHPA urges CMS to continue working closely with OIG to ensure that the key terms that serve as the foundation for the new Stark exceptions and new AKS safe harbors 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 Stark Proposed Rule apply equally to the AKS Proposed Rule (and will be reflected in our comments to OIG).

CMS's proposed definitions of the terms "value-based enterprise" and "value-based arrangement" reflect a commitment to ensuring that the new Stark exceptions will work for physicians in independent gastroenterology (and other specialty) practices. We agree with CMS that, in defining what can constitute a "value-based entity" ("VBE"), the Agency should not dictate or limit the appropriate legal structures for qualifying as a VBE.[23] Hospital systems and ACOs are not the only entities that will seek to develop VBAs;

[23] Stark Proposed Rule, 84 Fed. Reg. at 55774.

DHPA's member group practices—which range in size from five to more than 150 physicians—are equally committed to collaborating with other independent specialty practices, hospitals and health systems to develop and operate VBAs in furtherance of the goals of a value-based health care system. The proposed definition of "VBA" similarly provides flexibility for those physicians and practices that desire to develop and operationalize VBAs. In order to maintain that flexibility, however, CMS should not narrow the definition of VBA, as it said it is considering, by requiring care coordination and management in order to qualify as a VBA.[24]

We were pleased to see that CMS apparently is not considering a revision to the definition of "target population" that OIG stated that it is contemplating in the AKS Proposed Rule. For its part, OIG is evaluating whether to narrow the definition of "target population" to include only patients with a shared disease state or chronic condition.[25] 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 our member practices 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. We urge CMS to 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 protection under the newly-created Stark exceptions.

We support the flexible definition that CMS 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.[26] The newly proposed exceptions 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 CMS 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.[27] Maintaining high quality care while furnishing that care more efficiently is an equally valid "value-based purpose."

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[24] *Id.* Along those same lines, and in order to ensure maximum flexibility, CMS should not define the term "coordinating and managing care," notwithstanding the fact that OIG is contemplating doing so in the AKS Proposed Rule. *Id.* at 55775.

[25] AKS Proposed Rule, 84 Fed. Reg. at 55702-03.

[26] Stark Proposed Rule, 84 Fed. Reg. at 55774-75.

[27] *Id.*

IV. With Limited Modifications, CMS Should Finalize the Newly Proposed Exceptions Applicable to Value-Based Arrangements to Unlock Innovative Care Delivery Models in the Independent Medical Practice Setting.

In proposing three new Stark exceptions applicable to VBAs in which participants take on different levels of financial risk (or, in certain instances, no financial risk), we believe CMS struck an appropriate balance between maintaining the Stark Law's protections for Medicare beneficiaries and incentivizing physicians in independent practice to develop and implement value-based care delivery and payment models. The most important aspect of these three new exceptions is that they are not subject to the requirements in the historical, fee-for-service exceptions to the Stark Law of setting compensation in advance, at fair market value, and in a way that does not take into account the volume or value of physician referrals or other business generated between the physician and health care entity.

A. Exception for Value-Based Arrangements Regardless of Financial Risk

We expect that this exception, especially in the near-term, will be of greatest practical utility for independent medical practices, particularly smaller group practices.[28] Without this exception, there would be no mechanism available to physicians and physician groups to develop care and payment delivery models that only involve the assumption of upside financial risk or, for that matter, no financial risk at all. Such models are incredibly important to encourage the "behavior shaping" that CMS appropriately identified as necessary for success in a value-based payment system.[29] Although many DHPA member practices are already in the process of developing and implementing value-based models that involve financial risk—at least in the commercial payor setting—we expect that dozens of our member practices will prefer entering the world of value-based care delivery and payment systems without having to absorb downside financial risk. If CMS's aim is to provide flexibility that, in turn, will encourage broader participation in value-based models, then this general exception for VBAs should not be limited to in-kind remuneration. CMS should finalize the exception—as proposed—to permit both monetary and nonmonetary remuneration between the parties.

As CMS recognized throughout the Proposed Rule, the severe liability that attaches to violations of the Stark Law (and False Claims Act) chills innovation. We agree with CMS's assessment, which is why we believe CMS needs to build into the exception for VBAs a period in which a VBE can remediate value-based activities that are not achieving the articulated value-based purposes of the VBA. If, on the other hand, parties to a VBE believe that they will forfeit protection under the new Stark exception the moment their VBA fails to

[28] *Id*. at 55783-86.
[29] *Id*. at 55783.

satisfy a value-based purpose, then individual physicians and independent practices will be less likely to run the risk that, despite their best efforts, a VBA might fall out of compliance with the VBA exception. CMS should build into the exception a period of 120 days for the parties to a VBE to remediate any deficiencies in their VBA.

B. Full Financial Risk & Meaningful Downside Financial Risk to Physician Exceptions

The Full Financial Risk and Meaningful Downside Financial Risk to the Physician Exceptions 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 exceptions and focus on ways in which CMS should modify the two exceptions 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 CMS build into the two exceptions a substantial period prior to the date by which the VBE and/or physician must assume full or meaningful downside financial risk. The proposed 6-month period might be adequate for larger health care entities,[30] but it is equally important that smaller provider entities, including independent specialty practices, be encouraged to develop VBAs without concern that they might violate the Stark Law and trigger potential liability under Stark and the False Claims Act. Providing protection under these exceptions for 12 months before a VBE or physician must assume financial risk will incentivize smaller health care provider entities to create VBAs.

In keeping with CMS's stated goal of encouraging physicians across sites of service to participate in value-based care delivery and payment systems that require the assumption of financial risk, we also support CMS's proposal to allow VBEs to be at full financial risk for a defined set of health care services and not only for all health care services.[31]

V. DHPA Supports Key Clarifying Changes that CMS Is Proposing to Other Aspects of the Stark Regulations.

DHPA appreciates that CMS has also proposed a series of clarifications to key terminology in the Stark regulations that is relevant to fee-for-service and value-based payment systems. We support, with limited modifications, the proposals CMS has made with respect to the definition of the term "commercially reasonable," the volume or value and other business generated standards, and the definition of the term "fair market value."

[30] *Id*. at 55780, 55782.
[31] *Id*. at 55779.

CMS should finalize a definition of the term "commercially reasonable" that provides maximum flexibility to physicians and health care entities in constructing compensation arrangements. We agree with CMS that "commercial reasonableness" should be assessed by evaluating whether the "particular arrangement furthers a legitimate business purpose of the parties."[32] If the arrangement furthers a *legitimate* business purpose, then we do not believe it is necessary to further limit commercial reasonableness based on comparing the terms and conditions of the arrangement to "like" arrangements. A compensation arrangement that furthers a legitimate business purpose and "makes sense as a means to accomplish the parties' goals"[33] should be deemed "commercially reasonable."

DHPA agrees with CMS's decision to create an objective test for determining whether compensation takes into account the volume or value of referrals or the volume or value of other business generated by the physician.[34] If the formula for setting compensation between a physician and entity does not include the physician's referrals as a variable, then the arrangement will not have taken into account the volume or value of the physician's referrals to the entity or the physician's generation of other business for the entity.

Finally, we applaud CMS for disentangling the definition of "fair market value" and the "volume or value" standard. CMS has created an objective, bright line rule for determining whether compensation arrangements take into account the volume or value of a physician's referrals; it is unnecessary for the Agency to graft the volume or value standard on to the definition of the distinct term, "fair market value."

VI. The Stark Law's In-Office Ancillary Services Exception Remains a Critical Component of Delivering Comprehensive, Coordinated Care.

Our comments have focused on CMS's proposed regulatory 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, some stakeholders seeking to create monopolies over the furnishing of certain ancillary services have proposed narrowing protection under the IOASE or eliminating the provision altogether.

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[32] *Id*. at 55790.
[33] *Id*.
[34] *Id*. at 55791-95.

There is no basis for changing the application or scope of the IOASE 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.[35] 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."[36] Any narrowing of protections under the IOASE would undermine the Administration's efforts to enhance care coordination and promote value-based payment models.

VII. Request for Action

DHPA looks forward to working with CMS 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 CMS recognizes, the evolution from fee-for-service to value-based care delivery demands modifications to the Stark regulations. To that end, we respectfully request that, subject to the modifications we outlined above, CMS promptly finalize the newly proposed exceptions for VBAs and the proposed changes to key terminology in the Stark regulations. These regulatory changes will 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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[35] American Medical Association, Milliman Study, March 2015, *available at* https://www.ama-assn.org/practice-management/medicare-office-ancillary-services-exception (last accessed Dec. 15, 2019); Digestive Health Physicians Association, Milliman Study, February 2015, *available at* https://www.dhpassociation.org/wordpress/wp-content/uploads/2015/07/milliman-03-2009-2013-medicare-utilization-analysis.pdf (last accessed Dec. 15, 2019).

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

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