American Gastroenterological Association

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December 31, 2019

Joanne M. Chiedi
Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P
Cohen Building
330 Independence Avenue SW
Washington, DC 20201

Submitted via www.regulations.gov

Dear Acting Inspector General Chiedi,

The American Gastroenterological Association (AGA) appreciates the opportunity to comment on the U.S. Department of Health and Services Office of the Inspector General (OIG) proposed rule, Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements [OIG-0936- AA10-P]. Founded in 1897, AGA is the trusted voice of the gastroenterology community that has grown to include more than 16,000 members from around the globe who are involved in all aspects of the science, practice and advancement of gastroenterology.

As you are aware, the anti-kickback statute (AKS) provides criminal penalties for whoever "knowingly and willfully offers, pays, solicits, or receives remuneration to induce or reward the referral of business reimbursable under and of the Federal health care programs" unless an AKS safe harbor exists to protect the arrangement. Those safe harbors include multiple safeguards,

which, in many cases, include that remuneration under the protected arrangement may not take into account the "volume or value of referrals" or "other business generated" and must be based on "fair market value." ***The AGA is extremely appreciative that the OIG has reviewed its regulations to determine whether the rules and safe harbor requirements are appropriately structured in light of the evolving health care delivery system, development of quality measures, and drive toward implementing payment systems based on "value."*** We share the OIG's interest in protecting patients and the Medicare program from abuses, and we firmly believe that steps can and should be taken to take into account "value-based" payment models while continuing to protect against program and patient abuse. While we provide some suggestions and concerns below, we believe that these proposals have largely succeeded at striking that balance.

AKS Proposals for Safe Harbors Directed at Value-Based Arrangements

Definitions: Value-Based Participant

As part of the general proposals applicable to all of the value-based arrangement exceptions, the OIG proposes, in alignment with the Stark exception proposals, to define a Value-based Entity (VBE) participant as "an individual or entity that engages in at least one value-based activity as part of a value-based enterprise." The OIG goes on further to seek input on whether to exclude from the "VBE participant" definition the following: pharmaceutical manufacturers, manufacturers and distributors of DMEPOS, pharmacy benefit managers (PBMs), wholesalers, and distributors. We recognize the OIG sentiment to keep the arrangements for which it is providing protection focused on providers of health care and not necessarily on suppliers and manufacturers.

Our members are focused on providing patients with high quality, evidence-based care, and it is an AGA priority to support our members with the educational opportunities and information available to be able to do that. As part of these efforts, we are acutely aware of how treatments can vary for patients when gastroenterologists provide high-value, patient-focused care. Complex conditions such as inflammatory bowel disease (IBD) and Crohn's disease require frequent patient assessment and adjustment of

pharmaceutical treatments based on each individual's response to therapy. Gastroenterologists make pharmaceutical adjustments based on the disease severity, phenotype, degree of inflammation, use of immunomodulator, patient sex, and body-mass index, as well as variability in drug clearance through immune- and nonimmune-mediated mechanisms. The AGA provides education and guidance on pharmaceutical treatment and adjustments through our Clinical Practice Guidelines and Clinical Care Pathways.

Given the potential for future model development that has perhaps not yet been conceived, ***the AGA recommends that the OIG neither explicitly include or exclude these entities in its definition of VBE participant, but rather, administer the exclusions on a safe harbor-by-safe harbor basis, where the OIG might be able to more accurately assess whether there is a role in the arrangement for these entities.*** By structuring the regulations in this way, it also provides an opportunity for the OIG to make refinements in future rulemaking without having to alter the definitions that branch out to multiple exceptions, thus creating a more workable framework for future improvements.

List of Safe Harbors

The OIG proposes a series of new safe harbors directed at "value-based arrangements," which the OIG proposes to define as "an arrangement for the provision of at least one value-based activity for a target patient population between or among: (A) the value-based enterprise and one or more of its VBE participants; or (B) VBE participants in the same value-based
enterprise." Derivative of this definition are the newly proposed safe harbors, which include:

- The "Care Coordination Arrangements" Safe Harbor
- The "Substantial Downside Financial Risk" Safe Harbor
- The "Full Downside Financial Risk" Safe Harbor
- The Patient Engagement and Support Safe Harbor

- The "Care Delivery and Payment Arrangements & Beneficiary Incentives" Safe Harbor

In addition, separate from the newly proposed value-based exceptions, the OIG proposes changes to the current Personal Services and Management Contracts Safe Harbor to account for arrangements with "outcomes- based payments."

As mentioned, the AGA is cognizant of the balance that the OIG must strike in its proposals to promote flexibility while simultaneously protecting against program and patient abuse. We also appreciate that these proposals are made in the context of the efforts by the Centers for Medicare and Medicaid Services (CMS) to reduce administrative burden under the *Patients Over Paperwork* initiative. In that light, ***the AGA appreciates the OIG's proposal to include the safe harbor for "Care Delivery and Payment Arrangements & Beneficiary Incentives," which provides protections to "CMS-sponsored models."*** While the safe harbor proposal still allows CMS discretion to provide protection on a model-by-model basis, we believe that the OIG has capitalized on the opportunity to streamline rulemaking and reduce compliance burden by including this proposal to provide a direct exception for "CMS-sponsored models." We believe that the proposed safeguards included in this proposal help protect against program and patient abuse.

Financial Risk Requirements for Value-Based Arrangement Exceptions

In order for a compensation arrangement to avail itself of the proposed protections (via the Value-Based Arrangement exceptions), the OIG puts forth a series of proposals focused on the financial risk that must be undertaken as part of the Value-Based Arrangement:

- "Full Downside Financial Risk" Safe Harbor: As part of the proposals related to this safe harbor, the OIG defines "full downside financial risk" as "the VBE is financially responsible for the cost of all items and services covered by the applicable payor for each patient in the target patient population and is

prospectively paid by the applicable payor." The OIG notes that partial capitation would *not* meet this threshold.

- "Substantial Downside Financial Risk" Safe Harbor: As part of the proposals related to this safe harbor, the OIG states that the arrangement would entail "substantial downside risk" under any of the following scenarios:
    - "Shared savings with a repayment obligation to the payor of at least 40 percent of any shared losses, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures";
    - "A repayment obligation to the payor under an episodic or bundled payment arrangement of at least 20 percent of any total loss, where loss is determined based upon a comparison of costs to historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures";
    - "A prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population, where such payment is determined based upon a review of historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures"; or
    - "A partial capitated payment from the payor for a set of items and services for the target patient population where such capitated payment reflects a discount equal to at least 60 percent of the total expected FFS payments based on historical expenditures, or to the extent such data is unavailable, evidence-based, comparable expenditures of the VBE participants to the value-based arrangements."

The OIG also states that one of the conditions of the safe harbor is that "the terms of the value-based arrangement require the VBE participant to meaningfully share in the VBE's substantial downside financial risk for providing or arranging for items and services for the target patient population" and then proposes that in

order to "meaningfully share" in the "substantial downside financial risk," the value-based arrangement must contain one of the following:

- "a risk-sharing payment pursuant to which the VBE participant is at risk for 8 percent of the amount for which the VBE is at risk under its agreement with the applicable payor (e.g., an 8-percent withhold, recoupment payment, or shared losses payment)";
- "a partial or full capitated payment or similar payment methodology (excluding the prospective payment systems for acute inpatient hospitals, home health agencies, hospice, outpatient hospitals, inpatient psychiatric facilities, inpatient rehabilitation facilities, long-term care hospitals, and SNFs or other like payment methodologies)"; or
- "in the case of a VBE participant that is a physician, a payment that meets the requirements of the physician self-referral law's regulatory exception for value based arrangements with meaningful downside financial risk . . ."

The OIG also specifically asks if "Advanced APMs" and "Other Payor Advanced APMs should be directly included in the definition of "substantial downside financial risk."

While we appreciate that not all of the proposed safe harbors require the VBE or its participants to assume downside risk, as well as that an arrangement that requires "full financial risk" generally has inherent safeguards that are part of the arrangement, ***the AGA is concerned that the proposed financial risk requirements for the "Full Financial Risk" Safe Harbor and the "Substantial Downside Risk" Exception are unnecessarily stringent and would benefit from a more narrow application or reduced thresholds.***

First, with regard to the "Full Financial Risk" Exception, we believe that requiring the VBE to take on the risk for total cost of care is unnecessarily restrictive. We believe that this is particularly restrictive for specialists, such as gastroenterologists, who might be willing and in an excellent position to take on "full financial risk" for *related* care, but who are not well-positioned to take on the financial risk for all health care spending for

a patient. In addition, we believe that the OIG proposals have already introduced a safeguard that will help facilitate the introduction of a more narrow definition of "full financial risk" by requiring that the "value-based activity" be focused on a "target patient population." The focus on the "target patient population" not only ensures that the value-based payment arrangement is designed to address specific needs for a specific set of patients, but it also introduces the structure to allow for "full financial risk" to be taken on for a defined set of patient care services that are narrowly tailored to the activities of the model rather than requiring the participants to take on the risk of total cost of care, thus limiting the utility of this exception. Therefore, ***the AGA recommends that the OIG finalize a "full financial risk" standard aligned with the alternative offered by CMS in its Stark exception proposals where the risk is focused on "the cost of only a defined set of patient care services for a target population."***

With regard to the "Substantial Downside Risk" Exception, the AGA recommends that CMS finalize the proposals without any reference to "total cost of care." Again, to ensure that these exceptions are applicable to specialty-focused models as those we envision in GI, we do not believe that taking on the risk for "total cost of care" is necessary to provide the necessary safeguards needed to protect against program and patient abuse. Regarding the proposed thresholds for defining "substantial downside risk," we are concerned that the requirements are complicated, unnecessarily high for purposes of providing adequate safeguards, seem arbitrary in their selection, and are out of alignment with the current CMS thresholds for "more than nominal risk" under the criteria for Advanced Alternative Payment Models (Advanced APMs) that are part of the Quality Payment Program. Therefore, ***the AGA recommends that the OIG define "substantial downside risk" more similarly to how CMS defines "more than nominal risk" to create alignment between these protections and the Advanced APM rules.*** We believe that this will facilitate greater proliferation of value-based payment models with continuity between the standards. In addition, we believe it will help to reduce the administrative burden associated with compliance under both the QPP rules and the Stark rule protections by creating a more harmonious set of standards. Ideally, the

standards would not be repeated, but the rules here will incorporate by reference the standards set under the "more than nominal risk" standard.

Local Transportation Safe Harbor

Separate from its discussion of value-based arrangements and in recognition of the impact that transportation can have on "patient access to care, quality of care, healthcare outcomes, and effective care coordination for patients," the OIG puts forward several changes for its Local Transportation Safe Harbor:

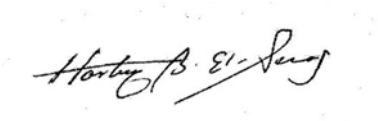
- The OIG proposes to "expand the distance which residents of rural areas may be transported" by expanding the limit on transportation of residents in rural communities to 75 miles (up from 50 miles).
- The OIG proposes to *remove* mileage limits on "transportation of a patient from a healthcare facility from which the patient has been discharged to the patient's residence" and stated that the distance limit elimination for patients who have been discharged as an inpatient from a facility applies "regardless of whether the patient resides in an urban or rural area, if the transportation is to the patient's residence, another residence of the patient's choice (such as the residence of a friend or relative who is caring for the patient post-discharge)."

The AGA supports the OIG proposals aimed at reducing or eliminating the mileage limitations in connection with the Local Transportation Safe Harbor. In addition, the OIG sought comment on whether it should protect transportation "for purposes other than to obtain medically necessary items or services," citing that it previously stated it would consider "transportation to non-medical services that are part of care coordination arrangements or are related to improving health care." On this topic, ***the AGA encourages the OIG to expand these protections for these "non-medical services," certainly those that are provided in the context of a care coordination arrangement, but also for those that just generally improve health care outcomes.*** We believe this is an important contributor to health care outcomes and general patient wellness *in particular* for the

patients that gastroenterologists treat. Gastroenterologists treat patients suffering from chronic, debilitating conditions such as obesity, Crohn's disease and inflammatory bowel disease (IBD) which can limit patients' mobility, quality of life, and mental and physical health. The AGA's Clinical Practice Guidelines, Clinical Care Pathways and bundled payment episode of care white papers for these conditions highlight the necessity of meeting patients' needs for "non-medical services" such as mental health therapy, nutritional therapy, and exercise for successful treatment of the disease. AGA's treatment resources call upon gastroenterologists to coordinate care for the non-medical services (e.g., mental health therapy, nutritional therapy, and exercise) that have been scientifically proven to improve outcomes for patients suffering from these diseases. ***Therefore, we ask the OIG to expand the definition of "non-medical services" to include services that are part of obesity, Crohn's disease and IBD Clinical Practice Guidelines and Clinical Care Pathways such as coordination of mental health therapy, nutritional therapy (including both dietician counseling and access to quality food), mental health counseling, and supervised exercise and behavior modification programs.***

Again, the AGA appreciates the opportunity to provide comments on the physician self-referral proposed rule. We look forward to a continuing dialogue with CMS to support access to and the delivery of high quality, efficient care for our patients. For additional information or questions, please do not hesitate to contact Kathleen Teixeira, Vice President of Government Affairs, by email at Kteixeira@gastro.org or telephone at 240-482-3222.

Sincerely,



Hashem El-Serag, MD, MPH, AGAF
President

Supporting Materials

- AGA Guidelines and Clinical Care Pathways for IBD and Crohn's Disease: https://www.improveibdcare.com/clinical-pathways.html

- AGA Practice Guidance on Obesity: https://www.gastro.org/practice-guidance/practice-updates/obesity-practice-guide

- AGA White Paper - An Episode-of-Care Framework for the Management of Obesity: https://www.cghjournal.org/article/S1542-3565(17)30146-5/fulltext