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December 31, 2019

Seema Verma, MPH  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1720-P  
Baltimore, Maryland 21244-1850

Submitted via [www.regulations.gov](http://www.regulations.gov)

Dear Administrator Verma:

The American Gastroenterological Association (AGA) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services proposed rule, Modernizing and Clarifying the Physician Self-Referral Regulations [CMS-1720-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 physician self-referral law and regulations (i.e. Stark rules), in part, prohibit a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship unless an exception applies. Those exceptions 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 CMS has reviewed its regulations to determine whether the rules and exceptions 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 Agency’s interest in protecting patients and the Medicare program from abuses, and we firmly believe that steps can and should be taken to make allowances for “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.

### **Stark Proposals for Exceptions Directed at Value-Based Arrangements**

#### ***Definitions: Value-Based Participant***

As part of the general proposal’s applicability to all of the value-based arrangement exceptions, CMS proposes 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.” CMS 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 CMS’ 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 CMS neither explicitly include or exclude these entities in its definition of VBE participant, but rather, administer the exclusions on an exception-by-exception basis, where CMS 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 CMS 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 Exceptions

CMS proposes a series of new exceptions directed at “value-based arrangements,” which CMS proposes to define as “an arrangement for the provision of at least one value-based activity for a target patient population between or among (1) the value-based enterprise and one or more of its VBE participants; or (2) VBE participants in the same value-based enterprise.” Derivative of this definition are the newly proposed exceptions, which include:

- The Value-based Arrangement “Full Financial Risk” Exception
- The Value-based Arrangement “Meaningful Downside Financial Risk to the Physician” Exception
- General “Value -based Arrangements” Exception

In addition, separate from the newly proposed value-based exceptions, CMS proposes that when the value-based arrangement is the link in the chain closest to the physician (i.e., the physician is a direct party (not just with an ownership interest) to the value-

based arrangement), the indirect compensation arrangement would qualify as a value-based arrangement for purposes of the new exception.

As mentioned, the AGA is cognizant of the balance that CMS must strike in its proposals to promote flexibility while simultaneously protecting against program and patient abuse. We also appreciate that these proposals stem from the effort that CMS has put toward its *Patients Over Paperwork* initiative. In that light, we believe that CMS could provide decreased burden while still balancing other interests by adding an additional exception that provides greater assurance that certain arrangements are protected. ***As such, the AGA recommends that CMS also include a Stark exception, or create an extension of the current exceptions, modeled after the Office of the Inspector General's Safe Harbor for Care Delivery and Payment Arrangements & Beneficiary Incentives, which provides protections to "CMS-sponsored models."*** While that Safe Harbor proposal still allows CMS discretion to provide protection on a model-by-model basis, we believe that there is an opportunity to streamline rulemaking and reduce compliance burden by altering the proposals to provide a more direct exception for "CMS-sponsored models." We believe that the proposed safeguards included in that proposal help protect against program and patient abuse. And while we understand that CMS has written the proposed exceptions to extend beyond CMS-sponsored models, which we support, we also believe that CMS-sponsored models already contain enhanced safeguards that could allow a more streamlined application of a Stark exception.

#### *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), CMS puts forth a series of proposals focused on the financial risk that must be undertaken as part of the Value-Based Arrangement:

- *"Full Financial Risk" Exception*: As part of the proposals related to this exception, CMS states that it will interpret the requirement that the VBE accept "full financial risk" to mean that "the value-based enterprise, at a minimum, be responsible for all items and services covered under Parts A and B." CMS states

that “full financial risk” could be a capitated payment or a global budget payment “that compensates the value-based enterprise for providing all patient care items and services for a target patient population for a predetermined period of time,” but that it does not intend to prohibit other approaches to “full financial risk.” However, CMS also goes on to request input on whether there are situations where CMS should consider a VBE to be at “full financial risk” where it is “responsible for the cost of only a defined set of patient care services for a target population.”

- “Meaningful Downside Financial Risk to the Physician” Exception: As part of this exception, CMS proposes defining “meaningful downside financial risk” as “that the physician is responsible to pay the entity no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement.” In addition, CMS seeks comment on whether excluding a specific reference to “total cost of care” and premising “downside risk for 25 percent of only a nominal amount of remuneration” is sufficient.

While we appreciate that the separate exception (the General “Value-based Arrangements” Exception) does not require participants to take on downside risk (and thus has enhanced safeguards that must be met), 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” Exception and the “Meaningful 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 “all items and services covered under Parts A and B” 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 Part A and Part B services. In addition, we believe that the CMS

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.

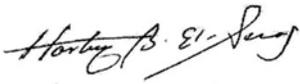
Therefore, ***the AGA recommends that CMS finalize a “full financial risk” standard aligned with the alternative offered in the proposed rule where the risk is focused on “the cost of only a defined set of patient care services for a target population.”***

***With regard to the “Meaningful 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 threshold for defining “meaningful downside risk,” we are concerned that “no less than 25 percent of the value of the remuneration the physician receives under the value-based arrangement” is unnecessarily high for purposes of providing adequate safeguards, seems arbitrary in its selection, and is 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 CMS define “meaningful downside risk” more similarly to how it 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.

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](mailto:Kteixeira@gastro.org) or telephone at 240-482-3222.

Sincerely,

A handwritten signature in black ink, appearing to read "Hashem El-Serag". The signature is written in a cursive style and is positioned above the typed name.

Hashem El-Serag, MD, MPH, AGAF  
President