AGS Geriatrics Healthcare Professionals

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Joanne Chiedi
Acting Inspector General
Office of Inspector General
Department of Health and Human Services
ATTN: OIG-0936-AA10-P
Cohen Building, Room 5521
330 Independence Avenue, S.W.
Washington, DC 20201

Re: [OIG-0936-AA10-P] Medicare and State Healthcare Programs; Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements

Dear Ms. Chiedi:

The American Geriatrics Society ("AGS") greatly appreciates the opportunity to comment on the proposed rule published by the HHS Office of the Inspector General ("OIG") regarding changes to the safe harbors under the Federal Anti-Kickback Statute ("AKS") and exceptions to the Civil Monetary Penalty ("CMP") rules related to beneficiary inducements ("Proposed Rule").[1] The AGS is a not-for-profit organization comprised of nearly 6,000 physician and non-physician practitioners ("NPPs') who are devoted to improving the health, independence and quality of life of all older adults. The AGS provides leadership to healthcare professionals, policy makers, and the public by implementing and advocating for programs in patient care, research, professional and public education, and public policy. One goal of our mission is to improve care coordination for patients with multiple chronic conditions. This will not only improve the quality of care these individuals receive, but will also increase beneficiary satisfaction and reduce the growth in Medicare spending.

The AGS is pleased that OIG has proposed revisions and updates to safe harbors under the AKS, and believes that, generally, protecting the types of arrangements contemplated in the Proposed Rule will be beneficial to healthcare providers ("HCPs") and patients. The AGS particularly appreciates OIG's efforts to facilitate "more effective coordination and management of patient care and delivery of value-based care that improves quality of care, health outcomes, and efficiency."[2] Nevertheless, AGS is concerned that, as currently proposed, certain of the safe harbors will have limited utility without modification.. Both our general support for the proposals and our specific concerns and recommendations regarding the proposals are described in more detail below.

[1] 84 Fed. Reg. 55694 (Oct. 17, 2019).
[2] 84 Fed. Reg. at 55694.

I. Recommendations

AGS recommends that OIG:

- Define "full financial risk" to include arrangements where the risk pertains to a limited bundle of services and excludes certain extraordinarily expensive and infrequently furnished items and services from risk;
- Redefine the level of risk required to meet the definition of "substantial downside financial risk" to align with Advanced Alternative Payment Models and other Innovation Center models;
- Modify the proposed safe harbor that protects certain value-based arrangements without requiring the value-based enterprise to take on financial risk to require fewer conditions and clarify certain of the conditions;
- Remove the 15 percent contribution requirement for all practices proposed as a condition of the proposed new cybersecurity safe harbor;
- Protect outcomes-based payment arrangements that involve payment for maintaining high quality, and refrain from requiring parties to periodically rebase outcomes measures;
- Clarify that the proposed safe harbor for furnishing patient engagement tools or supports does not indicate that other low-risk, beneficial patient support activities are prohibited under the AKS and remove the requirement from the proposed safe harbor that patient engagement tools or supports must be furnished "directly" by a value-based enterprise participant;
- Finalize the proposed safe harbor to protect certain arrangements between or among parties to a CMS-sponsored model for which CMS has determined that the safe harbor is available and to protect participants that furnish certain incentives to patients in those models;
- Expand the distance which residents of rural areas may be transported and eliminate any mileage limitation on transportation of a patient discharged from an inpatient stay under the safe harbor for local transportation;
- Codify the statutory exception to the definition of "remuneration" to provide that "remuneration" not include an incentive payment made to a Medicare Part A or Part B beneficiary by an Accountable Care Organization's beneficiary incentive program; and
- Clarify that the non-discrimination requirement related to the safe harbor for the provision of telehealth technologies allows providers to develop criteria that would limit the provision to a subset of similarly situated patients.

II. Exception to "All Items and Services" in the Definition of "Full Financial Risk"

In the Proposed Rule, OIG proposes that "full financial risk" for purposes of the safe harbor for value-based arrangements ("VBAs") with full financial risk will mean that "the value-based enterprise ("VBE") is financial 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."[3] In other words, OIG, proposes that an enterprise may be protected only if it receives a prospective, capitated payment for all items and services covered by Medicare Parts A and B. OIG clarifies that "global risk adjustments, risk corridors, reinsurance, or stop loss agreement - to protect against catastrophic losses" would be permissible under the safe harbor,[4] but an enterprise would not be

[3] 84 Fed. Reg. at 55764.
[4] 84 Fed. Reg. at 55719.

protected if it receives 1) a partial capitated payment that covers a limited set of items/services; or 2) a combination of reduced fee-for-service payments and capitation payments.[5] OIG does not define "all items and services" and does not provide for any exceptions to the definition of "full financial risk."

The AGS strongly recommends that OIG define full financial risk to include arrangements where the "full financial risk" pertains to only items and services related to a disease or condition for a defined patient population (*e.g.*, an arrangement under which the physician receives an episode-based payment for all care related to one disease) and that exclude certain extraordinarily expensive and infrequently furnished items and services from full financial risk. Medicare has developed a number of payment models that utilize bundled payments and episodes of care over the past few years that should qualify under this safe harbor provision. For example, there have been a number of episode-based payment initiatives developed by the Center for Medicare & Medicaid Innovation ("CMMI"), such as the Comprehensive Care for Joint Replacement Model and the Medicare Acute Care Episode Demonstration, both of which involve testing episode-based payments to physicians. We recommend that OIG implement a policy that protects value-based arrangements between VBE participants who are subject to financial risk similar to providers participating in such CMMI demonstrations. We also recommend that OIG implement a policy that protects value-based arrangements between VBE participants that involve capitated payments for a limited set of services. In some cases, such as with respect to arrangements that involve primary care services, the limited set of services could represent nearly the entire payment received by the provider.

Additionally, the AGS believes that forcing the VBE to bear the financial burden of extraordinarily expensive and infrequently furnished items and services, or of costs unrelated to the disease or condition covered by the arrangement, is unreasonable and would deter providers from entering into such agreements. We believe defining "full financial risk" to allow exclusions of such items aligns with OIG's goals related to facilitating coordinated care, with a low risk of fraud and abuse. Further, permitting a VBA to exclude extraordinarily expensive and infrequently furnished items and services aligns with other policies related to such items and services. For example, some Medicare Advantage plans place provider entities at full risk, but exclude extraordinarily expensive and infrequently furnished items, such as organ transplants, which are not services evenly furnished by different provider specialties. Even with stop-loss programs, Medicare has recognized that such extraordinary costs should be excluded. To ensure the proposed safe harbor aligns with these current coverage policies, the AGS believes that a VBA should be permitted to exclude extraordinarily expensive and infrequently furnished items and services, or costs unrelated to the relevant disease or condition in bundled payment arrangements. Without such changes, this safe harbor may be irrelevant and unavailable to even large provider entities, which would need to rely upon a different safe harbor.

III. Proposed Definition of "Substantial Downside Financial Risk"

In the Proposed Rule, OIG proposes that "substantial downside financial risk" for purposes of the safe harbor for VBAs with substantial downside financial risk will be defined as risk to the VBE in the form of:

[5] 84 Fed. Reg. at 55719.

- shared savings with a repayment obligation to the payor of at least 40% 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% 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% 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 VBAs.[6]

The AGS is disappointed with OIG's proposed definition of "substantial downside financial risk." We believe that the risk levels proposed are too high to allow most providers to utilize the safe harbor. However, we believe that OIG's definition of risk for purposes of this safe harbor is crucial to encourage providers to utilize this safe harbor and enter into value-based arrangements. The level of risk OIG proposes to require is daunting and would deter physicians and physician groups from entering into such VBAs and, therefore, the proposal is inconsistent with OIG's intent to encourage participation in VBAs. The AGS encourages OIG to develop a definition of "substantial downside financial risk" that imposes a more restrained risk requirement and that would, therefore, maintain incentives for providers to enter into VBAs.

Payment models that would facilitate protection under the proposed safe harbor are relatively new to most provider participants, and therefore most providers, particularly healthcare professionals, would find it extremely challenging to take on substantial downside financial risk, as currently defined. A repayment obligation to the payor of 40% of shared losses could easily exceed the total payments the physician earns, which would make entering into such payment arrangement a potentially financially devastating endeavor. For example, if a practice has expense equal to 50% of revenue, and yet receives a capitated payment reflecting a discount equal to at least 60% of the total expected FFS payments based on historical expenditures, the practice's expected take home dollars start at 20% of historical payments. This possible take home payment amount is unlikely to attract providers, such as primary care physicians, that might otherwise be interested in capitation for a defined set of capitated primary care services. Therefore, AGS strongly believes that OIG should modify the proposed definition of "substantial downside financial risk." We recommend that OIG align the amount of risk required to meet the definition of "substantial downside financial risk" with the amount of risk that Advanced Alternative Payment Models are required to take on under the CMS Quality Payment Program ("QPP") or that providers are required to take on under other CMMI payment models. The amounts of risk required by the QPP and CMMI payment models has been tested, validated, and implemented, and are a reasonable basis for establishing a financial risk requirement in the proposed safe harbor. Additionally, the AGS believes that "historical expenditures," as used in the definition of "substantial downside financial risk," should include any comparisons, or methodology for determining historical

[6] 84 Fed. Reg. at 55717.

expenditures, agreed upon by the parties to the arrangement. The OIG should not require participants to use a particular historical comparison methodology, given that such methodologies have been controversial in the past (*e.g.*, calculation of benchmarks and regional adjustments in CMMI models).

IV. Safe Harbor for Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency

In the Proposed Rule, OIG proposes to protect certain financial arrangements for in-kind remuneration that promote value-based care and facilitate care coordination for a target population, regardless of the level of risk undertaken by the VBE or any of its participants. The AGS strongly supports finalizing a safe harbor that protects certain value-based arrangements without requiring any enterprise to take on financial risk. However, we believe that the final safe harbor should include fewer conditions than were proposed. We believe such a final safe harbor will help OIG's efforts to achieve more effective coordination and management of patient care and delivery of value-based care that improves quality of care, health outcomes, and efficiency.

OIG proposes a large number of conditions that must be met for an enterprise to fit within the safe harbor, including:

- The VBE participants must establish one or more valid outcomes measures against which the recipient will be measured and the parties reasonably anticipate will advance the coordination and management of care of the target population;
- The arrangement must be commercially reasonable;
- The arrangement must be set forth in writing;
- The remuneration must be in-kind;
- The remuneration is used primarily to engage in value-based activities directly connected to the coordination and management of care for the target population;
- The remuneration is for or results from activities undertaken for patients in the target population;
- The offeror of the remuneration does not take into account the volume or value of referrals;
- The recipient pays at least 15% of the offeror's cost for the in-kind remuneration;
- The VBA is directly connected to the coordination and management of care of the target population;
- An accountable body or responsible person performs monitoring, assessment, and reporting duties;
- The offeror does not, and should not, know that the remuneration is likely to be diverted, resold, or used by the recipient for an unlawful purpose; and
- Records must be made available to the Secretary of HHS upon request.[7]

Although AGS generally supports the purpose of this safe harbor, we believe that the proposed requirements present unnecessary hurdles for physicians to overcome to enter into a protected arrangement. The AGS has serious concerns that the scope and number of requirements proposed by OIG will deter providers from attempting to enter into arrangements that meet the requirements of the proposed safe harbor. In addition, some of the proposed requirements are vague and providers may

[7] 84 Fed. Reg. at 55708-14.

have difficulty confirming that each requirement has been met. Utilizing the proposed safe harbor may be particularly difficult for small physician practices, solo practitioners, and rural practitioners who may not have the resources required to set up and enter into a protected arrangement. Moreover, providers that do attempt to satisfy all these requirements may have difficulty doing so, despite their best efforts, potentially exposing them to liability under the AKS.

For example, the AGS believes that a requirement under which a recipient must pay at least 15% of the offeror's cost for in-kind remuneration is onerous and would cause many physicians to struggle to meet the requirements of the safe harbor. In the Proposed Rule, OIG describes an arrangement that would meet the proposed safe harbor in which a hospital might provide a behavioral health nurse to follow designated inpatients with mental health disorders in the event of discharge to a skilled nursing facility (SNF). The SNF, in turn, would either provide staff to the hospital to help coordinate designated patients' care through the discharge planning process or provide office space for the behavioral health nurse. See Fed. Reg. at 55708. It may be possible for a hospital or SNF value-based arrangement participant, such as the participants described in OIG's example, to pay at least 15% of the offeror's cost for in-kind remuneration. But an individual provider or small group practice may struggle greatly to make the same financial contribution for in-kind remuneration.

Additionally, because OIG does not define "primarily," the proposed requirement that remuneration be used "primarily" for value-based activities is vague and would be difficult to implement and monitor. The AGS believes that the proposed requirement that the remuneration be "directly connected" to one or more value-based purpose, at least one of which must be coordination and management of care, is also vague. We recommend removing the word "directly" from this proposed requirement to help value-based arrangement participants meet the requirement. Moreover, the requirement that the offeror "does not, and should not know" that the remuneration is likely to be diverted, sold, or utilized by the patient for an alternative purpose is not specifically defined and would be difficult for individual providers and small group practices to understand and to ensure compliance.

These examples demonstrate that the proposed safe harbor is overly burdensome and vague, and will be difficult to implement. Therefore, AGS recommends that OIG redesign the proposed safe harbor to include fewer hurdles to implement a protected arrangement.

V. Safe Harbor for the Provision of Cybersecurity and EHR Technology

The AGS supports OIG' proposal to add a new cybersecurity safe harbor that would protect donations of software or other non-hardware information technology that are "necessary and used predominantly" to "protect information by preventing, detecting, and responding to cyberattacks."[8] The AGS supports OIG's proposal not to require a recipient contribution requirement as part of the proposed safe harbor. As healthcare providers work to improve information sharing across care transitions and foster coordination, it is critical that health IT systems are protected against cyberattacks. Vulnerabilities in physicians' IT systems expose other providers, such as hospitals, skilled nursing facilities, and other outpatient facilities, to attack. Therefore, it is appropriate and in the best interest of patients' health and information security to allow entities with the financial ability to donate cybersecurity technology to other providers with whom they coordinate care.

[8] 84 Fed. Reg. at 55734.

In addition, the AGS generally supports OIG's proposal to update EHR technology safe harbor provisions pertaining to interoperability and data lock-in, clarify that donations of certain cybersecurity software and services are permitted, remove the existing sunset provisions, and modify the definitions of "electronic health record" and "interoperable" to be consistent with the 21st Century Cures Act. However, the AGS disagrees with OIG's proposal to retain the requirement the recipient to pay 15% of the donor's cost of the technology. Instead, the AGS supports the alternative proposal to waive the percentage contribution requirement for all practices.[9] The AGS believes any contribution requirement may be burdensome for a physician practice and would deter physician practices from adopting modern EHR systems and cybersecurity technology that will help protect patients and patient data. Certain organizations will only permit practices to utilize their EHR systems if the physician has certain cybersecurity protections, but the cybersecurity system provides no other benefit to the practice other than enabling the use of an integrated EHR system. Therefore, it is appropriate that the party requiring the cybersecurity protection pay any costs associated with the system. Practices may not otherwise have access to patient information through an EHR system for timely care coordination. In the alternative, we recommend that OIG adopt its alternative proposal to eliminate the contribution requirement for small and rural practices. As OIG implicitly acknowledges, small and rural practices typically do not have the resources to contribute to EHR and cybersecurity technology. Requiring any contribution for such technology would deter widespread adoption of interoperable EHR and cybersecurity.

VI. Safe Harbor for Outcomes-Based Payments

The AGS generally supports OIG's proposal to add a new safe harbor provision to protect "outcomes-based payments" made between or among parties that are collaborating to (i) measurably improve (or maintain improvement in) quality of patient care; or (ii) appropriately and materially reduce costs to, or growth in expenditures of, payors while improving, or maintaining the improved, quality of care for patients.

In its discussion of this proposal, OIG seeks comments on whether it should protect arrangements that involve payments for maintaining high quality and, relatedly, proposes to require parties to "rebase" outcomes measure benchmarks periodically to take into account improvements in performance. In our view, it is both appropriate and in the best interest of patients to reward high performers, including those that have plateaued, because it incentivizes maintenance of high quality care. As we have observed with respect to quality measures associated with the Merit-based Incentive Payment System ("MIPS"), it is naïve to assume that high performance once achieved is immutable. Given the limited resources and time available to many providers, financial incentives can have an impact quality of care, and conversely, quality of care may lower when financial incentives are removed. While we understand OIG's concern that these arrangements could be used to disguise referrals, we believe that basing payment on evidence-based, valid outcome measures, which are developed by disinterested third party experts -- coupled with the other safeguards OIG proposes -- mitigates that risk.

We do not support OIG's proposed requirement that the parties periodically "rebase" the outcomes measures. It was unclear to us whether OIG intends to require that parties periodically rebase outcomes measures or only evaluate whether it would be appropriate to rebase. Whether or not to rebase an outcomes measure is a measure- and parties- specific inquiry. It is neither appropriate nor

[9] 84 Fed. Reg. at 55743.

realistic for OIG to establish uniform requirements for rebasing that would be applicable across all outcomes-based payment arrangements. Because the appropriateness of rebasing is so fact specific, we also are concerned about requiring parties to evaluate whether rebasing should occur. How would OIG confirm that the parties adequately considered rebasing? Because the decision whether or not to rebase is so subjective, such a requirement likely would expose parties to uncertainly regarding whether their arrangement is protected by the safe harbor.

VII. Safe Harbor for Arrangements for Patient Engagement and Support

The AGS generally supports OIG's proposed safe harbor to protect certain arrangements under which in-kind patient engagement tools or supports are furnished directly by a VBE participant to a patient in a target patient population, provided that certain conditions are met.[10] The AGS strongly supports the goals of the proposed safe harbor to enhance patient adherence to a treatment regimen, drug regiment, or follow-up plan; manage a disease or condition as directed by the patient's provider; improve health outcomes; and ensure patient safety. In addition, the AGS agrees with OIG that there is a high risk of fraud and abuse when pharmaceutical manufacturers are permitted to provide patient engagement tools or supports, and therefore supports excluding from this safe harbor pharmaceutical manufacturers; manufacturers, distributors, and suppliers of durable medical equipment, prosthetics, orthotics, or supplies; and laboratories.

Although the AGS generally agrees with the proposed safe harbor as proposed, we encourage OIG to clarify that the safe harbor is not an indication that other low-risk, beneficial patient support activities are impermissible under the AKS. For example, given the patient population we treat, some geriatricians provide group education activities. Such group education activities, which are beneficial to patients and their families, should not be considered remuneration under the AKS, are otherwise low risk, and do not require safe harbor protection. We urge OIG to ensure such flexibility for physicians remains when finalizing the proposed safe harbor for patient engagement and support.

In addition, the AGS does not support the proposed requirement that patient engagement tools or supports must be furnished "directly" by a VBE participant. The AGS believes that an agent of a VBE participant, such as a vendor, contractor, or employee of the participant, should also be permitted to furnish the patient engagement tools or supports at the direction of the VBE participant.

VIII. Safe Harbor for CMS-Sponsored Model Arrangements and Patient Incentives

The AGS supports OIG's proposed safe harbor to protect certain arrangements between or among parties to a CMS-sponsored model for which CMS has determined that the safe harbor is available and to protect participants that furnish certain incentives to patients in those models. We agree that the proposed safe harbor would "streamline participation in existing and future CMS-sponsored models [and] reduce complexity and the administrative burden on participants that seek protection under the fraud and abuse laws while participating in a CMS-sponsored model."[11] We hope that this proposal will help facilitate patient access to high quality of care by reducing complexity and lessening the administrative burden of CMS-sponsored models on model participants.

[10] 84 Fed. Reg. at 55721-30.
[11] 84 Fed. Reg. at 55758.

IX. Safe Harbor for Local Transportation

In the Proposed Rule, OIG seeks information regarding the scope of transportation protected by the safe harbor for local transportation previously finalized in 2016 and currently codified at 42 C.F.R. § 1001.952(bb). Specifically, OIG requests comment on 1) expanding the distance which residents of rural areas may be transported from 50 miles to 75 miles; and 2) eliminating any mileage limitation on transportation of a patient at discharge from a healthcare facility following an inpatient stay.[12] The AGS strongly supports both expanding the distance which residents of rural areas may be transported and eliminating any mileage limitation on transportation of a patient discharged from an inpatient stay. However, with respect to transportation for residents of rural areas, the AGS recommends that the permissible distance be increased from 50 miles to 100 miles, as some patients in rural areas, such as rural areas in the Midwest, may have to travel distances greater than 75 miles.

X. ACO Beneficiary Incentive Program

The AGS supports OIG's proposal to codify in regulation the statutory exception to the definition of "remuneration," which provides that "remuneration" does not include an incentive payment made to a Medicare Part A or B beneficiary by an Accountable Care Organization's beneficiary incentive program. In particular, the AGS agrees with OIG that codification of Social Security Act section 1899(m) does not require OIG to promulgate additional requirements found outside of that statutory section.

XI. Telehealth Technologies

The AGS generally supports OIG's proposal to codify the exception to the definition of "remuneration" in the beneficiary inducement civil monetary penalty provision for the provision of telehealth technology to patients with End Stage Renal Disease ("ESRD"). In addition, the AGS supports OIG's proposal to define "telehealth technologies" as "multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner used in the diagnosis, intervention, or ongoing care management—paid for by Medicare Part B — between a patient and the remote healthcare provider. Telephones, facsimile machines, and electronic mail systems are not telehealth technologies."[13] However, the AGS recommends that OIG expand the definition to also include other supporting technologies, such as webcams, software, and internet access that facilitate communication between a patient and a provider.

The AGS strongly believes that telehealth is a critical, and growing, part of the provision of healthcare. Telehealth has the potential to greatly improve outcomes for chronically ill, multi-morbid patients, including patients that are homebound and patients living in underserved areas by facilitating patient access to geriatrics and other health professionals. Therefore, the AGS supports greater flexibility for telehealth services to help extend the reach of vital medical care.

However, the AGS has concerns regarding the non-discrimination requirement, which would require providers to provide the same telehealth technologies to any Medicare Part B eligible patient receiving in-home dialysis, or to otherwise consistently offer telehealth technologies to all patients that

[12] 84 Fed. Reg. at 55750-51.
[13] 84 Fed. Reg. at 55755.

satisfy a uniform criteria. The AGS strongly recommends that OIG clarify that providers would have flexibility under the non-discrimination requirement to establish criteria under which only a subset of patients would be offered telehealth technologies. The AGS reminds OIG that not every patient requires the same type of care. For example, a physician may wish to offer telehealth services to certain elderly patients with comorbidities that make it difficult for the patient to travel to the physician's office, but not offer the same telehealth services to other patients who are easily able to travel to the physician office. Therefore, OIG should clarify that providers may establish criteria that considers patient mobility, access to transportation options, financial status, and health condition in determining whether a patient qualified for free telehealth technologies.

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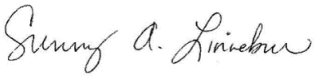
Thank you for the opportunity to submit these comments. We would be pleased to answer any questions you may have. Please contact Alanna Goldstein, agoldstein@americangeriatrics.org.

Sincerely,



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