AMGA
Advancing High Performance Health

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Acting Inspector General Joanne Chiedi
Office of the Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P
Room 5521
Cohen Building
330 Independence Ave, SW
Washington, DC 20201

Dear Acting Inspector General:

On behalf of AMGA and its members, I are pleased to provide comments on the "Medicare and State Healthcare Programs: Fraud and Abuse; Revisions To Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty (CMP) Rules Regarding Beneficiary Inducements proposed rule (RIN 0936-AA10)."

Founded in 1950, AMGA represents more than 450 multispecialty medical groups and integrated delivery systems representing approximately 177,000 physicians who care for one in three Americans. Our member medical groups work diligently to provide innovative, high-quality, patient-centered cost-effective medical care.

AMGA supports policies that reduce the Medicare programs' regulatory complexity so our members are better able to focus on providing the best possible patient care, rather than divert their attention toward regulatory compliance activities that do not improve the patient experience. Our overarching legislative and regulatory goals revolve around advancing the shift from fee-for-service (FFS) payments to reimbursement based on the value of the care provided. AMGA believes regulations should support the ability to deliver care through innovative models focused on quality and outcomes. Value-based models, such as Accountable Care Organizations (ACOs) and other Alternative Payment Models (APMs), remove the misaligned financial incentives that grew out of the FFS system, while also entrusting providers with the responsibility for the health of not just individual patients, but an assigned patient population. The regulatory framework governing these models of care delivery should reflect this key difference.

The Department of Health and Human Services Office of Inspector General (OIG) has recognized that the Anti-Kickback Statute may hinder the adoption of value-based care models. AMGA recommends the safe harbor protections under the Federal Anti-Kickback Statute reflect

advancements in care delivery. AMGA appreciates the difficulty in providing regulatory relief for care delivery models through a statutory framework that prohibits payment or receipt of remuneration for referral of program beneficiaries.

In its efforts to create new safe harbors, modify existing ones, and revise terminology, AMGA is concerned that the OIG's proposal may inadvertently create confusion and burden for the provider community. Instead, AMGA member organizations need clear and workable standards and guidance before they will be comfortable relying on a safe harbor. The rule notes that the OIG has not made any final determination that the proposed safe harbors will be exempt from liability under the Anti-Kickback Statute. Given the criminal nature of the statute and the potential for liability, providers will need clear guidance and a workable timeframe to implement a financial risk arrangement. AMGA is concerned that a prospective framework, while well intentioned, will not offer the guidance necessary for providers to develop value-based models of care. Complying with the proposed safe harbors and their associated reporting requirements likely will increase administrative and compliance burden.

AMGA is pleased to offer the following recommendations on the OIG's proposed rule.

**Key Recommendations**

***Value-Based Arrangement Safe Harbors***
OIG is proposing a tiered structure of safe harbors that offer greater flexibilities as providers assume more downside risk. AMGA opposes structuring safe harbors based on the level of risk, as changing the regulatory framework for providers as they transition into increased risk introduces confusion and complexity into the model. Rather than acting as an incentive, a tiered structure requires our member groups to revise their practices as they assume additional financial risk. This structure also discounts the investments made in those models that do not feature downside risk. In addition, the safe harbors that OIG is proposing are stricter than the exceptions that the Centers for Medicare & Medicaid Services (CMS) has proposed in its corresponding Physician Self-Referral proposed rule. AMGA members will need to structure any arrangements so that they meet the most stringent standard. Providers will not be able to benefit from any flexibilities from one set of regulations if others governing different aspects of the same model require a stricter standard. AMGA recommends that OIG synchronize the proposals with CMS to ensure clarity in the provider community.

***CMS-Sponsored Model Safe Harbor***
AMGA supports the creation of a safe harbor that is offered in connection with CMS-sponsored models. This will alleviate the need for providers to seek distinct fraud-and-abuse waivers and provide clarity on which activities are permitted as part of participation in a CMS model.

***Timeframe***
OIG is proposing a six-month implementation period for parties to implement a full financial risk arrangement. This aggressive timeframe would limit any safe harbor to only the most advanced and experienced providers. It would preclude any providers from learning how to take on risk and work within the safe harbor before moving into a full-risk arrangement.

**Comments**

***Proposed Value-Based Arrangement Safe Harbors***

OIG is proposing a new Anti-Kickback safe harbor framework to help support the transition to value-based care. Importantly, OIG designed these proposed safe harbors to foster new value-based enterprises and not to provide new or modified safe harbors for any existing models. These proposals are prospective in nature only and rely on providers to ensure they comply with them. AMGA recommends that OIG reconsider this and apply retrospective protection. These safe harbors also must meet the requirements of existing safe harbors, namely commercial reasonableness, fair market value, and the volume or value of referrals. These requirements represent a significant obstacle to the broader adoption of value-based models of care.

The current Anti-Kickback Statute language and safe harbors represent a response to FFS reimbursement. AMGA appreciates that OIG is attempting to revise its regulations in recognition of the advances in healthcare delivery. The proposed rule also explains that OIG's effort is intended to remove regulatory barriers to promote "industry-led" innovation to healthcare delivery. AMGA appreciates this effort, but several barriers must be addressed before providers will be able to work with other stakeholders and deploy value-based care and payment models. For example, our members report that access to commercial risk products is limited. Beyond that, there are additional impediments to participating in value-based models of care, most notably a lack of access to administrative claims data from payers, lack of uniform data submission and reporting standards, multiple quality measure programs, and issues with financial benchmarking and risk-adjustment methodologies. As a result, as well intentioned as the proposed safe harbors are, several impediments will continue to hinder the transition to value-based care.

The three new proposed safe harbors for value-based arrangements vary by the types of remuneration protected and the level of financial risk assumed. These three new safe harbors are:

1. A safe harbor for certain *in-kind remuneration* exchanged between qualifying value-based enterprise (VBE) participants for value-based activities that are directly connected to care coordination and care management
2. A safe harbor for certain *in-kind and monetary arrangements* where the VBE assumes substantial downside risk from a payer
3. A safe harbor for certain *in-kind and monetary arrangements* where the VBE assumes full downside financial risk from a payer.

As OIG is aware, meeting a safe harbor is voluntary and failure to meet a safe harbor does not necessarily mean that providers violated the Anti-Kickback Statute. However, given the criminal nature of the law, providers take compliance with safe harbors seriously. AMGA is concerned that while complimentary to the protections that CMS is proposing for Stark Law exceptions, the proposed safe harbors are in many cases, as OIG notes, "more restrictive than CMS' comparable proposals." AMGA members will structure their practices to meet the most stringent requirements. Any flexibility provided in related regulation will be moot should OIG adopt a standard that differs from CMS. AMGA recommends that OIG and CMS synchronize their standards.

OIG is proposing a tiered structure of safe harbors that offer greater flexibilities as providers assume more downside risk. AMGA opposes structuring safe harbors based on the level of risk, as changing the regulatory framework for providers as they transition into increased risk introduces confusion and complexity into the model. The types of remuneration protected (in-kind, monetary, or both) should be consistent so that providers will have as much flexibility as possible. Basing safe harbors on the level downside risk ignores the significant capital investment in staff, facilities, and other infrastructure required to succeed in any value-based model, including those based on shared savings.

OIG designed these new proposed safe harbors with future models of care in mind, which differs from existing safe harbors, which were structured with specific models in mind. Providers are accustomed to seeking a waiver for their participation in a specific model. For example, a safe harbor exists for Medicare Shared Savings Program (MSSP) Accountable Care Organization (ACO) participants. This safe harbor allows ACOs to distribute shared savings among ACO participants during the year in which the shared savings were earned. OIG reverses this paradigm in the proposed rule. Instead of voluntarily entering a model, the rule provides a framework for providers to construct a model that may qualify for safe harbor protection. This framework, however, is not a roadmap to constructing a new value-based model. As the proposed rule notes, any new model will remain subject to case-by-case review under the Anti-Kickback Statute and a "facts and circumstances" analysis to determine if a safe harbor applies. While AMGA recognizes that OIG is attempting to avoid being prescriptive in creating its new framework, we believe that providers likely will need additional clarification or examples of the types of arrangements that will qualify for the safe harbors before they undergo the time and expense of creating a new model that may not meet the standards.

***Safe Harbors as an Incentive to Assume Financial Risk***

The greatest flexibility in the proposed safe harbor is for those value-based arrangements that assume full financial risk. Under the proposed rule, the financial risk must be prospective, and the arrangement cannot include additional payments to cover the cost of the patient care.

Effectively, this requires providers to provide care for a target patient population and receive a prospective payment that is determined in advance, such as capitated payments for all covered services. Those providers who receive partially capitated payments or a blend of capitated and FFS payments would not qualify for this proposed safe harbor. Assuming full risk, however, requires significant experience in value-based models, as well as the supporting infrastructure. It also requires a willing partner in the payer community. Based on a survey of our members, commercial payers generally are not offering risk products, let alone those based on full provider risk. While OIG holds out increased flexibility as an incentive, the lack of available risk products likely will limit the number of providers who are able to benefit from this proposed safe harbor. AMGA agrees with offering a safe harbor for in-kind and monetary arrangements. We do not support restricting access to this safe harbor to only those providers that have the means and opportunity to assume full financial risk.

OIG's use of safe harbors as incentives to transition to value is misplaced. Rather than acting as an incentive, a tiered structure requires our member groups to revise their practices as they assume additional financial risks. Changing the tools or protections that are available to providers or an entity that varies based on the level of risk does not serve as an incentive.

Instead, it creates a confusing regulatory landscape for providers. AMGA believes that a consistent regulatory framework provides stability and predictability for providers that opt to move from FFS reimbursement and into a risk-based model. Limiting the availability of the flexibilities providers need to succeed will not encourage the transition to value-based care, but rather add increased uncertainty, as well as administrative and compliance burdens.

Beyond our overall concern with the tiered structure of the three, new proposed safe harbors for value-based arrangements, AMGA has specific concerns with each.

AMGA's members are invested in the transition to risk. However, years of experience are required before a provider group is in a position to assume full financial risk. OIG is defining full risk as the cost of all patient care items and services. If OIG is going to include prescription drugs in the definition of all items and services, it is important pharmaceutical manufacturers be eligible to participate in the VBE.

Given the obstacles to assuming full risk, the substantial downside risk safe harbor provides more immediate opportunities. As proposed, to qualify for the substantial downside financial risk safe harbor, a value-based entity must meets any of the following.

- Shared savings with a repayment obligation to the payer of at least 40% of any shared losses
- A repayment obligation to the payer under an episodic or bundled payment arrangement of at least 20% of any total loss
- A prospectively paid population-based payment for a defined subset of the total cost of care of a target patient population
- A partial capitated payment from the payer 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

Based on our experience, we believe the provider community is unlikely to meet these arbitrary percentages. However, OIG is seeking comment on whether the Advanced Alternative Payment Models (APMs) under CMS' Quality Payment Program would meet the definition of substantial downside risk. AMGA supports including Advanced APMs and other payer APMs in this definition.

The care coordination arrangement safe harbor does not require parties to bear or assume downside financial risk. It would provide a safe harbor for in-kind remuneration between value-based entity participants to facilitate care coordination and management. To qualify, however, the VBE would be required, among other things, to establish an outcome measure. While supportive of appropriate quality measurement and the emphasis on outcomes, OIG needs to provide additional clarity on this requirement. AMGA's membership is invested in models of care based on coordination. However, this is a means to delivering high-quality care and not an end. In addition, the safe harbor would require that recipients contribute at least 15% of the cost of the in-kind remuneration. AMGA does not believe this is necessary, as the requirement likely will add complexity and may be cost prohibitive.

**Proposed Value-Based Terminology**

AMGA offers the following recommendations for the proposed terminology.

The safe harbors that OIG is proposing are available to a "value-based enterprise," which describes the network of individuals and entities that would collaborate on a value-based activity. This enterprise must have an accountable body, government documentation, compliance program, and other requirements. AMGA is concerned that creating a new accountable body and the associated documentation will require significant legal expenses, which may discourage participation.

The safe harbors would be open to "value-based entity participants" which would include clinicians, providers, and suppliers and companies providing mobile health and digital technologies to physicians, hospitals, patients, and others for the coordination and management of patients and their health care. OIG proposes to exclude pharmaceutical manufacturers, durable medical equipment manufacturers, distributors, and suppliers, as well as laboratories from the definition. As a result, the proposed rule would exclude these entities from participation in value-based models that the proposed safe harbors cover. AMGA disagrees with excluding these entities. OIG is concerned that such entities are heavily dependent on practitioner referrals and "might misuse" the proposed safe harbors. However, these suppliers can work closely with providers within a value-based arrangement to improve quality and control costs. By including such entities, providers will have access to additional data on how and when their patients receive care and will better be able to understand DME and pharmacy utilization and spending. With this data, our members can better care for their patients and reduce their cost of care through better utilization of costly services. In addition, CMS is not excluding these providers from its definition. AMGA recommends OIG and CMS align the definitions and include these entities in the definition.

OIG proposes to define "target patient population" as "an identified patient population selected by the VBE or its VBE participants using legitimate and verifiable criteria." AMGA appreciates that the definition is broad and offers significant discretion on how a model will identify and serve a patient population. OIG is seeking comment on whether the proposed safe harbors should be limited to only those with a chronic condition. AMGA opposes such a restriction, as it would require the models to be based on specific conditions and may preclude providers from developing a value-based entity focused on prevention and addressing multiple conditions. While disease-specific models may be one approach to constructing a value-based model, it should not preclude the healthcare community from investigating other approaches. The definition also requires value-based entities to select a target population based on "legitimate and verifiable criteria." AMGA is concerned that "legitimate" is vague and subject to interpretation.

**Additional Safe Harbors**

AMGA is pleased to offer comments on OIG's additional proposed safe harbors.

***CMS-Sponsored Models***

The OIG proposal would create a safe harbor that would protect remuneration between parties under an APM or other demonstration or initiative being tested by the Center for Medicare &

Medicaid Innovation. This safe harbor also would apply to the MSSP. AMGA supports this safe harbor and appreciates that OIG is looking to consolidate the various fraud and abuse waivers that are available for each specific CMS model or demonstration.

***Cybersecurity Technology and Services***

The OIG is proposing a new safe harbor to protect donation of select cybersecurity technology and related services, including installation, training, data recovery services, and risk assessments, among other things. However, the safe harbor as proposed would not include hardware. AMGA would ask that the OIG reconsider this, as hardware donation may be appropriate and necessary for a provider to move to value and benefit from the latest technology.

We thank OIG for consideration of our comments. Should you have questions, please do not hesitate to contact AMGA's Darryl M. Drevna, senior director for regulatory affairs, at 703.838.0033 ext. 339 or at ddrevna@amga.org.

Sincerely,

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