December 31, 2019  

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

Re: 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 Acting Inspector General Chiedi:

The Physicians Advocacy Institute (PAI) appreciates the opportunity 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 Rules Regarding Beneficiary Inducements proposed rule, published in the Federal Register on October 17, 2019.

PAI is a not-for-profit organization that was established to advance fair and transparent policies in the health care system to sustain the profession of medicine for the benefit of patients. As part of this mission, PAI seeks to better understand the challenges facing physicians and their patients and to also educate policymakers about these challenges. PAI also develops tools to help physicians prepare for and respond to policies and marketplace trends that impact their ability to practice medicine. PAI’s Board of Directors is comprised of CEOs and former CEOs from nine state medical associations: California Medical Association, Connecticut State Medical Society, Medical Association of Georgia, Nebraska Medical Association, Medical Society of the State of New York, North Carolina Medical Society, South Carolina Medical Association, Tennessee Medical Association, and Texas Medical Association, and a physician member from Kentucky. As a physician-based organization, PAI is equipped to provide comments and insight into many of the challenges facing the medical profession.

PAI is committed to helping physicians adapt to and succeed under the Medicare program, especially the Quality Payment Program (QPP) as well as alternative payment models (APMs) and other value-based arrangements (VBAs). PAI strongly supports the Department of Health and Human Services' (Department’s) Regulatory Sprint to Coordinated Care (Regulatory Sprint) to remove regulatory barriers associated with four key laws and regulations: 1) the physician self-referral law; 2) the
Federal anti-kickback statute; the Health Insurance Portability and Accountability Act of 1996 (HIPAA); and 4) rules under 42 CFR part 2 related to substance use disorder treatment.

Overview

Congress enacted the Anti-Kickback Statute in 1972 to deter arrangements under which patient and service referrals were induced or rewarded in the form of kickbacks, bribes, rebates, etc.; the Statute’s purpose was to deter arrangements under which providers put their financial motives ahead of patient needs. In response to concerns that some prohibited, but beneficial, arrangements should be allowed, Congress established “safe harbors” to the Statute in 1987. Similarly, Congress established the beneficiary inducements CMP to deter waivers, co-payment or deductible adjustments, etc., that could influence a patient’s decision to receive care from a particular provider and/or facility. While the existing safe harbors and waivers have had a positive impact on the practice of medicine, many health system stakeholders consider the Statute and CMP obstacles to the development of integrated delivery models, APMs, and other VBAs.

In recent years, CMS has been encouraging physicians and practices to bear more accountability for the total costs of their patients’ care, both through APMs involving two-sided risk and through the Quality Payment Program (QPP). These programs and opportunities help limit the concerns that gave rise to self-referral restrictions because these new payment model approaches discourage provision of low-value care. For these efforts to succeed, however, physicians not only need appropriate incentives but also tools to better coordinate their patients’ care and manage their illnesses and their health effectively and efficiently.

In this comment letter, PAI echoes the recommendations and comments we submitted in response to the Anti-Kickback Statute and Physician Self-Referral Law Requests for Information (RFIs) last year, as well as the comments submitted in response to the Physician Self-Referral Proposed Rule. PAI believes that there should be as much alignment between the Physician Self-Referral Law exceptions and the Anti-Kickback Statute exceptions. Importantly, there should not be unnecessary complications and complexities due to potential conflicts between the two. We encourage the Department to provide increased and more uniform flexibilities across the Physician Self-Referral Law and the Anti-Kickback Statute that encourage participation in APMs and innovative payment arrangements. Lastly, modernization efforts also should ensure that the guiding laws and regulations at both the federal and state level are updated and keep pace with health care delivery system innovations and advancements.

Proposed Definitions

The Office of the Inspector General (OIG) is proposing several new definitions for protected entities and activities. These include definitions for the following terms: Value-based enterprise (VBE); VBE Participant; Value-based Arrangement; and Value-Based Activity.

Value-Based Enterprise

PAI is supportive of the proposed definition for a VBE, however, we request further clarification on the following: 1) responsibilities, requirements, structure, and composition of the “accountable
body,” as well as requirements of the “governing document;” and 2) whether such requirements may be met through existing payer (including Medicare) contracts and agreements (i.e., a new contract or agreement would not be necessary if one already exists). For example, we seek clarification on whether the governing body must be exclusively providers and entities providing care, or if they can also include other third parties that are helping support the infrastructure and care delivery in other ways. PAI also seeks feedback on the requirements necessary to certify a VBE for the purposes of these protections. PAI believes that a VBE should be perceived or be de facto “clinically integrated” under federal rules (including Federal Trade Commission (FTC) and Department of Justice (DOJ) rules).

**VBE Participant**
PAI is supportive of the broad definition encompassing VBE participants. We believe that there is an array of health professionals that could benefit from participating in such entities, including those who have not realized the benefits of AKS safe harbors to-date. With regards to excluded participants, specifically health technology companies and device manufacturers, we believe that there may be some value in allowing them to become VBE participants, but with guardrails to ensure that they are supporting the goals of the VBA but are not controlling or taking over ownership of the VBE or its goals and services.

**Value-Based Arrangements (VBAs) and Target Patient Population**
PAI is generally supportive of the VBA definition, but reiterates the need for clarification that existing contracts under the VBE can be used to satisfy the VBA requirements. Additionally, PAI has several concerns with the definition of a “target patient population” as defined within a VBA. First, we seek clarification that this would include patient populations that are retroactively attributed under VBAs (e.g., using a claims-based methodology). There are also concerns with patient populations that are of more transient nature (e.g., “snowbirds”) who may have different providers in different geographic locations responsible for their care at various times through the year. We believe that the “target patient population” definition should consider these additional factors, and that the definition be more inclusive of non-health-related factors, aside from geographic characteristics and payor status.

VBAs are most effective when tailored to the varying socio-economic and socio-cultural barriers that affect care access among underserved communities. Thus, PAI believes this definition should be more inclusive of such factors. Furthermore, target patient populations, when determined retrospectively, will by their very nature introduce uncertainty and we recommend that protections be extended to patients reasonably expected to meet the definition of “target patient population.” For convenience and consistency, we propose that any patient retrospectively attributed under a VBA in the previous performance period be automatically categorized as a member of the “target patient population.”

**Value-Based Activity, Reasonably Designed, and Value-Based Purpose**
PAI is generally supportive of these definitions, however we question the need for documenting both a “value-based activity” and a “value-based purpose,” and if such components can be embedded within a single definition to reduce administrative complexity when documenting VBA performance as well as prospective written agreements. PAI does not recommend basing the “reasonably designed” on evidence-based processes as many value-based activities may be in demonstration or pilot stages under value-based arrangements to test their impact and effectiveness. Furthermore, we
believe the value-based purpose and value-based activity should recognize the importance of not only improving quality and coordinating and managing care, but also maintaining care and outcomes at an acceptable level. We are also requesting further clarification on what is considered “legitimate and verifiable criteria” when determining a target patient population, and to what extent such criteria may encompass social determinants of health and other non-health related factors.

Safe Harbor for Care Coordination Arrangements (CCAs)
The OIG is proposing a new safe harbor protection for CCAs that would protect in-kind remunerations only between qualifying VBE participants with CCA-VBAs that satisfy 3 key criteria. PAI supports this proposed safe harbor, as well as OIG’s proposal to tie such VBAs to evidence-based outcomes. However, not all specialties have outcomes-based measures available currently, so we would urge the OIG to modify this requirement to “specific evidence-based measures against which the recipient would be measured.” PAI is requesting further clarification from OIG on the determination of what is considered “commercially reasonable” under AKS standards.

PAI also supports OIG’s efforts to ensure such VBAs are accurately documented. However, we propose that such documentation requirements not require an exhaustive list of all value-based activities to be undertaken, but rather the value-based purpose of the VBA. We believe that requiring an exhaustive and prospective list of all permissible value-based activities may ultimately limit the scope of value-based care services/items provided pursuant to the VBA.

Contribution Requirement
The OIG is proposing that there be recipient contribution (e.g., of 15%) of the offeror’s cost for in-kind remuneration. PAI cautions the OIG against only using monetary value for meeting the contribution requirement. We believe that this could adversely impact small and rural practices pursuing such agreements, whom should be exempt from this contribution. Additionally, non-monetary contributions should be considered as it is possible that they could be things that are important but not quantifiable, e.g., extended office hours.

Safe Harbor for VBAs with Substantial Downside Risk
The OIG is proposing a safe harbor for VBAs involving VBEs that assume “substantial downside risk” defined as meeting one of four criteria. PAI supports the proposed safe harbor but recommends lower benchmarks. There should also be reference to and inclusion of Advanced and Other Payer APMs as defined under the QPP. Additionally, we believe that risk-sharing requirements should be optional but not imposed on VBE participants and that how “risk-sharing” is defined be more flexible. For example, we believe that risk could be shared if the participants share staffing or services and/or buy into a technology or platform. In these situations, each participant is contributing and buying into a service/product that should satisfy the risk-sharing requirement.

Safe Harbor for VBAs with Full Financial Risk
The OIG is proposing a third safe harbor for VBEs that are “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.” This safe harbor would not be extended to partial
payment agreements that blend partial capitation with reduced FFS (including, e.g., bundled/episodic payments for hospitals for a knee surgery because hospital is not responsible for total cost of care). However, the safe harbor would not prohibit a VBE from entering into agreements to protect against catastrophic losses (e.g., risk corridors, global risk adjustment, reinsurance, or stop loss agreements).

PAI supports the proposed new safe harbor for models taking full financial risk. However, we request further clarification that even under a “prospectively paid” arrangement, retrospective reconciliation could occur and would be permissible, as well as what can be counted towards “full financial risk.” PAI has concerns that this safe harbor would only be made available to larger, more integrated systems, and that smaller and rural practices may not be able to enter traditionally defined “full risk” models even though they are embracing downside risk.

Safe Harbor for Patient Engagement and Support Arrangements

The OIG is proposing a safe harbor to protect arrangements for patient engagement tools and supports furnished to improve care adherence, provided specifically by VBE participants. Specifically, this would be limited to “in-kind, preventive items, goods, or services, or items, goods, or services such as health-related technology, patient health-related monitoring tools and services, or supports and services designed to identify and address a patient’s social determinants of health, that have a direct connection to the coordination and management of care of the target patient population.”

PAI supports the proposed safe harbor for arrangements covering in-kind “patient engagement and support” arrangements, and strongly supports focusing on improving access to items, services, and supports that address social determinants of health (SDOH).

**Purposes of Tools and Supports**

OIG is proposing that tools and supports would have to advance one or some combination of the following enumerated goals: adherence to a treatment regimen; adherence to a drug regimen; adherence to a follow-up care plan; management of a disease or condition; improvement in evidence-based measurable health outcomes for a patient or the target patient population; and/or ensuring patient safety. Generally, these enumerated goals are wide-reaching—however, we request further clarification on measurement/compliance requirements that may ultimately narrow the ability of certain providers to offer innovative SDOH-related tools and supports as those may not directly link to one of these goals and it may be difficult to satisfy this requirement. We also urge the OIG to permit tools and supports that are aimed at patient and caregiver education, training, and/or support.

**Defining Social Determinants of Health**

The OIG is seeking comments on how to best define SDOH services under this safe harbor. PAI recommends not restricting or enumerating SDOH supports and services as these are tailored to specific patients, conditions, and/or diseases. OIG could reference inclusion of those services that are offered as supplemental benefits within Medicare Advantage as well as the special supplemental benefits for the chronically ill included in the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act. SDOH should also be defined to include cultural and social
personal identification elements. For example, understanding one's sexual orientation or country of origin can help with understanding patients’ perspectives on medicine and health care services.

**Cash and Cash Equivalent Incentives**

The OIG is considering protections for patient incentives and supports in the form of cash and cash equivalents. The OIG is soliciting comments on the following: safeguards to prevent misuse; whether there should be a value cap and for what amount; and whether incentives should be limited to patients for attending medically necessary primary care or other clinically prescribed treatment visits. Furthermore, the OIG is considering the following additional protections and safeguards under consideration for this safe harbor: protections for waivers or reductions in cost-sharing; protections for gift cards; a provision capping total patient remunerations to $500 annually; and a provision that would require the retrieval of items and goods that pass a minimum threshold in value (e.g., $100, $200, $300, etc.) when the patient is no longer party to the VBA.

PAI supports all proposed safe harbors that protect tools and supports aimed at improving patient care adherence, including the use of cash and cash equivalent incentives. We also believe that such incentives should not be limited to patients for attending medically necessary primary care or other clinically prescribed treatment visits, but also expand to community-based services that largely impact clinical outcomes through addressing SDOH. PAI does not believe there should be value caps or other limitations for primary care, chronic care, and disease management related incentives.

Furthermore, PAI urges the OIG to consider additional safe harbor protections for other cash equivalent incentives, such as patient coupons or discount cards. We believe that expanding the safe harbor to include gift cards, discount cards, and coupons towards future services would support the viability of smaller independent practices that operate in consolidated markets and are competing against hospitals and health systems.

**Blanket Safe Harbor for Center for Medicare and Medicaid Innovation (CMMI) Model Participants**

The OIG is proposing a new safe harbor for protection of remunerations pursuant to VBAs under CMMI models. Unlike other proposed safe harbors, the OIG has defined these protections vaguely, and is providing CMS the jurisdiction to decide what will be required from entities to gain protections. Furthermore, due to the flexibility of this safe harbor, the OIG is proposing that CMS may extend (if they choose) protections to entities that have been blocked from other safe harbor protections, such as DME suppliers and manufacturers, and pharmaceutical manufacturers, among others. The OIG is also proposing to specify the requirements of the parties that would be protected under this safe harbor.

PAI supports OIG’s proposal to provide an all-encompassing safe harbor for CMMI model participants. We also support the Office’s decision to defer eligibility and requirements of protections to CMS, as each innovation lab model presents different considerations for the AKS. With regard to the specific protected parties, PAI believes that these requirements are redundant as they are already currently embedded within most of the CMMI model participation requirements.
Safe Harbor for Donation of Certain Cybersecurity Technology and Related Services

The OIG is proposing a new safe harbor to protect certain nonmonetary donations of cybersecurity technology and related services. In this context “Cybersecurity” is defined as “the process of protecting information by preventing, detecting, and responding to cyberattacks,” which would include any software or other types of information technology, other than hardware. The OIG is soliciting comment on if, and if so, what type of, hardware should be protected under the safe harbor, as certain involved parties may require hardware donation to install technologies and related services.

PAI supports the proposed safe harbor for the donation of certain cybersecurity technology and related services. We believe this protection will significantly benefit small and rural provider groups that lack the required resources to install needed cybersecurity measures. Moreover, we also support the protection of certain hardware services provided to small and rural practices. However, we urge the OIG to ensure that the donors must donate the technology with “no strings attached” tied to future upgrades, maintenance costs, etc. Often times, these down-the-road expenses are costlier than the actual technology itself and can be burdensome for physicians and practices with limited resources.

PAI is also supportive of the examples the OIG provides for “protected services.” We encourage the OIG to also include care coordination and monitoring services that may include technology to the list of examples, but also urge the OIG to ensure that these remain as examples and clarify that they should not be interpreted as the exhaustive list of the types of services that would be protected under the safe harbor.

Furthermore, PAI believes that this safe harbor correctly aligns with the goals of the proposed rule as well as limits integrity risk. We request that OIG consider allowing certain hardware donations as well as these may be more appropriate for certain practices based on their settings and geographic location. We believe prohibiting such donations could effectively nullify the benefits of a cybersecurity donation if recipients lack the resources to install such services.

Safe Harbor for Outcomes-Based Payment Arrangements

The OIG is proposing to establish a new safe harbor protection for outcomes-based payment arrangements (under the existing ‘Personal Services and Management Contracts’ protections). The OIG defines “outcomes-based payment arrangements” as “payments from a principal to an agent that: 1) reward the agent for improving (or maintaining improvement in) patient or population health by achieving one or more outcome measures that effectively and efficiently coordinate care across care settings; or, 2) achieve one or more outcome measures that appropriately reduce payor costs while improving, or maintaining the improved, quality of care for patients.” These would include shared savings/losses arrangements, gainsharing payments, pay-for-performance arrangements, and episodic or bundled payments.

PAI supports the creation of this new safe harbor for outcomes-based proposal and the general requirements the OIG is proposing, as most active outcomes-based models (within the commercial
landscape as well as currently protected arrangements under the MSSP and CMMI) currently encompass such conditions. We encourage the OIG to also include capitation payments (full or partial), especially for specialty services, to be included and covered under this safe harbor. PAI is also supportive of the determination of the aggregate outcomes-based payment approach, as they apply to all safe harbor AKS protections, as well as Stark Law exceptions, pursuant to such agreements.

**Updates to the Electronic Health Record (EHR) Safe Harbor**

The OIG is proposing several technical changes to the EHR safe harbor, including those related to the following: deeming provision; information blocking; cybersecurity; sunset provision; contribution requirement; replacement technology; and protected donors.

PAI opposes the proposal related to the deeming provision which would provide certainty to parties seeking protection of the EHR safe harbor by providing an optional method of ensuring that donated items or services meet interoperable conditions by “deeming” the software to be interoperable if it is certified under the certification program. We believe it is critical to require interoperability be certified to further support the goal of VBAs and VBEs. We believe that the definitions and requirements for certification, as well as the terminology, should align and be consistent with existing statutory definitions, e.g., those established under the 21st Century Cures Act. PAI supports the OIG’s proposed changes to expand the EHR exception to protect donations of software and services related to cybersecurity; and to eliminate the sunset provision. PAI supports the elimination of a contribution requirement related to EHR donations for small or rural providers. We promote this exclusion to other safe harbors proposed within this rule that are proposing a contribution requirement, as discussed in other sections of this comment letter.

As the OIG considers adjustments and updates to the EHR safe harbor, PAI strongly suggests that the OIG continue to consider how data is actually being shared and ensure that information blocking is not occurring. Currently, such practices limit the ability of independent providers and practices to port patient data into their respective electronic medical records (EMRs), which has a direct negative impact on patient care coordination and integration efforts. Thus, for a safe harbors exception, we believe that all VBE Participants should not only be able to review and have access to information on different EMR systems used under the VBA, but they should also have the ability to import/export data that can help further the purpose of the VBA.

Furthermore, physicians and others providing care to beneficiaries under these VBAs should have the ability to select the EHRs that are best suited for their patient population. Under some current practices, the EHR safe harbor exceptions are being used to coerce physicians into using certain EHRs that may not be the best for the patients they are caring for, e.g., being required to use a generic EHR when a specialty-specific EHR that has better connectivity with other care equipment or lab services may be more appropriate. Under VBAs where physicians and VBE participants are being held responsible for the cost and care of their patients, it is important that the safe harbors be designed in a way that allows physicians to exercise their expertise and clinical judgment.
Updates to the Warranties Safe Harbor

The OIG is proposing additional changes to the existing safe harbor for warranties to “promote higher value items covered.” Specifically, OIG is proposing changes to allow 1) the protection of bundled warranties, and 2) allow for outcomes-based warranty agreements that are currently blocked by existing reporting requirements. The proposed rule outlines the following three specific changes to the current safe harbor: extend protection to bundled warranties—meaning “warranties for one or more items and related services upon certain conditions;” redefine “warranty” so that protections encompass bundled arrangements; and considering the exclusion or modification of certain reporting requirements to allow for the protection of outcomes-based warranties (e.g., specifically, for agreements that require delayed reporting).

PAI supports all proposed changes to the warranties safe harbor. We believe that, by extending protections to bundled and outcomes-based arrangements, this proposed protection will significantly increase the uptake of such VBAs.

Updates to the Local Transportation Safe Harbor

The OIG is proposing to expand the current Local Transportation safe harbor in a way that: 1) expands the distance which residents of rural areas may be transported; and 2) remove any mileage limit on transportation of a patient from a healthcare facility from which the patient has been discharged to the patient’s residence. The OIG further clarifies that the current safe harbor definition does not extend to ride-sharing services. However, it is soliciting comment on the potential of expanding protection for ride-sharing services for the final rule.

PAI supports the expansion of the safe harbor, specifically to include ride-sharing services. We urge the OIG to further extend this safe harbor’s protections to those in any area, including urban areas, as well as to “provide a ride” and telephonic-related programs and services, as transportation-related costs can be barriers to receiving care.

Updates to the ACO Beneficiary Incentive Program

The OIG is proposing to codify the statutory exception to the definition of “remuneration,” and is also soliciting comment on any additional conditions that should be added to this safe harbor. PAI supports codification of protections for beneficiary incentives under the ACO program. However, we believe additional guidance is required on the specifics of the protected remunerations under the ACO beneficiary incentive program.

Exceptions for Telehealth Technology Donations for In-Home Dialysis

The OIG is proposing additional changes, interpretation, and codification to exemptions established in statute for telehealth technologies subject to the beneficiary inducements CMP rule. While PAI supports the additional requirements outlined, we request further clarification on what donations would be considered of “excessive value,” as this could be difficult to define objectively without taking into consideration the entire context and situation.
We do not support the requirement that donations be available to all eligible Part B beneficiaries, as this may restrict small and rural providers from offering such donations entirely. Aligning with Medicare Physician Fee Schedule services, we also recommend that the OIG expand this exception to communications-based technologies in addition to telehealth technologies.

**Conclusion**

Overall, PAI supports the Department's efforts to address the complexities and obstacles currently created by the Statute and CMP. We also support strategic use of exceptions to expedite those changes. The associations represented on the PAI Board of Directors welcome the opportunity to work with the Department to further modify existing policies and advance new policies. We look forward to exploring ways that allow physicians to provide higher quality, coordinated, integrated, and holistic care to their patients, while decreasing costs and increasing competition and choice in the health care market for patients and physicians. We reaffirm our belief that opportunities exist to improve the health care system and believe this should be done by enacting policies and modernizing antiquated regulations, which serve to foster innovative approaches to physician collaboration that will bring the benefits of competition to patients. If you have any questions, please contact me at rseligson@ncmedsoc.org, or Kelly C. Kenney, PAI's CEO, at k2strategiesllc@gmail.com.

Sincerely,

Robert W. Seligson, MBA, MA
President, Physicians Advocacy Institute