



October 25, 2018

Ms. Susan Edwards
Office of Inspector General
Department of Health and Human Services
Attention: CMS-0803-N
Room 5513
Cohen Building
330 Independence Avenue, SW
Washington, DC 20201

Re: Medicare and State Health Care Programs: Fraud and Abuse; Request for Information (RFI) Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP

Dear Ms. Edwards:

The Physicians Advocacy Institute (PAI) appreciates the opportunity to provide comments on the Request for Information (RFI) regarding the Anti-Kickback Statute and Beneficiary Inducements CMP (collectively referred to as "Statute and CMP"). Through the RFI, the Department of Health and Human Services (Department) is seeking comments on modifying or adding new safe harbors to the Anti-Kickback Statute, as well as exceptions to the definition of "remuneration" to foster arrangements that would promote care coordination and advance the delivery of value-based care.

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 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 strongly supports the Department's efforts to modernize the Statute and CMP and adopt policies that promote patient choice and access to care. We share the Department's priority of "removing unnecessary government obstacles to care coordination." We believe efforts to modernize the Statute and CMP will enhance opportunities to improve the health care system with innovative approaches to physician collaboration and physician-patient relationships while taking into consideration the law's original goal to

protect patients and Federal health care programs from fraud and abuse. Based on our members' extensive expertise, we provide comments and proposals in response to questions posed in the RFI.

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, alternative payment models (APMs), and other value-based payment arrangements.

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.

As described in greater detail below, the existing Statute and CMP inhibit the development of coordinated care models that are focused on ensuring patient access to health care services at the appropriate setting and time and from the most appropriate provider. Specifically, the Statute and CMP can deter physicians from independently pursuing innovative approaches and instead to seek employment in larger health systems or closed referral networks. Additionally, they may prevent smaller practices from testing or adopting new approaches to care delivery. Without changes in the laws and regulations, the result may instead be greater consolidation and employment of physicians into group arrangements that would not implicate the Statute. The resulting reduction of competition in physician markets could raise costs for health care, reduce quality of care, or both.

To address those constraints and promote the adoption and development of value-based care models, PAI recommends the following key steps:

1. Establish clear exceptions to the Statute and CMP restrictions for payment models and demonstrations and other arrangements that promote physician-led initiatives to value-based care.
2. Allow physicians to align with other high-quality providers (clinical and non-clinical, including social support organizations) for greater coordinated care and a more holistic approach to patient care.
3. Encourage physician-patient relationships through greater patient incentives and rewards that promote and support the delivery of high-value, low-cost care and contribute towards greater coordinated care that improves outcomes.

In this RFI response, PAI echoes the recommendations and comments it submitted in response to the Physician Self-Referral Law RFI, as many of the policy recommendations are applicable to the Anti-Kickback Statute and beneficiary inducements CMP RFI questions and issues (*Addendum A*). PAI believes that there should be as much alignment between 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.

Payment arrangements that should be supported under a modernized regulatory environment

The Department is seeking input on the types of arrangements that stakeholders would like to pursue that may involve the Anti-Kickback Statute and/or conflict with the current definition of remuneration. PAI believes the Department should take into consideration the many kinds of payment arrangements that already exist and those in development. These include but are not limited to: APMs; Center for Medicare and Medicaid Innovation (CMMI) initiatives and demonstrations; value-based payment arrangements with payers (e.g., Medicare Advantage and other managed care organizations) and accountable care organizations (ACOs); arrangements among and between high-quality physicians and clinicians, as well as community-based organizations; and integrated/coordinated arrangements that align and support physician-patient relationships and incentives. Additionally, PAI believes that limitations should not be placed on the number or types of value-based arrangements a physician or practice could enter in to, and physicians should be permitted to mix and match models and enter into blended models that support high-quality, cost-effective care.

In addition to these more “traditional” arrangements, the Department also should consider some new approaches to care delivery between physicians and other providers and social support services and organizations. Physicians’ current movement towards taking on additional risk and responsibility for the total cost of care for their patients has encouraged the adoption of care models that take a more patient-centered approach. As a result, many are exploring and incorporating the impact of non-medical interventions and factors (i.e., socioeconomic factors and social determinants of health) on health care services, outcomes, utilization, and costs. PAI believes this greater alignment between clinical and non-clinical organizations is critical to a holistic approach to patients’ care and encourages the Department to provide flexibilities in the Statute and CMP that help foster the development of these valuable relationships.

PAI Recommendation

Potential flexibilities we urge the Department to consider include permitting physicians and practices to enter into group purchasing arrangements for medical equipment and social support services on behalf of their patients. The discounted rates and savings achieved from a group purchasing arrangement could be passed on to the patients, making the needed equipment and services more affordable and easily accessible for patients.

The utility and limitations of current exceptions and need for additional exceptions

The Department is seeking input on whether any additional or modified safe harbors to the Anti-Kickback Statute and/or exceptions to the definition of remuneration are necessary to pursue arrangements that promote value and care coordination. While existing safe harbor exceptions have helped support the formation and sustainability of entities that provide coordinated and integrated care, additional exceptions and modifications are necessary to further advance the goals of improving patient outcomes and quality of care. The three key relationships where additional exceptions and safe harbors are necessary are: 1)

relationships that allow for greater financial alignment between high-quality physicians and other providers; and 2) relationships that allow for greater patient-physician alignment and coordination; and 3) relationships that allow for greater alignment between physician and electronic health record (EHR) vendors and health information exchanges (HIEs).

Greater Financial Alignment for High-Quality Providers

Many of the existing APMs and arrangements encourage greater care coordination, however, the safe harbors and exceptions are limited in application. The Statute and CMP often hinder the development of these relationships to their full potential. For example, preferred provider arrangements are permitted under the Next Generation ACO model but are not permitted under other APMs or demonstrations. This inability to align with and create preferred provider relationships across models can be an obstacle to coordinated, patient-centered care that allows for a more interdisciplinary team and services.

PAI Recommendation

PAI recommends that modernization of the Statute allow and provide for the infrastructure support and financial incentives necessary for value-based arrangements, for both physicians and patients. The current exceptions, safe harbors, and waivers limited to certain models should be expanded to other APMs, demonstrations, and similar arrangements. PAI believes that physicians and practices should have greater flexibilities to establish relationships and align with other high-quality providers with shared patient-centered goals and care models. However, we do not believe that restrictive requirements should be imposed on these integrated models. For example, integration or alignment should not require different physicians or practices to share a similar tax identification number (TIN). Instead, physicians and practices should be able to define their own parameters for integration and do so in a way that allows them to maintain their independence. For example, financial integration under potential arrangements could be linked to shared technology, administrative staff, care coordinators, or other resources.

Greater Physician-Patient Alignment

Furthermore, in the absence of additional patient incentives, physicians have few or no tools that encourage patient adherence to the care plans they have collaboratively developed, despite physician participation in and contribution to a value-based payment arrangement. Physicians have expressed concerns that they are often responsible for patients who are “attributed” based on APM attribution methodologies but who are not really their patients because the physician has not seen that patient in months or is unable to get them back into the office for necessary visits and care. While voluntary alignment helps mediate this problem, additional incentives, rewards, and inducements are necessary to drive changes in patients’ behaviors and attitudes towards their care that do not limit, but rather expand, access to care and are focused on quality improvement and not just cost reduction.

PAI Recommendation

PAI believes it is important that the Department help ensure that the physician-patient relationship is aligned and strengthened so that patients are just as mutually invested in their care as their physicians. Physicians and practices should be equipped with tools that allow them to ensure their patients adhere to their care plans. Patient incentives could be aligned by allowing waivers or deductions of co-pays, payouts of care coordination bonuses (similar to those offered under the Next Generation ACO program), the ability to share in shared savings, payments for “quality care actions” (e.g., scheduling necessary follow-up visits), etc. We do not believe that there should be an arbitrary and uniform limit set on the amounts of these incentives. Rather, any potential limits on the incentive amounts should take into consideration various factors, including the type of arrangement and stakeholders involved and the importance of the

service/“quality care action.” There should also be consideration of allowing for greater flexibilities in emergency/disaster situations that hinder patient access and continuity of care.

PAI also supports potential patient incentives related to medication adherence. Many patients, especially with complex and chronic conditions, often find it difficult to afford necessary medications. We believe that the Department should permit arrangements that encourage medication adherence, including those that allow for reduced cost-sharing for medications or reward programs that provide rebates for when a patient picks up their prescribed medications. These should be permitted between patients and their physicians, plans, and pharmacies. Relatedly, PAI would like to express concern over the flexibility afforded under the Statute to pharmacy benefit managers (PBMs). While PBMs can receive rebates and negotiate discounts, these cost savings are not passed down to patients, who must still pay high out-of-pocket costs. PAI believes that these cost savings should be passed down to and shared with patients, and that PBMs should be held to stricter standards under the Statute. Additionally, there should be greater transparency on rebates, discounts, and other drug pricing related arrangements.

Greater Physician-Vendor Alignment

Lastly, many physicians have limited access to EHR systems due to their high costs. EHR acquisition requires an upfront financial investment to purchase the system, which is then followed by ongoing costs for maintenance/upgrades for continued compliance with program requirements and interoperability functionality. Greater health information exchange between physicians and settings contributes to a more complete patient profile that can help providers make more informed care decisions for their patients, leading to improved patient outcomes and quality of care and decreased utilization of unnecessary and/or redundant services.

PAI Recommendation

PAI believes interoperability is a key component of success in value-based arrangements. Therefore, PAI recommends that the Department create additional safe harbor exceptions that allow physicians to establish arrangements with vendors that allow them greater access to EHR systems that can support their value-based initiatives and do not restrict patient data flow based on cost or other barriers.

Terminology used within the Anti-Kickback Statute and beneficiary inducement CMP

The Department is requesting input on terminology and definitions on existing and new terms that may be appropriate in the context of that Statute and CMP. PAI agrees that current approaches can lead to confusion among physicians seeking compliance with the law in their practices. It is important that the terminology be standard in use and definition across regulations, laws, waivers, exceptions, and payment models and arrangements. More specifically, the Department is seeking input on how the term “value” could be defined and used within a safe harbor or exception and for evaluating whether an arrangement promotes “value.”

PAI Recommendation

PAI cautions the Department from arbitrarily defining “value” for purposes of a safe harbor, exception, or for evaluation purposes. The term “value” and “value-based” care has different meanings for different patients, services, care models, etc. Rather than inappropriately applying an objective standard to a subjective concept, we believe that a broader definition that captures the key goals of “value” and “value-based” care could be appropriate. A starting point of reference could be the Institute for Healthcare Improvement’s framework for value-based care, and other factors the Department should take into

consideration include: patient ability to engage in and perform activities of daily living (ADLs), patient mobility, patient satisfaction, patient functionality, etc.

Furthermore, PAI believes additional clarification about “risk” could support APMs and other value-based payment arrangements in the context of the Anti-Kickback policy. Specifically, it is important to have clear guidance about how “risk” is being taken under a given model, especially given the cross-disciplinary team that “touches” the patient. The guidance should define who is “directly” responsible for that risk, and how that determination is used to identify which referral relationships and constructs are permitted and which are prohibited. Under different payment models and arrangements, some physicians may take on varying degrees of risk. The focus should be on incentives for patient-centered care and understanding what increases access and the availability of necessary services for patients. This is especially true for preventive and chronic care management services that have a significant impact on patient outcomes. Relatedly, it is important to provide more clarification on “care coordination” so there is an understanding of who is responsible for a patient at any given time, but still allowing for flexibility for allowing a physician or practice to contract for “care coordination” services with other providers.

It is also important that the Department re-evaluate the definition of “market/market share” and the application of these terms to APM entities, virtual groups, and other entities. In certain rural and urban areas, limitations on market share can be impediments to patient access to care. Physicians should be able to enter arrangements that drive down costs and improve quality without fear that they may implicate and potentially violate market share provisions. For example, it is possible that a particular rural area may have only two cardiology groups, but these groups may not be able to enter into effective agreements with each other and possible other groups due to their market shares within the geographic area. As such, it is important to allow for greater flexibilities to market share restrictions for private and independent physicians and practices, similar to those currently permitted for larger health systems and hospitals.

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,



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