



October 25, 2018

Susan Edwards  
Office of Inspector General  
Department for Health and Human Services  
Cohen Building, Room 5513  
330 Independence Ave, SW  
Washington, DC 20201

Re: Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements  
CMP [OIG-0803-N]

Dear Ms. Edwards,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Office of the Inspector General's (OIG) Request for Information Regarding the Anti-Kickback Statute (AKS) and Beneficiary Inducements CMP. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

ACP applauds the administration's focus on regulatory reform that reduces unnecessary administrative burden and gives physicians more flexibility in providing patients with high-quality care. We appreciate the opportunity to provide comments on necessary changes. Under current law, AKS prohibits soliciting or receiving anything of value in return for the referral, recommendation, or arrangement of any item or service paid for in part by a federal health care program. Since AKS is a criminal statute, knowing and willing violations of prohibited referrals can result in a felony and can be punishable by civil monetary penalties (CMP) in the tens of thousands of dollars per incident, unless the business arrangement falls within a safe harbor. AKS has been crucial in protecting the integrity of the Medicare program by reducing fraud and abuse, preventing corrupt medical decision making, and ensuring taxpayers' resources are utilized effectively in the provision of necessary care. However, updating the AKS

would be a positive step in reducing the Statute's unnecessary negative impacts on administrative burden and patient outcomes.

In the years since the last time AKS was significantly modified, Congress has undertaken legislative efforts through the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA) to transform the health care system from one that is volume-based to one that is value-based. Under MACRA, physicians are incentivized to participate in Alternative Payment Models (APMs) that financially reward physicians for providing high-quality care with reduced costs through care coordination and risk sharing. In a system where physicians are inherently penalized for inefficient and ineffective care, the risk of overutilization greatly diminishes. Conversely, these regulatory controls actually inhibit innovations in care integration, care coordination, and patient engagement, which are beneficial both to the health of individual Medicare beneficiaries and the long-term solvency of the Medicare Trust Fund.

ACP believes that existing fraud and abuse laws and their enforcement are burdensome on practicing internists and have created an environment where physicians feel almost all of their behavior is suspect and inadvertent billing and coding errors made in the context of a complex system are being treated as fraud. While it is important to prevent and punish fraud in federal health care programs, this goal must be balanced with reducing unnecessary burdens for physicians who do not engage in illegal activities. The College offers comments on the following items on modernizing anti-kickback fraud and abuse law for the current medical environment which are discussed in greater detail within this letter:

### **Value-Based Arrangement Safe Harbor**

The College supports the AKS' overall goals of decreasing overutilization and improper utilization, protecting the integrity of the Medicare program, and countering the adverse influence of financial incentives on medical decision-making. At the same time, we recognize the need and support efforts to modernize fraud and abuse laws to reduce administrative burdens on physicians and clinicians as well as reduce unnecessary barriers to physician and other healthcare professionals working together through APMs to improve patient outcomes, quality, and value of care. The move towards APMs and a value-based system is centered on the idea that emphasizing care coordination and integration and tying payments to outcomes for episodes of care are integral to reducing costs and increasing quality of care. However, APMs support team based care and appropriate referrals that may currently violate the AKS. Participating in value-based models may require practice transformations and capital investments that are financially untenable for physicians in smaller practices, especially with the risk and long-term uncertainty involved. Under the broad definition of "remuneration," receiving technology and infrastructure to promote care coordination or being paid under innovative payment models that reward value and cost savings could violate current law.

Such restrictions prevent APMs from financially rewarding participating physicians for providing high-quality care and holding them accountable for failing to adhere to best practices and patient outcome standards. For example, current law interferes with the implementation of gainsharing arrangements, where institutions award physicians a share of reduction of patient

care costs. While these positive financial incentives can innovate care delivery and services, save patients and government payers money, and improve the patient experience through encouraging quality and efficient care, this arrangement could be perceived as a remuneration to induce referral under the AKS and CMP. To achieve the goal of the Medicare program in transforming to a value-based system, a minimum degree of coordination and integration is required. However, the threat of violating the AKS in achieving this goal stifles physicians from pursuing the innovative and collaborative approaches needed to fully realize the benefits of a value-based system.

The misalignment in goals between existing fraud and abuse laws and new payment and delivery reforms has created an environment unsupportive of the development of new APMs. Currently, new APMs cannot be field tested during the approval process without waivers assuring their protection from the AKS; however, current requirements mandate that an APM must be approved before it can be granted a waiver. Groups are hesitant to invest the substantial time and resources in designing and developing new innovative payment models if they aren't assured that they will be able to test it before finalizing it, or else run the risk of running afoul of the AKS. This current paradigm creates a paradoxical situation for providers, drastically restricting the growth and development of APMs.

**To better fulfil the goals of the Medicare program and improve the AKS, OIG should establish a new comprehensive value-based arrangement safe harbor that provides physicians flexibility in engaging with innovative models.** Any new safe harbor that OIG establishes should be broad in applicability and should be permanent without a sunset date. The safe harbor should apply to the entire timeline of an APM and should cover the development, testing, and operation of a model. To better facilitate care coordination, it should apply to all those involved throughout the continuum of care and cover remuneration including value-based compensation, financial assistance for infrastructure, or donations of systems and technology like EHRs, cybersecurity, telehealth, and clinical data analysis. The safe harbor must appropriately balance the flexibility needed for value-based innovation while upholding the integrity of federal health care programs. The safe harbor must require transparency and accountability measures, such as a written arrangement outlining the items and services covered, as well as the quality, outcome, utilization, and cost goals of the arrangement. So long as the arrangement fulfills the objectives of promoting care coordination, achieving gains in outcomes and cost reductions while maintaining quality, and encouraging high-value delivery reform, it should be protected under the safe harbor. Such a safe harbor would allow for the appropriate and necessary alignment of interests, resources, costs, and benefits between all involved in the provision of care needed to realize decreased costs and improved patient outcomes.

### **Beneficiary Assistance Safe Harbor, Cost-Sharing, and the ACO Beneficiary Incentive Program**

The College strongly supports efforts to implement public policy interventions with the goal of reducing socioeconomic inequalities that have a negative impact on health, including the use of positive beneficiary incentives to promote behavior change and high-quality health care. Incentives to promote behavior change should be designed to allocate health care resources

fairly without discriminating against a class or category of people. The incentive structure must not penalize individuals by withholding benefits for behaviors or actions that may be beyond their control. Supportive public policies that address downstream environmental, geographical, occupational, educational, and nutritional social determinants of health should be implemented to reduce health disparities and encourage health equity.

In transitioning to a value-based care system, we must begin to view the health of individuals in totality rather than separate encounters. The delivery and management of care can no longer end at the door of the physician's office. Ensuring patients are empowered with the resources and support they need within their communities to adhere to care plans and engage in healthy activities can reduce costs and improve outcomes by preventing additional hospitalizations and office visits. For example, patients living in a "food desert" may have difficulties obtaining fresh foods that are not high in sugars and fats, potentially leading to increased health care costs down the road if they develop nutritional issues that require medical attention. Similarly, patients lacking adequate reliable transportation options may avoid filling a prescription or visiting the doctor until their ailment is at an advanced stage that is more difficult and expensive to treat. Positively reinforcing healthy decisions at the primary care level can preserve health and avoid increased health care costs from being accrued at the specialty and emergency level. This is particularly important given the shift to compensation models that pay for episodes of care and leave physicians with the financial risk of future readmissions.

ACP appreciates that OIG has already issued a final rule that allowed for eligible health care providers to provide free or discounted transportation for established patients to and from the provider as long as they met certain maximum distance and advertising requirements. While this safe harbor is a step in the right direction, it does not go far enough to address the multitude of factors that impact a patient's health and outcomes. **ACP urges OIG to create a new safe harbor for patient assistance and incentives to promote access to care that goes beyond OIG's current safe harbor and encompasses other aspects of social determinants of health.** In addition to generally supporting a safe harbor for beneficiary incentive programs, **the College is also supportive of an exception that would give APMs, including accountable care organizations (ACO) the flexibility to use funds to encourage positive patient behavior as outlined in Section 50341(b) of the Bipartisan Budget Act of 2018.**

Unlike other safe harbors, OIG should expand covered services beyond "medically necessary care" as other socioeconomic factors can have just as much of an impact on health status as obtaining care has and would align with the Medicare program's value-based vision. Covered assistance could include both financial and material assistance, such as expanded transportation, counselling and coaching, meal preparation, existing and emerging self-monitoring health technologies, among others that promote convenience, independence, and positive health outcomes. ACP emphasizes that transparency and clarity are critical to effective implementation of innovative approaches to health care like the use of benefits and incentives to motivate behavioral change.

**The College also suggests that income-adjusted cost-sharing approaches that reduce or directly subsidize the expected out-of-pocket contribution of lower-income patients would be**

**beneficial for patient outcomes and should be included under the beneficiary incentive safe harbor.** Cost-sharing provisions should be designed to encourage patient cost consciousness without deterring patients from receiving needed and appropriate services or participating in their care. Alleviating the financial burden of obtaining medical services for patients would reduce the barriers to care and make it more likely one could identify and address a medical condition before it worsens and requires more complex specialty or emergency care. Reducing medication copays could also improve treatment plan adherence rates. Doing so would increase access to health care for those that need it most and could result in cost savings down the road by reducing more expensive advanced care and hospital readmissions, aligning with Medicare's goal of providing high-value care.

### **Cybersecurity Safe Harbor**

With the implementation of federal health information technology (IT) legislation in recent years, electronic systems have played an increasingly prevalent role in the delivery of patient care. While the uptake of this technology can simplify and streamline processes, it also comes with the costly challenge of cybersecurity. The success of any health care system is built on mutual trust between the physician and the patient. Cybersecurity breaches could harm patient safety in exposing confidential patient information and breaking that patient-physician trust. Further, reliance on electronic health records (EHRs) and other electronic physician-physician and physician-patient communication systems creates a scenario where cyberattacks that disable these networks take down these systems and cause an interruption in the provision of patient care. Cybersecurity must be treated as crucial national infrastructure and must be a priority of OIG and HHS.

In recent years, the Health Information Technology for Economic and Clinical Health Act (HITECH Act) sought to facilitate the expanded adoption and utilization of electronic health records (EHR) and other health IT as well as improve security and privacy standards. Through the subsequent Meaningful Use/EHR Incentive Program, physicians were financially incentivized to utilize EHRs in a meaningful way that promoted care coordination and improved outcomes, sparking the rapid uptake in EHRs and electronic communication methods. Similarly, with MACRA's push for value-based payments based on the submission of data and measures, the adoption and proper implementation and utilization of EHRs will continue to be extremely important to the future of health care reform. This digital push in health care means systems are more connected and there will be more access points for cyberattacks than ever before.

Despite the clear and present danger, many physicians and practices are inadequately prepared for such an attack. The cost of the infrastructure, technology, and professional staff needed to establish an adequate defense exceeds hundreds of thousands of dollars per year, putting it out of reach for many small and independent practices. These barriers can pose a barrier for Medicare's transition to a value-based program as it makes having EHRs and electronic care coordination more costly and can make it difficult for small practices that can't afford these cybersecurity technologies to join ACOs and other models that require it. However, while many hospitals and larger institutions and practices are willing to donate or subsidize cybersecurity services for smaller practices, doing so could be considered remuneration under the AKS.

Hence, **ACP believes OIG should establish a cybersecurity safe harbor to empower physicians to protect their patients and defend critical health care networks.**

In 2013, the Centers for Medicare and Medicaid Services (CMS) and OIG issued new final rules that updated and extended the EHR AKS safe harbor that was due to expire. Under this safe harbor, physicians are permitted to receive donated EHR systems and services so long as the systems meet interoperability requirements and physicians pay for at least 15 percent of the costs. However, CMS and OIG extended these safe harbors only through December 31, 2021. Physicians need stability in order to plan for upcoming years' reporting requirements, meaningful use incentives, and practice expenses—establishing a permanent cybersecurity and EHR safe harbor would help facilitate this stability.

Any new cybersecurity safe harbor should be clear, yet broad in scope of people, entities, items, and services it covers and permanent in duration, with measures in place to protect the integrity of federal health programs by avoiding overutilization and corruption. The entire spectrum of cybersecurity services and items should be protected, including hardware, software, training services, support services, and maintenance services. It should also be broad in covering the continuum of care and protect health care providers who provide medical items and services to federal health program beneficiaries in providing cybersecurity items and services to physicians, clinicians, and facilities that provide health care services to federal health program beneficiaries. Similarly, it should allow for the sharing of cybersecurity items and services amongst physicians and practices. The College also calls on OIG to consider reducing or removing the requirement that physicians cover 15 percent of costs as exists in the current EHR safe harbor and consider creating an exception for small or rural practices.

Transparency and accountability must be at the forefront of any safe harbor so that cybersecurity can be implemented en masse while physicians maintain their independence in medical decision making. In order to comply with the AKS under this safe harbor, parties involved should engage in a written agreement that outlines the extent and terms of the services and items donated or shared. Further, the donated or shared items or services should not be a condition of doing business nor should they be restricted in use by specific patients or physicians. The safe harbor should not protect the donation or sharing of items or services in order to induce referrals or by taking into account the volume or value of referrals.

### **Telehealth (Section 50302(c) of the Bipartisan Budget Act of 2018)**

ACP is generally supportive of expanding the availability of telehealth technologies and services as a method of health care delivery that may enhance patient-physician collaborations, improve health outcomes, increase access to care and members of a patient's health care team, and reduce medical costs when used as a component of a patient's longitudinal care. Any use of telehealth technologies and services should be episodic and is most beneficial between a patient and a physician with an established, ongoing relationship.

Provisions of the Creating High-Quality Results and Outcomes Necessary to Improve Chronic (CHRONIC) Care Act of 2017 authorize a home dialysis patient's monthly clinical visits to be


conducted via telehealth with the home as an originating site. After Congress appropriated funding for those provisions in the Bipartisan Budget Act of 2018, many physicians were unclear whether providing patients with a tablet in order to conduct the home visit would be considered remuneration, and hence prohibited, under the AKS. Utilizing technology for telehealth visits can improve patient outcomes and quality of care by allowing physicians to remotely monitor symptoms and providing help and advice in administering home dialysis care. **In order to facilitate high-value, high-quality care, the College supports OIG efforts for an exception that would allow physicians, clinicians, and dialysis providers to provide their home dialysis telehealth patients with telehealth technologies like tablets.** ACP contends that “telehealth technologies” should include the hardware, support, maintenance and educational services, as well as the software or applications that may be required to conduct the telehealth service. Any exception should have safeguards that prevent against fraud and abuse in federal health programs.

## Conclusion

With the continued transition of the American health care system to one focused on value, stakeholders should review and consider streamlining or eliminating duplicative requirements. The College urges the Secretary to identify barriers and unnecessary burdens that the AKS place on the delivery of value-oriented care that the administration will intend to address and begin identifying solutions to minimize or remove these barriers and burdens that could include but is not limited to expanding existing and creating new safe harbors to address the entire continuum of care and revise or terminate provisions inhibiting value-based compensation models for physicians. ACP reiterates the importance of HHS and OIG engaging stakeholders throughout the entirety of the process of reevaluating the fraud and abuse laws in the era of value-based payment and delivery reforms.

Thank you for considering our comments. Please contact Brian Outland by phone at 202-261-4544 or email at [boutland@acponline.org](mailto:boutland@acponline.org) if you have any questions or need additional information.

Sincerely,



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