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December 20, 2019

Joanne 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:

On behalf of the more than 80,000 members of the American College of Surgeons (the "College," or "ACS"), we appreciate the opportunity to submit comments to the Office of the Inspector General, Department of Health and Human Services 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. The ACS is a scientific and educational association of surgeons, founded in 1913, to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Given the efforts of the health care industry to invest in the development of value-based care systems and alternative payment models (APMs), the College is pleased that the Agency is seeking input on how the Anti-Kickback Statute should be modified in order to accommodate these payment reforms.

The breadth of these regulations, as well as the potential serious consequences of running afoul of them, have impeded the industry from efficiently moving toward value-based care models. Whether real or perceived, barriers to care coordination or other team-based care models have caused unintended delays to improving the quality and efficiency of care to patients, and the College appreciates the proposed changes to better allow for this shift. The focus on increasing access to health information technology (HIT), such as Electronic Health Records (EHRs) and cybersecurity technology, will allow for better



care coordination, increased interoperability, and enhanced privacy and security for protected health information, allowing physicians to use HIT as a tool in the move to value-based care. The accessibility and increased use of advanced HIT will further aid the growth of innovative payment models that encourage patient-centric, team-based care models. The following comments address the College's recommendations regarding EHR, cybersecurity, and value-based payment models, as put forward in the OIG's Anti-Kickback Statute proposed rule.

### **FACILITATING THE TRANSITION TO VALUE-BASED CARE AND FOSTERING CARE COORDINATION**

**The OIG proposes new safe harbors to the AKS law for compensation arrangements that satisfy specified requirements based on the characteristics of the arrangement and the level of financial risk undertaken by the parties to the arrangement or the value-based enterprise of which they are participants.**

The ACS welcomes both the additional safe harbors to accommodate innovation in alternative payment models and other value-based payment arrangements. It is imperative that implementing regulations to the AKS be modernized to reflect the changing nature of payment models in health care. The focus on team-based, coordinated, high-value care over siloed, fee-for-service based payments will result in innovative models, both in federal health programs and in the wider commercial market, that will have different financial incentives and goals than what were in place when current regulations were written. To a large extent, these payment and delivery system models will obviate the need for such prohibitions and penalties, as participants refocus efforts on providing better outcomes, through team-based care, care coordination, and other methods. The changes included in the proposed rule will go a long way toward encouraging an environment where this type of activity can prosper.

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## PROPOSED “VALUE-BASED” TERMINOLOGY

### Target Patient Population

**The OIG solicits comments on limiting the definition of “target patient population” to patients with a chronic condition, or alternatively, limiting any or all of the proposed safe harbors that use the target patient population definition to value-based arrangements for patients with a chronic condition.**

The ACS argues that paying physicians for the quality of care provided to *all* patients through value-based payment arrangements is the most efficient and effective way of removing incentives for unwarranted care. Therefore, the Agency should strive to maintain the maximum level of flexibility possible to allow for innovation in these types of models. For example, limiting the definition of “target patient population” to patients with a chronic condition could prevent the development of APMs or other value-based payment arrangements aimed at comprehensive care of a specific service line. Such a model could include taking on full risk for a defined population with relation to a health care service line paid on a PMPM basis. This would in many ways be similar to a managed care model but limited to a specific type of care, such as breast care, and participants would receive the same level of payment regardless of the amount of care provided (or not provided). Such a model would take away incentives to refer patients for unnecessary services, and in fact, should require incorporation of quality metrics to ensure patients were not being under-treated and incentives to ensure patients were being offered and provided recommended screenings. In this example, the target population would not necessarily have a chronic condition or any health condition, but the APM entity would be paid for all covered individuals on a PMPM basis to cover all ongoing services related to breast care from outreach and screening to treatment of breast cancer or other diseases of the breast.

### PROPOSED Safe Harbors

#### *Risk*

In general, we are concerned that the definitions of what constitute risk, including both “full financial risk” and “substantial downside financial risk,” may be too restrictive to allow for innovation. These definitions will be overly restrictive for models at the initial stages of being proposed and tested, which is exactly where innovation into value-based payment models occurs and

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where the safe harbors in the proposed rule could have the greatest impact on the future of health care. In recognition of the difficulty many entities have with taking on immediate risk, many current CMS-developed models either began as one-sided risk models or have initial periods of one-sided risk before the downside risk commences in later performance periods with risk levels that can slowly increase over time. Providing protections only for models with total risk, or extreme levels of risk beyond what is required even in Advanced Alternative Payment Models (Advanced APMs) under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), seems counter to broader goals of moving away from fee-for-service and the associated incentives to increase volume. In addition, as you balance the flexibility you seek to provide with these protections with the need to protect against program and patient abuse, we would ask you to consider the potential negative program and patient consequences of incentivizing payment arrangements to require extreme levels of financial risk from the outset. The ACS would instead urge the agency to consider more broadly-applicable rules to capture relationships that should be protected in safe-harbors.

**The OIG seeks comment regarding whether a value-based enterprise should be considered to be at “full financial risk” if it is responsible for the cost of only a defined set of patient care services for a target patient population and whether it should require a minimum period of time during which the value-based enterprise is at full financial risk.**

The ACS thinks such a safe harbor would be reasonable, particularly as taking on “full financial risk” in the form of an episodic value-based arrangement for a specific aspect of care may be an invaluable step toward moving away from fee-for-service payment toward fully capitated payments. Such a safe harbor should not be limited to a specific time period but instead should be in effect for the duration of a contractual relationship to provide care to allow for per member, per month (PMPM) arrangements. For example, this could take the form of a large group practice taking on full risk for a defined population with relation to a health care service line paid on a PMPM basis. This would in many ways be similar to a managed care model but limited to a specific type of care, such as breast care, and participants would receive the same level of payment regardless of the amount of care provided (or not provided). In this example, rather than having a pre-specified time window, the APM entity would be paid for all covered individuals on a PMPM basis to cover all ongoing services related to breast care from outreach and screening to treatment of breast cancer or other diseases of the breast. Such a model would

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take away incentives to refer patients for unnecessary services, and in fact, should require incorporation of quality metrics to ensure patients were not being under-treated, resulting in a decrease in quality of care. We firmly believe that a model designed as discussed in this example is appropriately deserving of the protections afforded by the Full Financial Risk Safe Harbor as a model that takes on the risk for total cost of care and presents no additional concerns for program or patient abuse.

## **PRICE TRANSPARENCY**

The ACS continues to contend that true price transparency could both help provide patients with meaningful information they need to support their health decisions and serve as an additional safeguard against unwarranted self-referrals. However, the information currently available to patients, and the current proposals fall short of what would be needed to meet the above goals. There is no single source of accurate information on patient out-of-pocket cost or total cost of care. Recent proposals are not patient-centered and instead focus on hospitals and insurers. The information made available could therefore vary widely as it will be for a single service or commonly bundled set of services, and would not necessarily reflect the full range of care experienced by the patient during his or her care journey.

The ACS advocates for the adoption of another potential way to fill the current gaps in price transparency through the work of the PACES Center for Value in Health Care. The work of the PACES Center is based on the Episode Grouper for Medicare (EGM), which was originally developed for CMS to organize claims information into logical episodes of care. The PACES Center is capable of providing narrow, but representative, ranges of expected costs based on the specific patient's characteristics, health history, insurance, and diagnosis. This allows for remarkable insights not only to patients, but also to the care team and payers. This type of information would be especially invaluable in situations more complex than a single service or simple bundle of care. To achieve the highest level of utility to patient consumers, the information provided would need to be put into a proper format such as an interactive rate book, where patients could see estimated ranges of out-of-pocket and total cost based on historical claims of patients with similar comorbid conditions and other factors. While we may differ from CMS in our preferred approach to increasing cost transparency, we encourage the OIG to defer to CMS in its pursuit of goals related to cost transparency and empowerment of patients with information on their out-of-pocket costs through initiatives like those discussed

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here. Further, we encourage OIG to defer to CMS' existing rulemaking directed at requirements for hospitals to post information on negotiated charges and estimates of patient out-of-pocket costs. Therefore, regulators could avoid transporting those requirements into the AKS safe harbors for value-based arrangements, thus potentially complicating AKS-related rulemaking and unintentionally inhibiting development of value-based payment arrangements.

### **CYBERSECURITY TECHNOLOGY AND RELATED SERVICES**

The ACS thanks the Agency for the proposed changes to the Electronic Health Records safe harbor and exception. The updated definition and focus on interoperability are of particular import in light of the 21st Century Cures Act (Cures) and the associated Office of the National Coordinator for Health Information Technology (ONC) and Centers for Medicare and Medicaid Services (CMS) rules.

Cybersecurity is of growing import for healthcare. As data breaches become more common and barriers to interoperability decrease, cybersecurity is critical to safeguarding patient privacy and protected health information (PHI). The College strongly supports the addition of a cybersecurity technology safe harbor.

**Scope of Protected Technology.** The Agency proposed that the donation of cybersecurity technology needs to be specific to cybersecurity (e.g., it cannot be multi-use software); could be hosted locally or in the cloud; and could include an assessment of need as well as staff training. The Agency asked for feedback on whether hardware should also be included as protected under the safe harbor. The College recommends that hardware be assessed on a case-by-case basis; depending on the completed assessment, the recipient may also need hardware that is able to run the cybersecurity software. There may be instances where hardware is too outdated to be able to run certain software or may be unable to allow security features such as biometric screening or multi-factor authorization. In these cases, the hardware would be a foundational requirement for the use of the cybersecurity product and may be appropriate as part of the donation or it may be appropriate for the practice to cover part of the cost of the new hardware to reduce the overall value incurred.

Technology training for the recipient staff is of particular importance, and the College agrees that it should be included as a possible donated service under the cybersecurity safe harbor. It is vital that staff understand not just how the software or technology functions but also how breaches could occur and steps

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needed to protect their systems and information in the event of a breach. Relatedly, the College agrees that performing a risk assessment should be required in order to receive the donated cybersecurity product(s), as a risk assessment can determine what type of protection is needed, where there are vulnerabilities, and ensure that the cybersecurity product is effective once implemented. The College recommends, however, that this not be a requirement for the *recipient* to perform the assessment, as they may not have the appropriate level of understanding to conduct the assessment itself. Instead, the assessment could be performed by the recipient if they have the knowledge and expertise to do so; else, it could also be completed by the donor or a qualified third-party. As the assessment would inform the needs of the recipient, it is important that it is done correctly and by those with the expertise to do so.

**Recipient Contribution Requirement.** The College agrees that there should not be a requirement for recipients to contribute a certain dollar amount or percentage to the costs of the donated cybersecurity technology, as there are situations where the recipient may truly not be able to afford the technology but needs it to be protected from possible breaches or malware. It is appropriate that the donor could request a certain dollar amount or percentage from the recipient (assuming that the donor is consistent in the way in which they do so, if they make multiple donations), but it should not be required.

**Additional Safeguards.** The College agrees that having a signed agreement is a necessary requirement, as it ensures that both the donor and the recipient understand what is being donated and the terms of the agreement, including the long-term maintenance and support of the product(s).

## ELECTRONIC HEALTH RECORDS

**Information Blocking.** The College agrees that any EHR product that falls under the safe harbor protections should be ONC-certified and have no activities that meet the Cures definition of information blocking. The additional language to prohibit using the donation of an EHR to block data exchange aligns with the proposed Cures information blocking regulations and will help ensure that the donation does not "data-lock" the recipient. The ability to share health information bidirectionally through national standards is a vital component of EHRs and is necessary in order to have a more complete patient record.

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**General Proposals.** The College further agrees that any donated EHR should be certified to *current* ONC standards for Certified Electronic Health Record Technology (CEHRT), including the current standards for interoperability. The distinction of being current with these standards at the time of donation is an important clarification, as the technology standards can change frequently, and it is important that donated EHRs meet those standards at the *time of donation*. The College recommends that the Agency clarify language in these rules in order for these protections to apply to investments that hospitals or other applicable stakeholders make to update these donated systems to ensure they comply with the most recent standards. The College further recommends that there should be no cost-sharing requirement for upgrading EHRs, as staying consistent with system updates and upgrades is vital to meet current federal standards for data exchange.

**Recipient Donation Requirement.** Generally, the College does not believe that there should be cost-sharing requirements for the recipient for the initial implementation nor for any upgrades to the system. While this is particularly important for small or rural clinicians, there are many clinicians that would not be able to afford a cost-sharing requirement for donated EHR technology, as the costs could remain prohibitive. Rather, ACS believes that this should be at the discretion of the donor, as long as the donor consistently and fairly applies their policy for cost-sharing to all recipients.

**Replacement Technology.** Applying the same safe harbor protections for replacement EHR technology is a needed addition. Many EHRs have not been able to maintain certification as interoperability and patient engagement became required functionalities. Further, many systems remain outdated and clunky and add significant administrative burden for physicians. Replacing these systems is a need similar to replacing paper and allowing for replacement EHRs to be covered will allow more physicians to use higher quality certified systems, improving ease of use and decreasing administrative burden.

**Elimination of Sunset Date.** Lastly, the College appreciates that the end date of December 2021 for the EHR safe harbor was removed and that no new end date was established. EHRs remain important for the exchange of health information and the creation of a more complete patient health record, yet their implementation and maintenance costs remain too onerous for many clinicians, particularly those in small practices or in rural areas of the country. As certification standards increase and the options for digital health continue to grow, EHR costs are not likely to reduce in the near future, making the safe

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harbor for EHR donations an important path for clinicians to have the opportunity to be a part of the digital health landscape.

The College appreciates the opportunity to comment on the proposed changes to the AKS regulations. If you have any questions about our comments, please contact Vinita Mujumdar, Regulatory Affairs Manager, at [vmujumdar@facs.org](mailto:vmujumdar@facs.org).

Sincerely,

David B. Hoyt, MD, FACS

Executive Director

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