



October 26, 2018

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

**Re: Comments on RIN 0936-AA10 Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP**

Dear Ms. Susan Edwards:

On behalf of the Healthcare Quality Coalition (HQC), we are writing to respond to the request for comments relating to the proposed changes to the Anti-Kickback Statute within *The Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP* Request for information. We appreciate the administration's commitment to reducing regulatory barriers to providing patient and community care.

We look forward to addressing the numerous concerns and questions from the Office of the Inspector General (OIG) regarding Anti-Kickback Statute and its impact on healthcare delivery. In this comment we will identify barriers and challenges that we have encountered in our efforts to support community care and suggest changes that will ease regulatory burdens. We will also comment specifically on modifying existing and new safe harbors with specific considerations to care coordination, population health programming, and rural providers.

**Background of the Anti-Kickback Statute**

The Federal Anti-Kickback Statute was added to Section 1128B(b) of the Social Security Act via the Social Security Amendments of 1972<sup>1</sup>. This statute provides criminal penalties for individuals or entities

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<sup>1</sup> Ball, Robert. Social Security Amendments of 1972: Summary and Legislative History. Historical Document. Social Security Administration. <https://www.ssa.gov/history/1972amend.html>

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that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward the referral of business reimbursable under Federal healthcare programs. The intent of this law was to protect patients and Federal programs from fraud and abuse, but has become a barrier to innovative care delivery models.

To minimize the unanticipated consequences of the law, in 1987 Congress authorized the HHS to create “Safe Harbors”. This included evolving rules periodically updated to reflect changing care delivery practices and technologies in the healthcare industry<sup>2</sup>. With modifications to existing Safe Harbors and implementation of new protections, healthcare organizations can promote improved care coordination in tandem with the reduction of regulatory impediments to value-based care delivery. **Overall, the HQC appreciates the focus on reducing barriers to healthcare delivery. We ask the OIG continue to collaborate with healthcare systems to bring the Safe Harbor regulations up to date and are pleased to provide our comments throughout this process.**

### **Anti-Kickback Policies and Regulations**

#### **Exemptions/Safe Harbors to Remuneration**

The Anti-Kickback Statute stresses remuneration as major violation of the statute. This entails rewarding patients or organizations for referrals to specific healthcare providers. These “rewards” may be anything of monetary value, such as free services or some form of compensation. The statute contains a limited number of exceptions in accordance with Safe Harbor exceptions. For example, exemptions already include: management contracts, electronic health record arrangements, transportation, warranties, and promoting access to care, such as telehealth. We ask that OIG consider our suggestions as additional exemptions to remuneration.

Care coordination is a key component to engaging our patients and community in the continuity of care outside of the walls of the clinic and hospital. Effective value-based care integrates care coordination and population health often fosters partnerships with healthcare and community organizations to act beyond the scope of the medical care provider<sup>3</sup>. In the best interests for these community partnerships, we encourage OIG to evaluate new Safe Harbors and exemptions to further this practice.

*Defining Care Coordination* – The care coordination definition should include terminology that allows for care delivery in collaboration with multiple organizations, providers, and individuals in and outside the core healthcare institution intended to reduce unnecessary utilization (such as emergency room visits and readmissions), lower cost, and improve quality. The definition should create ample flexibility for “integrated care models” to be developed, tested, and implemented.

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<sup>2</sup> H.R. Rep. No. 100-85, Pt. 2, at 27 (1987).

<sup>3</sup> Fenton, M. "Health care's blind side: the overlooked connection between social needs and good health". The Robert Wood Johnson Foundation. (2011).

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*Defining Alternative Payment Model*—Alternative payment models for medical care services should be defined as those not based primarily on fee-for-service. This should be broad to include, but not be limited to, bundled payments, capitation, shared savings, and performance-based adjustments. We ask the OIG to not narrowly define Alternative Payment Models within the context of those approved by the Centers for Medicare and Medicaid Innovation, but include those developed by state Medicaid programs and private insurance and managed care plans.

*Value-based care*—Any definition for value-based care should allow for metrics that account for patient complexity as well as outcomes, and not focus on “process” or reporting measures.

*Safe Harbors*—The HQC supports the creation of safe harbors that foster and support care coordination, community health, and implementation of alternative payment models. We recommend **a new, broad Safe Harbor be made available to exempt remuneration for programming that focuses on quality improvement and population health under the goal of ultimately reducing the unnecessary utilization of medical services, such as emergency room visits and readmissions.** The safe harbor should be expanded to include providers, organizations, and individuals outside of the medical facility.

*Patient Discharge*—We request OIG consider expanding the permissible transportation radius under the existing transportation Safe Harbor. In rural areas and communities, it is common for patients to require lengthy travel for healthcare services. The current transportation Safe Harbor only covers a 50-mile radius limit for rural patients from the provider’s location<sup>4</sup>. This creates a challenge during patient discharge when a healthcare facility cannot assist with home transportation beyond the 50-mile limit. **We ask that transportation safe harbor be expanded to 150 miles so healthcare providers can better serve our rural communities.**

*Patient Transfers*—We ask the OIG to investigate exemptions for remuneration to a lower-level healthcare facility to accept a transferred patient. A Skilled Nursing Facility (SNF) or home health agency costs the government less per day than an in-patient hospital stay. To this extent, a hospital should be able to provide remuneration in some form (e.g. access to provider advice, training, rental of specialty equipment, etc.) to a lower-level care facility that would be more appropriate for the patient. This would not result in an increased cost to the government and have little risk of impacting referrals back to higher care level institutions. In addition, we believe that this would enable a more appropriate use and access to care at hospital facilities.

## **Civil Monetary Penalty**

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<sup>4</sup> Department of Health and Human Services. Office of Inspector General. Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements. *Federal Register*. December 7, 2016. <https://www.gpo.gov/fdsys/pkg/FR-2016-12-07/pdf/2016-28297.pdf>.

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In addition to the AKS, the Civil-Monetary Penalty (CMP) Law has separate prohibitions on “beneficiary inducement” (i.e., offering gifts or incentives to patients). In an effort to promote care coordination and value based care, we have evaluated the OIG policy statement regarding “Gifts of Nominal Value to Medicare and Medicaid Beneficiaries<sup>5</sup>” regarding the limitations on “nominal values”. The implication of both laws promotes complexity in compliance. **The HQC believes remuneration implicating beneficiary inducement is more efficiently pursued under the AKS.**

We would like to suggest an adjustment to the interpretation of nominal values. The HQC believes that there should be a periodic automatic adjustment to the amount to account for inflation. **We ask that the nominal amount limit should be higher for healthcare-related items aimed at improving health and reducing the frequency or severity of needed care.** Tracking has become challenging to maintain compliance with the established nominal limit in the per patient aggregate amount as our locations have different populations needs and continually tracking under this limit restricts us from serving all our communities in an appropriate way

Adjusting nominal values would better appropriately serve our patients with the items they need for care. We recommend that for healthcare-related items there be different established nominal values for goods and services that HHS would determine adjusted for inflation. As it stands, there are very few healthcare services valued at less than \$15. For example, one free meeting with a dietician or a therapist may get an individual important baseline information useful for improving their health but be unlikely to direct the patient towards additional unneeded care. However, because this service is valued at over \$15, we are not able to provide this to our communities. **In addition, we would support the raising of the per patient aggregate limit under “nominal values.” Any inflation value should be no less than the CPI for medical services (CPI-M).**

### **Roles of Transparency & Ways to Mitigate Abuse**

Maintaining integrity and compliance with the AKS is imperative. The HQC believes other methods can be utilized to meet the statutory requirements of the law while ensuring Medicare beneficiaries are protected. Providing a balance in the regulations will help minimize abuse while fostering innovative care delivery models.

Transparency in care delivery model designs and care options can help meet the intent of the AKS while ensuring beneficiary choice, awareness, and education. Disclosure of relationships and potential benefit of referral versus actions required of the patient should be openly encouraged and discussed. Focusing on the interactions of care with the patient—rather than documentation and administrative tasks on ensuring the model meets the specific definitions of financial relationships can help mitigate the barriers faced by providers and hospitals.

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<sup>5</sup> Department of Health and Human Services. Office of Inspector General. Policy Statement Regarding Gifts of Nominal Value to Medicare and Medicaid Beneficiaries (Dec. 7, 2016), <https://oig.hhs.gov/fraud/docs/alertsandbulletins/OIG-Policy-Statement-Gifts-of-Nominal-Value.pdf>.

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To utilize the care coordination, population health, and alternative payment model safe harbor, providers should be allotted flexibility to document how the model addresses improved quality of care while ensuring beneficiary protection.

### **Conclusion**

The HQC appreciates CMS undertaking efforts to examine AKS policy issues. We strongly support reforming regulatory and administrative barriers inhibiting value-based care design and delivery, and believe the long-term viability of the Medicare program lies in crafting reimbursement policies that reflect robust value-based policy. We ask CMS to also examine ways to reform the Anti-Kickback Statute in tandem with the Physician Self-Referral Law and look forward to being an active partner with the agency on seeking solutions to removing regulatory barriers to value-based care delivery.

Please feel free to contact us with any questions.

Sincerely,

### **The Healthcare Quality Coalition**

The Healthcare Quality Coalition (HQC) is comprised of clinicians, hospitals, associations, and cooperatives dedicated to value-based care. In short, we believe healthcare providers should be held accountable for the quality and value provided to their patients and communities. The HQC is committed to supporting value-based initiatives in a way that encourages fair reimbursement to providers delivering high value care to the patients they serve. [www.qualitycoalition.net](http://www.qualitycoalition.net)

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