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Submitted Electronically

Daniel R. Levinson
Inspector General
Department of Health and Human Services
330 Independence Avenue, SW, Room 5250
Washington, DC 20201

RE: OIG—0803—N, Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducement CMP

Dear Mr. Levinson:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, our clinical partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Office of Inspector General's (OIG) Request for Information (RFI) on ways to modify or add regulatory safe harbors and exceptions for the Anti-Kickback Statute (AKS) and beneficiary inducement Civil Monetary Penalty (CMP) to foster arrangements that would promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse.

We welcome the OIG's recognition that the broad reach of these fraud and abuse statutes is a potential impediment to beneficial arrangements that would advance coordinated care. The AHA and America's hospitals and health systems stand ready to assist the OIG in tackling the barriers created by the AKS and CMP. We believe meaningful changes to the regulations will advance the goals of the Department's *Regulatory Sprint to Coordinated Care* and achieve significant improvements in patient care.

Our response to the RFI highlights the obstacles hospitals face working with physicians and other providers in moving to a value-based system while navigating fraud and abuse regulations built for the very different fee-for-service reimbursement model. We previously discussed the adverse impacts that the AKS and CMP have on patient care

in AHA's report, *Legal (Fraud and Abuse) Barriers to Care Transformation and How to Address Them…Wayne's World*. That is why we recommend specific changes that will foster and enable the relationships between hospitals, physicians, and beneficiaries to work together to achieve value-based care and a patient-centered system.

Our recommended changes include:

- **Protection for value-based payment methodologies** – specifically, a new safe harbor for value-based payment arrangements.
- **Protection for assistance to patients** – specifically, a new safe harbor for assistance to patients to achieve care coordination.

Again, we thank you for your focus on this critical issue and for your consideration of our comments. Our detailed comments and suggested regulatory text are attached. Please contact me if you have any questions at mhatton@aha.org or (202) 626-2336.

Sincerely,

/s/

Melinda Reid Hatton
General Counsel

AMERICAN HOSPITAL ASSOCIATION (AHA)
DETAILED COMMENTS ON ANTI-KICKBACK STATUTE (AKS) AND CIVIL MONETARY PENALTY (CMP) REQUEST FOR INFORMATION (RFI)

ACCELERATE TRANSFORMATION TO A VALUE-BASED SYSTEM OF COORDINATED CARE AND IMPROVED PATIENT OUTCOMES

The Department of Health and Human Services (HHS), the Centers for Medicare & Medicaid Services (CMS), the Office of the Inspector General (OIG), hospitals, and health systems all agree that fraud and abuse laws can be an impediment to the development and implementation of value-based payment models that reward providers for delivering higher-quality, cost-effective care with better outcomes. (See HHS's Medicare Access and CHIP Reauthorization Act (MACRA)-mandated report to Congress, 2016.) **To reach the full potential of a value-based system, we urge creation of two new AKS safe harbors: one for value-based payment arrangements, and the other for assistance to patients for better health.**

For providers, designing flexible payment terms that reward physicians and other caregivers who help them achieve care coordination and improved patient outcomes is a significant challenge. The Medicare program has implemented new payment methodologies in the context of traditional Medicare fee-for-service reimbursement that can only be effectively implemented if physicians, hospitals and other caregivers actively collaborate toward the shared goal of high-quality, low-cost care.

Outside of Medicare, many health systems and other providers are exploring partnerships with physicians to develop new payment and delivery models that encourage the same kinds of improvements in the quality and efficiency of care for all patients and communities. Yet, due to the broad definition of "remuneration," providers are concerned that even innovative payments based solely on the delivery of high-quality, cost-effective care to self-pay or commercial insurance patients can run afoul of the fraud and abuse laws. Uncertainty about the application of the AKS, coupled with the potentially devastating consequences for being wrong when combined with the False Claims Act (FCA), have impeded those efforts.

Providing assistance to help a patient recuperate post-discharge and maintain her health after she recovers is also a challenge because of limitations on the types of assistance a hospital may provide. Hospital responsibility for patient care no longer begins and ends at the hospital door. The kinds of support a patient needs to avoid an unnecessary readmission go beyond just medical care.

The need for change is clear. Failure to transform the fraud and abuse laws for a value-based system is not an option. Congress has repeatedly recognized that new models for delivering health care cannot go forward under the current fraud and abuse regime by authorizing waivers from those laws. (Specific waivers were authorized for the

Medicare Shared Savings Program (MSSP) and the Secretary was authorized to create waivers for any program initiated through the Center for Medicare and Medicaid Innovation (CMMI).) Waivers, however, are insufficient – they protect only arrangements specific to the waivered program and are limited in duration. Congress also made modest changes in the Affordable Care Act to remove limitations on hospitals providing coordinated care support to beneficiaries. However, OIG's implementation of those Civil Monetary Penalty (CMP) changes is insufficient and unreasonably narrow in scope. New comprehensive regulatory safe harbors for value-based arrangements and assistance to patients should be created.

NEW VALUE-BASED PAYMENT SAFE HARBOR

The rigid contours of existing safe harbors combine to inhibit the innovation necessary to re-invent systems for the efficient delivery of high-quality health care services.

Today, hospitals and other providers are more accountable than ever to improve patient outcomes in a cost-effective manner across the entire spectrum of patient care. Collective accountability requires that hospitals, physicians, and allied health professionals work together in new ways. Care coordination and innovation are critical to meeting the demands of collective accountability and to building a better health care system – one that controls cost, improves quality, and increases efficiency.

To achieve these goals and live up to new standards of accountability, hospitals, physicians, and other allied health professionals must align their interests and share resources, risks, and rewards. Building clinically integrated networks and relationships requires substantial investments in information systems and coordination of care. Hospitals have the capability and incentives to contribute resources to operationalize the value-based delivery model. As hospitals have assumed greater accountability for the health outcomes of patients inside and outside of the hospital setting, they have been required to make investments that directly or indirectly benefit physicians and other providers who share accountability for patient care. Physicians often lack the capital for such investments and are reluctant to invest their scarce financial resources in building new value-based models, particularly when the long-term reward is uncertain.

The reasons that leading, innovative hospitals contribute such resources are two-fold. First, they need tools for working with other providers to improve outcomes and manage the risk of accountability for those outcomes. Second, they also seek to engage clinicians to join and commit to participating in new care models and bring the benefit of the improved care delivery models to their patients. Innovative hospitals want their care and system improvements to succeed – their success is inextricably linked to other providers joining forces with them to serve the patients of the hospital, physicians, and other clinicians and provide better, lower cost care.

The AKS is a substantial impediment to care coordination and innovation as it is currently enforced. Today, any transfer of remuneration (e.g., cybersecurity or telehealth resources) from a hospital or other health care provider to a potential referral source (the physicians participating in the value-based delivery model) is prohibited if an imputed purpose for the transfer (coordinated care that improves the health and well-being of a patient or individual) could be to encourage referrals (the choice by a physician to provide her patient the benefit of better outcomes through the value-based model implemented by the hospital). This paradigm stifles and potentially forecloses new value-based delivery models necessary to achieve a value-based health care system – the goal of the Medicare program.

Innovation requires investment and integration, and integration influences referrals within a provider network. That purpose of coordinating care among providers, together with the hospital's disproportionate investment of resources in network infrastructure – "remuneration" – puts these innovative efforts squarely in the zone of scrutiny under the AKS, even when the reason for them is to foster better patient outcomes at lower costs. If enforcement of the AKS and FCA prevent these types of investments and integration, it also will prevent a value-based delivery system. That, in short, is why patients and providers need a clearly defined safe harbor for well-intended investments in care coordination and clinical integration.

Congress has long recognized that the AKS is overly broad and potentially affects many innocuous or beneficial arrangements. In 1987, Congress authorized the HHS Secretary to create "safe harbors" protecting such arrangements, intending "safe harbors" to be evolving protections that would be periodically updated to reflect changing business practices and technologies.

In the House Committee Report accompanying Pub.L.100-93, the Committee stated that it "believes that a mechanism for periodic public input is necessary to ensure that the regulations remain relevant in light of changes in health care delivery and payment and to ensure that published interpretations of the law are not impeding legitimate and beneficial activities."

However, instead of creating safe harbors for beneficial arrangements, the OIG historically has constructed safe harbors with the assumption that the parties may have unlawful intent. That premise has resulted in existing safe harbors that are overly prescriptive and of limited benefit.

The vast majority of the safe harbors require that any transfer of remuneration between referral sources result in a "fair market value" exchange that is set in advance. Those requirements leave little to no room for asymmetric investments in infrastructure or innovative shared savings designed to advance and reward success against metrics tied to quality or cost savings. Attempts by CMS and the OIG to develop safe harbors for innovative payment methodologies have repeatedly foundered on the OIG's

insistence on applying an outdated regime of constraints on "legitimate and beneficial activities."

The AHA proposes creation of a safe harbor specific and dedicated to value-based arrangements. It would protect arrangements and any transfer of remuneration, a principal purpose of which is to achieve the care coordination underpinning a value-based system. By focusing on the purpose for the arrangement, the safe harbor will provide substantially more flexibility for hospitals and providers to innovate and experiment in developing these new and necessary systems of care.

Transparency and financial accountability now protect against the corrupting influence of financial self-interest that lies at the core of the AKS and the related "one-purpose test." The proposed safe harbor will fulfill Congress' intent that the AKS "remain relevant in light of changes to health care delivery and payment and… not [impede] legitimate and beneficial activities."

Components of the Safe Harbor. The safe harbor would protect only those arrangements with a declared objective of achieving one or more of the pillars of coordinated care:

- Promoting accountability for the quality, cost, and overall care for patients.
- Managing care for patients across and among other providers.
- Encouraging investment in infrastructure and redesigned care processes for high-quality and efficient care delivery for patients.

Remuneration reasonably related to, and used to achieve, one or more of the pillars of coordinated care described above would be protected. Remuneration should include incentive payments, shared savings payments based on actual cost savings, and infrastructure payments or in-kind assistance (including, but not limited to, electronic health records (EHRs) technology, telehealth and cybersecurity resources, data or clinical analysis tools, and start-up support).

The safe harbor also should establish the basic accountabilities for the use of financial incentives or in-kind assistance, such as:

- *Transparency*: Documentation of the use of incentives or other assistance must be maintained and available to HHS upon request.

- *Recognizable improvement processes*: Any performance standards used (e.g., required care protocols, metrics used to award performance bonuses) must be consistent with accepted medical standards and reasonably fit the purpose of improving patient care.

- *Monitoring*: Performance under improvement processes must be internally reviewed to guard against adverse effects and documentation of those reviews must be maintained and available to HHS upon request.

Currently, there is both internal and external oversight of quality and patient safety in a hospital. State licensing agencies and accrediting organizations have an ongoing role. Medicare Quality Improvement Organizations continuously review the quality of care for beneficiaries. Other Medicare program oversight includes the hospital inpatient and outpatient quality reporting programs, the readmissions program, and the value-based purchasing program. **The safe harbor should not try to supplant, duplicate, or recreate existing quality improvement processes or mechanisms for monitoring quality of care in hospitals.**

As a close out to this section, we note that AHA submitted a companion exception for value-based arrangements in our response to CMS's request for information (RFI) on the self-referral law. In response to the question in this RFI whether an intersecting AKS safe harbor and Stark exception should be aligned, our answer is an emphatic "yes," and our companion Stark exception and this safe harbor demonstrate how that can be accomplished.

Proposed safe harbor text begins on p. 9 of this letter.

NEW SAFE HARBOR FOR PATIENT ASSISTANCE

As we have observed, new reimbursement models extend hospital accountability for a patient's health beyond inpatient or outpatient care. Those models effectively charge hospitals with responsibility for encouraging, supporting, and helping patients to access care at home and in the community, in some cases by making it more convenient. Hospitals need greater flexibility to promote health in the community and reduce unnecessary expenditures on costly inpatient services. From transportation to social services and counseling, from health coaching to telecommunications with patients and non-reimbursable home visits and meal preparation, there is a range of assistance patients may need after discharge for the best health outcomes.

In 2016, the OIG created a safe harbor for certain transportation assistance. However, it did not provide safe harbor protection for assistance that promotes access to care or is based on financial need. The OIG should remedy that discrepancy by exercising its discretionary authority to create a safe harbor for assistance to patients that promotes access to care or is based on financial need. The statutory grant of discretionary authority to create AKS safe harbors lists, as its first criterion, beneficiary access to care. In addition, the definition of "care" should be broader than the OIG's current interpretation, which is limited to "medically necessary" items or services. It should include assistance that directly or indirectly provides for other basic needs essential to health – food, shelter and safety – the "social determinants" of health.

Components of Safe Harbor. The safe harbor should protect the assistance patients need to realize the benefits of their discharge plan and maintain their health and their independence, to the extent possible, in the community. Arrangements protected under the safe harbor also would be protected from financial penalties under the CMP.

The safe harbor should:

- Protect encouraging, supporting or helping patients to access care or make access more convenient.

- Recognize that access to care includes more than medical or clinical care, including addressing the social determinants of health.

- Permit support that is financial (such as transportation vouchers) or in-kind (such as scales or meal preparation).

Proposed safe harbor text begins on p. 9 of this letter.

Finally, in issuing new safe harbors, we urge the OIG to once again make clear that parties who comply with a safe harbor are fully protected from liability under the AKS, regardless of intent.

Proposed Text

42 CFR 1001.952 ESTABLISHMENT OF A VALUE-BASED PAYMENT SAFE HARBOR TO FOSTER COLLABORATION AND ENCOURAGE EFFICIENT IMPROVEMENTS IN THE DELIVERY OF HEALTH CARE

"(cc) Any remuneration provided pursuant to a value-based payment arrangement that meets the following conditions:

(A) The arrangement is for one or more of the following purposes:

(1) Promoting accountability for the quality, cost, or overall care for patients.

(2) Managing and coordinating care for patients.

(3) Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients."

(B) Structure.

(1) The remuneration is provided directly or indirectly by a provider or supplier (including a hospital) in a value-based arrangement to a provider or supplier (including a physician or physician practice) that is participating in the value-based arrangement.

(2) The remuneration consists of (i) incentive payments, (ii) shared savings payments based on actual cost savings, or (iii) infrastructure payments or in-kind assistance (including, but not limited to, EHR technology, cybersecurity resources, data or clinical analysis tools, and start-up support) reasonably related to and used in the implementation of a value-based arrangement.

(C) The remuneration under an incentive-payment or shared-savings program must be paid in accordance with performance standards that:

(1) Use an objective methodology for evaluation, be documented and verifiable, and be supported by credible medical evidence.

(2) Are separately identified and measured.

(3) Are reasonable for patient care purposes.

(4) Are monitored throughout the term of the arrangement to protect against reductions or limitations of medically necessary patient care service.

(5) Reflect the achievements of the participant receiving payment under the arrangement (or the achievements of another provider or supplier under that participant's oversight) or of the program.

(D) An officer, director, or authorized representative of the party making infrastructure payments or providing in-kind assistance, as well as of the party receiving payment or assistance, must certify in writing that the remuneration is reasonably related to, and used in, the implementation of a value-based arrangement.

(E) The remuneration (or the formula for determining the specific remuneration to be provided) and the timing for any payment, must be set in advance in writing. Records of remuneration paid or provided must be maintained.

(F) Documentation maintained pursuant to this section shall be made available to the Secretary upon request.

42 CFR 1001.952 ESTABLISHMENT OF A SAFE HARBOR AND AN EXCEPTION TO PROVIDE PROTECTION FOR ITEMS AND SERVICES OFFERED TO BENEFICIARIES TO PROMOTE BETTER CARE OR REDUCE OVERALL COSTS

(dd) items or services provided to a patient for free or at less than fair market value by a provider of services or a supplier (as those terms are defined in section 1861), if the items or services:

A. Are reasonably related to medical care that the patient has previously received from the provider or supplier, or promote access to care.
B. Are not offered as part of any advertisement or solicitation that is issued prior to the patient receiving medical care from the provider or supplier.
C. Are not provided upon the condition that the patient will obtain future treatment from any particular provider or supplier.
D. Are offered to all patients on equal terms, regardless of coverage by a federal health care program or other insurance coverage.
E. Satisfy one of the following criteria:

(I) the items or services promote adherence to a prescribed drug or treatment regime, promote adherence to a follow-up care plan, are provided to assist in the management of a chronic disease or condition according to a care plan for that disease or condition, are preventive care items or services, nonclinical services related to health (e.g., social services, counseling, food bank); or

(II) the items or services are provided following a bona fide determination that the patient is in financial need and the items or services consist of reducing or eliminating patient copayments or deductibles, financial support (not including cash) for transportation costs, or in-kind products designed to promote patient safety or to prevent visits to the provider or supplier for emergency care.

42 CFR 1003.110

Remuneration, … does not include:

…(10) any items or services satisfying the requirements of 1001.952 (dd)