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Submitted Electronically

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

RE: OIG—403—P3, REVISIONS TO SAFE HARBORS UNDER THE ANTI-KICKBACK STATUTE, AND CIVIL MONETARY PENALTY RULES REGARDING BENEFICIARY INDUCEMENTS AND GAINSHARING

Dear Mr. Levinson:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, we appreciate this opportunity to comment on the Office of Inspector General's (OIG) proposed revisions to the anti-kickback (AKS), beneficiary inducement and gainsharing civil monetary penalty (CMP) rules.

A proliferation of public and private forces is reshaping the health care landscape. Hospitals across the nation are adapting to these changes by eliminating silos and replacing them with a continuum of care to improve quality, access and affordability (the Triple Aim). One of the most frustrating barriers to the success of this effort is an outdated regulatory apparatus predicated on enforcing rules no longer compatible with the changing health care landscape.

Chief among these outdated regulatory barriers are significant portions of the AKS and CMP rules. Congress recognized this and made modest changes four years ago in the Affordable Care Act, which are, in part, the subject of the OIG's regulatory proposal. These include provisions that allow hospitals broad latitude to provide items and services to Medicare patients to improve their access to care. The ability for hospitals to provide transportation and medical products, such as scales and blood pressure cuffs, to monitor health status is long overdue. These types of changes should be implemented without delay or many of the complicated qualifiers the OIG suggests in the proposed rule.

In the proposed rule, the OIG only suggests that it might alter its misbegotten interpretation of the gainsharing CMP law that prevents hospitals from rewarding physicians for following

protocols that call for the delivery of medically necessary services. The OIG's current interpretation potentially penalizes any change in a physician's prior practice regardless of whether it is in service of improving quality, access or affordability. The OIG needs to tackle this barrier directly.

We stand ready to work with the OIG to achieve regulatory guidance that fosters rather than frustrates achievement of the Triple Aim. As you are aware, much of what is in the proposed rule is effectively a request for information from the OIG. We expect that the next step in the process will be the issuance of proposed regulations with a notice-and-comment period.

Please feel free to contact Melinda Hatton, senior vice president and general counsel, at (202) 626-2336 or mhatton@aha.org with any comments or questions.

Sincerely,

/s/

Rick Pollack
Executive Vice President

AMERICAN HOSPITAL ASSOCIATION (AHA) DETAILED COMMENTS ON THE OFFICE OF INSPECTOR GENERAL'S (OIG)
REVISIONS TO SAFE HARBORS UNDER THE ANTI-KICKBACK STATUTE, AND CIVIL MONETARY PENALTY RULES REGARDING BENEFICIARY INDUCEMENTS AND GAINSHARING

RELATIONSHIPS WITH BENEFICIARIES

THE OIG'S REGULATIONS SHOULD PROVIDE PROTECTION UNDER THE ANTI-KICKBACK AND CIVIL MONETARY PENALTY STATUTES FOR HOSPITALS' ASSISTANCE TO BENEFICIARIES TO FACILITATE ACCESS TO CARE

The proposed rule provides protection to hospitals for offering transportation under the anti-kickback statute (AKS) (which automatically results in protection under the civil monetary penalty (CMP) statute). However, the proposed rule's protections related to support for beneficiaries that promotes access to care and poses low risk (to beneficiaries and the federal health care programs), or that is based on financial need – two exceptions created by the Affordable Care Act (ACA) – apply under only the CMP statute. The OIG should exercise its discretionary authority to create AKS safe harbors to match the two ACA exceptions.

The statutory grant of discretionary authority to create AKS safe harbors lists, as its first criterion, beneficiary access to care. Congress' creation of the two exceptions under the ACA is evidence of the need for, and appropriateness of, hospitals providing support to beneficiaries that promotes access to care (in addition to support that is based on financial need). Hospitals should not have to piece together protections to achieve the quality and efficiency imperatives created by statute and regulation.

THE REGULATIONS SHOULD RECOGNIZE THE UNIQUE OBLIGATIONS OF HOSPITALS AND THE CLINICALLY INTEGRATED DELIVERY SYSTEMS THROUGH WHICH THEY CARE FOR BENEFICIARIES

Hospital responsibility for patient care no longer begins and ends at the inpatient setting or any other site of care provided by the hospital. While discharge planning has long been a condition of participation in the Medicare program, post-discharge monitoring of beneficiary follow-up and treatment plans has become equally important from a patient care and Medicare payment perspective. The Medicare readmission penalties effectively hold hospitals accountable for the success of the post-discharge treatment plan. And individual or episodic patient care is no longer the only focus. Hospitals, through their participation in clinically integrated, accountable care networks, are assuming an increasingly important role in reducing unnecessary health care expenditures while improving care and health outcomes through population health initiatives.

Hospitals need certain tools and flexibility to promote the health of their patients and their communities, while reducing unnecessary health care expenditures. One example is the ability to provide transportation for medically appropriate health care services to a beneficiary, a need that the OIG acknowledges has been brought to its attention for years. This literally can mean the

difference between a patient receiving or not receiving necessary care. Hospitals also need the ability to provide other types of post-discharge and post-hospital outpatient care support to better enable beneficiaries to follow-through on their post-care plans, whether it is continuing a course of care, electronic monitoring, maintaining a medication regimen or taking steps to maintain or improve their health status.

Transportation
The core requirements of the proposed regulation need improvement. Allowing transportation for only an "established patient" is too limiting. Requiring that transport be a distance no greater than 25 miles will potentially prevent Medicare beneficiaries living in rural areas from accessing needed care. The distance limit also could affect Medicare beneficiaries' receipt of the right care at the right time and in the right place to achieve the ACA's Triple Aim.

Established patient. The OIG proposes to limit safe harbor protection for transportation provided to only "established patients" where a patient has selected a provider and attended an appointment with the provider. This limitation would unreasonably prevent a hospital from assisting a beneficiary in keeping the critical first appointment or in completing registration in advance of the visit. For hospitals with an extended campus operating a shuttle, it would be impractical to try and screen out those who do not meet that definition. Once a beneficiary has selected a provider and scheduled an appointment, there should be sufficient evidence to demonstrate an established relationship with the provider, and hospitals should be allowed flexibility in providing transportation to the beneficiary to ensure follow-up care is received. An additional complication in defining an established patient (as discussed below) is how the term would be applied in connection with an integrated delivery system with multiple providers.

25-mile limitation. Setting 25 miles as the outer distance for transport would effectively preclude critical access hospitals and sole community hospitals from meeting the transportation needs of those they serve. By definition, they must be at least 35 miles away from the nearest like facility. Clinically integrated networks may span even larger distances. Medically underserved or remote areas also may require that individuals travel greater distances to access appropriate services.

Transportation between or among providers. There are a series of questions in the preamble to the proposed rule related to whether a provider should be permitted to offer a beneficiary transportation to another provider. This is essential for hospitals. Whether on campus or in the community, if the beneficiary is an established patient of the hospital, that should be sufficient to permit the hospital to offer post-care transportation to an affiliated provider site of care or for medically required services that are part of the post-hospital care treatment plan.

Transportation for purposes that relate to the patient's health care. Again, in the context of hospitals, there should be broad latitude, consistent with their broad accountability for preventing readmissions. Implementing the medical care components of a post-discharge plan is only the start. As discussed below, maintaining or improving a beneficiary's health may require many types of services, and lack of transportation can be a major stumbling block to achieving that goal.

Finally, the protection for transportation should apply whether the transportation is provided directly, through vouchers or cash reimbursement; it should cover transportation for planned-in-advance or ad hoc services when an individual's need arises unexpectedly. Offering examples to illustrate the regulation text can be can be helpful; however, they should be clearly presented as *nonexclusive* illustrations.

Encouraging follow-through on post-discharge treatment plan
Congress has provided blanket protection for providing support to beneficiaries that promotes access to care while posing a low-risk of harm to federal health care programs. Access to *care* should be interpreted more broadly than only access to *medically necessary* services or items. Indeed, it is significant that this exception was created at the same time Congress created expectations that hospitals focus on beneficiaries' health post-inpatient discharge, with penalties for failure to do so.

Promoting access to care should encompass *encouraging, supporting or helping patients* to access care, or making access *more convenient for patients*. This would include removing barriers or hurdles for beneficiaries as well as filling gaps in needed support. Examples would include providing transportation, self-monitoring tools (e.g., scales, blood pressure cuffs), post-discharge contacts by a clinician (by phone or other electronic means, or in-person) to ensure follow-through with the patient's post-discharge treatment plan, and provision of educational materials. Access to care should also include *nonclinical care* that is reasonably related to the patient's medical care. Examples would include social services, counseling, health coaching, non-reimbursable home visits and meal preparation.

Experience also has shown that, for some individuals, a care plan involving a series of treatments (e.g., physical therapy or rehabilitation services) or a drug regimen will compete for the same dollars as other needs and may lead to skipping appointments or medication dosages. Offering discounts for combined co-pays or gift cards could make a difference in avoiding an impairment of health that results in a beneficiary's return trip to the emergency department or a readmission. The nature of these supports would present no risk to the beneficiary. The risk to the federal program would be low – the hospital is already accountable for ensuring that the beneficiary's post-discharge treatment plan is effectively carried out to avoid readmission penalties, and the treatment plan itself would be a guidepost for the needs of the beneficiary.

Financial need-based assistance
It is unclear from the discussion in the proposed rule what could be offered to a beneficiary under this exception that would not also be protected under promoting access to care. In the absence of proposed regulation text that goes beyond the text of the statute, it is difficult to evaluate this proposal. Hospitals have longstanding policies and procedures for awarding financial assistance to patients. The regulations should not create new or different documentation requirements.

RELATIONSHIPS WITH PHYSICIANS

IMPLEMENTATION OF THE AKS AND GAINSHARING CMP SHOULD FACILITATE HOSPITAL-PHYSICIAN QUALITY IMPROVEMENT INITIATIVES AND THE CLINICALLY INTEGRATED PROGRAMS AND NETWORKS THROUGH WHICH THEY CARE FOR BENEFICIARIES

The OIG's apparent readiness to change its unreasonably broad interpretation of what is a prohibited inducement to a physician to reduce or limit services is welcome. However, in the absence of proposed regulatory text, there is no way to evaluate whether the current position – that any change in a physician's practice is a potential violation – will be sufficiently changed. The OIG's stated intent is to create a definition of "reduce or limit services" as the means to effectuate its change. Based on that approach, we are renewing our proposal that the prohibition should be interpreted to mean to reduce or limit *medically necessary* services. We are concerned further by the OIG's statement at the end of this section in the preamble that this approach would result in an interpretation of the statute and not an exception. While helpful, publishing a new interpretation of these provisions will not afford hospitals adequate protection from third-party challengers or the predictability necessary to foster innovation and investment. With that as background, we respond to several of the specific questions posed by the OIG in the proposed rule.

A hospital's decision to standardize certain items (e.g., surgical instruments, medical devices or drugs) should not be treated as reducing or limiting services under the statute. Standardization serves many legitimate purposes, including quality control and selection of superior items that promote enhanced patient care.

There should be protection for shared savings and incentive programs and quality improvement initiatives. A decision by a hospital and physicians to follow protocols that are based on objective quality metrics for certain procedures should not be treated as reducing or limiting services under the statute. As the OIG recognized in the preamble discussion, the use of incentives to foster improvement in quality and efficiency is embedded in many federal health care initiatives. Value-based purchasing and pay-for-performance programs are two examples that create an imperative for hospital leaders and physicians to work together to efficiently bring patients the right care, at the right time, in the right setting, and incentive programs can play an important role.

It would be difficult for hospitals to advance programs involving quality and efficiency incentives if the adoption of objection metrics could be deemed to cause a violation. In practice, adherence to objective metrics – including the Physician Quality Reporting System quality measures and other metrics utilized by the Centers for Medicare & Medicaid Services – will, on a frequent basis, lead to change in a physician's practice.

While concerns about increasing health expenditures have been discussed for decades, recent attention is also turning to whether increased costs lead to better outcomes. The result is a spotlight on whether medical resources are being used appropriately. The OIG's longstanding interpretation of the reduction/limitation prohibition is at odds with current knowledge. Clinical

knowledge doubles as fast as every two years, making changes in clinical protocols and practices part of the norm rather than an aberration. From imaging for lower back pain and the use of antibiotic prescriptions to angioplasty and the use of the intensive care unit for imminently terminal illness, efforts are underway to identify the conditions for optimal use of all medical resources available. By reducing the utilization of non-beneficial care – the care that increases costs without a concomitant increase in value for patients – the delivery system can achieve the Triple Aim: improved health, a quality patient experience and lowered costs. This is the backdrop against which the design and execution of incentive programs and quality initiatives should be seen.

The regulation should not, and need not, try to supplant, duplicate or recreate existing quality improvement processes or the structures for monitoring quality of care in hospitals. These programs will be established within the larger quality and patient safety program at a hospital. The regulation should establish the basic accountabilities for a program. The patient care or cost-saving practices should be supported by credible medical evidence; the program must have ongoing monitoring to protect against inappropriate reductions or limitations in patient care services; payments to physicians should reflect the physician's contributions and achievements; documentation should be maintained on the design and implementation of the program and the amount and calculation of payments to be made under the program.

There should not be a requirement that potentially affected patients be notified about the program. The general experience of beneficiaries receiving boilerplate Medicare notifications is confusion. In addition, a physician's responsibility and interaction with the patient would not be affected by the existence or non-existence of a notification. Physicians would continue to have the same responsibility to make medically appropriate decisions in consultation with the individual patient. Disclosures related to treatment decisions should not be any different in this context.