Via electronic submission

October 24, 2018

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

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

Dear Mr. Levinson:

On behalf of the New Jersey Hospital Association (NJHA) and its over 400 members, thank you for the opportunity to respond to the Office of the 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.

NJHA appreciates the OIG's attention to removing obstacles to care coordination. We share OIG's belief that healthcare must transform to deliver higher quality care at a better value. We applaud the goals of HHS's *Regulatory Sprint to Coordinated Care* to tackle obstacles to care coordination. Meaningful movement on this issue will help accelerate the transition to value-based care already being pursued by many of New Jersey's hospitals, health systems and post-acute providers.

Specifically, NJHA's comments will address issues surrounding **protection for assistance to patients**, **protection for value-based payment systems** and **a specific safe harbor for gainsharing programs**.

Protecting Assistance to Patients

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. Due to the broad definition of "remuneration," however, 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.

Assisting recuperating patients post-discharge can pose a challenge to hospitals due to 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.

NJHA has heard that, in some instances, hospitals are reluctant to fully deploy community health strategies because of fear of running afoul of the AKS. One specific example includes a hospital placing restrictive limits on community engagement teams, which are designed to work within communities to address social determinants of health. **The delivery of healthcare continues to move beyond the walls of traditional institutions. Accordingly, efforts to reach patients where they live and work and improve population health must be provided through evolving safe harbors.**

Specifically, NJHA supports a safe harbor that protects the assistance patients need to realize the benefits of their discharge plans 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).

Protection for Value-Based Payment Systems

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 healthcare 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 healthcare 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 his/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 healthcare 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.

NJHA supports creation of a safe harbor specifically dedicated to value-based arrangements. It would protect arrangements and any transfer of remuneration, with the principal purpose of achieving 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.

<u>Safe Harbor for Gainsharing Programs</u>

NJHA has had unique and valuable experience with the value and utility of gainsharing in enlisting physicians to reduce inpatient costs of care. Beginning in 2009, NJHA and its member hospitals have piloted two CMS demonstrations involving gainsharing. We were naturally pleased with the important improvements seen in the relationship between hospitals and physicians. Both projects proceeded smoothly and without incident. And we were encouraged to see gainsharing subsequently adopted as a component of various CMS initiatives. Based on our observations, we believe that gainsharing works and works well; to reach its potential, provider payment reforms will need a gainsharing component to enlist the support and skill of their physicians to re-engineer the delivery of provider care.

A specific gainsharing safe harbor would provide welcome clarity to healthcare providers. While gainsharing programs can already be structured to comply with the AKS, a specific safe harbor would remove the regulatory uncertainty and litigation risk that have constrained their adoption and providers' ability to promote cost-effective care redesign.

Important Components of An Effective Gainsharing Program

Based on NJHA's experience, we believe there are several key supports that OIG could further implement that would bolster the success and efficacy of gainsharing methodologies. As a threshold matter, we want to emphasize that gainsharing is a tool to implement payment reform; not an end in itself. Whatever the goal of payment reform at the CMS level, gainsharing allows the providers to enlist the active help and skill of physicians to achieve the necessary changes to implement the reform. Physicians are already fully committed to dealing with their own practices. To enlist them in changes to the larger healthcare delivery system, they must see a financial benefit for themselves to account for their increased investment.

Second, task lists must not be prescribed; individual health systems and physicians need the flexibility to devise their own care redesign interventions tailored to their needs. Our experience has demonstrated the

need for effective gainsharing arrangements to provide the hospitals and physicians broad flexibility to address systems and processes that are identified by internal hospital committees. Inefficiencies in hospitals go well beyond specific surgical specialties and lists of clinical tasks. As the demonstration process showed, many internal hospital problems relate to patient management – discharge planning, the use of consultants, the turnaround of diagnostics, OR scheduling, the utilization of step-down units and so forth. Some can be addressed through care coordination, but others are unique to the practice habits of individual physicians and require re-engineering of processes and procedures through an iterative process.

Third, incentives need to be based on individual physician performance. They must reward both improvements in quality and savings, as well as maintenance of effort. The industry believed it was important to long-term success to recognize the efficient practice that some physicians had already achieved, as well as encouraging less efficient physicians to improve their performance. Accordingly, the demonstration methodology employed separate calculations to recognize "Performance," a physician's resource use compared to his/her peers, adjusted for case mix and severity of illness; and "Improvement," a physician's performance compared to his/her own performance over time, adjusted for case mix and severity of illness. In both cases, savings are computed based on the appropriate comparison and incentive amounts determined as a percentage of the savings, up to a cap. Viewed over the long term, the failure to recognize continuing efficient performance will compromise the sustainability of gainsharing.

Fourth, the gainsharing methodology must be maintained in place for a sufficient period of time to motivate and institutionalize change. Re-engineering systems and behaviors takes time; providers must work together to identify bottlenecks, devise solutions and implement reforms. Short-term programs will not work. Three to five years is more likely to provide lasting change.

Ensuring Gainsharing Program Integrity
In our experience, the potential for program or patient abuse from gainsharing is more theoretical than actual. We respectfully suggest that OIG should focus regulation of gainsharing on actual instances of program or patient abuse. Also, NJHA believes that it may be relatively simple to address the various program integrity issues that have been raised from time to time:

- *Sham Savings.* The OIG has raised concerns that providers might game the accounting to reward physicians for non-existent savings. The key to addressing that concern is to require a consistent methodology over the arrangement, which will result in apples-to-apples comparisons. Hospital costs can be captured utilizing industry standard accounting practices, such as the ratio of cost to charges used by the Medicare program. Uniform application eliminates opportunities for "phantom savings" and neutralizes incentives for patient steering.

- *Cherry Picking.* The NJHA demonstration utilized APR DRGs, DRGs adjusted for severity of illness ("SOI"). By adjusting the methodology to account for the correct amount of resources that may be required by an individual patient, given that patient's medical condition, SOI directly addresses "cherry picking," "quicker sicker," "stinting" and "steering." As additional safeguards against any incentive to compromise quality of care, physicians were held harmless for outliers, patients requiring unusual amounts of resources, and, equally important, no incentive was given for physician performance beyond established "best practice norms." Incorporating the SOI adjustment eliminates incentives to withhold medically necessary care, or to divert incentive programs to uses such as "payment for referrals" (see below).

- *Payments for Referrals*. The NJHA demonstration addressed the potential for gainsharing to improperly influence referrals through several mechanisms. Participating physicians had to be on staff for at least 12 months prior to enrolling in the program. Physicians that have staff privileges at other hospitals were capped at the prior year volume.

Above are some of the most significant components of the NJ/CMS gainsharing demonstrations. A more complete discussion that includes a fuller description of the demonstrations' individual elements, as well as its overall framework, is included in the NJHA RFI comment submitted in September 2015, and the NJHA comment regarding physician self-referral laws submitted in July 2018.

Again, the New Jersey Hospital Association thanks the Office of Inspector General for the opportunity to respond to this RFI and supports the direction it is taking toward AKS and other regulatory obstacles. Should you have any questions or would like more information, please do not hesitate to contact me directly at kali@njha.com, 609.275.4089.

Sincerely,

Karen S. Ali

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General Counsel