Texas Hospital Association

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Via electronic submission

PUBLIC COMMENT LETTER

Daniel R. Levinson
Inspector General
U.S. 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 more than 450 member hospitals and health systems, including rural, urban, children's, teaching and specialty hospitals, the Texas Hospital Association appreciates the opportunity to respond to the Office of Inspector General's Request for Information regarding modifications to the Federal Anti-Kickback statute to foster arrangements that would promote care coordination and advance the delivery of value-based care. THA is grateful to the U.S. Department of Health and Human Services for its continuation of its *Regulatory Sprint to Coordinated Care*, and believes there is opportunity for improved patient outcomes, decreased regulatory burden and reduced costs.

When the federal Anti-Kickback Statute was enacted in 1972, health care, and particularly the way it was paid for, was very different from what it is today. The majority of care was delivered through a fee-for-service model where payment followed a service. In recent years, new payment models have emerged that reward positive outcomes, efficiency and other measures of quality. This trend is often described as the shift from volume to value or value-based payment. Much like the Physician Self-Referral law, the Anti-Kickback Statute is a barrier to the growth and maturation of these value-based models in large part because of uncertainty, potential criminal penalties and the significant fees associated with violations. To reach the full potential of a value-based system, THA urges the creation of two new AKS safe harbors:

1) For value-based payment arrangements.
2) For assistance to patients for better health.

Designing flexible payment terms that reward physicians and other clinicians who help coordinate care and improve patient outcomes is a significant challenge. The Medicare program and Texas Medicaid have adopted new payment methodologies rewarding outcomes that can only be effectively implemented if physicians, hospitals and other providers within the health care continuum actively collaborate toward the shared goal of high-quality, low-cost care. Outside of Medicare and Medicaid, many health systems and other providers are

exploring partnerships with physicians to develop new payment and delivery models that encourage 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 violate the fraud and abuse laws. Hospitals and other providers incur millions of dollars in legal fees to attempt to comply with the AKS — often to vet and structure well-intentioned arrangements so that they do not result in criminal liability and program exclusion.

The existing safe harbors inhibit the innovation necessary to re-invent systems for the efficient delivery of high-quality health care services. The cornerstone of quality health care is a team-based approach. Hospitals should have the tools to work with other providers to improve outcomes with appropriately aligned incentives and manage the risk of accountability for those outcomes. In addition, hospitals would like to engage clinicians to actively participate in new care models, and bring the benefit of the improved care delivery models to their patients.

Under its current enforcement scheme, the AKS is punitive and a substantial impediment to care coordination and innovation. 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 wellbeing of a patient or individual) *could be* to encourage referrals — despite the inherent value across the continuum of care.

The majority of existing safe harbors require that any transfer of remuneration between referral sources result in a "fair market value" exchange that is set in advance, which inhibits care coordination because it artificially requires up-front investment and disregards long-term value. THA supports the American Hospital Association's proposal to create a safe harbor specific and dedicated to value-based arrangements. It would protect arrangements and any transfer of remuneration if a principle purpose of the arrangement is to achieve the care coordination underpinning a value-based system, effectively eliminating the "one purpose" test for these types of arrangements. 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.

To protect against fraud and abuse, the safe harbor also should establish 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.

In addition, THA asks that the OIG create a safe harbor for financial assistance to patients based on financial need that promotes access to care. 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. Under the proposal, arrangements protected under the safe harbor also would be protected from financial penalties under the Civil Monetary Penalty Statute.

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).

THA refers you to AHA's comments regarding the language and parameters of this safe harbor for more detail.

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.

Thank you for your consideration of these comments. We look forward to working with you to build an effective value-based health care system. Should you have any questions, please do not hesitate to contact me at cduncan@tha.org or 512/465-1539.

Respectfully submitted,

Cameron Duncan
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Texas Hospital Association