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PUBLIC COMMENT LETTER

Joanne Chiedi
Acting Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building
330 Independence Avenue, S.W., Room 5521
Washington, DC 20201

RE: OIG-0936-AA10-P Proposed Rule—Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements

Dear Ms. Chiedi:

On behalf of our over 450 member hospitals and health systems, the Texas Hospital Association (THA) appreciates the opportunity to comment on the Department of Health and Human Services (HHS) Office of Inspector General (OIG) proposed rule revising the safe harbors under the federal anti-kickback statute (AKS) and civil monetary penalty (CMP) rules regarding beneficiary inducements. We applaud OIG for its commitment to removing potential barriers to more effective coordination and management of patient care and delivery of value-based care that improves quality of care, health outcomes, and efficiency. In furtherance of those aims, we refer OIG to the American Hospital Association's (AHA) detailed comments provided to OIG, which we support.

The delivery of health care and the associated payment methodologies have grown increasingly complex over the past decade. Texas hospitals are working to deliver more value-based care to patients, and to meet the demands of patients, other providers, the government, and other payers for accountability and affordability. However, the development of innovative arrangements designed to meet these complex and often overlapping priorities has been greatly inhibited by the historical application of the AKS and CMP laws. We therefore welcome the changes intended to eliminate regulatory obstacles to coordinated care and unnecessary regulatory burden, and promote flexibility, which are useful for a range of individuals and entities engaged in the coordination and management of patient care.

Our comments on the proposed rules follow. THA joins the AHA and America's hospitals and health systems in their commitment to continue assisting OIG in modernizing the AKS and CMP laws for the era of value-based care and payment. Like the AHA, we are pleased to see so many of the real-world issues and concerns hospitals experience every day addressed in the proposed rule. However, like the AHA, we believe that the OIG's

proposals, especially as compared to the parallel exceptions the Centers for Medicare & Medicaid Services (CMS) has proposed for exceptions to the Stark self-referral prohibition, are too narrow. In finalizing the rule, OIG should adapt its proposed safe harbors to protect the broader universe of the innovative, value-based arrangements made possible by the CMS exceptions. Most importantly, the final rule should create a robust safe harbor for non-risk value-based arrangements, modeled on CMS's proposed exception for the same type of arrangements. While CMS's flexible non-risk exception makes significant progress in fostering and supporting efforts to achieve a system of value-based care, OIG's equivalent safe harbor for care coordination arrangements is significantly more constrained and is unlikely to allow or incentivize innovation in payment models, beyond what is already permitted under the AKS.

New Value-Based Safe Harbors

THA supports safe harbor protection for value-based arrangements (VBAs). We believe that OIG's two proposed risk-based safe harbors would offer some new protection for hospitals seeking to transition to a more efficient, more patient-centered, value-based system. We encourage OIG to finalize these proposals with the addition of the important clarifications and revisions suggested in these comments.

The proposed safe harbor for care coordination arrangements, however, requires substantially more work to allow and incentivize innovation in payment models. Non-risk value-based arrangements are of critical importance because few physicians or other health care professionals have the financial resources to invest in the infrastructure necessary to build coordinated clinical care networks, especially since the success of such efforts are speculative. THA urges OIG to complete the suite of value-based safe harbors and match the strength of the parallel Stark Law exception proposed by CMS.

With regard to OIG's proposed definitions:

- **We support OIG's proposed definition of a Value-based Arrangement**, which is flexible enough to accommodate many diverse and innovative models. With respect to the definition of Value-based Enterprise, **we support the proposed definition of VBE with one modification**. The definition of "value-based enterprise" requires that the VBE "have a governing document that describes the VBE and how the VBE participants intend to achieve the value-based purpose(s)." We request OIG to allow compliance with this requirement through a collection of documents, as opposed to only through a single document as suggested. We propose revising the reference to "a governing document or a collection of documents," which would allow a VBE to rely on a combination of its governing documents, provider participation agreements, payer agreements, and written policies and procedures to describe how the participants will achieve the purposes of the VBE and meet the definition of VBE. We are concerned that the absence of a reference to a collection of documents would create potential compliance issues if a single, standalone document does not adequately describe the arrangement, and the proposed change reflects the practical reality of how many value-based arrangements are structured.

- **THA generally supports the proposed definition of a value-based activity, but we encourage OIG to address aspects of the proposal that may lead to further clarity and flexibility**. Specifically, the proposed regulation would provide that a value-based activity "does not include the making of a referral," and OIG states in the preamble to the proposed rule that "under no circumstances would simply making a

referral constitute a 'value-based activity.'" We are concerned that this regulatory text and related commentary could be misread as prohibiting safe harbor protection for VBAs in which payments or other remuneration may depend in part on the referrals made within the network, which is an important component of any VBA. We request confirmation in the final rule that such arrangements would not be considered a prohibited payment for referral.

- **With one modification, we agree with the proposed definition of target patient population**, which will allow hospitals the latitude to identify and focus on health issues specific to their community. However, requiring that the criteria for selecting the population be "legitimate" introduces ambiguity that in the current enforcement climate is likely to lead to endless litigation over its meaning and the threat of exorbitant penalties under the AKS and/or the False Claims Act for noncompliance. We support clear and unambiguous language in the regulatory text aimed at the specifically-identified abusive practices and any other types of behaviors that OIG believes are abusive, but elimination of the problematic "legitimate" standard.

- The proposed definition of value-based purpose is sufficiently flexible to accommodate a wide range of beneficial VBAs, but OIG should not finalize a requirement that any protected VBA must directly further the first of the four value-based purposes. VBA participants should have the latitude to choose which among the value-based purpose(s) fit the goals of their own initiative.

Value-based Arrangements Safe Harbors

Non-Risk VBAs

THA strongly supports the creation of a new safe harbor to protect VBAs that are not linked to an agreement with a payor to take on financial risk. Unfortunately, OIG's proposed safe harbor for non-risk-based VBAs would take away flexibility and impose requirements so onerous that the safe harbor would be of little use to entities seeking to collaborate to deliver better care. OIG's proposed non-risk safe harbor does not match the reality of innovative value-based relationships, nor does it match the scope of CMS's proposed reforms to the Stark exceptions in opening the way to more of these potentially beneficial relationships. We urge the following improvements to the proposed safe harbor:

- OIG should broaden the safe harbor to allow monetary remuneration that will advance a value-based purpose. Limiting the safe harbor to in-kind remuneration would stand in the way of many beneficial arrangements, such as financial incentives to adhere to care protocols.
- OIG should reduce or eliminate the requirement that recipients share at least 15% of the cost. This requirement would make the safe harbor useful only when both parties to a VBA are able and willing to invest capital in a joint initiative, which often is not the case.
- Any required outcome measure should be defined broadly and flexibly. To that end, OIG should not require the use of measures from the Quality Payment Program (QPP) in the outcome measure requirement. We also encourage OIG to allow the use of patient satisfaction and experience of care measures to qualify as outcome measures under the safe harbor. OIG also should clarify that the requirement of an outcome measure does not mean that a certain level of actual performance on the measure is required for the VBA to be protected. Such a requirement would be arbitrary, especially in

cases where the measure(s) being used is relatively novel and did not have prior performance data. Finally, we encourage OIG not to require regular "rebasing" of outcome measures, which would be duplicative of the requirement that the measure must "advance the coordination and management of care of the target patient population."

- We agree that the safe harbor should be available even if the remuneration benefits patients outside the target patient population, and we urge OIG not to adopt its alternative proposal to require that the remuneration "only benefit the target patient population."
- OIG should not introduce the vague standard of commercial reasonableness into the standards required for protection of a VBA, especially not with its proposed new definition. If commercial reasonableness is included at all in the value-based safe harbors, OIG should not define "commercially reasonable" as an arrangement that "would make commercial sense" if entered into by entities of similar type and size without the potential for referrals. This definition flies in the face of OIG's historical and sensible understanding of the term. In 1994, OIG proposed to add a condition to the space and equipment lease and personal services safe harbors to require that the services contracted for "do not exceed those which are reasonably necessary to accomplish the legitimate business purpose of the services." In 1999, OIG finalized the proposed modifications to the safe harbors but changed the language from "legitimate business purpose" to "commercially reasonable business purpose." That definition has been clearly understood for over 20 years. Moreover, few arrangements would ever satisfy the additional requirement of making commercial sense without the potential for referrals. Simply put, VBAs do not make any commercial sense without the potential for referrals.

Risk-Based VBAs

THA supports OIG's proposals to create two new AKS safe harbors for risk-based VBAs. However, we encourage OIG to adopt lower thresholds for "substantial downside financial risk." The proposed thresholds are unlikely to incentivize use of such risk-based VBAs. OIG's proposed thresholds – shared losses of at least 40%; shared losses of at least 20% for episodic or bundled payment arrangements; or a partial capitated payment with a discount of at least 60% off of total expected FFS payments – are much higher than necessary to incentivize providers to seek new efficiencies in care delivery.

With respect to the Full Financial Risk Safe Harbor, we encourage OIG to finalize a broader definition of "full financial risk." Under the proposed rule, "full financial risk" is defined such that the VBE is accountable for the cost of all patient care items and services covered by the applicable payor(s) in the target population. This should be revised to focus on whether the enterprise has full financial risk for the items and services to which the protected remuneration relates.

New Patient Engagement Tools Safe Harbor

THA strongly supports OIG's proposal to create a new safe harbor for patient engagement tools. We commend OIG for recognizing the need both to engage patients in their own care and to assist them in overcoming societal obstacles to obtaining necessary care. We believe the proposed safe harbor will provide much needed clarity regarding such assistance and advance population health efforts that are already under way, but could be improved in several respects:

- We support a broad definition of "social determinants of health," and strongly urge that OIG not distinguish between certain categories of social determinants, as suggested in the commentary, effectively suggesting only some would be worthy of protection and others would not.
- The proposed safe harbor would protect patient engagement tools that are offered to patients in a target population, but the safe harbor also should protect giving the same tool to patients who present with conditions or in circumstances similar to those of the target population. Hospitals are deeply committed to providing equitable care to all patients. Restricting the safe harbor to just the target population could hinder the ability of hospitals to apply the tools to additional patients who could also benefit from them, and as a consequence hinder improvements in access to care and health equity.
- We also support extending the safe harbor to protect providers in rural or underserved areas even if they are not part of a VBE. In many cases, these providers will not have sufficient patient populations or resources to create or participate in a VBE, but their patients will benefit as much (if not more) from the provider's engagement with them in coordinating and managing their care.
- We strongly oppose OIG's alternative proposal to limit the safe harbor to VBAs involving assumption of financial risk. There is no logical connection between the provider's financial risk and the benefits of patient engagement. We also oppose requiring offerors of patient engagement tools to engage in reasonable efforts to retrieve items or goods furnished under the safe harbor. Such a rule would be administratively burdensome for the provider -- and deny a patient a resource that is important to maintaining her health.
- We support extending safe harbor protection to the waiver of copayments for care coordination services. OIG's longstanding concern about cost-sharing waivers is that they can improperly induce the patient to use the service without exercising prudence about the cost of the service. But CMS covers and pays for care coordination services to promote the same objectives that OIG is pursuing in this proposed rule – better managed, better coordinated care. Too often, patients decline care coordination services when they learn about cost. We believe it would be self-defeating to withhold protection from providers who seek to maximize the benefit of these care coordination services by covering the beneficiary contribution.
- Finally, we oppose adding a requirement that the patient's licensed health care provider certify in writing that a particular item or service is recommended solely to treat a documented chronic condition of a patient in a target patient population. Such a requirement is far too narrow and would undercut providers' flexibility to offer patient engagement tools and support that more broadly allow patients access to and engagement with primary preventive care, immediate support for an acute care episode, or interventions to address social determinants of health. We also are concerned that a rigid documentation requirement (with criminal penalties attached) would be a significant obstacle to making broader support for patient engagement a reality.

Revisions to the Local Transportation Safe Harbor

THA supports the proposed revisions to the safe harbor for local transportation. This safe harbor has helped to protect transportation services for patients in rural and underserved communities, where a patient's inability to get a ride to or from care usually means that the patient simply does not receive the care that she needs. We appreciate OIG's recognition that the current mileage limits were insufficient to meet patient needs. To maximize the benefit of the proposed revisions, we encourage OIG to refine the safe harbor further as follows:

- Given the variability of rural settings and the continuing trend of rural providers closing their doors, allowing providers to offer transportation within 75 miles still may not suffice to allow certain patients to gain access to necessary care, particularly in a large state like Texas with large distances between certain types of services. We encourage OIG to provide a pathway for providers to offer transportation services beyond 75 miles for such patients, for example, by extending safe harbor protection to transportation for patients who reside in a rural area where the provider certifies in writing that there is no alternative provider available within 75 miles of the patient's residence.
- THA strongly supports removing the mileage limit for transportation when a patient is discharged from an inpatient facility to the patient's residence or to another residence of the patient's choice. We encourage OIG to extend this policy to cover situations where a patient is discharged from an inpatient facility to another facility, such as a skilled nursing facility. In many cases, a patient's medical needs require that she be discharged from an inpatient facility directly to post-acute care. Given the limited access to such facilities in rural communities, it is critical that providers be able to support transportation from one facility to another without limitations on mileage. We also ask OIG to clarify that the mileage limit would not apply to transportation following discharge from an inpatient facility, even when the patient was treated in observation status or as an outpatient. Many patients treated under observation status or in an outpatient procedure will have spent significant time or undergone significant treatment at the facility, and their need for transportation home or to another facility is not necessarily any less pressing because of how the stay has been classified.
- Finally, we encourage OIG to extend the safe harbor further to cover transportation to services that promote and assist with social determinants of health, even if those services do not constitute medical care. For example, in some rural areas, senior centers or other elder service hubs provide opportunities for social connection, health education, nutrition, and other services that contribute to improved well-being and health outcomes by fostering physical, mental, and emotional health. The safe harbor should protect transportation to these services as well, as they are an important part of promoting a patient's overall health.

Changes to Other Existing Safe Harbors

Personal Services Arrangements. THA strongly supports OIG's proposed changes to the safe harbor for personal services arrangements to conform to the Stark exception. We welcome OIG's proposal to remove the requirements that aggregate compensation for the year be set in advance and that the exact schedule for the performance of part time services be set out in the contract, and we commend the OIG for harmonizing the AKS safe harbor with CMS's proposed changes to the Stark law regulations' parallel exception. However, THA believes that the proposed revisions related to outcomes-based payments are unnecessarily limited and would protect only arrangements that do not need protection because they do not implicate the AKS. THA urges OIG to broaden the protection of the outcomes-based provisions to include cost reductions to providers. OIG should include in the final rule a clear statement that outcomes-based payments that do not qualify for the safe harbor do not necessarily implicate or violate the AKS and may be protected under the other provisions of the safe harbor for personal services arrangements. By excluding payments for cost reductions from the outcomes-based provisions of the safe harbor, OIG casts doubt on the legality of such arrangements and threatens to undo much of the progress that has been made. Without necessary clarifications, we are concerned that the proposed rule will subject widespread and longstanding arrangements to frivolous and expensive litigation by calling such arrangements into question.

Electronic Health Records and Cybersecurity

THA appreciates OIG's inclusion of updates to the current EHR provisions and urge the removal of remaining barriers and uncertainty from the exception in connection with the adoption of EHR technology. Removal of the "Sunset" Provision will provide needed certainty and will support EHR adoption by new physicians entering the market as well as assist late adopters in implementing technology critical to supporting patient care.

We also urge removal of the 15% recipient contribution requirement for all physician recipients. Removing it for small and rural practices, as proposed, is helpful; however, removing it for all recipients would make an important difference in achieving the shift to value-based care arrangements. It would remove a barrier to the kind of data integration and real-time information sharing that is essential.

For similar reasons, THA supports OIG's proposal to allow for donation of replacement EHR technology. There are many situations where a physician practice may wish to migrate to a different EHR product; however switching to a new EHR vendor system often presents financial and technical challenges, leaving providers to choose between keeping the substandard system and paying the full amount for a new system.

The cybersecurity exception should be adopted with a modification providing protection for hardware. Protecting hardware necessary for fully functioning cybersecurity systems is important, and the protection should be broad enough to encompass advances in cybersecurity technology, including advances in hardware. Cybersecurity is necessary to enable safe, effective health information exchange, and thus is crucial to improved care coordination and improved health outcomes at the individual and population levels.

The proposed rule also omits the word "reestablish" in the first condition for the new safe harbor, making it inconsistent with the new exception to the Stark Law as proposed by CMS. THA urges OIG to adopt text that includes "reestablish" in the first condition. Specifically, THA urges that the final text for the first condition to the safe harbor should read, "The technology and services are necessary and used predominantly to implement, maintain, or reestablish effective cybersecurity." The inclusion of "reestablish" cybersecurity in the safe harbor would make explicit that the safe harbor's protection extends to post-incident activities.

Thank you for your consideration of these comments. Should you have any questions, please do not hesitate to contact me at swohleb@tha.org or 512/465-1000.

Respectfully submitted,

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