Texas Hospital Association

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Via Electronic Submission (*www.regulations.gov*)

PUBLIC COMMENT LETTER

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Service
Attention: CMS-1720-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS–1720–P Proposed Rule—Modernizing and Clarifying the Physician Self-Referral Regulations

Dear Ms. Verma:

On behalf of our over 450 member hospitals and health systems, the Texas Hospital Association appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule to modernize and clarify the physician self-referral law, also known as the Stark Law. We join the American Hospital Association in applauding CMS's acknowledgment of the chilling effect the Stark Law has had and continues to have on innovation and the transition to a value-based health care system, and refer you to the detailed comments provided to CMS by the AHA, 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 stymied by the historical application of the Stark Law. Further, the Stark Law has created unnecessary burdens both inside and outside the value-based context. We therefore welcome the many changes intended to eliminate regulatory obstacles to coordinated care and unnecessary regulatory burden.

Our comments on the proposed rules follow. THA joins the AHA and America's hospitals and health systems in their commitment to continue assisting CMS in modernizing the Stark Law 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 managing within the current Stark regime addressed in the proposed rule.

New Exceptions for Value-Based Arrangements – General Comments

The creation of new exceptions designed specifically to foster and support efforts to achieve a system of value-based care is extremely significant. We urge CMS to adopt the proposed general framework and related definitions as soon as possible. Flexibility and clarity should be the hallmarks of the new exceptions. We therefore agree with CMS's commentary and its embodiment in the text of the proposed rule that the Stark regulations should not require particular legal structures for a value-based enterprise or other foundational aspects of the proposed rule, nor should any particular type of payment model (such as a shared savings or capitation model) be a precondition to receiving protection under the new exceptions. Additionally, we agree with the AHA and refer you to their more detailed comments regarding the following:

- **None of the exceptions should limit the types of remuneration protected**. Narrowing or limiting the types of remuneration protected would severely curtail the needed flexibility that is central to the proposed rule and re-create the pitfalls for transformative value-based arrangements that the current law imposes.
- **The benefits of a value-based arrangement need not be limited to a target patient population.** CMS should add language making it clear that value-based arrangements may benefit patients beyond their targets without risk of losing protection from liability.
- **The exceptions should not include fair market value, commercial reasonableness, or "volume or value of referrals" conditions.** To do so would significantly stifle the progress of the proposed exceptions and the regulatory drag on the advancement of value-based movement would be left essentially where it is today.
- **CMS should not adopt the proposal described in the commentary to prohibit value-based remuneration that is "conditioned on referrals."** A key aspect of value-based care is to encourage change in the way physicians make orders or recommendations – for instance, in a manner that is coordinated with care furnished by other providers, reduces overall utilization, improves clinical outcomes, or provides another form of value. If the finalized exceptions were to require a complete disconnection between what the physician receives and the medical judgments the physician makes, the value-based arrangement exceptions would be of minimal utility.
- **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 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 CMS believes are abusive. Further, CMS should specify that the potential for cost-reduction, in itself, will not be viewed as problematic.
- With respect to CMS's suggestion that its regulations give rise to "implicit" compliance obligations, we are concerned that this will create confusion and likely litigation over whether requirements not stated explicitly in the regulation are conditions to be met in order to avoid liability. **Any monitoring or other requirement that is a condition of compliance should be explicitly stated in the regulatory text. Further, if any monitoring or compliance requirement is adopted, CMS must be clear on what exactly hospitals are being called upon to monitor or undertake.** This clarity is not provided in the

proposed rule or commentary. Finally, we urge CMS to consider the burdens of any such requirements, which could be significant.

Definition of "Value-based enterprise"

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 CMS 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.

Comments on proposed rule 411.357(aa) (Arrangements that facilitate value-based health care delivery and payment.)

Subpart (1) – "Full Financial Risk" Exception. CMS should revise the "full financial risk" exception to focus on whether the value-based enterprise (network of participants in a value-based initiative) has full financial risk for the items and services to which the protected remuneration relates. Under the proposed rule, "full financial risk" is defined such that the value-based enterprise is accountable for the cost of all patient care items and services covered by the applicable payor(s) in the target population. We are concerned that for Medicare, the commentary interprets that to mean responsibility for all items and services covered under Parts A and B. As a result, a hospital providing care management analytics or pay-for-performance bonuses tied solely to reducing the costs of inpatient care would not be protected. The "full financial risk" exception should allow hospitals to furnish incentives related to inpatient care, outpatient care, or both, regardless of whether the enterprise also is accountable for other items and services. Such arrangements pose little risk of encouraging inappropriate utilization because hospitals already bear accountability for the cost of inpatient and outpatient services through inpatient and outpatient prospective payment rates and readmission and other downside penalties.

Subpart (2) – "Meaningful Downside Risk" Exception. The 25% threshold in the proposed rule is far too high. We do not have a specific proposed threshold, but we believe that anything in excess of 10% will significantly limit the exception's usefulness. It is an unreasonable expectation and highly unlikely that physicians will put 25% of their compensation at risk, especially "downside" risk, as the proposed rule would require.

Subpart (3) - "Value-Based Arrangement" Exception. We urge CMS to finalize the "Value-Based Arrangement" exception without adding financial risk or other limitations. Finalizing an exception that is not tied to financial risk is essential to spurring the shift to value-based payment models. Many existing or contemplated arrangements do not involve financial risk but are nonetheless effective in achieving better care outcomes and/or reduced costs. Including a financial risk component would significantly limit the laudable goals of the proposed rule. CMS should further decline to adopt the three alternative proposals discussed in the commentary that would each dramatically reduce the utility of the exception. Specifically, CMS should not limit the scope of the proposed

exception to nonmonetary remuneration as this would unduly limit many legitimate and commonplace value-based arrangement structures, such as financial incentives to adhere to care protocols and shared savings models; CMS should not require 15% or any other cost sharing by value-based arrangement participants, as this requirement would preclude a host of innovative arrangements and take a disproportionate toll on small and rural physician practices; and CMS should not require that "performance or quality standards must be designed to drive meaningful improvements in physician performance, quality, health outcomes, or efficiencies in care delivery" as this alternative presents too ambiguous a standard.

Price Transparency

We urge CMS not to move forward with a requirement for physicians to provide a notice or have a policy regarding the provision of a notice that advises patients that their out-of-pocket costs may differ depending on their insurance coverage and where the services are delivered. Such a requirement would be counter to the agency's efforts to reduce unnecessary paperwork that benefits neither patients nor providers, but worse, it is likely to both concern and confuse patients.

"Commercial Reasonableness," "Taking Into Account," and "Fair Market Value"

The significance of CMS's proposed clarifications to clarify the concepts of commercially reasonable, taking into account the volume or value of referrals, and fair market value cannot be overemphasized. These components have long been the source of uncertainty, often leading to contentious and costly litigation. We believe CMS's efforts at clarifying these concepts are a significant improvement to the Stark Law.

Commercially Reasonable. CMS's discussion of the meaning of "commercially reasonable" in the commentary is extremely helpful. We do not think the last sentence of the proposed definition, however, which states that an arrangement "may be commercially reasonable even if it does not result in profit for one or more of the parties," fully reflects that discussion. CMS should finalize the proposed definition of "commercially reasonable" with one modification — the last sentence should state that "Commercial reasonableness is unrelated to the profitability of the arrangement to one or more of the parties." Given the degree of confusion related to this term and the severe consequences if a court concludes there has been a violation, CMS should leave no room for anyone to attempt to make a connection to profit.

Takes into Account the Volume or Value of Referrals. The proposed definition of "takes into account the volume or value of referrals" provides much-needed clarification of terms that have proven to be a source of confusion among providers, physicians, enforcement agencies, qui tam relators and courts. However, further clarification is necessary with respect to productivity compensation and indirect compensation arrangements. We support the proposed definition's focus on whether DHS referrals appear in the plain terms of the formula used for compensation (in the words of the proposed rule, "include the physician's referrals as a variable"). Similarly, we commend CMS for reiterating prior commentary addressing productivity incentives for proceduralists and other hospital-based physicians – that productivity bonuses for physicians working in a hospital will not take into account the volume or value of the physician's DHS referrals to the hospital, even if a hospital facility fee is "inevitably" linked to the physician's work. However, this aspect of the definition needs to go farther. CMS should make clear in regulatory text that compensation for personal productivity is permissible under the personal

services, fair market value compensation, and indirect compensation arrangements exceptions to remove any lingering confusion arising from this disparity.

Fair Market Value. CMS should finalize the proposed clarification of the "fair market value" definition, and also address key concerns created by the commentary. CMS should adopt the proposed clarification that fair market value does not turn in any way on whether compensation takes into account or anticipates referrals. It also should finalize a proposed change in the definition of "general market value," — the language "bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party" should be deleted. As CMS has recognized, "fair market value" and "taking into account referrals" are distinct concepts that serve different functions in Stark Law analysis. The changes CMS has proposed are essential to restoring clarity to the definitions.

Limited Remuneration Exception

THA supports the "limited remuneration to a physician" exception for annual payments under $3,500. We believe this will be helpful to avoid liability for clearly non-abusive conduct.

Deletion of Anti-Kickback Statute Compliance

THA supports the deletion of Anti-Kickback Statute compliance as condition of regulatory exceptions. We would further support and urge CMS to consider deleting requirements of compliance with state/billing/claims submission laws.

Special Rule on Parties Being Permitted to Execute Writings Within 90 Days.

THA supports the rule permitting parties to execute writings within 90 days. We would further support and urge CMS to consider additional language that states that a compensation arrangement is also deemed to satisfy the writing requirement if the arrangement constitutes an enforceable contract under applicable state law.

Isolated Transactions.

We urge CMS to reconsider the isolated transactions exception in the final rule and permit isolated payments for services that may have been already commenced. This would be consistent with the agency's stated objective to interpret the referral and billing prohibitions narrowly and the exceptions broadly.

Electronic Health Records and Cybersecurity

Sunset Provision, 15% Contribution Rule, and Replacement EHR Technology. We support removal of the existing "sunset" provision for the reasons stated by CMS in its commentary. We further 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. Finally, we support CMS'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, including to achieve advanced functionalities or to improve health information exchange capabilities. Switching

to a new EHR vendor system often presents financial and technical challenges because, as CMS observed, under the current exception, physicians are forced to choose between keeping the substandard system and paying the full amount for a new system.

Cyber Security Exception. The cybersecurity exception should be adopted with a modification providing protection for hardware. Cybersecurity remains one of the highest areas of concerns in the health care industry. The creation of this exception, long advocated for by hospitals and health systems, will support more robust capabilities for health care providers to protect against and respond to growing cybersecurity threats. 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.

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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Texas Hospital Association