Texas Hospital Association

1108 Lavaca Street, Suite 700, Austin, Texas 78701
512/465-1000
www.tha.org

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Via electronic submission

PUBLIC COMMENT LETTER

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd
Baltimore, MD 21244

Re: CMS-1720-NC, Request for Information: Centers for Medicare & Medicaid Services, Physician Self-Referral Law

Dear Ms. Verma:

On behalf of our more than 465 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 Centers for Medicare & Medicaid Services' Request for Information on reducing the administrative burden imposed by the physician self-referral law ("Stark law"). THA appreciates CMS' commitment to identifying and removing the obstacles the Stark law imposes on existing and evolving models of payment and care delivery.

When the Stark law was enacted in 1989, the state of health care, and in particular the way it was reimbursed, was very different than it is today, with the majority of care delivered through a fee-for-service model where payment followed a service. As the cost of health care has increased, 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.

However, the Stark law is a barrier to the growth and maturation of these models in large part because of the hefty fees associated with violating the law's often uncertain parameters. The Stark law is a strict liability statute that carries penalties of up to $15,000 for each claim based on a prohibited referral, plus three times the amount of the government overpayment. Of potentially even greater financial cost is the risk of outright exclusion from participation in Medicaid and Medicare. The consequences for even an inadvertent or technical violation of the law can be ruinous.

Texas hospitals are committed to delivering high-quality health care that is affordable and accountable, and the migration to value-based care is essential to this goal. Texas hospitals are eager to work with a variety of partners to deliver comprehensive, coordinated care to patients. We are hopeful that CMS' modifications to the Stark law will help Texas hospitals achieve this goal by allowing the development and implementation of innovative

programs that align providers through financial incentives, among other tools. We are confident that, with changes to the Stark law that support the adoption of value-based payment arrangements while removing obstacles to care coordination, Texas hospitals can improve patient outcomes and the patient experience while increasing efficiency and reducing costs.

THA's recommends that modernizing and updating the Stark Law:

1. Protect and promote value-based payment arrangements.
2. Provide clear, authoritative and timely guidance on compliance.
3. Narrow the law's focus on arrangements that produce overutilization.

These recommendations address the Stark law's burdensome and unnecessary barriers that Texas hospitals frequently encounter.

The Stark law should protect and promote value-based payment arrangements. Instead of financially rewarding health care providers for the quantity of services rendered, value-based payment arrangements reward them for delivering high-quality, cost-effective care with better outcomes. However, the Stark law makes it nearly impossible for Texas hospitals to collaborate and partner with physicians to confidently design flexible payment terms to achieve these goals. In order for innovative payment arrangements involving new relationships with physicians to succeed, Texas hospitals need the ability to make significant investments in care coordination without risking violation of the Stark law. THA encourages the creation or adoption of compensation exceptions to the Stark law to enable hospitals and physicians, working together, to coordinate care and improve patient outcomes.

Hospitals experience problems in designing flexible payment terms that reward physicians who help them achieve care coordination and improved patient outcomes. CMS has put forth new payment methodologies in the context of traditional Medicare fee-for-service reimbursement that can be implemented effectively only if physicians, hospitals and other caregivers actively collaborate toward a shared goal of high-quality, low-cost care. In addition, Medicare imposes financial penalties if hospitals do not meet targets related to readmissions and other quality metrics. For all of these initiatives, the active participation of physicians is paramount. At the same time, CMS' current Stark law compensation regulations constrain innovation and hamstring hospitals in achieving quality and cost goals. The regulations discourage the development and adoption of rewards that encourage change on a broad scale, across all patient populations and payer types, and over indefinite periods of time. The regulations also fail to recognize that relationships among payers, providers, physicians, and patients have transformed significantly over time and that those new relationships already address many of the risks the Stark law was enacted to prevent.

Outside of Medicare, 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 quality and efficiency of care for all patients and communities. However, due to the broad definition of "financial relationship" under the Stark law, 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 Stark law's payment and referral prohibitions. Uncertainty about the application of the Stark law and the potentially devastating consequences it imposes for violations have impeded those efforts. For example, earlier this month, during a presentation describing a Texas Medicaid newborn maternity care payment bundle rewarding providers

for efficient positive outcomes, stakeholders discussed fundamental limitations on the model's growth imposed by the Stark law and other enforcement laws.

The U.S. Congress has authorized waivers from the Stark law for the Medicare Shared Savings Program, and authorized the Secretary of the U.S. Department of Health and Human Services to create waivers for any programs initiated through the Center for Medicare and Medicaid Innovation. However, waivers under the Stark law are narrow in scope and time-limited. In order to promote systematic growth and innovation in value-based care, the Stark law's compensation regulations must be reframed to meet the objectives of the new system, through the creation of a new exception designed specifically for value-based payment methodologies, and reforms to the personal services, employment, and risk sharing exceptions. THA, therefore, supports the American Hospital Association's recommendation that CMS create a new innovative payment exception for value-based payment arrangements. The new exception should cover 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.

THA believes that implementing an innovative payment exception will promote payment and care delivery models that benefit patients through care coordination and increase efficiency through investment in electronic health record and other technological infrastructure that promotes coordination across the continuum of care, incentivizing efficient treatment, and rewarding team-based care coordination among physicians and other clinicians. In addition, THA supports the AHA's recommendations regarding modifying personal services and risk-sharing exceptions so that they are not limited to private insurance plans, and further agrees with AHA's assertion that modifying these exceptions alone is not a substitute for a comprehensive exception for value-based care arrangements.

CMS should provide clear, unambiguous definitions of critical requirements regarding compliance with the Stark law. Hospitals and providers spend countless hours attempting to structure arrangements in order to comply with the Stark law. However, even after extensive due diligence, Texas hospitals often are uncertain about what is acceptable under the law's requirements. Hospitals should know, in advance, exactly what is required so they can operate in compliance with the law. By providing clear, authoritative and timely guidance and clarity around the requirements with which hospitals need to comply in order to receive payment, CMS will enable Texas hospitals to invest in integrated care and innovative payment arrangements in a manner that is compliant with the Stark law. THA supports AHA's recommendation that CMS accept questions through the advisory opinion process that are deemed to result in favorable determination if unanswered within 90 days pending a formal CMS opinion.

Narrowing the Stark law's focus on arrangements that produce overutilization. The Stark law was intended to regulate compensation arrangements that reward self-referrals and improperly encourage utilization. Any requirement imposed should serve that purpose, or be eliminated.

Distinguish technical violations from substantive violations of the Stark law. THA believes significant compliance expenses incurred by Texas hospitals are to prevent technical violations of the Stark law—such as administrative

errors—rather than prevent substantive violations reflecting the law's intent. CMS should treat technical violations that result in little or no harm to the Medicare program with leniency, provide a mechanism for resolving Stark law complaints without implicating the False Claims Act, and/or establish a fixed penalty structure as a means to resolve all violations of Stark law. These recommendations would continue to forward the intent of the law while reducing enforcement-related costs incurred by physicians and hospitals.

Fair market value. Hospitals should be able to rely on the opinions of independent experts regarding fair market value. Hospitals routinely engage the services of third-party valuation consultants to evaluate physician compensation arrangements for compliance with the fair market value requirement under the Stark law. However, the Stark law does not provide any safe harbors or concrete protections for relying on these valuations. THA supports AHA's recommendation that compensation should be presumed to be fair market value if a hospital has received and acted in reliance of a valuation performed by an independent valuator.

In addition, the current CMS definition of "fair market value" under the Stark law creates significant uncertainty for hospitals and physicians. We strongly recommend that CMS restore the definition of fair market value to the original language of the statute. Guidance from 2001 made "general market value" (a subset of the definition of "fair market value") appear to require an examination of whether compensation takes into account the volume or value of referrals. The prohibition on taking into account the volume or value of referrals is separate and independent from fair market value; restoring the original statutory definition would clarify the difference.

Compensation that does not take into account the volume or value of referrals. The Stark law's prohibition on taking into account the volume or value of referrals has created confusion for providers and hospitals. CMS should make clear that the "volume or value" test is an objective test that does not depend on the subjective intent of the parties. If the arrangement does not involve a methodology for physician compensation that utilizes the volume or value of physician referrals, then there should be no violation. In addition, THA recommends that CMS clarify, for a fixed payment, the amount of compensation does not vary or take into account the volume or value of referrals if the amount is initially determined by a methodology that does not take into account referrals and is not subsequently adjusted during the term of the agreement based on referrals. Further, the Stark law should be amended to confirm that payments to physicians for personally performed services do not violate the volume or value prohibition, even if the personally performed services are related to (or correlated with) designated health services ordered by the physician. CMS has made it clear in rulemaking and published guidance that hospitals may pay physicians for their own personally performed work even if that work relates to DHS ordered by the physician. Despite this guidance, the Department of Justice has taken the position in enforcement actions that per-unit payments, *e.g.*, a per work RVU payment for services personally performed by the physician, are improper if that service also generates or is correlated with a DHS.

Commercial reasonableness. Despite guidance over the years on the definition of commercial reasonableness, there is still concern about what is needed to satisfy that prong of certain Stark law exceptions. Commercial reasonableness is focused on the need for and utility of the items or services purchased—the level of compensation is addressed by the Stark law's fair market value requirement. THA urges CMS either to abandon the commercial reasonableness prong altogether or to clarify that commercial reasonableness means that the services are reasonable and necessary for the legitimate business purposes of the arrangement. Ambiguity in the regulations has resulted in interpretations that go beyond the plain meaning of the statute.

Referral. THA recommends that CMS modify the definition of a referral in the regulations to clarify that an impermissible "referral" under the Stark law must result in either an additional payment or an increase in payment. Many interactions that qualify as a referral under the current definition do not actually result in any payment by Medicare. For example, an attending physician may order a consultation by a specialist for an already admitted inpatient. The specialist's consultation may result in an order for additional testing but will not affect the DRG payment to the hospital. The overutilization concern underlying Stark law is not present in this situation. However, under the current regulations, if the specialist has a financial relationship with the hospital that does not qualify for an exception, arguably the hospital's claim for the entire inpatient stay is subject to denial. This scenario contradicts Congressional intent as there is no risk of increased costs if the referral does not result in an increase in payment.

Alternative method of satisfying documentation requirements. Many of the compensation exceptions also contain writing and signature requirements at the inception of the arrangement. Although some of these requirements have been relaxed through recent legislation, the existing documentation requirements do not add any additional substantive protection against problematic arrangements. Instead, they serve as an audit trail to assess if there is a binding agreement. In practice, these paperwork requirements subject providers to potentially catastrophic payment denials for clerical errors even when an arrangement actually satisfies the substantive elements of an exception. THA urges a different approach: a hospital should be deemed to satisfy the writing and signature requirements when it demonstrates the existence of a binding, enforceable contract under applicable state law. There will not be any increase in the risk of problematic arrangements because the substantive protections are intact, and there will be a significant reduction in the potential for disallowances based on paperwork mistakes.

Compensation arrangement end-date. Currently, there is no fixed end-point for purposes of setting the period of disallowance on claims to Medicare for services referred by a physician who is a party to the arrangement. As a result, the potential is great for large disallowances that are wholly disproportionate to the non-compliance. A compensation arrangement should terminate 30 days after the physician or family member last receives compensation from the entity or items or services are provided under that arrangement. The fixed date will provide certainty to hospitals and the health care field, while maintaining a period of disallowance that will impose significant penalties and incentive to self-police.

Payments by a physician exception. THA urges a return to the Stark law's statutory language that broadly protected any payments made by a physician as long as the payment was consistent with the fair market value. CMS' regulations unreasonably narrowed application of the exception and as a result, innocuous arrangements that are not structured to incentivize utilization can result in large payment denials. There is no reason to deny hospitals the benefit of the breadth of Congress' exception. To the extent the same arrangement also might be covered by another exception, that should not prevent a hospital from relying on the payment-by-physician exception that provides a less cumbersome method of complying.

Eliminate requirement to comply with Anti-Kickback Statute. Finally, in order to give effect to any modifications made to the Stark law, THA urges CMS to de-couple Stark law and the anti-kickback statute by eliminating from regulatory exceptions to the Stark law the requirement that financial arrangements must not violate the federal AKS. Unlike the Stark law, which includes clear exceptions, the AKS uses safe harbors with lists of additional elements necessary for compliance. Coupling the Stark law with the AKS is unnecessary, duplicative and is an impediment to comprehensive, coordinated care by, for example, placing an unreasonable burden of proof on

entities seeking payment with no offsetting benefit or protection to the Medicare program. For the same reasons, the requirement that arrangements must not violate any federal or state billing or claims submission rules also should be removed. Providers have an independent obligation to comply with such rules. Inclusion of pre-existing legal requirements as an additional element for a self-referral exception provides no additional protection to federal health care programs or patients.

Thank you for your consideration of these comments. THA looks forward to working with the agency on reform to the Stark law. Should you have any questions, please do not hesitate to contact me at cduncan@tha.org or 512/465-1539.

Respectfully submitted,

Cameron Duncan
Assistant General Counsel
Texas Hospital Association