Testimony for the Record
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United States Senate Committee on Finance
for the Hearing Entitled
"Examining the Stark Law: Current Issues and Opportunities"

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Peter B. Mancino
Deputy General Counsel of
The Johns Hopkins Health System Corporation

Chairman Hatch and members of the Senate Committee on Finance, thank you for the opportunity to submit testimony on the timely and important subject of the "Stark Law."[1]

The Johns Hopkins Health System Corporation is a non-profit organization affiliated with The Johns Hopkins University School of Medicine. We serve as the parent to three academic medical centers, three community hospitals, and several physician groups. On the payor side, our health system includes a Medicaid managed care plan, a Medicare managed care plan, and other related businesses.

Since we are active on both the payor and provider sides and on both the academic medical center and community hospital sides, our health system has a unique perspective on the Stark Law. We view the Stark Law as the top compliance risk of our health system, because it is very easy to inadvertently violate Stark and the penalties are substantial. As a result, we have a keen interest in promoting common-sense revisions that will make Stark more understandable and less burdensome to providers.

We estimate that our health system currently spends over $600K dollars per year just on Stark compliance. Our compliance program includes regular Stark audits, training programs, and various contract and other tracking programs. Our compliance office includes a full-time Stark attorney, and we routinely seek outside counsel and consultant assistance with difficult Stark issues and fair market value reviews. We believe that an updated Stark Law could foster the Triple Aim while reducing the costs of compliance.

To be clear, we have no interest in facilitating overutilization of health care services or promoting health care fraud. Our health plan experience has demonstrated to us the importance of supporting the Triple Aim and high quality, cost-effective health care. However, our provider experience also has shown us how difficult and unfair the Stark Law can be.

[1] Section 1877 of the Social Security Act, 42 U.S.C. § 1395nn.

This testimony will focus on three dimensions in particular that would greatly improve the Stark Law and allow health care providers to partner with physicians to improve quality and reduce costs.

1. Eliminate the Ambiguity of Key Stark Terms

When the Stark Law was originally enacted by Congress,[2] the goal was to create a bright line test to address the overutilization of health care services resulting from inappropriate physician referrals. The problem is that this bright line test has been transformed over time into a complex and highly technical rule that includes over three dozen statutory and regulatory exceptions. Each exception contains a number of technical requirements, many of which are ambiguous and counterintuitive. In some cases, the exceptions have been redefined and reinterpreted on multiple occasions by the Centers for Medicare & Medicaid Services ("CMS"), and the advisory opinion process and recent judicial decisions have not provided needed clarity. Further, recent CMS Stark regulations, while helpful, have not addressed the core issues. As a result, considerable confusion remains in the provider community about Stark requirements.

Most notably, the terms "commercial reasonableness," "fair market value," and "varies with or takes into account " the "volume or value" of referrals each lack the clear definition necessary for providers to be certain of compliance despite their best efforts. As a health law attorney for twenty years, I have been confronted with numerous physician recruitments and other transactions that raise questions about the meaning of these terms, and no matter how much time, money or effort is expended in analyzing the issues, I have often had the unpleasant duty of informing a client that there are no clear or 100% safe answers. Given that Stark was intended to be an easy bright line test, we believe that the Stark Law should be amended to clarify key terms. Further, there should be a workable process for hospitals and other health care providers to obtain clear and timely compliance guidance.

2. Make Stark Penalties More Reasonable

The Stark Law's complexity and ambiguity has made it extremely difficult for even diligent health care providers with robust compliance programs to comply with Stark. Failure to satisfy even one of its technical requirements can result in a violation, and despite the best compliance efforts, unintentional mistakes occur.

Liability under the Stark Law can be staggering even for minor violations. For example, a provider may be required to refund any Medicare reimbursement received from impermissible physician referrals even when the violation concerns a low value contract, and additional penalties or treble damages may be assessed. The potential liability associated with an alleged Stark violation

[2] Section 6204 of the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989) – Pub. L. 101-239, December 19, 1989 – adding section 1877 to the Social Security Act prohibiting physician referrals for clinical laboratory services. This provision, known as Stark I, became effective January, 1992. Section 13562 of Omnibus Budget Reconciliation Act of 1993 – Pub. L. 103-66, August 10, 1993 - expanded the prohibition to ten designated health services (DHS) in addition to clinical laboratory services. This provision, known as Stark II, became effective January, 1995.

creates an enormous barrier to a provider's ability to defend against a claim, even when a provider has valid defenses. When faced with potential Stark liability, providers are often forced to settle. A federal appellate court judge recently highlighted this troubling result in a concurring opinion to a decision upholding a $237 million dollar judgment against Tuomey Healthcare System, stating, "even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure – especially when coupled with the False Claims Act."[3]

Most health care providers want to be compliant and are willing to be accountable for mistakes. However, accountability should not entail ruinous penalties. Recent judicial decisions like the Tuomey case have had a chilling effect on the health care industry causing clients to be reluctant to try creative arrangements (e.g., gainsharing, physician alignment strategies for population health, etc.) at a time when innovation is most needed. Accordingly, the Stark Law should be amended to make the potential penalties associated with Stark violations more reasonable.

3. Reform the Stark Law to Permit Innovative Payment Methodologies

The Stark Law imposes substantial limits on a hospital's ability to participate in innovative payment arrangements with physicians. For example, gainsharing and value-based payment arrangements are often problematic under Stark, because they are not susceptible to fair market value assessment and may take into account the volume or value of physician services. However, these types of arrangements promote care coordination, enhance quality, improve patient care experience and control costs. Given the changing face of medicine, including the recent enactment of MACRA,[4] innovative payment arrangements are needed.

Therefore, we support reforming Stark to allow hospitals to make incentive payments to physicians based on the physicians' achievement of quality metrics and cost-reduction targets. This change would be consistent with MACRA and the Triple Aim and would give hospitals an important tool in their efforts to enhance quality and reduce health care costs. We also support providing the health care community the ability to create other value-based payment arrangements that meet the same goals.

Conclusion

Now is the time for Congress to modernize the Stark Law to promote fairness and further the goals of MACRA and the Triple Aim. MACRA requires providers to innovate, but we need the tools and the freedom to do so. We urge Congress to act quickly to address our concerns so that the health care industry can transform itself to meet today's challenges.

Thank you for your consideration of this important topic.

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[3] *United States ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, No. 13-2219, 2015 U.S. App. LEXIS 11460 at *56, *69 (4th Cir. July 2, 2015) (Wynn, J., concurring).

[4] Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Pub. L. No. 114-10 (2015).