August 24, 2018

**VIA ELECTRONIC MAIL**

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Re: Request for Information regarding the physician self-referral law

Dear Administrator Verma:

The Health Care Transformation Task Force ("HCTTF or Task Force") would like to thank the Centers for Medicare and Medicaid Services (CMS) for seeking information from the public on how to address any undue regulatory impact and burden of the physician self-referral ("Stark") law on advancing a transition to value-based care.

The Task Force is a group of private sector stakeholders that support accelerating the pace of delivery system transformation. Representing a diverse set of organizations from various segments of the industry – including providers, health plans, employers, and consumers – we share a common commitment to transform our respective businesses and clinical models to deliver the triple aim of better health, better care, and reduced costs. Our member organizations aspire to have 75 percent of their business in triple aim focused, value-based arrangements by 2020. We strive to provide a critical mass of policy, operational, and technical support from the private sector that, when combined with the work being done by CMS and other public and private stakeholders, can increase the momentum of delivery system transformation.

When physicians are financially incentivized not by the volume of services but by the efficiency of services and treatment outcomes, their economic self-interest aligns with the interest to eliminate unnecessary services. Increasingly, the law intended to protect from overutilization and decisions based on financial interest – the Stark law -- has become a significant impediment to value-based payment models. In addition, CMS should consider additional areas for regulatory relief and become more flexible in payment policies to complete the journey to a person–centered health care system that promotes choice and emphasizes high quality, efficiency, and affordable care.

In this letter, the Task Force identifies areas where CMS can mitigate the impact of the Stark law on providers participating in alternative payment models to encourage better care coordination. There

are desired changes that will take an act of Congress, while CMS can accomplish other changes through rulemaking. In addition, CMS could provide sub-regulatory guidance through issuing Frequently Asked Questions and better guidance on existing waivers to the Stark law, which could also clarify misconceptions and alleviate existing but unnecessary burdens.

## I. Expand sub-regulatory guidance regarding the applicability of Stark law

With the implementation of Alternate Payment Models (APMs), CMS has recognized the need to waive certain fee-for-service requirements for APM participants.[1] Through existing waivers, APM participants have been able to better meet the needs of individual patients in a variety of innovative ways. Our members have been early adopters of Medicare's APMs and utilize the fraud and abuse waivers to support improved patient care. However, given the novelty of APMs, providers are understandably cautious to utilize waivers when applicability is unclear. Our members report uncertainty around the availability of particular waivers due to limited commentary about CMS's intended scope or applicability for particular APM participants. Given that waivers are currently available on an opt-in basis, this uncertainty has led some stakeholders to decline the opportunity out of fear of noncompliance if they implement a waiver incorrectly.

Despite CMS defining the methodology and program rules for APMs as well as administering program integrity oversight for APM participants, the Agency is currently not authorized to comment, informally or formally, on the application of the fraud and abuse waivers issued for the Model to each potential participant's unique circumstances. While this limitation is understandable, **we urge CMS to expedite and regularly update Frequently Asked Questions guidance documents and/or commentaries in response to recurrent questions regarding common provider circumstances**.[2] HCTTF would be pleased to collaborate with CMS in developing common provider situations on which guidance would be helpful. CMS and the Office of the Inspector General should also explore mechanisms for providers to ask questions for guidance about the waivers short of a traditional Advisory Opinion.

When regulated entities have abundant sub-regulatory guidance on their legal compliance requirements under Stark, entities will have a better understanding of what activities are and are not permitted. If CMS were to provide more frequent and timely sub-regulatory guidance on Stark, this in itself could reduce some of the regulatory burden of Stark compliance and may encourage more providers to participate in APMs.

## II. Streamline available waivers in the context of alternative payment model arrangements

CMS should also specify a core set of waivers for all APMs which would serve as a minimum approach to regulatory relief, without the need for an opt-in approach, and CMS could add additional waivers on a model-by-model basis. With the plethora of APMs now being tested by CMMI, a hodgepodge of regulatory waivers exists. With different waivers applying to different models, there is confusion about the applicability of these waivers. For instance, there is extreme confusion in the

[1] https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Fraud-and-Abuse-Waivers.html

[2] We note that CMS has issued numerous FAQs under other statutes, as have other agencies, to provide regulated entities guidance on frequently-occurring fact patterns to assist in compliance.

market place about how the BPCI program gainsharing waivers and Medicare Shared Savings Program (MSSP) waivers interact when an entity is participating in both programs.

HCTTF believes that a core set of waivers for all APMs would go a long way in alleviating the current confusion. Additionally, members report that the process for implementing the waivers can be burdensome and confusing as it differs among models, and requires additional data collection and reporting to comply. HCTTF recommends that CMS establish one uniform process for waiver implementation, to assist in compliance. CMS should align waiver language and applicability around the APM entity definitions defined by the Quality Payment Program to further gain efficiencies across multiple CMS programs.

## III. Modify existing exceptions to the physician self-referral prohibition and/or create new exceptions for risk-taking alternative payment model participants

CMS also needs to modernize its fraud and abuse policies through regulation to support value-based care and allow for greater care coordination within the construct of APMs. With the risk-sharing provisions of advanced APMs, providers are taking on a given percentage of risk related to overall revenue. This type of risk arrangement between providers and payers for services provided to APM-aligned beneficiaries is analogous to the risk arrangements defined in existing exceptions. The current risk-sharing exceptions to Stark law referral prohibitions in 42 CFR § 411.357(n) need to be modified.[3] **CMS should expand this existing exception to apply to compensation arrangements as a part of alternative payment models.**

## IV. Recommendations on Stark definitions

### *a. Fair Market Value*

The Stark law generally requires remuneration to be set at fair market value (FMV) and not determined in a way that takes into account the volume or value of referrals to the entity. In Question 10 of the RFI, CMS solicits comments on possible approaches to modifying the definition of FMV. HCTTF recommends that CMS clarify, in regulation or guidance, the definition of fair market value (FMV), and establish simpler and standard processes for establishing FMV. We recommend redefining FMV to account for value-based payment models and provide flexibility to allow collaboration among various stakeholders. Additionally, HCTTF recommends that CMS issue regulations or guidance on establishing and documenting FMV in value-based payment settings. A new definition of FMV and standards for documenting FMV should include safeguards relating to quality, payment caps, and similar criteria to ensure accurate assessment in a value-based environment without compromising program integrity or patient access.

### *b. Volume or Value*

The Stark law and Anti-Kickback Statute prohibit the payment or receipt of remuneration based on the volume or value of referrals of services paid for by a federal healthcare program. Question 11

[3] Exceptions to Stark law referral prohibition are defined at 42 CFR § 411.357(n) for compensation pursuant to risk-sharing arrangements between a managed care organization or independent physician association and a physician for services provided to enrollees of a health plan.

solicits comments as to when, in the Stark context, compensation should be considered to "take into account the volume or value of referrals." While not specifically addressing CMS' request, we believe that CMS could also make changes to this requirement to ease its application.

HCTTF proposes that CMS issue regulatory guidance on how to apply the "volume or value of referrals" standard within the changing healthcare payment environment. For example, this guidance could clarify whether incentive payments to improve quality, even if they partially reflect the volume or value of a provider's referrals, are permissible. To protect against fraud or abuse, the definition could include quality of care requirements to ensure that variable payment rates based on volume or value vary solely or primarily on outcomes. CMS should solicit stakeholder input on the quality of care requirements to apply in this definition.

## V. Legislative action needed to further modernize fraud and abuse laws

There are clear actions that CMS can take now to improve the impact of the Stark law on innovative new payment models that hold providers accountable for cost and quality outcomes, but further action is needed from Congress to create a policy framework conducive to shifting care to value-based models. CMS and Congress should work to align the Stark Law with the Anti-Kickback Statute, to ensure consistency across governing agency interpretations. This may include making conforming changes to the Anti-Kickback Statute and/or its implementing regulations, ensuring that modified Stark language aligns with existing Anti-Kickback provisions, and/or issuing joint agency guidance discussing how to approach and manage changes to either or both laws.

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The Task Force appreciates the opportunity to advise CMS regarding the impact of the Stark law on success of alternative payment models and anticipates upcoming opportunities to offer recommendations to the Office of the Inspector General regarding the impact of the Antikickback Statute on the ability to innovate. Please contact HCTTF Executive Director Jeff Micklos (jeff.micklos@hcttf.org or 202.774.1415) with questions related to this statement.

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