Cancer Treatment Centers of America®

Comprehensive Cancer Care Network

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August 24, 2018

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

Re: **Comments in Response to CMS–1720–NC, Request for Information Regarding the Physician Self-Referral Law**

Dear Administrator Verma,

We strongly support CMS's efforts to address the regulatory burden and obstacles to innovation imposed by the Stark Law and are pleased to provide comments to assist CMS in understanding how reform can remove barriers to healthcare quality and efficiency.

Cancer Treatment Centers of America, Comprehensive Cancer Care Network ("CTCA") is the only national network of cancer care hospitals (as well as clinics and physician practices) specializing in the treatment of cancer. Founded in 1988 on a personalized, patient-centered approach to cancer care, CTCA tailors a combination of cancer treatments to the needs of each individual patient. From genomic tumor assessments to state-of-the-art technologies and evidence-informed supportive therapies that target cancer-related side effects, comprehensive services are delivered by a team of cancer experts, all under one roof. As CTCA seeks to extend its patient-centered approach and meet the growing national demand for cancer care by partnering with physicians' practices and other providers, we encounter regulatory limitations that we believe unreasonably limit these arrangements. As explained more fully below, many of these limitations arise under the Stark Law and discourage or prohibit otherwise lawful and economically reasonable arrangements.

The Stark Law is ill-suited to the realities of the current healthcare marketplace – a marketplace that has undergone fundamental transformation since the Stark Law

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was first enacted in 1989. The Stark Law imposes arbitrary rules that impede development of new and innovative arrangements designed to achieve CMS's Triple Aim of improving patient care, reducing healthcare costs, and improving population health.

We recognize that CMS is constrained by the statutory language in the Stark Law, but we believe the agency has the authority to make meaningful changes to the Stark Law regulations that will better effectuate Congress's intent and align the Stark Law with the realities of the current healthcare marketplace and enforcement environment. Without these changes, the Stark Law will continue to frustrate efforts to achieve a value-based, patient-centered health care system.

1. CMS should assess the Stark Law and its implementing regulations from the perspective of the realities of the current landscape.

Enacted almost thirty years ago in the context of a healthcare delivery system that bears little resemblance to the landscape in 2018, the Stark Law has become an anachronism. In the 1990s, Medicare was a fee-for-service program that provided substantial incentives for overutilization. Today, the Medicare program has been transformed into a complex system of alternative payment models, including bundled payments and other risk-sharing arrangements. This transformation continues, with providers facing continuing pressure to embrace value-based care. In a value-based health care system, physician compensation is tied to efficiency and quality of care, not volume. As a result of the evolving payment model, physician economic self-interest aligns with the interest in eliminating unnecessary services. Indeed as explained more fully below, the Stark Law in its current form severely inhibits innovation that could otherwise accelerate the shift toward quality of care models and improved patient outcomes.

The health care enforcement landscape has also undergone substantial transformation since the time the Stark Law was first enacted. At that time, there was concern that regulators were constrained by the heightened burden of proof and expense of pursuing criminal prosecutions under the Federal Anti-Kickback Statute ("AKS"). Those limitations no longer exist as Congress has adopted civil monetary penalties to address AKS violations, requiring a lower burden of proof. The AKS has thus become a dominant force in the regulation of physician arrangements, particularly when coupled with the Federal False Claims Act ("FCA") and the growth of the relator bar.

CMS's understanding of the Stark Law and the agency's role in implementing the law's requirements must necessarily take into account these changes to the health care marketplace and the enforcement landscape.

2. The Stark Law imposes arbitrary restrictions on permissible physician arrangements, needlessly restricting a health system's ability to enter into meaningful alignments with physicians.

Since its enactment, the Stark Law has evolved into a hopelessly complex regulatory scheme that imposes arbitrary restrictions on physician arrangements. These arbitrary restrictions inhibit the ability of health systems and physicians to develop meaningful alliances, stifling innovation in favor of a series of Hobson's choices that inevitably fall well short of achieving meaningful change.

Ultimately, what the Stark Law allows versus what it prohibits bears no meaningful relationship to the risk of overutilization, which is the fundamental policy concern the Stark Law is intended to address.

For example, the Stark Law allows a single oncology group to own capital-intensive therapeutics – such as a radiation therapy center – to which the group's physicians refer all of their patients, and to distribute to those referring physicians the profits from all the radiation therapy services furnished at the center. The Stark Law does not, however, allow multiple oncology groups to pool their capital to create a single freestanding radiation therapy center to which they refer their patients and distribute the profits out to the referring physicians. As a result, there is inefficient and duplicative deployment of capital, adding needless costs to the health care delivery system. Similarly, the Stark Law allows an oncology group to operate an infusion center and distribute the profit from infusion services out to the group's physicians who refer their patients for chemotherapy. In contrast, if a hospital joint ventures with an oncology group and, for reasons of efficiency, care coordination, and optimal clinical care, the physicians refer patients to a hospital-based infusion center, the Stark Law would prohibit the joint venture from distributing profits from those infusion services out to physicians. The Stark Law directly incentivizes physician groups to do alone what they cannot do through partnerships, discouraging collaboration in favor of siloed care.

We encourage CMS to consider the inequities that result from the web of arbitrary rules reflected in the current regulations. In particular, we encourage CMS to allow for more meaningful hospital-physician alignments, including joint ownership and shared-profit distributions for ancillary services. We believe that with appropriate safeguards, these types of arrangements can more effectively align physician and hospital economic interests with the goals of meaningful care coordination and cost containment.

Specifically, we believe CMS should consider modifications to the In-Office Ancillary Services exception and the definition of "Group Practice" to allow physician groups to enter into joint ventures for ancillary services that do not present any greater risk of program or patient abuse

than arrangements that are currently permissible under the Stark Law. In particular, we believe that the *nature of the ancillary services* at issue and *the parties to the joint venture* are key factors in safeguarding against such risk. For example, we believe hospital-physician joint ventures for ancillary services where the ancillary services at issue are a natural extension of the physician practice's operations (e.g., a medical oncology practice joint venture for an infusion center) promote care coordination and accountability and present minimal risk. Similarly, we believe that CMS should allow physician practices to enter into joint venture arrangements where the nature of the services and the parties to the joint venture clearly demonstrate that the arrangement is intended to facilitate vertical alignment to provide coordinated care. CMS can allow these types of arrangements by modifying the In-Office Ancillary Services exception, which currently allows designated health services to be performed by a wholly-owned subsidiary of a single group practice, to extend to designated health services performed by a subsidiary that is partly-owned by a hospital.

3. CMS should address ambiguities in the existing regulations by adopting bright line rules for the core substantive requirements regarding fair market value, takes into account, and commercial reasonableness.

The Stark Law imposes a substantial regulatory burden on hospitals and physicians, which ultimately has the effect of driving increased costs for the entire healthcare system. Among the key drivers of this burden is the lack of objectivity and clarity in the three core requirements that are included in virtually every compensation exception: fair market value, takes into account, and commercial reasonableness. We believe that adopting clear, bright line rules surrounding these requirements will introduce much needed certainty and, ultimately, alleviate the regulatory burden and associated administrative costs. We note that "bright line" rules were exactly what the Stark Law was supposed to provide, in the words of Congressman Pete Stark himself:

> "What is needed is what lawyers call a bright line rule to give providers and physicians unequivocal guidance as to the arrangements that are prohibited. If the law is clear and the penalties are substantial, we can rely on self-enforcement. Few physicians will knowingly break the law. The Ethics in Patient Referrals Act provides this bright line rule."[1]

We also believe that the ambiguities in these standards are the principle obstacle to development of new value-based payment models. Clarity and certainty surrounding these standards will thus directly serve CMS's goal of promoting innovation. While we support potential new exceptions that are specifically targeted at alternative payment models, we do not believe such exceptions can adequately address the existing Stark Law obstacles without CMS directly addressing the

[1] 135 CONG. REC. H240-01 (daily ed. Feb 9, 1989)(statement of Rep. Stark).

need for bright line rules surrounding *fair market value, takes into account,* and *commercial reasonableness*.

These three concepts have also become needlessly and incorrectly conflated. We encourage CMS to return them to their intended meaning, where fair market value is a question of the *amount* of compensation under an arrangement, takes into account is a question of the *nature* of the compensation under arrangement, and commercial reasonableness is a question of the *rationale* for the arrangement.

(a) Fair Market Value

We recommend that CMS adopt a clear, objective standard for fair market value and establish a presumption that arrangements are fair market value unless proven otherwise.

Fair market value should be defined in a clear, straightforward manner as the range of values that two hypothetical parties, negotiating in good faith, would agree upon as the price, which is exactly how fair market value is understood in every other sector of our economy. Under the current Stark framework, fair market value is defined as the result of bona fide bargaining between well-informed parties who are not otherwise in a position to generate business for the other party. Whether the parties are in a position to generate business for each other should not be part of the equation, and is not mentioned in the statutory text. The concept of fair market value is that the open marketplace determines value. Introducing consideration of what a particular party or person might have been thinking at the time of a transaction introduces a subjectivity to the assessment that creates uncertainty and adds unnecessary complexity. The parties to a transaction may enter into that transaction for any number of reasons. Fair market value is not intended to police the rationale for a transaction; it is intended to ensure the actual economic value is within an acceptable range as determined by the marketplace.

CMS should establish that an arrangement is presumed to be fair market value unless proven otherwise. Under the current Stark Law framework, because fair market value is an element of the exception, the burden rests entirely on the entity – in our case, the hospital – to demonstrate that an arrangement is fair market value. The courts have characterized it as an affirmative defense. As a result, qui tam relators have been able to bring baseless claims of excessive compensation in FCA actions and survive motions to dismiss, forcing hospitals to choose between massive legal expenses to pursue discovery and prove their compensation arrangements are compliant or entering into a settlement to end the matter – paying what amounts to nothing more than a ransom payment.

The current framework, which presumes that compensation is *not* fair market value, also reflects an outdated view of hospital-physician arrangements. At the time of the Stark Law's enactment,

providers and physicians operated as separate and distinct components in the marketplace. Today, the lines between these components have been all but erased in favor of alignments that promote accountability and coordination across the full continuum of care. A regulatory posture that disfavors these types of arrangements is an anachronism that counterproductively creates a substantial regulatory burden on providers.

(b) Takes Into Account

The concept of "takes into account" has become a catch-all, potentially ensnaring any compensation where a party considered the potential referrals that may result from an arrangement. We encourage CMS to instead adopt a bright line rule that makes clear that compensation that does not fluctuate with a physician's referrals does not take into account the volume or value of his or her referrals. CMS can establish this type of rule through a deeming provision, similar to the other deeming provisions currently set forth at 42 C.F.R. § 411.354(d). Such an approach would offer much needed certainty to providers in developing their compensation models without creating any risk of program abuse. To the extent the non-fluctuating compensation is actually excessive, that would still be addressed under the fair market value requirement. If the non-compensation terms of the arrangement inappropriately favored the physician, this could be addressed under the commercial reasonableness requirement. The concept of "takes into account" would be rightfully limited to an inquiry into the form of the compensation.

We are also aware that, notwithstanding CMS's repeated statements that all physicians may be paid a productivity bonus based on their personally performed services, other government agencies have continued to advance a theory that such bonuses impermissibly take into account the volume or value of a physician's referrals when they generate a corresponding facility fee. We believe this "correlation" theory is directly at odds with the plain meaning of the existing Stark Law regulations, and we believe CMS has been clear in its view. Nonetheless, providers are being forced to defend against this legal theory, and it has gained the apparent support of at least one court[2]. We therefore encourage CMS to adopt clear regulatory language that a bonus based on personally performed services that generate a corresponding facility fee does not result in compensation that "takes into account" the volume or value of referrals. We believe this can be accomplished in a number of ways, including through the deeming provision at 42 C.F.R. § 411.354(d) suggested above.

[2] *See United States ex rel. Drakeford v. Tuomey (Tuomey II)*, 792 F.3d 364, 379-380 (4th Cir. 2015).

(c) Commercial Reasonableness

We believe that the question of "commercial reasonableness" should be understood as an inquiry into whether the items or services being purchased are useful in the purchaser's business and purchased on terms and conditions typical of similar arrangements between similarly situated parties. The concept should be limited to the noneconomic aspects of the arrangement. The amount and nature of the payments are properly and separately addressed under the fair market value and takes into account requirements.

4. Preemption of State Laws

The proliferation of so called "mini Stark" laws among the states should be addressed in manner to eliminate conflicts between these state statutes and the Stark Law (as reformed based on the suggestions above). The existence of multiple and often conflicting state rules has the natural effect of limiting the development of a national market in healthcare services, reducing choices for consumers and raising the cost of healthcare. We recognize that preemption of such laws may be a more proper subject for action by Congress rather than agency regulation. We include this suggestion here, however, to urge CMS to consider supporting legislation to achieve this end.

Respectfully Submitted,

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