



August 24, 2018

Seema Verma  
Administrator  
Centers for Medicare and Medicaid Services  
Hubert H. Humphrey Building, Room 445-G  
200 Independence Ave, SW  
Washington, DC 20201

Re: Request for Information Regarding Physician Self-Referral Law [CMS-1720-NC]

Dear Administrator Verma,

On behalf of the American College of Physicians (ACP), I am pleased to share our comments on the Centers for Medicare and Medicaid Services (CMS') Request for Information Regarding Physician Self-Referral Law. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

ACP commends the administration for recognizing the need to update the physician self-referral (e.g. "Stark") law and reducing its unnecessary negative impact on administrative burden. We appreciate the opportunity to provide comments on necessary changes. Under a fee-for-service system (FFS), there are certain financial incentives for providers to self-refer patients or over-utilize services. As a result, the Stark Law draws a hard line and prohibits physicians from referring Medicare and Medicaid patients to an entity in which the referring physician has a "financial relationship" in for certain "designated health services" (DHS). Violations of these prohibited referrals are punishable by civil monetary penalties in the tens of thousands of dollars per incident, regardless of intent. Stark Law has been central to protecting the integrity of the Medicare program in a volume-based system by reducing fraud and abuse and ensuring taxpayers' resources utilized effectively in the provision of necessary care.

However, since the last time Stark Law was significantly modified in 1993, Congress has undertaken legislative efforts through the *Medicare Access and CHIP Reauthorization Act of 2015* (MACRA) to transform the health care system from one that is volume-based to one that is value-based. Under MACRA, physicians are incentivized to participate in Alternative Payment Models (APMs) that financially reward physicians for providing high-quality care with reduced costs through care coordination and risk sharing. In a system where physicians are inherently penalized for inefficient and ineffective care, the risk of overutilization greatly diminishes. Accordingly, the hard lines drawn by Stark Law impose burdens and barriers that are no longer necessary under a value-based payment system. Of even greater concern, these regulatory controls actually inhibit innovations in care integration, care coordination, and patient engagement, which are beneficial both to the health of individual Medicare beneficiaries and the long-term solvency of the Medicare Trust Fund.

The College offers comments on the following questions on modernizing physician self-referral law for the current medical environment which are discussed in greater detail within this letter:

**2. What, if any, additional exceptions to the physician self-referral law are necessary to protect financial arrangements between DHS entities and referring physicians who participate in the same alternative payment model?**

The College supports the Stark Law's overall goals of decreasing overutilization and improper utilization, protecting the integrity of the Medicare program, and countering the adverse influence of financial incentives on medical decision-making. At the same time, we recognize the need and support efforts to modernize the Stark Law to reduce administrative burdens on physicians and clinicians as well as reduce unnecessary barriers to physician and other healthcare professionals working together through APMs to improve patient outcomes, quality, and value of care. Under current law, physicians are prevented from being paid when their revenue is derived based on the "volume or value" of DHS referrals. The move towards APMs and a value-based system is centered on the idea that emphasizing care coordination and integration and tying payments to outcomes for episodes of care are integral to reducing costs and increasing quality of care. While the "volume or value" prohibition may have made sense in a FFS system where clinicians may have had a financial incentive to induce the provision of unnecessary care, it prevents APMs from financially rewarding participating physicians for providing high-quality care and holding them accountable for failing to adhere to best practices and patient outcome standards. For example, current law interferes with the implementation of gainsharing arrangements, where institutions award physicians a share of reduction of patient care costs. While these positive financial incentives can innovate care delivery and services, save patients and government payers money, and improve the patient experience through encouraging quality and efficient care, this arrangement could be perceived as running afoul of the "volume or value" provision of the Stark Law.

The misalignment in goals between existing self-referral law and new payment and delivery reforms has created an environment unsupportive of the development of new APMs. Currently, new APMs cannot be field tested during the approval process without waivers assuring their protection from self-referral law; however, current requirements mandate that an APM must

be approved before it can be granted a waiver. Groups are hesitant to invest the substantial time and resources in designing and developing new innovative payment models if they aren't assured that they will be able to test it before finalizing it, or else run the risk of running afoul of the Stark Law. This current paradigm creates a paradoxical situation for providers, drastically restricting the growth and development of APMs.

Through existing law, Congress laid the groundwork for providing flexibility in the transition from FFS to value-based payments. Provisions in the law authorize the Secretary of Health and Human Services (HHS) to create Stark Law waivers and exemptions for innovative payment and delivery service models. As a result, participants of the Bundled Payments for Care Improvement initiative (BPCI), Medicare Shared Savings Programs (MSSP), Comprehensive Care for Joint Replacement (CJR), and Accountable Care Organizations (ACOs) have been exempted from Stark Law requirements. While existing waivers have provided some flexibility for physicians, they are limited in utility because they are specific to certain arrangements and are limited in duration.

**In improving the Stark Law, CMS should expand waivers to Stark Law provisions to promote increased innovation and participation in new value-oriented APMs.** This expansion should include new programs being developed and tested through the Center for Medicare and Medicaid Innovation (CMMI) and qualifying APMs under MACRA. For example, waivers that were authorized under 42 U.S.C. 1395jjj(f) to protect ACOs eligible for MSSP could be expanded to cover physicians engaged in APMs in order to protect the wide variety of different approaches undertaken to improve quality and reduce costs of care. Exceptions at 42 U.S.C. 1395nn(b), which currently applies to ACOs, could be expanded to standardize the application of the Stark Law to all federally authorized innovative payment models.

New exceptions should be created for value-based payment arrangements that allow for physicians to be compensated based on "value or volume" of referred DHSs in the context of APM risk-sharing and gainsharing mechanisms. Similarly, new exceptions should be created to authorize innovative and collaborative care delivery approaches, such as integrated delivery systems and care coordination, by allowing incentive and infrastructure compensation and assistance to reward high-quality and efficient care delivery. For example, facilities and physicians would have an aligned incentive to coordinate in order to provide quality and efficient care to patients that enables high outcomes at low costs. Electronic health record (EHR) systems are instrumental in facilitating this care coordination by transmitting patient information throughout the continuum of care to enable appropriate diagnoses and treatments and track outcomes. However, existing law limits facilities from financing costly EHR and data analysis infrastructure for physicians, even when such coordination can improve decision making and is in the best interests of the patient, treatment facility, and physician.

Additionally, CMS should make the temporary exceptions and waivers permanent in order to give physicians certainty and stability while making MACRA participation decisions.

**9. Please share your thoughts on possible approaches to defining "commercial reasonableness" in the context of the exceptions to the physician self-referral law.**

In order to significantly improve the Stark Law, compensation rules need to be modernized, including clarifying and broadening the methodology used to define terminology relating to Stark Law compliance, including “commercial reasonableness”. CMS considers “commercial reasonableness” to mean that “an arrangement appears to be a sensible, prudent business agreement, from the perspective of the particular parties involved, even in the absence of any potential referrals.” Meeting “commercial reasonableness” is a required criterion for eight of the existing exceptions under the Stark Law. ACP contends that the current definition is too subjective and vague, making it difficult for physicians to understand and comply. As the definition currently stands, it could be interpreted in a way that discourages the integration of different types of providers in an effort to promote care coordination. For example, a group’s employment of a physician or acquisition of a practice may be a net loss for the group and hence fail to meet “commercial reasonableness” standards, even if it results in more effective and high-quality care for the patient through care coordination. In order to facilitate physicians’ transition to a value-based system, CMS should clarify the definition of “commercial reasonableness” and make it clear that value-based and care-coordination centric relationships would not violate this clause because the amounts appear “unreasonable” from a purely business standpoint.

**10. Please share your thoughts on possible approaches to modifying the definition of “fair market value” consistent with the statute and in the context of the exceptions to the physician self-referral law.**

Similar to the uncertainty and confusion surrounding “commercial reasonableness,” the definition for fair market value (FMV) must be clarified in order to reduce confusion amongst physicians seeking exceptions under the Stark Law. The Stark Law currently defines FMV as “the value in arm’s-length transactions, consistent with the general market value... where the price or compensation has not been determined in any manner that takes into account the volume or value of anticipated or actual referrals,” with “general market value” defined as “the compensation that would be included in a service agreement as the result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party on the date of the acquisition of the asset or at the time of the service agreement.” Many existing exceptions to the Stark Law rely on the FMV criteria to determine eligibility. However, the lack of precise standards as to what qualifies FMV creates immense administrative burden and confusion for physicians, and many must rely on costly consultants to make evaluations. The College urges CMS to provide additional guidance on this definition so physicians may have more clarity and certainty in whether they are in compliance. **Specifically, CMS should remove the “volume and value” aspect from the definition of “fair market value” in order to accommodate APMs and other innovative care delivery and payment models that enable and reward physicians for providing efficient and effective quality care.** Under the current definition of FMV, compensation arrangements that reward physicians for providing high-quality, cost-effective care could be interpreted as violating the “volume and value” provision—seemingly at odds with Medicare’s payment and delivery reforms.

**13. Please share your thoughts regarding whether and, if so, what barriers exist to qualifying as a “group practice” under the regulations at 42 CFR 411.352.**

The College is concerned about potential unintended liability under the Stark Law within the MIPS track under MACRA in the context of the existing requirements to qualify as a “group practice.” To be considered a group practice under 42 CFR 411.352, the practice must be (a) a single legal entity (b) made up of at least two physicians who are members of the group that (c) provide a variety of care services and are a unified business with centralized decision making, billing, and accounting. Further, at least 75% of the services provided by the group members must be furnished and billed under the group billing number, with exceptions for those located in or providing services in a Health Professional Shortage Area (HPSA). Group members cannot receive compensation based on volume or value of referrals.

Under MIPS, practices are permitted to combine with others and form a “voluntary virtual group” to establish formally or informally a set of agreed-upon clinical protocols that will be used by all virtual group participants to try to achieve a high performance score within the quality performance category in MIPS. It is possible that in forming virtual groups, practices may begin to resemble the characteristics of a group practice, yet may not meet the defined requirements of being classified as a group practice for purposes of the Stark Law. Hence, ACP calls on CMS to investigate this potential unintended liability and either expand the definition of a “group practice” to encompass virtual groups or create a safe harbor for MIPS virtual groups.

**18. Please share your thoughts on the compliance costs for regulated entities.**

The College warns against requirements and regulations that add unnecessary administrative burden that keep physicians away from their patients and contend that the added costs for compliance run counter to CMS’ goal of providing efficient and effective care. To comply with the Stark Law, practices must expend additional resources employing attorneys, analysts, and compliance specialists to evaluate their financial relationships and compensation arrangements. For example, contracting consultants to ensure physician compensation complies with the Stark Law can cost upwards of tens of thousands of dollars to review just one compensation agreement. For small practices, these costs cut deep into slim operating budgets while for large practices, compliance costs can easily add up to hundreds of thousands, if not millions, of dollars, which ultimately increases the cost of care for patients. **In line with the College’s [Patients Before Paperwork initiative](#), ACP calls for rigorous research on the effect of Stark Law-related administrative tasks on our health care system in terms of quality outcomes, staff time, and cost of care for clinicians and practice staff, as well as patients and their families.**

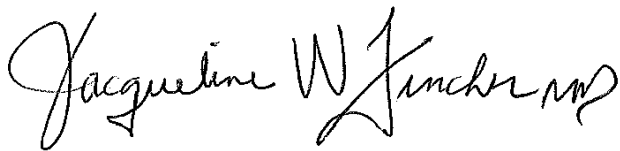
**Conclusion**

As the American health care system evolves to focus on value, stakeholders should review and consider streamlining or eliminating duplicative requirements. The College urges the Secretary to: 1) identify barriers and unnecessary burdens that the Stark Law and related regulations

place on the delivery of value-oriented care that the administration will intend to address, and 2) begin identifying solutions to minimize or remove these barriers and burdens that could include but is not limited to expanding existing and creating new waivers and exceptions, clarifying existing terminology and providing additional context for common scenarios that do and do not violate Stark provisions, and address or terminate provisions inhibiting value-based compensation models for physicians. ACP further stresses the importance to the Secretary of engaging stakeholders throughout the entirety of the process of reevaluating the Stark Law in the era of value-based payment and delivery reforms.

Thank you for considering our comments. Please contact Brian Outland by phone at 202-261-4544 or email at [boutland@acponline.org](mailto:boutland@acponline.org) if you have any questions or need additional information.

Sincerely,

A handwritten signature in black ink that reads "Jacqueline W. Fincher MD". The signature is written in a cursive, flowing style.

Jacqueline W. Fincher, MD, MACP  
Chair, Medical Practice and Quality Committee  
American College of Physicians