August 24, 2018

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

Re: Medicare Program; Request for Information Regarding the Physician Self-Referral Law

Dear Administrator Verma:

The Physicians Advocacy Institute (PAI) appreciates the opportunity to provide comments on the Request for Information (RFI) Regarding the Physician Self-Referral Law. Through the RFI, the agency is seeking comments on how the existing self-referral law (commonly known as “Stark Law”) creates barriers to participation in and implementation of effective integrated delivery models, alternative payment models (APMs), and other value-based care arrangements. Additionally, the RFI seeks input on potential revisions or additions to exceptions to the physician self-referral law, as well as on the appropriate terminology and definitions that could be considered for adoption and on the role of transparency safeguards.

PAI is a not-for-profit organization that was established to advance fair and transparent policies in the health care system to sustain the profession of medicine for the benefit of patients. As part of this mission, PAI seeks to better understand the challenges facing physicians and their patients and to educate policymakers about these challenges. PAI also develops tools to help physicians prepare for and respond to policies and marketplace trends that impact their ability to practice medicine. PAI’s Board of Directors is comprised of CEOs and former CEOs from nine state medical associations: California Medical Association, Connecticut State Medical Society, Medical Association of Georgia, Nebraska Medical Association, Medical Society of the State of New York, North Carolina Medical Society, South Carolina Medical Association, Tennessee Medical Association, and Texas Medical Association, and a physician member from Kentucky. As a physician-based organization, PAI is equipped to provide comments and insight into many of the challenges facing the medical profession.

PAI strongly supports the agency’s efforts to modernize the physician self-referral law and adopt policies that promote patient choice and access to care. We share the agency’s goal to reduce “regulatory burden and dismantling barriers to value-based care transformation, while also protecting the integrity of the Medicare program.” We believe efforts to modernize the self-referral law will enhance opportunities to improve the health care system with innovative approaches to physician collaboration while taking into consideration the law’s original goal to deter care decisions motivated by financial self-interests. Based on our members’ extensive expertise, we provide comments and proposals in response to questions posed in the RFI.
Overview
The physician self-referral law was enacted in 1989 to help ensure that health care decisions be driven by patient choice and needs and not by physicians’ personal financial interests and profits. There was concern that there may be overutilization of unnecessary and more expensive services that may be low-quality care. In response, under the law, physicians are prohibited from making referrals for certain designated health services (DHS) to an entity with which either the physician or an immediate family member may have a financial interest. Certain exceptions exist to the law. However, as noted by CMS, the law is often considered a key obstacle to participation in integrated delivery models, alternative payment models (APMs), and other value-based payment arrangements. These care innovations are a testament to the evolution of medicine after the law’s 1989 enactment, which also merit its modernization.

CMS has been encouraging physicians to bear more accountability for the total costs of their patients’ care, both through APMs involving two-sided risk and through the Quality Payment Program (QP). These programs and opportunities help limit the concerns that gave rise to self-referral restrictions because these new payment model approaches discourage provision of low-value care. In order for these efforts to succeed; however, providers need not only appropriate incentives but also tools to coordinate their patients’ care and manage their illnesses and their health effectively and efficiently. Physicians often seek employment arrangements that protect them against the risk of self-referral penalties. Without changes in the regulations governing self-referral, the result may instead be greater consolidation of providers into large groups. The resulting reduction of competition in provider markets could raise costs for health care, reduce quality of care, or both.

As described in greater detail below, the existing self-referral law inhibits the development of new financing and care delivery arrangements focused on care coordination and improving outcomes. Specifically, the law restricts certain types of practice arrangements and adds administrative complexity. Those factors can lead physicians desiring to pursue innovative approaches to seek employment in larger health systems or closed referral networks. Additionally, they may prevent smaller practices from testing or adopting new approaches to care delivery.

To address those constraints and promote the adoption and development of value-based care models, PAI recommends the following key steps:

- Establish clear exceptions to self-referral restrictions for payment models that promote value-based care.
- Provide exceptions for smaller physician practices that lack the resources to conduct exhaustive compliance reviews and limit penalties for initial violations to encourage innovation.
- Revisit and lift restrictions on physician-owned hospitals to promote physician-led initiatives to deliver value-based care.
- Provide additional clarity about risk as well as flexibility in the application of “fair market value” standards given the difficulties in measurement.

Barriers created by physician self-referral laws
The self-referral law significantly impedes physician participation in as well as functions of existing and potential APMs and other novel financial arrangements in several ways:

- Physicians find that the law is complex and difficult to navigate, particularly with the web of referral relationships and corporate structures (and related tax issues) that have evolved since its implementation. Obstacles presented by those relationships—especially administrative and
reporting burdens—can prevent, stall, or delay collaborative activities and payment arrangements. This can hinder the provision of high-quality, coordinated care, and access to and availability of necessary services.

- There is confusion about when and how the law and its waivers and exceptions apply, especially given inconsistent interpretations of permitted arrangements at both federal and state levels. Because of this inconsistency, physicians face burdensome compliance costs. Particularly, small and medium-sized practices, and especially solo practitioners may be interested in entering innovative arrangements but fear the potential risk of the liability under the law.

- Strict liability under the current law adds to compliance costs and a general apprehension that can often deter physicians and others from participating in value-based and patient-centered care models. Furthermore, the excessive and high damages under the law serve as “red lights” that deter even initial discussions into exploration of innovative payment arrangements for some physicians and practices.

**PAI Recommendations**

Taking those factors into account, modernization of the current self-referral law should include several important elements. Changes to the law should allow and provide for the infrastructure support and financial incentives necessary for APM participation. Additionally, changes should account for compliance costs and burdens. Less stringent standards should be provided that do not penalize unintentional errors that may occur as physicians, practices, and others are looking to experiment and learn through demonstration models and work towards identifying ideal care models.

Modernization efforts should also ensure that the guiding laws and regulations at both the federal and state level are updated and keep pace with health care delivery system innovations and advancements. There should be alignment between federal and state self-referral policies to not create additional unnecessary complexities and confusion.

**The utility and limitations of current exceptions and need for additional exceptions**

The agency is seeking input on additional exceptions that are necessary, specifically to protect accountable care organization (ACO) models, bundled payment models, two-sided risk models, and other payment models, as well as for arrangements that integrate and coordinate care outside of an APM. Current exceptions to the self-referral law, while helpful, are limited. These existing exceptions have helped support the formation and improve the sustainability of entities that provide coordinated and integrated care. Expansion of these existing waivers and additional exceptions are still necessary to advance the agency’s goals of improving patient outcomes and quality of care.

For example, the exceptions and waivers available under the Medicare Shared Savings Program (MSSP) have supported increases in care coordination. They have allowed different practices, specialties, and stakeholders to financially align and create a network of services for their patients. However, ACOs and other integrated delivery models need additional exceptions and flexibilities to better manage their patients’ care. Specifically, they need additional flexibilities that account for variations in the physicians and practices, as well as other stakeholders, services, technologies, and tools that support models and care coordination.

**PAI Recommendations**

PAI recommends the following new exceptions to the self-referral law:

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• The exceptions and waivers available under the MSSP should also be expanded to other APMs, demonstrations, and similar arrangements. Additionally, further clarification and guidance on these existing waivers is necessary.

• Revisions to the law should include exceptions for small practices\(^1\) that face high costs and administrative burden. These practices may not have the resources, financial and otherwise, to ensure compliance with all aspects of the law. These providers and their patients can benefit from alignment and partnership with other high-quality providers, but self-referral may deter them from exploring such arrangements.

• The agency could implement exceptions that exempt practices from the self-referral law for significant participation in an APM or other innovative payment arrangement. For example, practices, virtual groups, and other “APM Entities” could be exempt if participating in the Merit-based Incentive Payment System (MIPS) or if they receive a significant portion of their revenue through an Advanced APM.

• Based on the complexities at both the federal and state levels, there should not be strict liability under the law. There should be a focus on providing greater physician education and opportunity to take remedial actions prior to penalizing physicians who are thought to be non-compliant. For example, physicians and practices could be subject to auditing and/or a probationary education period for non-compliance with the law, and then be subject to a fine if there is ongoing non-compliance.

PAI believes it is important that the self-referral law align with the shared goal of physicians, other stakeholders, and APMs and contribute to the delivery of high-quality, cost-effective care. It is important to have policies that do not limit patient choice or access, and that support fair practices, bargaining power, and market conditions. Physicians and practices already in the market must be able to continue to provide higher-coordinated care to their patients.

Furthermore, PAI-Avalere health recently conducted a study about trends in hospital acquisitions of physician practices and physician employment and the costs associated with changes in site of care (from physician office to facility).\(^2\) The study found that this trend results in more care being provided in hospital-owned settings over an episode of care and generally involves higher Medicare payments for the same services than if they were provided in the physician-office setting. Avalere researchers studied Medicare spending for four cardiology, gastroenterology, and orthopedic services, and found that Medicare spent $2.7 billion more for services provided in hospital-owned settings and beneficiaries paid $411 million more in cost-sharing over the three-year study period than if those services had been provided in the physician-office setting. While the expectation is that greater integration leads to increased care coordination and quality of care and decreased overall costs, substantial concerns remain about whether those integrated systems are contributing to higher costs overall. As this study demonstrates, there are opportunities to decrease costs if certain self-referrals are permitted where there is demonstrated alignment and a patient-centered approach for such referrals.

\(^1\) The QPP definition for small practices—15 or fewer clinicians—could be adopted for the self-referral law for consistency across the Medicare program.

**Physician-Owned Hospitals (POHs)**

Despite allowances for exceptions for certain POHs, other restrictions exist related to the creation and expansion of POHs. The original implementation of those restrictions was due to self-referral concerns, including that physicians would refer patients to a hospital in which they shared an ownership interest, and that physicians would overutilize the services in those hospitals. As the delivery system has evolved, however, those restrictions increasingly serve as a barrier to the development of physician-led delivery systems. Recent studies have challenged whether those restrictive policies have been effective at preventing inappropriate self-referrals. Instead, they show that POHs perform equally as well as non-POHs in quality and cost, and, in some cases, provide even higher quality care at a lower cost in a way that increases patient satisfaction.\(^3\)\(^4\) For example, a patient treated at a POH costs Medicare 4.6% less than if the patient had received those services at a non-POH.\(^5\)

PAI believes that revisiting and lifting restrictions on further formation and establishment of POHs can encourage more competition among physicians and between physicians and larger integrated health systems and hospitals. Additionally, expanding POHs would contribute to increasing patient choice for where and from whom they receive their care.

**Approaches to address the application of the physician self-referral law**

In the RFI, the agency is requesting comments on whether a single exception would suffice for all types of arrangements, and whether a multi-faceted approach amending existing exceptions and/or establishing new exceptions is preferable. Current law is ambiguous and needs clarification related to the application and interpretation of the current self-referral law and its existing waivers and exceptions. In general, PAI believes that it would be helpful if the agency standardized a single exception for all APMs, Center for Medicare and Medicaid Innovation (CMMI) demonstrations, and other value-based payment arrangements.

**PAI Recommendations**

PAI recommends the use of applicable exceptions and waivers that are entity-, provider-, and model-agnostic. For example, CMS could offer a uniform exception for all CMMI demonstration models. CMMI models encourage and incentivize coordinated care approaches and participants are often held accountable for a certain level of upside/downside risk for the care provided. Allowing a uniform exception would provide more predictability, certainty, and “security” for participation in these models.

**State Application of the Self-Referral Law**

The self-referral law has implications at the state level which modernization efforts should recognize, particularly in state application to physicians. State laws governing diagnostic imaging, state certificate of needs (CONs), and ambulatory surgical centers (ASCs) that are partially or wholly-owned by physicians may vary due to state interpretation. In some cases, this results in limited access to convenient and high-quality care.

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services for patients. In other cases, variations exist in state application of the law among specialists and multi-specialty groups and their ability to provide and furnish certain services.

For example, patients may not be able to go to an ASC that offers them high-quality and convenient service because the ASC is owned by their physician. This creates an obstacle for a more systematic approach to patient care, often requiring ASCs to adopt different corporate and tax structures that would allow patients to continue to access their services without violating the self-referral law. Another example is that while dentists may be able to offer imaging services in their practice, multi-specialty groups may be unable to obtain an imaging machine due to the state’s CON law or may be unable to self-refer given the specific make-up of the multi-specialty group that prevents it from making self-referral within itself for such imaging services. There should be consistency in the application and interpretation of the self-referral law at both the federal and state levels.

Terminology used within the self-referral law
CMS is requesting input on terminology and definitions on existing and new terms that may be appropriate in the context of self-referral. PAI agrees that current approaches can lead to confusion among providers seeking compliance with the law in their practices. It is important that the terminology be standard in use and definition across regulations, laws, waivers, exceptions, and payment models and arrangements.

PAI Recommendation
PAI believes additional clarification about “risk” could support APMs and other value-based payment arrangements in the context of self-referral policy. Specifically, it is important to have clear guidance about how “risk” is being taken under a given model. The guidance should define who is “directly” responsible for that risk, and how that determination is used to identify which referral relationships and constructs are permitted and which are prohibited. Under different payment models and arrangements, some participants may take on varying degrees of risk. However, this should not be the determining factor for whether self-referrals within an arrangement are permitted. The focus should be on incentives for patient-centered care and understanding what increases access and the availability of necessary services for patients. This is especially true for preventive and chronic care management services that have great impacts on patient outcomes.

Fair Market Value and Physician Compensation
CMS seeks input on modifying the definition of “fair market value” in the physician self-referral context. In this era of evolving payment and delivery models, PAI believes that fair market value should take into account more than just monetary value; many of the items and services exchanged under value-based models may not be purely monetary and are instead tools and other supports and services. Other factors for consideration include a physician’s experience, knowledge, training, clinical judgment, specialty and expertise, and board certification and other certifications.

PAI Recommendation
PAI’s experience shows that determining fair market value for physician compensation is difficult. This difficulty is amplified given vertical and horizontal integration in the sector more broadly, and trends for employment of physicians by hospitals. In the self-referral context, we believe that physician compensation should not be defined at a regulatory level. Instead, it should be left to the individual market participants as part of their normal course of dealings. Physician compensation should also include other external factors including, for example, patient demographics, characteristics, socioeconomic-based needs, and volume.
The need for transparency within the physician self-referral context

Lastly, a question is posed in the RFI about whether and how the agency could design a model to test whether transparency safeguards other than those that currently exist that could effectively address the impact of financial self-interest on physician medical decision-making. PAI supports and values transparency. We also support the agency’s interest in deterring inappropriate practices that lead to high costs and lower quality.

PAI believes transparency is necessary for patients to make more informed decisions about their care. It is important that transparency provisions be put in place, which empower patients to more directly engage in their care decisions and determine where and to whom they go for their health care services.

PAI Recommendation

PAI recommends that in lieu of developing models or demonstrations, the agency could test transparency elements by incorporating requirements into new exceptions/waivers for existing models. As the agency develops any approach in this area, we caution the need to preserve proprietary information regarding the relationships which allow for the facilitation of coordinated, integrated, and high-quality care that has been discussed throughout these comments. The agency could develop a standardized template or form for disclosure of any financial interests that could trigger self-referral or create a website where such information is publicly posted for all practices or begin including this information in an accurate and valid manner on the Medicare Physician Compare website.

Conclusion

Overall, PAI supports the agency’s efforts to address the complexities and obstacles currently created by the physician self-referral law. We also support strategic use of exceptions to expedite those changes. The associations represented on the PAI Board of Directors welcome the opportunity to work with the agency to further modify existing policies and advance new policies. We look forward to exploring ways that allow physicians to provide higher quality, coordinated, integrated, and holistic care to their patients, while decreasing costs and increasing competition and choice in the health care market for patients and physicians. We reaffirm our belief that opportunities exist to improve the health care system and believe this should be done by enacting policies and modernizing antiquated regulations, which serve to foster innovative approaches to physician collaboration that will bring the benefits of competition to patients.

If you have any questions, please contact me at rseligson@ncmedsoc.org, or Kelly C. Kenney, PAI’s CEO, at k2strategiesllc@gmail.com.

Sincerely,

Robert W. Seligson, MBA, MA
President, Physicians Advocacy Institute