AdvocateAuroraHealth

Advocate Health Care Aurora Health Care

August 24, 2018

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Dear Administrator Verma:

Advocate Aurora Health, the nation's 10th largest not-for-profit health care system, with more than 500 sites of care across Illinois and Wisconsin, is pleased to provide our comments on the Request for Information (RFI) regarding the Physician Self-Referral Law (a.k.a. the Stark Law).

As an overview, Advocate Aurora Health supports modernization of the Stark Law to eliminate the regulatory barriers it is imposing on providers and integrated delivery systems that are seeking to move to a value-based care system. The Stark Law was originally enacted in 1989 with the intention of curbing self-referral and inappropriate or overutilization in Medicare. In principle, the law was necessary and well-intended, but now, in 2018, often impedes innovation by prohibiting essential care coordination and financial arrangements. Our health system is now more accountable than ever for financial and patient outcomes across the entire continuum of care. Yet, the Stark Law and its implementing regulations fail to recognize that relationships between payers, providers, physicians, and patients have transformed significantly over time and that those new relationships already address many of the risks that the Stark Law was enacted to prevent.

To improve the Stark Law regulations, we support the following modernization efforts, which fall under four distinct categories:

(1) Create a Value-Based Arrangements Exception: The exception would protect all arrangements where compensation is reasonably related to value-based goals, such as bundled payment models and Accountable Care Organizations (ACOs), regardless of whether entities are participating in a Medicare value based model. This would avoid creating separate exceptions for different type of models or payers, which only adds complexity to compliance requirements.

(2) Addressing Strict Liability: A major problem with the Stark Law is that it is a strict liability statute; intent to violate the law is not considered, and all noncompliance, however minor or innocent, constitutes a violation of the law. This strict liability means that providers are often not willing to enter into value-based arrangements if there is even a remote possibility of violating Stark. While we understand that Congress would likely need to act to change this requirement, policymakers should encourage removing or otherwise mitigating this significant impact on providers.

(3) Provide Clarifying Language: We ask that CMS provide clarity on three key terms – fair market value, volume and value of referrals, and commercial reasonableness – that are commonly used in Stark Law exceptions. These terms should have bright-line rules that providers can use to ensure they are compliant.

(4) Make Technical Changes to Reduce Burdens on Providers While Protecting Patients and Taxpayer Resources: HHS should focus resources on violations that directly harm beneficiaries as opposed to mere technical violations. In particular we urge:

- Using the advisory opinion process to clarify and give certainty to providers regarding the proper interpretation of the regulations.
- Mitigating enforcement of technical violations that pose little or no harm to beneficiaries (e.g., compliance with signature requirements).

Below we provide more detail on improvements that can be made and respond to specific questions included in the RFI.

ANSWERS TO SPECIFIC QUESTIONS

Question 1: Please tell us about either existing or potential arrangement that involve DHS entities and referring physicians that participate in APMs or other novel financial arrangements, whether or not such models and financial arrangements are sponsored by CMS.

Advocate Aurora Health is committed to value-based reform and has successfully participated in many advanced care models, but the Stark Law has limited our efforts to fully engage in arrangements that could further improve care coordination. Our system includes a number of different ACO models, including commercial global capitation, commercial shared savings, Medicare Advantage global capitation, Medicaid Managed Care shared savings, and the Medicare Shared Savings Program (MSSP). Under the MSSP, we were able to make use of Stark law waivers and achieved millions in cost savings (in 2016 Advocate's MSSP ACO achieved over $60 million in savings and Aurora's ACO cut costs by $200 per beneficiary) while maintaining the highest standards in quality of care. Yet, our organization has continued to face barriers in pursuing broader incentive-based or gainsharing arrangements that could further enhance care quality and facilitate the movement to coordinated care.

Specifically, we have sought to implement arrangements that adjust to reward high quality, cost-effective care, such as amending our compensation arrangements to account for value. The Stark Law, however, impedes us from making meaningful reform by preventing us from implementing a program that would pay our physicians a portion of realized shared savings. Such a program would save our system, patients, and the government money and would improve care by providing high quality and efficient services. Yet, we found that this could be construed as a Stark violation because the sharing of savings is not fully covered by an exception and, in turn, could be viewed as payment on the basis of the "volume or value of their referrals." As a result, we adopted a gainsharing program on a limited basis, which we believe poses reduced risk under Stark, but also does not harness the fullest potential in improving patient care, reducing costs, and increasing quality.

Question 2: What, if any, additional exceptions to the physician self-referral law are necessary to protect financial arrangements between DHS entities and referring physician who participate in the same alternative payment model? Specifically what additional exceptions are necessary to protect accountable care organization, bundled payment models and two-sided risk models in a FFS environment?

Existing waivers do not protect all APMs or only provide temporary relief, which undercuts a provider's ability to adopt permanent changes across all patient populations. For example, waivers used for certain models developed by the Center for Medicare and Medicaid Innovation (CMMI) are done on a case-by-case basis and oftentimes program applicants do not have up-front guidance regarding which requirements will or will not apply. In addition, some waivers provide only limited protections, are only applicable to Medicare payments, or do not include certain downstream entities. Furthermore, every model and every model's waivers are different. This continues to create complications, especially for those stakeholders who are seeking to make broad healthcare improvements that cut across different sectors and integrate different levels of care.

Since properly structured APMs typically have built-in safeguards, such as careful monitoring by CMS and a payment system that rewards value and inherently protects against inappropriate self-referral and over or mis-utilization, we urge CMS to adopt a broad exemption. The exemption should protect arrangements where compensation is reasonably related to value-based goals. We believe a single exception, rather than exceptions for each type of model, is the most effective and efficient way to provide the certainty and protection hospitals and physicians need to join forces in achieving coordinate care.

In addition, the value-based exception should not be limited to arrangements with providers or a single payer. Rather, the exception needs to address all the patients we see in our system and the new role of innovative technologies that are now driving the trend toward value-based care. Collaborations with manufacturers and inventors should therefore be included in the development of new models. For example, a model could focus on a health information technology and the achievement of clinical outcomes associated with this new tool.

We also ask that any new exception not require two-sided or downside financial risk. While we believe that controlling cost is a key component of any model, there are so few arrangements, at this time, that meet this criteria that we believe it would significantly limit the utility of a value-based exception. We also believe that the exception should be sufficiently flexible to recognize future delivery arrangements that may take different approaches to controlling costs and improving quality.

By adopting a new value-based exception, we expect more health care providers will be willing to commit the time and resources needed to transform to a value-based system. It will also address some of the specific barriers we are now seeing to fully coordinate care, which is currently divided by payers and care settings due to the fragmented structure of some of the existing Stark exceptions and waivers. More explicit and predictable guidance on when an arrangement will or will not prompt federal government action under the fraud and abuse laws

could have the dual effect of safeguarding against patient or program abuse while facilitating desired delivery system reform.

Question 3: What, if any, additional exceptions to the physician self-referral law are necessary to protect financial arrangements that involve integrating and coordinating care outside of an alternative payment model? Specifically, what types of financial arrangements and/or remuneration related to care integration and coordination should be protected and why?

Even outside of APMs, there are several efforts to coordinate care that have faced barriers due to the Stark Law as well as other program integrity rules and regulations. The following are examples of such efforts that we believe would significantly benefit our patients and pose little risk of harm to the Medicare program. CMS should consider new exceptions or provide guidance so that providers can participate in these important care coordination activities without risking unintended implications of the Stark Law.

a. **Community Partnerships and Addressing Patient Needs**

As Wisconsin's and Illinois' largest Medicaid and Medicare provider, we serve a diverse population. Many of our patients have significant needs that extend well beyond access to health care. We have considered services such as complimentary transportation, housing, and nutritional programs that support our patients' ability to live well, but are challenged with fraud and abuse laws that prohibit providing such conveniences to patients for fear of subjecting the organization to penalties and potential liability.

One specific example is our collaborative work with Federally Qualified Health Centers (FQHCs) to help provide care for underserved populations. Our health system wanted to financially support an FQHC to open urgent and primary care centers within one of our urban hospitals so that patients would have immediate access to appropriate care and not end up in more fragmented and costly settings, such as the emergency department. After further evaluation, we did provide the funding, because it was the right thing to do for these patients, but also recognize that this contribution was made with legal risk. In addition, every time one of our employed physicians provides services at this location, we have to align their compensation with burdensome Stark requirements. A broader exception that could protect investments in improving community partnerships would help us to continue to provide and enhance these benefits for our patients.

b. **Data Analytics**

Other innovative efforts that have been restricted due to compliance with Stark include limitations on the use of health information technology. Specifically, Stark hinders our ability to both use and invest in technology in the ways that will truly add value to our overall health care system. Congress wisely provided an exception from Stark that permitted health systems to provide a subsidy to physicians to acquire an electronic health record (EHR). Yet, while the EHR is a necessary step to succeed in the value world, it is not just collecting the data in the EHR but developing the analytical tools physicians need to guide their decision-making. Similar exceptions could be made for other tools and technologies that provide analytic capabilities or are not interoperable with an EHR. Physicians need access to these tools and

technologies to succeed in a value-based system and, without subsidies, the chances of physicians obtaining them are significantly reduced.

c. **Innovation**

We would like to promote our physicians who already work with us and know our patients. Many times these physicians are best at developing innovative services and technologies that can help improve care quality within our system. Ironically, because of Stark, it is riskier for us to work with a physician that provides care to our patients than with a physician who is completely apart from our system. It is also much harder to determine fair market value (FMV) of a start-up than an established business, making it more difficult to accurately evaluate Stark Law requirements and comply with the regulations.

As a specific example where our efforts to spur innovation have run into difficulty, Advocate Aurora recently became a sponsor of a Chicago based start-up incubator. In so doing, we agreed to jointly launch a health-tech competition where early stage companies could submit their business ideas and plans. The winner and runners-up would receive an investment or grant from Advocate Aurora and/or access to some Advocate Aurora resources (e.g., subject matter experts, business units). Because of Stark, we were advised by outside counsel to exclude from the competition any business entering the incubator that had an investor that was a physician (or an immediate family member) on the medical staff of one of our hospitals or that made referrals to Advocate Aurora. Again, we believe CMS could address these barriers and allow us to better work with our physicians.

Questions 9-12: Please share your thoughts on possible approaches to defining "commercial reasonableness", "fair market value", "take into account the volume or value of referrals" and "take into account other business generated".

Central to many of the Stark Law exceptions are broad definitions, such as commercial reasonableness, fair market value, volume or value of referrals, and others that depend upon an evaluation that has no precise standard. Many stakeholders feel that these terms lead to more confusion and compliance burdens.

As a solution, we recommend that CMS provide clarity regarding some of these key definitions. While we understand that a narrow definition may not be possible, we would welcome bright-line guidance that providers can use to help ensure that they are compliant or can meet this standard with a reasonable degree of certainty. Explicit examples and/or limiting the use of such broad terms would be a significant improvement over the current compliance regime.

In addition, we would welcome CMS to consider a greater focus on harm to beneficiaries as opposed to these vague terms that only look at the financial components of an arrangement. CMS could better use its advisory opinion process to give certainty to situations that pose little to no risk of abuse. This could include more appropriate guidance on how to address mere technical violations, like signature requirements, keeping documentation etc., that are inadvertent actions and do not directly impact the quality of care.

Question 16: Please share your thoughts on the role of transparency in the context of the physician self-referral law. For example, if provided by the referring physician to a beneficiary, would transparency about physician's financial relationships, price transparency, or the availability of other data necessary for informed consumer purchasing reduce or eliminate the harms to the Medicare program and its beneficiaries that the physician self-referral law is intended to address?

Advocate Aurora is committed to empowering patients with the information they need to understand their out-of-pocket costs. Such information helps not only patients to make informed decisions but increases engagement and helps us to move toward a value-based care system. We believe that disclosing information about price and patient out-of-pocket costs could mitigate the problems the Stark Law is intended to address and should be seen by CMS as a safeguard. Where entities have sought to improve price transparency for patients, CMS could potentially relax some of the more complex or burdensome aspects of the Stark requirements, thus promoting transparency efforts. In particular, Advocate Aurora has worked to standardize our charges for routine services and procedures across our broad network and have patient service representatives that can help navigate and provide accurate cost estimates for ordered and scheduled services. We are also working to pro-actively provide cost information to our patients and generally promote additional transparency efforts. We would welcome further engagement with CMS to discuss these issues in more detail.

Question 18: Please share your thoughts on compliance costs for regulated entities.

For Advocate Aurora, and many other health systems, more and more resources are being directed at complying with Stark Law and other laws rather than patient care. As an example, our employed physician arrangements require thorough analysis, which often necessitates regular engagement of valuation consultants to ensure minimal Stark risk. Engagement of consultants can cost in excess of $20,000 to review a single physician compensation agreement to ensure compliance with Stark requirements. Because Aurora enters into thousands of contracts with physicians each year, this cost can become astronomical, yet is needed to document compliance even when we know that no payment is being made in exchange for referrals.

The law's strict liability regime and potential for massive penalties is a major reason for an overly cautious approach. Even with regulatory exceptions and guidance, the law has an extremely broad prohibition on physician referrals that prevents us from considering many types of value-based arrangements because we would not want to run the risk of facing enormous penalties. For example, even when the objective of a model is to improve patients' outcomes, an arrangement focused on best practices may be viewed as an effort to induce future referrals and still be subject to stiff penalties under Stark because it is a strict liability statute. This means we are trying to craft innovative care models in a way that essentially excludes physicians or truly doesn't address the main drivers of cost, poor quality, and waste in our health care system.

CONCLUSION

Our organization maintains a strong commitment to moving toward value-based care and supports HHS' launch of its "Regulatory Sprint to Coordinate Care." We encourage CMS to take the most wide-

ranging and comprehensive regulatory action needed to eliminate the Stark Law's extensive regulatory burdens. Advocate Aurora stands ready to work with federal policymakers to identify regulations, requirements, and provisions that are thwarting the transformation of our nation's health care system.

Sincerely,

Michael Lappin
Chief Integration Officer
Advocate Aurora Health