AdvocateAuroraHealth

Statement for the Record:
U.S. House of Representatives Committee on Ways and Means Subcommittee on Health

Advocate Aurora Health
Michael Lappin, Chief Integration Officer
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Advocate Aurora Health appreciates the opportunity to provide testimony before the House Ways and Means Subcommittee on Health in support of modernizing the Stark Law to ensure the successful transition from volume to value in the Medicare Program. The following provides an overview of some of the more significant barriers we have faced as a result of the Stark Law and other laws and regulations, as well as a number of solutions we urge Congress to consider. To put it simply, the law needs to be modernized to ensure meaningful movement from a fee-for-service environment to a system that can better manage patient care and reduce costs.

Proposed solutions include:

1. Providing exemptions for value-based arrangements
2. Addressing strict liability and substantive versus technical violations
3. Clarifying "fair market value" and other definitions
4. Providing the administration rulemaking authority to create a cohesive regulatory regime that could protect patients while still allowing for innovative care arrangements.

Advocate Aurora Overview

Advocate Aurora Health (Advocate Aurora) is the 10th largest not-for-profit, integrated health care system in the United States and a leading employer in the Midwest with more than 70,000 employees, including more than 3,300 employed physicians and 4,500 closely aligned independent physicians, 22,000 nurses and the region's largest home health organization. An international leader in clinical innovation, health outcomes, consumer experience, and value-based care, the system serves nearly three million patients annually in Illinois and Wisconsin across more than 500 sites of care. Advocate Aurora is engaged in hundreds of clinical trials and research studies and is nationally-recognized for its expertise in cardiology, neurosciences, oncology, and pediatrics. Aurora Health Care and Advocate Health Care merged in April 2018. One of the foundational elements of the merger was a mutual commitment to value-based care.

Advocate Aurora's Commitment to Advancing Value-Based Care

Health care is being disrupted. Care is too expensive and does not provide the patient experience and health outcomes that one would expect of the world's leading economy. The alignment of incentives to reward high quality and low cost care is critical to fostering this necessary reform. The Medicare Access and CHIP Reauthorization Act (MACRA) and components of the Patient Protection and Affordable Care Act (ACA) have laid the essential groundwork to move toward a value-based system, but regulatory barriers make it difficult to achieve the benefits of this new payment paradigm. Advocate Aurora is fully committed to this important work, but our success is limited due to Stark Law restrictions. Our newly-formed system has a strong track record of success in the delivery of value-based care and

participation in innovative care models. With more than one million value-based lives, the Advocate legacy organization has one of the largest Accountable Care Organizations (ACOs) in the country. Advocate's ACO includes commercial global capitation, commercial shared savings, Medicare Advantage global capitation, Medicaid Managed Care shared savings, and the Medicare Shared Savings Program (MSSP). As one of 392 ACOs participating in the MSSP in 2015, Advocate alone realized $72 million worth of cost savings for taxpayers and, of 410 participating ACOs in 2016, we achieved $60.6 million in savings. Advocate also achieved the country's second highest total of taxpayer savings and remains among the highest in our quality results at 97.28% of total points in 2016.

The Aurora legacy organization was also an early and successful participant in the MSSP. Aurora's ACO earned high quality ratings (with a score of 95.31%) and shared savings of nearly $3 million. By leveraging our integrated delivery system to manage patient care transitions, we were able to reduce costs by $200 per beneficiary (from $7,500 to $7,300) in 2015. The Aurora ACO is now moving to the Track 3 MSSP model, and expects that we will continue our success under this more advanced stage of the program. Aurora has also developed a commercial ACO with Anthem Blue Cross and Blue Shield that allows us to exchange clinical data, co-manage patient cases, and enhance health outcomes. Like the Aurora Medicare ACO, this model has proven successful and enhanced quality while reducing costs.

The success that Aurora and Advocate have had through participation in our respective ACOs, MSSP and other value-based arrangements demonstrates the potential of a future value-based system, but that success is impeded by regulatory barriers.

Why Modernize the Stark Law

The Physician Self- Referral Law (also known as the Stark Law)[1] was passed over two decades ago to address concerns about physician self-dealing. In a fee-for-service environment, physicians have financial incentive to inappropriately self-refer patients or over utilize certain services. The law's intent was to counteract these inherent problems of a volume-based system to ensure medical professionals place patient care over profit.

Yet, as our healthcare system is changing with new laws and regulations driving towards value-based care, the Stark Law has turned into an outdated set of legal requirements that is now inhibiting innovation and blocking ability to realize the benefits of value-based care. The risk of overutilization is largely or entirely eliminated in models where physicians are paid on value and not by the volume of services. New quality programs have also placed greater emphasis on treatment outcomes and efficiency, creating penalties instead of financial rewards for excessively ordering tests or unnecessarily referring patients.

In this new environment, the Stark law is now impeding our ability to efficiently coordinate care, rather than helping our patients. 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.

[1] 42 U.S.C. § 1395nn

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.

Specific Examples of Unintended Barriers

1) **Gainsharing**

Like most systems, Advocate Aurora has historically based compensation arrangements on relative value units. In order to harness the full benefits of a value-based payment system, these arrangements must adjust to reward high quality, cost-effective care. Advocate Aurora has amended its compensation arrangements to account for value, but Stark Law impedes us from making meaningful reform.

One example is gainsharing arrangements. Advocate Aurora has sought to implement a program that incentivizes savings through innovative care design and services. To effectively change practices, we wanted to institute a program that would pay our physicians a portion of realized shared savings related to these innovative practices. This 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 creating such a program could be construed as a Stark violation because the sharing of savings is not 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.

2) **Community Partnership 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.[2] 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 applicable Stark requirements.

[2] 42 U.S.C. § 1320a-7a (Civil Monetary Penalties statute); 42 C.F.R. § 1320a-7b (Anti-Kickback statute)

3) 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), but this exception is scheduled to sunset on December 31, 2021. While the EHR is a necessary step in order 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. There is currently not an exception for subsidies related to an analytics tool like there is for an EHR. Similar examples could be made for other tools and technologies that 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.

As a specific example, our value-based models are data driven and rely on predictive analytics to identify where we can make changes to improve quality and reduce costs. We have used this technology, especially through our shared EHR system, to dramatically decrease the number of high-risk heart failure patients presenting for admissions to our hospitals and emergency rooms. Having all of our clinicians access our shared EHR is fundamental to our success in value-based care. Yet, our system had to work through complicated Stark requirements to offset the costs of adopting EHRs, and there is no exception that would allow us to subsidize other innovative technology.

4) Innovation

As in other industries, there is a tremendous amount of innovation, especially technological innovation, in health care. We would like to promote our physicians who work with us to develop new and innovative services and technologies.

Ironically, because of Stark it is riskier for us to work with a new business venture started by a physician that makes referrals to us than with a physician who does not. Those risks arise when making an investment in the new business. It is much harder to determine fair market value (FMV) of a start-up than an established business. Risks also arise when providing services and advice to a new business that is owned, in whole or in part, by a referring physician or his/her immediate family member. In many cases, the needs of a new business are much greater, making it more difficult to accurately evaluate the FMV of the services being provided.

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.

Potential Solutions

Advocate Aurora believes that the modernization of legal parameters, such as Stark and Anti-kickback, will enable health care providers to promote value-based systems.

1. Exemptions for Value-Based Arrangements

We appreciate that Congress and the Centers for Medicare & Medicaid Services (CMS) are working to provide incentives for clinicians to develop and participate in new alternative payment models (APMs) that focus on higher quality care and better choices for patients. From our experience, coordination of care between different providers and settings is critical to the success of most models, but this can often be seen as a potential Stark law violation. Indeed, Congress recognized this potential problem and provided certain waivers for some innovative models.[3]

Yet, existing waivers do not protect all APMs or only provide temporary relief, which undercuts a providers' 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 the requirements that 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.

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. An exception to the Stark law should be adopted that protects arrangements where compensation is reasonably related to value-based goals, such as bundled payment models and ACOs, regardless of whether entities are participating in a Medicare value based model. To support this, Congress should grant the U.S. Department of Health & Human Services (HHS) greater fraud and abuse law exception authority for any arrangement that is "reasonably related" to advanced APMs under the Quality Payment Program (QPP) as well as any CMMI programs or APMs that are made permanent.

Overall, current fraud and abuse laws and regulations discourage physicians from using innovative incentive plans and other arrangements that would – if permitted – improve care quality and reduce costs. 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.

In addition, the value-based exception should not be limited to arrangements with providers. Rather, the exceptions need to be updated to recognize the new role of innovative technologies and other partnerships that are now driving the trend toward value-based care. Collaborations with manufacturers and inventors should therefore be included in the

[3] Patient Protection and Affordable Care Act, Pub. L. no. 111-148, § 3022 (2010).

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.

2. Strict Liability; Substantive vs. Technical Violations

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. Policymakers need to address this fundamental problem first and foremost to ensure that the unintended consequences the law is causing are eliminated. Without addressing the root of the problem—the strict liability issue—efforts to modernize Stark will fail to achieve substantive and meaningful reform.

The Stark statute and regulations do not formally distinguish between substantive and technical violations, meaning unintentional actions (e.g., missing or out-of-date paperwork) can lead to extreme penalties. The potential for such violations presents a serious challenge to health care providers who make a good faith effort to satisfy the law's complex technical requirements but then may be subject to millions in penalties or other enforcement actions.

One solution we would welcome is legislation that could provide a clear definition of "technical noncompliance" or otherwise mitigate the strict liability nature of the current Stark law. This would ensure that violations solely because an agreement is "not set forth in writing," "not signed by one or more parties," or simply expired are recognized as different from those with serious risk of harming patients. Clarifying these different levels of violations, along with alternative sanctions for such oversights, could be of significant help in streamlining the complex Stark Law regime and would allow government entities to focus on those violations that are truly impacting patient care. We understand the Committee has supported legislation on this topic and would encourage continued action to see its passage.

3. Clarifying "Fair Market Value" and Other Definitions

Central to many of the Stark Law exceptions is the concept of "fair market value." The statute defines "fair market value," in relevant part, as "the value in arm's-length transactions, consistent with the general market value."[4] The Stark regulations further define that "general market value" means, "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…at the time of the service agreement."[5]

As such, the fair market value exception depends upon an evaluation that has no precise standard. Many stakeholders feel that this term, along with other definitions, such as "take into account," "commercially reasonable" and "volume or value of referrals," lead to more confusion and compliance burdens.

As a solution, we recommend that Congress provide clarity regarding some of these key definitions. While we understand that a single definition may not be possible, we would

[4] 42 U.S.C. § 1395nn(h)(3).
[5] 42 C.F.R. § 411.351.

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.

4. Intersection of Fraud and Abuse Laws

While beyond the scope of this hearing, we also wanted to highlight broader problems with intersecting fraud and abuse laws, including the Anti-Kickback Statute (AKS)[6] and False Claims Act (FCA)[7]. These, and other program integrity laws, often overlap, creating greater confusion and additional compliance burdens for health care providers, thereby limiting our ability to effectively manage the health of our patients. We are often faced with trying to decipher when and how each of these laws apply to a single type of arrangement or model, complicating what standards are required or what actions are waived or permitted.

In addition, each of these laws are governed by different entities—the Office of Inspector General (OIG) overseeing AKS, while CMS is the lead on the Stark Law and the Department of Justice (DOJ) having different levels of influence on both statutes. This divided jurisdiction only adds to the problems of trying to understand and comply with each law's requirements. For instance, a streamlined and coherent fraud and abuse regulatory system will establish clearer parameters on community partnerships, such as the aforementioned FQHC collaboration example, and may lead to more investment in community collaboration and social determinant patient resources. We would urge Congress to provide HHS and OIG with greater rulemaking authority to align Stark Law exceptions and other laws' requirements to create a cohesive regulatory regime that could protect patients while still allowing for innovative care arrangements.

Conclusion

While we have achieved significant success to date, we strongly feel that there are additional opportunities to unlock the full potential of innovative APMs for improving care quality and reducing costs for patients, taxpayers, and the nation. Yet, the broad prohibitions and ambiguity surrounding components of the Stark law are preventing Advocate Aurora, as well as many other healthcare stakeholders, from moving to more advanced value-based arrangements.

We have submitted recommendations to CMMI and CMS on how we would like to move our existing value-based models forward, including better coordination within our own provider-based network and promoting population health models that would allow us to manage the needs of an entire patient population, rather than focusing on only a specific procedure or episode of care. If our system had clear exception authority or assurance that certain high quality initiatives would not run afoul of existing Stark requirements, we believe we could take on more risk and move more quickly to implement a truly value-based health care system. For these reasons, we commend your prioritization of this critically important issue and are eager to work with the Committee and your colleagues to modernize the Stark Law and other laws that impede value-based care progress. Congress must play an active role in this reform to properly align necessary protections, while also reducing limitations to innovate and better manage patient care. Advocate Aurora appreciates the opportunity to play a leading role in supporting the transformation of our nation's delivery system to one that rewards quality and value, not volume, while still protecting our patients, taxpayer investments and the Medicare trust fund.

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[6] 42 U.S.C § 1320a-7b.
[7] 31 U.S.C. § 3729 et seq.