August 24, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Attention: CMS-1693-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted electronically via https://www.regulations.gov

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

Dear Administrator Verma,

On behalf of the National Association of Accountable Care Organizations (NAACOS), the largest association of Accountable Care Organizations (ACOs) representing more than 5 million beneficiary lives through more than 330 ACOs, I am pleased to provide our comments on the Centers for Medicare & Medicaid Services (CMS) request for information regarding the Physician Self-Referral Law (the Stark Law). NAACOS is an ACO member-led and member-owned non-profit organization that works on behalf of ACOs across the nation, including Medicare Shared Savings Program (MSSP), Next Generation, and commercial ACOs, to improve the quality of Medicare delivery, population health and outcomes, and health care cost efficiency. We share the Administration's goal to accelerate value-based transformation and appreciate the opportunity to provide our views on how modifications to the Stark Law can further that goal.

Our specific recommendations as outlined below include:

- CMS should be mindful of Congressional intent to provide unique flexibility for ACOs;
- CMS should codify the MSSP waivers to afford participants certainty and stability;
- CMS should modify the MSSP waivers to clarify that ACOs can extend waiver protection to other models, provide latitude for technical violations, and provide certainty that MSSP waivers will not be revoked by Administrative action; *and*
- CMS should coordinate with other Agencies regarding the application of MSSP waivers;

Introduction

As a strict liability statute with limited, complicated, and technical exceptions, the Stark Law inherently creates a chilling effect on strategies to bring providers together. As a result, healthcare providers and their advisors have grown accustomed to analyzing any novel arrangement involving Medicare-participating providers through the lens of the Stark Law. This may have been appropriate in a purely

fee-for-service system, in which provider financial incentives might directly relate to overutilization or inappropriate utilization of healthcare services. But, as CMS takes bold moves to transition Medicare reimbursement from volume to value-based systems, the kind of siloed care encouraged by the Stark Law should no longer play a foundational role in our healthcare system. In this letter, we discuss several areas where CMS can improve the functioning of the Stark Law to support ACOs and other value-based models under its existing regulatory authorities.

At the same time, CMS should be thoughtful and measured in its efforts to modernize the Stark Law. ACOs are built on the premise that tools like shared savings payments coupled with objective quality measurement can incentivize positive changes in practice patterns, culture, and clinical integration. However, all of these positive effects are based on a formal program with clear oversight by CMS and other regulators, public transparency, and a publicized and well-understood methodology for achieving, calculating, and verifying savings. Unfortunately, not all of the value-based payment programs available in the market have these features. Since most Medicare physician payments continue to be based on a fee-for-service system, uncontrolled physician self-referral can still create overutilization, inappropriate utilization, and referrals otherwise based on financial, rather than clinical, goals. These outcomes would seriously undermine CMS's efforts to achieve the three-part aim of better care for individuals, better health for populations, and lower per-capita costs. Therefore, CMS should ensure that any efforts to modify the Stark Law carefully build on its existing, thoughtful efforts to expand the law while protecting Medicare beneficiaries and the program.

Recommendation 1: CMS should be mindful of Congressional intent to provide unique flexibility for ACOs.

The MSSP is the only permanent program authorized by Congress as an advanced payment model. CMS should bear this in mind as it develops additional flexibility under the Stark Law, particularly if these flexibilities extend to other kinds of payment models. The MSSP allows Medicare patients to be attributed to providers, for providers' performance to be assessed on quality or cost measures, and for CMS to calculate payments based on these metrics. Importantly, the MSSP also includes a number of established protections to ensure that collaborative relationships between physicians and other entities (including "DHS Entities" regulated by the Stark Law) are truly intended to achieve beneficial policy goals. For example, all participants in ACOs undergo thorough advance screening by the Office of Inspector General ("OIG") and law enforcement agencies. Most importantly, ACOs and their participants do not earn federal shared savings payments unless they actually succeed at reducing the costs of care and meeting patient quality benchmarks.

Further, the MSSP has continued to satisfy Congress's intent here, with a track record of meaningfully improving quality and reducing Medicare spending. ACOs have grown into a major part of the delivery system, with over 10.5 million beneficiaries attributed to ACOs (or nearly 1/5 of the Medicare-covered population).[1] As the Department of Health & Human Services ("HHS") itself determined, MSSP ACOs achieved a net spending reduction of over $1 billion in the first three years of the program, with the overwhelming majority of ACOs also improving their performance on quality measures.[2] This number

[1] *Compare* CMS, Medicare Shared Savings Program Fast Facts, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/SSP-2018-Fast-Facts.pdf (January 2018), *with* CMS, Fast Facts (July 2018), https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/CMS-Fast-Facts/index.html.

[2] HHS Office of Inspector General, Medicare Shared Savings Program Accountable Care Organizations Have Shown Potential for Reducing Spending and Improving Quality, OEI-02-15-00450 (August 2017), https://oig.hhs.gov/oei/reports/oei-02-15-00450.pdf.

is based on CMS's own benchmarking methodology, which likely understates the true savings generated by individual ACOs compared to their own historic costs.[3]

Moreover, CMS has relied heavily on the operational infrastructure of the MSSP to influence virtually all of its other quality payment initiatives. For example, the attribution methodology used in the ACO model has been used in several models operated by the Center for Medicare and Medicaid Innovation ("CMMI") models as well as the Medicare Quality Payment Program.

Recommendation 2: CMS should codify the MSSP waivers to afford participants certainty and stability.

In 2011, HHS issued joint waivers of the Anti-Kickback Statute, Stark Law, and Civil Monetary Penalty Law.[4] Since HHS first issued these waivers, they have become an essential tool to support the goals of the MSSP. Physicians, hospitals, and other ACO participants could not establish the kinds of relationships necessary to truly redesign care processes, without the flexibility afforded by the waivers. Unfortunately, CMS has also created serious uncertainty about the long-term viability of these waivers. As part of its efforts to modernize the Stark Law, CMS should take the opportunity to confirm that the flexibilities of the waivers will remain a permanent part of the program.

The creation of an ACO requires a large initial capital investment to establish the required infrastructure, engage necessary care coordinators and other personnel, fund care redesign processes, and establish new incentives. At the same time, during this start-up period ACOs often lack visibility into the reasoning behind administrative changes, shifts in policy focus, and modifications in MSSP administrative priorities. Regulatory uncertainty can make it difficult for prospective ACO entities to justify the capital requirements to develop an ACO. Unfortunately, through its public statements regarding the waivers, HHS has introduced exactly this kind of regulatory uncertainty regarding the permanence of the fraud and abuse waivers.

HHS did not initially establish the waivers through formal notice-and-comment rulemaking, which carries the highest degree of legal protection under the Federal Administrative Procedure Act. Instead, it has issued a series of notices published in the Federal Register. While HHS has committed to using notice-and-comment procedures if it changes the waivers, its choice of this less-formal structure has created industry concern that the waivers could be reversed at any time. HHS's own statements have introduced additional uncertainty to the process. In the initial notice establishing the waivers, HHS warned that: "We plan to narrow the waivers . . . unless the Secretary determines that information gathered through monitoring or other means suggests that such waivers have not had the unintended effect of shielding abusive arrangements."[5] This language strongly suggested that HHS would narrow or eliminate these essential protections unexpectedly, based on any isolated finding of an improper relationship. While HHS slightly softened this statement in updated waivers issued in 2015, it also reiterated that: "[s]hould we identify specific areas of fraud or abuse resulting from arrangements covered by the waivers, or if we determine that the risks of fraud and abuse associated with waiving our laws for certain arrangements outweigh the benefits associated with the Shared Savings Program, we may propose to revise these waivers or take other appropriate action to address our concerns."[6] These statements create significant uncertainty for ACOs, ACO participants, ACO professionals, and prospective ACO participants.

[3] See e.g., Michael E. Chernew, Christopher Barbey, J. Michael McWilliams, Savings Reported By CMS Do Not Measure True ACO Savings, Health Affairs Blog, June 19, 2017;
[4] 76 Fed. Reg. 67992.
[5] 76 Fed. Reg. 68008.
[6] 80 Fed. Reg. 66471.

In the same 2015 rule, HHS refused requests to codify the waivers as a permanent part of the Code of Federal Regulations.[7] It cited a number of reasons, including the fact that other waivers (such as waivers of Medicaid rules under Section 11115 of the Social Security Act), are not typically codified, and that it would be administratively complex to codify both Stark Law and Anti-Kickback Statute provisions. We request that the agency reconsider this determination, particularly in light of its acknowledgement that it would engage in notice-and-comment rulemaking to alter the waivers.[8] We believe these provisions of the fraud and abuse laws are not comparable to the Section 1115 waivers, in part because they modify (but do not replace) existing and complex program integrity structures for wholly federal programs. While the Medicaid waiver relate to state flexibility under a joint federal-state program, the ACO waivers directly impact the overall federal fraud and abuse regulatory regime that would otherwise apply to Medicare ACOs. Further, if HHS finds it administratively burdensome to codify the Stark Law and Anti-Kickback Statute provisions, we request that CMS should at a minimum codify the Stark Law provisions. This is because the Stark Law is a strict liability statute, such that many arrangements might immediately violate the law if the waivers were revoked – regardless of the parties' good faith intent to work towards the goals of the MSSP.

Alternatively, in light of HHS's long experience in operating the MSSP waivers, CMS should also consider simply adopting the provisions of the waivers as a new exception to the Stark Law. CMS has the statutory ability to create new regulatory exceptions to the Stark Law to protect financial relationships that do not pose a risk of program or patient abuse; the agency has used this authority many times.[9] Given the positive track record of compliance with the waivers, CMS should consider using the waivers as the basis of a new regulatory exception (or a group of exceptions) for ACO financial arrangements.

By codifying the Stark Law provisions of the waivers, HHS (and/or CMS) would assure ACOs of the permanence and reliability of the waivers, regardless of any underlying programmatic changes or other considerations. This would represent a simple, concrete action that the agency could take to provide much assurance that it remains committed to the success of the MSSP.

Recommendation 3: CMS should modify the MSSP waivers to clarify that ACOs can extend waiver protection to other models and provide latitude for technical violations.

CMS should build on its extensive efforts in developing and applying the MSSP ACO waivers as it considers further expansions to the Stark Law. The agency already has the regulatory authority necessary to fix two longstanding issues with the waivers that may be limiting participants' ability to engage effectively.

Since HHS finalized the MSSP ACO waivers, they have become powerful tools to help ACOs encourage various types of providers to work together. However, they have important limitations. Most importantly, the waivers are only available for financial relationships connected to the MSSP (e.g., relationships that are either "reasonably related to the purposes" of the MSSP or based on shared savings earned by an ACO). However, we are concerned that the waivers may not extend to many other kinds of arrangements involving ACOs.

The two broadest ACO waivers protect arrangements that are "reasonably related to the purposes of the Shared Savings Program." But in the waivers, HHS stated that arrangements "that are unrelated to

[7] Id.
[8] Id.
[9] 42 U.S.C. § 1395nn(b)(4). See also 42 C.F.R. §§ 411.357(j)-(y).

the Shared Savings Program are not covered by the term 'purposes of the Shared Savings Program."[10] At the same time, the agency observed, "[a]rrangements that involve care for non-Medicare patients **as well as** Medicare beneficiaries are eligible for the waiver."[11] This set of statements creates ambiguity that makes it difficult for ACOs to understand how to leverage their existing, redesigned Medicare care models for other purposes (including participation in Medicaid and Medicare Advantage models). ACOs are consistently the first movers among providers to adopt a population health perspective for healthcare delivery, integrate data into patient care operations, and develop new ways to incentivize better care. Each of these factors could be extremely valuable for patients covered by other payers. Unfortunately, CMS's existing statements create confusion about MSSP's participants to use their current models to succeed in other contexts. CMS could easily address this uncertainty by clarifying that MSSP ACOs can use the relationships they have already put in place to enter into agreements with Medicaid, commercial, or non-governmental payers.

Similarly, we are concerned that the waivers continue to create opportunities for technical violations. One of the challenges of the Stark Law's strict liability nature is that minor and immaterial deviations from the complex standards of an exception can cause large liability. Avoidance of these technical violations creates an enormous compliance challenge for entities participating in Medicare. To a large degree, the ACO waivers are designed to minimize the opportunities for such technical non-compliance, by establishing a flexible approach in which the ACO's governing body is primarily responsible for determining whether an arrangement should be waived. However, certain statements made in CMS's most recent reauthorization of the waivers in 2015 appear to open the door for new kinds of technical violations.

For example, CMS states that the waivers will not cover arrangements "unless all criteria for the applicable waiver are met," and provides the example that "an ACO that fails to have its governing body properly make and authorize a bona fide determination that an arrangement is reasonably related to the purposes of the Shared Savings Program, which is required for the pre-participation and participation waivers, would not have the protection of the waiver unless and until the ACO meets the requirements in this final rule."[12] This hypothetical scenario raised by CMS potentially creates liability based on unintentional and immaterial delays in obtaining governing body approval. This echoes other kinds of technical violations possible under the Stark Law – which the waivers were partly intended to avoid. This approach is doubly confusing because nothing in the statute requires the waivers to adopt the highly technical approach used by Stark Law exceptions. We urge CMS to reconsider this interpretation and instead confirm that it will consider the intent of the parties and their good faith efforts to comply with the waiver standards before imposing any Stark Law liability.

These modifications to the MSSP ACO waivers are entirely within CMS's regulatory authority. They represent powerful ways to provide added flexibility to ACOs and improve the operation of the MSSP, without engaging in wholesale rewriting of the law. As a result, we ask the agency to consider these relatively simple – though important – modifications to the waivers.

Recommendation 4: CMS should coordinate with other Agencies regarding the application of MSSP waivers and other fraud and abuse rules related to ACOs.

We appreciate that CMS is taking action to address the barriers created by the Stark Law for ACOs and other entities participating in value-based payment arrangements. But the Stark Law does not operate

[10] 76 Fed. Reg. 68002.
[11] Id. Emphasis added.
[12] 80 Fed. Reg. 66741.

in a vacuum. While it certainly creates limitations for providers, these limitations are often exacerbated in connection with other legal limitations. While we recognize that CMS does not have direct legal authority over these distinct governmental entities, its position carries persuasive weight because it is the primary operator of Medicare value-based payment models. As a result, we hope that CMS pursues a strategy of coordinating its Stark Law modifications with similar efforts to reduce regulatory burden elsewhere.

Within the federal government itself, several additional regulatory regimes create limitations for ACOs. As it considers any modification to the Stark Law, CMS should continue its tradition of working with the HHS OIG to consider modifications or clarifications to the Anti-Kickback Statute to parallel any improvements to the Stark Law. Further, we hope that CMS will expand its focus to collaborate with other federal agencies, such as the Internal Revenue Service ("IRS"), to address the regulatory barriers created by these entities for coordinated care. For example, IRS regulations continue to limit the ways that non-profit entities (including many hospitals) can work with for-profit entities (including most physician practices, post-acute care providers, and vendors). Under current IRS guidance, non-profit entities that are part of ACOs (including MSSP ACOs) may threaten their tax exempt status by engaging in "private benefit" – including by helping their for-profit ACO partners enter into value-based arrangements with commercial payers.[13] This limits the growth of value-based payment, as it keeps ACOs from leveraging their existing investment in care redesign to treat patients covered under commercial contracts. CMS has the opportunity to use its leadership in creating value-based payment models to drive change across the federal government.

CMS also has the opportunity to work to reduce barriers outside the federal government. Many states continue to have "baby Stark" laws – state-level restrictions that mirror the federal Stark Law. Most of these were adopted early in the Stark Law's history, and have not been updated with more recent developments, including interpretive changes, regulatory clarifications, and additional exceptions. Others claim to parallel the Stark Law because they cite various sections of the statute or regulations (although even this is ambiguous in the ACO context, since the waivers are not codified in regulatory text). CMS has traditionally remained silent on these state-level provisions, claiming that it has no authority to preempt state law. Whether or not this is true, the agency has relationships with appropriate regulators throughout state governments. It could easily reach out to states to encourage voluntary efforts to modernize these state-level barriers limiting integrated care. We ask the agency to take this simple step to reduce regulatory burden.

Conclusion

On behalf of the member ACOs of NAACOS, thank you for the opportunity to share our views on the Stark Law and the MSSP waivers, specifically. Should you have any questions about this letter or the ACO programs, please contact Allison Brennan at abrennan@naacos.com.

Sincerely,

Clif Gaus
President & CEO

[13] See e.g., IRS Notice 2011-20; PLR 201615022.