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Acting Inspector General
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U.S. Dept. of Health & Human Services
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Washington, DC 20201

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Dept. of Health & Human Services
200 Independence Avenue, SW
Washington, DC 20201

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

Re: Comments on Notice of Proposed Rulemaking related to the Stark and Anti-kickback Statutes [OIG-0936-AA10-P and CMS-1720-P]

Dear Acting Inspector General Chiedi and Administrator Verma,

On behalf of the National Association of ACOs (NAACOS), thank you for the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) and Office of Inspector General, U.S. Department of Health and Human Services (OIG, collectively with CMS the Agencies) proposed changes to the rules implementing the Federal physician self-referral or Stark Law, and the Federal Antikickback Statute (AKS) (the NPRM). Specifically, our recommendations on the NPRM are as follows:

- **NAACOS supports the NPRM overall and the Agencies should finalize the NPRM without delay to support the goals of value based care;**
- **The Agencies should ensure that the safeguards that have been successfully deployed in the Medicare Shared Savings Program (MSSP) for Accountable Care Organizations (ACOs) are correspondingly employed in the new waivers;**
- **The Agencies should expand the proposed waivers for non-risk baring value-based arrangements to allow those arrangements to thrive and develop;**
- **The Agencies should clearly state in this final rulemaking, as stated in the NPRM, that these waivers do not supersede waivers previously promulgated by the Agencies for ACOs who participate in the MSSP; and**
- **The Agencies should further clarify the reach of the MSSP waivers to address confusion regarding outside parties and non-Medicare patients.**

We offer further background and detail on NAACOS' recommendations below.

Background
NAACOS works to advance population health-focused payment and delivery models and represents hundreds of organizations who serve 12 million beneficiary lives by participating in models in Medicare, Medicaid, and commercial health plans. This includes the MSSP, Next Generation ACO Model, Medicare Advantage and alternative payment models supported by a myriad of commercial health plans.

NAACOS members have tremendous experience with realizing the promise of value-based models via the early and continued success of the ACO model. ACOs have been instrumental in Medicare's shift to value-based care. The origin of Medicare ACOs dates back to the George W. Bush administration, and now nearly 560 ACOs operate in Medicare, covering nearly 13 million beneficiaries. Population-health model ACOs are a market-based solution to fragmented and costly care that empowers local physicians, hospitals, and other providers to work together and take responsibility for improving quality, enhancing patient experience, and reducing waste. Importantly, the ACO model also maintains patient choice of clinicians.

This month, an independent evaluation found ACOs lowered spending by $3.53 billion from 2013 to 2017 and saved $755 million after paying shared savings. Results show the MSSP's benefits continue to grow. This evaluation, conducted by the analytic firm Dobson | DaVanzo & Associates, compared ACO spending to similar non-ACO providers and patients to determine what spending would be in the absence of ACOs. The firm used research methods called as-treated difference-in-differences design, which are rigorous and widely accepted to estimate savings and losses. The Medicare Payment Advisory Commission (MedPAC) has used a similar approach to analyze ACO savings. The results continue a strong and growing trend of the Medicare ACO program saving money, and ACOs also demonstrate impressive quality. For example, in 2018 ACOs had an average quality score of almost 93 percent.
To build upon this success, NAACOS shares the Agencies' goal of continuing efforts to support value-based payment systems and the cost reductions and quality improvements they bring. ACOs have for years invested in resources, such as data analytics, information technology, and care coordinators, and worked to change institutional culture to focus on prevention and care coordination so that they can succeed in alternative payment models. Our recommendations reflect our desire to enhance care coordination and health outcomes for patients, reduce healthcare costs, and improve quality in the country's health care system.

Recommendation 1: NAACOS supports the expansion of the Stark Law and AKS exceptions and safe harbors to ease burdens for providers engaged in value-based payment, including outside an ACO and recommends that the Agencies finalize the NPRM to accomplish those goals.

Overall, NAACOS strongly supports the focus of the Agencies' efforts as reflected in the NPRM, including the overall theme of increased flexibility in the Agencies' application of the Stark Law and AKS to foster the growth of value-based arrangements. As we detailed our August 2018 comments and August 2019 comments to the Agencies, strict application of the Stark Law and AKS is a barrier to value-based models and must be addressed by the Agencies. We understand that the modifications of the Stark Law and AKS required significant effort and deliberation by

the Agencies, and we thank you for your thorough work to propose waivers that are appropriately tailored and flexible.

NAACOS also strongly supports the Agencies proposal of an ACO Beneficiary Incentive Program safe harbor as detailed in the NPRM. As this program grows to include additional meaningful incentives for ACO beneficiaries, the proposed safe harbor will be instrumental in allowing the appropriate flexibility to ensure success for patients and providers. We urge this be finalized.

Recommendation 2: NAACOS urges CMS to ensure that the safeguards which have been successfully deployed in the MSSP for ACOs are correspondingly employed in the new waivers.

Congress envisioned that MSSP ACOs would require flexibility under the Stark Law and AKS and passed explicit waiver authority in 2010 for such models by enacting Section 1899(f) of the Social Security Act. In late 2011, the Agencies published final waivers in connection with the MSSP and have further expanded upon these waivers in subsequent rulemaking and guidance in 2014, 2015, and 2018.

The flexibility of the MSSP waivers has allowed ACOs to thrive and produce savings for the Medicare program, and those waivers also contain key safeguards that ensure appropriate use. For example, the MSSP waivers require the ACO governing body make a bona fide determination that an arrangement is reasonably related to the purposes of the MSSP. At the time of publication of the MSSP waivers, the Agencies underscored a key role of the ACO governing body is to evaluate and identify clearly whether arrangements are reasonably related to one or more purposes of the MSSP. An ACO governing body may not "rubber stamp" an approval of an arrangement and is expected to employ a thoughtful, deliberative process for making a determination that an arrangement is reasonably related to the purposes of the MSSP.

In addition, the Agencies finalized certain transparency measures for ACOs utilizing the MSSP waivers, including a public posting of the use of the waivers. This posting requirement may be met by posting information identifying the parties to the agreement and the type of item, service, good, or facility provided under the arrangement on a public website belonging to the ACO or an individual or entity forming the ACO, clearly labeled as an arrangement for which waiver protection was sought, within 60 days of the date of the arrangement. ACOs are expected to stay up to date with the Agencies guidance regarding transparency and public posting.

To avoid confusion among value-based arrangement participants who participate in MSSP ACOs and other value-based arrangements which may qualify for a waiver under the Agencies' proposed rules once finalized, we urge the Agency to ensure that the new waivers require corresponding safeguards, namely, governing body approval, website posting, and a reasonable relation to the purpose of the value-based arrangement.

For example, we have concerns that the "Accountable Body" or "Gatekeeper" requirement may cause confusion in the marketplace. The Agencies proposed that a value-based entity ("VBE") must have an accountable body (such as a board of directors or other governing body) *or person* (which, depending on the size and scope of the VBE, may be an entity, such as a hospital or physician practice that is among the VBE participants, or an individual) responsible for financial and operational oversight of the VBE. As part of its oversight role, the Agencies state an expectation that the accountable body or responsible person would serve as the ''gatekeeper'' to the VBE, with a process and criteria to ensure that those admitted to the VBE after its formation as VBE participants have a legitimate role in the VBE, and that VBE participants are not participants in name only. The Agencies go on to say that, in addition to

ensuring operational and financial oversight, the accountable body or responsible person would be positioned to identify program integrity issues and to initiate action to address them, as necessary and appropriate.

We believe that the duplication created between this requirement and the longstanding requirement of a governing body may cause concern for ACOs who have already established a governing body for purposes of meeting the requirements under the MSSP waivers. We urge the Agencies to clarify in the final rule that ACOs that already have governing bodies in place do not need to also establish a Accountable Body or "responsible person," and that these new requirements under the proposed rule for non-MSSP value-based arrangements at least meet the level of rigor required for ACO governing bodies.

Recommendation 3: NAACOS urges expansion of proposed waivers for non-risk bearing arrangements.

NAACOS urges the Agencies to consider that predicating the availability of Stark Law and AKS waivers on the degree of risk that a value-based arrangement has assumed may prove to dissuade early entrants to value-based care design who are not yet ready for significant or full financial risk and are instead beginning with one-sided risk. The reliance of risk as a measure for whether a Stark or AKS waiver should be available (or to what extent it should provide flexibility) may have the impact of precluding shared savings or one-sided risk arrangements, which themselves produce significant savings for the Medicare program and, in many cases, mature to risk-bearing arrangements over time. In fact, studies have shown that even one-sided ACOs are at substantial risk for their start-up costs even before they see their first patient. These costs often easily exceed $1 million and are at risk not being recovered if the ACO does not achieve savings.

Research shows that shared savings-only models save money and improve quality for the patients they serve. The MSSP performance year 2018 results show net savings to the Medicare Trust Fund of $739 million, which is after accounting for shared savings payments made to ACOs and losses paid back to Medicare. It's important to note that ACOs in both shared savings-only and risk-based models showed reductions in spending per beneficiary relative to their benchmarks. Further, as noted in the June 2018 Medicare Payment Advisory Commission (MedPAC) report, *Chapter 8*, *Medicare Accountable Care Organization Models: Recent Performance and Long-term Issues*, there are a number of scientific evaluations that show ACO savings. For example, the aforementioned peer-reviewed study by Harvard University researchers found that the MSSP saved more than $200 million in 2013 and 2014 and $144.6 million in 2015 after accounting for shared savings bonuses earned by ACOs. These analyses provide important evidence that ACOs save more money for Medicare than what is reflected in basic evaluations of performance compared to CMS benchmarks.

And, in the context of ACOs, the data also shows that performance improves over time. ACOs participating in the MSSP over a longer period of time show greater improvement in financial performance, demonstrating the value of such models and the need to allow ACOs sufficient time to demonstrate positive results. For example, it took the average ACO that earned savings in 2017 three years to initially generate savings. Of the 142 ACOs that earned shared savings payments in 2017 and had prior program experience, 36 percent had losses (i.e., expenditures higher than benchmarks) in one of their first two years of the program.

ACOs have also demonstrated impressive quality results. A 2017 OIG report, *Medicare Program Shared Savings ACOs Have Shown Potential for Reducing Spending and Improving Quality*, found that ACOs achieved high quality and in particular noted progress on important measures including reduced

hospital readmissions and screening beneficiaries for risk of falling and depression. In PY 2018, MSSP ACOs had an average quality score of almost 93 percent, and
ACOs that joined the program in 2016 or 2017 improved their quality measure performance by an average of 27 percent in 2018.

Evidence clearly shows that ACOs improve over time in the program and that shared savings-only models generate savings to CMS and improve quality of care for the patients they serve. Therefore, it is critical that the Agencies not constrain one-sided value-based arrangements from utilizing the flexibility of the waivers outlined in the proposed rule. Benefiting from tools such as waivers enables success in value-based arrangements, which is a necessary precursor for the path to assuming risk. Specifically, we request that the Agencies decrease the litany of requirements for the Care Coordination Arrangements safe harbor (and any other exception the Agencies finalize for non-risk bearing arrangements), as these requirements are more onerous than those proposed for the risk-bearing safe harbors and exceptions.

Lastly, on the topic of risk, we appreciate the Agencies' use of consistent definitions of "full financial risk," and specifying that arrangements that qualify as involving "meaningful financial risk" under the proposed Stark Law financial risk exception will also meet the "substantial downside financial risk requirements" of the proposed AKS safe harbor.

Recommendation 4: NAACOS thanks CMS for clarifying that the new regulations do not impact the existing waivers for MSSP ACOs and urges the Agencies to codify such waivers in the Code of Federal Regulations.

NAACOS strongly supports the Agencies' clarification in the NPRM that the MSSP waivers are not impacted by this rulemaking. NAACOS strongly supports the retention of the existing MSSP waivers for all ACOs and we believe it is essential that ACOs participating in these programs still have the opportunity and flexibility to use the applicable waivers, *in addition to* using any new value-based exceptions and/or safe harbors that may be finalized. The flexibility of the MSSP and Next Generation fraud and abuse waivers should be retained and continue to be available to ACOs participating is these programs.

As the Agencies will recall, the Agencies did not establish the MSSP waivers through formal notice-and-comment rulemaking, which carries the highest degree of legal protection under the Federal Administrative Procedure Act. Instead, the Agencies have issued a series of notices published in the Federal Register. While the Agencies have 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.

While NAACOS strongly supports the creation of the new waivers detailed in the NPRM, we urge the Agencies to also codify the MSSP waivers to avoid confusion, which may be particularly acute once the Stark Law and AKS waivers proposed in the NPRM are finalized. It is important to assure those ACOs who have long relied on the MSSP waivers 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 demonstrated success of the MSSP.

<u>Recommendation 5:</u> NAACOS urges the Agencies to further clarify the reach of the MSSP waivers to address confusion regarding outside parties and non-Medicare patients.

While the MSSP waivers have effectively allowed ACOs to form and be successful, they are too limited. For example, in order for an ACO to effectively promote accountability for the quality, cost, and overall care for both Medicare and other patient populations, the ACO and its participants must (1) enter into arrangements with outside parties and (2) address more than just Medicare fee-for-service patients.

With respect to the first issue, although the preamble to the waivers suggests that third-party arrangements are permissible, the waiver language itself is ambiguous, providing that MSSP waivers protect arrangements "of an ACO, one or more of its ACO participants or its ACO providers/suppliers, or a combination thereof." 80 Fed. Reg. 66726, 66735-36 (preamble) and 66743 (participation waiver) (Oct. 29, 2015).

Regarding the second issue, while the existing fraud and abuse waivers may protect shared savings arrangements with providers as they relate to the specific federal program at issue (e.g., the MSSP), it is less clear that they protect such arrangements as they relate to other patient categories (e.g., commercially insured patients). As a result, there is significant uncertainty concerning whether or the extent to which an incentive program offered to a physician with respect to his or her assigned MSSP patients may, without creating potential Stark Law issues, also be offered to the same physician for his or her non-MSSP patients.

This uncertainty inhibits the implementation of efficient, broad-based, clinically supported incentive programs that might otherwise serve to promote accountability for the quality, cost, and overall care for both Medicare and other patient populations. We urge the Agencies to further clarify the reach of the MSSP waivers, especially as it pertains to addressing the uncertainty about acceptable arrangements with parties outside of the ACO and for patients beyond traditional Medicare.

NAACOS requests that CMS and OIG expressly include in the waiver text the following:

- Affirmative statements that arrangements with “outside parties” to the ACO (i.e., individuals/providers/suppliers/entities that are not ACO participants, ACO provider/suppliers or ACO professionals) may be protected by the waivers; *and*

- Affirmative statements that arrangements involving commercial, self-insured and patients other than Medicare beneficiaries, including associated programs, compensation, incentives associated with or derived from such programs, may be protected by the waivers, and the inclusion of non-Medicare FFS beneficiaries does not impact the waivers’ application.

Finally, there remains a lack of clarity regarding the scope of the MSSP waivers, and many ACOs don’t take full advantage of the flexibility afforded by the MSSP waivers for this reason. We request that the Agencies provide detailed descriptions and examples of the applicability of both the MSSP waivers and the new exceptions and safe harbors created under this rulemaking to further guide value based program or arrangement participants.

Conclusion

On behalf of the member ACOs of NAACOS, thank you for the opportunity to share our views on these proposals to provide greater flexibility in the application of the Stark Law and AKS for value-based arrangements. Should you have any questions about this letter or the ACO programs, please contact Allison Brennan at abrennan@naacos.com.

Sincerely,

Clif Gaus, Sc.D.
President and CEO
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