# New Stark & AKS Waivers: Top 7 Takeaways for ACOs

On November 20, 2020, the Centers for Medicare & Medicaid Services (CMS) and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) finalized rules creating new exceptions to the Federal Physician Self-Referral or "Stark Law" and safe harbors under the Federal Anti-Kickback Statute (AKS).

- NAACOS comments on the proposed version of these rules are available here.
- NAACOS comments on ways to improve the Stark Law waivers for ACOs are available here.

Here are the Top 7 takeaways for ACOs:

1. **The waivers do not replace the Medicare Shared Savings Program (MSSP) Waivers for ACOs.**
   While the rules create new flexibilities for value based care organizations, they do not replace or change the MSSP waivers of the Stark and AKS for MSSP participant ACOs. Those waivers were promulgated following the passage of the Affordable Care Act (ACA) and have not been rescinded by the Agencies. The new waivers are worth noting, however, as they reveal these enforcement Agencies' current thinking on waiver design for value based care organizations, including ACOs, and are helpful context as ACOs engage in new arrangements with non-traditional entities (for example, digital health providers).

2. **CMS made a couple modest changes with specific impact for ACOs:**
   The new rules create a safe harbor for certain remuneration provided in connection with a CMS-sponsored model. This change would reduce the need for separate and distinct fraud and abuse waivers for new CMS-sponsored models. The rules also codify the statutory exception to the definition of remuneration under the AKS related to the ACO Beneficiary Incentive Programs for the MSSP.
   - CMS fact sheet is available here.
   - HHS OIG fact sheet is available here.
   - A summary of the rules from NAACOS' government affairs consultants at Polsinelli PC is available here.

3. **The new value-based care exceptions and safe harbors do not require existing arrangements to be re-negotiated.**
   ACOs who have developed compliance planning to ensure that their existing arrangements fit the MSSP waivers for ACOs can continue to operate under the MSSP waivers. Depending on your organization's specific situation, however, there may be a scenario in which it would be productive to incorporate some of the protections afforded by the new MSSP waivers into your organization and related arrangements. For example, under the new rules, technology providers may have additional flexibilities to engage in a creative arrangement with an ACO.

4. **The new rules rely on a risk continuum framework.**
   Much like CMS' Pathways to Success rule for MSSP ACOs, the new rules embrace the concept that value-based care organizations that assume more risk should be rewarded with greater regulatory flexibilities. Specifically, the new rules assign arrangements to tiers of flexibility based on the perceived risk inherent in each type of value-based design (for example, an outcomes based arrangement is considered to be less "risk bearing" than a shared savings arrangement with a percentage at risk). While the concept that greater risk should merit greater regulatory flexibility is not universally accepted, it may be helpful for ACOs and other value-based care organizations to keep in mind as they engage in long term strategic planning and perform due diligence on future arrangements and participation agreements.

5. **The new exceptions and safe harbors are extremely complex and will require significant legal counsel to implement in a compliant manner.**
   While CMS and OIG's finalization of the new rules is a major step forward in adopting appropriate fraud and abuse rules for dynamic value-based care organizations, the rules themselves are highly complex, employ a number of new legal analyses and structures, and are not always consistent across Agencies. Adoption of new care arrangements that enjoy protection under the new rules will require legal counsel and significant investment by value-based care organizations.

6. **The new rules embrace digital health as a major player in value-based care design.**
   Under the new rules, the definitions of remuneration, Fair Market Value, and other traditional fraud and abuse analysis terms are updated, allowing greater incorporation of digital health, such as remote patient monitoring, care coordination digital services, and telehealth as drivers of value-based care. For example, the OIG added a limited exception to Civil Monetary Penalties law for the provision of certain telehealth technologies related to in-home dialysis services.

7. **We are likely to see terminology and definitions adopted as part of the rules incorporated into value-based care programs and regulations moving forward.**
   The new rules include material definitions for the terms "value-based participants," "value-based enterprise," "value-based activities," "target patient population," "value-based purpose," and others. These terms are employed throughout CMS and OIG's rulemaking and the applicability of many of the exceptions and safe harbors turns on whether an organization qualified under this terminology. While these terms are not currently applicable in regulation pertaining to MSSP ACOs, familiarizing yourself with these terms is worthwhile as we may see them adopted in future Centers for Medicare & Medicaid Innovation (CMMI) work and other federal programs.

This resource is for informational purposes only and does not constitute legal advice or counsel. Readers should consult their own attorney or advisor to understand how the laws and regulations cited herein may apply to their specific situation. This resource reflects information available at the time of publication and is subject to change. NAACOS shall have no liability whatsoever to the reader concerning the use of this document.