On June 4, 2015, the Center for Medicare & Medicaid Services ("CMS") released the highly anticipated Final Rule ("Final Rule") updating the Medicare Shared Savings Program ("Shared Savings Program"). One of the few provisions in the Patient Protection and Affordable Care Act ("ACA") designed to directly address rising health care costs, the Shared Savings Program utilizes accountable care organizations ("ACOs") to encourage greater cooperation and coordination among health care providers to improve quality of care while achieving cost savings for the Medicare program. In the press release and corresponding fact sheet announcing the Final Rule, CMS pointed to the more than 400 participating ACOs, serving over 7 million Medicare beneficiaries, as evidence of the growing impact that the Shared Savings Program and Pioneer ACO initiatives have had on the US health care system.

Under the Shared Savings Program, providers and suppliers participating in an ACO continue to receive traditional Medicare fee-for-service payments under Parts A and B, but the ACO may be eligible to receive shared savings payments if it meets specified quality and savings requirements. The Shared Savings Program has continued to evolve as an alternative payment model with respect to providing additional tools for providers as well as flexible approaches to bearing risk. After releasing the initial Shared Savings Program regulations in 2011, CMS proposed certain refinements by way of a Proposed Rule in December of 2014 (the "Proposed Rule") in order to continue/increase industry participation. The Final Rule released last week implements many of these refinements, while also addressing the more than 250 comments that CMS received regarding the Proposed Rule. It also clarifies and codifies existing guidance in a number of areas, including:

1. data-sharing requirements;
2. eligibility and other requirements related to ACO participants and ACO providers/suppliers;
3. clarifications and updates to application requirements;
4. eligibility requirements related to the ACO's number of beneficiaries, required processes for coordinating care, the ACO's legal structure and governing body, and its leadership and management structure;
5. the beneficiary assignment methodology;
6. the methodology for determining ACO financial performance; and
7. issues related to program integrity and transparency, such as public reporting, terminations, and reconsideration review.

In addition to clarifying and codifying current guidance related to the participation agreements between the ACOs and Medicare, the Final Rule fundamentally alters the Shared Savings Program by finalizing certain modifications to the so-called "tracks" that are available to ACOs. Prior to the Final Rule, participants could choose to participate on either Track 1 or Track 2. ACOs on Track 1 may share in up to 50% of the savings that they generate, but are not required to assume any downside risk for losses incurred by the ACO. ACOs on Track 2 are able to share in a greater percentage of any shared savings, but are responsible for a percentage of any shared losses. Nearly all of the 400 current ACOs are participating on Track 1. The Final Rule adopts changes
affecting both Tracks 1 and 2, while creating a new Track 3 that offers participants greater shared savings in exchange for greater shared losses.

Highlights of the Final Rule include the following:

**No Forced Exit for Track 1 ACOs.** Originally, all Track 1 ACOs would be required to transition to Track 2 after the end of their initial three year participation agreement. The Final Rule clarifies that ACOs currently participating on Track 1 can renew their Track 1 participation agreements for one additional three-year period, provided they have met their quality performance standard in at least one of the first two years of their initial three-year agreement period, and are otherwise in good standing in the program.

**Changes to Beneficiary Assignment.** Prior to the Final Rule, beneficiaries were assigned in two steps based on the plurality of primary care services furnished (1) by primary care physicians, and (2) by specialist physicians, nurse practitioners, physician assistants and clinical nurse specialists. The Final Rule revises the way in which beneficiaries are assigned by removing from Step 2 certain specialty types whose services are not likely to be indicative of primary care services. In addition, the Final Rule recognizes the expanding role of non-physician practitioners in the delivery of primary care services, and includes primary care services furnished by nurse practitioners, physician assistants, and clinical nurse specialists for purposes of Step 1 of the beneficiary assignment process.

**Retaining 50% Maximum Sharing Rate for Track 1 ACOs.** The Final Rule clarifies changes to the sharing rates that apply to ACOs. In its Proposed Rule, CMS suggested limiting the maximum sharing rate for Track 1 ACOs in their second agreement period. CMS contemplated reducing the savings rate from 50% to 40% as an incentive for an ACO to take on two-sided performance-based risk (i.e., move from Track 1 to Track 2). A majority of commenters were strongly opposed to this change. These commenters cautioned CMS that such a policy could have an adverse effect on participation. In the Final Rule, CMS capitulates on this issue, agreeing that any reduction in the sharing rate for Track 1 ACOs will not necessarily increase the attractiveness of Track 2 or Track 3. Consequently, ACOs remaining on Track 1 will continue to have the ability to share in up to 50% of the savings that they generate. CMS also finalized a proposal to permit previously terminated Track 1 ACOs to reapply under Track 1 or Track 2. Accordingly, the Final Rule now provides for a re-application process that takes into account the timing of the ACO's termination.

**Incentives for Track 2 ACOs.** While CMS did relent on lowering the sharing rate for Track 1 ACOs, the Final Rule nevertheless seeks to incentivize ACOs to enter into risk-based agreements. One such incentive offers Track 2 ACOs flexibility in how shared savings and losses are calculated. Under the Final Rule, Track 2 ACOs can choose from the following MSR/MLR frameworks: (1) 0% MSR/MLR; (2) symmetrical MSR/MLR in a 0.5% increment between 0.5 - 2.0%; and (3) symmetrical MSR/MLR that varies based on the ACO's number of assigned beneficiaries according to the methodology established under the one-sided model.

**Creation of Track 3 ACOs.** One of the most notable changes in the Final Rule is the creation of Track 3 ACOs. In creating Track 3 ACOs, CMS borrows heavily from the features of the Pioneer ACO Model – an ACO model that is separate and distinct from the Shared Savings Program, but which has seen success in generating shared savings in a more aggressive two-sided risk model. As CMS notes, the creation of Track 3 requires CMS to exercise its authority under Section 1899(i)(3) of the ACA, as it did when creating Track 2. This authority requires that CMS determine that the model (i) does not result in spending more for such ACO for such beneficiaries that would otherwise be expended if the model were not implemented and (ii) will improve the quality and efficiency of items and services furnished under the ACA. The Final Rule establishes Track 3 ACOs with the following features distinguishing it from Tracks 1 and 2:

- **Prospective Assignment of Beneficiaries.** Track 3 beneficiaries, unlike beneficiaries assigned to Track 1 and Track 2 ACOs, will be assigned to a Track 3 ACO on a prospective, rather than a retrospective, basis. Track 3 ACOs will be accountable for beneficiaries who were prospectively assigned to the ACO based on having received primary care services from ACO professionals in the past.
Increased Shared Savings Compared to other Tracks. Track 3 ACOs have the potential to capture 75% of their shared savings in conjunction with accepting risk for up to 75% of their shared losses, depending on quality performance measurements similar to Track 2 ACOs. The Final Rule limits the amount of shared savings and shared losses for Track 3 ACOs. Under the Final Rule, Track 3 ACOs will be limited to shared savings equal to 20% of their updated benchmark, and a loss recoupment of 15% of their updated benchmark.

Determining Benchmark and Performance Year Expenditures. CMS had proposed to use the same general methodology for determining benchmark and performance year expenditures under Track 3 as is currently used for Tracks 1 and 2, with the exception of certain modifications to account for the changes to beneficiary assignment, discussed above. The Final Rule finalizes this proposal, establishing that benchmark year expenditures for Track 3 ACOs will be determined using the calendar year expenditures for prospectively assigned beneficiaries, allowing for a 3-month claims run out.

Risk Adjusting the Benchmark for Track 3 ACOs. CMS initially proposed to apply the same general risk adjustment methodology in Track 3, with certain refinements to account for the prospective assignment of beneficiaries. The Final Rule confirms that CMS will be adopting its proposal.

Waiver of 3 day hospitalization rule for skilled nursing facility services. The Final Rule includes a number of waivers to existing Medicare fee-for-service rules. For example, ACOs operating on Track 3 can apply for a waiver of the general Medicare requirement that beneficiaries have a prior inpatient stay of no fewer than three consecutive days in order to be eligible for Medicare coverage of inpatient skilled nursing facility care. This type of waiver had been tested under the Pioneer ACO to see if it could improve the quality of care.

As providers react to this Final Rule and seek to find ways to provide higher quality care in more cost-effective ways, they must carefully chart a path through the ACA while remaining compliant with other applicable state and federal laws affecting health care providers, which do not always support implementation of the ACA. For example, it is important that they keep the antitrust laws in mind.

Antitrust officials have continued to aggressively enforce the antitrust laws in the wake of the ACA, and in some instances have made it clear that providers' desires to participate in alternative payment models is not a suitable justification for consolidations that the FTC otherwise views as anticompetitive. As noted by FTC Bureau of Competition Director, Debbie Feinstein in a speech at the Fifth National ACO Summit last June, "The passage of the [ACA] has not altered the antitrust standard that would apply to similar collaborations designed to reduce costs and improve the quality of health care." Similarly, FTC Chairwoman Edith Ramirez continues to reiterate the FTC's view that there is no tension between rigorous antitrust enforcement and the goals of health care reform, and notes that health care antitrust enforcement remains one of the agency's top priorities. Thus, while the FTC seems to recognize and acknowledge that ACOs can help improve the quality of care and generate efficiencies that benefit consumers, the FTC will closely evaluate ACOs when their formation and operation create or enhance market power.

Conclusion

Although the Final Rule has addressed some key areas of industry concern, the lack of significant Medicare payment rule waivers will be seen as a disappointment to many current and potential ACOs. Additionally, stakeholders may anticipate more regulations, such as a methodology resetting cost benchmarks to reward ACOs that show improvement relative to their fee-for-service region, as well as additional beneficiary assignment flexibility.

It is also likely that CMS is working to scale additional alternative payment models apart from ACOs in the near future, though on a smaller scale than their efforts to scale ACOs. Ultimately, the Final Rule further solidifies the ACO model as the Obama Administration's leading initiative to reform the health care delivery system.
If you have any questions about this topic, please contact the authors or your principal Mintz Levin attorney.