CMS Rule Improves Business Case for ACOs, But Challenges Remain

The Centers for Medicare & Medicaid Services (CMS) recently released a final rule[1] implementing the Medicare Shared Savings Program (MSSP), pursuant to the 2010 healthcare reform law.[2] Qualifying Accountable Care Organizations (ACOs) will be eligible to participate in the Medicare fee-for-service program, starting in 2012.

An ACO is a voluntary organization of healthcare providers who agree to be accountable for the quality and overall cost of care of those beneficiaries that receive the bulk of their primary care services from providers in the ACO. The ACO model is embedded within the Medicare fee-for-service program: Beneficiaries remain free to seek care from any providers, and providers will continue to be paid on a fee-for-service basis, with some exceptions. The experience of those beneficiaries assigned to the ACO will be tracked, and if quality standards are met, the ACO's providers will be able to share in savings, if any, to the Medicare program.

In this rule, CMS adopted various changes in response to common criticisms that the proposed rule[3] would make the MSSP unattractive to potential applicants. The following paragraphs summarize and assess a number of the salient points on which the regulations were changed. We consider how the rule, in comparison to the proposal:

- Reduces the risk to potential applicants;
- Facilitates better management of ACO caseloads by providing the ACOs information in advance regarding which beneficiaries are likely to be assigned; and
- Reduces the up-front and ongoing investment requirements.

Because antitrust issues continue to be a significant concern for ACOs, we conclude with a brief description of the Antitrust Policy Statement on ACOs issued by the Federal Trade Commission and the Department of Justice. Future Advisories will treat several accompanying rules and policy statements.

1 The final rule was posted by CMS on October 20, 2011, and is *available at* http://www.ofr.gov/OFRUpload/OFRData/2011-27461_PI.pdf. The anticipated *Federal Register* publication date is November 2, 2011.

2 Section 3022 of the Patient Protection and Affordable Care Act of 2010 ("PPACA," P.L. 111-148), as modified by section 10307 of the same act. This provision is codified as section 1899 of the Social Security Act.

3 "Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations" 76 Fed. Reg. 19528 (April 7, 2011), *available at* http://www.gpo.gov/fdsys/pkg/FR-2011-04-07/pdf/2011-7880.pdf.

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This Advisory emphasizes selected areas where CMS introduced key changes from its proposed rule. It does not provide a full summary of the final rule.

I. Changes Decreasing the Risks of ACO Participation

The final rule incorporates a number of significant changes that were intended to make participation in the MSSP more attractive to ACOs by reducing the risks and increasing the benefits of participation.

Removal of the Risk Requirement During the Initial Agreement Period (pp. 374-394)[4]

Like the proposed rule, the final rule permits participating ACOs to choose between two tracks with varying risks and rewards. Unlike the proposed rule, however, the final rule now offers a modified Track 1, a pure one-sided shared savings option, in which participating ACOs will be able to share in savings but will not be at risk during the initial agreement period if Medicare spending for their assigned beneficiaries exceeds benchmark expenditure levels. (Under Track 1 of the proposed rule, ACOs could elect a one-sided model for the first two years of their initial agreement period, but would be required to automatically transition to a two-sided model and share losses as well as savings for the third year of the initial agreement). The design of Track 2 has not changed from the proposed rule. ACOs selecting this track will be eligible for a higher share of achieved savings than would be available under Track 1, though the ACO will be at risk for losses for all years of its agreement.

CMS was persuaded to make Track 1 less risky because "ACOs new to the accountable care model—and particularly small, rural, safety net, and physician-only ACOs—would benefit from additional time under the one-sided model before being required to accept risk."[5] However, CMS emphasizes in the final rule its belief "that models that hold a degree of risk have the potential to induce more meaningful changes."[6] Therefore, ACOs will only be eligible for the Track 1 model during their initial agreement period. While there is no requirement that ACOs enter into subsequent agreements, ACOs choosing to continue their participation in the MSSP will be required to adopt Track 2 during subsequent agreement periods.

Increased Sharing Caps (pp. 486 - 492)

ACOs participating in the MSSP may share in a percentage of savings that increases with their scores on quality measures (as discussed below) subject to two limits: a "maximum sharing rate" and a separate cap on the total amount payable (calculated as a percentage of the ACO's benchmark for the performance year). In the final rule, CMS finalizes its proposal for a maximum sharing rate of 60 percent of savings for ACOs in the two-sided model, compared with 50 percent of savings for those in the one-sided model.[7]

The final rule increases, however, the separate caps on the total amount payable—from 7.5 percent under the proposed rule to 10 percent under the final rule for the one-sided model, and from 10 percent under the proposed rule to 15 percent under the final rule for the two-sided model. CMS rejected certain commenters' requests to remove the sharing caps entirely, stating that "retaining the performance payment limits is necessary to comply with the statute and important for ensuring against providing an overly large incentive that may encourage an ACO to generate savings through inappropriate limitations on necessary care."[8]

Availability of "First Dollar" Savings Under Both Risk Models (pp. 481-486)

The final rule also expands the availability of "first dollar" savings to ACOs selecting the one-sided risk model. Under the proposed rule, ACOs that selected the two-sided risk model and that achieved savings that exceeded the minimum savings rate (MSR) would have been eligible to share in all savings generated (i.e., the ACO would be

4 Page numbers refer to the version of the Final Rule posted by CMS on October 20, 2011. *See* footnote 1.

5 Final Rule at. 386.

6 *Id.*

7 *Id.* at 472.

8 *Id.* at 491.

eligible to share in savings on a "first dollar" basis). However, CMS proposed that ACOs selecting the one-sided risk model would be required to exceed the MSR to be eligible for savings *and* would only be permitted to share savings in excess of a 2 percent threshold, calculated as 2 percent of the ACO's benchmark level of savings.[9]

According to CMS, most commenters recommended sharing on a first dollar basis for all ACOs. Therefore, the final rule eliminates the 2 percent net sharing rate for ACOs selecting the one-sided risk model. CMS was persuaded by commenters that the 2 percent net sharing threshold could deter participating and that "sharing on a first dollar basis with all ACOs will be important for encouraging participating and ensuring ACOs receive capital to invest in achieving the program's goals and achieve a return on investment."[10] This change will make Track 1 a more attractive option for providers, by increasing the shared savings available for ACOs under the one-sided model.

However, ACOs selecting either Track 1 or Track 2 will still be required to meet or exceed the MSR in order to be eligible for any shared savings. According to CMS, allowing ACOs to share only in savings that meet or exceed the MSR will "reduce the probability that shared savings are earned as a result of chance or lower pre-existing expenditure trends due to existing efficiencies."[11]

Removal of the 25 Percent Withhold of Shared Savings (pp. 511-515)

The final rule eliminates the 25 percent withhold requirement in the proposed rule, which provided that the full amount of shared savings payments would not be paid in the year in which the shared savings accrued. Under the proposed rule, a flat 25 percent withholding rate would be applied annually to any shared savings payment earned by the ACO, in order to ensure that the ACO would be able to repay Medicare for any incurred losses in subsequent years. CMS proposed that at the end of each agreement period, positive balances would be returned to the ACO, but if the ACO did not complete its agreement period, the ACO would forfeit any savings withheld.

According to CMS, "nearly all commenters opposed the proposed 25 percent withhold, suggesting that given the anticipated slow return on investment and potentially high startup and operating costs, it would adversely affect participation or pose financial hardship on ACOs by restricting necessary capital."[12] Therefore, CMS eliminated the 25 percent withhold requirement, concluding that "the withhold may be an ineffective mechanism for ensuring repayment of potential losses" because "the withhold could serve as a penalty for successful ACOs while doing little to protect the Trust Fund against underperforming ACOs."[13] CMS expressed concern that the forfeiture requirement could punish ACOs terminated from the program for circumstances beyond their control and that the withhold could pose a financial hardship for ACOs and thus could be a potential barrier to the formation of ACOs.

While the removal of the withhold requirement will likely ease the financial burdens on ACOs of participating in the shared savings model, it is important to note that CMS is retaining other potentially burdensome requirements to ensure ACOs repay losses. In particular, CMS is finalizing the requirement for ACOs to demonstrate, on an annual basis, that they have established a self-executing method for repaying losses to the Medicare program.[14] The repayment mechanism must be sufficient to ensure repayment of potential losses equal to at least one percent of per capita expenditures for assigned beneficiaries from the most recent year available. ACOs may choose to elect an annual withhold on savings as part of their repayment mechanism.

9 76 Fed. Reg. at 19613. Under the proposed rule, ACOs that meet certain criteria would be exempt from the two percent net savings threshold and would instead share on first dollar savings under the one-sided model. *Id.*

10 Final Rule at 485.

11 *Id.* at 482.

12 Final Rule at 512.

13 *Id.* at 514.

14 76 Fed Reg. at 19622.

II. Provisions That Will Give Participants Better Knowledge of Who Assigned Beneficiaries Are

Beneficiary Assignment Rules (pp. 185-255)

One key component of the MSSP will be the method for "assigning" beneficiaries to an ACO—an operational process to determine if an individual beneficiary has received a sufficient level of primary care services from an ACO to justify holding that organization responsible for the quality and cost of the beneficiary's care. The agency's proposed rule came under considerable criticism from across the industry for failing to provide a sufficient process for ACOs to know which beneficiaries would be assigned to an ACO and included in the quality and cost-savings analyses. Many prospective applicants and commenters on the proposed rule expressed dismay that beneficiaries would be free to go to non-ACO providers or to access specialty care without hindrance, while the ACO to which they were assigned would be accountable for the cost and quality of their care. Many also expressed strong interest in permitting ACOs to engage ACO beneficiaries in the care management process.

CMS appears to have taken these concerns into consideration by adopting in the final rule a "hybrid" approach to the identification of assigned beneficiaries that should help ACOs manage and coordinate care across providers and settings. The agency also appears to be particularly opposed, however, to any approach that would "lock-in" or otherwise limit beneficiaries to particular providers, and it has resisted any changes to the MSSP that create financial or other penalties for beneficiaries who seek care outside of an ACO.

Under the proposed rule, CMS would have assigned beneficiaries to an ACO retrospectively. From a practical perspective, a retrospective approach meant that an ACO would not have known whether CMS was attributing responsibility for the costs and quality of a specific patient's care to the ACO until after the care had already been delivered. This posture drew substantial criticism from providers, who argued that the lack of information would limit their ability to manage the care of these beneficiaries with maximum effectiveness. This retrospective assignment technique was also cited as a factor that could discourage participation in the MSSP. CMS, on the other hand, argued that the "systematic, positive change" that will be realized from ACO-based care interventions could advantage all patients similarly and should be applied evenly in order to avoid creating a "two-tier system."[15]

CMS adopted a more complicated arrangement in the final rule, referred to as "preliminary prospective assignment." Under this hybrid approach, an ACO will be given a list at the start of each performance year of beneficiaries that appear likely, based on the most recent data available, to be assigned to the ACO. In this way, the ACO and its providers will know in advance which patients may be assigned to the entity. The list will be refreshed quarterly, based on the most recent 12 months of data.

CMS has also finalized a retrospective step in the assignment process in order to avoid holding an ACO accountable for managing beneficiaries to whom it no longer provides primary care. Accordingly, final assignment to an ACO will be made at the end of the performance year based on charge data from actual service use during that year. This compromise position will hopefully provide ACOs with enough information to manage and coordinate care during the year for the beneficiaries likely to be assigned to them, while final accountability is based on those beneficiaries who in fact received the plurality of their primary care from the ACO's providers.

CMS will be implementing its hybrid assignment approach based on the plurality of primary care services that beneficiaries receive during a performance year. While the proposed rule would have assigned beneficiaries to an ACO based on whether those individuals received the plurality of their primary care from primary care physicians

15 Final Rule at 232.

participating in the ACO,[16] CMS will expand its procedures to include the possibility of assignment based on primary care services received from a specialist.[17] This step will open the door to assignment of beneficiaries who receive their primary care services from specialists, such as cardiologists or nephrologists, who may be treating them for a chronic condition. This second step may thus result in somewhat more beneficiaries being assigned to ACOs, greater involvement of specialists, and the development of more disease-specific care management models.

III. Areas Where Changes Decrease Investment Requirements by Applicants

Quality Measurement Provisions (pp. 255-372)

Reporting by ACOs of measures of the quality of care they deliver are important in the ACO model for assuring minimum levels of quality and for promoting quality improvement. CMS has finalized 33 quality of care measures that ACOs must report, in 4 domains: Patient Experience of Care (7 measures), Care Coordination/Patient Safety (6), Preventive Health (8), and At-Risk Population (12).[18] CMS had proposed 65 measures, but the burden of collecting data drew extensive criticism, and in the final rule CMS pared down the measure set to those that "will have the most impact and are most aligned with ACO goals."[19] CMS omitted measures of Healthcare Acquired Conditions from the final list, a change that should be helpful to those ACOs that do not include a hospital.

CMS also attempted to align the measures more fully with those from other reporting initiatives, such as the Physician Quality Reporting System, in order to reduce duplication and confusion. In general, CMS used measures endorsed by a national stakeholder organization (such as the National Quality Forum), but it did exercise its discretion in a few instances to use a non-endorsed measure where no other option was available for a measure it regarded as critical.

CMS may still calculate some of the omitted proposed measures for monitoring and informational purposes. Further, CMS makes clear that it intends to add additional measures in future years.

CMS adopted a more gradual phase-in of quality performance assessment than it had proposed. In the second year, rather than assessing quality performance on the basis of the entire measure set, CMS will score performance on 25 measures, with reporting required on the other eight, while in the third year, performance will be assessed on 32 of the 33 measures.[20] For scoring purposes, the four domains are equally weighted.

In each year, ACOs must meet or exceed a "minimum attainment level" on at least 70 percent of the measures in each domain in order to avoid a corrective action plan and to share in savings. This standard is more relaxed than that in the proposed rule, which would have required ACOs to meet the minimum attainment level on every measure in order to share in savings. In the first year, full and accurate reporting measures are needed; in subsequent years, performance will be rated using national benchmarks, to be released at start of second year; performance above the minimum attainment level will score points on a sliding scale used to determine level of shared savings.

CMS finalized a requirement that measures of patient experience be gathered using the Consumer Assessment of Health Providers and Systems (CAHPS) survey. However, CMS concluded it would conduct the survey for 2012 and 2013, relieving ACOs of this burden. For 2014 and

16 For the MSSP, CMS defines "primary care services" as those services identified by these HCPCS codes: 99201 through 99215; 99304 through 99340; and 99341 through 99350; as well as the Welcome to Medicare visit (G0402) and the annual wellness visits (G0438 and G0439). CMS defines primary care physicians for this purpose as those in internal medicine, general practice, family practice, and geriatric medicine.

17 In the first step of the final model, CMS will assign beneficiaries to an ACO if those individuals received a plurality of their primary care services from primary care physicians in that ACO. For a beneficiary who has not received any primary care services from a primary care physician, CMS would assign those individuals to an ACO if the beneficiary has received at least one primary care service from an ACO physician and if the beneficiary has received the plurality of his or her primary care services from other professionals affiliated with that ACO. The relevant ACO professionals for assignment of this second group of beneficiaries will include specialists, nurse practitioners, physician assistants, and clinical nurse specialists.

18 The measures are listed in Table 1 in the Final Rule at 324-326.

19 Final Rule at 286

20 In the first year, as in the proposed rule, ACOs are only required to report values for measures but are not scored on their performance on those measures.

subsequent years, however, the ACOs will have to arrange and pay for administration of this survey.

Electronic Health Records (pp. 341-372)
CMS continues to stress the importance of electronic health records (EHRs) for ACOs, while changing the specific provisions relating to them. CMS backed away from a requirement for use of EHRs as a condition of participation in favor of emphasizing such use in a quality metric. CMS's proposal would have required that the majority of an ACO's primary care physicians be "meaningful users" of electronic health records by the start of the second year of the agreement period. CMS did not finalize this proposal, a step that should result in a somewhat smaller burden on some applicants.

CMS did not abandon its emphasis on EHRs, however. It finalized an EHR quality measure (one of two that had been proposed)—the percent of primary care providers in the ACO who successfully qualify for an EHR incentive program. CMS gave this measure a double weight "in an effort to signal the importance of EHR adoption to ACOs for achieving success" in the MSSP. Because of the double weighting, the effect of a low score on this measure would be amplified. If an ACO failed on this measure, it could score zero for the Care Coordination/Patient Safety domain (which only contains five other measures). Failure to meet the minimum attainment level for this domain, or any of the four domains described above, would result in a corrective action plan with possible termination after the following year and would prevent the ACO from sharing in any savings for the current year. Thus, while high EHR use is not a condition of participation as an ACO under the final rule, the emphasis on EHR use in the quality scoring procedures nonetheless provides a very strong incentive for ACOs to ensure their participants qualify for an EHR incentive program.

Elimination of Requirement for Prior Antitrust Review for Certain ACOs (pp. 145-158)
CMS had proposed that if two or more participants in a newly formed ACO that provide a "common service" have a combined market share over 50 percent for that service in the same "Primary Service Area," it would mandate a review by the "Antitrust Agencies" (the Federal Trade Commission and the Department of Justice). CMS would require any such applicant to submit, as a condition of participation, a letter from the reviewing agency confirming it had no present intent to challenge or recommend challenging the proposed ACO. In the final rule, CMS dropped the requirement for advanced review, although it emphasizes that all participants in the MSSP remain subject to antitrust laws. The Antitrust Agencies will offer voluntary expedited antitrust reviews, and CMS strongly encourages ACOs that may present competitive issues or are uncertain about the legality of their arrangements to take advantage of this opportunity. Applicants that might have been subjected to the mandated review will no longer be required to take this step, and CMS notes this change will reduce the burden and cost for applicants. The Antitrust Agencies' final policy statement is described more fully in the next section.

IV. Antitrust Policy Toward ACOs

Simultaneously with release of the CMS rule, the Antitrust Agencies issued a "Final Statement of Antitrust Policy Regarding ACOs Participating in the Medicare Shared Savings Program" to accompany the CMS final rule.[21] This Policy Statement gives guidance on identifying and mitigating the risk of antitrust enforcement actions to ACOs that participate in commercial markets.

Significant Differences from the Proposed Policy Statement
The Final Policy Statement differs from the Agencies' April 2011 proposal in two significant respects: (1) broader applicability; and (2) no mandatory advance review by the Agencies.

- **Applicability:** The Agencies' proposed policy statement was limited only to provider collaborations formed after the enactment of the PPACA. In response to concerns raised regarding the potential for unequal treatment of ACOs, the Agencies have expanded the applicability of

21 The statement is *available at* http://www.ftc.gov/opp/aco/.

the Policy to any collaboration (short of an integrated single entity or merger) among otherwise independent providers that are eligible and intend, or have been approved, to participate in the MSSP.

- **No Mandatory Antitrust Review:** The Agencies' proposed policy statement required a mandatory review of ACO if the combined market shares of participants who perform common services was 50 percent or more. In response to concerns raised regarding the potential burden on applicants of a mandatory filing to obtain antitrust clearance prior to obtaining approval from CMS for the MSSP, the final CMS rule does not require antitrust pre-approval for any ACO. The Antitrust Agencies continue to provide a process for voluntary review. Although the Antitrust Agencies' mandatory review process is not in the Policy Statement, for reasons discussed below, it is still advisable for applicants to calculate their market shares and carefully consider the other guidance set forth in the Policy Statement in an attempt to limit antitrust risk.

Safety Zone

Similar to the Agencies' proposal, the Policy Statement describes a market share threshold and other criteria that, if met, would give ACOs reasonable assurance that the Antitrust Agencies are unlikely to challenge them absent extraordinary circumstances. The criteria for this antitrust "safety zone" are:

- Independent ACO participants that provide the same service (a "common service") must have a combined share of 30 percent or less in the same Primary Service Area. The Policy Statement describes how market shares should be calculated.[22]
- Regardless of market shares, hospitals and ambulatory surgical centers participating in the ACO must be non-exclusive to the ACO.
- Any "Dominant Provider" must be non-exclusive to the ACO. A Dominant Provider is an ACO participant providing a service no other ACO participant provides and with a market share greater than 50 percent in its PSA for that service.

Antitrust Guidance for ACOs

The Policy Statement counsels all ACOs, whether they fall within the safety zone or not, to refrain from, and implement appropriate safeguards against, conduct that may facilitate collusion among ACO participants in the sale of competing services that are outside the scope of the ACO.

For ACOs that fall outside of the safety zone, the Agencies identified conduct listed below that increases antitrust risk:

- Using contractual terms that have the effect of discouraging commercial payers from directing or incentivizing patients to choose certain providers, such as "anti-steering," "guaranteed inclusion," "product participation," "price parity," and most-favored nations clauses or similar;
- Conditioning (either explicitly or through pricing) the ACO's services on a commercial payer's purchase of other services from providers outside the ACO and vice versa;
- Making any of the ACO's participants (including hospitals, ambulatory surgery centers, and specialists) except for primary care physicians exclusive to the ACO; and
- Restricting a commercial payer's ability to make available to enrollees information similar to the Shared Success performance measures.

Voluntary Antitrust Review Available

Any newly formed ACO (i.e., collaborations that were not jointly negotiated with private payors prior to enactment of the PPACA) can seek a 90-day review from the Antitrust Agencies before entering the MSSP.

22 ACOs operating in certain rural areas (described in the Policy Statement) that exceed the safety zone market share threshold may still qualify for the safety zone if the ACO includes only one physician or physician group practice per specialty for each county that meets the rural description in the Policy Statement.

V. Conclusion

In general, CMS appears to have attempted to improve the business case for ACO participation. MSSP ACOs will be much more likely to diffuse than would have been the case had CMS finalized the policies in its proposed rule without changes, including but not limited to the changes outlined above.

However, the challenges of setting up and operating an ACO are still significant, and applicants cannot be sure that they will succeed in improving quality and achieving Medicare savings in which they can share. Both investment and operating costs will be large, though they are hard to predict with precision, because they may be expected to vary depending on experience, size, and funding available to the participating ACO. One indicator is the cost estimates used by CMS in deriving its aggregate estimates: Average estimates of US$0.58 million for start-up investment costs and US$1.27 million in annual operating costs for participating ACOs.

The extent of participation in the MSSP, and how quickly it will ramp up, thus remains to be seen. Considering the uncertainty surrounding likely participation, CMS in its proposed rule displayed estimates that ranged from 75 to 150 participants, with the assignment of roughly 1.5 to 4 million beneficiaries in the first three years. CMS now similarly estimates that the number of ACOs participating in the MSSP program could range from 50 to 270, including from one to five million beneficiaries.

We hope you have found this Advisory useful. Please feel free to contact your Arnold & Porter attorney, or any of the contacts below, if you have further questions:

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