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ADVISORY

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Accountable Care Organization Final Rule and Guidance Includes Substantial Changes to Encourage Participation

On October 20, 2011, the Centers for Medicare and Medicaid Services (CMS) posted its final rule governing the development of Accountable Care Organizations (ACOs) to participate in the Medicare Shared Savings Program (MSSP). At the same time, the HHS Office of Inspector General, the Federal Trade Commission, the Department of Justice, and the Internal Revenue Service issued related rules and guidance.

An ACO is a voluntary organization composed of health care 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 new program will be effective January 1, 2012, and the first ACOs will be operational under Medicare starting on April 1 or July 1 of 2012. Additional ACOs may join the program on January 1 of each subsequent year. Each ACO will enter a three-year agreement with CMS (though the terms for the initial ACOs commencing in 2012 will be somewhat longer). Under the law, ACOs will become an ongoing part of the Medicare fee-for-service program.

Arnold & Porter has prepared the attached chart to summarize a number of policy changes made by CMS in response to comments on its proposed rule. It also provides page numbers to guide the reader to the discussion of the modifications in the preamble to the rule, together with brief quotes that summarizes CMS's decisions. The proposed rule generated a wide array of criticism from across the health care industry, and CMS appears to have responded in an attempt to make the program more attractive to potential participants. Arnold & Porter will make further analyses of the rule and related documents available shortly.

The final rule, which is slated for publication in the *Federal Register* on November 2, 2011, is accessible at http://www.ofr.gov/OFRUpload/OFRData/2011-27461_PI.pdf. CMS's Fact Sheets that summarize various aspects of the rule may be accessed at https://www.cms.gov/apps/media/fact_sheets.asp.

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Several related documents that will govern various aspects of the MSSP have also made available:

- CMS and the HHS Office of Inspector General posted a companion rule that addresses waivers under anti-fraud statutes available to ACOs. This regulation can be accessed at http://www.ofr.gov/OFRUpload/OFRData/2011-27460_PI.pdf
- The Federal Trade Commission and the Department of Justice issued a joint anti-trust policy statement in relation to ACOs. It is accessible at http://www.ftc.gov/opp/aco/
- The Internal Revenue Service issued a Fact Sheet regarding the treatment of tax-exempt organizations participating in the Medicare Shared Savings Programs. It can be found at http://www.irs.gov/newsroom/article/0,,id=248490,00.html
- CMS issued a notice on the "Advanced Payment Model," which permits ACOs to receive funds anticipated to arise from shared savings in advance for investment in setting up an ACO. http://www.ofr.gov/OFRUpload/OFRData/2011-27458_PI.pdf

Please feel free to contact your Arnold & Porter attorney if you have any questions.

Topic	Proposed Rule	Modifications in the Final Rule	Citation and Key Quotation
Risk-sharing: transition to risk in Track 1	ACOs could choose from two tracks, each entailing a three-year agreement. Track 1 would involve 2 years of one-sided shared savings with a mandatory transition in year 3 to performance-based risk under a two-sided model of shared savings and losses. Track 2 would comprise 3 years all under the two-sided model.	Remove requirement for two-sided risk from Track 1 for the initial 3-year period. The two tracks would still be offered for ACOs at different levels of readiness, with one providing higher sharing rates for ACOs willing to also share in losses. As in the proposed rule, all ACOs would have to bear the risk of losses in subsequent agreement periods.	p. 374 - 394 Final Decision: p. 394 "While making final our proposal to offer ACOs a choice of two tracks, we are modifying our proposal for Track 1 so that it will be a shared savings only model for the duration of the ACO's first agreement period… We are also finalizing our proposal to require all ACOs to participate in the two-sided model in agreement periods subsequent to the initial agreement period." p. 394

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Prospective vs. retrospective assignment of beneficiaries	Retrospective assignment based on utilization of primary care services, with prospective identification of a benchmark population.	A preliminary prospective-assignment method with beneficiaries identified quarterly; final reconciliation after each performance year based on patients served by the ACO. ACOs would know in advance what beneficiaries are tentatively assigned to them, but shared savings would be determined on a retrospective basis.	p. 222 - 244 Final Decision: p. 243 - 244 "[W]e are revising our proposed policy to provide for prospective assignment of beneficiaries to ACOs in a preliminary manner at the beginning of a performance year based on most recent data available." p. 243
Measures to assess quality	65 measures in 5 domains, including patient experience of care, claims–based utilization measures, and measures assessing process and outcomes. Pay for full and accurate reporting first year, pay for performance in subsequent years. Alignment of proposed measures with existing quality programs and private-sector initiatives.	33 measures in 4 domains. (CMS notes that the claims-based measures not finalized for measuring performance in determination of shared savings will be used for more general monitoring of ACOs.) Longer phase-in measures over course of agreement: first year, pay for reporting; second year and third year, pay for reporting and performance. Finalize as proposed.	p. 256 - 329 Final Decision: p. 327 - 329 "We believe judiciously removing certain redundant, operationally complex, or burdensome measures would still provide a high standard of quality for participating ACOs while providing greater alignment with other CMS and HHS quality improvement initiatives." p. 327 "Rather than transition all measures from pay for reporting to pay for performance in the second performance year of the ACO agreement period as proposed, we will transition only a portion of the measures to pay for performance in the second performance year, and then all but one of the measures to pay for performance in the third performance year..." p. 329

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Sharing savings	One-sided risk model: sharing beginning at 2% of savings, with some exceptions for small, physician-only, and rural ACOs. Two-sided risk model: sharing from first dollar.	Savings shared from first dollar for all ACOs in both models once minimum savings rate has been achieved.	p. 481 - 486 Final Decision: p. 486 "We are persuaded by comments suggesting the elimination of the 2 percent net sharing rate. Commenters made it clear that the option we proposed would unlikely achieve the balance we sought between a threshold low enough to ensure participation while protecting the Trust Funds from paying ACOs for results based on random variation." P. 485
Sharing beneficiary claims data	Claims data shared only for patients seen by ACO primary care physician during performance year; beneficiaries given opportunity to decline sharing of these data at the point of care.	The ACO may contact beneficiaries from provided quarterly lists to notify them of data sharing and their opportunity to decline.	p. 168 – 185 Final Decision p. 185 "[W]e are modifying this proposal…to allow the ACO the option of contacting beneficiaries from the list of preliminarily prospectively assigned beneficiaries in order to notify them of the ACO's participation in the program and their intent to request beneficiary identifiable data." p. 185

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Start date	Agreement for 3 years with uniform annual start date; performance years based on calendar years.	Program established by January 1, 2012; first round of applications are due in early 2012. The first ACO agreements will start 4/1/2012 and 7/1/2012; those ACOs will have agreements with a first performance "year" of 18 or 21 months. Those ACOs would be required to report quality measures for CY 2013 (but not CY 2012) to qualify for shared savings in the first performance "year." Start date for subsequent years only on January 1.	p. 126 – 132 Final Decision: p. 132 "ACOs will be afforded the flexibility to submit to begin participation in the program on April 1 (resulting in an agreement period of 3 performance years with the first performance year of the agreement consisting of 21 months) or July 1 (resulting in an agreement period of 3 years with the first performance year of the agreement consisting of 18 months)." p. 132
Aggregate reports and preliminary prospective assigned beneficiary list	Reports will be provided at the beginning of each performance year and include: name, date of birth, sex, and health insurance claim number.	Additional reports will be provided quarterly	p. 159 – 168 Final Decision: p. 163 and p. 168 "We agree with commenters that providing quarterly aggregate reports on the preliminarily prospective assigned population would assist ACOs in conducting population-based activities relating to improving health or reducing costs, protocol development, case management and care coordination." p. 167

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Assignment process	One-step assignment process: beneficiaries assigned on the basis of a plurality of allowed charges for primary care services rendered by primary care physicians (internal medicine, general practice, family practice, and geriatric medicine).	Two step assignment process: • Step 1: Assign beneficiaries based on plurality of allowed charges for primary care services rendered by a primary care physician in the ACO. • Step 2: For beneficiaries who have not received any primary care services from a primary care physician, use plurality of allowed charges for primary care services rendered by any other ACO professional.	p. 193 – 202 Final Decision: p. 202 "Under this approach, beneficiaries are first assigned to ACOs on the basis of utilization of primary care services provided by primary care physicians. Those beneficiaries who are not seeing any primary care physician may be assigned to an ACO on the basis of primary care services provided by other physicians." p. 202
Marketing guidelines	All marketing materials must be approved by the Centers for Medicare & Medicaid Services (CMS).	"File and use" 5 days after submission if the ACO certifies compliance with marketing guidelines. ACOs must use " template" language developed by CMS, if available.	p. 532 – 537 Final Decision: p. 537 "[T]his final rule allows ACOs to use marketing materials 5 days after filing them with CMS if the organization certifies that the marketing materials comply with all applicable marketing requirements." p. 537