Proskauer

CMS’s Final Rule on Medicare Shared Saving Program Eases Some Regulations But Leaves Unanswered A Number Of Questions

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The Medicare Shared Savings Program (MSSP) final rule will be published in the Federal Register on November 2, 2011, approximately seven months after it was proposed. The final rule is the next major step by the Department of Health and Human Services (DHHS) in the establishment of accountable care organizations (ACOs) under the 2010 Affordable Care Act (ACA).[1] The Centers for Medicare and Medicaid Services (CMS) much-anticipated and well publicized final rule includes a number of changes to the proposed rule directly in response to over 1300 comments and feedback received from the health care community. Writing in the *New England Journal of Medicine*, Donald M. Berwick, M.D., Administrator of CMS, asserted that many of the changes in the final rule significantly reduce barriers to entry by streamlining governance and reporting burdens on potential ACOs.

A. Summary of Final Rule

The final rule includes a number of changes to the proposed rule to more effectively fulfill the intent of MSSP's three-part aim consisting of: (1) better care for individuals; (2) better health for populations; and (3) lower growth in expenditures. The key modifications that illustrate CMS's attempt to reduce or eliminate the burdensome requirements that could discourage participation in ACOs include the following:

- **Greater flexibility in eligibility to participate in MSSP**. The final rule adds Federal Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) as eligible to form and participate in an ACO. The proposed rule allowed FQHCs and RHCs to participate but not form an ACO independently. CMS also launched a complementary program – the Advance Payment Model – for ACOs in need of prepaid savings to build their ACO systems. The Advance Payment Model is

scheduled to begin in 2012 with application deadlines that mirror those for MSSP.

- **Greater flexibility in the legal structure of an ACO**. Existing legal entities which are eligible to be ACOs are permitted to continue to use their existing legal structure as long as they meet other ACO eligibility and governance requirements.
- **Greater flexibility in the governance structure of an ACO**. Unike the draft rule, which required all ACO participants to be represented on the ACO's governing body, or have physicians and other health professionals as a majority of their governing bodies, the final rule simply requires 75 percent of the ACO governing body to be representative of ACO participants.
- **Multiple start dates in 2012 and a longer agreement period for the ACOs starting in 2012**. The final rule calls for the first round of applications by early 2012, with the ACO agreements starting on April 1, 2012 and July 1, 2012. Under the final rule, ACOs will have 18 or 21 months for the first "performance year."
- **More streamlined quality performance standards**. In response to industry comments, the final rule reduced the number of quality measures from 65 to 33. The final regulations also remove the complicated care coordination measures relating to chronic disease.
- **Eased electronic health record requirements**. The final rule removes the requirement that 50% of the primary care physicians in an ACO had to show Meaningful Use of an electronic health record by the beginning of the second year of the shared-savings program. Instead, CMS said that ACOs that have a high percentage of meaningful users have an opportunity to achieve higher quality scores in the new scoring method.
- **More, and more flexible, financial incentives**. The final rule makes adjustments to the financial model to increase financial incentives to participate. ACOs will be able to start sharing in the savings immediately rather than requiring the achievement of a threshold level of savings. The final rule also removes the 25% withholding of shared savings. In addition, ACOs can elect not to share losses during their first CMS contract period.
- **Prospective vs. Retrospective Assignment of Beneficiaries**. The final rule changes the way that assigned beneficiaries are indentified to the ACO. The new method is described as a "preliminary prospective-assignment method" whereby the beneficiaries are identified quarterly with a final reconciliation after each performance year. ACOs will also have the ability to contact beneficiaries from quarterly lists to notify them of date sharing and their ability to opt-out.

B. OIG, FTC, DOJ and IRS Updated Guidance

In a coordinated effort with CMS to encourage more participation in MSSP, the Department of Health and Human Services Office of Inspector General (OIG), the Federal Trade Commission (FTC), the Department of Justice (DOJ) and the Internal Revenue Services (IRS) addressed antitrust, fraud and abuse, and tax exemption concerns for ACOs. OIG issued an interim final rule establishing five waivers of the physician self-referral law, the anti-kickback statute and certain provisions of the civil monetary penalty (CMP) law in connection with the MSSP. The IRS issued Fact Sheet 2011-11 that clarifies some confusion about how the IRS will treat ACOs. The IRS expects that MSSP participation through an ACO "generally will further the charitable purpose of lessening the burdens of government" therefore qualifying the ACO for tax-exempt status.

A joint antitrust policy statement by the FTC and DOJ made two significant changes from the initial policy statement in an effort to reduce the administrative burden and encourage greater participation in ACOs. First, the final policy statement applies to all providers that are eligible or intend to participate in an ACO. The initial rule was limited to providers formed after the 2010 Affordable Care Act was passed. Second, the final policy eliminates the mandatory antitrust review as a condition of participation. Many healthcare industry leaders raised concerns to the federal agencies that the mandatory antitrust review was a significant barrier for increased ACO participation. Although the FTC and DOJ agreed to eliminate the mandatory antitrust review, they made clear that the agencies would be actively monitoring the competitive effects of ACOs and that the FTC and DOJ would be working with CMS in sharing ACOs' applications and data to ensure that the antitrust laws are enforced and that market competition is protected.

C. Open Questions Remain

Despite the approximately 700 pages of comments and responses by the federal agencies concerning ACOs, a number of questions still remain unanswered. These questions include:

1. Can ACO participants be contractually required to refer patients?
2. To what extent will the FTC and the DOJ evaluate ACO applications and how strictly will they apply the antitrust laws to ACOs?
3. Actuaries for CMS anticipate that MSSP could save Medicare $940 million over four years. Unfortunately, this is a small amount compared to the $2 trillion Medicare anticipates spending over the next four years. To what extent will CMS encourage

commercial entities to use CMS's ACO models to come up with new and innovative ways to lower health care costs and improve quality?

4. Will ACO strategies be adopted by providers and payers without any further incentives by CMS?
5. What will the impact of MSSP be on companies that deliver and pay for health services?
6. How will ACOs and similar "patient-centered" models change the profitability of the health care industry?
7. What are the investment opportunities for traditional and non-traditional health care companies to be successful in a value-based, integrated health care system?

If you have any questions about the CMS's final rule on ACOs, the final policy statement by the FTC and the DOJ or CMS's other initiatives please contact Richard J. Zall, Elizabeth M. Mills, Ryan P. Blaney, or a member of Proskauer's Health Care Team.

[1] The "Affordable Care Act" means The Patient Protection and Affordable Care Act ("PPACA") and the Health Care and Education Reconciliation Act of 2010 ("HCERA"). For more information about the Acts, please visit our Health Care Reform Task Force Web site at http://www.proskauer.com/practices/health-reform-task-force.