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CMS's Final Rule on Accountable Care Organizations

Changes to Proposed Rules Likely to Increase Formation of ACOs; Questions Remain Regarding California Medical Foundation Clinic Participation

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On October 20, 2011, the Centers for Medicare and Medicaid Services ("CMS") released a final rule (the "Final Rule") regarding the formation of accountable care organizations ("ACOs") and the implementation of the Shared Savings Program (the "Program"). The Final Rule takes into account the many comments received by CMS in response to its ACO proposed rules, which were issued on March 31, 2011 and were published in the April 7, 2011 Federal Register (the "Proposed Rules"). In connection with the Final Rule, CMS and the Department of Health and Human Services Office of Inspector General announced an interim final rule regarding the waiver of fraud and abuse laws for ACOs, the Department of Justice and Federal Trade Commission released an ACO antitrust policy statement, and the IRS issued further ACO-related guidance as well. The Final Rule will be published in the November 2, 2011 Federal Register.

Background

In an effort to slow the seemingly constant escalation of health care costs in this country, CMS established ACOs with the goal of providing individuals with better health and better care for lower costs. The Final Rule defines an ACO to be any legal entity that is recognized and authorized under applicable State, Federal or Tribal law, is identified by a Taxpayer Identification Number, and is formed by one or more ACO participants. The Final Rule defines "ACO participant" as an individual or group of ACO providers/suppliers that is identified by a Medicare-enrolled TIN and that alone or together with one or more other ACO participants comprises an ACO. Providers and suppliers that choose to join an ACO and participate in the Program are electing to better coordinate patient care, which is expected to result in both improved care and reduced costs. In order to encourage such participation, the Final Rule provides an ACO with the ability to share in all savings generated for the Medicare program.

Changes to the Proposed Rules – More Reason to Participate

No doubt as a reaction to the often negative comments it received in response to the Proposed Rules, CMS made many changes to the Final Rule that are likely to encourage participation in the Program

and result in more ACOs being formed. Some of the most significant changes to the Proposed Rules that seem likely to result in greater participation are:

1. One-Sided Risk Model. The Proposed Rules offered two tracks to participate in the Program – one track which involved two years of the ACO sharing in potential savings alone and a third year of the ACO sharing in potential savings and losses, and a second track which involved the sharing of potential savings and losses throughout each year of the agreement. The Final Rule leaves the second track unchanged, but revises the first track so that it only allows for sharing in potential savings, not losses. By eliminating the deterrent of possibly sharing in losses under the first track, the Final Rule is likely to encourage greater ACO experimentation and Program participation.

2. Governance and Management Structure. Whereas the Proposed Rules appeared to advance strict, rigid requirements for the governance and management structure of ACOs, the Final Rule has provided significantly more flexibility. The Final Rule removes the requirement that each ACO participant (or a representative of the participant) must have a seat on the ACO's governing body. Furthermore, it also enables organizations that would like to participate in the Program but do not meet all its normal prerequisites to explain to CMS why, even though it does not satisfy each requirement, its governance and management structure advances the goals of ACOs and the Program, which CMS will consider when accepting or denying applications.

3. Insurance Risk. There has been some debate regarding whether an ACO participating in the Program takes on insurance risk and whether the ACO would be required to obtain an insurance license, depending upon the particular state in which it operates. The comment section of the Final Rule reveals that CMS does not believe participation in the Program involves insurance risk to providers. CMS' view in this regard may influence the thinking of certain State insurance regulatory entities about the matter, and could make the Program more attractive to potential applicants. Nonetheless, for those ACOs participating under the Two-Sided Risk Model, it would be prudent to confirm with State officials that there is no need to obtain an insurance license in order to participate as an ACO.

4. Quality Measures. Under the Proposed Rules, 65 separate quality measures in 5 separate domains would be used to evaluate an ACO and determine compliance with Program requirements. The comment period revealed that many potential participants felt there were too many quality measures and that this was discouraging participation. The Final Rule cut the number of quality measures nearly in half, reducing the number to 33 and also reducing the number of domains to 4. This will reduce the burden of participation, and, as a result, is likely to encourage ACO formation.

5. Shared Savings. Although the Proposed Rules allowed those participating under the Two-Sided Risk Model to share in savings from the first dollar of savings, it provided that those participating under the One-Sided Risk Model could only share in savings generated beyond a minimum savings rate. The Final Rule eliminates this bias in favor of the Two-Sided Risk Model by providing that all ACOs, whether participating under track one or track two, will share in savings from the first dollar of savings once the minimum savings rate has been achieved.

6. Start Date. The Final Rule adds flexibility for those that seek to form an ACO and participate in the Program. Whereas the Proposed Rules required all applicants to begin participating at the

same time, the Final Rule establishes two different start dates to allow participation to begin at different times in 2012. CMS will begin accepting applications for the Program on January 1, 2012, and the two start dates are April 1, 2012 and July 1, 2012. By providing greater start date flexibility, the Final Rule is likely to accommodate more groups and thus further encourage participation.

7. Electronic Health Records. In order to participate in the Program, the Proposed Rules required that at least 50% of an ACO's primary care physicians be defined as meaningful users by the start of the second performance year. Although electronic health record use remains a quality measure to be considered in evaluating performance under the Final Rule, the 50% threshold requirement has been eliminated completely. To the extent this requirement acted as a barrier to entry under the Proposed Rules, the change in the Final Rule is likely to encourage greater participation.

8. Prospective Beneficiary Assignment. One of the popular criticisms of the Proposed Rules was the fact that it called for retrospective, rather than prospective, beneficiary assignment to ACOs. The Final Rule, however, provides that beneficiaries will be assigned to ACOs prospectively rather than retrospectively. This provides greater predictability to ACO participants and should thus make participation in the Program more appealing.

Can California Medical Foundation Clinics Become ACOs?

Similar to the Proposed Rules, the Final Rule refrains from expressly listing a medical foundation clinic as an entity that can independently establish an ACO, but does not appear to foreclose that possibility either. At least part of the answer may lie in the requirement that in certain circumstances a separate legal entity will be necessary in order to form an ACO. Part of the answer may also depend upon what kind of stake an ACO participant must have in the ACO itself.

According to the Final Rule, an ACO formed among two or more otherwise independent ACO participants will be required to pursue an ACO through a separate legal entity and TIN. Moreover, an ACO participant cannot serve as the entity that is the ACO itself. This may mean, for, example, that a medical foundation clinic with a nonprofit hospital corporation as its sole member may be permitted to serve as the ACO, with the nonprofit hospital as a member of the ACO and ACO participant.

However, available guidance has not offered a clear position about what kind of stake an ACO participant must have in the separate ACO entity. As a result, it is not clear at this point whether a group of physicians that wishes to participate in an ACO that is a medical foundation clinic would have to have corporate membership in the medical foundation clinic/ACO, or whether meaningful participation on the governing board of the ACO would constitute a sufficient stake in the entity. All potential ACO applicants and participants would benefit from increased clarity regarding what kind of stake ACO participants must have in the ACO itself, be it membership, equity interest or meaningful participation in ACO governance.

What does appear clear, however, in light of the guidance in the Final Rule that an ACO participant cannot also be the ACO itself, and that a separate legal entity must be established, is that medical foundation clinics that exist as internal corporate divisions of existing nonprofit public benefit corporations in California (and not separate legal entities) cannot become an ACO (although they should be able to be an ACO participant).

Take Away

While some may decide that the Final Rule still does not provide enough to incentivize formation of an ACO and participation in the Program, there can be little doubt that the Final Rule goes beyond the Proposed Rules in this regard and provides greater flexibility to ACO participants as a whole. Nonetheless, certain unanswered questions remain in the Final Rule, including, but not limited to, whether a California medical foundation clinic may itself serve as an ACO. Perhaps CMS' more flexible approach to ACOs in the Final Rule, including its governance and structure requirements, may bode well for medical foundation clinics that intend to become ACOs. Nonetheless, the ACO model may not be viable or appropriate for all healthcare providers. In some cases, it may make more sense for certain providers to pursue integration strategies and quality measures that resemble ACOs in some respects, but stop short of actually participating in the Program.

In all likelihood, entities seeking to form an ACO will be required to make various organizational and governance changes in order to meet the requirements for participation in the Program. For those providers that are interested in participating in the Program, it would be wise to read the Final Rule in its entirety and consider the necessary steps to proceed before making a final decision.

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If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings Los Angeles lawyers:

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