# ACO Final Rule and Guidance Documents Released

*By Adrienne Dresevic, Esq. and Carey F. Kalmowitz, Esq.*

On October 20, 2011, the Centers for Medicare & Medicaid Services (CMS) released the Accountable Care Organizations (ACOs) Final Rule. The highly anticipated release comes in the wake of the April 7, 2011 publication of the ACO Proposed Rule, which elicited a significant (and primarily negative) response from the provider community. According to CMS, the changes implemented within the Final Rule reflect its efforts at reducing participation burdens and costs for potential ACOs in light of concerns often expressed by stakeholders during the Proposed Rule comment period.

By way of background, two of the principal goals of the 2010 Patient Protection and Affordable Care Act (PPACA) were to improve the quality of Medicare services while simultaneously reducing ever-rising Medicare expenditures. As a result, numerous provisions of PPACA required the implementation of value-based purchasing programs. In particular, Section 3022 of PPACA mandated the establishment of the Medicare Shared Savings Program and aimed to encourage the creation of and participation in ACOs. Under the Shared Savings Program, ACO participants meeting certain quality and savings requirements would be eligible for financial incentives, with funds for these payments being drawn from the overall savings accomplished by the program.

**ACO Final Rule Modifications**

The Final Rule includes a number of substantial modifications intended to encourage ACO participation and ensure the success of the Shared Savings Program. These changes, a number of which materially diverge from the Proposed Rule, should be understood by every healthcare provider as the presence of ACOs as a fixture on the healthcare landscape is fast approaching. According to the Final Rule, ACOs wishing to begin participating in the Shared Savings Program in 2012 will be able to take advantage of multiple start dates (April 1 and July 1) and longer agreement periods (ie, term periods of 42 and 45 months in certain circumstances). However, in subsequent years, the start date will be standard (January 1), and each agreement will be valid for a three year term.

Overall, the Final Rule affords more flexibility in the legal and governance structure of ACOs relative to the Proposed Rule. For example, the Final Rule strikes the requirement that each participating ACO must have a proportionate share of control of the ACO governing body. Also, ACO participants, providers, and suppliers may now be admitted during the agreement term period, but certain other requirements established by the Final Rule must be met to comply with the regulations when additional entities join the ACO (eg, CMS notification within 30 days).

Further, the Final Rule modifies the beneficiary assignment policy, moving the rule comparatively towards the prospective end of the prospective-retrospective spectrum. Although CMS was unwilling to wholly abandon the retrospective approach to assignment, the Final Rule nonetheless permits an initially prospective assignment of beneficiaries (ie, a beneficiary list will be created and provided to each ACO). The assignment list will be periodically updated, and retrospective reconciliation will still occur at the end of each performance year to allow for anticipated changes in the composition of beneficiary groups actually served by each ACO. All shared savings or losses assignments will be made based on the retrospectively adjusted lists.

Additionally, quality performance standards for participants have been significantly simplified and streamlined under the Final Rule. For example, the number of required quality measures has been decreased significantly from 65 to 33 (scored as 23 measures). Under the Final Rule, these measures are divided into four domains in contrast to the previously proposed five. Likewise, the use of the electronic health record (EHR) to report these measures has been eliminated as a requirement for participation.

Furthermore, under the Final Rule, financial incentives to participate have been meaningfully increased. For instance, ACOs may now share in the first dollar of savings as of the point at which the minimum savings rate (MSR) is met or exceeded under both tracks (ie, the earlier 2% requirement is removed). Likewise, the 25% withholding of shared savings, initially pro-

posed to offset potential losses, has been withdrawn, and the sharing caps for both tracks have been increased under the Final Rule.

Changes to the two participation tracks have been made under the Final Rule allowing for a "savings only" option. The downside risk in Track 1 has been eliminated, and ACOs may complete their entire initial agreement under this track. (However, ACOs may not remain in Track 1 past the first contract period.) As a result, ACOs will be able to participate during their initial contracts without any financial risk if they choose to do so. (Greater financial incentives to join under Track 2 remain).

A number of other, varied modifications are embodied by the Final Rule. For example, greater timing flexibility for the evaluation of shared savings is now permitted. Additionally, greater flexibility in the timing for repayment of losses has been established under the Final Rule. Further, ACOs incurring net losses during the initial agreement term will not be precluded from future participation in the program.

**Additional Recent Governmental Guidance Relating to ACOs**

In addition to examining the Final Rule, CMS encourages potential participants, providers, and suppliers to review other governmental guidance relating to ACOs which was recently developed in connection with the Shared Savings Program. First, on October 20, 2011, CMS and the Office of Inspector General (OIG) also released their interim Final Rule establishing waivers of certain fraud and abuse laws (eg, provisions of the Stark Law, Civil Monetary Penalties Law, and Federal anti-kickback statute) as they relate to certain ACO agreements. These waivers afford further flexibility to the structure and operation of ACOs. Further, the IRS simultaneously published the Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care Organizations. Lastly, the antitrust agencies (ie, FTC and DOJ) released their Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Shared Savings Program.

In view of the modifications incorporated into the Final Rule, all providers (even those who initially were unreceptive to ACOs) should carefully review both the Final Rule and the accompanying (above referenced) regulatory guidance to evaluate whether to consider ACO participation and to understand the legal and financial implications associated with such participation. Finally, although primary care physicians are accorded a central role in the Shared Savings Program, insofar as ACOs are designed to improve the entire spectrum of care furnished to Medicare beneficiaries, it is anticipated that imaging and other radiology providers will have a role in the ACO landscape.

*Adrienne Dresevic, Esq. graduated Magna Cum Laude from Wayne State University Law School. Practicing healthcare law, she concentrates in Stark and fraud/abuse, representing various diagnostic imaging providers, eg, IDTFs, mobile leasing entities, and radiology and multi-specialty group practices.*

*Carey F. Kalmowitz, Esq. graduated from NYU Law School. Practicing healthcare law, he concentrates on corporate and financial aspects, eg, structuring physician group practice transactions; diagnostic imaging and ancillary services, IDTFs, provider acquisitions, CON, compliance, and Stark and fraud/abuse.*

*The authors are founding members of The Health Law Partners, P.C. and may be reached at (248) 996-8510 or (212) 734-0128, or at www.thehlp.com.*

***Commentary***

# Basic Imaging Management: Q&A with the Authors

*By AHRA Staff*

"Basic Imaging Management: A Reference Manual" was published this summer. It was written by AHRA members based on a first hand "start from scratch" experience. They were presented with a radiology leadership change at a small associated clinic/hospital and were asked to provide interim leadership support. There was a need to establish basic department infrastructure and formal documentation. From this experience, this publication was born.

*Link* recently spoke to the authors to help readers better understand their experiences and motivations for writing this publication.

***Link*:** Can you give us a little more background on the experience that was the foundation for this publication?

**Sue Ramthun, Sue A. Rysted, and Kathleen J. Williams:** Our initial focus was daily department operation oversight and locating employee, equipment, policy, and scheduling information, and associated documentation. When we couldn't locate the expected information, we leveraged our knowledge and experience to start the policy, procedure and employee documents from scratch.

At this point we recognized the importance of having an information infrastructure and how we took it for granted in our own institution.