BNA's
Health Law Reporter™

Reproduced with permission from BNA's Health Law Reporter, 20 HLR 1662, 11/10/2011. Copyright © 2011 by The Bureau of National Affairs, Inc. (800-372-1033) http://www.bna.com

The Medicare Shared Savings Program Final Rule: Observations at the Nexus of Policy, Business, and Law, Part III

By Douglas A. Hastings

On Oct. 20, the Centers for Medicare & Medicaid Services released its final rule implementing the voluntary Medicare Shared Savings Program (program) for accountable care organizations (ACOs) (20 HLR 1581, 10/27/11). The final rule was released in conjunction with revised antitrust guidance from the Federal Trade Commission and the Department of Justice, as well as with the establishment by CMS and the Department of Health and Human Services' Office of Inspector General (OIG) of several waivers from various fraud and abuse laws. As part of this interagency effort to facilitate participation in the program, the Internal Revenue Service also issued a fact sheet regarding nonprofit organizations' participation in ACOs.

Douglas A. Hastings is chair of the board of directors of Epstein Becker & Green PC, Washington. Hastings wrote about ACOs in the April 14, 2011, and June 24, 2010, issues of BNA's Health Law Reporter. See ''Assessing the Impact of the Medicare Shared Savings Program Proposed Rule on Accountable Care Organization Development: Further Observations at the Nexus of Policy, Business, and Law'' (20 HLR 566, 4/14/11) and ''Constructing Accountable Care Organizations: Some Practical Observations at the Nexus of Policy, Business, and Law'' (19 HLR 883, 6/24/10).

The author would like to thank his colleagues Jason Caron, Ross Friedberg, Shawn Gilman, Mark Lutes, David Matyas, Rene Quashie, Serra Schlanger, Lynn Snyder, Carrie Valiant, Dale Van Demark, Patricia Wagner and Lesley Yeung for their contributions to this article.

CMS's implementation of the very specific provisions of Section 3022 of the Affordable Care Act constitutes a thoughtful and comprehensive effort that will (1) create more consistency in the treatment of ACOs by all payers, (2) foster a better understanding of the minimum requirements to qualify as a Medicare ACO, and (3) indicate how enforcement agencies will view ACO activities in both the Medicare and commercial markets. With the final rule, CMS again has made a significant contribution to the national dialogue on accountable care and the important role ACOs can have in helping to achieve the ''triple aim'' (i.e., better care for individuals, better health for populations, and lower growth in expenditures). Moreover, while all stakeholders may not agree with every revision made in the final rule, CMS clearly has responded carefully and thoughtfully to the over 1,300 comments received by stakeholders on the proposed rule. At the very least, this represents a healthy public-private dialogue on an important topic, which is how rulemaking is supposed to work.

Regardless of one's view of the provisions in the final rule, the lengthy preamble to the final rule represents a tremendously rich and intelligent discussion of the options that commenters suggested and the pros and cons that CMS considered. The analysis in the preamble will be instructive to state and commercial market ACO efforts even where different options and provisions are chosen.

Notwithstanding the fact that Section 3022 establishes a permanent program rather than a pilot or demonstration, the program will evolve over time, and it is only one component of the Affordable Care Act and of an overall, societal-wide period of testing and experimentation to find pathways for diverse providers to work together and with payers to deliver more accountable care. Along with the Pioneer ACO Model and state and private payer ACO programs, as well as the many other value-based payment initiatives blossoming throughout the United States, there is a legitimate basis for some optimism that we are making progress in payment and delivery reform despite the complexity.

Much has changed already since the March 31 issuance of the proposed rule (20 HLR 528, 4/7/11). At that point, there were, in my view, unrealistic expectations in the marketplace that CMS could succinctly outline a

COPYRIGHT © 2011 BY THE BUREAU OF NATIONAL AFFAIRS, INC. ISSN 1064-2137

program that could easily accommodate providers at widely different stages of development. There has been enough subsequent development of value-based programs and education around care coordination and clinical integration in the seven months since March 31 that the final rule is being issued in a more balanced environment.

Moreover, while the widespread negative reaction to the proposed rule may have been somewhat of an overreaction to CMS's attempt to set the bar to ACO entry high enough to advance the ball, there clearly were problems with it. In the final rule, CMS has gone a long way to addressing those problems while still keeping the bar reasonably high. Indeed, one can see some of the evolving thinking at CMS that went into the Pioneer ACO Model in the final rule.

Application Timeline and Agreement Term

For providers considering participation in the program, the final rule establishes a more detailed timeline than the proposed rule for applying to the program. Applications will be accepted beginning in January 2012, with April 1, 2012, and July 1, 2012, being the available start dates for participation in the first performance year. For 2013 and subsequent years, the start date will be Jan. 1.

As originally included in the proposed rule, program agreements will have a minimum term of three years. However, for ACO participants starting on April 1, 2012, the term of the agreement will be three years and nine months. For ACO participants starting July 1, 2012, the term of the agreement will be three years and six months. These ACOs may opt for an interim payment calculation to determine shared savings and losses at the end of their first 12 months of participation. For ACO participants starting in subsequent years, the ''performance year'' (for purposes of calculating shared savings and scoring quality performance) will be 12 months, from Jan. 1 to Dec. 31.

The program application requirements remain largely consistent with those set forth in the proposed rule. Entities that wish to become an ACO are required to submit an application to CMS along with a number of certifications and supporting documentation. In addition, the ACO must agree that CMS can share a copy of its application with the FTC and DOJ.

As part of the application, an ACO executive who has the authority to legally bind the ACO must certify that the information included in the application is accurate, complete, and truthful. Additional required certifications include:

- That the ACO's providers and suppliers have agreed to be held accountable for the quality, cost, and overall care of the beneficiaries assigned to the ACO;
- That the ACO is recognized as a legal entity authorized to conduct business in each area in which it operates;
- Whether the ACO (or any providers and suppliers that are part of the ACO) has participated in the program under the same or a different name; and
- Whether the ACO is related to, or has an affiliation with, another ACO participating in the program, and, if such an affiliation exists, whether the related ACO agreement currently is active or has been terminated.

In addition, supporting information that must be submitted to CMS with an ACO application includes documents that:

- Explain the ACO participants' rights and obligations in the ACO, including how shared savings will encourage quality assurance and program improvement (such as participation agreements and operating policies);
- Describe how the ACO will implement the processes and patient-centeredness criteria, including penalties and remedial measures that will apply if an ACO participant, provider, or supplier does not implement the processes;
- Outline the ACO's organization and management structure;
- Provide evidence to show that the ACO's governing body is an identifiable body that adheres to the control requirements described below;
- Explain the ACO's compliance plan; and
- Provide evidence to demonstrate that the ACO is capable of repaying losses or other monies determined to be owed to CMS, such as evidence that the ACO has acquired reinsurance, placed funds in escrow, obtained surety bonds, established a line of credit, or secured another appropriate repayment mechanism.

Upon request, an ACO must submit documents to CMS that demonstrate the ACO's formation and operations. Such documents may include:

- Charters;
- By-laws;
- Articles of incorporation;
- A partnership agreement or joint venture agreement;
- Management or asset purchase agreements;
- Financial statements and records; and
- Résumés and other documentation regarding the leaders of the ACO.

Finally, an ACO also must provide information regarding the individual participants, providers, and suppliers in the ACO, as well as a description of how it plans to use shared savings payments to achieve specific program goals and to achieve the ''triple aim.''

Framework for Analyzing the Rule

As an approach to assessing the final rule, I would pose the same five questions I used as a framework to analyze the proposed rule:

1. How well do CMS's requirements for ACO structure and governance balance the need for both flexibility and real change?
2. Does the way CMS handles provider risk, from both a financial and regulatory perspective, encourage ACO formation and participation in the program?

 COPYRIGHT © 2011 BY THE BUREAU OF NATIONAL AFFAIRS, INC. ISSN 1064-2137

3. Will the nature of the ACO-beneficiary relationship established under the final rule help avoid another managed care backlash?

4. Does the final rule advance the ball in measuring and promoting value in health care?

5. How well has CMS balanced the need to incentivize positive collaboration among providers to form effective ACOs, while also coordinating with the OIG, DOJ, FTC, and IRS in connection with their ongoing enforcement of the various laws regulating ACO participants?

Structure and Governance

Consistent with the proposed rule, the final rule provides that ACOs can be formed by the following entities or combinations of the following entities: hospitals and ACO professionals, group practices, hospitals employing ACO professionals, certain critical access hospitals, and networks of ACO professionals (which include physicians, nurse practitioners, physician assistants, and clinical nurse specialists). In addition, the final rule added federally qualified health centers (FQHCs) and rural health clinics (RHCs) to the above list of providers and suppliers eligible to form an ACO. The final rule also gives ACOs more flexibility to address care management challenges that emerge during a performance year by allowing the ACO to add to, or subtract from, its list of participants.

CMS has adopted most of the governance requirements set forth in the proposed rule. Specifically, the ACO must be a legal entity capable of receiving and distributing shared savings, repaying shared losses, and reporting quality performance data. The governing body is required to include ACO provider/supplier participants (ACO participants) or their designees who would have at least a 75 percent control of the governing body. Generally, the governing body of the ACO must include Medicare beneficiary representation. If the ACO is comprised of multiple independent entities, the governing board must be separate and unique to the ACO. For example, an ACO consisting of a hospital and a large independent primary care group practice could not have the same governing body as either the hospital or the primary care group practice.

The final rule, however, provides certain exceptions to these requirements to allow for greater flexibility in the manner in which ACOs are governed. Most significantly, the final rule provides an exception to the requirements that ACO participants have at least a 75 percent control of the ACO's governing body and beneficiary representation on the ACO's governing body. To qualify for this exception, the ACO must explain why it is not meeting the 75 percent control and/or beneficiary representation requirement, and how it will otherwise meaningfully involve ACO participants and/or Medicare beneficiaries in the ACO's governance. Moreover, and importantly, the requirement of ''proportionate control'' by each ACO participant is eliminated by the final rule. In addition, there is a useful discussion in the preamble about the oversight responsibilities of governing board members. As I and others have commented, board members will be fiduciaries of the entire ACO enterprise, not representatives of a faction.

Greater quality data reporting and transparency will require board oversight to assure that reporting is accurate, and compliance plans will need to be enhanced to address these expanded concerns. ACO boards and ACO sponsoring organization boards will need to ensure that appropriate and effective management and clinical personnel and protocols are in place to meet CMS requirements and to achieve the ACO's quality and financial goals. Health systems will need to consider which entity—one that currently exists or one to be formed—will serve as the ACO (including how many ACOs it may want to form or work with), and how to coordinate the ACO board or boards with other boards within the system. And finally, ACO boards and ACO sponsoring organization boards will need to review their committee structures related to quality in order to ensure that the board or board committee's charter requires attention to effectiveness, efficiency, and patient-centeredness in addition to patient safety.

Provider Financial Risk

Some providers viewed CMS's requirement in the proposed rule that ACOs bear risk under both the Track 1 and Track 2 models as a significant barrier to program participation. Although under the proposed rule, Track 1 ACOs would have been responsible for shared losses beginning in year three of the agreement term, CMS responded in the final rule by eliminating shared-loss risk from the Track 1 model.

The final rule gives each ACO the option to choose whether it will be subject to shared-loss risk during its initial performance year. ACOs that do not want to initially assume shared-loss risk have the option of choosing Track 1. ACOs that would like an opportunity to receive a greater amount of shared savings than the maximum amount available under Track 1 and are willing to share losses, if any are incurred, can choose Track 2.

The elimination of ''downside risk'' for Track 1 ACOs during the initial agreement term will permit ACO participants more flexibility to gradually ramp up their care management infrastructure over time. Although ACOs participating in Track 1 will not bear shared-loss risk during the initial agreement term, CMS states in the preamble to the final rule that all ACOs must participate in the Track 2 model in subsequent agreement periods.

The final rule defines ''savings'' as the difference between (1) actual Parts A and B spending during the relevant time period, and (2) CMS's predetermined spending ''benchmark'' for the particular ACO. The benchmark is risk adjusted, based on historical expenditures attributable to the ACO's assigned beneficiaries. Notably, whereas the proposed rule based the risk-adjusted benchmark on historical expenditure data for assigned beneficiaries, under the final rule, CMS will restate the risk-adjusted benchmark for each performance year, based on risk-adjusted severity and case-mix scores for assigned beneficiaries.

Generally, the final rule tracks the proposed rule's methodology for calculating shared savings. However, certain variables have been adjusted, such as the shared savings cap, the shared losses cap under Track 2, and the maximum percentage of shared savings. In many cases, these changes may enable ACO participants to receive a greater share of savings under both Track 1 and Track 2.

Track 1

According to the final rule, a Track 1 ACO, depending on its quality scores discussed below, is eligible to

share up to 50 percent of the savings it achieves. However, the total amount that a Track 1 ACO will receive under the formula is limited to 10 percent of the ACO's benchmark. The required minimum savings rate, which must be met or exceeded in order for an ACO to share in savings, for a Track 1 ACO varies between 2 percent and 3.9 percent, depending on the number of Medicare beneficiaries assigned to the ACO, with a lower level of Medicare beneficiaries correlating with a higher minimum savings rate (e.g., an ACO with 5,000 Medicare beneficiaries will have a minimum savings rate of 3.9 percent, and an ACO with 60,000+ Medicare beneficiaries will have a minimum savings rate of 2 percent).

Similar to the methodology used for calculating shared savings for Track 2 ACOs under the proposed rule, the final rule, for Track 1 ACOs, converts the minimum savings rate from a deductible to a ''basket'' that, once filled, permits first-dollar savings to be subject to the shared savings formula.

Track 2

According to the final rule, the required minimum savings rate for all Track 2 ACOs is 2 percent. Assuming that this basket/prerequisite has been satisfied, Track 2 ACOs can share, on a first-dollar basis, up to 60 percent of the savings they achieve, although the payment earned can be reduced under the quality metrics discussed below and it cannot exceed 15 percent of the benchmark. Track 2 ACOs do bear downside risk, carrying exposure of up to 60 percent of the losses, provided that the share does not exceed 5 percent of the benchmark in year one, 7.5 percent in year two, and 10 percent in year three. Consequently, Track 2 ACOs must demonstrate their ability to share in losses by obtaining reinsurance, placing funds in escrow, obtaining surety bonds, or establishing a line of credit as evidenced by a letter of credit that CMS can draw upon.

Under the final rule, CMS will not withhold 25 percent of shared savings payments in order to help ensure repayment of future losses. However, the final rule requires Track 2 ACOs to fully repay any shared losses to CMS within 90 days of being notified.

Finally, there are no material changes in the final rule relating to the regulation of provider risk-sharing, only the recognition that shared savings does not involve insurance risk. This nonchange leaves risk-sharing ACOs (even those with modest exposure under Track 2 or other limited risk models) subject to varying state laws and interpretations by state insurance commissioners both as to Medicare ACO participation as well as state and commercial market ACO participation. This issue represents a source of uncertainty and lack of uniformity that may be a real problem for some providers.

ACO-Beneficiary Relationship

CMS retains in the final rule the requirement that an ACO must have a strong primary care base and that a minimum of 5,000 beneficiaries must receive a plurality of their primary care from the ACO. In other words, to be ''assigned'' to an ACO, a beneficiary must receive more of his or her primary care from the ACO than from any other entity outside the ACO. Medicare beneficiaries are ''assigned'' to an ACO at the end of the reporting year (i.e., retrospectively).

In response to significant concerns that retrospective assignment would discourage provider participation in the program and impede efforts by providers to effectively target and focus the care management efforts of the ACO on the assigned beneficiaries, CMS has adopted a preliminary form of prospective assignment in the final rule as a supplement to retrospective assignment. While the actual assignment of beneficiaries under the final rule will remain retrospective for purposes of calculating the savings, CMS now will provide the ACO with quarterly reports based on the most recent data available, beginning with a report at the start of a performance year, listing the names, dates of birth, sex, and Medicare identifiers of beneficiaries who are on track to be assigned to the ACO.

The final rule also addresses concerns that limiting assignments to beneficiaries treated by primary care physicians will make it difficult for many provider groups to reach the 5,000-beneficiary threshold necessary to qualify as an ACO under the program. Whereas the proposed rule recognized primary care services provided by only primary care physicians, the final rule recognizes primary care services provided by specialists, physician assistants, clinical nurse specialists, and nurse practitioners in situations where the beneficiaries did not receive primary care services from a primary care physician. This change might make it possible for more provider groups to participate in the program, such as multispecialty group practices that rely on specialists to provide some primary care services to Medicare beneficiaries.

In response to public comment, another issue addressed in the final rule is whether primary care providers must be exclusive to one ACO. CMS clarifies in the final rule that this exclusivity restriction applies at the level of the ACO participant (i.e., the entity with a Medicare-enrolled tax identification number (TIN)) and only for Medicare beneficiary assignment purposes. Such exclusivity does not prohibit a primary care physician who is exclusive to one ACO from, for instance, seeing patients in facilities that are part of another ACO. Furthermore, if, for instance, a primary care physician medical group maintains multiple TINs, it may participate in multiple ACOs if it bills within each ACO utilizing a different TIN.

In the final rule, CMS states that it will share Medicare beneficiary claims data with an ACO upon request to assist the ACO with managing population health, coordinating care, and improving the quality and efficiency of care. It was proposed that the ACO would not receive the data in patient identifiable form until the beneficiary had been seen by a primary care ACO provider during the performance year, was informed about how the ACO intended to utilize the data, and had an opportunity to opt out of such use.

Given the centrality of advance data analysis and care management to address the utilization of data relating to complex patients and patients suffering from chronic conditions, many thought that this methodology posed a serious barrier to the timely application of lower-cost care paths for these beneficiaries. In the final rule, CMS has modified the data-sharing proposal to allow the ACO to contact beneficiaries before they are seen by an ACO provider during the performance year, using the quarterly list of beneficiaries likely to be assigned to the ACO provided by CMS. However, CMS preserves the beneficiaries' ability to opt out of data sharing. Beneficiaries have 30 days to decline data sharing and must be given the opportunity again during the

 COPYRIGHT © 2011 BY THE BUREAU OF NATIONAL AFFAIRS, INC. ISSN 1064-2137

next face-to-face encounter to decline to have their claims data shared with the ACO.

Measuring and Providing Value

Quality-measure reporting and performance attainment are important components of CMS's oversight of ACOs. To share in any savings generated through the program, an ACO must satisfy certain quality performance standards.

In response to concerns that the proposed rule imposed on providers an unmanageable number of quality measures for evaluating performance and calculating shared savings, CMS reduced the number of measures from 65 to 33 and the number of quality domains from five to four in the final rule. The four quality domains include patient/caregiver experience care, coordination/patient safety, preventive health, and at-risk population.

In the proposed rule, CMS suggested moving ACO participants from ''pay for reporting'' in the first performance year to ''pay for performance'' in subsequent years. While the final rule maintains this same structure, payment based on achieving minimum attainment levels will be phased in during the second and third performance years. Eligibility for shared savings in year two will depend on achieving minimum attainment levels for 25 measures and the reporting of the additional measures. By year three, eligibility will be based on achieving minimum attainment levels for 32 measures and the reporting of one additional measure.

To assist in the reporting of quality data to CMS and to spur the adoption of electronic health records (EHRs), CMS had proposed a requirement that at least 50 percent of an ACO's primary care physicians be ''meaningful users'' of EHRs by the start of the second performance year of the three-year agreement. However, CMS acknowledges in the final rule that the 50 percent meaningful use requirement may be a roadblock to participation and eliminated this requirement. Nonetheless, to emphasize the importance of EHR adoption, CMS has adopted one structural measure related to EHR incentive program participation and is requiring that this measure be double weighted for purposes of scoring and determining an ACO's performance.

To strike a balance between maintaining high performance standards and setting feasible attainment goals, CMS also has modified the program so that ACOs only need to achieve the minimum attainment level on 70 percent of the measures in each domain. This brings another level of comfort to providers that are worried that savings earned could be compromised by the arbitrary application of these metrics. However, to illustrate the importance of the double weight applied to the EHR measure, if an ACO fails to completely and accurately report the EHR measure, the ACO would miss the 70 percent cutoff for the care coordination domain and, thus, would not be eligible to share in savings.

Regulatory Oversight

Antitrust

Also on Oct. 20, the FTC and DOJ jointly released a Final Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (final statement) (20 HLR 1584, 10/27/11). Consistent with the proposed statement issued in April 2011 by the FTC and DOJ (proposed statement), the final statement accords presumptive ''rule of reason'' treatment to the concerted action of provider groups that are ''eligible and intend or have been approved to participate'' in the program. In other words, the antitrust agencies view CMS's eligibility criteria for ACOs as set forth in the final rule as broadly consistent with the indicia of clinical integration that the agencies previously have set forth, and, therefore, will provide rule of reason treatment, rather than *per se* treatment, as it might under current law, if, in the commercial market, the ACO uses the same governance and leadership structure and the same clinical and administration process that it uses to qualify and participate in the program.

Notably, in a significant departure from the proposed statement, the FTC and DOJ no longer are requiring ACOs in which two or more independent participants have a collective market of greater than 50 percent for shared services to request a prior antitrust review. The decision to remove this pre-clearance requirement eliminates a possibly unworkable provision from a timing standpoint and creates a less prescriptive framework for antitrust enforcement in connection with ACO formation and operation. The antitrust agencies clearly state that they will continue to protect competition in markets served by ACOs that participate in the program, including through monitoring of ACOs utilizing aggregate claims data provided by CMS. Moreover, the agencies will ''vigorously monitor complaints'' about ACO formation and conduct. As with the proposed statement, the final statement does not apply to merger transactions, which will continue to be assessed under current merger guidelines.

Consistent with the proposed statement, the final statement also provides a safety zone for certain ACOs if they meet the standards required by CMS and include independent participants that do not have a collective market share for shared services of greater than 30 percent. The market share determination must be made whenever two or more independent participants have a shared service, and the assessment must take into account the ''primary service area'' of each of those participants. Moreover, for an ACO to be within the safety zone, the final statement requires all hospitals and ambulatory surgery centers to be nonexclusive and requires any dominant provider (i.e., any provider with a greater than a 50 percent market share in its ''primary service area'') to be nonexclusive.

In addition, the final statement provides guidance for those ACOs in which two or more independent participants have a collective market share of greater than 30 percent for shared services. Five types of conduct that ''may raise competitive concerns'' are identified, including the improper sharing of competitively sensitive information and conduct that does or could ''prevent private payers from obtaining lower prices or better quality services for their enrollees,'' such as the tying of an ACO's services to the private payer's purchase of other services from providers outside the ACO, most-favored nations clauses, and exclusive contracts.

Finally, the agencies have created a voluntary expedited (90 day) antitrust review process for those ACOs seeking such review. Whether many organizations over the 30 percent threshold avail themselves of this expedited review process remains to be seen, but it may be a helpful option in some cases.

In general, I find the discussion of acceptable and suspect behavior more useful than the discussion of safety zones. I am somewhat of a skeptic about the helpfulness of market-percentage based safety zones. Besides the usual problems with market definition, they inevitably tend to make safe activities that everyone already basically knows are safe and then to some extent throw everything else into confusion. I find it more useful for the agencies to describe activities or situations that they generally would deem to be consistent with the goals of the ''triple aim'' as set forth in the Affordable Care Act—clinically integrated care that improves outcomes, patient satisfaction, and cost efficiency—as well as, on the other hand, activities or situations that they generally would deem to be problematic and of concern. Then providers can assess on their own how to proceed.

Market concentration and market power concerns remain the subject of an ongoing national policy debate. New forms of contracting (rather than mergers) among providers to accomplish accountable care goals through bundled and global payments may help create antitrust-acceptable pathways (i.e., if payment is based on measurable value (quality over cost), where is the harm?). The private sector would benefit from greater payer-provider collaboration and acceleration of the movement to accountable care. Failure to do so will put more onus on government to regulate the prices of both and to micromanage the contract provisions between them.

Fraud and Abuse

In a comparison document to the final rule, CMS and OIG issued an interim final rule with a comment period Oct. 20 (20 HLR 1589, 10/27/11) that establishes five waivers of application of the physician self-referral law (Stark law), the federal anti-kickback statute, the civil monetary penalty (CMP) provisions prohibiting hospital payments to physicians to reduce or limit services (the gainsharing CMP), and the CMP law prohibiting inducements to beneficiaries (the beneficiary inducements CMP) involving ACOs under the program, including ACOs participating in the Advance Payment ACO Model to be administered by the Center for Medicare and Medicaid Innovation (CMMI). However, CMS and OIG specifically note that these waivers do not apply to other demonstration programs sponsored by CMMI (e.g., Pioneer ACOs); instead, any waivers required under these programs will be addressed separately.

As previously noted, CMS and OIG are issuing the waivers as an ''Interim Final Rule with comment period.'' The public will have 60 days from the date of publication in the *Federal Register* to submit comments. Although the Social Security Act generally requires that at least 30 days pass before a final rule becomes effective after the issuance or publication of the rule, the secretary of the Department of Health and Human Services proposes to waive the 30-day delayed effective date on the grounds that such as delay would be contrary to the public interest. In the preamble to the interim final rule with comment period, CMS and OIG indicate that a number of commenters stated that ACO applicants would ''forego applying until final waivers have become effective and sufficient time has elapsed to allow the applicants to use the waivers in a manner that would support their applications and the purposes of the program.'' In light of those comments, the HHS secretary (through these agencies) stated that ''a 30-day delay in the effective date for the final waivers could jeopardize an ACO's ability to submit timely an application for a participation agreement commencing in 2012.''

In response to the many commenters who asked for more than the two waivers included in the proposed rule, the interim final rule includes three additional waivers for a total of five, which address several different circumstances:

1. An ''ACO pre-participation'' waiver of the Stark law, the anti-kickback statute, and the gainsharing CMP, which applies to ACO-related start-up arrangements in anticipation of participating in the program, subject to certain limitations, including limits on the duration of the waiver and the types of parties covered;

2. An ''ACO participation'' waiver of the Stark law, the anti-kickback statute, and the gainsharing CMP, which applies broadly to ACO-related arrangements during the term of the ACO's participation agreement under the program and for a specified time thereafter;

3. A ''shared savings distributions'' waiver of the Stark law, anti-kickback statute, and gainsharing CMP, which applies to distributions and uses of shared savings payments earned under the program;

4. A ''compliance with the Physician Self-Referral Law'' waiver of the gainsharing CMP and the anti-kickback statute, which applies to ACO arrangements that implicate the Stark law and meet an existing exception; and

5. A ''patient incentive'' waiver of the beneficiary inducements CMP and the anti-kickback statute, which applies to medically related incentives offered by ACOs under the program to beneficiaries to encourage preventive care and compliance with treatment regimes.

Again, it appears that the rulemaking process worked well here, and that CMS/OIG listened and provided additional flexibility in seeking to achieve the goals of the Affordable Care Act while also preserving their ability to conduct aggressive enforcement where warranted.

Procedurally, in contrast to the issuance of most final rules (including interim final rules) in which the text of the actual rule is defined as being located in a particular section of the Code of Federal Regulations, CMS and OIG stated in the preamble to the interim final rule with comment period that the text of the waivers will simply be included in the *Federal Register* and posted on the agencies' websites, but not actually be codified into the regulations. The agencies requested comments from the public on this approach:

> *For ease of reference, the entire set of waivers and applicable requirements is set forth in section IV.B. of this [Interim Final Rule with comment period]. We will also make the waiver text available on both the CMS and OIG Web sites. Because the waivers cover multiple legal authorities and to ensure that the waivers, if modified, remain consistent over time and across relevant laws, we are not codifying the waivers in the Code of Federal*

 COPYRIGHT © 2011 BY THE BUREAU OF NATIONAL AFFAIRS, INC. ISSN 1064-2137

Regulations. We solicit comments about this approach.

Tax-Exempt Organization Issues

The IRS also released Oct. 20 a fact sheet (FS-2011-11) updating and clarifying its initial analysis in Notice 2011-20 regarding the participation by Section 501(c)(3) tax-exempt organizations in the program through an ACO (20 HLR 1605, 10/27/11). The fact sheet is a helpful update on the IRS's thinking about ACO activities and provides clarification of some of the guidance in Notice 2011-20, which should give tax-exempt organizations enhanced comfort when participating in ACOs.

Importantly, the fact sheet clarifies that the list of factors from Notice 2011-20 that the IRS provided as demonstrating that a tax-exempt organization's participation in an ACO does not result in private inurement or private benefit is disjunctive, and that ''no particular factor must be satisfied in all circumstances to prevent inurement or impermissible private benefit.'' The IRS reiterated that whether impermissible inurement or private benefit occurred will depend on the entirety of facts and circumstances and that strict or literal compliance with the factors is not always required.

The fact sheet is particularly valuable in that it demonstrates that the IRS will be reasonably flexible in applying tax restrictions to Section 501(c)(3) organizations participating in an ACO. In particular, the IRS is more forceful than in Notice 2011-20 that not only is the IRS likely to view participation in the program consistent with charitable purposes, the IRS also is prepared to recognize that participation in a nonprogram ACO also can be consistent with charitable purpose and exempt status under certain circumstances.

Advance Payment ACO Model

With the final rule, CMMI announced the testing of an ''Advance Payment ACO Model,'' an initiative to provide selected participants in the program with advance payments to invest in the infrastructure necessary for ACO operations. This model is available to two types of organizations: (1) ACOs that do not include any inpatient facilities and have less than $50 million in total annual revenue, and (2) ACOs in which the only inpatient facilities are critical access hospitals and/or Medicare low-volume rural hospitals and have less than $80 million in total annual revenue. ACOs that are co-owned with a health plan are ineligible for participation in the model.

Participants in the model will receive three types of payment: (1) an up-front, fixed payment; (2) an up-front, variable payment based on the number of historically assigned beneficiaries; and (3) a monthly payment based on the number of historically assigned beneficiaries. CMS will recoup the advance payments from the shared savings earned by the ACO. Applications to participate in the model will be made available shortly and are due with the program application.

Conclusion

If the goal of this next period of payment and delivery reform is to test multiple models and achieve reasonably broad participation so that the best practices can be identified and brought to scale, the changes made in the final rule appear consistent with that goal. Coupled with the ''closer to capitation'' structure of the Pioneer ACO Model, we have three logical, distinct risk models—pure shared savings, two-sided risk, and partial or full capitation. Moreover, with the program's operational start date pushed back in the final rule until April 1 and July 1, 2012, the initial roll-out of Medicare ACOs will be sequenced logically, with the Pioneer program beginning in January followed by the program. With the Advance Payment ACO Model for ACOs in need of prepaid savings to build their ACO systems, CMS has implemented yet another trigger to incent participation in Medicare ACOs. CMS estimates 50 to 270 participants in the program. Elsewhere, CMMI continues to suggest that the Pioneer program is oversubscribed. We will see what level of participation actually ensues.

With this final rule, CMS has addressed the most strident concerns expressed by stakeholders and policy commentators about the program, and commentary already is generally favorable. However, these changes certainly do not guarantee widespread participation. Developing an effectively functioning ACO is expensive and complex and takes time—many, of course, have been years in the making. But the final rule, in my view, should cause many organizations to at least take a second look. Even though a great deal of challenging requirements remain, and the financial models are uncertain and may not be especially attractive to many providers, there may well be mission reasons, organizational focus reasons, experience gaining reasons, legal protection reasons and other reasons for participating. At the very least, I would argue, the program has a legitimate place in the constellation of ACO and other value-based payment options being developed in the public and private sectors that together, over time, will continue to lead to progress on the road to accountable care.