ACO FINAL RULE RELEASED

On Thursday, October 20, CMS announced the final rules for Accountable Care Organizations (ACOs). The agency received more than 1300 comments on the proposed rules published last March. While the basic structure of the Medicare shared savings program remains as proposed, CMS made a number of revisions in key areas to encourage providers to participate. These changes attempt to respond to the major criticisms of the proposed rule.

In a separate rulemaking, the Center for Medicare and Medicaid Innovation (CMMI) proposed a system of advance payments to provide initial capital for selected ACO applicants. The payments would be recouped over time out of the savings achieved by the ACO. The FTC and Department of Justice, HHS Office of Inspector General and Internal Revenue Service also released policy guidance addressing some of the issues within their jurisdiction implicated by the ACO program.

The rules will be effective 60 days after publication in the Federal Register and the program will launch officially on January 1, 2012.

Although many stakeholders praised the changes announced today, it is still not clear how many organizations will ultimately decide to participate.

CMMI is also poised to announce the organizations that will participate in the Pioneer ACO program, a separate demonstration program designed for mature integrated health systems.

The ACO program is voluntary and is intended to help doctors, hospitals, and other providers improve their ability to coordinate care across all health care settings. Providers who meet certain quality standards can share in any resulting savings. Federal savings could be up to $940 million over four years, according to agency estimates.

**Eligible Providers**

The final rule requires that each ACO be responsible for at least 5,000 beneficiaries annually for a period of three years. Each group must include health care providers and Medicare beneficiaries on its governing board.

All Medicare providers can participate in an ACO, but only certain types of providers are able to sponsor one. These include physicians in group practice arrangements, networks of individual practitioners, and hospitals that are partnering with or employ eligible physicians, nurse practitioners, physician assistants, and specialists. To help providers serving rural and other underserved areas, the final rule allows Rural Health Clinics (RHCs), certain critical access hospitals and Federally Qualified Health Centers to participate.

**Quality Improvement Requirements**

In order to share in any savings an ACO must meet quality standards. CMS will evaluate
performance on risk adjusted quality standards that relate to 1) patient experience; 2) care coordination and patient safety; 3) preventive health; and 4) at-risk populations.

To earn shared savings the first year, providers must fully and accurately report across all four domains of quality. Providers will begin to share in savings based on how they perform in some of those 33 quality measures in the second and third performance years. CMS had originally proposed 65 standards, but reduced the number after providers successfully made the case about the great difficulty in achieving success with such a high number of quality measures.

**Shared Savings and Shared Losses**

CMS is implementing two models: a one-sided shared savings model, in which providers only share in savings; and a two-sided shared savings and losses model, in which providers also share in losses if growth in costs go up. The proposed rule had required ACOs in the one-sided shared savings model to share losses in the third year of the agreement period. In response to comments, CMS has modified the proposal, and the final rule allows groups to participate under the one-sided shared savings-only model for the entire length of their first agreement period. CMS anticipates that this change will help organizations with less experience coordinating care, such as some physician organizations or small or rural providers, gain experience before taking on the responsibility of sharing losses. It also allows more experienced providers to take on the responsibility of losses in exchange for greater potential rewards. ACOs may share up to 50 percent of the savings under the one-sided model and up to 60 percent of the savings under the two-sided model, depending on their quality performance.

For each year, CMS will develop a target level of spending for each ACO to determine its financial performance. Because health care spending for any group of patients normally varies from year to year, CMS will also establish a minimum savings and minimum loss rate that would account for these variations. This protects the Medicare Trust Funds from sharing savings, and providers against sharing in losses, due to normal variation in Medicare spending. Both shared savings and shared losses will be calculated on the total savings or losses, not just the amount by which the savings or losses exceed the minimum savings or loss rate. In addition, the amount of shared savings would depend on how well the team of providers performs on the quality measures specified in the rule.

The CMS chart at the end of this summary highlights some of the key differences between the proposed and final rules. The Shared Savings Program final rule is posted at: [www.ofr.gov/inspection.aspx](http://www.ofr.gov/inspection.aspx). Once the rule is published in the Federal Register, this link will no longer be operative.

**Advance Payment Model**

The Advance Payment Model tests whether advancing a portion of an ACO’s future shared savings will increase participation from physician-owned and rural providers. The Advance Payment Model was designed to support physician-owned and rural ACOs with upfront infrastructure investments. These providers will receive payments in advance that will be recouped as they achieve savings.
This model is open only to physician-owned organizations, critical access hospitals, and rural providers participating in the shared savings program. For more details, visit http://innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/advance-payment/.

**Antitrust Guidance for Providers**

CMS worked with the Department of Justice (DOJ) and the Federal Trade Commission (FTC) to facilitate the creation of ACOs by giving providers guidance on how to form integrated health care delivery systems without raising antitrust issues.

DOJ and FTC have issued a joint Statement of Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program. The agencies will give rule of reason treatment to an ACO if it uses the same governance and leadership structure and the same clinical and administrative processes in the commercial market as it uses to qualify for and participate in the shared savings program. CMS has dropped mandatory antitrust review in the final rule.

In addition, the antitrust policy statement outlines an expedited process that ACOs can use to obtain further guidance about their antitrust concerns. For more details, visit www.ftc.gov/opp/aco/ and http://www.justice.gov/atr/public/health_care/aco.html.

**OIG and IRS Information**


The CMS Appendix which compares major changes between the proposed and final rules follows.
### APPENDIX

**Proposed Rule versus Final Rule for Accountable Care Organizations (ACOs)**

In the Medicare Shared Savings Program.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Proposed Rule</th>
<th>Modifications in Final Rule</th>
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<tbody>
<tr>
<td>Transition to risk in Track 1</td>
<td>ACOs could choose from two tracks, each entailing a 3-year agreement. Track 1 would comprise 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.</td>
<td>Remove two-sided risk from Track 1. 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.</td>
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<tr>
<td>Prospective vs. retrospective</td>
<td>Retrospective assignment based on utilization of primary care services, with prospective identification of a benchmark population.</td>
<td>A preliminary prospective-assignment method with beneficiaries identified quarterly; final reconciliation after each performance year based on patients served by the ACO.</td>
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<tr>
<td>Proposed measures to assess quality</td>
<td>65 measures in 5 domains, including patient experience of care, utilization claims–based 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</td>
<td>33 measures in 4 domains. (Note: Claims-based measures not finalized to be used for ACO-monitoring purposes) 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.</td>
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<tr>
<td>Sharing savings</td>
<td>One-sided risk model: sharing beginning at savings of 2%, with some exceptions for small, physician-only, and rural ACOs. Two-Sided Risk Model: sharing from first dollar.</td>
<td>Share on first dollar for all ACOs in both models once minimum savings rate has been achieved.</td>
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<tr>
<td>Sharing beneficiary ID Cl</td>
<td>Claims data shared only for patients seen by ACO primary care physician during performance year; beneficiaries given opportunity to decline at the point of care.</td>
<td>The ACO may contact beneficiaries from provided quarterly lists to notify them of data sharing and opportunity to decline.</td>
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<tr>
<td>Eligible entities</td>
<td>The four groups specified by the Affordable Care Act, as well as critical access hospitals paid through</td>
<td>In addition to groups included in the proposed rule, Federally Qualified Health Centers and Rural Health Clinics are also</td>
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</table>
Method II, are eligible to form an ACO. ACOs can be established with broad collaboration beyond these providers.

eligible to both form and participate in an ACO. In order for beneficiaries to be assigned on the basis of utilization of primary care services, these organizations must provide a list of practitioners who directly render primary care services in their facilities.

| 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. First ACO agreements start 4/1/2012 and 7/1/2012. ACOs will have agreements with a first performance “year” of 18 or 21 months. ACOs starting 4/1/2012 and 7/1/2012 have option for an interim payment if they report CY 2012 quality measures. ACO must report quality measures for CY 2013 to qualify for first-performance-year shared savings. |
| Aggregate reports and preliminary prospective 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. |
| Electronic health record (EHR) Use | Aligning ACO requirements with EHR requirements, 50% of primary care physicians must be defined as meaningful users by start of second performance year. | No longer a condition of participation. Retained EHR as quality measure but weighted higher than any other measure for quality-scoring purposes. |
| 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: for beneficiaries who have received at least one primary care service from a physician, use plurality of allowed charges for primary care services rendered by primary care physicians.  
- 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 |
| Marketing guidelines | All marketing materials must be approved by the Center for Medicare and Medicaid Services (CMS). | “File and use” 5 days after submission and after certifying compliance with marketing guidelines; CMS to provide approved language. |