Feds Release Proposed ACO Rules

On March 31 (published April 7), several federal agencies issued proposed rules for Accountable Care Organizations (ACOs) created under the Patient Protection and Affordable Care Act, and solicited public comment for 60 days. Although subject to change, the proposed rules offer a road map showing how the government wants ACOs to be designed and implemented.

Coordinated Guidance From CMS, OIG, FTC, Justice Department and IRS

Because hospitals, physicians and other providers had raised regulatory and legal issues about ACOs, and specifically the Medicare Shared Savings Program (MSSP), the agencies issued their proposed rules and requests for comment concurrently. The Centers for Medicare and Medicaid Services (CMS) detailed how ACOs should look and work; CMS and the Office of the Inspector General (OIG) described potential waivers from physician self-referral and anti-kickback laws; the FTC and the Antitrust Division of the Department of Justice (DOJ) proposed a “Safety Zone” for ACOs, offering protection from antitrust enforcement; and the Internal Revenue Service (IRS) weighed in on the tax implications for hospitals and other tax-exempt organizations participating in ACOs.

Shared Savings Program

The MSSP is intended to enhance the care provided to a population of Medicare beneficiaries by using ACOs to coordinate the care, provide accountability, encourage innovation, and reward cost savings. Providers will continue to be paid by Medicare on a fee-for-service basis, but if ACOs work as hoped they will reward providers who improve efficiencies. CMS will do so by sharing savings and (for some ACOs) requiring re-payments of losses.

The Proposed Rules Do the Following:

1. Define ACOs and describe their structure.
2. Set guidelines for MSSP eligibility.
3. Establish an application and agreement process.
4. Outline criteria for measuring the success by ACOs.
5. Assure qualifying ACOs of protection from adverse regulatory consequences, including Antitrust enforcement.
6. Continue regulatory emphasis on Electronic Health Records (EHR) technology.
7. Reward savings with payments of up to 50% - 60% of savings from an ACO’s historical expenditure “benchmark” level.

An Outline of the Provisions

I. ACOs Defined/ Agreements Required

   A. ACO is a legal entity with its own Taxpayer Identification Number (TIN) with a specified governance structure.
      1. Made up of “ACO Participants” (primarily Medicare-enrolled providers or suppliers).
      2. Organized with a governing body (e.g., Board of Directors), which must include a patient/beneficiary as member.
      3. Managed by operating leaders/executives controlled by the governing body.
         a. Senior level medical director, who must be a board-certified physician.
         b. Responsible for clinical program which is:
            i. “evidence-based”
ii. improves care for individuals
iii. provides better health for population served
iv. lowers pace of expenditure growth
v. shares outcomes data/provides feedback to enhance services at the point of care

B. ACOs to sign 3-year agreements with CMS
   1. Success measured during each year of period.
   2. “Withhold” 25% of savings to cover/offset losses.
   3. If ACO “succeeds” and the withhold is not needed to cover losses, it will be used to pay savings to ACO Participants.

C. Beneficiaries
   1. Assigned to ACO based upon CMS’ retroactive review of primary care utilization.
   2. “Primary Care” means general practice, family practice, internal medicine and geriatrics.
   3. Minimum number is 5000; generally, the smaller the population, the higher the minimum savings rate (MSR).

II. Two “Tracks” for Payment Models
   A. Pure Savings Model (One-sided Model)
      1. First 2 years - share in savings, and no risk of losses.
      2. Year 3 - share in savings and losses.
      3. Sharing rate is 50%.
   B. Risk-based Model (Two-sided Model)
      1. ACO elects to share savings and losses all 3 years.
      2. Makes ACO eligible for higher 60% sharing rate.

III. How Are Shared Savings Payments Calculated?
   A. Expenditure Benchmarks
      1. Each ACO is given an expenditure benchmark.
      2. The benchmark is determined using historical costs (time-weighted) of assigned beneficiaries, using a retrospective review of assigned beneficiaries’ per capita data.
   B. “Cap” on Shared Savings
      1. CMS proposes a “cap” on the total amount of shared savings (7.5% of benchmark in first 2 years for Track 1 ACOs, and 10% of benchmark in year 3 and for all 3 years for Track 2 ACOs).
   C. Minimum Savings Rate (MSR)
      1. An ACO is eligible to receive payment for shared savings only if the estimated average per capita Medicare expenditures for its beneficiaries, adjusted for beneficiary characteristics, is at least the MSR.
      2. The MSR will account for normal variations in expenditures; ACOs are to be compensated for their quality and efficiency gains, not normal fluctuations in services; however, a higher MSR will result in fewer savings, potentially leading to fewer ACOs participating in the program.
      3. CMS proposes a sliding scale for MSRs, determined by both the number of beneficiaries assigned to an ACO and a “confidence interval” assigned to an ACO based upon its size and sophistication. Generally, a larger ACO will have a smaller MSR than those with fewer beneficiaries, with a floor of 2% for larger ACOs. However, to encourage a small ACO in a rural area to participate, the confidence interval may be adjusted to provide it with a smaller MSR.
   D. Net Sharing Rate
      1. All ACOs must exceed the MSR to be eligible for savings, and CMS will only share savings in excess of a certain threshold, although exceptions will be made so that some ACOs could share in first dollar savings.
      2. Generally, ACOs that exceed the MSR are eligible for a share of net savings above a 2% threshold (2% of its benchmark).
      3. ACOs would share in first dollar savings if they have fewer than 10,000 beneficiaries and are either ACOs with only
group practices or networks of ACO professionals, or serve certain rural or underserved areas or through extensive patient encounters at participating FQHCs.

IV. Quality Measures – Must be satisfied before any shared savings can be earned

   1. Patient/caregiver experience.
   2. Care coordination.
   3. Patient safety.
   4. Preventative healthcare.
   5. At-risk population/frail elderly care.

B. After 2012, CMS will offer other rules
   1. Based upon outcomes in early ACO experience.
   2. Data-gathering to be enhanced (CMS will make its GPRO tool available to participating ACOs).

V. Assurances from Other Regulators

A. ACOs can get waivers from:
   1. Civil Monetary Penalty (CMP) laws (e.g., “Gainsharing” restrictions).
   4. Waivers would protect providers as to distribution of shared ACO savings and other payments “necessary and directly related to participation with and operation of ACO program.”

B. Some ACOs will fit in Antitrust “Safety Zone”
   1. The FTC and the Department of Justice will evaluate the antitrust exposure of ACOs based on the “rule of reason” standard rather than a per se illegal standard. The “rule of reason,” very generally, weighs the likely procompetitive effects of the ACO against any anticompetitive effects.
   2. Level of antitrust scrutiny will depend upon ACO’s share of each common service in each participant’s PSA.
   3. If ACO’s “combined share” of each common service is 30% or less in its Primary Service Area (PSA), the ACO will fall within an antitrust “safety zone” and the agencies will not challenge the ACO on antitrust grounds.
   4. If ACO’s share of any common service is greater than 30% but none of the common services are more than 50% in its PSA, the ACO will be subject to antitrust review under the “rule of reason” standard. ACOs will have the option of obtaining agency review on an expedited basis in this case but may instead choose to “proceed without scrutiny.”
   5. If ACO’s share of any common service is greater than 50% in its PSA (and not within a “Rural Exception”), an antitrust submission and review will be required, and ACO participation is conditioned upon a favorable ruling (more pro-competitive than anti-competitive).
   6. When conducting required or optional reviews, the agencies have articulated certain practices – e.g., exclusive dealing, tying, certain restrictions on commercial payers, sharing competitively sensitive information – that will be viewed as particularly problematic from an antitrust perspective.
   7. Although the antitrust guides represent the views of the two federal antitrust agencies and are premised on existing law, they do not bind private parties (e.g., payers) or state antitrust enforcement officials and, hence, careful consideration of the antitrust issues related to ACOs is advisable.

Where Do We Go From Here?
Providers now have guidance, subject to finalization of the rules after the 60-day comment period. Those who have been standing on the sidelines pending this guidance may now get started, with significant assurance that their ACO design can meet regulatory acceptance.

2012 will be here soon enough. Those attracted to the availability of shared savings payments should proceed forward, with caution but also with enhanced confidence in the outcome.
First Steps in Responding to Rules
While the public comment/revisions/finalization process moves forward in the next three to four months, those considering forming an ACO should undertake the following steps:

1. Estimate the likely number and identity of beneficiaries who would be assigned to your ACO, based upon Primary Care Physicians who would be participants (for guidance, see Section II(D), “Assignment of Medicare Fee-For-Service Beneficiaries,” and its associated subsections in the Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations Notice of Proposed Rule)

2. Analyze/test your “combined share of common services” in your Primary Service Area, to see if you will be in an antitrust law “Safety Zone” (see “The Agencies’ Antitrust Analysis of ACOs That Meet CMS Eligibility Criteria” for explanation, and “Appendix” for sample calculations, in the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program)

3. Determine if the potential shared savings are attractive enough.

4. If a Medicare Shared Savings Program ACO is not for you, consider designing and implementing a program like an MSSP, but offer it outside the Medicare system to patients enrolled in commercial payment plans.

Conclusion
We can expect the health care industry to respond vigorously during the comment period. During this intervening period, clients should analyze where their ACO might fit in this regulatory scheme, if at all. Godfrey & Kahn attorneys will continue to monitor the developments involving ACOs and keep clients informed. If you have any questions about the proposed ACO rules or if you would like assistance with the first steps identified above, please contact Jeff Riester (920.831.6340 or jriester@gklaw.com) or Claire Finando (608.284.2605 or cfinando@gklaw.com) or another member of Godfrey & Kahn’s Health Care Practice Group.

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For additional resources, please see:
- Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations Notice of Proposed Rule
- Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program
- Notice of Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center
- IRS Notice 2011-20