SILHOL LAW
The law of health business

April 2011

ACOs Face Large Start-Up Costs Under Proposed Rules from CMS

Accountable Care Organizations (ACOs) will face large start-up costs under proposed rules issued on March 31 by the Centers for Medicare and Medicaid Services (CMS). An ACO is an organization of health care providers that agrees to be accountable for cost, quality and the overall care of Medicare beneficiaries who are assigned to it. ACOs are mandated under the Affordable Care Act (ACA). Because ACOs represent a new health care delivery and payment model, the proposed regulations were eagerly anticipated by the healthcare community.

CMS estimates average start-up costs and first-year operating expenses of $1.7 million for an ACO. The large costs are due to the numerous and highly detailed requirements that organizations must meet in order to be allowed to participate as an ACO under the Medicare Shared Savings Program (MSSP) established by ACA. CMS expects that 1.5 to 4 million Medicare beneficiaries will align with an ACO in the first three years and that an estimated 300 to 800 ACOs will participate in the program. The median estimate of savings to the Medicare program over the three-year period is $510 million.

The proposed rules (to be published in the April 7, 2011 Federal Register) are open for public comment for 60 days, after which CMS will issue final regulations. In conjunction with the proposed rules issued by CMS, the Internal Revenue Service (IRS), the Federal Trade Commission (FTC), the Department of Justice (DOJ), and the Department of Health and Human Services, Office of Inspector General (OIG) all issued notices explaining how those various agencies intend to treat ACOs.

Operational Requirements for ACOs

ACOs will face numerous requirements to be allowed to participate in the MSSP. Among them are establishment of a legal entity with shared governance by the various ACO members. The governing body of the ACO must be comprised of at least 75% ACO members, and include at least one Medicare beneficiary from the ACO service area. The ACO's operations must be managed by an executive acting under control of the governing board. There must also be a senior-level medical director, who is a board-certified physician. Moreover, there must be meaningful financial or human (time and effort) investment in clinical integration. The ACO must also develop evidence-based medical practices or clinical guidelines and have an IT infrastructure that allows for the collection and evaluation of clinical data.

ACOs will also be expected to have a designated compliance official who is not the ACO's legal counsel and who reports directly to the ACO governing board. There must be an effective compliance training program and adoption of a conflicts of interest policy. Participants cannot be added to an ACO after it is starts the three-year agreements, however, participants can be terminated from an ACO. Participation in the ACO cannot be conditioned on the referral of federal health care program beneficiaries.

Primary care providers must be exclusive to one ACO, however, specialty physicians, hospitals federally qualified health clinics and rural health centers may be participants in more than one ACO. An ACO may not participate in another Medicare program or demonstration involving shared savings, unless the ACO provider is an individual.

CMS retains the right to terminate an ACO for failure to meet reporting or quality requirements, or if the ACO fails to maintain at least 5,000 Medicare beneficiaries assigned to it. CMS must also approve all marketing and communication material that the ACO intends to use to educate, solicit, notify or contact Medicare beneficiaries regarding the ACO. CMS also has the right to conduct audits and monitor ACOs to verify compliance with program requirements.

Assignment of Beneficiaries

CMS proposes to assign Medicare fee for service beneficiaries to ACOs on a retrospective basis, depending on the ACO primary care physician that the beneficiary has seen the most during the preceding 12-month period. To address concerns that an ACO must have patient information in order to effectively manage a patient population, CMS proposes to provide ACOs, at the beginning of the calendar year, aggregated data on Medicare beneficiary use of health care services in the area the ACO serves. This data will be provided on a quarterly basis to ACOs and will be based on the most recent 12-month data.

ACOs must enter into a Data Use Agreement with CMS prior to the receipt of beneficiary indentifiable claims data. Beneficiaries will be given the option of opting-out of having his or her information shared with an ACO. The ACOs are responsible for notifying beneficiaries of the ACO's ability to request claims data about them if they do not object. ACOs must post signs in their facilities indicating their participation in the MSSP and provide other information to beneficiaries mandated by CMS.

Shared Savings and Shared Losses

ACOs must agree to a three-year agreement with CMS and can choose one of two models in which it can be eligible for shared savings. Under the "one-sided" model, an ACO will share in only the savings for the first two years and then be transitioned to a full risk model in the third year, when the ACO would be responsible for any losses to the Medicare program if costs exceed certain thresholds.

Under the "two-sided" model, the ACO would be responsible for any losses beginning in the first year, but in return, would be eligible for a greater percentage of any savings.

Shared savings will be determined based upon a comparison with a benchmark of expected average per capita Medicare fee for service expenditures. It will be risk adjusted for beneficiary characteristics. The proposed regulations also contain safeguards against ACO providers who attempt to "game" the system by coding changes without improved patient care.

Shared savings will be calculated using a 6-month claim run off period. CMS will withhold 25% of any earned performance payment to guard against losses in future years as well as to provide an incentive to ACOs to stay in the program for the full three-year period. At the end of the 3-year period, any positive balances will be returned to the ACO. If the ACO does not complete the three-year term, it will forfeit any withheld savings. ACOs must also establish a method by which any losses to the Medicare program are guaranteed, such as obtaining re-insurance, obtaining a surety bond, placing funds in escrow, or another method deemed acceptable by CMS. The ACO must guarantee losses equal to 1 percent of the per capita expenditures to its assigned beneficiaries for the most recent year available.

Coordination with Other Agencies

In connection with submitting an application to be accepted into the MSSP, ACOs must also seek a waiver from the OIG. The OIG has issued separate guidance indicating its proposed procedure for issuing waivers of the application of certain Civil Monetary Penalty law provisions, the Federal anti-kickback statute, and the physician self-referral (Stark) law to specified financial arrangements involving ACOs.

The DOJ and FTC have jointly issued a proposed Statement of Antitrust Enforcement Policy Regarding ACOs. The Statement sets forth a "safety zone" for ACOs that serve rural areas or that have a combined share of 30 percent or less of each common services in the ACO's Primary Service Area (PSA). If an ACO has a PSA share above 50% for any common service that two or more ACO participants provide, the ACO must obtain a letter from the DOJ or FTC confirming that it has no present intent to challenge the ACO on antitrust grounds. If the ACO's PSA share is between 30 and 50 percent for any common service provided by two or more ACO participants, the ACO may request an expedited review of its arrangement, or it may proceed without FTC/DOJ review and remain subject to an antitrust investigation.

The IRS also issued contemporaneously a solicitation for comments on what guidance, if any, is necessary for tax-exempt organizations participating in ACOs.