



Law Office:
428 McLaws Cr Suite 200
Williamsburg VA 23185

Voice 757.259.9200
Fax 757.259.9201
Toll free 877.635.5388 (Mellette)

Mailing Address:
P.O. Box 6133
Williamsburg VA 23188

CLIENT ADVISORY

CMS Issues Accountable Care Organizations Proposed Rule

On April 7, 2011, the Centers for Medicare and Medicaid Services (CMS) issued long-awaited proposed rules governing the establishment of Accountable Care Organizations (ACO). This Client Advisory provides a brief introduction to the concept of Accountable Care Organizations, their role in the Patient Protection and Affordable Care Act (ACA), and an overview of the opportunities and challenges for health care providers interested in becoming involved in or forming ACOs. Because of the scope of the proposed rules and the potential for ACOs to become a prevalent part of a healthcare delivery system, providers should familiarize themselves with the draft rules and consider submitting comments to CMS regarding specific concerns.

The ACO Concept and Role in Health Reform

The ACA, enacted in March 2010, requires the Secretary of Health and Human Services to establish a new program within Medicare that will contract with Accountable Care Organizations (ACOs). In brief, an ACO is a network of providers that work together to reduce healthcare costs for a defined patient population while delivering higher quality care through coordination and collaboration. To give providers incentives to create ACOs, the ACA authorizes the Secretary to launch a "Shared Savings Program" for these groups of health care providers and hospitals. Under the ACA, an ACO must, "be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it." In return, Medicare would return a percentage of any savings realized as a result of lower costs to the ACO. CMS aspires to launch ACOs as a new way of paying for medical care on January 1, 2012.

The proponents of ACOs believe that if ACOs have financial incentives to keep patients healthy through primary care and prevention, Medicare will achieve cost savings through fewer hospital admissions and expensive treatments. Federal health officials estimate that ACOs could save Medicare approximately \$510 million over three years. While such savings are modest in light of Medicare's \$519 billion in spending for 2010 alone, the hope is that ACOs will help create a new model to replace the current, less coordinated fee-for-service payment method – In addition, some experts predict private insurers will eventually adopt the ACO model being implemented by Medicare. The ACA seeks to use an ACO model to provide the benefits of managed care without the HMO consumer restrictions roundly disparaged in the 1990s.

Formation and Organization of ACOs

Under the ACO Proposed Rule, an ACO may be comprised of physicians and hospitals in group practices, networks of individual practices of ACO professionals, partnerships or joint venture arrangements between hospitals and ACO professionals, hospitals employing ACO professionals, and other Medicare providers and suppliers as determined by the Department of Health and Human Services (DHHS). Primary care providers may only participate in one ACO, but hospitals and medical and surgical specialists may participate in multiple ACOs. An ACO must enroll with CMS for at least a three-year period, with a once-a-year start date for new ACOs annually on January 1st. ACOs must get approval for any changes in ACO providers and certain changes may require an ACO to start over with a new three-year term or make an ACO ineligible for shared savings. ACO participants will not be eligible to participate in other Medicare shared savings programs, such as the independence at home program.

Shared-savings arrangements between providers could trigger ant-kickback rules and Stark law prohibitions under current law. However, CMS and the DHHS Office of the Inspector General have proposed waivers allowing for distributions of shared savings payments. In addition, the Federal Trade Commission and Department of Justice have issued a proposed policy as to ACOs that would prevent antitrust challenges so long as an ACO has less than a certain percentage (50%) in market share. The IRS has also issued guidance to tax-exempt entities wishing to participate in ACOs.

ACOs would have to serve a minimum of 5,000 Medicare beneficiaries. Current Medicare fee-for-service beneficiaries would be assigned to ACOs based on their primary care utilization during a “performance year.” Thus, if a beneficiary receives a plurality of their primary care from a physician from an ACO, the beneficiary would be assigned to the ACO. Although providers would be required to post signs and send letters notifying patients of the provider’s participation in an ACO, beneficiaries would not receive advance notice of their assignment. CMS projects that 1.5 to 4 million Medicare beneficiaries will receive care from providers participating in a shared savings program by 2015.

Governance of an ACO must consist of a board that includes representation from all ACO participants, as well as include members that are Medicare beneficiaries receiving care from the ACO. No more than 25 percent of board seats can be held by non-ACO participants such as payors and other non provider companies. Although the proposed regulations do not require ACOs to become separate legal entities from their participants, CMS is considering such a requirement.

The proposed regulations include 16 grounds for termination of an ACO’s shared savings agreement with CMS, such as failure to meet quality standards or avoidance of at-risk (and higher cost) beneficiaries. Several of these grounds are not subject to appeal.

Shared Savings Payment Structure

To provide incentives for providers to form ACOs, the ACA permits CMS to project a baseline cost, calculate savings achieved by the ACO, and share a portion of those savings with providers. CMS proposes a two “track” approach for shared savings agreements with different levels of risk. Under the first, “one-sided” approach, an ACO that achieves a minimum savings level would receive 50 percent of the money saved above that threshold, but would not be required to pay a penalty if it failed to reach target savings or spent above projections in the first two years. The minimum savings threshold required starts at 2 percent for the smallest ACOs and increases up to 3.9 percent for larger ACOs. Under the “two-sided” approach, an ACO could receive 60 percent of the money saved above the minimum savings threshold, but would be penalized if it incurred higher costs. Under both tracks, all ACOs would be responsible for losses in the third year of the ACO’s agreement with CMS.

CMS proposes to set savings benchmarks based on retrospective review of aggregate beneficiary-level data for the assigned ACO population. The benchmarks will be based on three years of data. Thus, CMS will project a spending target for the ACO and any spending below that figure would be considered savings and shared with the ACO if above the minimum savings threshold. CMS proposes that such savings payments will be made directly to the ACO, which is then responsible to equitably distribute the savings among participating entities. CMS also proposes that the agency have the authority to withhold up to 25 percent of shared savings in order to offset any future losses under the two-sided model, which would be released upon the completion of the ACO’s three-year agreement. Savings benchmarks may also be periodically adjusted by CMS based on several factors.

Quality Standards and Participation Requirements

For an ACO to be eligible to receive shared savings, the proposed regulations require that ACOs meet a number of quality, participation, and reporting standards. For example, CMS proposes that ACOs must document progress on 65 different “Quality Performance Standards.” The ACO must also develop a process that promotes evidence-based medicine, patient participation, and coordination of care. The ACO must develop and make available a patient survey tool, and have a process for evaluating the health needs of its patient population. A system to help identify high risk beneficiaries and develop individual care plans is required, and the ACO must also screen ACO participants and report and maintain a database of all ACO participants and their National Provider Identifiers.

Under CMS’ proposed regulations, ACOs must have a data-use agreement with CMS that will share beneficiary data. The ACO is required to supply beneficiaries with a form that allows them to opt-out of this data-sharing mechanism. The ACO must also provide aggregate population data regarding ACO beneficiaries to CMS several times per year, including financial performance, quality performance scores, aggregate metrics on the assigned population, utilization data at the start of the agreement period based on

historical beneficiaries, and identification of historically assigned beneficiaries used to calculate the benchmark.

To ensure accuracy, the ACO must be completely open to CMS audits of all ACO participants, including contractors and subcontractors. CMS will also monitor an ACO to ensure it is not avoiding at-risk beneficiaries who may incur higher costs. CMS must approve any marketing materials or other communications promoting the ACO. As well as being required to report data to CMS directly, each ACO will be required to publish information in a standardized format, including, among other elements, identification of participating providers, leadership, quality standard performance scores, shared savings information, and proportion of savings distributed to participants.

The regulations require that 50 percent of an ACO's primary care physicians must be meaningful Electronic Health Record users as defined by the HITECH Act and subsequent Medicare regulations.

Comments

ACOs have the potential to transform healthcare delivery by promoting quality while lowering overall costs through new efficiencies and coordination. However, the attempt of the proposed regulations to transform the visionary aspects of ACOs into specific rules and requirements is unlikely to translate into widespread provider enthusiasm to form ACOs. Although the draft regulations provide a blueprint for ACO participants to receive shared savings payments, those payments come with a good deal of uncertainty, extensive participation requirements, significant upfront costs, additional regulatory oversight, and significant financial risk.

Based on the scope and length of the proposed regulations, CMS will likely include significant changes in the final version of the draft rules. CMS is soliciting comments on the regulations, which are due by June 6, 2011. Providers who may be interested in participating in ACOs should consider submitting comments on the draft regulations.

Mellette PC is following legislative and regulatory actions regarding ACOs and related issues in health reform. If our firm can advise you further on ACOs or other matters, please let Peter Mellette, Harrison Gibbs, or Nathan Mortier know.