Alerts and Updates

MEDICARE SHARED SAVINGS PROGRAM AND ACO PROPOSED REGULATIONS: A SUMMARY

April 8, 2011

On March 30 2011, the Centers for Medicare and Medicaid ("CMS") issued the long-awaited, proposed regulations for the Medicare Shared Savings Program. These proposed regulations include details concerning the requirements for qualifying as an accountable care organization ("ACO"), such as:

- Eligible legal entities;
- Criteria for shared governance;
- Assignment of beneficiaries to ACOs;
- Different types of risk contracts;
- Benchmarks and calculations of savings; and
- Shared savings, antitrust issues and policies, Medicare anti-kickback, and other regulatory requirements as applied to ACOs.

This brief summary of the proposed regulations is not intended to be exhaustive. Rather, it is a description of several key highlights. A more detailed analysis will soon be available on the Healthcare Reform Center.

The Background

The Patient Protection and Affordable Care Act (Pub. L. No. 111-148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152), which amended certain provisions of Pub. L. No. 111-148 (collectively referred to as the "Act"), were passed on March 23 and March 30, 2011, respectively. Section 3022 of the Act added a new section under title XVIII, section 1899 of the Social Security Act which provides for a Medicare Shared Savings Program (the "Program") and the creation of ACOs. The Program is an extension of CMS's strategy to expand value-based purchasing concepts through a program that shares realized savings in the Medicare Fee For Service program, under parts A and B. Under the Program, providers and suppliers who participate in ACOs can continue to receive traditional fee-for-service payments under Parts A and B of Medicare as well as be eligible for additional payments based on meeting certain quality and savings requirements.

CMS is seeking comments on these proposed regulations by no later than May 28, 2011.

The Medicare Shared Savings Program

The Program is voluntary, and eligible entities are permitted to apply to the Program if they meet the requirements of an Accountable Care Organization. The Program must be implemented by CMS no later than January 1, 2012.

What Are Accountable Care Organizations?

The proposed regulations explain more fully the "bells and whistles" that make up an ACO. The eligible entities include: (1) "ACO Professionals," which are defined as physicians, nurse practitioners, physician assistants and clinical nurse practitioners; (2) hospitals that employ ACO Professionals; (3) a network of ACO Professionals, partnerships and joint ventures between hospitals and ACO Professionals; and (4) any other entity that the Secretary may approve. Several important points about ACOs under the Program are:

- ACOs must have shared governance that includes ACO suppliers, providers and beneficiaries in the governance structure, but not necessarily include members of the board of directors or managers, depending upon the structure. Shared governance may include advisory boards to the governing board of the ACO. Importantly, at least 75% of the control must be in the hands of the ACO participants—providers, suppliers and beneficiaries.

- Federally Qualified Health Centers ("FQHC") and Rural Health Centers ("RHC") are not considered eligible entities, but ACOs that include FQHCs and RHCs in their network will receive enhanced payments based on the number of visits.

- Each ACO must enter into an agreement with CMS for a three-year term and must have at least 5,000 beneficiaries assigned to the ACO.

- Under the Program, any agreement between CMS and an ACO may be terminated for failure to meet quality and other performance criteria, avoiding at-risk beneficiaries and other compliance requirements.

How Are Beneficiaries Assigned to ACOs?

Under the proposed regulations, the beneficiaries are allocated to the ACO based on the physicians with a specialty designation of general practice, family practice, geriatrics and internal medicine that provide the plurality of primary care services to the beneficiaries. The plurality is based on the sum of the allowable charges provided by the ACO physicians to the beneficiaries during the contract year.

How Are the Shared Savings Contracts Structured?

The total savings to be shared depends upon the type of risk contract the ACO enters into. There are two types of contracts: "One-Sided" and "Two-Sided" contracts. The One-Sided contract shares only the savings and not the losses between CMS and the ACO. In the Two-Sided risk contract, the ACO shares both the savings and the losses.

How Are the Shared Savings Calculated and Shared?

CMS will determine a benchmark, which includes the risk adjusted, per capita FFS expenditures for Parts A and B for the past three years. It will also be adjusted for certain trends for those beneficiaries assigned to the ACO. To minimize variation based on catastrophic claims, CMS will make certain adjustments to the benchmark.

A minimum savings rate ("MSR") will be determined by CMS based on a sliding scale of the total number of beneficiaries. As the number of beneficiaries increases, the MSR will decrease.

To determine the savings to be shared, the applicable minimum savings rate is applied to the benchmark, and if the ACO per capita expenditure for beneficiaries assigned to the ACO under Parts A and B is less than the adjusted benchmark, then the difference between the actual per capita expenditures and the benchmark reduced by the minimum savings rate will be shared between CMS and the ACO.

For One-Sided contracts, ACOs shall receive 50 percent of the savings, not to exceed 7.5 percent of the benchmark. For Two-Sided contracts, ACOs shall receive 60 percent of the shared savings up to 10 percent of the benchmark.

On all contracts, CMS may also withhold up to 25 percent of the savings to be shared to protect against premature termination. Each ACO with a Two-Sided contract must also provide for reinsurance and place funds in escrow, or other repayment mechanisms to assure the repayment of losses.

How Do Quality Measures Factor into the Savings Calculation?

In order to receive shared savings payments, the ACO must also meet certain quality performance measures which include patient safety, patient care, care coordination, high-risk/frail elderly and preventative health measures. In addition, the ACO must meet other related quality measures including but not limited to "Meaning Use" criteria required for electronic health records under the HITECH Act. Finally, all ACOs must demonstrate that their Programs are patient-centered.

What About Anti-trust Considerations Which ACOs Have Raised?

The Department of Justice and the Federal Trade Commission have issued an Antitrust Policy Statement that applies to ACOs approved for participation in the Program. The chart below illustrates what conditions necessitate antitrust review based on the potential for reducing competition within the primary service area ("PSA") by the ACO.

ACO PSA Share	Review Process
Less than 30 percent (with a rural exception)	*Safety Zone*—No antitrust review necessary by the antitrust agencies.
Greater than 30 percent and less than 50 percent	*Expedited Review—Comply with list of conduct restrictions, or proceed without antitrust assurances.* ACOs may: 1. Request an expedited review by the antitrust agencies and submit letter from the reviewing antitrust agency confirming that it has no present intent to challenge or recommend challenging the ACO, 2. Begin to operate and abide by a list of conduct restrictions, reducing significantly the likelihood of an antitrust investigation, or 3. Begin to operate and remain subject to antitrust investigation if it presents competitive concerns.

Greater than 50 percent	*Required Expedited Review*—ACO must seek review by the antitrust agencies to assess likelihood of procompetitive and anticompetitive effects. ACO eligibility to participate in Shared Savings Program is contingent on the ACO's submission of a letter from the reviewing antitrust agency confirming that it has no present intent to challenge or recommend challenging the proposed ACO.

No ACO will be approved for the Program if the ACO requires antitrust approval and does not receive it.

These proposed regulations are complex and offer many opportunities for innovative contracting. The payment system based on shared savings raises concerns about whether providers and suppliers will be better off financially under these programs. Providers and suppliers must consider all the financial, operational and governance ramifications before joining an ACO.

About Duane Morris

Duane Morris has an online Healthcare Reform Center to help guide employers, hospitals, physicians, nursing homes, and providers of home care services and new nursing home alternatives in their efforts to comply with the Patient Protection and Affordable Care Act of 2010. To access links to the relevant legislation and other online resources, a timeline of what to do and when to do it, and changes and provisions affecting healthcare providers, visit www.duanemorris.com/HealthcareReform.

For Further Information

If you have any questions about this *Alert* or would like more information, please contact C. Mitchell Goldman, any of the attorneys in our Health Law Practice Group or the attorney in the firm with whom you are regularly in contact.

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