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Alerts

CMS Posts Accountable Care Organization Final Rule

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Health Care Alert

On October 20, 2011, the Centers for Medicare and Medicaid Services (CMS) posted the final rule on the Medicare Shared Savings Program (MSSP) for accountable care organizations (ACOs) pursuant to Section 3022 of the Affordable Care Act (ACA). Under the MSSP, ACOs agree to be accountable for the quality, cost and overall care of the Medicare fee-for-service beneficiaries assigned to the organization. ACOs that meet specified quality performance standards will be eligible to receive a share of any savings if the actual per capita expenditures of their assigned Medicare beneficiaries are a sufficient percentage below benchmark amounts set by CMS.

The final rule includes a number of changes to the proposed rule (which was issued seven months ago) in response to comments from the health care industry. Changes include: greater flexibility in eligibility to participate in the MSSP; (2) multiple start dates in 2012; (3) establishment of a longer agreement period for those starting in 2012; (4) greater flexibility in the governance and legal structure of an ACO; (5) simpler and more streamlined quality performance standards; (6) adjustments to the financial model to increase financial incentives to participate; (7) increased sharing caps; (8) no downside risk and first-dollar sharing in Track 1; (9) removal of the 25 percent withhold of shared savings; (10) greater flexibility in timing for the evaluation of sharing savings (claims run-out reduced to three months); (11) greater flexibility in antitrust review; (12) greater flexibility in timing for repayment of losses; and (13) additional options for participation of federally qualified health centers (FQHCs) and rural health clinics (RHCs).

Eligibility to Independently Form an Accountable Care Organization

The ACA identifies four groups as eligible to participate in the shared savings program: (1) ACO professionals (i.e., hospitals and physicians) in group practice arrangements, (2) networks of individual practices of ACO professionals, (3) partnerships or joint venture arrangements between hospitals and ACO professionals, and (4) hospitals employing ACO professionals. The statute also gives the U.S. Secretary of Health and Human Services (Secretary) the discretion to expand eligibility to other groups of providers and suppliers as appropriate.

Under the final rule, the four statutorily identified groups, as well as critical access hospitals, FQHCs and RHCs, will be allowed to form ACOs independently. The proposed rule allowed FQHCs and RHCs to participate in ACOs, but not to form them independently.

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Legal Structure and Governance

Each ACO will be required to certify that it is recognized as a legal entity under state law. An ACO formed among two or more otherwise independent ACO participants (such as between a hospital and two physician group practices) will be required to establish a separate legal entity and to obtain a tax identification number (TIN).

An ACO must maintain an identifiable governing body with authority to execute the functions of the ACO, including but not limited to: the definition of processes to promote evidence-based medicine and patient engagement, reporting on quality and cost measures, and coordinating care. The governing body must have responsibility for oversight and strategic direction of the ACO. The ACO must provide for meaningful participation in the composition and control of its governing body for ACO participants or their designated representatives. At least 75 percent control of the ACO's governing body must be held by the ACO's participants.

Coordination of Care and Demonstrating Patient-Centeredness

In order to be eligible to participate in the MSSP, the ACO must provide documentation in its application describing its plans to: (1) promote evidence-based medicine; (2) promote beneficiary engagement; (3) report internally on quality and cost metrics; and (4) coordinate care. As part of these processes, an ACO is required to adopt a focus on patient-centeredness that is promoted by the governing body and integrated into practice by leadership and management working with the organization's health care teams.

Shared Savings Payment Models

As did the proposed rule, the final rule includes two shared-savings models. However, unlike the proposed rule, the final rule removes risk from the one-sided payment model, allowing providers to share in savings without the risk of sharing in losses. The proposed rule would have required all ACO providers to share in losses in the third year of their agreements.

Under the two-sided payment model, providers will share in savings and losses, with the added incentive of greater shared savings. Organizations that enter the MSSP under the first track, however, must switch to the second track for any subsequent participation in the program. Providers willing to take on more risk will be able to reap more shared savings under track two. 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 upon performance.

The final rule eliminates a 2 percent threshold for ACOs in the one-sided model to share in savings after reaching a minimum sharing rate (MSR). Instead, under both models, ACOs will receive shared savings for the first dollar after achieving the MSR. CMS will not require a "withhold" of part of any shared savings. Under the previously proposed rule, 25 percent of the shared savings would be withheld for a period of time. ACOs can opt for an interim payment if they report calendar year 2012 quality measures. ACOs must report quality measures for calendar year 2013 to qualify for first-performance-year shared savings.

Beneficiary Assignment

After identifying all patients who had a primary care service with a physician who is an ACO provider/supplier in an ACO, CMS will employ a stepwise approach as the basic assignment methodology. Under this approach, beneficiaries will be first assigned to ACOs on the basis of utilization of primary care services provided by primary care physicians. Those beneficiaries who are not seeing any primary care physician may be assigned to an ACO on the basis of primary care services provided by other physicians (e.g., specialist physicians). CMS will assign beneficiaries to ACOs that include FQHCs/RHCs in a manner consistent with how CMS assigns beneficiaries to other ACOs based on primary-care services performed by physicians.

An ACO must have a minimum of 5,000 beneficiaries assigned to it to participate in the MSSP.

Quality Measures and Performance

The final rule was modified to define the quality-performance standard at the reporting level in the first year and explain how quality performance will be determined in subsequent years. CMS reduced the number of quality measures for the first performance year from the proposed 65 to 33 in four, instead of five, domains: (1) patient experience, (2) care

coordination, (3) preventive health, and (4) caring for at-risk populations. The amount of an ACO's shared savings/losses is tied to performance on these quality measures.

ACOs will be required to completely and accurately report on all 33 measures for all reporting periods in each performance year of their agreement period, and CMS will phase in pay for performance in performance years two and three. ACOs must achieve the quality performance standard on 70 percent of the measures in each domain; if an ACO fails to do so, CMS will place it on a corrective action plan and re-evaluate the following year. If the ACO continues to underperform in the following year, the agreement would be terminated.

Additional Program Requirements

Beneficiary Protections. ACO participants are required to post signs in their facilities indicating their associated ACO provider's/supplier's participation in the MSSP and to make available standardized written notices developed by CMS to Medicare fee-for-service beneficiaries whom they serve. Standardized written notices must be furnished in settings in which ACO fee-for-service beneficiaries are receiving primary care services.

Auditing and Monitoring. CMS will use the many methods at its disposal to monitor ACO performance and ensure program integrity, including but not limited to, undertaking an audit. CMS may sanction ACOs for poor quality performance, and may impose immediate termination or a corrective action plan in addition to a warning letter for ACOs that are underperforming on quality performance standards.

Conflict of Interest Policies and Compliance Plans. All ACOs are required to adopt conflict-of-interest policies and compliance plans. ACOs may coordinate and streamline compliance efforts with those of its ACO participants and ACO providers/suppliers. Compliance plans must be updated periodically to reflect changes in law, including new regulations regarding mandatory compliance plan requirements of the ACA. ACOs will be required to submit annual compliance certifications by the timeframe that CMS will establish through guidance.

No Referral Requirement. ACOs, their participants, and their providers/suppliers are prohibited from conditioning participation in the ACO on referrals of federal health care program business to the ACO, its participants, or its providers/suppliers for services they know or should know are being provided to beneficiaries who are not assigned to the ACO.

Marketing Materials. An ACO may "file and use" marketing materials five days after submission if the ACO certifies compliance with marketing guidelines. ACOs will be required to use template language developed by CMS when available, must comply with prohibitions regarding certain beneficiary inducements, are prohibited from using marketing materials in a discriminatory manner or for discriminatory purposes, and are prohibited from using inaccurate or misleading marketing materials.

Beneficiary Inducements. An ACO, its participants, or its providers/suppliers may provide to beneficiaries items or services for free or below fair market value if all the following conditions are met:

- The ACO remains in good standing under its participation agreement.
- There is a reasonable connection between the items or services and the medical care of the beneficiary.
- The items or services are in-kind and either are preventive care items or services or advance one or more of the following clinical goals: adherence to a treatment regime; adherence to a drug regime; adherence to a follow-up care plan; or management of a chronic disease or condition.

Compliance with Program Requirements. CMS will use a variety of sanctions, such as warning letters and corrective-action plans to address noncompliance that CMS considers minor in nature and pose no immediate risk of harm to beneficiaries or impact on care. CMS may terminate an ACO's agreement for serious noncompliance with MSSP requirements, including those concerning maintaining eligibility.

ACO Application Requirements and Deadlines

The final rule calls for the first round of applications by early 2012, with the ACO agreements starting on April 1, 2012 and July 1, 2012. Additional ACOs may join the program on January 1 of each subsequent year. Each ACO will enter a three-year agreement with CMS. However, ACOs will have agreements with a first performance "year" of 18 or 21 months.

Download the final rule on the Medicare Shared Savings Program, which is slated for publication in the Federal Register on November 2, 2011. Download the CMS Fact Sheets that summarize the final rule on the Medicare Shared Savings Program.

Fraud and Abuse, Antitrust and Tax Implications

The U.S. Department of Health and Human Services Office of Inspector General and CMS have also jointly issued an interim final rule with comment period establishing waivers of certain federal laws—the physician self-referral law, the anti-kickback statute, and certain provisions of the civil monetary penalty law—in connection with the MSSP. In addition, the U.S. Department of Justice (DOJ) and the Federal Trade Commission (FTC) issued an antitrust policy statement, and the U.S. Internal Revenue Service (IRS) issued a fact sheet for tax-exempt organizations participating in the MSSP.

Download the interim final rule: Medicare Program; Final Waivers in Connection With the Shared Savings Program.

For more information, please contact Michael A. Dowell, or your regular Hinshaw attorney.

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