Accountable Care Organization ("ACO") - The Real Journey Begins

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Under the first track, an ACO operates through the one-sided model for the first two years, but is then required to operate under the two-sided model for the third and subsequent years. Under the second track, an ACO would participate in the two-sided model from the beginning. ACOs that select this second track would be eligible to receive a higher percentage of savings generated. Except as otherwise stated below, CMS has proposed that the majority of the requirements for ACOs participating in the one-sided model will also apply to those ACOs participating in the two-sided model.
The following types of health care entities are authorized to form ACOs under the Proposed Rule:

1. certain health care providers in group practices;
2. networks of individual practices;
3. partnerships or joint venture arrangements between hospitals and certain health care providers;
4. hospitals employing ACO professionals; and
5. certain Critical Access Hospitals ("CAHs").

In addition, these entities may establish ACOs with broader collaborations. Those collaborations may include additional health care providers and suppliers, many of whom would not be able to form ACOs and participate in the program independently.

A. Legal Structure and Governance

An ACO may be structured as a corporation, partnership, limited liability company, foundation, or other entity permitted by law to operate health care providers, including the quality performance standards; and (4) performing the other ACO functions identified in the statute.

Under the Proposed Rule, ACOs shall satisfy the following operational elements, among others: (1) at least 75% of control shall be by providers of services to Medicare beneficiaries; (2) there must be a quality assurance and improvement program which is physician-directed; (3) the ACO must implement evidence-based medical interventions; (4) the ACO must collect and communicate data; and (5) the ACO must comply with the requirements for program integrity.

B. Accountability for Beneficiaries, Distribution of Savings and Patient Threshold

The ACO participants must certify that they will become accountable for and report to CMS on the quality, cost, and overall care of the Medicare beneficiaries assigned to the ACO during the three-year agreement period. The number of Medicare patients assigned to the ACO over the three-year period must exceed 5,000 for each year the ACO participates in the Shared Savings Program. Shared savings distributions will be provided directly to the ACO, not to providers directly.

C. Processes, Marketing and Program Integrity Requirements

ACOs must develop and report to CMS its processes and plans to promote evidence-based medicine, patient engagement, reporting, and coordination of care. Additionally, all ACO marketing materials, both those used by the ACO and the ACO participants, must be approved in advance. The ACO must also have in place criteria for program integrity, including compliance plans with program requirements, a conflict of interests’ policy, screening methods for ACO applicants, and policies to prohibit conditioning participation in the ACO on referrals of Federal health care program business provided to beneficiaries who are not assigned to the ACO.
II. 3-Year Agreement for Participation in Shared Savings Program

The Proposed Rule permits CMS to provide substantial data to ACOs about their assigned beneficiaries’ use of health care services to help the ACO improve the quality of care, health, and efficiency of the delivery of services. Specifically, CMS would provide aggregate data reports that include historical utilization, some limited identification information (including name and date of birth), frequency of the beneficiary’s use of certain services such as emergency department visits, and Part D data for Medicare patients who have primary care visits with an ACO primary care physician. The ACO will be required to execute a Data Use Agreement with CMS (“DUA”) to receive this information.

IV. Assignment of Medicare Beneficiaries to ACOs

The Proposed Rule assigns beneficiaries to ACOs based solely on their utilization of primary care services provided by physician ACO participants. Thus, primary care physicians would be required to belong exclusively to one ACO, whereas other provider types could belong to multiple ACOs. CMS will develop a set of educational materials for beneficiaries about ACOs, and ACOs would be required to provide notification to beneficiaries when they seek services from ACO providers and suppliers. This notified must be provided through written information and through signs posted in the facilities of participating ACO providers and suppliers, of the organization’s status and the implications for the beneficiary. Beneficiaries must also be notified if an ACO is terminated or withdraws from the program.

V. Quality and Other Reporting Requirements

In an effort to reward providers for high quality care, the Proposed Rule sets forth certain quality measures and reporting requirements, including: (1) measures to assess quality; (2) instructions on how to report data; (3) performance standards; and (4) reporting requirements to CMS and the public.

The Proposed Rule proposes 65 measures relating to outcome, process and patient experience that are designed to promote better care to individuals and better health for certain populations. These
measures are designed to assess: (1) improved patient/caregiver experience; (2) care coordination; (3) patient safety; (4) preventive health; and (5) the health of at-risk populations, such as those with diabetes, heart failure, coronary artery disease, hypertension and the frailty. The specific measures for each of these categories can be found on pages 174-194 of the public display version of the Proposed Rule’s preamble. Additionally, ACOs must report certain data to CMS and the agency will establish collection tools to assist with that requirement.

B. Standards

The Proposed Rule proposes two alternatives for rewarding quality. The first option is Performance Scoring under which CMS would use quality performance standards to arrive at a total performance score for an ACO. That score would determine its shared savings percentage.

The second option is to establish a minimum Quality Threshold for participating ACOs using the same set of quality measures and benchmarks as the first option. If an ACO meets these thresholds, it would be eligible for a percentage of shared savings attributable to quality. If an ACO fails to meet this threshold, it would not be eligible for shared savings. CMS invites comments on these options, as well as on alternatives that would blend the two approaches.

C. PQRS/EHR

CMS has incorporated some existing Medicare Physician Quality Reporting System (“PQRS”) and EHR reporting requirements into the Shared Savings Program. Specifically, the Proposed Rule would require eligible professionals (i.e. physicians, physical therapists, and certain other providers) to use the PQRS group practice reporting option to provide data through the ACO, upon which an incentive payment would be conditioned. The Proposed Rule would also require that at least 50 percent of an ACO’s primary care physicians to be “meaningful EHR users” by the start of the ACO’s second performance year. CMS has invited comments on these proposals.

Finally, the Proposed Rule compels ACOs to publish a variety of information related to their operations and performance, including: (1) the identities of the ACO’s participating providers; (2) shared savings or losses; (3) the manner in which the ACO has used shared savings payments; and (4) quality performance standard scores.

VI. Determining Shared Savings

To be eligible for shared savings, an ACO must achieve a minimum threshold of savings above a benchmark amount in a given year. This minimum threshold is the “minimum savings rate” (“MSR”). The percentage of the savings that the ACO is eligible to receive is referred to as the “sharing rate” which is capped under the Proposed Rule.
The shared savings methodology requires three components to be determined. First, CMS sets an expenditure benchmark which will not be shared savings. The benchmark is based on the expected average per capita beneficiary spending in the area. The expected average per capita beneficiary spending is a measure of the area’s current average per capita beneficiary spending plus a risk adjustment factor to account for the area’s expected future changes in average per capita beneficiary spending.

Under the Proposed Rule, the MSR for the one-sided model ranges from 3.9 percent for an ACO with the minimum 5,000 or more beneficiaries assigned. The proposed MSR for all ACOs in the two-sided model would be 2 percent across the board.

Certain rural ACOs and those serving underserved populations may be exempt from the MSR and therefore, share in all the savings generated. ACOs eligible for up to a 2.5 percentage point increase in its shared savings rate for the first two years of its agreement.

ACOs in the one-sided model may be eligible for up to 50 percent of the total savings generated by the ACO above the MSR, while ACOs in the two-sided model, the proposed cap would be set at 10 percent of the ACO’s benchmark. CMS is soliciting comments on the payment caps and whether higher limits or different limits for different ACOs would be more appropriate.

For the benchmark calculation, CMS considered two approaches and requests comments on both. Under Option 1, the benchmark would be calculated as the average per capita beneficiary spending for the most recent calendar year. Under Option 2, the benchmark would be calculated as the average per capita beneficiary spending for the most recent calendar year plus a risk adjustment factor to account for the area’s expected future changes in average per capita beneficiary spending.

The ACO will also be required to submit a certification to CMS at the time it submits payment for such losses (as well as any other ACO activity) subject to claims under the Federal False Claims Act.

CMS has also requested comments on the two-sided model in regard to whether any of its proposals would trigger the requirement for ACOs, ACO participants, and ACO providers and suppliers to retain (and make available for audit and inspection) records of their activities for a period of ten (10) years from the end of the agreement period.

Significantly, CMS has also proposed that voluntary or involuntary of an ACO agreement would result in the loss of the ACO’s mandatory 25% withholding of shared savings. Further, CMS retains the ability to terminate an ACO for avoiding “patients at-risk.” CMS has also requested comments on its definition of “patients at-risk” and whether additional characteristics should be considered.

IX. Coordination with Other Agencies and Overlap with Other CMS Shared Savings Initiatives

Due to the scope of the Proposed Rule and its potential implication on other federal laws and policies, CMS coordinated with the HHS Office of Inspector General (“OIG”), the Federal Trade Commission, and the Department of Justice when issuing this Proposed Rule. The results of this coordination are further described below.

X. Waivers of CMP, Anti Kickback, and Physician Self Referral Laws
Section 1899(f) of the Social Security Act authorizes the Secretary to waive application of certain federal healthcare regulatory provisions – specifically, Civil Monetary Penalty Act (“CMP”), the Anti-Kickback Statute (“AKS”), and the Physician Self-Referral Law (the “Stark Law”) – in connection with operations of ACOs.

Section 1877 of the Act, or the Stark Law, is a civil statute prohibiting physicians from making referrals for so-called “designated health services” to other physicians or entities with which the referring physicians have a financial relationship. Distributions of shared savings would be considered a financial arrangement, and to the extent that ACO providers refer to one another, the Stark Law would be implicated.

However, under the proposed waivers, an ACO will receive waivers from application of the Stark Law application for distributions of shared savings received by the ACO from CMS if: a) the distribution is to or among ACO participants; or b) the distribution is for activity “necessary for and directly related to” the operation of the ACO, whether or not the recipient is participating in the ACO.

Financial relationships between the ACO and outside referring physicians will not be protected unless the physicians are being compensated for activities “necessary for and directly related to” the ACO’s operations and participation in the Shared Savings Program. This proposed waiver is limited to distributions of shared savings received from CMS; other financial relationships must still fit an exception within Stark.

Section 1128B(b) of the Act, or the AKS, provides criminal penalties for individuals and entities who knowingly give or receive remuneration to induce referrals of services payable by federal healthcare programs. Similar to the Stark Law, the AKS could be implicated by an ACO’s distributions of shared savings as between healthcare providers who refer to one another, if the distributions are intended to induce referrals. However, under the Proposed Rule, applicability of the AKS would be waived in the following two scenarios.

The first scenario addresses distribution of shared savings is to or among ACO participants, or the distribution is for activities “necessary for and directly related to” the operation of the ACO, whether or not the recipient is participating in the ACO. The second scenario addresses any financial relationship between or among the ACO participants/suppliers “necessary for and directly related to” the ACO’s operations in the Shared Savings Program that both a) implicates the Stark Law and b) fully complies with an existing Stark Law exception.

The Proposed Rule clarifies that the first scenario above is meant to protect financial arrangements created by the distribution of shared savings within the ACO and outside the ACO if the outside
activities are “necessary for and directly related to” the operation of the ACO.

Rarely does compliance with the Stark Law immunize conduct under the AKS or CMP. But in this case, for administrative and regulatory simplicity, the Secretary attempted to minimize the regulatory burden on ACOs and allow Stark Law compliance to act as a surrogate safety net in the AKS and CMP contexts as well.

D. Civil Monetary Penalties.

Section 1128A(b)(1) and (2) of the Act, or CMP, prohibits payments from hospitals to physicians to induce reduction or limitation of services to federal program beneficiaries. ACOs invite scrutiny under CMP to the extent that hospitals share distributions of shared savings with physicians who, given improper motive, could be incentivized to reduce or limit services to Medicare beneficiaries to artificially increase the ACO’s savings to Medicare and thus its remuneration under the Shared Savings Program.

These waivers from application of the Stark Law, the AKS, and the CMP will last as long as the ACO participates in the Shared Savings Program, even if the actual distributions of share savings come after the agreement between CMS and the ACO ends.

XI. IRS Guidance Relating to Tax Treatment of Shared Savings

The IRS has published a notice seeking comment on the issues presented by the Medicare Shared Savings Program’s Proposed Rule. The IRS anticipates that tax exempt organizations, such as hospitals and other health care organizations, will be participating in ACOs. The notice solicits comments on what, if any, additional exempt organization guidance is warranted in light of the Proposed Rule.

Comments to the IRS’s solicitation of comments are due May 31, 2011.
Along with CMS’s Proposed Rule on ACOs, the Federal Trade Commission (“FTC”) and the Antitrust Division of the Department of Justice (“DOJ”) published for notice and comment their “ACO Antitrust Policy Statement”, which applies to collaborations among otherwise independent providers and provider groups formed after the date of enactment of the ACA (March 23, 2010). FTC/DOJ stated that the ACO Antitrust Policy Statement was proposed (1) to clarify the antitrust analysis of newly formed collaborations among independent providers that seek to become ACOs in the Shared Savings Program; and, (2) to coordinate the antitrust analysis with the CMS review of ACO applications to participate.

For antitrust review purposes, ACOs will essentially be divided into three categories: (1) A “safety zone” or exemption for which no Antitrust Agency review is required; (2) a “Mandatory Review” category, for which pre-application review by the Antitrust Agencies is mandatory to securing Shared Savings Program participation; and (3) an intermediate category for which is no “safety zone” exemption, but no mandatory review. These ACOs would be entitled to an expedited review process.

ACOs must analyze market share based on the respective “common services” rendered by independent ACO participants performed within their respective “Primary Service Areas” or “PSAs”. Each ACO must perform and submit an analysis of collective market shares relevant to the primary service area of each independent provider of common services, using zip code.

The results of the PSA market share analyses will indicate to an ACO whether they are subject to mandatory review, qualify for a safety zone, or land in the middle ground. ACOs may not participate in the Shared Savings Program without performing the comprehensive market share analysis, which in turn will determine if review by the Antitrust Agencies under the proposed ACO Antitrust Policy Statement is required, optional, or unnecessary.

The requirements of the ACO Antitrust Policy Statement could turn out to be very burdensome on some ACO’s. The PSA market share analyses, along with a complete copy of the materials to be submitted to CMS for the Shared Savings Program application must be submitted to one of the Antitrust Agencies at least 90 days prior to the CMS deadline for submission of applications. ACOs must be ready to accelerate their formation process to complete its application to CMS with sufficient time for the Antitrust Agencies to complete their review.

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