

Commenters Disappointed in Long-Awaited Shared Savings Rule

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Within days after the Centers for Medicare and Medicaid Services (CMS) proposed regulations establishing the Medicare Shared Savings Program and the requirements for participating accountable care organizations (ACOs) (the Proposed Rule), stakeholders began expressing concerns about the Proposed Rule. By the close of the formal comment period on June 6, 2011, hundreds of organizations and individuals had submitted comments on the regulations, many of which were highly critical of CMS's policy choices embedded in the rule. Unless the final regulations undergo a major rewrite, it appears that participation in the Shared Savings Program may be extremely low, a disappointing outcome for what many considered to be the centerpiece of the Affordable Care Act's efforts to drive widespread, meaningful reform of the health care delivery system.

Eligibility and Governance

Under the Proposed Rule, "an ACO means a legal entity that is recognized and authorized under applicable State law, as identified by a Taxpayer Identification Number (TIN), and comprised of an eligible group . . . of ACO participants." Proposed Rule at 19537. These eligible groups of ACO participants are ACO professionals in a group practice arrangement, networks of individual practices of ACO professionals, partnerships or joint venture arrangements between hospitals and ACO professionals, and hospit-

als employing ACO professionals. "ACO professionals" include an ACO provider or supplier that is either a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist.

Shared governance is a statutory requirement for ACOs seeking to participate in the Shared Savings Program. CMS proposes that the governing body of the ACO must be comprised of ACO participants and Medicare beneficiary representatives. ACO operations would be managed by an individual whose appointment and removal is subject to the governing body's authority. CMS also proposed that ACO participants, as well as ACO providers and suppliers, must demonstrate a "meaningful" commitment to the ACO's clinical integration program, such as through a meaningful financial investment in the ACO or a meaningful investment of time and effort in ACO operations. CMS also included requirements for ACO clinical management and oversight as well as quality assurance and improvement.

The Affordable Care Act requires ACOs to include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service (FFS) beneficiaries assigned to the ACO and that the ACO have at least 5,000 such beneficiaries assigned to it. CMS will deem an ACO to have a sufficient number of primary care physicians and beneficiaries if the

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number of beneficiaries historically assigned to the ACO participants is 5,000 or more.

An ACO must also demonstrate that it meets “patient-centeredness” criteria. CMS has interpreted this to require that the governing body promote and achieve patient-centeredness by ensuring that ACO leadership and management work together with the ACO’s health care teams. ACO must address nine patient-centeredness concerns, including implementing a beneficiary experience of care survey and a plan to use the results to improve care.

These requirements have been criticized by some as overly prescriptive and burdensome, adding unnecessary administrative costs to the ACO operations. In particular, some provider groups have objected to detailed governance requirements, urging more flexibility for ACO participants to establish decision-making processes.

The ACO Agreement

CMS sets forth detailed requirements for the content and execution of participation agreements and data exchange between the ACO and CMS. An ACO’s agreement with the Secretary of the Department of Health and Human Services must be for a term of at least three years, signed by an authorized executive of the ACO and submitted to CMS for review and approval. The agreement would begin on January 1 of the year following the year in which CMS approves the ACO application and would have three 12-month performance periods. An ACO must specify in its application how it proposes to use potential shared savings payments, including criteria for distributing shared savings among ACO participants and ACO providers and suppliers.

Assignment of Medicare FFS Beneficiaries to an ACO

The Affordable Care Act delegated to CMS the authority to determine a process for assigning beneficiaries to ACOs. Emphasizing FFS beneficiaries’ right

to exercise complete freedom of choice of the physicians and other health care providers and suppliers from whom they receive services, CMS opted for a retrospective assignment process focusing on whether a beneficiary in fact received care through the ACO. As proposed, CMS would assign a beneficiary to an ACO at the end of the performance year by determining whether a beneficiary has received a plurality of allowed charges for primary care services from physicians associated with a specific ACO to a sufficient degree that the ACO may be designated as exercising responsibility for that beneficiary’s care. Many commenters have urged CMS to prospectively assign beneficiaries to an ACO so that the ACO will know which patients they will be held accountable for and target care management activities accordingly. (In fact, before the comment period for the Proposed Rule closed, CMS had already proposed an ACO alternative demonstration project through the Center for Medicare and Medicaid Innovation – the “Pioneer Model” – which would allow the ACO to choose between retrospective and prospective assignment.)

Another highly controversial aspect of CMS’s proposed assignment process is the limited set of services that would qualify as primary care services for purposes of determining ACO assignments. Under the Proposed Rule, only primary care services provided by physicians would count towards determining whether the beneficiary’s care is being provided by a particular ACO. Primary care provided by non-physician practitioners and by federally qualified health centers would not count, nor would primary care services provided by specialists.

Quality Measurement and Reporting Requirements

An ACO must meet the so-called “quality performance standard” in order to qualify for shared savings. CMS has proposed the use of 65 measures to calculate whether an ACO has met the quality performance standard. The proposed measures fall within the following five domains: (1) Patient/Caregiver Experience; (2) Care Coordination,

Transitions, and Information Systems; (3) Patient Safety; (4) Preventive Health; and (5) At-Risk Population/Frail Elderly Health. Results for the 65 measures will be calculated through claims data, survey data and a new data collection tool called the ACO Group Practice Reporting Option (GPRO).

CMS outlined a sliding scale quality performance measurement methodology that rewards ACOs that achieve higher scores on the quality performance measures with higher percentages of shared savings. The program would operate as a “pay for reporting” program during its first year: ACOs would achieve the maximum score, and the maximum percentage of shared savings, by submitting quality data for all 65 quality measures. After the first year, CMS proposed using a “performance scoring” approach to measuring quality, incorporating both a minimum attainment level and a benchmark level for most measures. The “performance scoring” approach would use the quality performance score percentage across all five domains to calculate the percentage of shared savings earned.

Providers have been concerned about both the number of quality measures required, and the nature of particular measures. In addition, critics are concerned that ACOs would have to meet the benchmark for all 65 measures in order to earn the full shared savings amounts available.

Shared Savings Models and Methodology

The Proposed Rule describes two Shared Savings Program models: In “Track 1” an ACO will have the opportunity to share in savings all three years, but will not be required to assume risk for losses until the third contract year. In “Track 2” an ACO will share in both savings and losses for all three contract years. After their first agreement period, all ACOs will be required to participate in Track 2. ACOs will be eligible for a greater percentage of shared savings in years in which they assume risk for losses.

To be eligible for shared savings, an ACO must (1) meet the quality requirements and (2) achieve savings in excess of a certain percentage of the ACO’s benchmark expenditures, defined as a minimum savings rate (MSR). ACOs will be eligible for a portion of shared savings, subject to a cap, and liable for a portion of shared losses (if applicable), likewise subject to a cap, on an annual basis as compared to a CMS-calculated benchmark. The purpose of the MSR threshold is to account for normal variations in spending that are unrelated to efficiency and quality gains. In those years in which an ACO is not at risk for loss, the MSR is set according to a sliding scale and decreases as the number of assigned beneficiaries increases (from 2 percent for ACOs with 50,000 or more beneficiaries to 3.9 percent for ACOs with only 5,000 beneficiaries). In those years in which an ACO is at risk, the MSR will be set at a flat 2 percent regardless of size, to incentivize ACOs to take on risk by making it easier for them to qualify for shared savings.

CMS will calculate an expenditure benchmark for each ACO based on the most recent three years of Part A and B expenditure data available for the beneficiaries that would have been assigned to the ACO in those years. CMS will risk-adjust this data to address demographic factors as well as relative health status, and update the benchmark annually. To determine an ACO’s savings or losses each year, CMS will calculate the average per capita Medicare FFS Part A and B expenditures for the ACO’s assigned beneficiaries in the ACO for each performance year.

Net savings are determined by comparing the ACO’s average per capita benchmark to the ACO’s actual average per capita expenditures in a year. For years in which an ACO participates in the one-sided model, if the ACO has achieved the above eligibility criteria, the ACO can share in savings in excess of a threshold of 2 percent of its benchmark. ACOs participating in the two-sided model, and certain exempt ACOs, are not subject to this threshold and can receive first-dollar savings.

The percentage of the savings that an ACO can receive is based primarily on quality measure performance. ACOs in the one-sided (non-risk) model will have their savings rate increased by up to 10 percentage points for each quality measure domain that is achieved for a maximum of 50 percent; ACOs in the two-sided model (in which they assume the risk of losses) will be eligible for up to 12 percentage points for each quality measure domain for a maximum of 60 percent. An ACO cannot receive shared savings in each agreement year of more than 7.5 percent under the one-sided model or 10 percent under the two-sided model.

To calculate losses, CMS proposes to apply the same benchmark and expenditure calculations described above. Under the two-sided model, if an ACO's expenditures are greater than the benchmark, the ACO will share in losses that exceed a minimum loss rate, which is calculated as 2 percent of benchmark. CMS proposes to calculate the shared loss rate as 1 minus the shared savings rate described above. Losses are capped at 5 percent in the first year in which an ACO bears risk, 7.5 percent in the second year, and 10 percent in the third year. For the third year of Track 1, the first year in which the ACO is at risk, the 5 percent cap will apply.

To enable ACOs to repay losses and to encourage ACOs to participate for the full three-year term, CMS will withhold 25 percent of an ACO's annual savings until the end of the agreement period. In addition to this withhold, prior to each year in which it will assume risk, an ACO must demonstrate that it is capable of repaying losses equal to at least 1 percent of per capita expenditures for its assigned beneficiaries.

This payment model has been highly criticized and is likely one of the primary reasons many providers are lacking enthusiasm for the program. The amount of potential shared savings is not seen as significant enough, nor is the likelihood of achieving the full shared savings amount certain enough, to

entice providers to invest in the MSSP model. Many believe that CMS has substantially underestimated the cost of establishing an ACO, and that the shared savings model does not offer sufficient confidence that the investment will be recovered. Several commenters have also urged for more options – including payment options in which an ACO is not required to share in losses at all, as well as partial or full capitation models.

Monitoring and Termination of ACOs

CMS will continually monitor ACOs and may terminate agreements with ACOs under certain circumstances. CMS will monitor ACOs to ensure that they do not take steps to avoid at-risk beneficiaries in order to reduce the likelihood of increasing ACO costs. CMS may terminate an ACO's agreement if the ACO is found to continue to avoid at-risk beneficiaries. CMS may also terminate an ACO agreement if the ACO, ACO participants, ACO providers and suppliers, and contracted entities performing services engage in certain proscribed activities, such as failing to comply with eligibility requirements, meet quality performance standards, or demonstrate that the ACO has or can maintain adequate resources to repay losses.

CMS and OIG ACO Fraud and Abuse Waivers

The Proposed Rule was part of a multi-agency collaboration to launch the Shared Savings Program. Several other federal agencies released proposed guidance to complement CMS's Proposed Rule.

CMS, in conjunction with the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services, issued a notice proposing specific fraud and abuse waivers in an effort to promote the formation of ACOs. First, CMS and OIG proposed a waiver of the Stark law's referral prohibition for the distribution of shared savings received by an ACO to ACO participants, ACO providers and suppliers, and parties outside the ACO for activities necessary for and directly related to the ACO's participation in

and operations under the Shared Savings Program. Second, CMS and OIG proposed protection from enforcement under the Anti-Kickback Statute for the distribution of shared savings covered by the Stark law waiver and other financial relationships among ACO participants that implicate the Stark law and fully comply with an existing Stark law exception. And third, CMS and OIG proposed protection from enforcement under the Civil Monetary Penalty statute for the distribution of shared savings by a hospital participating in an ACO to a physician participating in the ACO if the payments are not made knowingly to induce the physician to reduce or limit medically necessary items or services. Critics charge that these waivers did not go far enough to provide the kind of flexibility necessary to encourage establishment of ACOs, and are concerned that they are limited to participation only in the Medicare Shared Savings Program.

CMS and OIG, recognizing that the scope of their proposed waivers is relatively narrow, sought comments on whether broader waivers should be adopted to protect, among other things, remuneration related to ACO formation, ongoing operations of the ACO, achieving ACO goals, and distribution of shared savings payments received from private payers. Industry stakeholders generally have agreed that waivers are needed to protect capital investments in ACOs, both initial investments needed to develop an ACO's infrastructure and investments made after formation to improve ACO operations.

FTC and DOJ Joint Statement Regarding Antitrust Scrutiny of ACOs

In addition, the Federal Trade Commission (FTC) and Department of Justice (DOJ) issued a joint proposed enforcement policy (the Joint Statement) regarding antitrust regulation of ACOs. The Joint Statement classifies ACOs into three enforcement categories: a "safety zone"; a "mandatory review" category; and a third category, where a proposed ACO neither meets the safety zone requirements nor requires mandatory FTC/DOJ review. The en-

forcement category for a proposed ACO is determined on the basis of the ACO's share of services in each participant's Primary Service Area (PSA). The PSA is defined as the "lowest number of contiguous postal zip codes from which the ACO participant draws at least 75 percent of its patients for that service."

To qualify for the safety zone, any participants in the ACO that provide the same service must have a combined share of less than 30 percent of each such service in each participant's PSA. In addition, any hospital or ambulatory surgery center participating in an ACO must be non-exclusive to the ACO to fall within the safety zone, regardless of its PSA share. The non-exclusivity rule also applies to any "dominant provider"—a participant with greater than 50 percent share in its PSA of any service that no other ACO participant provides to patients in that PSA.

The mandatory review category is triggered if the ACO's share is over 50 percent for any common service that two or more independent participants provide to patients in the same PSA. Proposed ACOs in this category must submit various documents and information to the FTC/DOJ for assessment of competitive impact. ACOs will have an opportunity at that time to offer procompetitive justifications for the ACO and to provide data to suggest that the PSA shares are not reflective of the ACO's likely market power. If the proposed ACO is in the third category, it may voluntarily request review pursuant to the same 90-day period provided for proposed ACOs in the mandatory-review category, and thereby obtain greater clarity to move forward under CMS regulations.

IRS Guidance on ACOs

Lastly, the Internal Revenue Service (IRS) issued Notice 2011-20 (the Notice), which offers guidance to tax-exempt organizations seeking to participate in the Shared Savings Program. The Notice speculates that exempt organizations may participate in ACOs

with private parties. The Notice explains that the IRS does not generally expect that an exempt organization's participation in the Shared Savings Program through an ACO will result in impermissible private inurement or private benefit, provided the following five factors are present: (1) a written agreement negotiated at arm's length sets out the terms of the exempt organization's participation in the ACO; (2) CMS has accepted the ACO into the Shared Savings Program; (3) the exempt organization's share of economic benefits derived from the ACO is proportional to the benefits it provides to the ACO; (4) the exempt organization's share of the ACO's losses does not exceed the share of ACO benefits to which it is entitled; and (5) all contracts and transactions entered into by the exempt organization with the ACO and the other ACO participants and any other parties are at fair market value. The Notice also states that because an ACO's activities that generate Shared Savings Program payments lessen the burdens of government, these activities would be considered substantially related to the performance of a charitable purpose.

The Notice does not comment directly on whether an ACO could itself qualify as a tax-exempt organization, and focuses instead on implications for existing exempt organizations that choose to participate in ACOs. It therefore remains unclear whether there are particular requirements the IRS might impose on ACOs that apply for tax-exempt status.

CMS is under pressure to release a final rule by the end of the calendar year so that the Shared Savings Program can begin in January 2012. It is unclear how these deadlines will be met given the substantial push back from potential stakeholders. CMS's responsiveness to these varying critiques may dramatically impact the level of future participation. The Obama administration has a lot on the line: the Medicare Shared Savings Program represents not just a pillar of health care reform, but also a step towards reform of the entitlement programs generally. Establishing this program in a successful manner may have wider implications than just ACOs.

Barbara Eyman works with hospitals, academic medical centers and other providers to harness opportunities and overcome challenges posed by federal and state healthcare programs, including Medicaid, Medicare, the Children's Health Insurance Program (CHIP), and new programs being established under the Affordable Care Act. With a long health policy background and reimbursement expertise, Barbara assists clients in understanding the impact that rapidly-changing federal healthcare laws and regulations will have on their organizations, developing strategies to succeed under health care reform and mitigate the impact of shrinking public health care program budgets. She regularly advocates on behalf of providers before Congress, federal agencies, and in administrative or judicial proceedings.

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