CMS Releases Proposed Regulations Regarding Formation of Accountable Care Organizations

April 8, 2011

The Centers for Medicare & Medicaid Services (CMS) recently proposed regulations regarding the formation of accountable care organizations (ACOs). Part of a broader value-based purchasing initiative being adopted by CMS, ACOs are the mechanism through which the organization will implement the Shared Savings Program established by the Patient Protection and Affordable Care Act. CMS is accepting comments on the proposed rule through June 6, 2011.

On March 31, 2011, the U.S. Centers for Medicare & Medicaid Services (CMS) released proposed regulations regarding the formation of accountable care organizations (ACOs). ACOs are the mechanism through which CMS will implement the Shared Savings Program (SSP) established by Section 3022 of the Patient Protection and Affordable Care Act. ACOs are part of a broader value-based purchasing initiative being adopted by CMS in response to provisions of the act intended to promote the three aims of better care for individuals, better health for populations and lower growth in health care expenditures. ACO providers and suppliers that participate in the SSP would be ineligible to participate in certain other Medicare demonstration programs. CMS is accepting comments on the proposed rule through June 6, 2011.

As set forth in the proposed rule, an ACO is a group of Medicare-enrolled providers and suppliers that work together to coordinate and deliver health care services to the Medicare fee-for-service enrollees assigned to it. Providers eligible to form an ACO include any combination of "ACO professionals" (physicians and mid-level providers) in group practices, networks of ACO professionals, partnerships and joint ventures between hospitals and ACO professionals, hospitals employing ACO professionals and critical access hospitals billing under Method II. Each ACO would be required to establish a legal entity with its own tax identification number that is duly qualified to transact business in each applicable state, which can receive and distribute any shared savings bonuses, repay shared losses for which the ACO may be responsible, collect and report data, and ensure provider compliance with program standards. An integrated provider (*e.g.*, a hospital with employed physicians) could use its existing entity for this purpose as long as it meets CMS' criteria, however a new, separate legal entity would need to be established if that provider wishes to partner with any independent provider. CMS

proposes to require that the governing body of the ACO include proportional representation and control from each ACO participant, that ACO participants comprise at least 75 percent of the governing body and that the governing body include representation from Medicare beneficiaries. Community representation on the governing board is encouraged but not required. Each ACO would be required to establish a compliance plan headed by a compliance officer who is not legal counsel.

The Affordable Care Act requires each ACO to have a minimum of 5,000 assigned Medicare fee-for-service beneficiaries in order to participate in the SSP. CMS intends to retroactively assign beneficiaries to ACOs based on the primary care physician from whom each beneficiary receives a plurality of his or her primary care. Therefore, primary care physicians are only permitted to participate in one ACO. Specialist physicians, hospitals and other providers or suppliers may participate in multiple ACOs. Every individual and entity participating in the ACO would be required to notify beneficiaries of their participation in the ACO through CMS-approved written materials and posted signs. ACO participants would also be required to notify beneficiaries of the option to seek care from providers outside of the ACO and to opt out of having their health care information shared with other ACO participants. ACOs would continue to be responsible for managing the care of assigned beneficiaries that choose to opt out of data sharing. If an ACO's patient pool falls below 5,000 beneficiaries, CMS will establish a corrective action plan and the ACO must exceed 5,000 attributed beneficiaries in the next year or it will be ineligible to continue its participation in the SSP.

CMS would require an ACO to enter into a three-year agreement in order to participate in the SSP. By statute the SSP is supposed to begin on January 1, 2012, although CMS has solicited comments regarding whether this start date is still feasible. CMS would review all contract applications before the end of the year in which they are submitted, so that the contract period for all approved ACOs would commence on January 1. CMS is giving consideration to allowing an additional cohort of ACOs to enter the SSP on July 1, 2012, in which event the term of the initial agreement for this group would be three and a half years. The proposed regulation describes in detail the type of documentation that applicants would be required to submit.

ACOs would have the option to choose between two risk models. Under the first track, ACOs would be eligible to receive shared savings in all three years of the agreement, but in the final year would also be obligated to repay shared losses that exceed 2 percent of the annual expenditure benchmark established by CMS for each ACO, subject to a cap on losses equal to

5 percent of the expenditure bench for that year. An ACO following this "hybrid risk" track would be eligible to receive up to 50 percent of shared savings (or up to 52.5 percent if the ACO includes a Federally Qualified Health Center or Rural Health Center) depending on reporting of quality measures and the quality score achieved, up to a cap equal to 7.5 percent of the expenditure benchmark during the first two years and 10 percent of the expenditure benchmark in the third year.

ACOs that select the second track would be at risk for shared losses in all three years but would be eligible to receive a higher percentage of shared savings than ACOs in the hybrid risk model. ACOs in the "two-sided model" would be eligible to receive up to 60 percent (or up to 65 percent if the ACO includes a Federally Qualified Health Center or Rural Health Center) of their shared savings depending on reporting of quality measures and the quality score achieved, up to a cap equal to 10 percent of the expenditure benchmark. However, these ACOs would also be liable for a shared losses if expenditures exceed the benchmark by more than 2 percent, with such losses capped at 5 percent of the expenditure benchmark during the first year, 7.5 percent in the second year and 10 percent in the third year. CMS does not intend to specify a particular method for distributing shared savings among the ACO participants, but would require that each ACO submit a description of its plan for distributing any shared savings and an explanation of how its plan is consistent with the goals of the broader value-based purchasing initiative.

In the first year, eligibility for shared savings under the SSP will be determined based solely upon *reporting* of quality data, *i.e.*, an ACO could earn the maximum shared savings bonus for the first year simply by reporting all required quality data. In order to receive shared savings after the first year, ACOs would be responsible for meeting 65 separate quality and performance measures (including that at least 50 percent of the ACO's primary care physicians attain Stage 1 HITECH Act meaningful use requirements). These measures are grouped into five domains: patient/caregiver experience, care coordination, patient safety, preventive health and at-risk population/frail elderly health. CMS intends to collect data on these measures through a combination of attestations, survey instruments, claims data and data collection tools. CMS proposes to make ACO-reported quality scores available to the public. CMS could terminate an ACO's contract for failure to meet quality performance standards, although CMS proposes to provide a warning and one-year cure period to ACOs that fail to meet minimum quality levels in only one domain. ACOs would also be monitored and potentially subject to termination for avoidance of at-risk patients.

As mentioned above, those ACOs that meet quality performance thresholds would be eligible to receive shared savings if their Part A and Part B expenditures in each year of the agreement fall below established benchmarks. CMS plans to set a spending benchmark for each ACO based on spending data related to each beneficiary that could be assigned to the ACO for the three years prior to the year in which the ACO begins participation in the SSP. The benchmark would exclude incentive payments earned under value-based purchasing initiatives, but would include disproportionate share payments, teaching add-ons and geographic adjustments. The benchmark would be adjusted for overall growth and beneficiary characteristics and trended forward at the end of each year based on the projected absolute increase in national average per-beneficiary Part A and B expenditures. ACOs participating in the two-sided model would be eligible to receive shared savings from dollar one if the actual expenditures for their assigned populations are at least 2 percent less than the benchmark expenditures. Those ACOs participating in the hybrid risk model would be eligible to share in any savings that are 2 percent below the benchmark, but only if the ACO achieves a minimum savings rate that would vary between 2 percent and 3.9 percent of the benchmark threshold, depending on the size of an ACO's assigned population. Physician-led ACOs with less than 10,000 assigned beneficiaries, rural ACOs and ACOs with underserved populations would participate in shared savings from dollar one as long as the minimum savings rate requirement has been met. Under both tracks, CMS would withhold 25 percent of an ACO's shared savings bonuses to cover potential repayment obligations. Repayment of losses must be made within 30 days of notice from CMS. Under both tracks, CMS will use a six-month claims run out period to calculate the benchmarks and actual expenditures.

CMS would furnish aggregate, de-identified data reports on quality and utilization at the start of an agreement period based on the beneficiaries that could have been assigned to an ACO during the three years prior to the commencement of the contract period (the same population used to calculate the expenditure benchmark) and quarterly thereafter. At the beginning of the contract period and annual thereafter, ACOs can request a list of the beneficiaries assigned to an ACO, including name, birth date and Health Insurance Claim Number. Subject to HIPAA and beneficiaries' right to opt out of data sharing, ACOs can request and share monthly claims data under Parts A, B and D for potentially assigned beneficiaries.

CMS estimates that approximately 75–150 organizations will participate as ACOs in the SSP with average startup costs of around $1.75 million dollars. Total bonus payments over the initial three-year contract period are expected to be approximately $800 million with total penalties

paid to CMS of approximately $40 million. CMS estimates that the SSP will result in $510 million of savings to the Medicare program over the first three years.

McDermott will be distributing additional newsletters on other issues related to the new accountable care organization regulations, including Stark, Anti-kickback and CMP Law waiver provisions, antitrust guidance and related tax guidance from the Internal Revenue Service. Additionally, we will be releasing a White Paper that will serve as a key resource and reference document about the proposed regulations.