CMS' Proposed Rules for ACOs: A Summary

Apr 06 2011

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Practice Area: Health Law & Health Intellectual Property

On March 31st the Centers for Medicare and Medicaid Services ("CMS") released its proposed rule to establish the Medicare Shared Savings Program (the "Shared Savings Program"). The rule will be published in the Federal Register in the next few days. CMS will accept comments on the proposed rule for a period of 60 days after publication in the Federal Register, and will respond to comments in a final rule to be issued later this year. At the heart of the Shared Savings Program is the development of Accountable Care Organizations ("ACOs") to bring together providers and suppliers in an effort to coordinate care for Medicare fee-for-service ("FFS") beneficiaries. To participate in the Shared Savings Program, ACOs must submit an application, and if approved, enter into a three year agreement with CMS to be accountable for the quality, cost and overall care of at least 5,000 traditional FFS Medicare beneficiaries who may be assigned to it. The Shared Savings Program will begin operating on January 1, 2012.

Eligible Participants.
An ACO may include the following types of groups of providers and suppliers of Medicare-covered services:

- ACO professionals (i.e., physicians and hospitals meeting the statutory definition) in group practice arrangements;
- networks of individual practices of ACO professionals;
- partnerships or joint venture arrangements between hospitals and ACO professionals;
- hospitals employing ACO professionals; or
- critical access hospitals ("CAHs") that submit bills for both the facility and the professional services to its Medicare fiscal intermediary or its Medicare Part A/B Medicare Administrative Contractor ("MAC").

Notably, federally qualified health centers ("FQHCs"), rural health centers ("RHCs"), skilled nursing facilities ("SNFs"), nursing homes, longterm care hospitals ("LTCHs") and certain CAHs, among others, are not specifically designated as eligible participants in the Shared Savings Program. While these entities may not independently form an ACO, they and other Medicare enrolled providers and suppliers are permitted to participate in ACOs with one or more of the ACO eligible participants. CMS has not addressed what role, if any, parent organizations of multiple hospital systems may play in the ACO structure. In addition, Medicare providers that participate in other Medicare programs that include shared savings may not also participate in the Shared Savings Program as an ACO. Finally, primary care physicians may only participate in one ACO.

Legal Structure.
CMS has provided a great deal of latitude when it comes to the basic legal structure of ACOs. According to CMS, ACOs may be structured as corporations, partnerships, limited liability companies, foundations or other entities permitted by state law so long as the structure is capable of:

- receiving and distributing shared savings;
- repaying shared losses;
- establishing, reporting and ensuring ACO participant and ACO provider/supplier compliance with the Shared Savings Program requirements, including the quality performance standards; and
- performing the other ACO functions identified in the statute.

CMS will not require existing legal entities that satisfy these criteria to form a separate new entity for the purpose of participating in the Shared Savings Program. In order to receive direct payments from CMS, all ACOs must be identified by a taxpayer identification number ("TIN").

Governance.
Regardless of the form of legal entity, all ACOs must have a governing body that provides a mechanism for representation and control in shared decision making for all ACO participants. The ACO participants (as opposed to non-Medicare enrolled entities) must have at least 75% control of the ACO's governing body. To ensure that ACOs remain provider-driven, each ACO participant must choose an appropriate representative from within its organization to represent them on the governing body. According to CMS, the governance mechanism should also allow for appropriate "proportionate control" for ACO participants, giving each ACO participant a voice in the ACO's decision making process. It remains to be seen whether "reserved powers" to non-ACO participants will be permitted in light of these governance requirements.

ACOs will also be required to have Medicare beneficiaries serviced by the ACO represented on the ACO governing body. At this time, CMS is taking the position that a pure advisory committee or panel will not satisfy this requirement. CMS is, however, requesting comments on this issue as well as whether there should be a requirement for a specified minimum number of beneficiaries and/or a minimum proportion of control over an ACO's governing body.

In addition, ACOs must partner with community stakeholder organizations. According to CMS, community stakeholder organizations may include employers, commercial health plans, local businesses, State/local government agencies, local quality improvement organizations or collaboratives (such as health information exchanges). While not required, CMS has expressed that representation of community stakeholders on the governing board is one method for satisfying this partnership requirement.

Leadership and Management Structure.
All ACOs must have a leadership and management structure that includes clinical and administrative systems that satisfy the following criteria:

- The ACO's operations should be managed by an executive, officer, manager or general partner, whose appointment and removal are under control of the organization's governing body.
- Clinical management and oversight should be managed by a senior-level medical director.
- ACO participants and ACO providers/suppliers should have a meaningful financial and/or human investment in the ACO's clinical integration program to ensure its likely success.
- The ACO should have a physician-directed quality assurance and process improvement committee that oversees an ongoing quality assurance and improvement program.
- The ACO should develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care consistent with the goals of better care for individuals, better health for populations, and lower growth in expenditures (for example, through an integrated electronic health record with clinical decision support).
- The ACO should have an infrastructure, such as information technology, that enables the ACO to collect and evaluate data and provide feedback to the ACO providers/suppliers across the entire organization, including providing information to influence care at the point of care via, for example, shared clinical decision support, feedback from patient experience of care surveys or other internal or external quality and utilization assessments.

Agreement Requirements.
All ACOs will be required to enter into a three year participation agreement with CMS that will include annual performance periods that begin on January 1 of each respective year during the agreement period. The first three year agreement period will begin in January 1, 2012, and all subsequent three year periods will start on the January 1 following approval of an application. All ACOs that participate in the "two sided" model (discussed below) will be subject to a 25% withhold of shared savings in order to offset any future losses under the twosided model. If an ACO completes its three year agreement successfully, CMS will refund in full any portion of shared savings withheld during the course of the three year agreement period that is not needed to offset losses. If the agreement is terminated early, CMS will retain any portion of shared savings withheld.

An ACO may not add ACO participants during the course of the three year agreement. In order to maintain flexibility, however, an ACO may remove ACO participants or add/subtract ACO providers/suppliers. CMS cautions that expulsion cannot be used as a mechanism to avoid at-risk beneficiaries.

Distribution of Savings.
Shared savings payments will be made directly to the ACO as identified by its TIN. The TIN associated with the ACO's legal entity may, or may not, be enrolled in the Medicare program, unlike the ACO participant TINs that are Medicare-enrolled groups of providers of services and suppliers. ACOs must provide CMS with a description of the criteria they plan to employ for distributing shared savings among ACO participants and ACO providers/suppliers, and how any shared savings will be used to align the aims of better care for individuals, better health for populations and lower growth in expenditures. While CMS is not currently seeking to specify how shared savings must be distributed to ACO participants, CMS has indicated that the distribution methodologies should include safeguards to prevent improper financial incentives.

Processes to Promote Evidence-Based Medicine, Patient Engagement, Reporting and Coordination of Care.
In order to be eligible to participate in the Shared Savings Program, an ACO must provide CMS with documentation describing its plans to:

- promote evidence-based medicine;
- promote beneficiary engagement and patient "health literacy" (i.e., through decision support tools and shared decision making methods);
- report internally on quality and cost metrics (i.e., developing a population health data management capability or implementing practice and physician level data capabilities with point-of-service ("POS") reminder systems to drive improvement in quality and cost outcomes); and
- coordinate care, which may include predictive modeling, utilization of case managers in primary care offices, remote monitoring, telehealth, electronic health records and an electronic health information exchange.

ACOs will be prohibited from developing any policies that would restrict a beneficiary's freedom to seek care from providers and suppliers outside the ACO.

ACO Marketing Guidelines.
CMS has expressed a strong desire to prevent ACOs from misleading beneficiaries about services available from an ACO or about the providers or suppliers from whom they can receive services. As a result, all ACO marketing materials, communications and activities related to the ACO and its participation in the Shared Savings Program that are used to educate, solicit, notify or contact Medicare beneficiaries or providers/suppliers must be approved by CMS to ensure that they are not confusing or misleading. This preapproval process is extremely broad and applies to all general audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, mailings or other activities conducted by or on behalf of the ACO, or by ACO participants, or by ACO providers/suppliers participating in the ACO, or by other individuals on behalf of the ACO, or its participating providers and suppliers.

CMS has indicated that the following materials and activities would not be subject to approval:

- communications that are informational materials and are customized or limited to a subset of beneficiaries;
- materials that do not include information about the ACO or providers in the ACO;
- materials that cover beneficiary specific billing and claims issues or other specific individual health related issues; and
- educational information on specificmedical conditions (for example, flu shot reminders), or referrals and other exceptions to the definition of "marketing" under the HIPAA Privacy Rule.

Prior review by CMS of marketing materials could prove to be a significant obstacle and time constraint for emerging ACOs, especially given the aggressive January 1, 2012 implementation date. Additionally, CMS has not addressed how this requirement will impact ACOs that are also operating as ACOs in the commercial payor arena.

Data Sharing.
In agreeing to become accountable for a group of Medicare beneficiaries, participating ACOs must be able to independently identify and produce, or work toward independently identifying and producing, the data they believe is necessary to best evaluate the health needs of their patient population, improve health outcomes, monitor provider/supplier quality of care and patient experience of care and produce efficiencies in utilization of services. While ACOs must rely in large part on internal data, CMS will provide ACOs with the following data:

- the name, date of birth, sex and Health Insurance Claim Number ("HICN") of the historically assigned beneficiary population;
- CMS claims data on their potentially assigned beneficiary population;
- aggregate data reports which would include, when available, aggregated metrics on the assigned beneficiary population, and beneficiary utilization data at the start of the agreement period based on historical data used to calculate the benchmark; and
- certain limited beneficiary identifiable data at the beginning of the first performance year and thereafter on a monthly basis.

If an ACO chooses to request beneficiary identifiable claims data as part of the application process, the ACO will be required to explain to CMS how it intends to use this data to evaluate the performance of ACO participants and ACO providers/suppliers, conduct quality assessment and improvement activities and conduct population-based activities to improve the health of its assigned beneficiary population. An ACO must also inform beneficiaries of its ability to request claims data about them if they do not object. The only exceptions to this advanced notice is the initial four data points (the beneficiary's name, date of birth, sex, and HICN) that will be provided to ACOs for individuals in the three year data set used to determine the ACO's benchmark. ACOs will only be allowed to request beneficiary identifiable claims data for beneficiaries who have (1) visited a primary care participating provider during the performance year, and (2) have not chosen to opt out of claims data sharing.

The impact of this beneficiary opt out of data sharing will be that ACOs must find a way to provide the same quality services and treatment to these opt out beneficiaries despite the lack of data that will be used to help supplement and coordinate the high quality, efficient care of beneficiaries who have not opted out of data sharing.

Compliance Plans and Certifications.
All ACOs must have a compliance plan that addresses how the ACO will comply with applicable legal requirements. Specifically, an ACO must demonstrate that it has a compliance plan that includes at least the following elements:

- a designated compliance official or individual who is not legal counsel to the ACO and who reports directly to the ACO's governing body;
- mechanisms for identifying and addressing compliance problems related to the ACO's operations and performance;
- a method for employees or contractors of the ACO or ACO providers/suppliers to report suspected problems related to the ACO;
- compliance training of the ACO's employees and contractors; and
- a requirement to report suspected violations of law to an appropriate law enforcement agency.

CMS is also requiring that the ACO itself, as well as its participants and other downstream contractors and subcontractors, certify the accuracy, completeness and truthfulness of any information or data that will be used by CMS in determining the ACO's eligibility for, and the amount of, shared savings payments or the amount owed by the ACO to CMS. CMS is also requiring that these parties provide the government with access to such data for audit, evaluation and inspection.

Definition of Primary Care Services.
CMS considered three options in deciding how to define "primary care services" for purposes of assigning beneficiaries under the Shared Savings Program. Ultimately, CMS proposes assigning beneficiaries based on predefined primary care services and predefined primary care providers. Primary care providers are physicians (internal medicine, general practice, family practice and geriatric medicine) who are providing primary care services (determined based on a set of health care procedure codes) to beneficiaries. This definition places emphasis on the services of primary care physicians in the assignment process. It also allows ACOs to coordinate and redesign care for patients seeing primary care providers and creates incentives for ACOs to establish relationships between primary care physicians and patients. CMS is concerned that this definition may not capture primary care services being provided by specialists and may prevent some regions from forming ACOs due to an insufficient number of beneficiaries. The shortcomings of this definition may be especially evident in areas with primary care shortages. Thus, while CMS proposes to assign beneficiaries based on primary care physicians and services, it seeks comment on whether other definitions would be more appropriate.

Assignment of Medicare Beneficiaries.
CMS proposes retrospectively assigning beneficiaries to an ACO while at the same time providing ACOs with beneficiary data (name, date of birth, gender and other information) regarding the beneficiaries assigned to it in the benchmark period (i.e., the three-year period prior to the ACO's first performance year). This means that at the end of each year of an ACO agreement, beneficiaries would be assigned to an ACO based on the ACO's primary care physicians' provision of primary care services to beneficiaries during the prior year. CMS proposes that beneficiaries be assigned to the ACO that provided the beneficiary with the highest complexity and intensity of primary care services in that prior year. CMS believes the combination of retrospective and prospective assignment encourages ACOs to focus on improving care for all beneficiaries, rather than simply those that are assigned to the ACO for shared savings purposes yet provides ACOs with data on the population that the ACO will likely be responsible for. This will enable ACOs to target their care improvements, but not only to a specific subset of beneficiaries.

Notice & Communications with Beneficiaries.
CMS places high value on transparency and the right of beneficiaries to have a free choice of providers and adequate information to analyze choices. Due to retroactive beneficiary assignment based on actual primary care service utilization, the only practical way to provide advance notice to beneficiaries is for ACOs to provide the notice to beneficiaries when providing a service. To satisfy this requirement, ACOs must post signs indicating providers' participation in an ACO and offer standard written information about ACOs to Medicare FFS beneficiaries. ACOs must also offer beneficiaries a form allowing them to opt out of data sharing. CMS intends to develop a communication plan and educational materials designed to inform beneficiaries regarding the Shared Savings Program, ACOs, utilization of services, assignment to an ACO, quality and health information sharing and beneficiaries' right to opt out of data sharing. CMS is soliciting comments regarding the appropriate form, content and utility of the beneficiary notice information.

Shared Savings Determinations and the Two-Sided Model.
ACOs participating under the Affordable Care Act will continue to receive payment under the original Medicare FFS program in the same manner that they have received payment in the past. However, through the Shared Savings Program, a participating ACO may also receive payment for shared Medicare savings if the ACO (1) meets the applicable quality performance standards established by the Secretary of Health and Human Services (the "Secretary"), and (2) achieves certain levels of savings as compared to a benchmark of expected average per capita Medicare expenses.

CMS considered several payment model options in structuring the Shared Savings Program proposal. The first would allow ACOs to share in first dollar savings under the spending benchmark. This model could reward ACOs for natural fluctuations in spending and not just actual savings driven by an ACO's programs and policies. The second option would only allow ACOs to share in savings if the savings are in excess of a minimum savings rate ("MSR"). The MSR would be set at a level slightly less than expected expenses and therefore increase the likelihood that any shared savings would derive from actual ACO-related interventions.

The third option would be a hybrid approach, combining several elements of the first and second options. This approach would allow participation by less experienced ACOs, while allowing them an opportunity to gain "handson" population management experience. At the same time, the third option would also allow more experienced ACOs to participate in a payment model that permits greater reward for greater responsibility (i.e., down-side financial risk). CMS is recommending this third option, and proposing that ACO applicants choose between a "one-sided model" (Track 1) and a "two-sided model" (Track 2).

Under Track 1, ACOs would enter the Shared Savings Program under the one-sided model and be required to transition to the two-sided model for the third year of their initial three-year agreement period. The "one-sided model" would not require ACO responsibility for any portion of losses above the spending benchmark in years one and two of the ACO's agreement period. However, in year three of the agreement period, the ACO would be required to share in losses and savings, thereby automatically transitioningthe ACO to the "two-sided model." Thereafter, Track 1 ACOs could only participate in the two-sided model in subsequent agreement periods.

Under Track 2, ACOs would enter the two-sided model (i.e., share in any savings, as well as any losses, immediately), and remain in the two-sided model for the full three-year agreement period. Track 2 ACOs would also be required to participate in the two-sided model in subsequent agreement periods. Track 2 ACOs would be eligible for higher sharing rates than would be available to Track 1 ACOs under the one-sided model.

The regulator's hybrid approach is intended to allow different kinds of ACOs to timely participate in the processes of redesigning care and assuming accountability for costs and outcomes, while at the same time encourage all ACOs to take on greater risk and enjoy the opportunity for greater reward.

Quality Measures, Reporting and Performance.
Under CMS' proposed rule, achieving cost savings is not sufficient to participate and share in the savings. ACOs must also report quality measures and satisfy quality standards to earn shared savings.

Quality Measures.

- CMS proposes 65 measures for ACOs to report for the first performance period of the Shared Savings Program. The proposed quality measures include a mix of process, outcome and patient experience measures. Some of the process measures address the use of information systems, including meaningful use requirements for electronic health records, and electronic prescribing, among others. CMS will propose measures for the subsequent performance periods in future rulemaking. Future measures may address caregiver experience and additional settings (e.g., nursing homes). CMS aims to align the quality measures in the Shared Savings Program with the quality measures used in other quality programs, including the Physician Quality Reporting System.

Shared Savings for the First Year of the Shared Savings Program.

- CMS proposes that ACOs who report fully and accurately on the quality measures will earn their full share of the savings (50% under Track 1 or 60% under Track 2) for the first year of the Shared Savings Program.

Shared Savings for Subsequent Years.

- For subsequent years, ACOs must continue to report quality measures fully and accurately. However, an ACO's portion of shared savings, if any, would depend on its actual quality performance. An ACO would earn up to a maximum of 50% or 60% of shared savings, depending on its quality level. An ACO achieving higher quality would achieve a correspondingly higher percentage of shared savings thus rewarding higher quality. An ACO could not earn its full potential shared savings by merely satisfying a minimum quality threshold. CMS requests comments on an alternative "threshold approach" under which an ACO would earn its full portion (50% or 60%) of any shared savings simply by achieving a minimum quality threshold.

Reporting.

- CMS proposes a number of methods for reporting and collecting the data, including claims submission, survey instruments and a data collection tool. The data collection tool would allow ACOs to submit clinical information from electronic health records ("EHRs"), registries and administrative data sources. CMS anticipates that certified EHR technology will also be a reporting mechanism in future years. Failure to report accurately, completely and timely may result in sanctions, including termination from the Shared Savings Program.

Public Reporting.

- As noted above, CMS believes that each ACO's operations and performance should be publically transparent. CMS proposes to require ACOs to publicly report the following:

  o Name and location;

  o Primary contact;

  o Organizational information, including:

  · ACO participants;

  · ventures between ACO professionals and hospitals;

  · ACO participant representativeson the ACO's governing body; and

  · Associated committees andcommittee leadership;

  o Shared savings information, including:

  · Shared savings received by the ACO or the shared losses payable to CMS; and

  · The total proportion ofshared savings invested in infrastructure, redesigned care processes and other resources required to support better health for populations, better health care for individuals and lower growth in expenditures, including the proportion distributed among ACO participants; and

  o Quality performance standard scores.

Monitoring & Terminating ACOs.
CMS will monitor ACOs and those that incur large losses for the Medicare program will be subject to heightened oversight. ACOs, ACO participants, ACO providers/suppliers and contracted entities are required to maintain all information related to participation in an ACO for ten years from the end of an ACO agreement or from the date of completion of any audit, evaluation or inspection, whichever is later. The retention period may be extended six years based on certain criteria.

CMS is concerned that ACOs may be tempted to avoid patients who may increase the ACO's cost ("cherry picking"). These are patients who are considered high cost/risk due to having two or more hospitalizations or emergency room visits each year, being eligible for Medicare and Medicaid, having a high utilization pattern, having one or more chronic conditions (diabetes, heart failure, coronary artery disease, chronic obstructive pulmonary disease, depression, dementia, end stage renal disease) or who have a recent diagnosis that is expected to result in an increased cost. CMS will monitor patterns and trends that suggest patient avoidance. If CMS determines that an ACO has engaged in cherry picking, CMS may withhold the ACO's shared savings and/or terminate the ACO's participation in the program.

Non-compliance with quality performance standards and CMS' requirements, patient avoidance and material changes in eligibility criteria may result in an ACO's termination prior to the three-year contract period. ACOs will have appeal rights and may continue to participate during the review process. However, if a termination is upheld, the termination is effective as of the date indicated on the initial notice of termination.

Conclusion.
CMS' proposed rules for the Shared Savings Program are comprehensive and detailed, yet they are almost certain to undergo significant review and refinement as CMS receives comments and prepares for implementation prior to issuing final rules. We will continue to monitor CMS' guidance and report material changes.

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