

Accountable Care Organizations The CMS Final Rule

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The Medicare Shared Savings Program

- In the Affordable Care Act (ACA), Congress created the Medicare Shared Savings Program (MSSP) intended to encourage the development of Accountable Care Organizations (ACOs) in Medicare.
- On April 7, 2011, the Centers for Medicare & Medicaid Services (CMS) issued a Proposed Rule implementing the MSSP.
 - The Proposed Rule was poorly received by providers who considered the administrative burdens and risk of losses to great to participate.
 - CMS received over 1,300 comments on the Proposed Rule.
- The Final Rule was released October 20, 2011. It makes significant changes to the Proposed Rule.

Today's Briefing

- Will focus on areas in which there are significant changes between the Proposed and Final Rules
- Address other issues discussed in the Final Rule of interest to cancer patients and the providers who serve them
- Describe related notices issued by other federal agencies
- Discuss the likely impact of ACO
- ACCC submitted comments on the Proposed Rule that addressed the following issues, among others:
 - The creation of oncology-centered ACOs
 - Providing an option to participate without having to take on risk
 - Otherwise making financial incentives more appealing
 - Accounting for beneficiaries who do not receive all their care from one ACO
 - Eliminate savings withhold

Major Changes in Final Rule

- Major changes in the Final Rule include the following:
 - Provides extended first year with start date of April or July 2012 (running through December 31, 2013)
 - Makes beneficiary assignment more prospective
 - Allows for assignment based on primary care provided by specialists and non-physician providers
 - Gives option of two program tracks, one of which is up-side only (ACO does not bear risk for losses)
 - Reduces the number of quality measures
- These changes and other changes and clarifications will be described with respect to the following areas:
 - Eligibility and Governance
 - Agreements with the Secretary
 - Data Sharing/Beneficiary Opt Out
 - Assignment of Beneficiaries
 - Quality and Other Reporting Requirements
 - Shared Savings and Losses
 - Beneficiary Protections

What is an ACO?

- ACO is still defined as a legal entity comprised of an “eligible group” of ACO participants that works together to manage and coordinate care for Medicare fee-for-service beneficiaries and has established a mechanism for shared governance
- CMS clarifies that an ACO “participant” identified by a Taxpayer Identification Number (TIN) will be required to be exclusive to a single ACO if that TIN is used for purposes of assignment of beneficiaries, but individual “ACO providers/suppliers” identified by National Provider Identifier (NPI) can participate in multiple ACOs

Entities Eligible to Form or Join ACOs

- As provided in the statute, the following groups of providers and suppliers are eligible to participate as an ACO:
 - Physician group practices
 - Networks of individual physician practices
 - Joint ventures between hospitals and physicians
 - Hospitals employing physicians
- CMS also is allowing certain Critical Access Hospitals (CAHs) to independently form ACOs (as proposed), as well as Federally Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs)
 - As a result, there will no longer be incentives to include FQHCs and RHCs in an ACO
- Entities that may establish ACOs independently also may establish an ACO with broader collaborations by including additional Medicare-enrolled entities and Medicare-enrolled providers and suppliers.
- CMS declined to provide for the creation of cancer-specific ACOs

Governance Eligibility Requirements

- CMS relaxed the requirements for ACO governance
 - ACOs still must have a mechanism of shared governance
 - BUT CMS is not requiring that each ACO participant be represented on the governing body (instead the ACO must “provide meaningful participation in the composition and control of the ACO’s governing body for ACO participants and their designated representatives”)
 - AND ACOs can avoid the requirement that ACO participants have 75% control of the governing body and/or the requirement that it have a beneficiary representative if it describes why it seeks to differ from these requirements and how it will involve ACO participants in innovative ways in ACO governance and/or provide for meaningful participation in ACO governance by Medicare beneficiaries
 - CMS is not imposing a requirement (asked for by many commenters) that particular categories of providers and suppliers, i.e., specialists, or other stakeholders be represented on the governing body

Other Changes to Eligibility Requirements

- Does not require the ACO medical director to be full time
- Modifies the requirement for a physician-directed quality assurance and process improvement committee
- Streamlines documentation requests
- Declines to establish a process by which ACOs should develop evidence-based medicine guidelines

Agreements with the Secretary

- The statute requires a minimum 3-year agreement
 - Under the final rule, ACOs will have the option of starting April 1, 2012 or July 1, 2012
 - The first year of the agreement period will end December 31, 2013 and therefore will be 18 or 21 months
 - The first “three year” agreement period itself will end at the end of 2015
 - CMS believes this will provide an "on-ramp" for organizations to gain experience with measures reporting and data evaluation
 - The extended initial performance year will not be available to ACOs joining the MSSP after 2012
- CMS shortens the claims run-out period from 6 months to 3 months to in part to get shared savings to ACOs earlier to help offset start up costs
- CMS will allow an ACO the choice of whether to terminate its agreement without penalty when there are regulatory changes to the MSSP that impact the ability of the ACO to continue to participate
- ACOs will be allowed to add ACO participants during the 3-year agreement period as well as removing ACO participants (TINs) and adding or removing ACO providers/suppliers (NPIs)

Data Sharing

- CMS will provide the following data to ACOs (similar to Proposed Rule):
 - Aggregate data on the assigned beneficiary population and historical beneficiary utilization data;
 - The name, date of birth, sex, and health insurance claim number of preliminarily prospectively assigned beneficiaries (updated quarterly)
 - Beneficiary-identifiable claims data (including Part D data)
 - Must be requested by the ACO on a monthly basis
 - Content limited to minimum data necessary to coordinate care
 - ACO must first enter into Data Use Agreement with CMS
 - Beneficiaries must be given the opportunity to opt-out of sharing PHI with the ACO
 - ACOs must continue to provide the opportunity to opt out during a patient's first face-to-face encounter with the ACO, but also may contact beneficiaries on the list of preliminarily prospectively assigned beneficiaries and request beneficiary-identifiable claims data. If the beneficiary does not respond within 30 days, the ACO may request beneficiary-identifiable data from CMS. This allows the ACO to access the beneficiary's data before the beneficiary is seen by the ACO.
- The Final Rule does not include any proposals with regard to data sharing among participants in an ACO and/or others outside the ACO providing services to the ACO

Assignment of Beneficiaries

- Under the Final Rule, assignment will be *more* prospective (not completely prospective to ensure ACOs are not accountable for care of patients they do not see in a year).
- ACOs will receive a list of beneficiaries likely to receive care from the ACO based on primary care utilization during the most recent period for which adequate data are available (likely to be last year of benchmark), and provide a copy of this list to the ACO
- The list will be updated quarterly to allow the ACO to adjust to likely changes in its assigned population
- At the end of the year, CMS will reconcile the list to reflect beneficiaries who actually meet the criteria for assignment to the ACO during the performance year. **Determinations for shared savings or losses for the ACO will be based on the final, reconciled population.**

Assignment of Beneficiaries

- CMS will allow for assignment based on primary care provided by specialists if the beneficiary does not have a primary care service provided by a primary care physician in year.
- Assignment will occur in a step-wise fashion:
 - First, CMS will look to see if the beneficiary received a primary care service from a primary care physician in a year. If the answer is yes, assignment will be based on the plurality of primary care services received from primary care physicians.
 - Second, if the beneficiary does not receive a primary care service from a primary care physician in a year, CMS will look to see if the beneficiary received **a primary care service** from any physician (regardless of specialty). If the answer is yes, assignment will be based on the plurality of primary care services received from physicians **and** non-physician practitioners.
 - Still primary care based, but allowing for assignment based on primary care services received from specialists and non-physician practitioners
 - Means that TIN through which specialist/non-physician practitioner bills will have to be exclusive to a single ACO
- No accommodation for “snowbirds” – CMS does not think it will be a big problem for ACOs and says that because all beneficiaries retain the freedom of choice, even if they stay in a single location, it will not make changes for those that move between various locations

Quality Reporting & Measurement

- CMS reduced the number of quality measures from 65 to 33 and the number of domains from 5 to 4.
 - CMS eliminated measures perceived as redundant, operationally or administratively complex, or outdated in order to reduce the overall reporting burden for ACOs and to focus on certain "high impact" measures for improving the quality of care and reducing costs.
 - This includes eliminating the measure for the % of All Physicians Meeting Stage 1 HITECH Meaningful Use Requirements. (CMS also eliminated requirement that 50% of primary care physicians be meaningful users as eligibility criteria.) CMS retained its measure as to Primary Care Physicians, but modified it to be based on Successful Qualification for Electronic Health Record (EHR) Incentives, and not only Meeting Meaningful Use Requirements
 - Added an Access to Specialist Measure through the CAHPS survey
- Each of these 33 measures is weighted equally within each domain (except for the EHR measure that is given double weight), and each domain is weighted equally in order to calculate an ACO's overall performance score

Quality Reporting & Measurement

- Performance benchmarks have been modified:
 - In the first year, performance will be based on reporting (same as proposed).
 - In the second year, 8 measures will be based on reporting; 25 will be “pay-for-performance”
 - In the third year, 1 measure will be based on reporting (Health Status/Functional Status); 32 will be “pay-for-performance”
- CMS has relaxed the overall pay-for-performance standard to require ACOs to achieve the quality performance benchmarks on at least 70 percent of the measures in each domain, rather than on every one of the 33 quality measures, in order to earn the maximum savings rate
- If an ACO scores a zero for an entire measure domain, it would not be eligible to share any savings for that period
- CMS has still not specified the performance benchmarks for the 33 final measures but intends to do so through sub-regulatory guidance at the start of the second year of the three-year ACO agreement period

Payment Mechanism

- CMS finalizes two program tracks:
 - **Track 1:** An ACO is eligible for shared savings payments in all 3 years of the agreement without the risk of being responsible for repaying any losses if actual expenditures exceed the benchmark (one-sided model)
 - **Track 2:** An ACO is eligible for a higher percentage of shared savings for all 3 years, but with potential liability in each of the 3 years for annual expenditures that exceed the benchmark (two-sided model)
- This responds to commenters request for an “upside only” track
- After the first agreement period (3 years), ACOs will have to participate under Track 2

Payment Mechanism

- The benchmark still will be determined based on the Medicare expenditures in the three years prior to the start of the agreement for the beneficiaries who would have been assigned to the ACO for those years
- CMS will establish and update the benchmark and determine performance year expenditures using “cost categories” for each of the following populations of beneficiaries: (i) End Stage Renal Disease (ESRD), (ii) disabled, (iii) aged/dual eligible Medicare and Medicaid beneficiaries, and (iv) aged/non-dual eligible Medicare and Medicaid beneficiaries
- CMS will update annually an ACO's risk score to adjust for changes in health status and case mix for beneficiaries contrary to its proposal to not update the risk adjustment
- CMS finalizes its proposal to truncate a beneficiary's Part A and Part B expenditures for the benchmark and performance years at the 99th percentile (roughly \$100,000 in 2008) and does not adopt any other mechanism to account for new technologies or other high-cost items or services

Payment Mechanism

	One-Sided Model Proposed	One-Sided Model Final	Two-Sided Model (Savings) Proposed	Two-Sided Model (Savings) Final	Two-Sided Model (Losses) Proposed	Two-Sided Model (Losses) Final
Minimum Savings/ Loss Rate	Ranges between 2% and 3.9% depending on size of ACO	Same	2% regardless of size of ACO	Same	2% regardless of size of ACO	Same
Maximum Sharing Rate	52.5% - up to 50% based on quality performance; up to 2.5% based of FQHC/RHC participation in ACO	50%	65% - up to 60% based on quality performance; up to 5% based of FQHC/RHC participation in ACO	60%	1 – sharing rate (liability for losses reflects quality performance and FQHC/RHC participation - may be as low as 35%)	Same but no greater than 60%
Maximum Sharing Cap	7.5% of benchmark	10% of benchmark	10% of benchmark	15% of benchmark	5% of benchmark in Y1, 7.5% in Y2, and 10% in Y3	Same
Sharing Threshold	Unless exempted, share in savings above 2% of benchmark	First Dollar	None. Share in savings on first dollar basis.	Same	None. Share in losses of first dollar basis.	Same

Payment Mechanism

- ACOs that have a net loss in their first agreement period will be able to continue to participate in the MSSP if they meet all other participation requirements but must:
 - explain the causes for the net loss during their first agreement period
 - specify the safeguards in place to enable the ACO to achieve savings in the next agreement period
- CMS eliminates the 25% withhold of shared savings earned
 - Intended to make it easier for ACOs to afford to participate
 - ACOs still will have to establish a self-executing method of repayment (e.g., surety bond) equal to 1% of per capita expenditures for assigned beneficiaries for most recent year available

Monitoring & Enforcement

- CMS finalizes its proposal to use methods developed for the Medicare Advantage and Part D programs to monitor and assess ACOs
- CMS modifies the requirement to have all marketing requirements pre-cleared and adopts a “file and use” policy under which ACOs can use marketing materials five days after they are submitted to CMS for review
- The final rule prohibits an ACO from requiring referrals within an ACO, but includes an exception for “employees or contractors who are operating within the scope of their employment or contractual arrangement” so long as the employee or contractor is free to make referrals outside the ACO in the following circumstances:
 - Where the patient expresses a preference for a different provider
 - Where the patient’s insurer demands a different provider
 - Where the referral is not in the patient’s best medical interest

Advanced Payment Model

- The same day the Final Rule was released, CMS released a solicitation for the Advanced Payment Model, run by the Center for Medicare and Medicaid Innovation (CMMI)
- This model will provide payments to certain ACOs that lack access to capital to help them with start-up and initial operating costs
- CMS will recoup payments through shared savings, if there are any. ACOs that don't generate savings will be required to refund to CMS amounts advanced only if they do not finish the agreement period.
- One of a number of actions meant to address high start-up costs as a barrier to participation, including
 - Shortening the claims run-out period to 3 months
 - Eliminating the 25% withhold
 - Funding the CAHPS survey in the first two years
 - Allowing all ACOs to share in savings on first dollar basis

Coordination with other Agencies

- The same day the Final Rule was released, the following additional notices also were released:
 - An Interim Final Rule from CMS and Department of Health and Human Services Office of the Inspector General (OIG)
 - An Antitrust Policy Statement issued by Federal Trade Commission (FTC) and Department of Justice (DOJ)
 - An Internal Revenue Service (IRS) Fact Sheet

CMS/OIG Interim Final Rule with Comment Period (IFC)

- CMS and OIG published an IFC in which they announced five new waivers to the following health care fraud and abuse laws:
 - the federal anti self-referral law (a/k/a "Stark Law");
 - the federal antikickback statute;
 - the civil money penalty provisions addressing hospital payments to physicians (a/k/a "Gainsharing CMP");
 - and the federal healthcare programs beneficiary inducement civil monetary penalty (a/k/a "Beneficiary Inducement CMP").
- These five waivers are as follows:
 - ACO pre-participation waiver. Applies with respect to start-up arrangements that pre-date an ACO's participation agreement.
 - ACO participation waiver. Applies with respect to arrangements between an ACO, one or more of its ACO participants or its ACO providers/suppliers (or a combination thereof).
 - Shared savings distribution waiver. Applies with respect to distributions or use of shared savings earned by an ACO under the MSSP.
 - Compliance with the Physician Self-Referral Law (Stark) waiver. Applies with respect to any financial relationship between or among the ACO, its ACO participants, and its ACO providers/suppliers that implicates the Physician Self-Referral Law.
 - Waiver for patient incentives. Applies with respect to items or services provided by an ACO, its ACO participants, or its ACO providers/suppliers to beneficiaries for free or below fair-market-value.
- ACOs do not have to apply for waiver. If they meet numerous conditions described in the IFC, the activity is protected.
- CMS and OIG are accepting comments, which are due by January 3, 2012.

DOJ/FTC Statement of Antitrust Policy

- The Final DOJ/FTC Statement is substantially the same as the Proposed Statement except that it eliminates the mandatory antitrust review for ACOs that exceed certain minimum share thresholds for any service in which they are bringing together competing providers
- ACOs formed after the effective date of ACA (March 23, 2010), still will be able to voluntarily seek expedited DOJ/FTC review of their arrangements
- In addition, ACOs that fall below certain share thresholds will qualify for an "antitrust safety zone"
 - These thresholds are set relatively low and many ACOs are not likely to qualify
 - ACOs that do not meet the safety zone requirements may nevertheless be lawful

IRS Fact Sheet

- The IRS fact sheet details tax considerations for tax-exempt organizations participating in ACOs.
- It provides that participation in MSSP should not jeopardize an organization's tax-exempt status and should not generate unrelated business income tax (UBIT), although each ACO arrangement would be reviewed based on all facts and circumstances.
- According to the IRS, non-MSSP activities conducted by ACOs will be evaluated based on all the facts and circumstances to determine if they jeopardize an organization's tax-exempt status or generate UBIT. The facts and circumstances to be considered include whether the non-MSSP activities:
 - further a charitable purpose described in Code § 501(c)(3);
 - are attributed to the tax-exempt participant or represent an insubstantial part of the participant's total activities; and
 - do not result in inurement of the tax-exempt participant's net earnings or in the participant conferring impermissible private benefit.
- The IRS explained that even if the non-MSSP activities do not further a charitable purpose, a tax-exempt organization will not lose its status so long as the activity is either not attributed to the participant, or, if attributed, forms an insubstantial part of the tax-exempt participant's total activities.
- The IRS also confirmed that it will grant tax-exempt status to an ACO if the ACO is structured as a corporation, furthers a charitable purpose and meets all the other requirements for exemption under Code § 501(c)(3). Both ACOs engaged exclusively in MSSP activities and ACOs that conduct MSSP and non-MSSP activities may qualify for exemption.

Anticipated Impacts

- CMS has not substantially revised its estimated impacts from the proposed rule
- While reaction to the Final Rule has been positive, it is still not clear who will apply or how many applications there will be
- The application still is not posted
 - Notice of intent is due by Jan. 6, 2012 for April 1 start and Feb. 17, 2012 for July 1 start
 - Applications are due by Jan. 20 and March 30, respectively
 - Decisions will be made by March 16th for April 1 start, and May 31st for July 1 start
- The MSSP is one of several programs and demonstrations that entities can choose to participate in with varying levels of incentives and risk
 - Others include Pioneer ACOs, Comprehensive Primary Care Initiative, Bundled Payment Demos

Key Take-Aways

- CMS made significant revisions to the Final Rule based on stakeholder feedback to make the program more attractive and encourage participation
 - Changes were praised by several groups such as the American Medical Association, the American College of Physicians and Premier healthcare alliance.
 - At least one physician group source as indicated that the changes are likely to increase interest in *Pioneer* ACOs because it decreases the burdens of participation. There is more upside under Pioneer ACOs and the larger ACOs CMS was targeting with the demo are not worried about the risk involved.
- But, concerns remain that may limit participation, especially in early years
 - **Start-up and operating costs remain high.** Avalere Health noted that while the final rule is much easier for providers to handle it will still be difficult for most systems to pursue the ACOs called for under the Medicare Shared Savings Program. CMS estimates that the start-up investment costs for participating ACOs range from \$29 million to \$157 million, and annual operating costs will range from \$63 million to \$342 million.
 - **The ACO as an organizational structure is still very different from how most health systems and physicians operate today.** Jack Lewin, CEO of the American College of Cardiology, said ACOs may still be a challenge to participate in for the majority of doctors and small hospitals that are not integrated.
 - **Beneficiaries continue to have the right to opt out of data sharing.** Premier said in a statement that without beneficiary data ACOs will be hamstrung in their efforts to target interventions that could improve quality.
- Although there is more of a role for specialists, the program remains primary care focused
- CMS will continue to tweak the program through future rulemakings although it is likely to become more, not less, burdensome

CMS Website

- CMS has created a website specific to the MSSP
www.cms.gov/sharedsavingsprogram
- This site has links to the:
 - Final Rule
 - “Fact Sheets” with additional information
 - Information regarding the application process
- New information regarding the MSSP will be added to this website

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