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Final Regulations on Accountable Care Organizations Released

On October 20, 2011, after analyzing the public's feedback regarding the proposed requirements and guidance for accountable care organization (ACO) participation in the Medicare Shared Savings Program (Proposed Rule), the Centers for Medicare & Medicaid Services (CMS) released the final regulations (Final Rule) addressing ACO requirements for participation in the Shared Savings Program.

The Shared Savings Program is part of the federal government's broad attempt to improve care for individuals, improve health for populations and reduce growth in health care expenses (the Three-Part Aim). Under the Shared Savings Program, certain medical providers and suppliers, as described in more detail below, that meet eligibility criteria established by the Secretary of the Department of Health and Human Services (HHS) may establish an ACO and certain other providers and suppliers enrolled in Medicare may participate in, but may not individually establish, an ACO (collectively, ACO Participants).

Under the Shared Savings Program, ACO Participants will be held accountable for the quality, cost and overall care of the traditional fee-for-service Medicare beneficiaries assigned to the ACO. If the ACO holds costs below certain benchmarks and satisfies the quality standards established by HHS, the ACO will receive a shared savings payment, in addition to the fee-for-service (FFS) payments the ACO Participants and providers and suppliers receive under Medicare Parts A and B for medical services rendered.

Below are highlights of CMS's final requirements for participation in the Shared Savings Program. In a subsequent article, we will provide summaries of the interim final rule regarding the waivers to the fraud and abuse laws concerning the Shared Savings Program issued by CMS and the Department of Health and Human Services Office of Inspector General (OIG), the final guidance for tax-exempt organizations participating in the Shared Savings Program issued by the Internal Revenue Service (IRS), and the final joint statement of antitrust policy enforcement regarding ACOs issued by the Antitrust Division of the Department of Justice (DOJ) and the Federal Trade Commission (FTC). Anyone considering forming or participating in an ACO should carefully consider the requirements to form or participate in an ACO with their legal counsel.

ACO FINAL RULE

ACO Participants

In addition to the suppliers and providers that were identified as eligible entities in the Proposed Rule, federally qualified health centers (FQHCs) and rural health clinics are now eligible to form and participate in an ACO. The final list of providers and suppliers who are eligible to form an ACO include the following:

- Physicians, physician assistants, nurse practitioners and clinical nurse specialists (ACO Professionals) in group practice arrangements
- Networks of individual practices of ACO Professionals
- Partnerships or joint venture arrangements between hospitals and ACO Professionals
- Hospitals paid under the Inpatient Prospective Payment System and that employ ACO Professionals
- Certain critical access hospitals
- FQHCs
- Rural Health Clinics

Any Medicare enrolled providers or suppliers not specified as eligible to form an ACO can participate in the Shared Savings Program as ACO Participants by joining an ACO comprised of one or more of the foregoing entities.

Legal Structure & Governance

An ACO must be a legal entity formed under state, federal, or tribal law, be authorized to conduct business in each state in which it operates, and have its own Tax Identification Number (TIN). An ACO must have a governing body that has broad responsibility for the ACO's administrative, fiduciary, and clinical operations. ACO Participants must have at least 75 percent control of the ACO's governing body. The governing body must also include at least one Medicare fee-for-service beneficiary who is served by the ACO and does not have a conflict of interest with the ACO.

Individuals who serve on the ACO's governing body may also serve on the governing body of an ACO Participant. Multiple independent entities that join together to form an ACO must have or form a separate legal entity to serve as their ACO. However, if the ACO is a single legal entity that is financially and clinically integrated, has a governing body that consists of at least 75 percent of its own representatives, and satisfies all other eligibility and governance requirements, the ACO governing body may be the same as the governing body of that entity.

If the composition of the ACO's governing body does not satisfy the 75 percent ACO Participant control threshold or include the required Medicare beneficiary representation, the ACO must, in its application for participation in the Shared Savings Program, describe why it seeks to differ from the established requirements and how the ACO will involve ACO Participants and Medicare beneficiaries in ACO governance.

Leadership and Management

The ACO's operations must be managed by an officer, general partner, or other executive or manager who is subject to the governing body's control and whose leadership team has

demonstrated the ability to improve efficiency processes and outcomes. Clinical operations must be managed by a senior-level medical director who is one of the ACO's physicians, who is board-certified, licensed in one of the states in which the ACO operates, and physically present on a regular basis at one of the ACO's established locations.

ACO Participants, providers, and suppliers must have a meaningful commitment to the ACO's clinical integration program to ensure its likely success. Meaningful commitment may include financial investment and/or investments of time and effort in the ACO's operations. The Final Rule eliminates the requirement that ACOs establish a physician-directed quality assurance and process improvement committee. Rather, as part of an ACO's application, an ACO must describe how it will establish and maintain an ongoing quality assurance and improvement program led by a qualified health care professional.

ACOs must define, establish, implement, and periodically update evidence-based guidelines to ensure that the care provided by the ACO is consistent with the Three-Part Aim. ACOs maintain flexibility in defining the processes that are best suited to their own practices and patient populations. ACO Participants, providers, and suppliers must agree to comply with such guidelines and be subject to performance evaluations and remedial actions or expulsion in the event they fail to comply. The ACO must have a technological infrastructure that enables it to collect and evaluate data to improve the quality of care rendered to patients. While the Proposed Rule required at least 50 percent of an ACO's primary care physicians to be meaningful EHR users by the start of the second performance year to continue in the Shared Savings Program, the Final Rule eliminates this requirement as a condition of participation, but includes it as a quality measure that is weighted higher than any other quality measure.

Responsibility for Beneficiaries

ACOs must certify that ACO Participants have agreed to become accountable for and report to CMS on the cost, quality, and care of all Medicare fee-for-service beneficiaries (FFS Beneficiaries) assigned to the ACO. ACOs that attempt to exclude high-risk FFS Beneficiaries will be subject to sanctions, including termination from the Shared Savings Program. CMS will monitor an ACO's activities to ensure it is not taking steps to avoid high-risk beneficiaries.

Minimum Number of Beneficiaries and Assignment Methodology

An ACO must have at least 5,000 FFS Beneficiaries assigned to it and have sufficient primary care professionals within the ACO to care for such individuals. An ACO will be deemed to meet the 5,000 beneficiary requirement if it has historically been assigned 5,000 or more FFS Beneficiaries. If the number of assigned beneficiaries is less than 5,000 at the end of a performance year, CMS will issue a warning to the ACO and the ACO will be subject to a Corrective Action Plan (CAP). ACOs will remain eligible for Shared Savings Program payments (and losses) during a performance year in which they are subject to the CAP. If, by the end of the next performance year, the ACO does not have at least 5,000 FFS Beneficiaries assigned to it, then CMS will terminate the ACO's agreement and the ACO will not be eligible for Shared Savings Program payments for that year.

Instead of assigning FFS Beneficiaries retroactively to an ACO based on their utilization of primary care services (as provided in the Proposed Rule), FFS Beneficiaries will be assigned prospectively at the beginning of the performance year based on their past utilization of primary care services and the most recent data available. Assignment will then be updated quarterly based on the most recent 12 months of data. The final assignment is ultimately determined after the end of each performance year based on data from that year. It is important to note that a FFS Beneficiary's assignment to a particular ACO does not prohibit the

beneficiary from choosing to seek care from a provider unaffiliated with the ACO, and the ACO may not develop policies that would restrict a beneficiary's freedom to seek care from providers and suppliers outside of the ACO.

Three-Year Commitment

An ACO must agree to enter into a three-year written agreement with CMS to participate in the Shared Savings Program. All contractors, providers, suppliers and ACO Participants must agree to comply with the terms of the participation agreement.

Because CMS assigns FFS Beneficiaries to an ACO based on the FFS Beneficiaries' use of primary care services, primary care physicians can only participate in one ACO per three-year period. All other ACO Participants, providers, and suppliers can participate in more than one ACO during a three-year period.

For the first year of the Shared Savings Program, ACOs may submit applications for a start date of April 1, 2012, or July 1, 2012. All ACOs that start in 2012 will have agreement periods that terminate at the end of 2015. As such, ACOs that begin on April 1, 2012, or July 1, 2012, will have an 18 month or 21 month first performance period, respectively. Such ACOs will also have the option of receiving an interim payment if they report certain quality measures for the year 2012. ACOs must report quality measures for the year 2013 to qualify for shared savings for their first performance year.

Patient Centeredness

ACOs must focus on patient centeredness and demonstrate that they are "patient-centered" by doing the following:

- Implementing a beneficiary care survey and describing how it will use the results of the survey to improve quality of care
- Ensuring patients are involved in ACO governance
- Implementing a procedure for evaluating the health needs of FFS Beneficiaries assigned to it, and implementing a plan that addresses those needs and takes into account the diversity of the ACO's patient population
- Identifying high-risk individuals and developing individualized care plans for such individuals that include community resources based on each patient's needs
- Coordinating care through the use of care coordinators, technology, or both
- Communicating clinical knowledge and evidenced-based medicine to FFS Beneficiaries in a way that is understandable to them
- Engaging beneficiaries in shared decision-making in a way that takes into account their needs, values, priorities, and preferences
- Having a process for communicating to beneficiaries and a separate process that allows beneficiaries to access their medical records
- Having internal systems to measure physician performance that the ACO can use to improve the care and services it provides to beneficiaries

Information to HHS

ACOs must provide HHS with sufficient information on the ACO's Participants so that HHS can assign FFS Beneficiaries to the ACO, implement reporting requirements (including quality reporting requirements), and determine eligibility for Shared Savings Program payments. ACOs must report the TIN of the ACO Participants, along with a list of associated National

Provider Identifiers (NPIs).

Demonstrate Compliance with Quality Criteria

CMS will calculate a score for each ACO based on its satisfaction of certain quality performance standards and measures established by CMS. For the first year of participation, ACOs are only required to report on quality. The number of measures has been reduced to 33 measures in the Final Rule, rather than the 65 originally proposed measures. The measures are now grouped into four "domains:" patient/care giver experience; care coordination/patient safety; preventative health; and at-risk population (for example, diabetes, hypertension, ischemic vascular disease, heart failure, and coronary artery disease). These measures will be the starting point for measuring ACO performance. Such measures may be modified in future reporting cycles to reflect changes in practice and quality of care improvement. CMS will assign performance benchmarks and a point scale for each category. An ACO's performance on each measure in the first performance year will be determined based on data reported by the ACO to CMS. For subsequent performance years, the ACO's performance will be determined either by data reported to CMS by the ACO or by CMS's measurement of the ACO's performance, depending on the particular measure. To earn a shared savings payment, ACOs will have to satisfy at least 70 percent of the measures in each domain. The first time an ACO fails to meet the 70 percent standard, it will be placed on a CAP and CMS will re-evaluate the ACO's performance for the following year. If the ACO continues to underperform in the following year, the ACO's participation agreement will be terminated. If an ACO fails to achieve the minimum attainment level on all measures in any domain, it will not be eligible to receive a shared savings payment. Additionally, if an ACO fails to report one or more measures, CMS will send the ACO a written request to submit the required data by a specified date and to provide reasonable explanation for its delay in reporting the required information. If the ACO fails to report by such deadline or does not provide a reasonable explanation for delayed reporting, CMS will immediately terminate the ACO for failing to report quality measures. ACOs that exhibit a pattern of inaccurate or incomplete reporting or fail to make timely corrections following notice to resubmit from CMS may also be terminated from the Shared Savings Program.

ACO performance and continued eligibility will be monitored through various methods including data analysis; site visits; reviewing complaints from providers and beneficiaries; conducting claims, medical record, and coding audits; and beneficiary survey reviews.

SHARED SAVINGS PAYMENT METHODOLOGY

Shared Savings Program payments will be based on an ACO's ability to keep costs below applicable benchmarks while meeting the quality and other requirements of the Shared Savings Program. CMS will establish the benchmark for each ACO by determining the per capita Medicare Part A and B expenditures for beneficiaries who would have been assigned to the ACO under the beneficiary assignment rules in any of the prior three most recent years, and then adjusting for health status and demographics, as well as overall growth trends.

There are two models for ACO participation, referred to as the "one-sided" model and the "two-sided" model. Under the one-sided model, an ACO is eligible to receive Shared Savings Program payments but is not at risk for any losses. Under the two-sided model, an ACO is eligible to receive a greater share of Shared Savings Program payments, but is also responsible for sharing losses if its expenditures are above its benchmark.

An ACO may elect to participate under the one-sided model for its first-agreement term of three years, but must convert to the two-sided model for any subsequent terms. This is a change from the Proposed Rule, which required an ACO to share downside risk during the third performance year under its original three-year term of participation. This method of participation is referred to as Track 1. In the alternative, an ACO may elect to participate under the two-sided model from the start. This method of participation is referred to as Track 2. ACOs may elect to participate under Track 1 or Track 2 depending on their risk tolerance level. Track 2 is an option for more experienced ACOs that wish to participate under the two-sided model from the start and be eligible for a greater share of savings while also responsible for sharing potential losses.

Under Track 1, as noted, an ACO has no downside risk and may earn up to 50 percent of its savings, depending on quality performance. To receive a shared savings payment, an ACO's expenditures must be below the "minimum savings rate" (MSR), which is applied to account for normal variations in expenditures. Under Track 1, the MSR will be finalized based on the total number of assigned FFS Beneficiaries (the greater the number of assigned beneficiaries, the lower the MSR). Once an ACO has surpassed its MSR under the one-sided model, the ACO would then share in first dollar sharing. Under the one-sided model, shared savings payments will be capped at 10 percent of the ACO's benchmark (increased from 7.5 percent in the Proposed Rule). An ACO that has requested an interim payment must demonstrate during the application process that it has established a repayment mechanism if such interim payments result in an overpayment to the ACO.

Under Track 2, an ACO has the opportunity to share in upside risk by accepting liability for downside risk under the two-sided model during all three years of its agreement with CMS. The percent of shared savings increases under the two-sided model to up to 60 percent depending on quality performance. The MSR is fixed at 2 percent and the minimum loss rate under the two-sided model for an ACO will be determined based on the inverse of its final sharing rate as determined for that ACO and may not exceed 60 percent. The ACO will share in first dollar savings if its expenditures for the performance year are at least 2 percent below its benchmark for the year, or will be responsible for sharing losses if its expenditures are at least 2 percent above its benchmark. Shared savings payments under the two-sided model are capped at 15 percent of an ACO's benchmark (increased from 10 percent in the Proposed Rule). ACOs will not be subject to a withhold on shared savings payments to serve as a surety against the ACO's repayment of any future losses. That said, an ACO must submit documentation with its application demonstrating its ability to repay any losses and must also demonstrate the adequacy of its repayment mechanisms before the start of each performance year. The repayment mechanism must be sufficient to ensure repayment of potential losses equal to at least 1 percent of total per capita FFS Beneficiaries for assigned beneficiaries based either on expenditures for the most recent performance year or expenditures used to establish the benchmark. All ACOs must participate under Track 2 after their initial agreement period with CMS.

Termination

An ACO failing to comply with applicable regulations may be subject to termination. Moreover, CMS may terminate an ACO's agreement immediately for serious violations, including by way of example, if CMS determines that an ACO has been avoiding at-risk beneficiaries. However, CMS has discretion to take certain actions prior to termination, including providing the ACO with a warning notice, instituting a CAP or imposing a special monitoring plan. However, if the ACO violates the antitrust or fraud and abuse laws, CMS will reassess the ACO's eligibility to participate in the Shared Savings Program.

The Final Rule provides 16 grounds on which an ACO may be terminated. By way of example, these include avoidance of at-risk beneficiaries; failure to meet quality performance standards; failure to submit complete and accurate information; failure to meet eligibility requirements, including failures due to the ACO's material change (such as a material change in the ACO's governing body) or any adverse action (including sanctions) imposed by a federal, state, or local governmental agency; violation of Stark, Anti-Kickback, Civil Monetary Penalty law, antitrust, or other laws, rules, and regulations "relevant" to ACO operations; failure to provide beneficiaries with an opt-out option for sharing claims information; exclusion by OIG; use or disclosure of claims information received from CMS in violation of the Privacy Act, the Medicare Part D Data Rule, the HIPAA Privacy Rule, or the data use agreement; or failure to demonstrate an ability to repay losses, or failure to maintain such capability during the term of the ACO agreement. Termination can be based on the conduct of the ACO itself or on the conduct of any of its participants, providers, suppliers, or contracted parties.

An ACO may voluntarily terminate its agreement with CMS. The ACO must provide at least 60 days notice to CMS and the ACO Participants. An ACO that terminates its participation agreement early will not share in any savings for the performance year during which it notifies CMS of its decision to terminate the participation agreement. A terminated ACO must wait until the original three-year period expires before being eligible to reapply to CMS to participate in the Shared Savings Program.

Additional Highlights of the ACO Final Rule

Data Sharing

ACOs can obtain data from CMS about beneficiaries participating in the ACO to assist ACOs in better coordinating care and understanding their patient population. The data available to ACOs may include aggregate (financial, quality performance, and utilization) and beneficiary-identifiable claims data (including Parts A, B, and D data elements). The aggregate data will be available at the beginning of each performance year and quarterly thereafter, and beneficiary-identifiable claims data will be available monthly. Significantly, however, beneficiaries will be permitted to opt-out of sharing their claims data with the ACO, with the exception of CMS' initial provision of such beneficiary's name, date of birth, sex, and health insurance claim number and ACOs must provide beneficiaries with a "meaningful opportunity" to exercise this opt-out right. ACOs must request data from CMS in accordance with regulatory requirements, which include an obligation to enter into a Data Use Agreement (DUA). The DUA obligates the ACO to comply with applicable privacy and confidentiality requirements, including HIPAA, and to use the requested information only for permitted purposes. Misuse or unauthorized disclosure of data will render the ACO unable to receive further data and could result in termination from the Shared Savings Program and the imposition of sanctions or other penalties.

Marketing Materials

ACOs must submit all marketing materials and activities to CMS. However, under the Final Rule, ACOs are allowed to use marketing materials five days after filing them with CMS if the ACO certifies that the marketing materials comply with all applicable marketing requirements and CMS does not disapprove during this timeframe. All marketing materials and activities must (1) use template language provided by CMS when available, (2) comply with prohibitions regarding beneficiary inducements, (3) not be used in a discriminatory manner or for discriminatory purposes, and (4) not be inaccurate or misleading. Marketing materials are defined broadly to include, without limitation the following:

[G]eneral audience materials such as brochures, advertisements, outreach events, letters to beneficiaries, web pages, data sharing opt out letters, mailings, or other activities conducted by or on behalf of the ACO, or by ACO Participants, or ACO providers/suppliers participating in the ACO, or by other individuals on behalf of the ACO or its participating providers and suppliers when used to educate, solicit, notify, or contact Medicare beneficiaries or providers and suppliers regarding the Shared Saving Program.

CMS has discretion to impose a CAP or terminate an ACO that does not comply with these marketing requirements.

Notice to Beneficiaries

Each ACO Participant must notify its FFS Beneficiaries that it participates in an ACO by posting a sign in each of its facilities and notifying patients in writing about its participation in the Shared Savings Program.

Public Reporting

ACOs are required to make information relating to quality and cost available to the public. This information must be accessible in a manner that will be established by CMS. Publicly-available information includes the ACO's name, primary location, and contact information; the names of participating providers and suppliers; the identity of each member of the governing body; identification of any joint ventures between ACO Participants and hospitals; shared savings and loss information; the amount of any Shared Savings payments received or losses repaid to CMS; and the total proportion of savings distributed among ACO Participants, along with the total proportion of the distribution that was used by the ACO to support quality performance and in furtherance of the Three-Part Aim. CMS anticipates releasing further guidance later this year regarding public reporting of quality performance scores.

Compliance Plan

Among other Medicare program integrity requirements, ACOs must have a compliance plan that includes at least the following elements:

- A designated compliance official or individual who is not legal counsel to the ACO 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, ACO Participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to ACO activities to anonymously report suspected problems related to the ACO to the compliance official
- Compliance training for the ACO, the ACO Participants, and the ACO providers and suppliers
- A requirement for the ACO to report probable violations of law to an appropriate law enforcement agency

ACOs that are existing entities may use the current compliance officer if the compliance officer reports to the governing body and is not legal counsel. The ACO's compliance plan must also be in compliance with, and be updated periodically to reflect changes in, laws and regulations.

If you have any questions about the Final Rule or any other issues regarding ACOs, please contact a member of Robinson & Cole's [Health Law Group](#).

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