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## ASCO Summary of ACO Proposed Rule

On Thursday, March 31, 2011 CMS released a notice of proposed rulemaking to establish a statutorily-required Shared Savings program for Accountable Care Organizations (ACOs). The rule was published in the April 7, 2011 Federal Register. Comments are due on June 6.

The rule establishing the Shared Savings program was much anticipated, and various stakeholders are now reviewing the rule and related documents to determine both how to comment to CMS and whether they will attempt to participate in the program. ASCO staff members have reviewed the rule with assistance from reimbursement experts from The Moran Company who are following these issues in detail.

This document presents highlights of the CMS rule, along with preliminary considerations regarding the Shared Savings program that the agency proposed to establish for qualifying ACOs. The more detailed summary following the highlights covers each major policy area, identifies highlights from the underlying detail that are potentially important, and identifies implications of proposed policies for success of the program.

Please note that the analysis represents our initial impressions of the possible impact of the proposed rule; these may change over time and we will keep you informed of any additional analyses. *Nothing in this document should be construed as representing financial or legal advice. The proposed rules are complex and subject to change at the time of final rule publication.*

## Highlights of the Proposed Rule

- While the rule contemplates participation by a variety of different types of physician and hospital organizations, patient assignment will be made retrospectively based on patients who receive a plurality of primary care services from particular types of primary care physicians.

- Thus, there will not be “specialty-specific” ACOs, but specialists—in contrast to primary care physicians—will be able to participate in multiple ACOs.
- Nothing in the rule prevents patients from receiving care from their physicians of choice—even after they have been assigned to ACOs.
- ACOs will be accountable for the patients retrospectively assigned to them and will be eligible to share in savings relative to their individual benchmarks of spending under Parts A and B of the Medicare program.
- Each ACO applying for the program will have a choice of participating in shared savings only for the first two years of the program, with shared savings of up to 52.5% relative to their benchmarks.
- Organizations ready to accept risk in year one will be able to share in a higher percentage of savings (up to 65% in some instances).
- While CMS permits organizations to apply for a model in which there are only upside rewards and no downside risks, ACOs enrolling on this basis will be required to accept risk for potential losses in the third year of the program.
- All participating ACOs will be at risk for losses in the third program year.
- While the policy contemplates a three-year agreement, ACOs are permitted to terminate with sixty days notice, making it possible for ACOs to exit the program before the onset of two-sided risk in year three.
- The CMS model pushes the governance of an ACO in the direction of local public accountability, and suggests that CMS will be active in overseeing the degree of operating control given to various components of each ACO.

## Preliminary Considerations

The following represents our initial impressions of the possible impact of the proposed rule; these may change over time and we will keep our members informed of any additional analyses. Please note that the analysis represents our initial impressions of the possible impact of the proposed rule; these may change over time and we will keep you informed of any additional analyses. *Nothing in this document should be construed as representing financial or legal advice. The proposed rules are complex and subject to change at the time of final rule publication.*

- The CMS ACO model is structured as a formulaic payment system, and is not a framework in which the financial terms of the shared savings program

can be customized to fit the facts and circumstances of each potential provider combination.

- Any potential shared savings may be affected by CMS' proposed use of quality performance measurement scores.
- For ACOs that do not achieve set performance measurement performance measurement scores, shared savings will be decreased even if their cost management performance was positive.
- CMS is placing significant emphasis on quality measurement. ACOs will need to make this a key focus as well.

The more detailed summary below covers each major policy area, identifies highlights from the underlying detail that are potentially important, and identifies implications of proposed policies for success of the program. Please note that the analysis represents our initial impressions of the possible impact of the proposed rule; these may change over time and we will keep you informed of any additional analyses. *Nothing in this document should be construed as representing financial or legal advice. The proposed rules are complex and subject to change at the time of final rule publication.*

## A. Organization of the Proposed Rule

### Policy Overview

This section, in addition to providing an introduction to the organization of the rulemaking, contains the definition of an “ACO,” an “ACO participant,” and an “ACO provider/supplier.”

### Highlights

- An **ACO** is defined as a discrete legal entity, linked to a discrete Taxpayer Identification Number (TIN), comprised as an “eligible group” of “ACO participants” under a “shared governance” framework that affords participants “appropriate proportionate control” over the ACO’s decision-making process.
- An eligible **ACO participant** is defined, in this section, simply as a Medicare-enrolled provider or supplier, subject to the provisions of section B.

- An **ACO provider/supplier** is defined as a provider entity that bills under the TIN of an ACO participant.

## **Analysis**

While this section contains no substantive requirements, the definition of an ACO telegraphs the fact that CMS intends to look behind the governance structure of the organization to ensure that the providers whose characteristics make them “eligible” (see section B) are in fact in control of the organization, and not simply figureheads.

## **B. Eligibility & Governance**

### **Policy Overview**

This section describes the characteristics of ACO participants that make them eligible to become an ACO, and then describes how the ACO must be organized and governed in order to qualify. The general policy is that an ACO must be a provider-controlled organization, built around one or more provider organizations that meet the eligibility criteria. CMS has concluded that each of the four statutorily-specified categories of eligible organizations will in fact be eligible. In addition, Critical Access Hospitals (CAHs) will be eligible to be form or join an ACO under certain circumstances.

### **Highlights**

- While CMS was urged to narrow the definition of an ACO, all four categories of statutorily-specified eligibility categories will be eligible:
  - ❖ Physician group practices;
  - ❖ Networks of individual or group practices;
  - ❖ Joint ventures between physician organizations and hospitals; and
  - ❖ Hospitals that employ ACO physicians.
- In addition, CAHs who bill line item fee-for-service (reimbursement Method II) will also be eligible.
- Otherwise, only hospitals reimbursed under the Inpatient Prospective Payment system (so-called “1886(d) hospitals”) qualify as hospitals for the purpose of determining eligibility to form an ACO.
- The entity must satisfy the statutory requirement that it has sufficient primary care providers to care for at least 5,000 Medicare beneficiaries. ACOs that fall below the 5,000 threshold in a year will be placed on a corrective action

plan and will be terminated if they do not exceed the threshold by the end of the next performance year

- The ACO entity itself need not be enrolled in Medicare.
- There is a general expectation that, in addition to provider representation, the governing body of the entity should have a beneficiary representative, and must “partner” with “community stakeholders.”
- CMS reiterates its requirement for “appropriate proportional control,” but does not further define it.
- Non-provider owners are permitted, but provider entities must hold at least a 75% interest in the ACO.
- The agreement must pre-specify how shared savings will be distributed.
- In the statutory requirements for “patient-centeredness,” CMS finds the authority to require that the ACO commit significant resources to linkages with community health activities.
- ACOs will be required to develop and implement evidence-based care coordination techniques, but CMS will not, at this time, be prescriptive pending the collection of evidence regarding best practices.

## **Analysis**

The requirements CMS is proposing echo the statutory expectation that ACOs will be provider-controlled entities, but go substantially farther than the statute in specifying that an ACO must also be accountable to local community interests. While not-for-profit hospitals typically face such requirements, physician group practices do not typically admit non-physicians to governance roles. This fact may be what motivates CMS to require that organizations formed to seek ACO status expand their governance structure beyond the provider community.

## **C. Establishing the Three-Year Agreement with the Secretary**

### **Policy Overview**

The proposed rules contemplate that those seeking ACO designation will enter into a three-year agreements with the Secretary. The general expectation is that, beginning January 1, 2012, ACO entities will enter in annual cohorts based on their readiness to

meet the requirements with existing resources. Those requiring more time to meet the requirements would enter in later years.

## Highlights

- To facilitate preparation to enroll, CMS will make claims data available, subject to a Data Use Agreement (DUA).
- That data will include identified information regarding beneficiaries that would have been assigned to an ACO in prior periods under the assignment algorithm proposed (see section D).
- CMS also proposes to share aggregated information about potentially assigned beneficiaries in advance of the performance year and in quarterly updates thereafter.
- While shared savings will be calculated on the basis of spending under Parts A and B, CMS proposes to share Part D data with ACOs also, with an eye toward providing information on medication adherence, etc.
- CMS requests comments on whether beneficiaries should have to “opt in” before data can be shared, but has proposed to provide beneficiaries with notice that their provider is an ACO SSP participant and given an opportunity to object to data sharing.
- ACOs entering into an agreement must agree to contract terms that permit CMS to modify the rules in years two and three of the agreement.
- For each contract cohort, however, the rules regarding organizational eligibility (see B), the savings sharing rate (see F and G), and beneficiary assignments (see D) will remain fixed throughout the term of the three-year agreement.
- Under the agreement, the ACO may change “provider/suppliers,” but cannot change “participants,” i.e., those eligible organizations that comprise the governance of the ACO.
- While the agreement contemplates a three-year commitment, ACOs can withdraw from the Shared Savings program with 60-day notice.
- An ACO that terminates, however, cannot reapply until after the expiration of the original contract term.

## **Analysis**

As CMS suggests in its discussion in this section, the late release of this NPRM may induce CMS to modify the contracting strategy described above in the final rule. While it is reasonable to expect them to use the annual cohort model for a variety of reasons they state in the preamble, they may provide for semi-annual entry points (at least in 2012) to provide an entry mechanism for those who are committed to participate, but who cannot come into full compliance before January 1, 2012.

The provision providing for termination by an ACO with 60 days notice is a significant feature of the proposed contract. As the discussion in later sections will make clear, the program design CMS is proposing is not without risks for participants. The 60-day termination clause is therefore a potentially valuable “safety valve.”

## **D. Assignment of Medicare Fee-for-Service Beneficiaries**

### **Policy Overview**

CMS proposes to assign beneficiaries to ACOs “retrospectively”—meaning that the cohort of beneficiaries against which the ACO’s performance will be measured in a given year will be identified at the conclusion of the performance measurement year. The intent is to hold each ACO accountable for the patients that actually used that ACO’s providers in the measurement year. Hence, while beneficiaries will receive various forms of information if assigned to an ACO (and even before they receive care from an ACO provider), they will not be offered the option of either opting in or opting out of the retrospective assignment. Beneficiaries will retain their full freedom of choice rights; they are under no obligation to use the services of the providers in the ACO to which they have been assigned.

### **Highlights**

- The assignment algorithm CMS proposes will be based on identifying beneficiaries who received a plurality (not a majority) of their primary care services from primary care physicians who are on the roster of the ACO.
- Physician designation as a primary care physician will be based on a physician’s self-reported Medicare specialty (general practice, family practice, internal medicine and geriatric medicine); identification will be based on the physician’s TIN.
- Primary care physicians must, therefore, be exclusive to a single ACO; specialists, by contrast, can be involved in more than one ACO.

- Assignment will be based on allowed charges, not service counts, to prevent the need for tie-breakers.
- Beneficiaries will have notice that a provider from whom they receive care is part of an ACO and could, if they chose, elect not to receive care from that provider, but they cannot opt out of retrospective assignment to the ACO.
- However, beneficiaries can opt out of having their protected health information shared within the ACO without their express consent.

## Analysis

CMS's arguments for retrospective assignment are strong. Research suggests that, if they had opted for prospective enrollment, as many as 25% of the beneficiaries assigned to an ACO for a year would receive no services from that ACO's provider in the measurement year. Attempting to wire around this problem would substantially complicate performance measurement, increasing financial risks for all parties.

In discussing beneficiary retention of freedom of choice rights, CMS makes the observation that "...if a beneficiary's physician becomes part of an ACO and the beneficiary does not wish to receive health care services under the ACO care coordination and management efforts (*sic*), the beneficiary has the freedom of choice to go to a different physician.<sup>1</sup>" Hence while beneficiaries retain the right to select their physicians, assignment to an ACO may limit their ability to receive treatment from that physician if they do not wish to be part of the ACO.

## E. Quality & Other Reporting Requirements

### Policy Overview

The Shared Savings program will have a very significant "value-based purchasing" (VBP) component, under which an ACO's ability to receive shared saving payments, and the amount of payments it will receive, will turn on the ACO's performance score against a set of quality measures. In the first year, an ACO's score would be based on complete reporting for 100% of all performance measures; in subsequent years, an explicit performance score would govern payment. The program will initially employ a set of 65 measures, organized into five "domains" for measurement purposes. To the maximum extent possible, CMS will seek to align measures used across all of its VBP initiatives; the expectation is that CMS will "raise the bar" each year by adding more challenging measures as the program goes forward.

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<sup>1</sup> p. 161 of the rule's display copy.

## Highlights

- While CMS considered using the quality performance score as a threshold for eligibility to receive shared savings rewards, the agency is proposing a continuous measure under which the maximum percentage of shared savings achievable is adjusted based on the score.
- Each metric will have a “minimum attainment level,” (30<sup>th</sup> percentile of performance), and a benchmark (90<sup>th</sup> percentile).
- Failure to achieve the minimum attainment level for any of the 65 measures will result in a warning, which may lead to termination in a subsequent year if performance doesn’t improve.
- Between the minimum attainment level and the benchmark, points would be awarded on a sliding scale based on a 2 point maximum for each of the 65 measures.
- Each ACO would receive a score between zero and 130, which is then divided by 130 (the maximum possible score) to determine the percentage of the maximum possible shared savings that could be awarded.
- In addition to applying these quality metrics (which include measures of health information technology use), at least 50% of an ACO’s primary care physicians must be “meaningful users” of health information technology.
- Sixteen of the quality measures are specifically related to the prescribing and administration of particular drugs in patients with various conditions.
- ACOs will be required to document “convincing evidence of concrete and effective plans” to satisfy requirements to promote evidence based medicine (EBM), patient engagement and coordination of care.
- Initially, CMS proposes substantial flexibility for ACOs to choose the tools they will use to EBM and patient engagement, to coordinate care and to report on cost and quality metrics. The agency states that it may be more prescriptive over time as it learns which strategies are successful.
- The rule describes patient engagement as the “active participation of patients and their families in the process of making medical decisions.” ACOs will be expected to implement decision support tools, shared decision-making and health literacy efforts.
- The rule describes a number of ways that ACOs will be required to foster “patient centeredness,” including individualized care, beneficiary access to

records and integration with community resources necessary to maintain patient well-being.

- CMS expects ACOs to engage in a variety of strategies to coordinate care, including case management, predictive modeling to anticipate likely needs, care transition programs, remote monitoring and telehealth services. The agency notes that care coordination strategies “should not impede” the ability of beneficiaries to seek care outside an ACO.

## **Analysis**

The quality performance scoring methodology proposed will have an important impact on the dynamics of the shared savings program.

Quality performance scoring will affect the total amount of shared savings from cost management performance. ACOs that do not achieve 130/130 in quality performance scoring would see their overall shared savings reduced.

## **F. Shared Savings Determination**

### **Policy Overview**

CMS is proposing a shared savings arrangement under which ACOs can pursue two discrete tracks.

In the first track, ACOs would sign up for a “one-sided” shared savings arrangement during the first two years, under which ACOs could qualify for shared savings if they meet quality and cost measures, but would not be subject to penalties for adverse performance. In the third year, ACOs would be converted to a “two-sided” shared savings model, under which penalties for poor performance would be introduced.

In the second track, ACOs that believed themselves ready to do so could sign up for three years under the “two-sided” shared savings model (see Section G for further discussion of the two-sided model).

Under either option, a benchmark would be established based on historical cost performance of the assigned population, trended forward. A “minimum savings rate” (MSR) would be established for each ACO to ensure that measured differences from the benchmark were real, and not an artifact of the measurement process. Those who exceeded their adjusted benchmarks by a specified percentage could share in savings (positive or negative in the two-sided model). Their maximum share of the excess would be 50% under the one-sided model, and 60% under the two-sided model. As noted in Section E, however, that maximum would be reduced based on the quality performance score.

The total amount payable would be constrained to a fixed percentage of each ACO's benchmark for a year: the one-sided model would be capped at 7.5%, while the two-sided model would be capped at 10%. If savings are payable to an ACO, CMS will withhold 25% as a reserve against future losses. ACOs that terminate before the end of the three-year agreement would forfeit any unpaid amounts withheld.

## Highlights

- The benchmark would be calculated based on the population that would have been assigned to the ACO under the assignment algorithm in a three year base period. The benchmark would be risk adjusted using the Medicare Advantage risk adjustment methodology (CMS-HCC), and weighted toward the more recent data.
- Savings would be calculated based on all spending under Parts A and B of the Medicare program.
  - CMS proposes to exclude only catastrophic outliers (99<sup>th</sup> percentile of costs).
  - Part D costs are not included, but ACOs would be permitted to request Part D data in order to track beneficiary adherence to prescription drug regimens.
- While the rule itself will not cause changes to drug coverage rules, ACO providers will have incentives with regard to Part B drugs to choose the most cost effective options available while still providing high quality care.
- While the cost of Part D drugs will not be considered in determining SSP performance, providers who believe that improved adherence to prescription regimens will help to reduce costs will have clear incentives to encourage beneficiary compliance.
- Bonus payments and penalties under other incentive programs would be excluded, but other payments (e.g., IME and DSH) would be included.
- The benchmark would be trended to the first program year using a national percentage growth factor.
- Thereafter, it would be trended forward using a national flat dollar increment in per capita spending.
- The MSR for each ACO would be set between 2% and about 4% based on the size of the ACO.
- For organizations participating in the one-sided model that achieved the MSR, shared savings would accrue for savings above 2% of their benchmarks (though certain small ACOs might be exempted from the 2% increment).

- Additional incentives would be offered to ACOs that contracted with Federally-Qualified Health Centers (FQHCs) and Rural Health Centers (RHCs).

## **Analysis**

Unlike a commercial managed care arrangement, under which rates are set via negotiation, this arrangement requires an ACO to commit to a three-year rate schedule, which the ACO has not yet seen, without an opportunity to negotiate terms. Considerations associated with the two-sided model will be discussed in our analysis of Section G below. The quality performance adjustments are notable in that regard, because CMS has announced its intention to add new and more challenging measures each year, and eligibility for any form of payment is contingent on satisfactory performance.

## **G. Two-Sided Model**

### **Policy Overview**

The two-sided model differs from the one-sided model in two important ways.

First, as an incentive to undertake such an arrangement, the upside rewards are enhanced relative to the one-sided model. In lieu of a threshold for shared savings of two percent for organizations that achieve savings in excess of the MSR, ACOs in the two-sided model that exceed 2%, savings share in the “first dollar” over the benchmark. The value of the FQHC/RHC incentive is doubled to 5%. The maximum share of savings is increased to  $60 + 5\% = 65\%$  for two-sided arrangements, and the cap on the maximum payout is increased to 10%.

Second, the two-sided arrangement has a downside: ACOs under a two-sided arrangements share in “negative savings” when expenditures exceed the benchmark by more than the 2% flat “minimum loss rate.” In this circumstance, however, positive quality performance reduces the ACO’s share of those losses below the 60% share (adjusted for quality performance) applied to the upside. Losses are also capped at 5%, 7.5% and 10% over the three years of the agreement, respectively.

### **Highlights**

- The prospect that the ACO may owe CMS necessitates a mechanism to ensure repayment.
- ACOs seeking two-sided contracts must establish “self-executing arrangements” that ensure that payment will be made when due without further discretionary action by the ACO.

- The rule provides flexibility for ACOs to craft those arrangements using a variety of building-blocks, e.g., performance bonds and reinsurance arrangements.

## **Analysis**

As in the case of the one-sided arrangement, the ultimate financial outcome is highly dependent on an ACO's quality performance score. ACOs with "middle of the field" quality performance scores will face smaller positive shared savings and higher downside risks than will those with higher scores. If an ACO's performance score is lower than 130/130 the amount of shared savings realized by the ACO will be reduced.

## **H. Monitoring & Termination**

### **Policy Overview**

CMS will apply all of the monitoring tools it has developed under its fee-for-service payment systems and managed care contracting programs to scrutinize performance by ACOs. An important focus will be on whether ACOs seek to deter high risk individuals from seeking care at their facilities (and hence becoming part of the ACO's assigned population). ACOs that terminate before the end of the three-year term forfeit any unpaid withhold amounts. If a terminated ACO reapplies (after year three), they must enroll in Track Two (the two-sided arrangement).

### **Analysis**

Present Medicare providers are subject to comparable scrutiny. It is not completely clear how CMS will specify what constitutes an effort to deter high risk individuals.

## **I. Coordination with Other Agencies**

### **Policy Overview**

The proposed rule summarizes provisions proposed in guidance simultaneously published by the CMS Office of the Inspector General, the Internal Revenue Service, and the "antitrust agencies" (Justice and FTC) regarding enforcement of statutory policies prohibiting improper financial inducements, provider self-referral, price fixing and monopolization. Nothing in the rule or these other documents suggests that current law policies will be relaxed for ACOs. Rather, the focus is on expedited review of proposed arrangements to prevent the prospect that CMS would approve an ACO that would subsequently be challenged as unlawful.

## Highlights

- With respect to HHS waivers and policy regarding provider tax exemption, the rule refers readers to the separately published notices by the respective enforcement agencies.
- With respect to antitrust policy, it announces a “safety zone” with respect to concerns about monopolization.
- Applicants must determine whether the proposed business combination contemplated by the ACO results in market shares in excess of 30% for any separate line of business.
- If the proposed ACO passes this test in all relevant business lines, CMS will not require certification by an enforcement agency in order to approve the application.
- If the proposed ACO would result in a market share in any line of business greater than 50%, CMS will not approve the application without a letter from the cognizant enforcement agency indicating that it will not prosecute.
- The area between 30% and 50% remains a gray area in which potential applicants may wish to seek expedited review.

## Analysis

The proposed policy, as outlined, makes clear that provider entities forming ACOs must structure their arrangements in a manner consistent with all presently-applicable bars against improper payments, improper communications and monopolization of various lines of business. This means that many arrangements that might make sense within an ACO from a health policy perspective may be barred on other grounds. This policy will impose practical limits on the amount of “inter-organization integration” that can take place in the ACO context.

## J. Overlap with Other Shared Savings Initiatives

### Policy Overview

The Shared Savings program for ACOs cannot overlap with any other CMS program in which shared savings payments are made to individual providers (defined as discrete TINs). The Primary Group Practice demonstration will be transitioned to the ACO model. Programs developed by the Centers for

Medicare & Medicaid Intervention (CMMI) will be designed to avoid duplication of ACO incentives.

### **Analysis**

Non-governmental entities promoting innovative payment policies to the CMMI must be mindful of this constraint.

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