

## Health Reform Alert

### CMS Releases Proposed Rule on ACO Shared Savings Program

April 3, 2011

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On March 31, 2011, the Centers for Medicare & Medicaid Services (CMS or the “Agency”), along with several other federal agencies, released a long-awaited proposed rule and other notices that would implement the Medicare Shared Savings Program and Accountable Care Organization (ACO) provisions of the Patient Protection and Affordable Care Act (PPACA). The proposed ACO regulations and policies are contained in four separate documents: (1) a CMS proposed rule establishing ACOs; (2) a Department of Health and Human Services Office of Inspector General/CMS notice with comment period proposing waivers for the Anti-Kickback Statute, the Physician Self-Referral Law (the “Stark Law”) and certain provisions of the Civil Monetary Penalties law; (3) a Federal Trade Commission/Department of Justice proposed statement of antitrust enforcement policy for ACOs; and (4) an Internal Revenue Service request for comments addressing guidance for tax-exempt organizations participating in the program. This health reform update gives a preliminary analysis of CMS’s proposed rule. The other three publications are reviewed in separate updates prepared by members of Akin Gump’s ACO team.

Although the CMS proposed rule has only been issued in draft form, publication in the *Federal Register* is expected on or around April 7, 2011. **Comments on the rulemaking must be submitted to CMS within 60 days of publication.**

Health industry stakeholders highly anticipated the release of this rule and early CMS estimates indicate that 1.5 to 4 million beneficiaries would be assigned to ACOs in the first three years of the program (as compared to 45 million beneficiaries who have traditional fee-for-service (FFS) Medicare coverage). This estimate reflects only those enrolled in the Medicare Shared Savings Program; additional individuals are anticipated to be enrolled in commercial and Medicaid ACOs. In press conferences and releases surrounding the announcement of the proposed rule, CMS appears confident that the ACO Shared Savings Program will incent providers to furnish coordinated and efficient care and ultimately lower costs throughout the health care delivery system. Summarized below are some noteworthy takeaways from the ACO proposed rule.

### ACO Participants

The PPACA delineated four groups of providers and suppliers that would be eligible to participate as ACOs: ACO professionals (e.g., physicians, physician assistants, nurse practitioners, clinical nurse specialists) in group practice arrangements; networks of individual practices of ACO professionals; partnerships or joint ventures between PPS hospitals and ACO professionals; and PPS hospitals employing ACO professionals. Congress also gave the Secretary the authority to permit additional groups of providers or suppliers to participate as ACOs. In the proposed rule, CMS employs this authority to expand the initial list of four groups to include certain critical access hospitals.

Significantly, CMS also proposed creating a distinct group of ACO participants—those entities that may collaborate with and participate in an independent ACO (and thus share in the savings achieved), but may not themselves *form* an ACO. That expanded list of eligible participants now appears to include any Medicare-enrolled entity, including federally qualified health centers (FQHCs), rural health clinics (RHCs) and post-acute care providers. CMS reasoned that this flexible approach would allow for the best opportunity to broadly transform the health care delivery system by



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including providers along the entire continuum of care. Of note, CMS also proposed that ACOs which include FQHCs and RHCs as participants would be able to share in a greater percentage of any achieved savings.

Notably, CMS's use of its broad authority may be a positive development for the many providers that were not originally included in section 3022. CMS's open-ended proposal will, however, require that these entities make their own case to various ACOs as to why they should be able to participate in the ACO. CMS requested comments on whether it should use its broad authority under the PPACA to further expand the list of entities eligible to form and/or participate in an ACO.

## ACO Beneficiary Issues

### Retrospective Beneficiary Assignment

Consistent with the expectations of many stakeholders and CMS's experience with the Physician Group Practice Demonstration, the Agency proposed retrospectively assigning beneficiaries to an ACO. This means that, at the end of each year of an ACO agreement (which are proposed to be three years in duration), beneficiaries would be assigned to an ACO based on the provision of primary care services to beneficiaries by the ACO's primary care physicians during the prior year. Specifically, beneficiaries would be assigned to the ACO that provided the beneficiary with the highest complexity and intensity of primary care services in that prior year (i.e., plurality of allowed charges for primary care services). CMS rationalized its approach as being preferable to a prospective method, stating that the Agency wants to ensure that ACOs are focused on improving care for all beneficiaries, rather than simply those that are assigned to the ACO for shared savings purposes.

Significantly, however, CMS proposed providing ACOs at the beginning of the agreement period with aggregate beneficiary level data (date of birth, gender, name and health insurance claim number) regarding the beneficiaries assigned to it in the benchmark period (i.e., the three-year period prior to the ACO's first performance year that would be used to set the ACO's expenditure target against which actual expenditures would be measured). CMS stated that this approach would allow the ACO to improve care coordination and target inefficiencies by having some indication of the population it is working with in the Medicare Shared Savings Program. ACOs would also be provided throughout the agreement period with aggregate data on beneficiary use of health services, as well as some claims data, including Part D claims. CMS explained that this data would assist providers in developing beneficiaries' plans of care. Although beneficiaries would be allowed to "opt-out" of having their individual claims data shared with the ACO, CMS would still collect information on ACO beneficiaries for purposes of determining ACO costs, quality performance and shared savings.

### Prohibition of Beneficiary Cherry Picking

Out of concern that ACOs could avoid at-risk patients in order to reduce costs, the PPACA permits the Secretary to impose appropriate sanctions on ACOs that engage in "cherry picking." The proposed rule described at-risk patients as those beneficiaries who have high risk scores on the CMS-Hierarchical Condition Category risk adjustment model, are considered high cost due to having two or more hospitalizations or emergency room visits each year, are Medicare/Medicaid dual-eligibles, have a high utilization pattern, have one or more chronic conditions or are beneficiaries with a recent diagnosis (for example, a newly diagnosed cancer) that is expected to result in increased costs. The Agency proposed using various methods to identify trends and patterns indicative of cherry picking and seeks comments on the definition of such patients and whether other characteristics should be considered in determining at-risk status. If an ACO is believed to be avoiding at-risk patients, CMS has the authority to open a thorough investigation, prevent the ACO from sharing in any achieved savings or terminate the ACO's participation in the program.

### Beneficiary Notification and Communications

CMS reiterated throughout the proposed rule that transparency and the right of each beneficiary to have a free choice of providers are important goals of the Medicare Shared Savings Program. Specifically, beneficiaries are free to seek care from any providers, just as they currently do under traditional FFS Medicare. Further, the Agency explained that free choice can be undermined or nullified if beneficiaries do not have adequate information about their available options.

Acknowledging that notifying a patient about a provider's participation in an ACO is challenging in light of the retrospective enrollment feature, CMS proposed requiring that providers/suppliers notify beneficiaries that they are obtaining care from a participating ACO at the time the patient seeks care (e.g., posting signs in the facilities, distributing standardized written information). The Agency also proposed requiring that it review and approve all ACO communications that are used to "educate, solicit, notify, or contact Medicare beneficiaries or providers/suppliers regarding the ACO and its participation in the [Program]." CMS is concerned that confusing or misleading marketing would be antithetical to the patient-centeredness requirements for ACOs. The Agency believes that reviewing and approving these materials can help to preserve the goals of the ACO program.

ACOs would be responsible for making certain data publicly available through a standardized format that will be prescribed by CMS in forthcoming subregulatory guidance. Specifically, CMS noted that the public should be informed about each ACO's makeup, shared savings results and quality performance scores.

## ACO Payment: Two Payment Tracks

Industry stakeholders expected that the CMS shared savings model would simply allow ACOs to share in the savings they achieved relative to their benchmarks. In one of the biggest surprises of the rulemaking, however, CMS introduced two payment tracks, both of which include a "downside risk" component that holds ACOs accountable for failing to achieve savings as compared to their benchmarks. The Agency recognized that organizations with available financial reserves, which are experienced with integrated care and risk-based arrangements, may be ready and willing to accept risk beginning in the first program year, but others will need time to build up to that point.

As a result, in track one, the Agency proposed that for performance years one and two, ACOs would not be subject to any downside risk. The Agency refers to this as a "one-sided" payment model. This means that they would be eligible for a percentage of shared savings in these years, but would not be responsible for sharing in expenditures above the benchmark. In performance year three, track one ACOs would be transitioned to a "two-sided" payment model (described below).

To qualify to receive shared savings, all ACOs must meet a minimum savings rate (MSR). The MSR is the required percentage that ACO expenditures fall below the benchmark. In the one-sided model, the MSR ranges from 2.0 percent to 3.9 percent depending upon the number of beneficiaries assigned to the ACO. Once the ACO has achieved savings in excess of the MSR, the ACO is eligible to share in the savings above the MSR amount. In other words, the ACO is not eligible for "first dollar" savings. Under the one-sided model, ACOs are eligible to receive a maximum of 52.5 percent of the savings they achieve—50 percent for quality performance and an additional amount, up to 2.5 percent, for including an FQHC or RHC as a participant in the ACO. Total savings that may be shared are also capped at a certain percentage of the ACO's benchmark on a sliding scale determined by the number of beneficiaries assigned to the ACO. CMS is seeking comments on whether it should increase the potential shared savings if the ACO cares for a certain number of Medicare/Medicaid dual-eligible patients.

In track two (and in the third performance year of track one), ACOs would operate under a two-sided model under which ACOs would accept risk for losses once the minimum loss rate ("MLR") is exceeded. The MLR is intended to mirror the MSR, but it is set at 2.0 percent for all two-sided model ACOs, regardless of the number of beneficiaries assigned. Losses are shared on a first dollar basis and a cap, calculated as a percentage of the benchmark, on the ACO's share of the losses is phased in over the three-year agreement.

CMS has proposed additional incentives to reward providers who select participation in track two, including: a 65 percent maximum sharing rate (i.e., up to 60 percent based on quality performance and up to five additional percentage points for including an FQHC or RHC in the ACO); and sharing in total savings that exceed the benchmark (i.e., first dollar savings).

Rather unexpectedly, CMS proposed limiting an ACO's ability to obtain its full incentive payments under both tracks by proposing to withhold 25 percent of an ACO's annual shared savings until the end of the three-year contract. The

withholding provision is intended to ensure that ACOs complete the full three-year program since, under this proposal, ACOs that leave before their three-year agreement concludes or who are terminated will forfeit the withheld payment. This 25 percent hold-back would also help to ensure that the ACO is able to pay back to CMS any losses associated with participation in either track.

### **Additional Shared Savings Payment Considerations**

As required by the PPACA, CMS must develop a benchmark for each ACO to serve as the standard against which to compare an ACO's actual expenditures. CMS proposed to base this benchmark on Part A and B expenditures for those beneficiaries who would have been assigned to the ACO during the benchmark period. That is to say, CMS proposed using the claim records of ACO participants to determine a list of beneficiaries who, using the assignment methodology described above, would have been assigned to the ACO in each of the three most recent years prior to the ACO's first performance year. The Agency proposed adjusting this historic data to account for beneficiary health status and trending this data forward using national Medicare expenditure data. The Agency commented that the use of a national benchmark would "help to ensure that ACOs in both high spending, high growth and low spending, low growth areas will have appropriate incentives to participate in the [Program], while also moving toward establishing a national standard for calculating and measuring ACO financial performance."

In addition to beneficiaries' Part A and B fee-for-service expenditures, some Medicare add-on payments—indirect medical education payments, disproportionate share hospital payments and the geographic practice cost index adjustments—will be included in the benchmark. Significantly, however, certain Medicare incentive payments are treated inconsistently in the proposed rule. Specifically, the hospital incentive payments and penalties from the Electronic Health Record (EHR) and value-based purchasing programs are included in calculating the benchmark, but physician incentive payments and penalties from the EHR, electronic prescribing and Physician Quality Reporting System (PQRS) are excluded from the benchmark.

### **Key ACO Quality and Outcome Reporting Requirements**

CMS proposed 65 clinical measures to assess the quality of care furnished by an ACO. Those measures were split into five "domains," each of which is weighted equally to determine quality performance. The majority of the measures focus on process, with the remainder evaluating outcomes and patient experiences. While ACOs will be evaluated based on their performance in achieving these measures in future years, during the first year, CMS proposed to evaluate performance solely by complete and accurate reporting of the measures. The specific measures would be revisited each year through rulemaking; thus, the list is likely to expand in future years. In particular, CMS noted its intent to add specific hospice care and nursing home measures in the future. The proposed rule contains a detailed explanation of proposed scoring and benchmarking methodologies, and requests comments on those processes and on the specific measures chosen. ACOs would report on quality measures through a combination of surveys, claims data and data collection tools that are similar to those already used in other initiatives such as the PQRS).

On a positive note, CMS determined that eligible professionals within an ACO that satisfactorily report on the ACO measures could automatically qualify for the PQRS incentive payment. CMS decided not to implement a similar automatic deeming process for the EHR program because that incentive program ends in 2013. CMS emphasized, however, the importance of EHR implementation by proposing that 50 percent of an ACO's primary care physicians must be "meaningful users" of EHRs, as defined in the Health Information Technology for Economic and Clinical Health Act of 2009, by the start of the ACO's second performance year in order to be considered a qualifying ACO. CMS requested comments on whether a similar requirement should be put in place for hospitals.

Failure to report on one or more of the quality measures in the first year would result in a warning letter requesting that the ACO submit the measure with an explanation for the delay by a certain date. If the ACO fails to provide a satisfactory report and explain its delay by the deadline, it can be immediately terminated. After the first year, any ACOs not meeting performance thresholds for all proposed measures would become ineligible for shared savings, regardless of the cost reductions achieved by the ACO.

## Interplay with other CMS Shared Savings Initiatives

In the proposed rule, CMS states its concern that the Medicare Shared Savings Program has the potential to duplicate other programs or demonstrations involving Medicare Part A and B services under which the payment methodology also involves a form of shared savings. The Agency expressed its interest in preventing a provider or supplier from being rewarded twice for achieving savings in providing care to the same beneficiary. Thus, CMS has proposed that Medicare-enrolled providers and suppliers could not participate in both the ACO Shared Savings Program and any of the following: (1) the Independence at Home Medical Practice Demonstration; (2) Medicare Health Care Quality Demonstrations; (3) medical home demonstrations with a shared savings element; or (4) the Physician Group Practice Transition Demonstration.

## The Innovation Center and Additional ACO Opportunities

The Center for Medicare and Medicaid Innovation has recently announced its intent to release a request for applications, which would include ACO applications, after the publication of the ACO proposed rule. The ACO proposed rule makes multiple references to these ongoing efforts at the Innovation Center. Notably:

- CMS stated that the Innovation Center is seeking input as to how it can test different models that provide financial and technical assistance to groups of providers and suppliers that may wish to develop an ACO.
- CMS indicated that it intends to coordinate its efforts with the Innovation Center to ensure that there is no duplication of participation in the Medicare Shared Savings Program and other shared savings models tested by the Center.

The potential opportunities available through the Innovation Center pose an important consideration for providers who are considering developing ACO models, since the legal authority establishing the Innovation Center provides the Secretary broad discretion to test a variety of payment models, including different types of ACOs. It is critically important to follow Innovation Center developments in the coming months.

## Conclusion

The shared savings ACO model raises many important considerations for health industry stakeholders that are considering their involvement in this program. In the coming weeks, the Akin Gump ACO team will provide additional analysis of this proposed rule and other ACO information and guidance coming out of the Administration and Capitol Hill.

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