



## APPLYING THE ACO REGULATIONS IN MY PRACTICE

The Health Care Reform Act<sup>1</sup> has set created quite a conundrum for physicians. At the center of this miasma is the enigmatic Accountable Care Organization (ACO), the entity borne of PPACA. The idea of an accountable care organization holds so much promise: a separate entity owned, for the most part, by physicians and certainly driven by physicians, which would provide quality care to patients through collaborative efforts among the physicians and with other providers and community resources with the dual goal of a healthier population and dramatically reduced costs. The prize awarded to the participants for their efforts would be a share of the savings accruing to the Medicare program in its fee for service (FFS) product.

Commercial payors have jumped on the bandwagon as well. The general consensus is that once an ACO is formed, with its sophisticated data collection and reporting capabilities and its focus on cost savings, the commercial payors will be able to participate directly as a contributor to the ACO or will at least be able to fashion shared savings programs with the ACO which will benefit the payor through a healthier insured population and care that is provided in a cost-effective manner.

On March 30, 2011 at 11:15 a.m., the Centers for Medicare and Medicaid Services (“CMS”) issued the much anticipated proposed regulations for ACOs. Following within the hour, the Federal Trade Commission (“FTC”) and Department of Justice (“DOJ”) issued a joint policy statement (“Policy Statement”) dealing with antitrust enforcement for participants in the Medicare/ACO Shared Savings Program. The proposed ACO regulations were published in the Federal Register on April 7, 2011 (the “Proposed ACO Regulations”) as were the Waiver Designs in Connection with the Shared Savings Program, adopted by the Office of Inspector General (“OIG”). This article will focus on the Proposed ACO Regulations.

### ISSUES RAISED BY THE ACO PROPOSED REGULATIONS

Many physicians were feeling pressure from hospitals and hospital systems that offered to buy their practices and bring them within the hospital management system in anticipation of being some of the first participants to be certified by Medicare as ACOs. Many physicians decided to wait and see what the Proposed ACO Regulations would say before either aligning their practice with a hospital or spend the money to create an entity which could be certified as an ACO. Now that the Proposed ACO Regulations are a fact, physicians face even more pressure.<sup>2</sup>

<sup>1</sup> Patient Protection and Affordable Care Act of 2010 (PPACA).

<sup>2</sup> These are proposed regulations. CMS will be looking at comments from the industry over the next 60 days and then, sometime thereafter, issue final regulations. We will update this article to the extent that final regulations differ materially from the proposed regulations.

Consider the following issues raised by the Proposed ACO Regulations:

**1. Sharing Losses.**

Section 3022 of PPACA created a shared savings program for which there was no shared loss component. Under the statutory provisions, CMS would assign Medicare beneficiaries (based on historic utilization) to the ACO and designate a baseline cost per beneficiary based on historic claims. If the ACO met the quality indicators and created savings over a threshold, those savings would be shared between the Medicare program and the ACO. The statute did not authorize a downside risk to the ACO if it was unable to save more than the threshold.

The Proposed ACO Regulations do have a penalty. If an ACO's average per capita Medicare expenditure falls above a minimum savings loss rate (which is the inverse of the minimum savings rate (MSR)), which at least for the first year is 2%, the ACO can be penalized up to a percentage of its benchmark. The percentage cap on losses is 5% in the first year losses are incurred for which the ACO is liable, 7.5% of the benchmark in the second year, and 10% of the benchmark in the third year.

The physicians saw the patients; the services were all provided; the physicians and their business partners spent a fair sum of money putting cost-saving programs in place; they spent more money on developing protocols for meeting and reporting the quality indicators; and yet if they are unable to save the program money, they must pay some percentage of the benchmark set by CMS to CMS. Under Option 1, the recoupment for losses occurs for all ACOs in the third year of the program. An ACO may elect Option 2, which would allow for a greater percentage of the savings from the beginning, in which case liability for losses would begin immediately.

CMS says in the Preamble that this stick (along with the carrot of shared savings) will encourage providers to continuously look for ways to improve care and save money. The benchmark is re-set annually.

**2. The Timing Issue**

Every ACO participant must sign on for a minimum of 3 years. During the course of that period, the ACO may remove participants but may not add new participants. This provision was intended to discourage applicants from being certified as an ACO with one set of participants only to have others join after the fact which would have precluded certification in the first place had the ACO applied with them as participants. The issue for wary physicians is that they don't get to wait and see how an ACO is doing before signing up. Or, if they sign on with one ACO and it turns out that the other participants are not as diligent about meeting the quality measures or following the protocols adopted by the group for cost savings, they cannot leave that ACO (they are committed for 3 years) and join a more successful ACO (the ACO may not add participants).

The timing issue may be intensified by the commercial insurers. If they contract with the ACO as and ACO, does either staying out of the ACO initially or dropping out of an ACO preclude the physician from participating in commercial contracts negotiated by the ACO?

**3. Am I a Provider/Supplier Participant or Just a Provider/Supplier and**

## **What are the Differences?**

The ACO Proposed Regulations are unclear with regard to the terms that they use. One example is the distinction between being an ACO provider/supplier and being an ACO provider/supplier, ACO professional, or ACO participant. An “ACO participant” is defined as a provider or supplier. An ACO provider/supplier means either a provider or a supplier as those terms are defined generally for Medicare. A physician fits into the definition of supplier. An ACO professional is an ACO provider/supplier who is a physician or a PA, nurse practitioner, or clinical nurse specialist.

These distinctions get blurred in the regulations. As just one example, the distinction is blurred in the provisions relating to assignment of beneficiaries.<sup>3</sup> The general rule says that beneficiaries are assigned to an ACO based on primary care services provided by an ACO provider/supplier. That statement might lead one to believe that a physician (supplier) may be able to contractually associate with an ACO without being a participant and have his patients be assigned to the ACO so that he could share in any savings, perhaps to a lesser extent than an ACO participant if, in fact, a participant really means a provider/supplier who may have put money into the start-up and operations of the ACO.

In the next section, which specifies the assignment methodology, however, the ACO must identify all primary care physicians who are participants. At the end of each performance year, the ACO is to determine all beneficiaries who received services from “primary care physicians in the ACO” who were identified as participants by the ACO. It is only a participant’s patients who can be assigned to the ACO. So, who is a participant?

### **4. Control of One’s Destiny**

If a physician looks at all of his/her options and decides to join either a hospital ACO or perhaps an ACO organized by an IPA or large physician group, the distribution of savings and the sharing of losses, if any, will be governed by the contractual arrangements within the ACO. This review of the documents must be thorough. As an example, it will be important to understand completely what the balance of power will be within the organization; how decisions regarding peer review will be made; how compliance or non-compliance with quality and efficiency protocols will be dealt with; what the due process review will be of adverse decisions; how the savings will be shared and how the losses will be allocated and paid; whether there are (or need to be) non-compete provisions in the documents; what the personal obligation may be for additional capital contributions or debt guarantees.

### **5. What an ACO Is and Is Not**

An ACO is only what CMS says that it is. A group which meets all of the requirements for certification by CMS is still only an ACO if CMS decides to certify that group as an ACO.

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<sup>3</sup> Section 425.6 of the proposed regulations.

There is now and there will be as time goes on, a whole host of entities which call themselves ACOs which may not be certified by CMS and which may not even participate in the Medicare or Medicaid programs. These ACOs will be engaging in business with the commercial payors and may even include commercial payors as part owners. These ACOs will adhere to quality performance measures, will endeavor to curtail costs through collaborative care, will decide how to distribute earnings to providers based on both quality measures and costs containment, and will be judged by their patients on both quality and cost. These entities will look and act like Medicare certified ACOs, although they may have less physician involvement in governance. The reason these entities are important is that, regardless of what happens to PPACA at the Supreme Court and regardless of what Congress may decide to de-fund or retract in subsequent legislation, these entities will shape care delivery and payment mechanisms for the foreseeable future. Physicians will need to decide where their place should be in ACOs no matter what happens to the Obama administration or to the Obama health care reform.

### **HOW TO BE CMS CERTIFIED AS AN ACO UNDER THE PROPOSED REGULATIONS**

Many physicians are considering establishing their own ACOs. This article looks at how CMS will certify ACOs and on what bases they will make their decisions.

In order to be certified, an ACO must:

1. Be a legal entity properly organized under state law;
2. Be one or a combination of the following, **SO LONG AS THEY HAVE A MECHANISM FOR SHARED GOVERNANCE**:
  - (a) A physician group (including MDs, DOs, Physician Assistants, Nurse Practitioners and/or Clinical Nurse Specialists—all referred to as “ACO Professionals”);
  - (b) A network of individual ACO Professionals;
  - (c) A partnership or joint venture organized between hospitals and ACO Professionals;
  - (d) A Hospital (defined in the Preamble as an acute care PPS hospital) which employs ACO Professionals;
  - (e) Providers or suppliers which are recognized under the Social Security Act that are not hospitals or ACO Professionals. The Preamble goes into great detail about which providers or suppliers might be eligible. This is a section which will likely require clarification because at the end of the discussion, CMS is not set on which entities should be included and is requesting comments from the industry. There is no suggestion that an insurer could form an ACO which would be eligible to participate in the Shared Savings Program;
  - (f) A critical access hospital (“CAH”) that can bill under Method II.

For Medicare purposes, a Provider is defined as a hospital, a CAH, a skilled nursing facility, a comprehensive outpatient rehabilitation facility, a home health agency, or a hospice that has in effect an agreement to participate in Medicare, or a clinic, a rehabilitation agency, or a public health agency that has in effect a similar agreement but only to furnish outpatient physical therapy or speech pathology services, or a community mental health center that has in effect a similar agreement but only to furnish partial hospitalization services. A supplier means a physician or other practitioner, or an entity other than a provider, that furnishes health care services under Medicare.

3. The shared system of governance MUST provide all ACO participants with an appropriate proportionate control over ACO decision-making.
4. Each participating entity upon which beneficiary assignment is dependent (the primary care physicians) must commit to a 3-year agreement to CMS to BE EXCLUSIVE TO ONE ACO. (42 C.F.R. § 425.5 (c)(2))

During the 3-year period, an ACO may remove but not add an ACO participant; but it may remove or add any of the ACO suppliers or providers that provide services to the ACO.

The ACO must certify to CMS that each of its providers and suppliers will be accountable for 3 years and will report on quality, cost and care to CMS for Medicare fee-for-service patients assigned to the ACO.

5. The ACO must make information on its accountability for quality, cost and care available to the public in a format determined by CMS.
6. An ACO with a primary service area (PSA) of greater than 50% must obtain an expedited review from the FTC and DOJ and submit, as part of its CMS application, a letter from the FTC and DOJ that they have no present intent to challenge the proposed ACO. An ACO with a PSA of greater than 30% but less than or equal to 50% may either obtain the review and letter required for ACOs with PSAs greater than 50% or it may abide by a list of conduct restrictions which reduce the likelihood of antitrust concern, or it may do nothing and remain subject to antitrust investigation if competitive concerns present.
7. The ACO will prepare and submit a Shared Savings Program application which will include information, including quality data, on which the shared savings payments (or shared losses—see below) will be calculated.
8. Any marketing materials must be approved by CMS prior to use.
9. The ACO participants must notify their patients that they are ACO participants. The notice must be approved by CMS prior to use.

10. The ACO legal structure must be sufficient to receive and distribute the shared savings; repay shared losses (more about that later); and establish and report provider compliance with the quality standards.
11. The ACO governing body:
  - (a) must be comprised of ACO participants (at least 75% of control of the governing body) AND Medicare beneficiary representatives served by the ACO;
  - (b) must have broad responsibility for the ACO's administrative and clinical operations;
  - (c) must be separate and unique to the ACO if the ACO is made up of multiple, independent entities;
  - (d) may be identical to the governing body if the ACO is comprised of a single entity which is financially and clinically integrated.
13. The ACO must elect whether it wants to be a Track 1 one-sided model or a Track 2 two-sided model. Track 1 is available for the first 2 years only. Thereafter, all ACOs will be Track 2. The essential difference is that Track 1 permits a new ACO to share only in savings during the initial 2 years. In the third year, Track 1 reverts to Track 2. In Track 2, the ACO participates in profits but it also participates in losses. The amount of losses will be calculated by determining the amount by which the ACO exceeds the minimum savings rate ("MSR") with a cap of 5% of its benchmark in year 1; 7.5% of its benchmark in year 2; and 10% of its benchmark in year 3. The ACO which elects immediate Track 2 will be eligible for a higher percentage (60% rather than 50%--see full discussion below) of any gains.

Under Track 2, the ACO will be subject to a 25% withhold to ensure repayment of losses AND the ACO must either obtain reinsurance, surety bonds, place funds in escrow, or establish a line of credit to insure repayment to Medicare of any losses.

14. ACO Leadership and Management Structure
  - (a) The chief executive officer must be able to influence or direct clinical practices as well as improve efficiency processes and outcomes.
  - (b) The clinical director must be a full-time senior level medical director.
  - (c) A physician-directed quality assurance and process improvement committee must establish internal performance standards for quality of care, cost effectiveness, and process and outcome improvements and enforce compliance by the participants with those standards. The ACO must be able to provide documentation to show that its plans can do all of the following:
    - (i) Promote evidence-based medicine;

- (ii) Promote beneficiary engagement, including Clinician and Group CAHPS surveys and shared medical decision making;
  - (iii) Internally report quality and cost metrics; and
  - (iv) Coordinate care, including processes to identify high risk individuals and multiple chronic condition patients to provide individualized care, including identifying community resources to address psychosocial needs.
- (d) Application documentation requirements, itemized at 42 C.F.R. § 425.2(b)(9), include organizational documents, participation agreements, employment contracts, operating policies and procedures.
- (e) The ACO must have a compliance plan complete with a compliance officer which may be coordinated with the compliance plans of the ACO participants.
15. The ACO must describe in its application how the shared savings will be distributed among participants.
16. The ACO must provide evidence that the primary care physicians in its ACO have a minimum of 5,000 Medicare beneficiaries for whom they are the primary physician care-givers. They need not have seen the patient a majority of the time (calculated by comparing allowed charges), but they must have seen each patient more than any other physician who saw that patient. These are the patients who are “assigned” to that ACO.

## **HOW AN ACO WORKS**

CMS will compute a per capita benchmark for the Medicare beneficiaries assigned to the ACO. The assigned beneficiaries are the minimum 5,000 Medicare patients who were already being seen most of the time by the primary care physicians who joined the ACO. The benchmark will be set using a 6-month claims run-out. The proposed regulations are a little vague on how that calculation will be made. They intend to “estimate a fixed benchmark that is adjusted for overall growth and beneficiary characteristics, including health status using prospective HCC adjustments.” The Preamble to the Proposed Regulations provide some proposed methods of calculation: the initial benchmark would be established based on claims which had been submitted for services provided to the ACO patients during the immediately preceding 3 years; those numbers would be trended forward using the national growth rate (not a flat dollar amount). The benchmarks will be calculated for both Part A and Part B and will be adjusted each year during the program using the claims data from patients who would have been assigned to the ACO during the immediately preceding 3 years. CMS has a mathematical adjustment methodology to minimize variations from catastrophically large claims.

The CMS benchmarks for Part A and B costs are used as a basis to establish health status indices for each year for the ACO. These indices are arrived at by CMS through comparisons with the national Medicare expenditure data compiled by the CMS Office of the Actuary. In performing these steps, CMS will not take

into account either savings or additional costs related to any of the HITECH value based purchasing demonstrations or programs.

For each year, CMS determines whether the average per capita Medicare expenditures, adjusted for beneficiary characteristics, is below the applicable benchmark. In order to qualify for shared savings, the ACO's average per capita expenditure must be below the benchmark by more than a MSR which CMS shall establish for the ACO. For example, if the ACO has the minimum 5,000 beneficiaries, the ACO's savings (i.e., the amount by which the actual per capita costs are less than the benchmark per capita costs) must exceed 3.9% in order to be eligible for any shared savings. Once the MSR has been exceeded, the ACO will participate in savings above 2% of its benchmark. An ACO electing Track 1 one-sided model treatment may be eligible for up to 50% of the shared savings. An ACO electing Track 2 two-sided model treatment may be eligible for up to 60% of the shared savings.

If an ACO has less than 10,000 assigned beneficiaries and it meets certain other criteria, one of which is an ACO made up entirely of physicians or physician groups, that ACO will share first dollar savings after they have exceeded the MSR. They will not be subject to the 2% net computation which is applicable to other ACOs.

The reason the shared savings are characterized as "up to" a percentage is that in addition to meeting the cost savings targets, the ACO must also have met the minimum quality performance standards (see below) and maintained its eligibility to participate in the program based on all of the other requirements, set out above.

The quality standards an ACO must meet will be established by CMS. Initially, the quality performance standard measures will be identified in 5 domains: (a) patient/care-giver experience; (b) care coordination; (c) patient safety; (d) preventive health; (e) at-risk population/frail elderly health. In the first year, CMS will measure quality simply on the basis of complete and accurate reporting. In subsequent years, CMS will establish performance benchmarks which must be met. The shared savings will be measured on an over-all performance score. Failure to meet the quality standards precludes sharing in any savings regardless of the amount of money saved.

CMS has proposed 65 quality measures which are spread over the 5 domains. The Preamble identifies the initial 65 quality measures in a chart which shows the measure title and description; the CMS Program, NQF Measure Number or Measure Steward for each measure; the method of data submission; and the measure type (e.g., patient experience of care; process or outcome). A performance score will be tabulated for each measure within a Domain. In the initial year, an ACO will be eligible for shared savings under both Tier 1 and Tier 2 so long as they have completed 100% complete and accurate reporting on all quality measures. CMS is requesting comments on establishing quality thresholds which must be met in each domain in order for an ACO to be eligible for sharing in the savings.

## **ADDITIONAL PROVISIONS OF THE PROPOSED ACO REGULATIONS**

In addition to the provisions discussed above, the Proposed ACO Regulations contain the bases on which an ACO may be terminated from the Shared Saving Program, which include avoiding at-risk beneficiaries, and due process for reconsideration of termination; use of electronic health records; monitoring

requirements; record maintenance and inspection obligations; data sharing between CMS and the ACOs; and public reporting and transparency. Of interest, public reporting requires disclosure of the ACO's quality performance standard scores; the shared savings or losses information; and the total proportion of shared savings that was distributed among ACO participants and the total proportion that was used to support quality performance and aims of better care.

### **WHY PHYSICIANS MIGHT STILL THINK AN ACO IS A GOOD IDEA**

CMS expects that 75 – 150 ACOs will be certified for participation in the Shared Savings Program. CMS estimates that on average it may cost up to \$1.75 million to start an ACO and operate it in its first year.

But an ACO can recoup those costs and take in considerably more money. That will happen if its outlays for the care of participating beneficiaries are well below its yearly spending target (while getting a good enough quality score).

The ACOs' allotted savings—referred to by CMS in the proposal as “bonuses”—will total \$800 million over 3 years, CMS estimates. Even with 150 participants, that could result in a per ACO 3-year “bonus” in excess of \$5.3 million.

That dollar amount reflects only the Medicare Shared Savings Program. It is likely that an ACO will also contract with commercial payors in similar programs which increase quality and reduce costs. In addition to the financial benefits, physicians and other health care providers will be focused on quality health care for all patients.

These are proposed regulations. CMS is accepting comments until May 29, 2011.

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## About Strasburger

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