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CMS Finally Speaks: The Accountable Care Organization (ACO) Proposed Regulations and What They Mean For Anesthesiologists

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Since the passage of the Affordable Care Act[1] and the establishment of the Medicare Shared Savings Program (the "Shared Savings Program"), ACOs have become the new hot topic.

Section 3022 of the Affordable Care Act provides that Medicare shall establish the Shared Savings Program and that healthcare providers and suppliers will participate in the Shared Savings Program through ACOs. According to CMS, "ACOs create incentives for healthcare providers to work together to treat an individual patient across care settings – including doctor's offices, hospitals, and long-term care facilities. The Shared Savings Program will reward ACOs that lower growth in healthcare costs while meeting performance standards on quality of care and putting patients first."[2]

If an ACO saves money by providing patients with efficient care, then the ACOs can share in a percentage of the savings with Medicare. However, should an ACO fail to provide efficient and cost-effective care, it may be required to pay money back to Medicare.[3]

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Accordingly, the Shared Savings Program and its ACOs are among the many examples of how the Affordable Care Act has embraced and advanced the popular notion of value-based purchasing. Through this change in payment methodology, the Centers for Medicare and Medicaid Services ("CMS") intends to achieve its three-part aim for the Shared Savings Program: (1) better care for individuals, (2) better health for populations, and (3) lower growth in expenditures.

For over a year, the healthcare community waited patiently for guidance on ACOs and, amidst all of the speculation as to what exactly ACOs will be, what they will do and how they will qualify for the Shared Savings Program, CMS issued its notice of proposed rulemaking with respect to the Shared Savings Program and ACOs on March 31, 2011 (the "Proposed Rule").

Although the Proposed Rule spans several pages and sets forth an abundance of detailed and mind-numbing requirements that ACOs will likely need to satisfy, those with a passion for healthcare policy and reform will find the document to be an interesting read as it sets forth a summary of the leading thoughts on these topics and a clear description of the philosophy upon which the Shared Savings Program has been built. Irrespective of whether you are a believer or a skeptic of the Affordable Care Act and its Shared Savings Program, this article provides you with a brief summary of certain key provisions of the Proposed Rule.

ELIGIBILITY AND GOVERNANCE

Although healthcare providers will be afforded substantial flexibility when structuring their ACOs, it is clear that

anesthesiologists desiring to participate in an ACO will need to do so in collaboration with others.

The Affordable Care Act provides that ACOs can take any of the following forms:

- Group practice arrangements comprised of ACO professionals (defined as physicians, physician assistants, nurse practitioners and clinical nurse specialists or practitioners);
- Networks of individual practices of ACO professionals;
- Partnerships or joint venture arrangements between hospitals and ACO professionals;
- Hospitals employing ACO professionals; and
- Such other groups of providers of services and suppliers as the Secretary determines appropriate.

Under the Proposed Rule, the Secretary utilized her discretion to also include critical access hospitals (CAHs) using certain Medicare billing procedures that provide the data elements necessary for an ACO to operate.

Each ACO will need to be a separate legal entity recognized under state law as a corporation, partnership, limited liability company, foundation or any other legal entity permissible under state law. CMS proposes that existing legal entities meeting the ACO eligibility requirements (e.g., hospitals employing ACO professionals) may operate as ACOs without having to form a separate legal entity; however, whether this offers any additional practical option for such entities is debatable. ACOs must have their own tax identification numbers (TINs), but need not be enrolled in Medicare (in contrast to the ACO participant, which must be enrolled in Medicare).

Irrespective of the type of business entity chosen, all ACOs must be governed in a manner that provides ACO participants with appropriate control over the ACO's decision making process (which is often referred to as "shared governance"). CMS proposes that ACOs must have governing boards (e.g., board of directors, board of managers, etc.). In an effort to ensure ACOs are provider-driven, 75% of the governing body's control would need to be in the hands of the ACO participants, which leaves up to 25% of the governing body's control to Medicare beneficiaries served by the ACO, non-providers and others. ACO participants would be able to achieve the integration necessary for shared governance through a variety of structures, including those that fall short of a merger.

Furthermore, the Affordable Care Act mandates that the leadership and management structure of each ACO include clinical and administrative systems. CMS expands upon this

[1] The "Affordable Care Act" refers to the Federal Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by the Federal Healthcare and Education Reconciliation Act of 2010 (Pub. L. 111-152).
[2] CMS Medicare Fact Sheet: Improving Quality of Care for Medicare Patients: Accountable Care Organizations.
[3] CMS Medicare Fact Sheet: What Providers Need to Know: Accountable Care Organizations.

requirement in the Proposed Rule by recommending that ACOs meet the following criteria:

- The ACO's operations would be managed by an executive officer, manager, or general partner, who can be appointed and removed by the governing body and whose leadership team can influence or direct clinical practice to improve efficiency processes and outcomes.
- The ACO's clinical management and oversight would be managed by a senior-level, board-certified medical director. The medical director would be licensed in the State in which the ACO operates, and would be physically present in that State.
- The ACO participants and ACO providers and suppliers would have a "meaningful" commitment (e.g., financial investment, human investment, etc.) to the ACO's clinical integration to ensure potential success.
- The ACO would have a physician-directed committee that oversees an ongoing quality assurance and improvement program. The quality assurance and improvement program would establish performance standards for quality of care and services, cost effectiveness, and process and outcome improvements, as well as establish procedures identifying compliance with the standards. The quality assurance and process improvement committee would hold ACO providers and suppliers accountable for meeting those standards.
- The ACO would develop and implement evidence-based medical practice or clinical guidelines and processes for delivering care to achieve CMS' three-part aim for ACOs, which is described further above.
- The ACO would have a collaborative infrastructure enabling the ACO to collect, evaluate and provide feedback on patient data to ACO providers and suppliers.

Reaching Critical Mass

The Shared Savings Program will require each of its ACOs to be assigned at least five thousand (5,000) Medicare fee-for-service beneficiaries. When considering this requirement, it is important to understand that Medicare beneficiaries (including those assigned to an ACO) will retain their freedom of choice under the Medicare program (i.e., Medicare beneficiaries assigned to an ACO may continue to obtain healthcare from outside of such ACO). For this reason and others, it is possible that an ACO will fall below the minimum number of Medicare fee-for-service beneficiaries just described.

In the instance that an ACO's assigned population drops below 5,000 beneficiaries, CMS proposes to place the ACO on a corrective action plan for the performance year during which it was issued. If the ACO fails to meet the 5,000 beneficiary mark by the end of the following performance year, it will be terminated from the Shared Savings Program and will lose any shared savings earned in that year.

CMS notes that while an ACO may incorporate a number of specialties, for purposes of assigning beneficiaries to an ACO, CMS will only take into account a beneficiary's utilization of primary care services (i.e., services rendered by general practice, internal medicine, family practice and geriatric medicine physicians). CMS established the following methodology for assigning beneficiaries to an ACO:

1. CMS will identify all primary care physicians who were ACO participants during the performance year;
2. At the conclusion of each performance year, CMS will determine all of the beneficiaries who received services from primary care physicians in the ACO;
3. CMS will determine the total allowed charges for the primary care services that each beneficiary identified received from any provider or supplier during the performance year;
4. Find the sum of the allowed charges for primary care services provided by the primary care physicians in each ACO; and
5. Assign a beneficiary to an ACO if the beneficiary received a plurality of his or her primary care services from primary care physicians who are ACO participants.

In other words, CMS will determine the ACOs from which a beneficiary obtains his/her primary care services. CMS will then assign the beneficiary to the ACO in which the beneficiary obtained a majority of his/her primary care services.

Since assignment of patients to an ACO is based upon the primary care physicians participating in the ACO, it is anticipated that, as a practical matter, primary care physicians (as opposed to specialists such as anesthesiologists) will have the most influence within the their respective ACOs.

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Putting Patients (And The Quality Of Their Care) First

As referenced above, the Shared Savings Program hopes to elicit a renewed focus on patients. The Proposed Rule is overflowing with references to the concept of "patient-centered" care, which CMS defines as "care that incorporates the values…of transparency, individualization, recognition, respect, dignity, and choice in all matters, without exception, related to one's person, circumstances, and relationships in healthcare." To this end, the Proposed Rule would require an ACO to provide CMS in its application to participate in the Shared Savings Program with documentation regarding its plans to do each of the following:

1. Promote evidence-based medicine (i.e., describing the evidence-based guidelines it anticipates establishing and implementing);
2. Promote beneficiary engagement (i.e., patient education);
3. Report internally on quality and cost metrics (i.e., describing the process and how the ACO intends to use it and respond to patient needs); and
4. Coordinate care, which involves strategies to promote and improve integration and consistency of care.

Furthermore, the Proposed Rule set forth numerous requirements designed to achieve these high aims. To promote the goal of improving health for individuals and populations, CMS proposes the following aspects of the Shared Savings Program: (1) a beneficiary experience of care survey; (2) patient involvement in governance; (3) evaluation of population health needs and consideration of diversity; (4) implementation of individualized care plans and integration of community resources; (5) numerous quality measures assessing the quality of care an ACO furnished, which will be deemed to have been met if the ACO reported quality measures and met the applicable performance criteria for each of its three performance years; (6) requirements for ACOs to submit data on quality measures via CMS-specified data collection tools and survey tools; (7) requirements for an ACO's public reporting of the following information: name, location, primary contact, organizational information, shared savings information, and quality performance standard scores; and (8) rewards for those ACOs achieving better performance (up to 60% of the total savings generated by the ACO, depending on the ACO's risk model, discussed below).

CMS proposes to monitor ACO performance by analyzing specific financial and quality data, performing site visits, assessing and following up investigations of beneficiary and provider complaints and performing audits. CMS also proposes to terminate ACOs based on its monitoring efforts. Prior to termination, however, CMS proposes it take any or all of the following actions: (1) providing the ACO a warning notice of the specific performance at issue; (2) requesting a corrective action plan from the ACO; and (3) placing the ACO on a special monitoring plan. In order to monitor the ACO, CMS proposes that ACOs, their participants, ACO providers and suppliers, and contracted entities performing services on behalf of the ACO be obligated to give the government the right to inspect all books, contracts, records, documents and other evidence sufficient to enable CMS to audit, evaluate and inspect the ACO's compliance with the program requirements.

Maintaining, Organizing and Sharing Information

Efficiently and effectively sharing information will be key to the success of any ACO. As a condition of receiving Medicare shared savings payments, ACOs will need to submit information to the Secretary of HHS that is necessary to determine the quality of care furnished by the ACO. Each ACO will need to have the information technology and other electronic health record infrastructure in place to maintain, share, retrieve, and report meaningful and usable data. This requirement dovetails with the measures and incentives for the "meaningful use" of certified electronic health records technology under the Health Information and Technology for Economic and Clinical Health Act of 2009 ("HITECH").

Not only will Medicare beneficiary data flow from the ACOs to CMS, but it will also flow from CMS to the ACOs. In order to provide ACOs with a more complete understanding of the services rendered to their assigned beneficiaries, CMS proposes that ACOs have an opportunity to request beneficiary identifiable claims data on a monthly basis in the form of a standardized data set, which will identify the services and supplies the beneficiaries

receive during the performance year, both within and outside of the ACO. CMS proposes requiring each ACO requesting such information to enter into a Data Use Agreement prior to receiving any claims data, which will prohibit the ACO from sharing the claims data with anyone outside of the ACO. Further, to participate in receipt of claims data, the beneficiaries must have the opportunity to opt out of the claims data sharing.

Further, even prior to participating in an ACO, anesthesiologists and others who desire to participate in an ACO need to acquire a solid understanding of their own financial data and performance. In order to prepare for participation through ACOs in the Shared Savings Program, it is advisable for physician groups to strengthen their own knowledge in this regard by entering discussions with their financial advisors and billing service providers to obtain the information they need to determine whether participation in an ACO under the Shared Savings Program is desirable and, if so, to maximize the benefits they receive from ACO participation.

Shared Savings Determination

Those healthcare providers and suppliers that participate in the Shared Savings Program through ACOs will receive not only traditional Medicare fee-for-service payments under Parts A and B but may also be eligible to share in available savings. To determine and share savings, CMS will establish (1) an expenditure benchmark; (2) a comparison of the benchmark to the assigned beneficiary per capita Medicare expenditures in each performance year to determine any savings; (3) the minimum savings rate, which is the percentage that expenditures must be below to account for normal expenditure variation; and (4) a sharing cap, which is the limit on the total amount of shared savings that an ACO may be paid. The Affordable Care Act provides that an ACO's eligibility for shared savings depends on the ACO's ability to keep its average per capita Medicare expenditures below the applicable benchmark. Because the Affordable Care Act does not provide for a method by which to distribute the shared savings to an ACO, CMS proposes the shared savings be paid to the ACO directly and that ACOs be required to submit their criteria for distribution of the savings with their application to participate in the Shared Savings Program (described further below).

Payment of shared savings also depends on the amount of risk an ACO assumes. The Affordable Care Act itself does not require ACOs to take on risk but the Secretary has proposed using her discretion to require ACOs to do so (at least eventually) under the Proposed Rule. Although this approach is not surprising, many contend that it is a deterrent for participation in the Shared Savings Program.

The Proposed Rule offers incentives and disincentives to those ACOs participating in the Shared Savings Program through two modes: (1) the one-sided risk model, and (2) the two-sided risk model.

- ***One-Sided Risk Model.*** The one-sided risk model has limited downside risk and, as a result, it will be a viable option for smaller and less experienced groups. CMS proposes, under this model, an ACO would share savings in the first two years of the three-year agreement and would not be responsible for any portion of the losses above the expenditure target. During the third year of the agreement, CMS proposes to establish an automatic transition of the ACO into an "alternative two-sided payment model" in which an ACO would be required to share in any losses *and* savings generated during that year. Under the Proposed Rule, election to participate in the one-sided risk model would only be an option for an ACO's initial period for participation in the Shared Savings Program. Those ACOs participating in the Shared Savings Program after the initial agreement period would automatically participate in the two-sided risk model thereafter. In other words, an ACO may only participate in the one-sided risk model for the first two years of its initial agreement with CMS.

- ***Two-Sided Risk Model.*** For those more experienced ACOs willing to take a greater risk, CMS proposes to allow them to choose the two-sided risk model upon entry into the Shared Savings Program. ACOs choosing this model will participate in the two-sided risk model for all three years of the ACO's agreement period with CMS and would be eligible for higher sharing rates than would otherwise be available under the one-sided risk sharing model.

CMS desires to impose a limit on how much an ACO may earn from the Shared Savings Program. CMS intends to impose a limit of 7.5% of an ACO's benchmark during the first two years of an ACO selecting the one-sided model, and a limit of 10% of an ACO's benchmark in the third year of an ACO under the one-sided model and during each year of an ACO under the two-sided model.

To protect the Medicare program against losses and to ensure an ACO has a

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mechanism by which to repay any losses, CMS proposes to withhold 25% of any earned performance payment. An ACO has the option of withholding more if its losses exceed the 25% automatically withheld. Further, if an ACO terminates its agreement, the ACO would be subject to a 25% withhold of shared savings to offset future losses under the two-sided risk model (described below). However, at the end of each agreement period, any ACO with a positive balance will have its monies returned to it.

The Application for and Termination of Participation

ACOs will not be automatically accepted into the Shared Savings Program. To be eligible to participate in the Shared Savings Program, providers and suppliers must form or join an ACO and submit an application to CMS, which will include specific and detailed plans for fulfilling the requirements summarized throughout this article. Further, it should be noted that existing ACOs are not automatically qualified for the Shared Savings Program and must also submit an application to CMS. Approved ACOs will be eligible to participate in the Shared Savings Program beginning January 1, 2012; however, CMS still has not solidified a date on which it will begin accepting applications from ACOs.

In their applications, CMS proposes ACOs disclose whether they have participated in the Shared Savings Program in the past. If the ACO was terminated from the program, the ACO must identify the cause of its termination and the safeguards it has employed since its termination to enable the ACO to participate for the full three-year agreement. CMS proposes to deny participation to those ACOs that were terminated due to their underperformance.

Moreover, CMS also proposes that an ACO executive, with authority to bind the ACO, be required to certify, in both the ACO's application and its agreement to participate in the Shared Savings Program, that "the ACO's participants are willing to become accountable for, and to report…on, the quality, cost, and overall care of the Medicare FFS beneficiaries assigned to the ACO."

The Affordable Care Act requires each ACO accepted into the Shared Savings Program enter into an agreement with CMS for not less than three years. Accordingly, CMS proposes requiring ACOs to enter into a three-year participation agreement with CMS.

In the instance the ACO makes a "significant" change (e.g., an ACO reorganizes its structure by excluding ACO participants or by adding or excluding ACO providers and/or suppliers, an ACO deviates from its approved application, etc.), the ACO must notify CMS within 30 days of the significant change so CMS may reevaluate the ACO's eligibility to continue participation in the Shared Savings Program.

CMS may terminate an ACO from the Shared Savings Program prior to the conclusion of the agreement period for a number of reasons (e.g., avoiding at-risk beneficiaries, failing to effectuate regulatory changes during the agreement period after being given an opportunity for a corrective action plan, failure to comply with reporting requirements, etc.). Any ACO would be permitted to terminate its Shared Savings Program agreement with CMS upon 60 days prior notice but such termination would result in forfeiture of its mandatory 25% withhold of shared savings.

The Affordable Care Act provides for a number actions pertaining to the Shared Savings Program for which there shall be no administrative or judicial review. For all other actions (e.g., denial of an ACO application or termination of an ACO agreement, in certain cases), an ACO, upon written request within 15 days of the adverse initial determination, may request a review by a CMS reconsideration official. If the ACO is unhappy with the CMS reconsideration official's decision, it may submit an explanation as to why it disagrees with the recommendation and it may request a record review of the initial determination and the recommendation of reconsideration by an independent CMS official.

To ensure continuity of ACOs while also implementing standards to improve the program, CMS proposes adopting changes to the Shared Savings Program in the future and thus subjecting ACOs to new program standards, with the exception of the following areas: (a) eligibility requirements concerning the structure and governance of ACOs; (b) calculating the sharing rate; and (c) assigning beneficiaries.

Operation of ACOs Under Applicable Law

In order to achieve the clinical and administrative coordination and sharing of information that will be necessary to the success of ACOs, physicians, hospitals, and other professionals will need to integrate, but within the constraints of applicable law, including without limitation the Federal Anti-Kickback, Stark, and Civil Monetary Penalty Laws, Federal tax exempt laws and Federal and state privacy laws, Federal antitrust laws, state insurance laws and state corporate practice of medicine doctrines.

In furtherance of CMS' efforts to prevent abuses of the federal healthcare programs, the Proposed Rule imposes numerous compliance-related requirements upon ACOs including requiring the following of each ACO: (1) a compliance plan; (2) certification of compliance with program requirements by someone legally authorized to bind the ACO; (3) a conflict of interest policy for members of the governing body; (4) screening the ACO during the application process; and (5) prohibiting certain referrals and cost shifting.

However, consistent with the foregoing, the Affordable Care Act also calls upon the Federal government to consider modifications to existing regulations that achieve that delicate balance between allowing ACOs and the Shared Savings Program to thrive while also protecting against abuses of the Medicare program under the guise of legitimate ACO activities. Accordingly, concurrent with the release of the Proposed Rule, the Federal government has issued three additional guidance documents focusing on specific aspects of the Shared Savings Program:

1. A joint CMS and HHS Office of Inspector General (OIG) Medicare Program notice and solicitation for comments titled Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center (CMS/OIG Waiver Design Guidance);[4]
2. A Federal Trade Commission (FTC) and Department of Justice (DOJ) (collectively, the Antitrust Agencies) document titled A Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program (the FTC/DOJ Proposed Antitrust Policy Statement);[5] and
3. An Internal Revenue Service (IRS) notice soliciting comments regarding the need for additional tax guidance for tax-exempt organizations (the IRS Notice).[6]

Conclusion

Anesthesiologists and the greater healthcare community are searching for answers. How can they be involved in the Shared Savings Program? What does it mean to participate in an ACO? How will such opportunities improve (or preserve) their bottom-line?

While much remains uncertain, anesthesiologists can be sure that Medicare payment methodologies will inevitably change. During this time of transition, anesthesiologists and anesthesia groups must actively engage the leadership of their hospitals and ASCs, and others in positions of power, to ensure anesthesia is not forgotten during this intense time of expansion and reform. Furthermore, anesthesiologists should remain attentive to Shared Savings Program developments and strategies by reaching out to their professional organizations (such as the American Society of Anesthesiologists) and legal advisors. It is also advisable to maintain as much flexibility as possible until the Federal government issues further guidance. Anesthesiologists should remember that the Proposed Rule is just that — a proposal — and while this article focuses on the Proposed Rule, all anesthesiologists should be attentive to CMS' Final Rule, which will be available later this year. However, if consistent with CMS' historical practice, the Final Rule will not stray far from the Proposed Rule discussed in this article.

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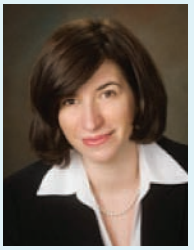

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[4] The CMS/OIG Waiver Design Guidance may be found at http://www.ofr.gov/OFRUpload/OFRData/2011-07884_PI.pdf.
[5] The FTC/DOJ Proposed Antitrust Policy Statement may be found at http://www.ftc.gov/os/fedreg/2011/03/110331acofrn.pdf.
[6] The IRS Notice may be found at http://www.irs.gov/pub/irs-drop/n-11-20.pdf