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December 3, 2010

Donald M. Berwick, M.D. Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services Room 445-G, Hubert H. Humphrey Building 200 Independence Avenue, SW Washington, DC 20201

Re: Medicare Program; Request for Information Regarding Accountable Care Organizations and the Medicare Shared Savings Program; 75 *Fed. Reg. 70,165* (November 17, 2010); CMS-1345-NC.

Dear Dr. Berwick:

The American Society of Anesthesiologists (ASA), an educational, research and scientific association representing over 45,000 members, appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) Request for Information regarding accountable care organizations (ACOs) and the Medicare Shared Savings Program. We urge CMS to incorporate the following responses as it proceeds with the rulemaking process for ACOs and the Medicare Shared Saving Program.

1. What policies or standards should we consider adopting to ensure that groups of solo and small practice providers have the opportunity to actively participate in the Medicare Shared Savings Program and the ACO models tested by the Center for Medicare and Medicaid Innovation (CMMI)?

ASA urges CMS to consider the following in order to ensure participation of solo and small practice providers in the ACO and Medicare Shared Savings Program models:

- Create explicit safe harbors from antitrust enforcement and waivers of the Civil Monetary Penalty statute, the Anti-Kickback statute, and the Ethics in Patient Referrals (Stark) statute so that small anesthesia practices can work with each other and collaborate with hospitals and other providers to deliver coordinated care for both Medicare beneficiaries and commercially-insured patients.
- Ease the administrative burden by limiting any requirements for the structure or internal systems of ACOs to items where there is clear evidence that high-quality, affordable care *cannot* be provided without such structures or systems. For example, purchasing and maintaining electronic health record systems is very expensive, particularly for small physician practices. While having such systems is *desirable*, there

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is no evidence that they are *essential* for physician practices to successfully coordinate care and manage costs. Indeed, there are many examples where physician practices deliver high quality, affordable, coordinated care without such systems, and there is evidence showing that implementation of such systems can have negative impacts on the quality and cost of care, particularly during implementation phases. Consequently, making acquisition and implementation of such systems a condition for being designated an ACO would be inappropriate.

- Take into account the difficulty of outcomes assessment for solo and small practices. Due to our leadership in patient safety, adverse outcomes in anesthesiology care are very rare; thus smaller anesthesia practices may have insufficient case volumes to support accurate risk-adjusted outcomes reporting. The design of an ACO and the Medicare Shared Savings Program should consider these realities during its rulemaking process.
- Provide timely, detailed data to physician practices to enable them to identify opportunities to make improvements in cost and quality and to successfully implement them. These data need to (a) include information on all services received by patients who have been treated by a physician in the practice during the previous year; (b) be provided in a format that allows detailed analysis and simulation of the potential impact of changes in care delivery on costs; and (c) be delivered to practices at least 6 months in advance of when applications to serve as an ACO are to be submitted to CMS, and on a monthly basis after they begin functioning as an ACO.
- 2. Many small practices may have limited access to capital or other resources to fund efforts from which "shared savings" could be generated. What payment models, financing mechanisms or other systems might we consider, either for the Shared Savings Program or as models under CMMI to address this issue? In addition to payment models, what other mechanisms could be created to provide access to capital?

ASA urges CMS to support small, rural anesthesia practices by providing similar incentives as those offered to other providers that practice in rural areas. Section 5501 of the Patient Protection and Affordable Care Act (PPACA) creates a 10 percent incentive payment increase for primary care physicians (family medicine, internal medicine, geriatric medicine and pediatric medicine), primary care mid-level providers, and general surgeons practicing in health professional shortage areas (HPSAs). No such incentive is provided for anesthesiologists practicing in HPSAs despite our critical role in surgery and perioperative care. Further, Section 5503 of PPACA addresses additional residency positions in rural areas for primary care physicians and surgeons but not for anesthesiologists. There are also rural physician training grants for medical colleges, increased graduate medical education funding, and increase in funding for loan repayments for primary care providers and general surgeons practicing in rural areas. Finally, Medicare Part A funds are provided for Certified Registered Nurse Anesthetists (CRNAs) but not for anesthesiologists. ASA urges CMS to include anesthesiologists in incentive programs to ensure adequate access to capital.

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In addition, creating loan, loan guarantee, and technical assistance programs will help small anesthesia practices make the investments needed to become ACOs. Many small physician practices and newly formed IPAs will require appropriate financing in order to make the upfront investments needed. Commercial lenders are unlikely to respond quickly or favorably to requests by ACOs for loans or lines of credit given the complexity of healthcare payments and the radical change that ACO payment systems represent. CMS could take several actions to increase the ability of small physician practices to obtain financing they need to become ACOs or to participate successfully in partnerships with other providers to form ACOs:

- Educate banks and other commercial lenders about the ways that physician practices participating in ACOs will have access to new revenue streams that can be used to repay loans.
- **Create a loan guarantee program**, similar to the Small Business Administration's successful 7(a) program for small businesses, which would enable small physician practices and IPAs to more easily obtain financing from commercial lenders.
- Make grants to non-profit community organizations, such as Regional Health Improvement Collaboratives, to provide grants, loans, and technical assistance to help small physician practices and IPAs form ACOs, particularly in communities where market conditions warrant special assistance. This program could be operated in collaboration with the Health Information Technology Extension Center (HITECH) program established under the HITECH Act.
- **3.** The process of attributing beneficiaries to an ACO is important to ensure that expenditures, as well as any savings achieved by the ACO, are appropriately calculated and that quality performance is accurately measured. Having a seamless attribution process will also help ACO's focus their efforts to deliver better care and promote better health. Some argue it is necessary to attribute beneficiaries before the start of a performance period, so the ACO can target care coordination strategies to those beneficiaries whose cost and quality information will be used to assess the ACO's performance; others argue the attribution should occur at the end of the performance period to ensure the ACO is held accountable for care provided to beneficiaries who are assigned to it based upon services they receive from the ACO during the performance period. How should we balance these two points of view in developing the patient attribution models for the Medicare Shared Savings Program and ACO models tested by CMMI?

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ASA firmly believes that anesthesiologists should receive attribution for any patients for whom they provide perioperative management of care, including pre-operative assessment or post operative management, such as pain management or ICU care. In addition, anesthesiologists should receive attribution of beneficiaries while applying Cost Utility Analysis (CUA) pre-operative evaluation tools based on Health Related Quality of Life (HRQoL) or Quality Adjusted Life Years (QALY) to prescreen patients to determine if they meet criteria for surgery. ASA believes that anesthesiologists are in a unique position, especially in rural areas, to apply CUA tools to assess the physical status of a patient to determine if the patient meets the new criteria (yet to be determined) for surgery. Therefore, ASA urges CMS to provide attribution of those beneficiaries to anesthesiologists for whom they provide essential perioperative care management.

More broadly, the core of any successful effort to reduce costs and improve quality in health care is a strong patient-physician relationship. This, in turn, is founded in a voluntary choice by both the patient and physician to begin and maintain that relationship. CMS should seek to encourage and reinforce such voluntary relationships between Medicare beneficiaries and physicians, not weaken them or create substitutes for them.

Retrospective attribution is particularly problematic, since neither the patient nor the physician knows that CMS is assigning accountability to the physician for the costs of all of the patient's care until after the care has already been delivered. Use of retrospective attribution could create an undesirable incentive for ACOs to avoid providing primary care services to new Medicare patients, since a single visit could result in all of the beneficiary's healthcare costs being attributed to the ACO.

Without active patient support and participation, the ability of physicians to help patients improve their health, avoid unnecessary hospitalizations, and reduce the use of unnecessary and duplicative services is inherently limited. If a Medicare beneficiary is unwilling or unable to participate in efforts to better coordinate and manage their care, then an ACO should not be held accountable for the overall costs of services associated with a beneficiary simply because a physician in that ACO provided the beneficiary with a needed primary care service (and as a result had the beneficiary "attributed" to the ACO). Conversely, if a beneficiary and a physician mutually agree to work together to provide high-quality care for the beneficiary's most critical needs, the ACO with which the physician is associated should not have any savings resulting from that care attributed to other providers based on an arbitrary statistical rule.

Consequently, CMS should seek to maximize the extent to which an ACO is held accountable only for those patients who voluntarily choose its physicians to provide or manage their care, and it should seek to minimize or eliminate the use of statistical attribution methodologies, particularly retrospective attribution after care has already been delivered. At a minimum, CMS should create one payment option as part of the Donald M. Berwick, M.D. December 3, 2010 Page 5 of 8

regulations under the Shared Savings Program that allows beneficiaries to elect participation in an ACO and makes ACO-related payments based only on the beneficiaries who make that election. Finally, ASA urges CMS to move away from a claims-based or statistical-based attribution, as claims-based data lack the specificity to describe the patient relationship to the ACO.

4. How should we assess beneficiary and caregiver experience of care as part of our assessment of ACO performance?

While ASA believes that beneficiary and caregiver experience measurement will be challenging, there are key principles that should be part of this assessment. There should be a common, validated instrument across all ACOs to allow comparison, prospective collection of data, and measurement in temporal proximity to an interaction, an event or an episode. A standard instrument and a standard method of patient data acquisition should be developed to incorporate events that are specific to anesthesia care, including patient-centered measures. ASA recommends that performance measures for anesthesiologists focus on improving safety and coordinating perioperative care. The following can be used to direct measure development: patient surgeries accomplished safely, surgeries accomplished under anesthesiologists' direction, and perioperative care that includes evaluations from anesthesiologists and following of anesthetic plans

Further, until the relationship between patient satisfaction and other outcomes is better understood, data collected on patient satisfaction is best used by physicians and health care organizations to identify opportunities for responding to patient needs. Because of the difficulty in determining whether responses to patient satisfaction surveys are a result of physician performance, health insurer demands or restrictions, or other factors outside a physician's control, the use of patient satisfaction data is not appropriate for public reporting or financial incentive programs. Moreover, until collection methods associated with patient experience information are uniform and validated, such information should not be used to assess ACO performance.

Specific to anesthesiology, patient satisfaction measures have been difficult to validate for patient-physician encounters that involve care in a traditional operating room environment. By its nature, the delivery of anesthesia care in this setting often results in patient amnesia. A number of instruments designed to measure patient satisfaction have not been able yet to overcome the impact of amnesia during anesthesia care. The specialty is working closely with the American Board of Medical Specialties to find creative measurement tools for this unique, but very real, consequence of anesthesiology.

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5. The Affordable Care Act requires us to develop patient-centeredness criteria for assessment of ACOs participating in the Medicare Shared Savings Program. What aspects of patient-centeredness are particularly important for us to consider and how should we evaluate them?

ASA believes that anesthesiologists can best participate in patient-centeredness by uniquely applying Cost Utility Analysis (CUA) tools to assess the physical status of a patient to determine if the patient meets the new criteria (yet to be determined) for surgery. Consequently, scoring criteria should be created to help guide patients and their families to decide if conservative therapy or a more invasive surgical procedure is best for the individual patient. This would help in determining whether the patient's experience was improved and whether an uncomfortable hospital stay was avoided through a meaningful patient-provider interaction.

CMS can further play a critical role in promoting patient-centeredness by appropriately structuring the payment systems and requirements for ACOs. In particular:

- An ACO needs to know who its patients are and have each patient actively working with the ACO to successfully manage his or her care. Consequently, allowing patients to select ACOs rather than using statistical attribution methods, and encouraging patients to work proactively with their physicians and other providers, as described in more detail in Section 3, will provide the foundation for more patient-centered care.
- Physicians need the flexibility to customize care for a particular patient in a way that works effectively for that patient (i.e., care that is patient-centered), rather than being forced to provide a particular type of care simply because it is covered under Medicare. For example, a physician should be paid for discussing issues with a patient via a phone call, email, or other media if that interaction will provide more timely, effective and patient-centered assistance than an office visit. CMS should make appropriate changes to the fee-for-service system so that physicians can be paid upfront for currently unreimbursed and under-reimbursed services that will improve care for patients and save money for the Medicare program.
- Physicians should not be penalized for accepting unusually sick patients into their care or customizing patients' care to meet their unique needs. Consequently, effective risk adjustment methodologies and risk limits must be included as part of any payment models implemented.

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6. In order for an ACO to share in savings under the Medicare Shared Savings Program, it must meet a quality performance standard determined by the Secretary. What quality measures should the Secretary use to determine performance in the Shared Savings Program?

At least in the initial years of the ACO program, CMS should avoid requiring ACOs to collect and report quality measures beyond those that are already being required under other CMS programs, such as the Physician Quality Reporting System (PQRS), formerly the PQRI. Although the PQRS and the hospital quality reporting set are imperfect, they are widely used and will provide important historical data for comparison.

Although additional quality measures may ultimately be warranted, it is impractical to develop a single national set of such measures prior to implementation of the Shared Savings Program, because the areas where ACOs will focus their cost reductions will likely vary significantly from region to region, and measures that may be appropriate for one ACO model may not be appropriate for another. ACOs should be allowed to report on a hybrid of nationally and locally focused quality measures related to their particular patient populations. At this early stage, when there is so much we do not yet know about ACOs, we believe that a one-size-fits-all approach would be a mistake and would limit innovation.

Additional resources and time are necessary to gather an evidence base, assess methodologies for risk-adjustment, and test the measures for feasibility and reliability prior to broad based implementation across health care settings.

7. What additional payment models should CMS consider in addition to the model laid out in Section 1899(d), either under the authority provided in 1899(i) or the authority under the CMMI? What are the relative advantages and disadvantages of any such alternative payment models?

ASA strongly promotes the concept of a coordinated perioperative or surgical home model in order to achieve better value for beneficiaries through care coordination led by anesthesiologists. This model would be the counterpart to the medical home model and would be particularly effective in managing health care expenses. Approximately 60-70% of a traditional hospital's expenses are associated with surgical and procedural (perioperative) care. The opportunity to reduce overall health care costs through improved coordination of surgical and procedural care is arguably better than the opportunity to reduce those care costs through a medical home model.

Anesthesiologists routinely interact with providers from different care settings and, thus, can effectively assess and manage risk across the full continuum of the perioperative setting. Anesthesiologists can and do partner with hospitals, proceduralists, and surgeons in determining cost-effective implants and pharmaceuticals to provide better quality of care at a

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lower cost. In addition, anesthesiologists can and do serve as physician managers and coordinators of operating and procedure room in terms of evaluating patients for potential appropriateness of proposed surgeries or other procedures. Those patients that elect to have less expensive conservative therapy after education, or who do not meet the new evidence-based Cost Utility Analysis (CUA) criteria, would create the shared savings for anesthesiologists. Additional shared savings would be derived from decreased tests and consults through pre-operative evaluations performed by Pre-Anesthesia Testing (PAT) clinics instead of hospitalists as well as reduced hospital length of stay and decreased hospital readmissions arising from 1) selection of appropriate candidates for surgery, and exclusion of those who will not benefit, 2) reduction of complications such as postoperative nausea and vomiting that increase length of stay or necessitate admission following outpatient surgery, and 3) improved perioperative management of pain and anxiety.

ASA believes that a medical home is primarily responsible for chronic care management while a perioperative or surgical home is responsible for management of anesthetic and sedation-based surgeries and procedures. Consequently, in order to ensure participation of anesthesiologists in ACOs, payment methodologies should emphasize anesthesiologists' involvement with and control over perioperative care management as opposed to chronic disease management.

ASA appreciates the opportunity to submit comments on CMS' Request for Information regarding ACOs and the Medicare Shared Savings Program. ASA believes that anesthesiologists are important care coordinators in the surgical setting and will be essential to achieving the goals of better quality of care at a lower cost. We look forward to working with CMS to implement this program to ensure anesthesiologists are able to participate in ACOs. Please do not hesitate to let us know if you have any questions.

Sincerely, Mark & Warne

Mark A. Warner, M.D. President American Society of Anesthesiologists