December 3, 2010

Donald Berwick, M.D.
Administrator
Centers for Medicare & 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 Administrator Berwick:

The undersigned organizations appreciate the opportunity to provide feedback on the Centers for Medicare & Medicaid Services' (CMS) request for information concerning Accountable Care Organizations (ACOs) and the Medicare Shared Savings Program. We strongly believe that a new delivery system must focus on promoting quality care, improving patient access, and, ultimately, provide cost-efficient care. We address some of the specific issues raised by CMS below.

What policies or standards should we consider adopting to ensure that groups of solo or 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)?

Surgical care is delivered in a variety of geographic locations and facility types, and policies should be put in place that recognize and reward physicians in all practice environments who demonstrate a proven commitment to the efficient delivery of high-quality care. We recognize that ACOs and other innovative payment models can help physicians to deliver more efficient and more effective care, but not all practices will be able to change their organizational structure and processes in order to participate in these new payment models. Small and rural surgical practices may have even less flexibility to make the necessary changes to be a successful ACO. Thus, ACOs must be completely voluntary and not penalize those physicians who cannot or choose not to participate.

We also believe it is critical to address legal concerns that might arise for those of our members who will provide care for their patients as part of an ACO. We are concerned that a general waiver of the rules on discretionary decisions to not pursue enforcement actions will not adequately protect providers of care within the context of the ACO. Accordingly, the Federal Trade Commission (FTC), CMS, and the Department of Health and Human Services Office of the Inspector General (OIG) must create explicit protections from the antitrust laws, the physician self-referral prohibition, the Federal

anti-kickback statute, and the civil monetary penalty law for physicians providing care in ACOs. These protections are necessary for all physicians providing care in the ACO context, but are especially relevant to small independent physician practices and rural providers.

CMS should limit 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. Making acquisition and implementation of something beyond such systems a condition for being designated an ACO would be inappropriate.

CMS should implement effective risk-adjustment methodologies and caps on the costs associated with individual patients so that ACOs are managing performance risk, not insurance risk. Any payment model that CMS implements should use an effective risk adjustment methodology so that ACOs are rewarded, not penalized, for accepting sick patients and for addressing their needs in the most effective way possible. But risk adjustment alone is not enough because some patients will have unique problems that require unusually expensive care not adequately captured by any risk adjustment methodology. Even a single patient of this nature could be financially devastating for a small physician practice, while having a relatively small impact on a large health system. Thus, in addition to appropriate risk adjustment methodologies, CMS should establish limits on an ACO's accountability for the total cost of services to any individual patient.

CMS should also provide timely and detailed feedback to physician practices to enable them to identify opportunities to make improvements in cost and quality and to successfully implement them.

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 ACOs 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?

The core of a successful effort to reduce cost and improve quality in health care is a strong patient-physician relationship. This, in turn, is based on a voluntary choice by

both the patient and the physician to begin and maintain that relationship. But any method for "attributing" patients to physicians puts CMS in a position of deciding which patients and physicians have a relationship, rather than that decision being made by the patients and physicians themselves. In addition, all attribution methodologies use inherently statistical rules that can create misclassifications.

Retrospective attribution is particularly problematic, since neither the patient nor the physician know 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. In a prospective model of enrollment, the ACO develops targets based on actuarial analysis and allows for all payers to agree upon such targets. We are unclear how this target is to be assured appropriate in the case of retrospective attribution to an ACO. It is also uncertain how an ACO would be able to track its performance quarterly of it does not know who are the enrolled beneficiaries, and where the ACO should focus its limited resources for improvement if it is not known who the focus for the improvement is. Retrospective attribution also raises the issue of how an ACO would assign its quality metrics to a population of it does not know what that population requires for quality improvement. As a result, we support prospective rather than retrospective attribution of beneficiaries.

In addition, although the Patient Protection Affordable Care Act (ACA) allows Medicare to assign a patient to an ACO without his or her knowledge, we believe that a patient should have full disclosure if he or she is being treated as a member of an ACO because the ACO model could create incentives that could potentially impact the treatment that the patient receives.

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

Considerable effort and resources have been devoted to developing, testing, and implementing the Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys and the CAHPS Surgical Care Survey (Surgical CAHPS). CMS should build on this work by using CAHPS surveys to help measure experience of care in ACOs. It is important to recognize, however, that patient and caregiver experience measures such as CAHPS and Surgical CAHPS cannot be collected through existing data systems such as claims data and electronic health records. They require special surveys of consumers, and the lack of resources available to conduct these surveys has been a principal barrier slowing their implementation. Consequently, CMS should provide financial support for the collection and reporting of consumer experience data. To ensure both objectivity and adequate participation, this needs to be done through independent, community-based organizations, such as Quality Improvement Organizations (QIOs) or Regional Health Improvement Collaboratives (RHICs). Several RHICs, including Massachusetts Health Quality Partners (www.mhqp.org) and Minnesota Community Measurement

(www.mnhealthscores.org), already collect and report measures of patient experience along with quality of care measures based on clinical and claims data. RHICs can provide an ideal platform for administering patient experience data with appropriate involvement of physicians and other providers.

Since CAHPS and Surgical CAHPS were developed to measure the care delivered by individual types of providers in a fee-for-service environment, additional survey questions will likely be required to measure patient experience issues that will be particularly affected by ACOs. CMS should work with the Agency for Healthcare Research and Quality (AHRQ) and the National Quality Forum (NQF) to ensure there is adequate funding for the development, testing, and implementation of new measures. Particularly in the near term, different measures may be required in different communities because the areas where ACOs will focus their cost reduction efforts will likely vary significantly from region to region. An efficient way to address this would be for CMS to provide support to multi-stakeholder Regional Health Improvement Collaboratives to develop and test new patient experience measures working in collaboration with the physicians and ACOs in their communities (more information on Regional Health Improvement Collaboratives is available from the Network for Regional Healthcare Improvement (www.NRHI.org).

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.

The ACA does not require public reporting of ACO performance information, and we urge that CMS approach both the collection and any reporting of such information, including patient experience data, thoughtfully to avoid having unintentional adverse consequences for patients

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?

We believe the following aspects of patient-centeredness should be considered with respect to ACOs:

- Provides care that is in the best interest of the patient
- Preserves the essential role of the patient-physician by promoting shared-decision making in developing an appropriate and evidence-based course of treatment
- Promotes patient access to appropriate, high-quality treatments and interventions
- Ensures patient education on important issues such as the potential benefits, associated risks, and potential costs of the full range of treatment options
- Recognizes that each patient is unique with regard to age, health status and biology, and also other factors such as place of residence, lifestyle, and socioeconomic issues that may impact level or risk of treatment options
- Protects and improves patient access to care in frontier, rural, and underserved communities

To promote patient-centered care, ACOs will require measures that apply across disciplines and settings, account for multiple chronic conditions, and provide information on the outcome of care. One approach by the medical community is to develop such measures as well as a framework for blending individual measures into a composite score that creates a more comprehensive picture of where improvement, resources, and incentive payments should be focused.

While physicians support the development and use of increasingly sophisticated measures, there are also significant methodological limitations regarding risk adjustment, attribution, and aggregation that must be taken into account. At this time, there are no widely accepted models that accurately attribute care provided through multidisciplinary teams, or when a patient's care is provided by multiple physicians or across two or more care settings. CMS' plan for evaluating patient-centered care should clearly address and resolve any attribution issues prior to requiring the collection and use of this information.

Also, it is critical that ACOs have a governance structure and agreements in place that secure the role of physicians and clearly define the shared savings that reward surgeons for their contributions to the ACO. The structure of ACOs will vary considerably, and many anticipate the role of hospitals to be central; however, it will be challenging for hospitals to manage their capital needs and the need to rebalance physicians' incomes across an ACO. In addition, the dominance of the hospital runs contrary to patient-centered care, which is focused on the patient-physician relationship. Accordingly, ACOs must have agreements in place that assure sustainable surgical care for the community, with a focus on the patient-physician relationship, with the hospital as a valued partner.

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?

Surgeons in ACOs should be measured for effectiveness in care, efficiency in care, and for patient experience of care. Programs such as the American College of Surgeons National Surgical Quality Improvement Program (NSQIP), The Society of Thoracic Surgeons National Database, the American Society of Plastic Surgeons' Tracking Outcomes in Plastic Surgery (TOPS), the American Society for Metabolic and Bariatric Surgery's Bariatric Outcomes Longitudinal Database (BOLD), and the American Association of Neurological Surgeons' NeuroPoint Alliance by their very design measure the quality of outcomes provided within a system of care, and support the ACO's goals of quality, safety, care coordination, and patient experience.

ACOs could also reward participation in other proven, physician-led quality improvement programs that promote quality outcomes for patients, such as the National Cancer Center Database (NCDB), the National Trauma Data Bank (NTDB), the Trauma Quality Improvement Project (TQIP),

In addition, we promote quality measures that lead the ACO improving and to publicly reporting aspects of quality that are meaningful to all stakeholders. The measures should be meaningful to the ACO's goals of improving quality and reducing cost, and the ACO should be allowed flexibility in selecting measures that fit their performance goals. We also support measurement innovation. To improve, a nimble system of measurement and improvement, such as NSQIP, is required. NSQIP has the capability to rapidly aggregate data, measure, inform, improve, redesign new measures, and move forward.

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 population. CMS should consult with measure developers as it seeks to define performance measures, including whether this information supports benchmarking for improvement at the population, organizational or group practice level. At this early stage, when there is so much we do not yet know about ACOs, a one-size-fits-all approach is not recommended.

In addition, because some specialties currently lack measures and a data collection and reporting system that addresses their scope of practice, reporting requirements should be phased in to ensure that physicians have the opportunity and resources to participate on a widespread basis.

ACOs should not be penalized for delivering care to individuals who are at higher risk for illness due to age, diagnosis, severity of illness, or multiple co-morbidities and both

quality and efficiency measures must be accurately risk-adjusted to account for these factors. Currently, no single risk adjustment methodology is appropriate across a spectrum of conditions or episodes of care, and CMS should invest in testing the accuracy and utility or various methods.

The standard of performance on any quality measures that CMS chooses should be "no decrease in quality," at least initially. CMS should not seek to force arbitrary improvements in quality measures on ACOs at the same time they are seeking ways to reduce costs without rationing care for patients. Although it is likely that in many cases, providers will improve quality either as a means of reducing costs or in conjunction with cost reduction efforts, it is impossible to predict in advance where those improvements will occur because, as noted earlier, the areas where cost reductions will be sought and the methods of doing so will differ from ACO to ACO. CMS should seek to assure patients that ACOs will not result in lower quality care, not to promise them that any particular aspect of quality will improve. CMS should also support the flexibility of ACOs to choose the areas where they focus quality improvement and cost reduction efforts, not distract them by imposing unrelated quality improvement goals (particularly without corresponding changes in payment).

We appreciate this opportunity to offer these comments and concerns and we support efforts to better align incentives to provide high quality care in a more efficient manner. If you have any questions about our comments, please contact Bob Jasak in our Washington office. He can be reached at bjasak@facs.org or at (202) 672-1508.

Sincerely,

American Academy of Otolaryngology-Head and Neck Surgery
American Association of Neurological Surgeons
American Association of Orthopaedic Surgeons
American College of Osteopathic Surgeons
American College of Surgeons
American Congress of Obstetricians and Gynecologists
American Osteopathic Academy of Orthopedics
American Society of Anesthesiologists
American Society for Metabolic and Bariatric Surgery
American Society of Plastic Surgeons
American Urogynecologic Society
American Urological Association
Congress of Neurological Surgeons
The Society of Thoracic Surgeons
Society of American Gastrointestinal and Endoscopic Surgeons
Society of Gynecologic Oncologists
Society for Vascular Surgery