June 2, 2011

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

Attention: CMS 1345-P

Re: Medicare' Shared Savings Program: Accountable Care Organizations Notice of Proposed Rulemaking

Dear Dr. Berwick:

On behalf of the American College of Emergency Physicians' (ACEP) more than 29,000 members, I am pleased to share our comments regarding the proposed regulation for implementation of PPACA Sec. 3022 – the Medicare Shared Savings Program: Accountable Care Organizations (ACO).

This long-awaited and much anticipated rule creates more sophisticated accountability requirements and legal structures for a refined approach to improve the effectiveness of the delivery system for Medicare patients. Numerous federal and private efforts over the past 20 years to manage "care" largely resulted in managing costs and constraining access. This proposal is designed to reward coordination among physicians for care they provide to patients, along with hospitals and other health care providers. ACEP supports the overall goal of the statute and this draft regulation.

CMS' estimate that 75 – 150 ACOs will participate in the first three-year contract period may seem low when compared with the level of initial interest in ACOs, but is likely high given the significant startup costs, legal complexities, introduction of risk in the proposed rule, and early provider response. And, though CMS leadership has been publicly encouraging physicians to form ACOs, the bar appears to be too high for all but the largest, most integrated and highly capitalized groups and systems, at least in the initial phase. Though primary care is at the heart of the ACO concept, reports from the field imply that there are simply not enough groups that have access to the capital needed for investments and to maintain cash flow during the early years. We urge CMS to provide broader opportunities for smaller physician-based groups, if not through the ACO door, then by testing other models through the Innovation Center. We are pleased to see that CMS has issued notice of other models and are reviewing the request for input on the Pioneer ACO and the Advance Payment Model.

From a practical standpoint, it appears that large hospitals and integrated delivery systems will be positioned to better undertake the financial and legal risks of ACO formation. For hospital-based specialists like emergency physicians, the proposed rule provides opportunities and challenges, but little or no guidance. Approximately two-thirds of emergency physicians are members of practice groups of varying sizes that contract with hospitals to provide 24/7 coverage of their emergency departments and

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the remainder are hospital employees. Rules for ACOs should acknowledge these varied relationships in participation and governance issues described below.

Administration officials and lawmakers have made reduction of what some label "expensive, inefficient" emergency visits as one of the goals of health reform. Our members firmly believe there is room for some reduction in emergency department (ED) use, particularly if beneficiaries with chronic conditions are more closely managed by their doctors (an ACO goal), and if there is adequate primary care coverage on nights and weekends. The most recent Centers for Disease Control survey statistics show that approximately 92% of ED visits (of 124 million in 2008) are for conditions that need treatment within two hours, hardly the level of inappropriate use touted so broadly.

Currently, fifty percent of Medicare admissions come through the emergency department and the majority of those patients have time-sensitive conditions. Our members play a critically important role coordinating care at the front end of an episode. They conduct a medical screening examination and assess the patient's need to be either admitted, treated and discharged, or kept in observation for several hours before a final disposition decision is made. Approximately 25 percent of U.S. hospitals have dedicated observation units and they are generally directed by emergency physicians. If the patient requires inpatient care, the emergency physician contacts the patient's treating physician – primary care and/or specialty – who actually admits the patient. If the patient has no physician, the decision often is made by a hospitalist or other hospital medical staff member. At the end of the inpatient stay, many patients are discharged into the community or to post acute care settings with little or no coordinated follow up. ACOs can improve continuity and coordination, and emergency physicians are well-positioned to facilitate these improvements.

Create ACO Parity with Medicare Advantage Plans

Further, if ACOs are to have incentives to provide care at the "right place at the right time", they should not be disadvantaged relative to Medicare Advantage plans in sending certain Medicare patients directly from the emergency department to a skilled nursing facility (SNF). The long-time requirement that fee-for-service Medicare beneficiaries must have a 3-day inpatient stay in the hospital before they can be admitted to a SNF is not reflective of today's medical practice and has led to inappropriate admissions so that Medicare will cover the SNF stay. We urge CMS to give ACOs the same flexibility to make appropriate clinical placement decisions that is given to MA plans.

The following are recommendations and concerns about specific provisions in the proposed rule:

Governance

We support CMS' proposal to require 75 percent of the ACO governance structure to consist of participants. If an ACO is to be successful, it must have the full support of physicians and other participants in making the necessary clinical changes in care delivery. This is particularly important for a hospital sponsored ACO with which emergency physicians would be more likely to have participating agreements. Not only has the typical hospital board been dominated by leaders in the local business

community, but most hospital efforts to create "provider sponsored networks" and "physician hospital organizations" in the mid-1990s were unsuccessful in changing care patterns and reducing admissions. While we do not believe that every hospital-based ACO candidate must be required to create a separate organization and board, we are unaware of current organizations that could meet CMS' proposed governing board composition requirements. **The broader physician participation in governance envisioned under the proposed rule is a positive development.**

We support the concept of each ACO having a beneficiary advisory panel (to be augmented with private sector enrollees if the ACO serves the commercial market as well). Given the nature of Medicare beneficiary assignment to the ACO, it is crucial that there be a platform for the governing board to hear patient voices via an advisory forum that is designed for that purpose.

We are concerned that some contractual and billing arrangements between hospitals and physicians could end up disenfranchising physicians (that is, prevent them from being considered ACO participants for the purposed of having representation on the ACO governing body, e.g. if the hospital bills for the emergency physician group or the physician is a hospital employee). It is our view that ACO effectiveness will be heavily dependent upon having a strong physician presence on the ACO governing body and we want to ensure that the very physicians who have a large role in making decisions that affect patient disposition are adequately represented. We ask that CMS address this issue in more detail in the final rule.

Quality Measures and Other Reporting Requirements

CMS proposes using process, outcome, and patient experience-of-care quality **measures in the following five domains: Patient/Caregiver Experience; Care** Coordination; Patient Safety; Preventive Health, and At-Risk Population/Frail Elderly Health. For the first performance year, CMS is proposing a total of 65 measures for ACOs. Measures for the remaining two years may be changed through future rule-making.

If an ACO fails to meet minimum performance standards in one or more domains, the ACO has one year to improve performance or the agreement will be terminated. Failure to report a measure or the reporting of inaccurate information could also result in termination.

We support the use of quality measures to evaluate system performance on quality care and efficiency and we believe CMS should use measures endorsed by the National Quality Forum (NQF), a voluntary consensus standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. Given the large number of quality measures physicians must report, we also appreciate CMS use of measures drawn from existing programs including the Electronic Health Record (EHR) Incentive Program and the Physician Quality Reporting System (PQRS).

In consideration of reporting burdens facing eligible professionals we urge CMS to go a step further and align the rulemaking, implementation and reporting rules of the ACO, PQRS and EHR incentive programs.

Data Submission/ Data Sharing

CMS plans to use the following data sources for the 65 measures: patient claims, Electronic Prescribing (eRx) and Health Information Technology for Economic and Clinical Health Act (HITECH) program data, Hospital Compare or the Centers for Disease Control and Prevention (CDC), the Group Practice Reporting Option (GPRO) data collection tool (incorporated from the Physician Quality Reporting System), and survey instruments, such as Consumer Assessment of Hospital Patient Satisfaction (CAHPS). **We support the proposal to derive claims-based measures using the above-mentioned tools.** We recommend that to the extent allowed by HIPAA, CMS require ACOs to give ACO providers/suppliers equal access to claims data, something which frequently does not occur today. This level of transparency is important in order to ensure that all ACO providers understand how their performance rates are being calculated.

Quality Performance Standards

We have specific concerns regarding measure #24 “Patient Safety: Health Care Acquired Conditions Composite.” While we support the inclusion of measures relating to treatment outcomes in the Program, we believe that the use of outcomes measures must include appropriate risk-adjustments. Patients with higher acuity are at much higher risk of acquiring pressure ulcers and other Hospital Acquired Conditions; therefore physicians and hospitals caring for more acute patients—who may carry a higher risk for poor outcomes—should not be subject to a “double penalty” for caring for patients with more unique needs.

In addition, we have concerns regarding two of the indicators of the Agency for Healthcare Research and Quality (AHRQ) Patient Safety Indicator (PSI) 90 Complication/Patient Safety for Selected Indicators composite measure: Accidental puncture or laceration (PSI 15) and Iatrogenic pneumothorax, adult. We appreciate the importance placed on patient safety in the value based purchasing program; however, including measures of rare complications such as these in a performance incentive framework is not an effective approach and may result in unintended consequences. The issue of ‘small numbers’ makes it difficult to identify statistically significant differences rather than random variation in the data. This means that the difference between above average and average performance (or poor performance) may just be one or two cases resulting in inaccurate comparisons across hospitals. Additionally, as emergency physicians, we believe that measuring such rare events could drive increased use of less safe procedures (such as femoral catheterization) to avoid the possibility of measure-related events.

CMS is proposing that all of the proposed quality measures must be reported by ACOs, rather than allowing ACOs to report a subset of these, based on their level of readiness for the Shared Savings Program. To encourage greater success—particularly in the first performance year, we urge CMS to allow ACOs to report on a subset of measures in each of the five domains, reflective of the patient population an ACO would serve, rather than requiring ACOs to meet all 65 measures.

Incorporation of Other Reporting Requirements Related to the Physician Quality Reporting System and Electronic Health Records Technology

We support CMS' further alignment of the Shared Savings Program with the PQRS by incorporating a PQRS group practice reporting option (GPRO) under the Shared Savings Program. Eligible professionals who are ACO participants would constitute a group practice for purposes of qualifying for a PQRS incentive payment on behalf of all of its providers—thus potentially alleviating some reporting requirements for ACO providers. This incorporation could allow many emergency physicians, who currently do not qualify as a PQRS 'group practice' to have another avenue under the Program.

Aligning ACO Quality Measures with Other Laws and Regulations

We urge CMS to further align ACO quality measures with other laws and regulations by using the same definition of domains, categories, specific measures, and rewards for performance quality standards across federal healthcare programs.

As CMS considers measures for future years, we urge the Agency to identify national measures for emergency medicine in each of the five domains that would also align with emergency medicine measures found in the PQRS, and the EHR Incentive Programs. In particular, we believe emergency department throughput measures adopted in the EHR Incentive program provide a reasonable way to assess the prevalence of "boarding" which is a patient stay in the ED after the patient has been admitted to the hospital but has not been transferred to an inpatient unit:

- ED–1 – Title: Emergency Department Throughput—admitted patients. Median time from ED arrival to ED departure for admitted patients. (NQF 0495),
- ED–2 – Title: Emergency Department Throughput—admitted patients. Admission decision time to ED departure time for admitted patients. (NQF 0497), and
- ED–3 – Title: Emergency Department Throughput—discharged patients. Median Time from ED Arrival to ED Departure for Discharged ED Patients. (NQF 0496).

These measures are significant to improving patient safety and quality, and a growing body of evidence has shown that boarding can increase the patient's length of stay in the hospital and compromise quality. (Chalfin DB, Trzeciak S, Likourezos A, et al. Impact of delayed transfer of critically ill patients from the emergency department to the intensive care unit. *Crit Care Med*. 2007; 35(6):1477-1483).

We also believe measures of care coordination in the emergency department should be considered and represent an opportunity for ACOs to improve care and efficiency. For example, NQF- endorsed measure #649 "Transition Record with Specified Elements Received by Discharged Patients (Emergency Department Discharges to Ambulatory Care [Home/Self Care])", focuses on patients, regardless of age, discharged from an emergency department (ED) to ambulatory care or home health care, or their caregiver(s), who received a transition record at the time of ED discharge including, at a minimum, all of the specified elements.

HIT and the Role for Emergency Physicians

Currently, emergency physicians are not eligible professional for participation under the EHR incentive program, but expect to be key participants with ACOs. Our members can improve transitions between sites of care, particularly when a patient comes to the emergency department with an acute exacerbation of a chronic health problem or returns after an inpatient stay within 30 days of discharge and is re-admitted. As electronic health records (EHR) continue to expand linking community-based physicians with the ED and other health care providers, emergency physicians will be able to play a more integral and expanded role in care coordination. Therefore, we urge CMS to select organizations that have implemented enterprise-wide EHRs with the primary care physicians meeting "meaningful use" standards.

Risk Assumption

We understand the pressures facing CMS in introducing risk sharing into the proposed rule. As noted above, it appears that the proposed standards are so strict that most of the applicants for the first 3-year agreements will need to have to have experience with integrated delivery to be in a financial position to take some level of risk. On balance, however the addition of risk assumption after two years for many aspiring physician-based groups wanting to form ACOs sets the bar too high. Further, we believe the early shared savings percentages are too low (in particular when compared with the 80 percent shared savings under the Physician Group Practice Demonstration). And, the proposed 25 percent withholds are unnecessary and would create further financial barriers to entry. We will review information on the Advance Payment model recently announced by the Innovation Center to see if barriers to entry were addressed.

While shared savings may be attractive for primary care providers who are integral to the ACO, we are concerned that the combination of the EMTALA mandate and the significant organizational efforts to create all the necessary components of managing care across the care continuum will take time. Therefore, emergency department visits may not show much reduction in the early stages of the ACO. We are concerned that this could lead to an ACO wanting to attribute costs or early losses to emergency physicians. It's important to remember that with ACA-guaranteed patient protections, neither provider nor patient should be penalized when a patient goes to seeks emergency care either in or out of network. In addition, we believe that a critical foundation of success for any ACO will be equitable payment to its providers. For this reason, we will work with our members to monitor ACOs' initial risk sharing plans among participants, and urge our members to use caution before accepting risk for resource use before coordination systems have been in place for a year or two.

Three-year Agreement

Three-year agreements may be too short a timeframe to generate shared savings, given the nature of startup programs and the lag in assignment of beneficiaries until the end of the first year. We support letting ACOs choose a longer agreement time and a delayed start date of July 1, 2011 to provide more time for applicants to meet the legal and structural requirements.

Anti-trust Concerns

ACEP has submitted detailed comments to the FTC on what we believe may be unintended consequences of the Proposed Statement of Anti-trust Enforcement Policy. In brief, we referenced the recent study (JAMA May 18, 2011) that shows that between 1990 and 2009, the number of emergency departments in non-rural areas has declined by 27%. The result of these closures may be that the remaining EDs provide services to larger and larger geographic areas, which in turn may trigger mandatory review by the anti-trust agencies in the description of what constitutes a "primary service area". We believe that under EMTALA, since emergency services are provided to everyone, anti-competitive behavior on the part of emergency departments and physicians is not a factor.

Support for Including FQHCs/CHCs in ACO

We support conceptually the proposal to encourage and reward ACOs with a greater share of savings if the ACO includes FQHCs and RHCs. These centers provide primary care to many in low income areas and some rural areas. Our experience is that there is room for improvement to steer more patients from EDs to FQHCs/ RHCs. However, it will be important to clarify how shared shavings and shared risk would work with these federally-funded organizations.

If you have any questions about our comments, please contact Barbara Tomar, ACEP's Federal Affairs Director at (202) 728-0610, ext. 3017.

Yours truly,

Sandra M. Schneider, MD, FACEP
President