



June 6, 2011

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: CMS-1345-P  
Proposed Rule on Medicare Shared Savings Program: Accountable Care Organizations

Dear Dr. Berwick:

The Cystic Fibrosis Foundation appreciates the opportunity to submit comments on the proposed rule for Accountable Care Organizations (ACOs) that will be implemented as the Shared Savings Program authorized by the Affordable Care Act. The CF Foundation represents the 30,000 Americans living with CF, supports an aggressive research program aimed at finding a cure for CF, and funds and coordinates a system for delivery of quality CF care to children and adults.

We enthusiastically endorse the effort to ensure that ACOS deliver better care for individuals, better health for populations, and lower growth in expenditures. We at the CF Foundation strive to meet these same high standards for those with CF.

### **Principles of Patient-Centeredness**

We applaud the Centers for Medicare and Medicaid Services (CMS) for delineating eight strong principles of patient-centeredness that will guide the development of ACOs and serve as the fundamental standards for judging their success. We commend CMS for including among the principles of patient-centeredness the development of individualized care plans based on the patient's needs, preferences, values, and priorities; the involvement of patients and families in evidence-based decision-making about care choices; and the development of processes to ease transitions of care among providers.

#### **National Office**

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These principles have been at the center of the CF system of care, which focuses on bringing patients and families into the system of care so that they can make informed decisions about their care and participate in management of their care.

CMS must assume an aggressive role in monitoring and evaluating ACOs to ensure that they design and implement systems of care that will guarantee that the principles of patient-centeredness are honored. Articulating principles of patient-centeredness is an important step, but transforming the system of care consistent with the principles must be the goal of ACOs. This transformation will not be easy, and the proposed rule is an important but only an initial step in that process.

### **Individualized Care Plans and Evidence-Based Decision-Making**

Patients with CF and their families adhere to a rigorous medical regimen to achieve the best possible outcomes with existing CF medications, therapies, and health care interventions. The individualized care plans utilized by CF patients are consistent with evidence-based clinical practice guidelines that define optimal CF care, facilitating efforts by patients and families to follow the best available evidence in making treatment decisions. To ensure that individualized care plans are consistent with the best evidence, CMS should require health care providers in ACOs to reference evidence-based guidelines in the care planning process.

We understand that a crucial part of the care planning process is the development and communication of the plan to the patient and the clarifying discussion that may occur when the health care provider shares the plan with the patient. However, the contents of the plan, its reliability, and its reliance on guidelines are of critical importance for individuals with chronic diseases who need access to sophisticated health care administered daily. For those with CF, it is also important that the care plan be updated and amended on the basis of new evidence, availability of new treatments, and in accordance with changes in the patient's condition.

### **Retrospective Assignment of Patients**

We understand that CMS went through a rigorous process to evaluate the respective advantages and disadvantages of prospective and retrospective assignment of patients to ACOs. We appreciate that retrospective assignment of patients may offer individuals with CF, who will be considered at-risk, some protection against discrimination or limits on access to care. In addition, retrospective assignment will encourage ACOs to improve the quality of care for all patients and not simply those who are assigned to the ACO. However, the advantages of prospective assignment may outweigh these potential protections associated with retrospective assignment.

Patients and families that are informed of their assignment to an ACO prospectively will be able to participate fully in their care through informed decision-making, active management of their care, and a strong relationship with their health care providers. In turn, ACOs will be able to communicate more effectively with Medicare ACO enrollees about care planning and coordination. General communication

with beneficiaries that their health care provider is participating in an ACO and that they may be assigned to the ACO will be unlikely to achieve the same kind of partnership for better health care that direct communication about assignment to an ACO would accomplish.

### **Data-Sharing**

We understand the concerns about protection of patient privacy that contributed to the decision to permit beneficiaries to opt out of claims data sharing. However, it is possible that limits on the data available to ACOs will adversely affect their ability to evaluate their delivery of care and develop quality improvement efforts. It is the experience of the CF Foundation that access to data is critical to quality assessment and improvement efforts, and we urge CMS to consider changes in the assignment of beneficiaries to ACOs that would encourage greater patient involvement in their care and would also facilitate greater willingness to share data. Prospective assignment of beneficiaries holds greater promise of achieving these goals than retrospective assignment.

### **Access to Specialty Care**

It is critical that CMS carefully monitor the performance of ACOs to ensure that they do not engage in activities to avoid high-risk individuals or to limit those beneficiaries' access to care. Care delivered to CF patients in accredited CF care centers is high quality care that is consistent with clinical practice guidelines, and access to care in such centers has contributed to the improvements in care for individuals with CF and to the advances in survival for these patients. ACOs should be encouraged to protect availability of care through CF care centers, as such care is consistent with the fundamental ACO principles of improving care for individuals, enhancing the health of populations, and slowing the rate of growth of care.

There are also certain life-saving treatments that should be available to those with CF and which ACOs should not discourage or inhibit. CF patients who have suffered serious lung damage as their disease progresses may ultimately have only the treatment option of a double lung transplant. If the patient is otherwise eligible for a transplant, the ACO should not function in a way that would hinder the CF patient's access to such transplant.

It is also likely that CF patients who are hospitalized for treatment of lung exacerbations will seek care in one of the CF centers with special expertise in CF treatment. These are often academic health centers that may have costs that are not reflected in the ACO spending calculation and therefore may not be preferred sites for referral by ACOs. We urge that protections be implemented so that ACOs do not discourage referral to such centers, where care will be of high quality and in the long run may be more efficient than care in a seemingly lower cost institution.

### **ACO Governance**

The CF Foundation applauds the proposal to include at least one Medicare beneficiary on the ACO governing board. We also endorse the formation of a beneficiary advisory committee to provide additional counsel and advice from the patient perspective. Patients representing those with chronic illnesses requiring intensive care should be included among the patient advisors, as they can share valuable perspectives regarding the coordination of care, health care provider-patient communication, and patients' participation in care. We do not recommend a beneficiary advisory committee as a replacement to a beneficiary participant on the ACO governing board but instead as a complement to that position.

### **Quality Measures**

The CF Foundation appreciates the significant challenge of selecting an initial set of quality measures for application to ACOs, and we commend the work of CMS on this matter. It is no easy task to balance the need for a rigorous set of measures, the ability of new ACOs to develop systems to report on these measures, and the requirement to update the guidelines based on new research and evolving standards of care. We also note the importance of including measures, developed and utilized by reliable organizations according to rigorous standards, which may apply to small populations of beneficiaries. For certain populations, the 65 measures identified by CMS for measurement of ACOs may do little to evaluate their performance related to care of specific populations of patients with special health care needs. This situation might be true for those with CF but for many other beneficiaries with rare diseases as well.

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The CF Foundation appreciates the opportunity to offer comments and looks forward to working with CMS for the implementation of Medicare ACOs.

Sincerely,

A handwritten signature in black ink, appearing to read "Robert J. Beall". The signature is fluid and cursive, with a large initial "R" and "B".

Robert J. Beall, Ph.D.  
President and Chief Executive Officer