



April 10, 2014

Patrick Conway, M.D.
Deputy Administrator for Innovation and Quality
Chief Medical Officer
Center for Medicare and Medicaid Innovation
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Request for Information on Specialty Practitioner Payment Model Opportunities

Dear Dr. Conway:

The Cystic Fibrosis Foundation appreciates the opportunity to submit comments regarding the Request for Information (RFI) on “Specialty Practitioner Payment Model Opportunities” published by the Center for Medicare and Medicaid Innovation (CMMI) on February 11, 2014.

The CF Foundation is a national organization that invests in research and development of cystic fibrosis (CF) therapies, supports a network of clinical research sites, contributes to a system of clinical care centers that are engaged in constant quality improvement, and provides a wide range of support services to individuals with cystic fibrosis and their families.

The CF Foundation and the physicians, other health professionals, health systems, and academic health centers providing care to children and adults with CF have engaged in long-term collaboration to improve the care of individuals with CF, an effort that has steadily improved the average life expectancy and quality of life for CF patients. The community of CF health providers is currently engaged in a range of experiments to improve CF care delivery and quality. We agree that additional payment and delivery reform efforts are necessary for further refinements of the CF care system, and we welcome the opportunity to work with the Centers for Medicare & Medicaid Services on this reform issue.

Individuals with CF are represented among beneficiaries enrolled in Medicare, Medicaid, and Children’s Health Insurance Program (CHIP), and those beneficiaries would benefit from specialty payment reform. We believe that the movement away from a volume-based system of payment and care delivery to a well-coordinated, patient-facilitated, and multi-disciplinary care system may provide better health outcomes, improve patient and clinician engagement, and lower health care costs.

We will focus our comments on complex and chronic disease management episode-based payment opportunities.

Defining a Complex Medical Management Model

Reference to the elements of cystic fibrosis care, as defined by practice guidelines and current clinical practice, should inform the design of an episode of care or a bundled system of care. This information, supplemented by the utilization data that are collected and analyzed in the CF Foundation Patient Registry, might also help to define the most appropriate length of episode or bundle and the reimbursement necessary to support the episode.

Although there are clearly articulated standards of care for CF patients, the overall patient population is heterogeneous. As a result, any system that is based on episodes of care should also include protections and adjustments for patients who are outliers and whose utilization of health care resources would be outside the norm for the episode payment. Additionally, there is a need for adaptability for the potential increase in disease severity that could arise and move a patient to another level of a bundled system of care. Mechanisms will be necessary to promptly respond to immediate and significant changes in disease circumstance.

Current practice would suggest that assigning the responsibility for care – that is, identifying the specialist practitioner or care team assuming responsibility for care – will not be especially difficult in the CF care system. Most CF patients currently receive their care at a multi-disciplinary care center, and either the care center or a specialist practitioner at the center should be assigned responsibility for coordinating care in the complex and chronic disease management model. In many cases, the specialist will be a pulmonologist or pediatric pulmonologist, but the identification of the multi-disciplinary center is the key to the success of the CF care model.

For the new episode-based payment system to improve beneficiary care, it must include the full network of multi-disciplinary providers required to address the complexity of caring for children and adults with CF. The network should include nurse practitioners, respiratory therapists, nutritionists, and social workers. The contributions of all members of the care team are critical to the development of a comprehensive and patient-centered plan of care. The episode of care payment level should reflect the costs associated with incorporating all of these health care providers into the chronic care system. Claims data, supplemented by data from academic health care systems that supply multi-disciplinary care, should support the identification of payment levels.

Payments for a CF episode-based complex and chronic care system should support a 7-day-a week, 24-hour-a-day system for supporting CF patients and responding to them regarding urgent care needs. This round-the-clock capacity would include response to patient and parent phone calls and patient text messages as well as utilization of telemedicine tools. This element is critical to ensuring that the chronic care system reduces the utilization of emergency department services and certain hospital admissions.

The quality of care in the episode-based system could immediately be assessed by measuring adherence to evidence-based clinical care guidelines. We also recommend the development of measures that would assess patient satisfaction with the episode-based care system, patient adherence to medication

regimens, and patient-reported outcomes related to health status. For a patient population that confronts the need to take medications and undergo respiratory therapy multiple times daily, measures of patient satisfaction, adherence, and patient-reported outcomes are critically important and will tell us much about the success of new structures and systems for care.

In fact, the ability to assess patient engagement in care represents a significant opportunity in a CF chronic and complex care episode-based payment system. We recommend that a chronic and complex care system incorporate mechanisms for capturing patient-generated health outcomes data, including information on disease burden, physical function, mental health, and success in meeting personal goals. The patient-generated data should be accompanied by clinical data in order to provide the best overview of health outcomes and to inform treatment management.

The CF Foundation and the care centers that it accredits have been engaged for a number of years in the collection of clinical data from CF patients, and these data have informed CF care improvements. We see the opportunity to strengthen the CF Foundation Patient Registry through collection of a broader data set that would be available as a result of a chronic and complex system that is episode-based. For example, data related to care provided by the multi-disciplinary care team might be more fully incorporated in the patient registry. We also see possible advantages to the collection and reporting of data from a fully integrated health care system.

We have significant misgivings about making the health care provider who is responsible for the episode of care accountable for the drugs that are prescribed to CF patients. Although the elements of an episode of care for children and adults with CF can be defined, it is still important to note that there is heterogeneity among the CF patient population. This heterogeneity results in differences in the intensity of services required by patients. In general, these differences in care requirements can be reflected in the payment level for the episodes of care.

However, prescription drugs cannot be easily incorporated into the CF ambulatory episode of care. The most important pharmaceutical product developments are CF transmembrane conductance regulator (CFTR) modulators that are targeted to CF patients with specific genetic profiles. The CFTR modulator that has been introduced to the market is indicated for only 4 percent of the 30,000 Americans with CF, and the modulators that are under development will be targeted to other patient populations according to the genetic profile of the patient. There is also the possibility that combinations of products will be prescribed, but these choices will also be driven by patient genetics. As a result, we do not believe that there is an “average” CF patient in terms of the pharmaceuticals that will be prescribed.

Considering the complexity and difficulty associated with describing a typical CF patient, we recommend that prescription drugs – or at least those products that address the fundamental defect causing CF, which are the products that are targeted to specific groups of patients – be reimbursed outside the episode of care. The transitional pass-through payments in Medicare’s Hospital Outpatient Prospective Payment System might serve as a model for payment for certain prescription drugs in the CF ambulatory

episode of care model. The pass-through system might also serve to provide incentives for new, innovative therapeutic advances.

We caution that reimbursing for prescription drugs outside the episode of care should not result in barriers to access to those drugs. To ensure access to drugs without delays that can affect health status, we urge that drugs for those served through an episode system of care be available according to Food and Drug Administration labeling and practice guidelines. Imposition of prior authorization requirements or burdensome cost-sharing responsibilities will only serve to undermine access to evidence-based treatments and threaten the possible benefits of an episode of care system.

Although we have recommended that drugs not be incorporated in the episode of care initially, this is an issue that may deserve revisiting in the future. For example, there may be some advantages -- after episodes of care are tested -- in including drugs for treating the symptoms of CF as part of the episode. Pancreatic enzymes and nutritional supplements might, in the future, be best managed as part of the episode. However, we do not believe that the modulators that address the underlying cause of CF -- and which are genetically targeted -- should be part of the episode in the beginning and do not foresee a time when those targeted therapies could be appropriately included in the episode of care payment.

Practitioner Participation

We anticipate significant practitioner interest in the episodes of care model, if health care professionals and health care systems can be assured that the payment for the episode of care has been calculated fairly and that adjustments are possible for patients who are true outliers in terms of resource utilization.

Adoption of Model by Other Payers and Challenges in Implementation of Model

A health system or physician providing care to CF patients typically finds that its patients are insured by a very wide range of public and private third-party payers. One of the greatest burdens that providers face is navigating coverage and payment rules for prescription drugs and many other CF procedures and interventions, with each payer implementing different rules and requirements. In addition, the nutritional support, social work services, and certain other elements of care that are integral to delivery of quality care for those with CF are simply not covered by many third-party payers. The practice of CF care is increasingly described by health professionals as a bureaucratic exercise of obtaining permission to prescribe and deliver care.

If a complex and chronic episode of care system could be implemented across payers, the obstacles to the delivery of CF care would be significantly addressed. Adoption by public payers of an episode of care system for CF care would represent an important step forward, but the full advantage of episodes of care (as described above) will be realized only the system cuts across all payers.

The development of practice guidelines for care of CF patients and the standardization of many procedures and interventions through the CF care center network should not confuse the fact that the CF patient population is heterogeneous in important ways. The disease presents in very different ways, with some diagnosed with severe disease and others not. In addition, patients of different ages and lung function measures may have very different health care needs. The design of the episodes of care system and the calculation of payment levels should permit adjustments for patients who are outliers in terms of the utilization of resources necessary to care for them. In addition, some health care centers may have developed specific expertise and skills that result in a patient population that has more significant health care needs than the CF patient population on average. Reformed payment systems must adjust to these distinctions among health centers.

Patient Cost-Sharing

Data regarding CF cost of care and patient cost-sharing responsibilities collected by the CF Foundation and care centers and published in the CF Patient Registry convey a disturbing situation that affects patient decision-making, health status, and outcomes. Our data show that many patients and families cannot manage their sometimes crippling cost-sharing responsibilities. In the face of such cost obstacles, patients make choices to forgo treatment, take smaller than optimal doses of prescription medications, or take other action to reduce their treatments and treatment-related financial responsibility. These choices may have serious adverse effects on CF patients' health status, and the long-term adverse effects on the health care system may be significant, too.

The overhaul of the structure for providing care and the reimbursement for such care presents an opportunity to reconsider patient cost-sharing responsibilities as well. We strongly recommend that patient cost-sharing be rationalized so that it does not create perverse incentives to forgo care and create greater costs for the health care system in the long term. Although we are recommending that accountability for drugs be outside the episode of care, we also recommend that cost-sharing for prescription drugs also be addressed so that patients are not forced to reject drug therapy, take suboptimal doses of drugs, or face bankruptcy if they do use prescribed drugs.

We appreciate the opportunity to comment on chronic and complex care episode of care systems. We look forward to a continued dialogue about options for improving payment and delivery of CF care.

Sincerely,



Senior Vice President for Policy
& CF Community Affairs