Cystic Fibrosis Foundation
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July 25, 2011

Donald M. Berwick, M.D., M.P.P.
Administrator
Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-9993-IFC2, Group Health Plans and Health Insurance Issuers: Rules Relating to Internal Claims and Appeals and External Review Processes

FILED ELECTRONICALLY at http://www.regulations.gov

Dear Dr. Berwick:

The Cystic Fibrosis Foundation (CFF) is dedicated to finding a cure for cystic fibrosis through an innovative and aggressive research program and at the same time enhancing the quality of care available to children and adults with CF. We are pleased to offer comments on the interim final rules on internal claims and appeals and external review processes. We are concerned that the revisions of the interim final rules that were originally issued in 2010 will provide individuals with CF inadequate protections in obtaining high-quality care, often provided by specialists who are outside the CF patients' plan network. Our comments focus on the timeline for benefit determination for urgent care and the scope of external review.

Timeline for Benefit Determination for Urgent Care

The interim final rules issued in 2010 would have imposed a 24-hour deadline for plans and issuers to notify a claimant of a benefit determination for urgent care. This standard afforded individuals with CF important tools in navigating the complex system of care and payment in order to receive urgent care without delay. Although those with CF must adhere to a stringent plan of daily health care, they also on occasion face the need for hospitalization or other urgent care for serious and life-threatening lung infections or other symptoms of CF.

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An individual with CF who needs urgent hospitalization or other emergency care is not adequately protected by the Emergency Medical Treatment and Labor Act (EMTALA), because the challenge facing those patients is not simply being stabilized but initiating care for pressing or emergency medical problems.

We are concerned that the interim final rules at hand would amend those standards issued in 2010 to permit plans and issuers up to 72 hours to provide a benefit determination for urgent care. This timeline is inadequate to protect those with CF who need emergency services and who face complications due to delays in initiation of urgent care.

We are not persuaded by arguments that plans and issuers will be unable to conduct quality reviews to support a benefit determination if they are facing a 24 hour deadline. If plans and issuers do not at the current time have the personnel or infrastructure to complete reviews of urgent care claims, we believe they can expeditiously develop such systems. In 2010, the agency cited improvements in electronic communication to support its decision to require a 24-hour claim determination deadline. We think that analysis by the agency was accurate and urge health plans and issuers to utilize technology to make benefit determinations for urgent care within 24 hours. This standard is important for individuals with CF and other serious and life-threatening illnesses, and we believe in the long-term it is in the best interest of plans and issuers that will benefit from care delivered timely and efficiently and in a manner that will protect against complications and rehospitalization or other intensive care.

Scope of Federal External Review Process

There are 30,000 Americans with CF, and those individuals rely on a network of CF care centers that are skilled in providing quality CF care consistent with current clinical practice standards. Because of the relatively limited incidence of CF and the development of a specialized network of care, issues related to access to out-of-network or specialty or subspecialty care arise routinely for CF patients and their physicians. In addition, a rich pipeline of potential new CF therapies for testing and a community of CF patients willing and enthusiastic to participate in clinical trials combine for high rates of enrollment in clinical studies among CF patients. However, enrollment in clinical trials also often triggers review by health plans and issuers.

We are concerned that changes in the scope of federal external review from the standards initially proposed in 2010 will create significant challenges for those with CF. By limiting federal external review to claims that include medical judgment or a rescission of coverage and specifically excluding review of legal and contractual issues, the agency may restrict protections provided to beneficiaries.

It would appear from language and examples included in the interim final rule and in the preamble that questions of investigational or experimental therapy would be within the scope of external review. We applaud the agency for including that matter within the scope of review, so that those with CF can anticipate a prompt and fair resolution of questions related to their enrollment in clinical research studies.

There is less clarity about the review of claims related to care out-of-network and care by specialists. In the case of claims related to out-of-network care, external review would be permitted only if the plan permits out-of-network access when such care is not available within the plan. We urge instead that all questions of out-of-network care be considered matters of medical judgment and therefore subject to external review. This level of protection is essential for those with CF, who may not be able to obtain medically appropriate care within the network.

Disputes about claims for care provided by specialists and sub-specialists should also be subject to external review. Those with CF need well-planned and well-coordinated care that may include services from a range of specialists. Questions about this care should also be considered matters of medical judgment and within the scope of external review.

The agency indicates that it will evaluate the implementation of the external review process standards, with the possibility of restoring the terms of the 2010 rule in the future. We urge that the revisions of the interim final rules related to external review of claims related to experimental care, out-of-network care, and specialty care be made immediately and that the evaluation of external review standards be completed promptly. We also urge implementation without delay of any changes identified in the agency assessment.

We appreciate the opportunity to offer comments on the interim final rule and urge the agency, in evaluating the comments on the revised interim final rules, to keep in mind the needs of those with chronic illnesses that require significant and sophisticated care delivered on a daily basis.

Sincerely,

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