



April 5, 2013

Carolyn W. Colvin  
Acting Commissioner  
Social Security Administration  
6401 Security Boulevard  
Baltimore, Maryland 21235-6401

Re: Notice of Proposed Rulemaking  
Revised Medical Criteria for Evaluating Respiratory System Disorders  
Docket No. SSA-2006-0149

Dear Commissioner Colvin:

The Cystic Fibrosis Foundation appreciates the opportunity to submit comments on the Revised Medical Criteria for Evaluating Respiratory System Disorders. In the preamble to the proposed new medical criteria for respiratory system disorders, the Social Security Administration (SSA) says, "We are proposing these revisions to reflect our program experience and medical advances in evaluating respiratory disorders." In our analysis, the listings are not consistent with patterns of care for those with cystic fibrosis (CF). As a result, we are concerned that the proposed listings do not serve as accurate measures of the disability of children and adults with CF.

*Listing 3.04C*

The proposed listings would permit eligibility for benefits to be established by "exacerbations or complications of CF (see 3.00J5) requiring three hospitalizations of any length within a 12-month period and at least 30 days apart." The preamble to the proposed rule explains that for complications in people with CF, the SSA will "no longer consider physician interventions, either as an outpatient or in an emergency department. When these types of complications occur, they are too severe to treat on an outpatient basis."

The experience of the CF Foundation and the physicians who care for children and adults with CF every day in the national network of CF Foundation-accredited CF care centers suggests that the standard of three hospitalizations for exacerbations in a 12-month period is not appropriate for establishing disability. Pulmonary exacerbations are an indicator of disease severity in CF. The CF patient who

experiences two or more exacerbations in a 12-month period is getting sicker and *is disabled*. Moreover, physicians address exacerbations in a variety of ways, including through use of home intravenous antibiotics or inhaled nebulized therapies, as well as through hospitalization. Proposed eligibility criteria are too narrow, and must address the severity of the disease rather than the setting of the treatment.

The statement in the preamble that complications of CF cannot be treated on an outpatient basis is not consistent with the practice of CF physicians and care centers. There is movement away from hospitalization for CF complications because of concerns about hospital-acquired infections as well as payment standards discouraging hospitalization. The complications from CF that physicians treat on an outpatient basis are serious complications, but the site of care is not by default the inpatient hospital setting. For example, home intravenous therapy is increasingly the preferred method of treatment for exacerbations, usually lasts two weeks during which parents or patients must increase the number of airway clearance treatments in addition to administering intravenous antibiotics, and definitely meets the standard for management of a serious complication.

We urge SSA to revise section 3.04C to permit establishment of eligibility if an individual has two or more exacerbations in a 12-month period that might be managed through a combination of hospitalization, home intravenous antibiotic administration or nebulized therapies for the treatment of the exacerbation. This listing would more accurately reflect the current experience of CF patients, seeking care for exacerbations in outpatient settings – including home care – whenever possible. In addition, this change to the listing would also reflect the current nature of the American health care system and the understandable pressure to avoid inpatient care if possible.

It is also important to note that adults with CF receive advice from their physicians to stop working so that they can more actively manage their disease – by avoiding infection risk, minimizing the stresses of the workplace, and engaging in even more active disease management strategies than the aggressive management efforts they have followed for a lifetime.

#### *Listing 3.04D*

In this listing, SSA proposes that eligibility could be established if an adult with CF has any two of the six listed complications within a 12-month period. There would need to be at least 30 days between a few of the acute complications.

The complications numbered one through four in the proposed rule are each serious health issues for someone with CF. Eligibility should be established if an adult with CF has ONE of these four complications.

We also recommend that the list of complications be modified. We suggest that complication number one be changed to read “Spontaneous pneumothorax, secondary to CF lung disease, requiring chest tube treatment.” Complication number two should read, “Respiratory failure (see 3.00N) requiring

continuous assisted (mechanical) ventilation or non-invasive ventilation for at least 48 hours, or for at least 72 hours if postoperatively.”

An additional complication – major depression – should be added to the list. For the final three criteria, including the addition of major depression, any two of the three criteria should be a qualifying standard.

#### *Listing 103.04E*

We recommend that the listing for children with CF be amended consistent with our proposed revision to 3.04D (above), with one additional modification. The listing for hypoxemia – “hypoxemia with the need for at least 1.0L/min of oxygen supplementation for at least 4 hours per day and for at least 90 consecutive days” – is significantly too rigorous. A child who meets that standard would be on a lung transplant list and would be far past the threshold of eligibility for disability.

#### *Listing 3.04A*

The proposed FEV-1 criteria for adults, which set different standards according to gender and also different standards for adults from age 18 to age 20 and adults age 20 and over, may present some implementation challenges. For example, will there be a review of eligibility at age 20 for the adult who met the criteria for those age 18 to 20? We believe that such a practice would pose difficulties for the adults whose eligibility is established prior to age 20 and also for SSA. We request that SSA clarify its intended plan for implementation of the new FEV-1 criteria.

#### *Listing 3.11*

We applaud the decision of SSA to revise the listing for those who have received a lung transplant. We are pleased that proposed listing 3.00N would consider a person who has received a lung transplant to be disabled for 3 years after transplant, as opposed to the current listing of 1 year. We believe this period of time is appropriate and will provide transplant patients critical time for recuperation after transplant.

#### *Listing 3.04B*

We urge SSA to reconsider listing 3.04B in its entirety. Arterial blood gas (ABG) as a measure of cystic fibrosis severity does not correlate well to disability, as seriously disabled patients may have normal blood gas measures. In addition, ABG measurement is not standard practice at most specialized CF care centers, and the ABG test is an uncomfortable one for patients.

*Comment Timeframe*

We have misgivings about the short period for public comment on a regulatory proposal that may have serious effects on vulnerable adults and children with cystic fibrosis. The Social Security Administration correctly points out that the current respiratory system listings have been in place since 1993 and that the SSA published an Advance Notice of Proposed Rulemaking (ANPRM) on this subject in 2005. The long tenure of the listings and the initiation of the regulatory process eight years ago with publication of an ANPRM do not address the fact that a major revision of the respiratory system listings was published on February 4, 2013, with no prior outreach to interested parties regarding the proposed rule and with a comment period that ends on April 5. This is a short period for interested parties to assess and comment on the specific new listings and for the agency to receive comments on such a significant matter.

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With incorporation of the changes we have recommended, the listings will reflect current CF care standards and establish eligibility for CF patients who are disabled.

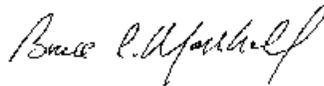
Sincerely,



Robert J. Beall, Ph.D.  
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