

## **Teleconference on Proposed Medical Criteria for Evaluating Cystic Fibrosis Under Listings 3.04 and 103.04 in the Listing of Impairments**

### **Introduction:**

Welcome to the Social Security Administration's teleconference on our proposed criteria for evaluating cystic fibrosis. While we are not taking any comments today, we want to provide you with an opportunity to hear from us what we have been working on with regard to listing criteria in 3.04 and 103.04 in the Listing of Impairments. My name is Art Spencer.

Today, I will:

- Give a short, general background on the disability program,
- Provide information on how we revise the listings,
- Share with you some important information pertaining to adults and children who have cystic fibrosis and who are currently receiving disability insurance benefits or supplemental security income, SSI, payments,
- Explain what information on cystic fibrosis that we considered when we drafted proposed listings 3.04 and 103.04, and
- Discuss the criteria in proposed listings 3.04 and 103.04.

### **Background on the Rulemaking Process:**

- We conduct rulemaking activities using the Administrative Procedure Act, or APA's, notice and comment rulemaking procedures. When we publish a proposed rule in the Federal Register, we notify the public of its opportunity to make comments and we consider all of the comments we receive.
- Rulemaking does not close until we address the public comments and publish a final rule. Right now, we are in the midst of the APA's rulemaking process with our proposed rules for evaluating respiratory disorders.
- When we determine it would be helpful to interact with members of the public during rulemaking, as we are doing today, we announce the meeting publically in the Federal Register. We also will publish a summary of the meeting as part of the rulemaking record for full disclosure to the public.

### **General Background on the Disability Program:**

At the Social Security Administration, SSA, we do everything within our power to meet the public's expectation of exceptional stewardship of the disability program. Too many people depend on us for us not to strive to do the job right the first time.

To give you some background of the disability program, I am going to share with you some basic information about how we evaluate disability claims, and this certainly pertains to cystic fibrosis claims. Under the Social Security Act (Act), "disability" is defined as the inability to engage in any substantial gainful activity due to any medically determinable physical or mental impairment which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months. For children under the SSI program, disability means that the child has a medically determinable physical or mental impairment, which results in marked and severe functional limitations, and which can be expected to result in death or

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which has lasted or can be expected to last for a continuous period of not less than 12 months.

We require objective medical evidence that show that a person has a medically determinable impairment, or MDI, that meets our disability requirements.

We evaluate initial adult disability claims under a standardized five-step evaluation process, what we call the sequential evaluation process. At step one, we determine whether the person is engaging in work, what we call substantial gainful activity or SGA. If the person is not engaging in SGA, we go to step two, where we assess whether he or she has a medically determinable impairment or combination of impairments that is severe. Throughout sequential evaluation, we consider the combined effect of all of the person's physical and mental impairments.

If we determine that the person does not have an MDI that is severe, we must find that he or she is not disabled. If the person's impairment, or combination of impairments, is severe, we go to step three.

At step three, and that's the issue here today, we determine whether the person's impairment or combination of impairments "meets" or "medically equals" the criteria of one of the listings in our regulations. For children, we consider whether the child's impairment or combination of impairments "meets" or "medically equals" the criteria of one of the listings, or whether it "functionally equals the listings." The listings describe, for each major body system, the impairments that we consider severe enough to prevent an adult from doing any gainful activity. For children, the listings describe impairments that cause "marked and severe functional limitations."

For children, when an impairment, alone or in combination with another impairment, is severe but does not meet or medically equal a listing in any affected body system, we determine whether it results in limitations that functionally equal the listings. By "functionally equal the listings," we mean that the child's impairment must be of listing-level severity, that is, it must result in "marked" limitation in two of the domains of functioning that we consider or "extreme" limitation in one domain. In evaluating the effects of a child's impairment on his or her functioning, we consider what the child cannot do, has difficulty doing, needs help doing, or is restricted from doing because of his or her impairment. If a child's impairment or combination of impairments meets or medically equals a listing, or functionally equals the listings, we allow the claim. If not, we deny the claim.

For adults, when an impairment, alone or in combination with another impairment, is severe but does not meet or medically equal a listing in any affected body system, we determine, at step four, whether a person's residual functional capacity, which is the most that we expect he or she can do despite the impairment, prevents the person from performing any past relevant work that he or she has done. If the person can perform his or her past relevant work, we find that he or she is not disabled.

If the person cannot perform past relevant work, or if the person did not have any past relevant work, we go to step five of sequential evaluation. At this step, we determine whether the person

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can do other work that exists in significant numbers in the national economy. If the person cannot perform other work, we will find that he or she is disabled.

### **The listings and how we revise them:**

The Social Security Act does not require the listings, but we have been using them in one form or another since 1955. Most of the listed impairments are permanent or can be expected to result in death. For some listings, we state a specific period of time for which the impairment will meet the listing. For all others, the evidence must show the impairment has lasted or can be expected to last for a continuous period of at least 12 months. If a person has an impairment or combination of impairments that meets or medically equals the criteria in a listing, or a child has an impairment or a combination of impairments that functionally equals the listings, we allow the disability claim.

We revise the listings on an ongoing basis using the Federal rulemaking process, which is the process we are using now to propose revisions to the respiratory listings. When we update listings, we gather information. We consider information from a variety of sources, including input from advocacy groups, and information gained from formal outreach, such as public comments in response to an advance notice of proposed rulemaking, and outreach meetings with medical experts, advocates, adjudicators, and people with impairments.

### **Individuals with cystic fibrosis who apply for Social Security disability or SSI:**

Our teleconference today focuses on step 3 of the sequential evaluation process - the listings - since we are proposing new rules for evaluating respiratory disorders, including cystic fibrosis, under the listings.

We expect that adults and children with cystic fibrosis who apply for Social Security disability or SSI today, and qualify under current rules, would also qualify under the proposed rules, if they were to be published as final rules.

### **Individuals with cystic fibrosis who are currently receiving Social Security disability benefits:**

For adults and children who are already receiving Social Security benefits or SSI payments, we want to assure you that you will not lose benefits as a result of these proposed changes to the listings. When we publish final rules, we include an effective date for the rules, and we begin to use the rules on their effective date. We apply any final rules to new applications filed on or after the effective date of the rules and to claims that are pending on or after the effective date.

We follow a different process when we decide whether a beneficiary is still disabled. As you know, we must periodically review all claims to determine whether a person's disability continues. We call this action a continuing disability review, or CDR. When we do a CDR, we will not find that a person's disability has ended based on a change in a listing. Rather, when we decide if a person whose condition has medically improved is still disabled, we look at whether

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his or her impairment or combination of impairments continues to meet or medically equal the same listing we used to make our most recent favorable medical decision. This is true even if we have since changed the criteria in the listing that we used to make the most recent favorable decision.

### **Information we received from medical experts and members of the public:**

When we developed the revised medical criteria for evaluating respiratory disorders that we proposed in the notice of proposed rulemaking, or NPRM, we considered public comments that we received in response to an advance notice of proposed rulemaking that we published in the Federal Register on April 13, 2005. In this publication, we invited the public to send us written comments on and suggestions for updating the respiratory body system.

We also considered the public comments that we received at an outreach policy conference on “Respiratory Disorders in the Disability Programs” that we hosted in Chicago, Illinois, on August 25 and 26, 2005.

Additionally, we used information from a variety of sources, including:

- Medical experts in the field of pulmonology, experts in other related fields, advocacy groups for people with respiratory disorders, and people with respiratory disorders and their families;
- People who make and review disability determinations and decisions for us in State agencies, in our Office of Quality Performance, and in our Office of Disability Adjudication and Review; and
- Published sources we listed in the References section at the end of the preamble in the NPRM.

In addition, the revisions that we have proposed to the respiratory body system reflect our program experience and medical advances in evaluating respiratory disorders.

### **Information on the elements in the proposed criteria in listings 3.04 and 103.04:**

The proposed cystic fibrosis listings include:

- Listings 3.04A and 103.04A for a severe ventilatory defect demonstrated by an FEV<sub>1</sub> value, which is the volume of air exhaled in the first second of a forced expiratory maneuver, obtained by spirometry.
- Listing 3.04B for a chronic impairment of gas exchange measured by arterial blood gas tests.
- Listing 103.04B for children under age 6, who have thickening of the proximal bronchial airways, nodular-cystic lesions, segmental or lobular atelectasis, or consolidation shown on imaging.
- Listing 103.04C for children who have hypoxemia with the need for continuous oxygen supplementation.
- Listings 3.04C and 103.04D for exacerbations and complications of cystic fibrosis, such as increased cough and sputum production and increased shortness of breath, requiring

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hospitalizations for any length of time.

- And, listings 3.04D and 103.04E for acute and chronic cystic fibrosis complications that, when in specified combinations, reflect a listing-level impairment.

We want to point out that only one of these criteria requires hospitalization. It is not our intent to encourage hospitalizations when, for many people with cystic fibrosis, the standard of care may certainly be outpatient treatment.

We are currently reviewing all of the public comments we received on the respiratory NPRM. We consider those comments as we draft the final rule. We may make changes to what we have proposed based on comments we received. As a matter of fact, we find some of the comments very persuasive. If we publish final rules, we will include a summary of those relevant comments we received along with responses and an explanation of how we will apply the new rules.

**Closing:**

We want to thank you for spending the time to meet with us today. Your comments on the respiratory NPRM have given us much to think about as we work toward revising our rules for evaluating respiratory disorders. At SSA, we are committed to providing the public with excellent administration of our disability program. We acknowledge that the success of our administration of our disability program is linked to public trust. We look forward to continuing to work with you and for you as we continue to seek improvements to the disability program.

We will be posting the transcript of this teleconference on our website at [www.socialsecurity.gov/disability](http://www.socialsecurity.gov/disability) and publishing the transcript as part of the rulemaking record.

You can reach Social Security toll-free, 7 AM to 7 PM, Monday to Friday, by calling: 1-800-772-1213 (TTY 1-800-325-0778). You can call during those hours to speak to a representative or to schedule an appointment for filing an application by phone or visiting one of our local field offices.