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SOCIAL SECURITY ADMINISTRATION

20 CFR Parts 404 and 416

[Docket No. SSA-2006-0149]

RIN 0960-AF58

Revised Medical Criteria for Evaluating Respiratory System Disorders

AGENCY: Social Security Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: We propose to revise the criteria in the Listing of Impairments (listings) that we use to evaluate claims involving respiratory disorders in adults and children under titles II and XVI of the Social Security Act (Act). The proposed revisions reflect our program experience, advances in medical knowledge, and comments we received from medical experts and the public at an outreach policy conference and in response to an Advance Notice of Proposed Rulemaking (ANPRM).

DATES: To ensure that your comments are considered, we must receive them by no later than [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments by any one of three methods – Internet, fax, or mail. Do not submit the same comments multiple times or by more than one method. Regardless of which method you choose, please state that your comments refer to Docket

No. SSA-2006-0149 so that we may associate your comments with the correct regulation.

CAUTION: You should be careful to include in your comments only information that you wish to make publicly available. We strongly urge you not to include in your comments any personal information, such as Social Security numbers or medical information.

1. Internet: We strongly recommend that you submit your comments via the Internet. Please visit the Federal eRulemaking portal at http://www.regulations.gov. Use the Search function to find docket number SSA-2006-0149. The system will issue you a tracking number to confirm your submission. You will not be able to view your comment immediately because we must post each comment manually. It may take up to a week for your comment to be viewable.

2. Fax: Fax comments to (410) 966-2830.

3. Mail: Address your comments to the Office of Regulations and Reports Clearance, Social Security Administration, 107 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235-6401.

Comments are available for public viewing on the Federal eRulemaking portal at http://www.regulations.gov or in person, during regular business hours, by arranging with the contact person identified below.

FOR FURTHER INFORMATION CONTACT: Cheryl Williams, Office of Medical Listings Improvement, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235-6401, (410) 965-1020. For information on eligibility or filing for benefits, call our national toll-free number, 1-800-772-1213, or TTY 1-800-325-0778, or visit our Internet site, Social Security Online, at http://www.socialsecurity.gov.

SUPPLEMENTARY INFORMATION:

What revisions are we proposing?

We propose to:

- Revise and expand the introductory text to the respiratory system listings for both adults (section 3.00) and children (section 103.00);

- Remove reference listings; and

- Update the listing criteria to reflect medical advances in evaluating respiratory disorders.

Why are we proposing these revisions and on what information are they based?

We are proposing these revisions to reflect our program experience and medical advances in evaluating respiratory disorders. We last published final rules making comprehensive revisions to section 3.00--the respiratory system listings for adults (people who are at least 18 years old)--and section 103.00--the respiratory system listings for children (people under age 18)--on October 7, 1993.[1] In the preamble to those rules, we indicated that we would periodically review and update the listings in light of medical advances and our program experience. Since that time, however, we have only extended the effective date of the rules.[2]

In developing these proposed rules, we considered the public comments that we received in response to an ANPRM that we published in the Federal Register on April 13, 2005.[3] In the ANPRM, we announced our plans to update and revise this body system, and we invited interested people and organizations to send us written comments and suggestions. We also received public comments at an outreach policy conference on "Respiratory Disorders in the Disability Programs" that we hosted in Chicago, Illinois, on August 25-26, 2005.[4]

In developing these proposed rules, we also used information from a variety of

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[1] 58 FR 52346; corrected at 59 FR 1274 (January 10, 1994). These listings appear in appendix 1 to subpart P of part 404.

[2] See 65 FR 57946 (2000), 67 FR 43537 (2002), 68 FR 36911 (2003), 70 FR 35028 (2005), 72 FR 33662 (2007), and 73 FR 31025 (2008). The current listings will no longer be effective as of July 2, 2012 unless we extend them. 75 FR 33166 (2010).

[3] 70 FR 19358 (2005).

[4] Although we indicated in the ANPRM that we would not summarize or respond to the comments, we read and considered them carefully. You can read the ANPRM, the comments we received in response to the ANPRM, and a transcript of the policy conference at http://www.regulations.gov. Use the Search function to find docket number SSA-2006-0149.

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

- The published sources we list in the References section at the end of this preamble.

We describe in more detail below the revisions we propose to make to the introductory text of the adult listings, the adult listings text, the introductory text of the childhood listings, and the childhood listings text.

What changes are we proposing to the introductory text of the respiratory disorders listings for adults?

In the following paragraphs, we describe the significant changes we propose to make to the introductory text of the adult respiratory listings in part A of appendix 1 to subpart P of part 404 using the order of the current introductory text.

Section 3.00A

We propose to reorganize and revise current 3.00A (Introduction) by creating separate sections for easier reference. These sections include the following: The kinds of disorders we evaluate in this body system (proposed 3.00A); the common signs and symptoms of respiratory disorders (proposed 3.00B); the abbreviations we use in this body system (proposed 3.00C); and the documentation we may need to evaluate respiratory disorders (proposed 3.00D).

We propose to clarify our guidance regarding documentation of respiratory disorders. For example, we state in proposed 3.00D1 that we may not need all of the different kinds of medical evidence we describe in that paragraph, depending upon the person's particular respiratory disorder and its effects on the person. We would also clarify in proposed 3.00D1 that medical evidence should include descriptions of any prescribed treatment and the response to it. We are including this provision because treatment may have improved a person's functional status. As under our current rules, however, we would not require a person to receive treatment to show the existence of an impairment that meets the criteria of a listing.

We also propose to add section 3.00S (How do we evaluate respiratory disorders that do not meet one of these listings?). For easier reference and to conform to the order in which this guidance appears in other body systems, we would include this guidance in

a new section at the end of the introductory text rather than in section 3.00A as it now appears in the current introductory text.

Section 3.00B

We propose to revise current 3.00B (Mycobacterial, mycotic, and other chronic persistent infections of the lung) and redesignate it as 3.00R (How do we evaluate mycobacterial, mycotic, and other chronic infections of the lungs?). We also propose to clarify that we would evaluate chronic infections of the lungs under 3.02.

Section 3.00C

We propose to remove current 3.00C (Episodic respiratory disease), which explains how we evaluate respiratory disorders that can be episodic in nature, such as asthma, cystic fibrosis (CF), and bronchiectasis. For easier reference, we would create separate sections for each of these disorders. The proposed sections are: 3.00I (What is asthma, and how do we evaluate it?), 3.00J (What is CF, and how do we evaluate it?), and 3.00L (What is bronchiectasis, and how do we evaluate it?). In these sections, we explain the nature of each disorder, the evidence we need to document the disorder, and how we would evaluate the disorder under the applicable listing.

Several of the proposed listings for episodic disorders would require a specific number of events within a 12-month period. We provide additional information about this

requirement in proposed 3.00O (How do we evaluate episodic respiratory disorders?). This guidance describing the 12-month period is not in current 3.00C.

Section 3.00D

As a result of the proposed changes to current 3.00C described above, we propose to revise current 3.00D (Cystic fibrosis) and redesignate it as 3.00J.

Sections 3.00E and 3.00F

We propose to reorganize and revise current 3.00E (Documentation of pulmonary function testing) and current 3.00F (Documentation of chronic impairment of gas exchange), by creating separate sections for three major types of pulmonary function tests (PFTs). The proposed sections for these tests are: Spirometry (3.00E, What is spirometry, and what are our requirements for an acceptable test and report?), diffusing capacity of the lungs for carbon monoxide (DLCO) (3.00F, What is a DLCO test, and what are our requirements for an acceptable test and report?), and arterial blood gas (ABG) testing (3.00G, What is an ABG test, and what are our requirements for an acceptable test and report?). In each of these sections, we explain the nature of each test and simplify our documentation requirements for an acceptable test and report.

We propose to modify some of our current documentation requirements for spirometry, which simply restate testing standards. Such testing standards are usually not

documented in medical records, and our program experience has shown that there is no need to require verification that the person administering the test followed such testing standards. For example, we would no longer require proof of equipment calibration on the day of the spirometric measurement because we believe that we can reasonably presume that the device has been properly calibrated. Daily equipment calibration is the current standard of care for providers who administer spirometry, and in our experience that standard of care has been met.

We would also no longer require the spirometric tracings for the satisfactory forced expiratory maneuvers. The current standard of care requires the performance of at least three satisfactory forced expiratory maneuvers. The person administering the test uses the spirometric tracings to determine whether the maneuvers are satisfactory before reporting the person's highest values. This modification would be consistent with our documentation requirements in other areas where we routinely rely on the reports of test results rather than require additional documentation to enable independent verification. For example, we rely on findings referenced in radiologists' reports; we do not require the x-rays to verify those findings independently.

We believe that these modifications of our current spirometry documentation requirements may reduce the number of CEs we purchase and decrease case processing time without affecting the quality of our determinations and decisions. We are specifically interested in any comments and suggestions you have about the proposed modifications to our current spirometry documentation requirements.

We also propose to remove the requirement that our program physician must determine whether obtaining a particular PFT would present a significant risk to the person because this requirement is redundant of our other regulations that require a program physician to approve the ordering of a test whenever there is any significant risk. See 20 CFR 404.1519m and 416.919m. However, we would include a reminder in each of the proposed sections on PFTs that the medical source we designate to administer the particular PFT is solely responsible for deciding whether it is safe for the person to do the test and for how to administer the test. This provision is consistent with our current regulations, which provide that the responsibility for deciding whether to administer the test rests with the medical source designated to perform the consultative examination.

We explain in proposed 3.00G3a that we would not purchase exercise ABG tests. Spirometry, DLCO tests, resting ABG tests, and pulse oximetry offer a sufficiently comprehensive range of PFTs to properly evaluate respiratory disorders. Therefore, we propose to remove current 3.00F3 and 3.00F4, which explain our rules for exercise testing with ABGs we may purchase under the current listings, because we would no longer need these sections.

We also propose to provide guidance on the use of pulse oximetry in proposed 3.00H (What is pulse oximetry, and what are our requirements for an acceptable test and report?). We explain the nature of the test and our documentation requirements for an acceptable test and report. We believe that, to evaluate impairments of gas exchange, we

may substitute an acceptable pulse oximetry test for DLCO and ABG tests, which are often difficult to obtain. Pulse oximetry is a simple, non-invasive method of assessing a person's respiratory function by measuring the oxygen saturation of arterial blood. To increase the reliability and validity of pulse oximetry results, we would require a graphical printout showing the oximetry values concurrently with the pulse (see proposed 3.00H3b). A pulse wave helps ensure that the associated pulse oximetry value is a true measure of the oxygen saturation of arterial blood and not the result of certain artifactual inaccuracies, such as movement. We recognize that printouts of pulse readings are not routinely done in pulse oximetry. Thus, we expect that we would use only pulse oximetry that we purchase to determine that an impairment meets proposed 3.02C4 or 3.04D4.

We provide guidance in proposed 3.00K (What is respiratory failure, and how do we evaluate it?) for the evaluation of respiratory failure because we are proposing a new separate listing, proposed 3.14 (Respiratory failure), and we include a criterion for respiratory failure associated with CF in proposed 3.04D2. Respiratory failure requiring continuous assisted (mechanical) ventilatory support for the period specified in 3.04D2 and 3.14 reflects the failure of the lungs to perform their basic function of gas exchange and is a serious complication regardless of the underlying chronic respiratory disorder.

Section 3.00G

We propose to redesignate and revise current 3.00G (Chronic cor pulmonale and pulmonary vascular disease) to proposed 3.00M (What is chronic pulmonary

hypertension, and how do we evaluate it?) to reflect current medical terminology for this disorder. We explain the nature of the disorder and our documentation requirements under proposed 3.09.

Section 3.00H

We propose to redesignate and revise current 3.00H (Sleep-related breathing disorders) to proposed 3.00Q (What are sleep-related breathing disorders, and how do we evaluate them?). Since we propose to remove current 3.10 (Sleep-related breathing disorders), we would further explain the nature of sleep-related breathing disorders and their complications, including how we evaluate those complications under the affected body system(s). We also state that we would not purchase a polysomnography test to evaluate a sleep-related breathing disorder.

Section 3.00I

We propose to redesignate and revise current 3.00I (Effects of obesity) to proposed 3.00P (How do we consider the effects of obesity when we evaluate your respiratory disorder?). We also propose minor editorial revisions in this section.

Section 3.00N

We propose to add 3.00N (How do we evaluate lung transplantation?) to explain

how we would evaluate a respiratory disorder after a person has received a lung transplant. Under current 3.11, we consider a person who has received a lung transplant to be disabled for 1 year after the date of transplantation. We propose to extend that time to 3 years. We base this proposal on a recommendation we received at our policy conference and on our program experience. The revision would recognize that, although most lung transplant recipients do well within 1 year of transplantation, nearly all deteriorate after 1 year. We also explain that lung transplant patients generally have impairments that meet our definition of disability before they get their transplants. This section would clarify that we may decide that a lung transplant recipient's disability began before the impairment met proposed 3.11. We would determine the onset of disability based on the facts of the case.

What changes are we proposing to the respiratory disorders listings for adults?

The following chart provides a comparison of the current adult listings and the proposed listings.

Current	Proposed
3.02 Chronic pulmonary insufficiency	3.02 Chronic respiratory disorders
3.03 Asthma	3.03 Asthma
3.04 Cystic fibrosis	3.04 Cystic fibrosis
3.05 [Reserved]	3.05 [Reserved]
3.06 Pneumoconiosis	3.06 [Reserved]

	Would be evaluated under proposed 3.02
3.07 Bronchiectasis	3.07 Bronchiectasis
3.08 Mycobacterial, mycotic, and other chronic persistent infections of the lung	3.08 [Reserved] Would be evaluated under proposed 3.02
3.09 Cor pulmonale secondary to chronic pulmonary vascular hypertension	3.09 Chronic pulmonary hypertension due to any cause
3.10 Sleep-related breathing disorders	3.10 [Reserved] Would be evaluated under a listing in the affected body system
3.11 Lung transplant	3.11 Lung transplantation
	3.12 [Reserved]
	3.13 [Reserved]
	3.14 Respiratory failure

We are proposing to remove current 3.06 (Pneumoconiosis), 3.07A (for bronchiectasis that results in pulmonary insufficiency), 3.08 (Mycobacterial, mycotic, and other chronic persistent infections of the lung), 3.09B (for cor pulmonale), and 3.10 (Sleep-related breathing disorders). These listings simply cross-refer to other listings and do not contain separate medical criteria. We would instead evaluate these disorders under proposed 3.02, another respiratory listing, or another listing in an affected body system. For example, we are including a reference to pneumoconiosis in proposed 3.00A1.

We describe the significant changes to the respiratory listings for adults below,

using the headings of the proposed listings.

Listing 3.02, Chronic respiratory disorders

We propose to make the following changes to current 3.02, which we use to evaluate chronic respiratory disorders that impair lung function, except for CF:

- Revise the heading of current 3.02, (Chronic pulmonary insufficiency), to Chronic respiratory disorders, to simplify our terminology. We also propose to clarify that this listing does not apply to people with CF because we would continue to have a separate listing to evaluate that disorder.

- Revise and reorganize current 3.02. Depending on the nature of the disorder, we may use the results of a number of PFTs to assess the severity of a person's respiratory disorder under 3.02. We explain each of these PFTs and our documentation requirements in proposed 3.00D, 3.00E, 3.00F, 3.00G, and 3.00H.

- Add categories for age and gender to the spirometry tables and modify the spirometry values for 3.02A (forced expiratory volume (FEV_1)) and 3.02B (forced vital capacity (FVC)) to recognize the differences in predicted normal values between females and males. We base the tables on reference values from Hankinson, et al.,[5] who used data

[5] Hankinson, J. L., Odencrantz, J. R., & Fedan, K. B. (1999). Spirometric reference values from a sample of the general U.S. population. American Journal of Respiratory and Critical Care Medicine, 159(1), 179-187. We relied on reference values from Hankinson, et al., in modifying all of the spirometric

from the Third National Health and Nutrition Examination Survey conducted by the Centers for Disease Control and Prevention (CDC).

- Revise the height categories in the spirometry tables to provide equivalent values for height both in centimeters and in inches.

- Provide separate tables for people age 18 to the attainment of age 20 (proposed tables I-A and II-A) and age 20 and older (proposed tables I-B and II-B) under proposed 3.02A and 3.02B to account for the continuing physical maturation process for such young adults.

- Remove the term "chronic obstructive pulmonary disease" from 3.02A and the term "chronic restrictive ventilatory disease" from current 3.02B, but retain revised FEV_1 and FVC tables (proposed tables I and II) for evaluating certain chronic respiratory disorders, except CF. A chronic respiratory disorder may be obstructive, restrictive, or a combination of both. The distinction is not important for our adjudicative purposes.

- Add a table (proposed table III) for evaluating chronic respiratory disorders under proposed 3.02C1 using DLCO. We are proposing this change because we believe that we need to provide specific values that account for a person's gender and height, as we do for the spirometry criteria under 3.02A and 3.02B.

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tables referenced in our proposed rules.

- Add a listing (proposed 3.02C4) based on a combination of pulse oximetry and spirometry results. The new listing would reflect technological advancements in the assessment of respiratory disorders that affect gas exchange impairment. We believe that, because of these advancements, we are now able to accept pulse oximetry, subject to the requirements in proposed 3.00H, as an alternative method for the assessment of respiratory disorders. We would also provide separate tables for the necessary spirometry values in proposed 3.02C4b(i) (tables V-A and V-B) and 3.02C4b(ii) (tables VI-A and VI-B).

Listing 3.03, Asthma

We propose to make the following changes to current 3.03:

- Remove current 3.03A because it only cross-refers to current 3.02A.

- Move the requirement for baseline airflow obstruction from current 3.00C to proposed 3.03A and add spirometry criteria to the proposed listing (using the spirometry values in proposed tables V-A and V-B) to quantify the degree of baseline airflow obstruction.

- Use the term "exacerbations" in proposed 3.03B, instead of "attacks," the term we use in current 3.03B, because we believe the term "exacerbations" provides a clearer and more medically appropriate description of the asthmatic condition.

- Revise the length of hospitalization due to an exacerbation of asthma from at least 24 hours to at least 48 hours, including hours in an emergency department immediately before the hospitalization. We would also require at least 30 days between each hospitalization to be certain that each exacerbation is a separate event. This provision for requiring at least 30 days between events is consistent with the criteria in similar listings in other body systems.

- Require three hospitalizations instead of exacerbations requiring outpatient physician intervention occurring every 2 months or at least six times a year. Based on the advice of medical experts and our program experience, we believe such interventions do not accurately identify people with listing-level impairments.

- Remove the requirement that an exacerbation occur despite following prescribed treatment. We would consider any hospitalization for an exacerbation of asthma lasting at least 48 hours to be despite prescribed treatment, unless we have evidence to the contrary.

- Add a criterion that we would consider a person to be disabled for 1 year from the discharge date of the last hospitalization. Our program experience has shown that people who have experienced the type of exacerbations in proposed 3.03B need a period of 1 year for medical improvement to occur.

Listing 3.04, Cystic fibrosis

We propose to make the following changes to current 3.04:

- Add categories for age and gender to the spirometry tables and modify the values in proposed 3.04A (FEV_1) to recognize the differences in predicted normal values between females and males.

- Provide separate tables for people age 18 to the attainment of age 20 (proposed table VII-A) and age 20 and older (proposed table VII-B) under proposed 3.04A to account for the continuing physical maturation process for such young adults.

- Require a less severe ventilatory defect for listing-level impairment in proposed 3.04A in recognition of the fact that people with CF are disabled at a comparatively higher level of lung function than others who do not have CF.

- Add criteria for evaluating a chronic impairment of gas exchange to include ABG test values for the evaluation of CF (proposed 3.04B).

- Replace current 3.04B (for episodes of bronchitis, pneumonia, hemoptysis, or respiratory failure) and current 3.04C (for persistent pulmonary infection) with proposed 3.04C, for exacerbations and complications of CF, and revise the criteria for how we consider hospitalizations under this proposed listing. We do not specify a minimum

length of hospitalization because hospitalizations for exacerbations and complications of CF are invariably long enough for purposes of our listings. For complications of bronchitis, pneumonia, or hemoptysis (more than blood-streaked sputum), in people with CF, we would no longer consider physician interventions, either as an outpatient or in an emergency department. When these types of complications in CF occur, they are too severe to treat on an outpatient basis. We consider this level of severity more reflective of a listing-level impairment.

- Provide an expanded list of acute and chronic CF complications that, when in specified combinations, reflect a listing-level impairment under proposed 3.04D. We would add the following criteria for acute CF complications: Spontaneous pneumothorax requiring chest tube treatment (proposed 3.04D1), respiratory failure requiring continuous assisted ventilation (proposed 3.04D2), and pulmonary hemorrhage requiring vascular embolization (proposed 3.04D3). We would also add the following criteria for chronic CF complications: Hypoxemia (proposed 3.04D4), weight loss accompanied by certain other requirements for a specified period (proposed 3.04D5), and CF-related diabetes (CFRD, proposed 3.04D6). We may also evaluate any of these complications under proposed 3.04C if they result in hospitalization.

Listing 3.07, Bronchiectasis

We propose to revise current 3.07, Bronchiectasis, by removing the criterion for outpatient physician intervention in current 3.07B for the same reason we propose to

remove the criterion from current 3.03B. We would include the same requirement for hospitalizations due to exacerbations or complications of bronchiectasis as in proposed 3.03B.

Listing 3.09, Chronic pulmonary hypertension due to any cause

We propose to rename and revise current 3.09, Cor pulmonale secondary to chronic pulmonary vascular hypertension, to Chronic pulmonary hypertension due to any cause, to reflect current medical terminology. We propose to remove the criterion for arterial hypoxemia (current 3.09B) because it only cross-refers to 3.02C2, and we are removing all reference listings. We would revise the criteria in current 3.09A for pulmonary mean artery pressure determined by cardiac catheterization to include 40 mm Hg based on a recommendation by the Institute of Medicine in its report, Cardiovascular Disability - Updating the Social Security Listings.[6]

We would add criteria in proposed 3.09B for systolic pulmonary artery pressure determined by echocardiogram. We have determined that the criteria we are proposing for echocardiography results would also be acceptable for our purposes, and we see the results of this kind of testing in medical evidence more often than cardiac catheterization. Thus, the proposed listing would help us to adjudicate some cases more quickly while still maintaining the accuracy of our adjudications.

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[6] Institute of Medicine. (2010). Cardiovascular disability: Updating the Social Security listings. Washington, DC: The National Academies Press.

Listing 3.11, Lung transplantation

We propose to rename and revise current 3.11 to be consistent with similar listings in other body systems. For reasons we have already explained, we also propose to extend the period for which the impairment would meet the listing from 1 year to 3 years. After that, we will evaluate the residual impairment(s) a person has to determine if he or she is still disabled. This provision for evaluating the residual impairment(s) is the same as in current 3.11 and is consistent with the criteria in similar listings in other body systems.

Listing 3.14, Respiratory failure

We propose to add 3.14, Respiratory failure, to provide criteria that recognize the medical severity of respiratory disorders that lead to two or more episodes of respiratory failure requiring continuous assisted ventilation for a specified period within a 12-month period.

What changes are we proposing to the introductory text of the respiratory disorders listings for children?

The same basic rules for evaluating respiratory disorders in adults also apply to children. Except for minor editorial changes to make the text specific to children, we have repeated much of the introductory text of proposed 3.00 in the introductory text of

proposed 103.00, although we provide fewer sections because we provide fewer childhood listings. Since we have already described these proposed rules under the explanation of proposed 3.00, we describe here only sections of the proposed rules that are unique to children or that require further explanation.

- We would remove the guidance regarding ABGs and pulse oximetry in current section 103.00C because we do not include this testing as a criterion in the proposed childhood listings. However, in the rare case where ABG or pulse oximetry results are in the medical evidence, we would consider these results in determining disability.

- In proposed section 103.00E (What is spirometry, and what are our requirements for an acceptable test and report?), we explain that before we purchase spirometry for children, a medical consultant, preferably one experienced in the care of children with respiratory disorders, must review the case record to determine if we need the test. Unlike adults, children do not routinely undergo spirometry, and we recognize that the decision to obtain spirometry for assessing disability in children involves medical expertise.

- We would redesignate and revise current 103.00E (Bronchopulmonary dysplasia (BPD)) to proposed 103.00F (What is CLD, and how do we evaluate it?). The change would reflect current medical terminology. There have been advances in the treatment and management of chronic lung disease of infancy (CLD), and we no longer

believe it is appropriate to find disability in all infants with CLD whose impairments meet the criteria of current 103.02E at birth or shortly after birth. Within the first 6 months of life, most infants with CLD improve and are successfully weaned from assisted ventilation and oxygen supplementation. The proposed rule provides that, if an infant with CLD receives oxygen supplementation, we would not evaluate the CLD under proposed 103.02C until he or she has attained age 6 months. If the child was born prematurely, we would use a corrected chronological age. The infant would need to be on oxygen supplementation then or afterwards to have CLD that meets this proposed listing. We also provide that we may make a fully favorable determination before age 6 months under other rules. For a child from birth up to the attainment of age 2, we would evaluate the frequency of the child's CLD exacerbations or related complications that require hospitalization under proposed 103.02E. After the child attains age 2, we would evaluate the CLD under the proposed 103.03 asthma listing.

- We would add guidance in proposed 103.00H (What is CF, and how do we evaluate it?) that is the same as in proposed 3.00J. We also indicate in proposed 103.00H7 that we can evaluate CF-related growth failure under 100.00 or 105.00, and CFRD under 109.00 or under another body system affected by the disorder.

- We would add proposed 103.00J (How do we evaluate growth failure due to any chronic respiratory disorder?) because we are removing current 103.02E6, 103.02F2, 103.02H, 103.03D, and 103.04E. We explain that we may evaluate growth failure under a growth impairment listing in 100.00 or under 105.00.

What changes are we proposing to the respiratory disorders listings for children?

The proposed childhood respiratory listings are designated 103.02, 103.03, 103.04, 103.11, and 103.14. They have the same headings as their counterparts in the proposed adult listings. Some of the criteria we propose for children are the same as, or based on, the current childhood respiratory criteria. For example, proposed 103.02D includes the same rule for children under age 3 who have tracheostomies as in current 103.02D, but also includes a new rule for children age 3 and older.

We are not proposing childhood rules to correspond to proposed adult listings 3.07 (for bronchiectasis) and 3.09 (for chronic pulmonary hypertension due to any cause). Bronchiectasis in children is not a distinct disorder as it is in adults, but is associated with CF, which we would evaluate under 103.04. Chronic pulmonary hypertension is unusual in children, but when it does occur, we can evaluate it under the adult listings or under 104.02 for chronic heart failure.

Listing 103.02, Chronic respiratory disorders

We propose to make the following changes to current 103.02:

- Revise the heading of current 103.02, Chronic pulmonary insufficiency, to Chronic respiratory disorders, to parallel what we proposed in 3.02 for adults because we

apply the same principles to children as we do for adults.

- Add categories for age and gender to the spirometry tables for children age 13 to the attainment of age 18 and modify the spirometry tables in 103.02A and 103.02B to recognize the differences in predicted normal values between females and males that start at puberty. For children age 6 to the attainment of age 13, we propose to add spirometry values without a distinction for gender, as prepubertal females and males have similar normal spirometry values. We do not include values for children under age 6 in our proposed tables because we do not expect those children to have undergone spirometric testing, and predicted normal values have not been established for this age group.

- Provide FEV_1 and FVC values for females and males age 13 to the attainment of age 18.

- Increase the number of height categories in the spirometry tables in 103.02A and 103.02B to provide better differentiation by height for listing-level impairments, and provide equivalent values for height both in centimeters and in inches.

- Remove current 103.02C1 (the frequent need for "mechanical ventilation") because we are proposing 103.14 for respiratory failure requiring continuous assisted ventilation and defining what we mean by how frequently such failure must occur under the listing.

- Revise the criterion for oxygen supplementation in current 103.02C2, and specify in proposed 103.02C the amount and duration of oxygen supplementation that is listing-level for children.

- Replace current 103.02E with the same requirement for three hospitalizations in a 12-month period as in other proposed listings. We would remove current 103.02E1 through 103.02E4 because these criteria are out of date. Due to advances in pediatric therapy, the clinical and radiographic findings and the bronchodilator and diuretic therapies in the current listing no longer reflect listing-level severity for CLD.

- Remove current 103.02E5 because we would evaluate the need for supplemental oxygen under proposed 103.02C.

- Remove current 103.02E6, which refers to involuntary weight loss or failure to gain weight at an appropriate rate, because we would evaluate growth failure due to any chronic respiratory disorder (not just CLD) under a growth impairment listing in 100.00 or under 105.00. We also provide that we would consider a child whose impairment meets 103.02E under a disability for 1 year from the discharge date of the last hospitalization or until the attainment of age 2, whichever is later, after which we would evaluate the impairment(s) under 103.03 or as otherwise appropriate. This is because CLD exacerbations after age 2 are clinically similar to asthmatic exacerbations, and medical treatment is the same as for asthma.

- Remove current 103.02F because we would evaluate hospitalizations due to a chronic respiratory disorder under proposed 103.02E and growth failure due to any chronic respiratory disorder under a growth listing in 100.00 or under 105.00.

- Remove current 103.02G, for chronic hypoventilation or chronic cor pulmonale. Chronic hypoventilation of the magnitude in current 103.02G (elevated P_aCO_2) is likely to be treated as respiratory failure, which we would evaluate under proposed 103.14, Respiratory failure. For chronic cor pulmonale, we only cross-refer to current 104.02, and we are removing all reference listings.

- Remove current 103.02H, which is a reference listing to 100.00. We would evaluate growth failure under a growth impairment listing in 100.00 or under 105.00.

Listing 103.03, Asthma

We propose to make the following changes to current 103.03:

- Provide the same listing criteria as in proposed 3.03B for adults. Current 103.03A is based on spirometry, and physicians rarely obtain spirometry for children with asthma because these children often have normal spirometry between asthma exacerbations. However, in the rare case where spirometry results are in the medical evidence, we would consider these results in determining disability.

- Remove current 103.03C because it is out of date. Persistent low-grade wheezing, nocturnal use of bronchodilators, and short-course steroids (current 103.03C) are no longer reliable indicators of listing-level severity.

- Remove current 103.03D because it only cross-refers to 100.00.

Listing 103.04, Cystic fibrosis

We propose to make the following changes to current 103.04:

- Add categories for age and gender to the spirometry tables for children age 13 to the attainment of age 18 and modify the spirometry tables in 103.04A to recognize the differences in predicted normal values between females and males starting at puberty. For children age 6 to the attainment of age 13, we would add spirometry values without a distinction for gender because prepubertal females and males have similar normal spirometry values.

- Revise and reorganize current 103.04B to clarify that the criteria in proposed 103.04B apply only to children under age 6 (that is, children who cannot have pulmonary function testing). We would require findings of abnormalities on imaging in every case because imaging is essential for identifying such abnormalities. We would also revise current 103.04B1 into two separate criteria for clarity and remove the criterion for cyanosis, which we would evaluate under proposed 103.04C.

- Add criteria for hypoxemia documented by a specified level of continuous oxygen supplementation in proposed 103.04C to parallel what we propose in 103.02C for chronic respiratory disorders due to any cause except CF.

- Remove current 103.04E for growth impairment (a reference listing to 100.00), and replace it with proposed 103.04E5 for weight loss in combination with another CF complication. We agreed with CF experts at our policy conference who told us that the decision to initiate and continue supplemental enteral or parenteral nutrition indicates a serious worsening of CF and in combination with another CF complication represents a listing-level impairment. We may also evaluate growth failure under a growth impairment listing in 100.00 or under 105.00.

Other change

We also propose to remove the first example of functional equivalence from 20 CFR 416.926a(m), which is for a documented need for major organ transplant. We no longer need this example because our rules now include specific listings for the major organs that can be transplanted.

What is our authority to make rules and set procedures for determining whether a person is disabled under the statutory definition?

Under the Act, we have full power and authority to make rules and regulations and to establish necessary and appropriate procedures to carry out such provisions. Sections 205(a), 702(a)(5), and 1631(d)(1).

How long would these proposed rules be effective?

If we publish these proposed rules as final rules, they will remain in effect for 5 years after the date they become effective, unless we extend them, or revise and issue them again.

Clarity of These Proposed Rules

Executive Order 12866, as supplemented by Executive Order 13563, requires each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make them easier to understand.

For example:

- Would more, but shorter sections be better?
- Are the requirements in the rules clearly stated?
- Have we organized the material to suit your needs?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?

- Do the rules contain technical language or jargon that is not clear?
- Would a different format make the rules easier to understand, e.g., grouping and order of sections, use of headings, paragraphing?

When will we start to use these rules?

We will not use these rules until we evaluate public comments and publish final rules in the Federal Register. All final rules we issue include an effective date. We will continue to use our current rules until that date. 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.

Regulatory Procedures

Executive Order 12866, as supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that these proposed rules meet the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB reviewed them.

Regulatory Flexibility Act

We certify that these proposed rules would not have a significant economic impact on a substantial number of small entities because they affect individuals only. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

These proposed rules do not create any new or affect any existing collections and do not require OMB approval under the Paperwork Reduction Act.

References

We consulted the following references when we developed these proposed rules:

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In addition, the American Thoracic Society (ATS) (www.thoracic.org) and the European Respiratory Society (ERS) (dev.ersnet.org) published the following joint statements:

– (2004). Standards for the diagnosis and treatment of patients with COPD: A summary of the ATS/ERS position paper. European Respiratory Journal, 23, 932-946.

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– (2005). General considerations for lung function testing. European Respiratory Journal, 26, 153-161. doi:10.1183/09031936.05.00034505

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– (2005). Standardisation of the single-breath determination of carbon monoxide uptake in the lung. European Respiratory Journal, 26, 720-735. doi:10.1183/09031936.05.00034905

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We will make these references available to you for inspection if you are interested in reading them. Please make arrangements with the contact person shown in this preamble if you would like to review any reference materials.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security — Disability Insurance; 96.002, Social Security — Retirement Insurance; 96.004, Social Security — Survivors Insurance; and 96.006, Supplemental Security Income).

List of Subjects

20 CFR Part 404

Administrative practice and procedure; Blind, Disability benefits; Old-Age, Survivors, and Disability Insurance; Reporting and recordkeeping requirements; Social Security.

20 CFR Part 416

Administrative practice and procedure; Aged, Blind, Disability benefits; Public assistance programs; Reporting and recordkeeping requirements; Supplemental Security Income (SSI).

Dated: January 25, 2013

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Michael J. Astrue,
Commissioner of Social Security.

For the reasons set out in the preamble, we propose to amend 20 CFR part 404 subpart P and part 416 subpart I as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950-)

Subpart P—[Amended]

1. The authority citation for subpart P of part 404 is revised to read as follows:

Authority: Secs. 202, 205(a)-(b) and (d)-(h), 216(i), 221(a), (i), and (j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)-(b) and (d)-(h), 416(i), 421(a), (i), and (j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104-193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108-203, 118 Stat. 509 (42 U.S.C. 902 note).

2. Amend appendix 1 to subpart P of part 404 by revising item 4 of the introductory text before part A of appendix 1 to read as follows:

APPENDIX 1 TO SUBPART P OF PART 404—LISTING OF IMPAIRMENTS

* * * * *

4. Respiratory Disorders (3.00 and 103.00): [DATE 5 YEARS FROM THE

EFFECTIVE DATE OF THE FINAL RULES].

* * * * *

3. Amend part A of appendix 1 to subpart P of part 404 by revising the body system name for section 3.00 in the table of contents to read as follows:

Part A

* * * * *

3.00 Respiratory Disorders.

* * * * *

4. Revise section 3.00 in part A of appendix 1 to subpart P of part 404 to read as follows:

* * * * *

3.00 RESPIRATORY DISORDERS

A. What disorders do we evaluate in this body system?

1. We evaluate respiratory disorders that result in obstruction (difficulty moving air out of the lungs) or restriction (difficulty moving air into the lungs), or that interfere with diffusion (gas exchange) across cell membranes in the lungs. Examples of such disorders and the listings we use to evaluate them include chronic obstructive pulmonary disease (primarily, chronic bronchitis and emphysema) (3.02), pulmonary fibrosis and pneumoconiosis (3.02), asthma (3.02 and 3.03), cystic fibrosis (3.04), and bronchiectasis (3.02 and 3.07). We also use listings in this body system to evaluate recurrent episodes of respiratory failure (3.04D2 and 3.14), chronic pulmonary hypertension due to any cause (3.09), and lung transplantation (3.11).

2. We evaluate cancers affecting the respiratory system under the malignant neoplastic diseases listings in 13.00. We evaluate neuromuscular disorders affecting the respiratory system under the neurological listings in 11.00 or under the immune system disorders listings in 14.00.

B. What are common signs and symptoms of respiratory disorders? Common signs and symptoms of respiratory disorders are shortness of breath, coughing, wheezing, sputum production, hemoptysis (coughing up blood from the respiratory tract), and chest pain.

C. What abbreviations do we use in this body system?

1. ABG means arterial blood gas.

2. BTPS means body temperature and ambient pressure, saturated with water vapor.

3. CF means cystic fibrosis.

4. CFRD means CF-related diabetes.

5. CO means carbon monoxide.

6. COPD means chronic obstructive pulmonary disease.

7. DLCO means diffusing capacity of the lungs for carbon monoxide.

8. FEV_1 means forced expiratory volume in the first second of a forced expiratory maneuver.

9. FVC means forced vital capacity.

10. L means liter.

11. mL CO (STPD)/min/mmHg means milliliters of carbon monoxide in standard

temperature and pressure, dry, per minute, per millimeters of mercury.

12. P_aO_2 means arterial blood partial pressure of oxygen.

13. P_aCO_2 means arterial blood partial pressure of carbon dioxide.

14. S_pO_2 means percentage of oxygen saturation of blood hemoglobin, as measured by pulse oximetry.

15. 6MWT means six-minute walk test, which is a standardized test of sub-maximal exercise ability in people with heart and respiratory disorders.

16. VI means volume of inhaled gas.

D. What documentation do we need to evaluate your respiratory disorder?

1. We need medical evidence to assess the effects of your respiratory disorder. Medical evidence should include your medical history, physical examination findings, the results of imaging (see 3.00D2), pulmonary function tests (see 3.00D3), other relevant laboratory tests, and descriptions of any prescribed treatment and your response to it. If you use supplemental oxygen, we still need medical evidence to establish the severity of your respiratory disorder. We may not need all of this information depending upon your particular respiratory disorder and its effects on you.

2. Imaging refers to medical imaging techniques, such as x-ray, computerized tomography, and echocardiography. The imaging must be consistent with the prevailing state of medical knowledge and clinical practice as the proper technique to support the evaluation of the disorder.

3. Pulmonary function tests include spirometry (which measures ventilation of the lungs), DLCO tests (which measures gas diffusion in the lungs), ABG tests (which measure dissolved oxygen and carbon dioxide in the arterial blood), and pulse oximetry (which measures oxygen saturation of hemoglobin in the blood). Pulmonary function tests must be conducted in accordance with the most recently published standards of the American Thoracic Society (ATS).

E. What is spirometry, and what are our requirements for an acceptable test and report?

1. Spirometry measures how well you move air into and out of your lungs. In accordance with ATS testing standards, spirometry involves at least three forced expiratory maneuvers. A forced expiratory maneuver is a maximum inhalation followed by a forced maximum exhalation, and measures exhaled volumes of air over time. The volume of air you exhale in the first second of the forced expiratory maneuver is the FEV_1. The total volume of air that you exhale during the entire forced expiratory maneuver is the FVC. We use your highest FEV_1 value to evaluate your respiratory

disorder under 3.02A, 3.02C4b(i), 3.03A, and 3.04A. We use your highest FVC value to evaluate your respiratory disorder under 3.02B and 3.02C4b(ii).

2. We have the following requirements for spirometry under these listings:

a. You must be medically stable at the time of the test. Examples of when we would not consider you to be medically stable include when you are:

(i) Within 2 weeks of a change in your prescribed respiratory medication.

(ii) Experiencing, or within 30 days of completion of treatment for, a lower respiratory tract infection.

(iii) Experiencing, or within 30 days of completion of treatment for, an acute exacerbation (temporary worsening) of a chronic respiratory disorder. Chronic wheezing by itself does not indicate that you are not medically stable.

(iv) Hospitalized for, or within 30 days of a hospital discharge for, an acute myocardial infarction (heart attack).

b. During testing, if your FEV_1 is less than 70 percent of your predicted normal value, we require repeat spirometry after inhalation of a bronchodilator to evaluate your respiratory disorder under these listings, unless it is medically contraindicated. If you

used a bronchodilator before the test and your FEV_1 is less than 70 percent of your predicted normal value, we still require a post-bronchodilator test unless the supervising physician determines that it is not safe for you to take a bronchodilator again. If you do not have post-bronchodilator spirometry, the test report must explain why. We can use the results of spirometry administered without bronchodilators when the use of bronchodilators is contraindicated.

c. We use the highest of at least three FEV_1 values and the highest of at least three FVC values obtained during the same test session, regardless of whether the highest FEV_1 value and the highest FVC value are from the same forced expiratory maneuver or different forced expiratory maneuvers. If the results of your spirometry include only one FEV_1 value and one FVC value, we will presume each reported value is the highest value from the test session, unless we have evidence to the contrary and subject to the post-bronchodilator requirements in 3.00E2b.

3. The spirometry report must include the following information:

a. The date of the test and your name, age or date of birth, gender, and height without shoes. (We will assume that your recorded height on the date of the test is without shoes, unless we have evidence to the contrary.) If your spine is abnormally curved (for example, you have kyphoscoliosis), we will substitute the longest distance between your outstretched fingertips with your arms abducted 90 degrees in place of your height when this measurement is greater than your standing height without shoes.

b. Any factors, if applicable, that can affect the interpretation of the test results (for example, your lack of cooperation or effort in doing the test).

4. If we purchase spirometry, the medical source we designate to administer the test is solely responsible for deciding whether it is safe for you to do the test and for how to administer it.

F. What is a DLCO test, and what are our requirements for an acceptable test and report?

1. A DLCO test measures the gas exchange across cell membranes in your lungs. It measures how well CO diffuses from the alveoli (air sacs) of your lungs into your blood. DLCO may be severely reduced in some disorders, such as interstitial lung disease (for example, idiopathic pulmonary fibrosis, asbestosis, and sarcoidosis) and COPD (particularly emphysema), even when the results of spirometry are not significantly reduced. We use your unadjusted measured DLCO (that is, uncorrected for hemoglobin concentration) reported in mL CO (STPD)/min/mmHg to evaluate your respiratory disorder under 3.02C1.

2. We have the following requirements for DLCO tests under these listings:

a. You must be medically stable at the time of the test. See 3.00E2a.

b. The test must use the single-breath technique.

(i) The VI during the DLCO maneuver must be at least 85 percent of your current FVC, and your time of inhalation must be less than 4 seconds. See 3.00E for our rules for programmatically acceptable spirometry. If you do not have an FVC measurement on the same day as the DLCO test, we may use a programmatically acceptable FVC administered no more than 90 days before the DLCO test.

(ii) Your breath-hold time must be between 8 and 12 seconds.

(iii) Your total exhalation time must be less than or equal to 4 seconds, with a sample collection time of less than 3 seconds. If your FVC is at least 2.0 L, the washout volume must be between 0.75 L and 1.0 L. If your FVC is less than 2.0 L, the washout volume must be at least 0.5 L.

3. The DLCO test report must include the following information:

a. The date of the test and your name, age or date of birth, gender, and height without shoes. (We will assume that your recorded height on the date of the test is without shoes, unless we have evidence to the contrary.) If your spine is abnormally curved (for example, you have kyphoscoliosis), we will substitute the longest distance between your outstretched fingertips with your arms abducted 90 degrees in place of your

height when this measurement is greater than your standing height without shoes.

b. Any factors, if applicable, that can affect the interpretation of the test results (for example, your lack of cooperation or effort in doing the test).

c. Tracings of your VI, breath-hold maneuver, and volume of exhaled gas showing your name and the date of the test for each DLCO maneuver.

d. The average of at least two acceptable DLCO measurements, as defined above (see 3.00F2), within 3 mL CO (STPD)/min/mmHg of each other or within 10 percent of the highest value.

4. We may need to purchase a DLCO test to determine whether your disorder meets 3.02C1 when we have evidence showing that you have a chronic respiratory disorder that could result in impaired gas exchange, unless we can make a fully favorably determination or decision on another basis. Since the DLCO calculation requires a current FVC measurement, we may also purchase spirometry at the same time as the DLCO test, even if we already have programmatically acceptable spirometry.

5. Before we purchase a DLCO test, a medical consultant (see §§404.1616 and 416.1016 of this chapter), preferably one with experience in the care of people with respiratory disorders, must review your case record to determine if we need the test. The medical source we designate to administer the test is solely responsible for deciding

whether it is safe for you to do the test and for how to administer it.

G. What is an ABG test, and what are our requirements for an acceptable test and report?

1. General. An ABG test measures P_aO_2, P_aCO_2, and the concentration of hydrogen ions in your arterial blood. We use a resting ABG measurement to evaluate your respiratory disorder under 3.02C2 and 3.04B1. We use an exercise ABG measurement to evaluate your respiratory disorder under 3.02C3 and 3.04B2.

2. Resting ABG tests.

a. We have the following requirements for resting ABG tests under these listings:

(i) You must be medically stable at the time of the test. See 3.00E2a.

(ii) The test must be administered while you are breathing room air; that is, without oxygen supplementation.

b. The resting ABG test report must include the following information:

(i) Your name, the date of the test, and either the altitude or both the city and State of the test site.

(ii) The P_aO_2 and P_aCO_2 values.

c. We may need to purchase resting ABG tests to determine whether your disorder meets 3.02C2 or 3.04B1 when we have evidence showing that you have a chronic respiratory disorder that could result in impaired gas exchange, unless we can make a fully favorably determination or decision on another basis. If your case record contains a report of one programmatically acceptable resting ABG test with the values in the appropriate table (Table IV-A, IV-B, or IV-C), we may purchase a second resting ABG test to determine if your disorder meets 3.02C2 or 3.04B1, even if you have not had programmatically acceptable spirometry or a DLCO test.

d. Before we purchase a resting ABG test, a medical consultant (see §§404.1616 and 416.1016 of this chapter), preferably one with experience in the care of people with respiratory disorders, must review your case record to determine if we need the test. The medical source we designate to administer the test is solely responsible for deciding whether it is safe for you to do the test and for how to administer it.

3. Exercise ABG tests.

a. We will not purchase an exercise ABG test. We have the following requirements for exercise ABG tests under these listings:

(i) You must have done the exercise under steady state conditions while breathing room air. If you were tested on a treadmill or bicycle ergometer, you generally must have exercised for at least 4 minutes at a grade and speed providing oxygen (O_2) consumption of approximately 17.5 ml/kg/min (5 metabolic equivalents (METs)).

(ii) We may use a test in which you have not exercised for at least 4 minutes. If you were unable to complete at least 4 minutes of steady state exercise, we need a statement by the person administering the test about whether the results are a valid indication of your respiratory status. For example, this statement may include information about your cooperation or effort in doing the test and whether you were limited in completing the test because of your respiratory disorder or another impairment.

b. The exercise ABG test report must include the following information:

(i) Your name, the date of the test, and either the altitude or both the city and State of the test site.

(ii) The P_aO_2 and P_aCO_2 values.

H. <u>What is pulse oximetry, and what are our requirements for an acceptable test and report?</u>

1. Pulse oximetry measures the S_pO_2 of blood hemoglobin. We need pulse

oximetry and spirometry to evaluate your respiratory disorder under 3.02C4 and only pulse oximetry to evaluate your CF under 3.04D4.

2. We have the following requirements for pulse oximetry under these listings:

a. You must be medically stable at the time of the test. See 3.00E2a.

b. Your pulse oximetry measurement must be recorded while you are breathing room air; that is, without oxygen supplementation.

c. Your pulse oximetry measurement (while at rest and, if needed, after a 6MWT) must be stable and show a concurrent, acceptable pulse wave, as described in 3.00H3b. By "stable," we mean that the range of pulse oximetry values (that is, lowest to highest) during any 15-second interval cannot exceed 2 percentage points. For example: (1) The measurement is stable if the lowest pulse oximetry value during a 15-second interval is 87 percent and the highest value is 89 percent—a range of 2 percentage points. (2) The measurement is not stable if the lowest value is 86 percent and the highest value is 89 percent—a range of 3 percentage points.

d. If you have had two tests (that is, at rest and after a 6MWT), we will use the values from the test with the lower oximetry values.

3. The pulse oximetry report must include the following information:

a. Your name, the date of the test, and either the altitude or both the city and State of the test site.

b. A graphical printout showing your pulse oximetry values concurrently with your pulse. An acceptable pulse wave is one that shows the characteristic pulse wave; that is, sawtooth-shaped with a rapid systolic upstroke (nearly vertical) followed by a slower diastolic downstroke (angled downward).

4. We may purchase resting pulse oximetry to determine whether your disorder meets 3.02C4 or 3.04D4 when we have evidence showing that you have a chronic respiratory disorder that could result in impaired gas exchange, unless we can make a fully favorably determination or decision on another basis. We may purchase pulse oximetry after a 6MWT if your resting pulse oximetry measurements are greater than the values in 3.02C4 or 3.04D4.

5. Before we purchase pulse oximetry, a medical consultant (see §§404.1616 and 416.1016 of this chapter), preferably one with experience in the care of people with respiratory disorders, must review your case record to determine if we need the test. The medical source we designate to administer the test is solely responsible for deciding whether it is safe for you to do the test and for how to administer it.

I. <u>What is asthma, and how do we evaluate it?</u>

1. Asthma is a chronic inflammatory disorder of the lung airways that we evaluate under 3.02 or 3.03.

2. Under 3.03:

a. We need evidence showing that you have documented baseline airflow obstruction (see Table V in 3.02) while you are medically stable.

b. The phrase "consider under a disability for 1 year" in 3.03B explains how long your asthma can meet the requirements of the listing. It does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your asthma continues to meet a listing or is otherwise disabling.

c. We will determine the onset of your disability based on the facts of your case, but it will be no later than the admission date of your first of three hospitalizations that satisfy the criteria of 3.03B.

J. What is CF, and how do we evaluate it?

1. CF, which we evaluate under 3.04, is a genetic disorder that results in abnormal functioning of the cells lining the lung airways and of the cells in other body systems. We need the evidence described in 3.00J2, 3.00J3, or 3.00J4 to establish that you have CF.

2. A report signed by a physician showing both a. and b.:

a. One of the following:

(i) A positive newborn screen for CF; or

(ii) A history of CF in a sibling; or

(iii) Documentation of at least one specific CF phenotype or clinical criterion (for example, chronic sino-pulmonary disease with persistent colonization or infections with typical CF pathogens, pancreatic insufficiency, or salt-loss syndromes); and

b. One of the following definitive laboratory tests:

(i) An elevated sweat chloride concentration equal to or greater than 60 millimoles per L; or

(ii) The identification of two CF gene mutations affecting the cystic fibrosis transmembrane conductance regulator (CFTR); or

(iii) Characteristic abnormalities in ion transport across the nasal epithelium.

3. When we have the report described in 3.00J2 but it is not signed by a physician, we also need a report from a physician stating that you have CF.

4. When we do not have the report described in 3.00J2, we need a report from a physician that is persuasive that a positive diagnosis was confirmed by appropriate laboratory analysis or another method. To be persuasive, this report must state that you had the appropriate definitive laboratory study or studies for diagnosing CF and provide the results or explain how your diagnosis was established by other methods consistent with the prevailing state of medical knowledge and clinical practice.

5. In 3.04C, examples of exacerbations or complications of CF that may result in hospitalizations include increased cough and sputum production, hemoptysis, increased shortness of breath, increased fatigue, and reduction in pulmonary function.

6. For 3.04D, you must have at least two complications from the list of complications in 3.04D1 through 3.04D6 occurring within a 12-month period. You may have two of the same complications or two different ones.

a. If you have two of the acute complications we describe in 3.04D1 (spontaneous pneumothorax), 3.04D2 (respiratory failure), and 3.04D3 (pulmonary hemorrhage), there must be at least 30 days between the two complications; for example, between an episode of spontaneous pneumothorax and an episode of respiratory failure or between two episodes of respiratory failure.

b. The chronic complications we describe in 3.04D4 through 3.04D6 can occur at the same time as any of the other complications in 3.04D. For example, your CF meets 3.04D if you have the weight loss we describe in 3.04D5 and the CFRD we describe in 3.04D6 even if they do not occur 30 days apart. Your CF also meets 3.04D if you have the weight loss we describe in 3.04D5 and the spontaneous pneumothorax we describe in 3.04D1 even if the spontaneous pneumothorax occurs during the same 90-day period we describe in 3.04D5.

c. Your CF also meets 3.04D if you have two episodes of one of the chronic complications in 3.04D4 through 3.04D6.

7. CF may also affect the digestive and endocrine body systems. We evaluate nonpulmonary CF-related digestive disorders that are not covered by 3.04D under 5.00. We evaluate CFRD under 3.04D or under a body system affected by the diabetes.

K. What is bronchiectasis, and how do we evaluate it? Bronchiectasis is a chronic respiratory disorder that is characterized by abnormal and irreversible dilatation of the bronchi (airways below the trachea), which may be associated with the accumulation of mucus, bacterial infections, and eventual airway scarring. We require imaging (see 3.00D2) to document this disorder. We evaluate your bronchiectasis under 3.02, or under 3.07 if you are having acute exacerbations.

L. What is chronic pulmonary hypertension, and how do we evaluate it?

1. Chronic pulmonary hypertension is an increase in the pressure of the blood vessels of the lungs. We evaluate chronic pulmonary hypertension due to any cause under 3.09.

2. We will not purchase cardiac catheterization. We may purchase echocardiography to determine if your impairment meets 3.09B. Before we purchase an echocardiogram, a medical consultant (see §§404.1616 and 416.1016 of this chapter), preferably one with experience in the care of people with respiratory disorders, must review your case record to determine if we need the test. The medical source we designate to administer the test is solely responsible for deciding whether it is safe for you to do the test and for how to administer it.

M. How do we evaluate lung transplantation? If you receive a lung transplant (or a lung transplant simultaneous with other organs, such as the heart), we will consider you to be disabled under 3.11 for 3 years from the date of the transplant. After that, we will evaluate your residual impairment(s) by considering the adequacy of your post-transplant function, the frequency and severity of any rejection episodes you have, complications in other body systems, and adverse treatment effects. People who receive organ transplants generally have impairments that meet our definition of disability before they undergo transplantation. We will determine the onset of your disability based on the facts of your case.

N. What is respiratory failure, and how do we evaluate it? Respiratory failure is the inability of the lungs to perform their basic function of gas exchange. We use 3.04D2 if you have CF-related respiratory failure. We use 3.14 if you have respiratory failure due to any other respiratory disorder. Respiratory therapy that only increases air pressure in your throat, such as continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BiPAP), does not meet the criterion for continuous assisted (mechanical) ventilation in 3.04D2 or 3.14.

O. How do we evaluate episodic respiratory disorders? Some respiratory disorders listings require a specific number of events within a 12-month period. See 3.02C2, 3.03B, 3.04B1, 3.04C, 3.04D, 3.07, and 3.14. When we use such criteria, the 12-month period must occur within the period we are considering in connection with your application or continuing disability review.

P. How do we consider the effects of obesity when we evaluate your respiratory disorder? Obesity is a medically determinable impairment that is often associated with disorders of the respiratory system. Obesity makes it harder for the chest and lungs to expand. This means that the respiratory system must work harder to provide needed oxygen. This in turn makes the heart work harder to pump blood to carry oxygen to the body. Since the body is working harder at rest, its ability to perform additional work is less than would otherwise be expected. Thus, the combined effects of obesity with respiratory impairments can be greater than the effects of each of the impairments

considered separately. We must consider any additional and cumulative effects of your obesity when we determine whether you have a severe respiratory impairment, a listing-level respiratory impairment, a combination of impairments that medically equals the severity of a listed impairment, and when we assess your residual functional capacity.

Q. What are sleep-related breathing disorders, and how do we evaluate them?

1. Sleep-related breathing disorders (for example, sleep apnea) are characterized by transient episodes of interrupted breathing during sleep that disrupt normal sleep patterns. Prolonged episodes can result in disorders such as hypoxemia (low blood oxygen) and pulmonary vasoconstriction (restricted blood flow in pulmonary blood vessels). Over time, these disorders may lead to chronic pulmonary hypertension. We will not purchase polysomnography (sleep study).

2. We evaluate the complications of sleep-related breathing disorders under the affected body system(s). For example, we evaluate chronic pulmonary hypertension due to any cause under 3.09; chronic heart failure under 4.02; and disturbances in mood, cognition, and behavior under 12.02 or another appropriate mental disorders listing.

R. How do we evaluate mycobacterial, mycotic, and other chronic infections of the lungs? We evaluate chronic infections of the lungs that result in limitations in your respiratory function under 3.02.

S. How do we evaluate respiratory disorders that do not meet one of these listings?

1. These listings are only examples of common respiratory disorders that we consider severe enough to prevent you from doing any gainful activity. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that meets the criteria of a listing in another body system. For example, if your CF has resulted in chronic pancreatic or hepatobiliary disease, we will evaluate your impairment under the digestive system listings in 5.00.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See §§404.1526 and 416.926 of this chapter. Respiratory disorders may be associated with disorders in other body systems, and we consider the combined effects of multiple impairments when we determine whether they medically equal a listing. If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. We proceed to the fourth step and, if necessary, the fifth step of the sequential evaluation process in §§404.1520 and 416.920 of this chapter. We use the rules in §§404.1594 and 416.994 of this chapter, as appropriate, when we decide whether you continue to be disabled.

3.01 Category of Impairments, Respiratory Disorders

3.02 Chronic respiratory disorders due to any cause except cystic fibrosis (see 3.04), with:

A. FEV_1 (see 3.00E1) less than or equal to the value in Table I-A or I-B for your age, gender, and height without shoes (see 3.00E3a).

OR

B. FVC (see 3.00E1) less than or equal to the value in Table II-A or II-B for your age, gender, and height without shoes (see 3.00E3a).

OR

C. Chronic impairment of gas exchange with one of the following:

1. Single-breath DLCO test (see 3.00F1) less than or equal to the value in Table III for your gender and height without shoes (see 3.00F3a); or

2. Arterial P_aO_2 and P_aCO_2 (see 3.00G1) measured concurrently while at rest breathing room air (see 3.00G2) less than or equal to the applicable values in Table IV-A, IV-B, or IV-C, twice within a 12-month period and at least 30 days apart; or

3. Arterial P_aO_2 and P_aCO_2 measured concurrently during steady state exercise

breathing room air (the level of exercise less than or equal to 17.5 mL O_2 consumption/kg/min) (see 3.00G3) less than or equal to the applicable values in Table IV-A, IV-B, or IV-C; or

4. With both a and b.

a. S_pO_2 measured by pulse oximetry (see 3.00H), either at rest or after a 6MWT, which is:

(i) Less than or equal to 87 percent for test sites less than 3,000 feet above sea level; or

(ii) Less than or equal to 85 percent for test sites from 3,000 through 6,000 feet above sea level; or

(iii) Less than or equal to 83 percent for test sites over 6,000 feet above sea level; and

b. One of the following:

(i) FEV_1 (see 3.00E1) less than or equal to the value in Table V-A or V-B for your age, gender, and height without shoes (see 3.00E3a); or

(ii) FVC (see 3.00E1) less than or equal to the value in Table VI-A or VI-B for your age, gender, and height without shoes (see 3.00E3a).

Table I: FEV_1 Criteria for 3.02A

Height without shoes (centimeters) < means less than	Height without shoes (inches) < means less than	Table I-A Age 18 to attainment of age 20		Table I-B Age 20 or older	
		Females FEV_1 less than or equal to (L, BTPS)	Males FEV_1 less than or equal to (L, BTPS)	Females FEV_1 less than or equal to (L, BTPS)	Males FEV_1 less than or equal to (L, BTPS)
<153.0	<60.25	1.30	1.40	1.10	1.20
153.0 to <159.0	60.25 to <62.50	1.40	1.50	1.20	1.30
159.0 to <164.0	62.50 to <64.50	1.50	1.60	1.30	1.40
164.0 to <169.0	64.50 to <66.50	1.60	1.70	1.40	1.50
169.0 to <174.0	66.50 to <68.50	1.70	1.80	1.50	1.60
174.0 to <180.0	68.50 to <70.75	1.80	1.90	1.60	1.70
180.0 to <185.0	70.75 to <72.75	1.90	2.00	1.70	1.80
185.0 or more	72.75 or more	2.00	2.10	1.80	1.90

Table II: FVC Criteria for 3.02B

Height without shoes (centimeters) < means less than	Height without shoes (inches) < means less than	Table II-A Age 18 to attainment of age 20		Table II-B Age 20 or older	
		Females FVC less than or equal to (L, BTPS)	Males FVC less than or equal to (L, BTPS)	Females FVC less than or equal to (L, BTPS)	Males FVC less than or equal to (L, BTPS)
<153.0	<60.25	1.55	1.65	1.35	1.45
153.0 to <159.0	60.25 to <62.50	1.65	1.75	1.45	1.55
159.0 to <164.0	62.50 to <64.50	1.75	1.85	1.55	1.65
164.0 to <169.0	64.50 to <66.50	1.85	1.95	1.65	1.75
169.0 to <174.0	66.50 to <68.50	1.95	2.05	1.75	1.85

174.0 to <180.0	68.50 to <70.75	2.05	2.15	1.85	1.95
180.0 to <185.0	70.75 to <72.75	2.15	2.25	1.95	2.05
185.0 or more	72.75 or more	2.25	2.35	2.05	2.15

Table III: DLCO Criteria for 3.02C1

Height without shoes (centimeters) < means less than	Height without shoes (inches) < means less than	Females DLCO less than or equal to (mL/min/mmHg)	Males DLCO less than or equal to (mL/min/mmHg)
<153.0	< 60.25	8.0	9.0
153.0 to <159.0	60.25 to <62.50	8.5	9.5
159.0 to <164.0	62.50 to <64.50	9.0	10.0
164.0 to <169.0	64.50 to <66.50	9.5	10.5
169.0 to <174.0	66.50 to <68.50	10.0	11.0
174.0 to <180.0	68.50 to <70.75	10.5	11.5
180.0 to <185.0	70.75 to <72.75	11.0	12.0
185.0 or more	72.75 or more	11.5	12.5

Tables IV-A, IV-B, and IV-C: ABG Criteria for 3.02C2, 3.02C3, and 3.04B

Table IV-A	
(Applicable at test sites less than 3,000 feet above sea level)	
Arterial P_aCO_2 (mm Hg) and	Arterial P_aO_2 less than or equal to (mm Hg)
30 or below	65
31	64
32	63
33	62
34	61
35	60
36	59
37	58

38	57
39	56
40 or above	55

Table IV-B	
(Applicable at test sites from 3,000 through 6,000 feet above sea level)	
Arterial P_aCO_2 (mm Hg) and	Arterial P_aO_2 less than or equal to (mm Hg)
30 or below	60
31	59
32	58
33	57
34	56
35	55
36	54
37	53
38	52
39	51
40 or above	50

Table IV-C	
(Applicable at test sites over 6,000 feet above sea level)	
Arterial P_aCO_2 (mm Hg) and	Arterial P_aO_2 less than or equal to (mm Hg)
30 or below	55
31	54
32	53
33	52
34	51
35	50
36	49
37	48
38	47
39	46
40 or above	45

Table V: FEV_1 Criteria for 3.02C4b(i) and 3.03A

Height without shoes (centimeters) < means less than	Height without shoes (inches) < means less than	Table V-A Age 18 to attainment of age 20		Table V-B Age 20 or older	
		Females FEV_1 less than or equal to (L, BTPS)	Males FEV_1 less than or equal to (L, BTPS)	Females FEV_1 less than or equal to (L, BTPS)	Males FEV_1 less than or equal to (L, BTPS)
<153.0	<60.25	1.55	1.65	1.35	1.45
153.0 to <159.0	60.25 to <62.50	1.65	1.75	1.45	1.55
159.0 to <164.0	62.50 to <64.50	1.75	1.85	1.55	1.65
164.0 to <169.0	64.50 to <66.50	1.85	1.95	1.65	1.75
169.0 to <174.0	66.50 to <68.50	1.95	2.05	1.75	1.85
174.0 to <180.0	68.50 to <70.75	2.05	2.15	1.85	1.95
180.0 to <185.0	70.75 to <72.75	2.15	2.25	1.95	2.05
185.0 or more	72.75 or more	2.25	2.35	2.05	2.15

Table VI: FVC Criteria for 3.02C4b(ii)

Height without shoes (centimeters) < means less than	Height without shoes (inches) < means less than	Table VI-A Age 18 to attainment of age 20		Table VI-B Age 20 or older	
		Females FVC less than or equal to (L, BTPS)	Males FVC less than or equal to (L, BTPS)	Females FVC less than or equal to (L, BTPS)	Males FVC less than or equal to (L, BTPS)
<153.0	<60.25	1.90	2.00	1.70	1.80
153.0 to <159.0	60.25 to <62.50	2.00	2.10	1.80	1.90
159.0 to <164.0	62.50 to <64.50	2.10	2.20	1.90	2.00
164.0 to <169.0	64.50 to <66.50	2.20	2.30	2.00	2.10
169.0 to <174.0	66.50 to <68.50	2.30	2.40	2.10	2.20
174.0 to <180.0	68.50 to <70.75	2.40	2.50	2.20	2.30
180.0 to <185.0	70.75 to <72.75	2.50	2.60	2.30	2.40
185.0 or more	72.75 or more	2.60	2.70	2.40	2.50

3.03 Asthma (see 3.00I), with both A and B:

A. FEV_1 (see 3.00E1) less than or equal to the value in Table V-A or V-B (under 3.02) for your age, gender, and height without shoes (see 3.00E3a) within the same 12-month period as the hospitalizations in 3.03B.

AND

B. Exacerbations requiring three hospitalizations within a 12-month period and at least 30 days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization. Consider under a disability for 1 year from the discharge date of the last hospitalization; after that, evaluate the residual impairment(s).

3.04 Cystic fibrosis (documented as described in 3.00J), with:

A. FEV_1 (see 3.00E1) less than or equal to the value in Table VII-A or VII-B for your age, gender, and height without shoes (see 3.00E3a).

Table VII: FEV_1 Criteria for 3.04A

Height without shoes (centimeters) < means less than	Height without shoes (inches) < means less than	Table VII-A		Table VII-B	
		Age 18 to attainment of age 20		Age 20 or older	
		Females FEV_1 less than or equal to (L, BTPS)	Males FEV_1 less than or equal to (L, BTPS)	Females FEV_1 less than or equal to (L, BTPS)	Males FEV_1 less than or equal to (L, BTPS)
<153.0	<60.25	1.55	1.65	1.35	1.45
153.0 to <159.0	60.25 to <62.50	1.65	1.75	1.45	1.55

159.0 to <164.0	62.50 to <64.50	1.75	1.85	1.55	1.65
164.0 to <169.0	64.50 to <66.50	1.85	1.95	1.65	1.75
169.0 to <174.0	66.50 to <68.50	1.95	2.05	1.75	1.85
174.0 to <180.0	68.50 to <70.75	2.05	2.15	1.85	1.95
180.0 to <185.0	70.75 to <72.75	2.15	2.25	1.95	2.05
185.0 or more	72.75 or more	2.25	2.35	2.05	2.15

OR

B. Chronic impairment of gas exchange with one of the following:

1. Arterial P_aO_2 and P_aCO_2 (see 3.00G1) measured concurrently while at rest breathing room air (see 3.00G2) less than or equal to the applicable values in Table IV-A, IV-B, or IV-C (under 3.02), twice within a 12-month period and at least 30 days apart; or

2. Arterial P_aO_2 and P_aCO_2 measured concurrently during steady state exercise breathing room air (see 3.00G3) less than or equal to the applicable values in Table IV-A, IV-B, or IV-C (under 3.02).

OR

C. 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.

OR

D. Any two of the following complications of CF that occur within a 12-month period. There must be at least 30 days between the acute complications in 3.04D1, 3.04D2, and 3.04D3 (see 3.00J6).

1. Spontaneous pneumothorax requiring chest tube treatment.

2. Respiratory failure (see 3.00N) requiring continuous assisted (mechanical) ventilation for at least 48 hours, or for at least 72 hours if postoperatively.

3. Pulmonary hemorrhage requiring vascular embolization to control bleeding.

4. Hypoxemia documented by one S_pO_2 measurement, measured by pulse oximetry (see 3.00H), which is:

a. Less than or equal to 89 percent for test sites less than 3,000 feet above sea level; or

b. Less than or equal to 87 percent for test sites from 3,000 through 6,000 feet above sea level; or

c. Less than or equal to 85 percent for test sites over 6,000 feet above sea level.

5. Weight loss requiring daily supplemental enteral nutrition via a gastrostomy for at least 90 consecutive days or parenteral nutrition via a central venous catheter for at least 90 consecutive days.

6. CFRD requiring daily insulin therapy for at least 90 consecutive days.

3.05 [Reserved]

3.06 [Reserved]

3.07 Bronchiectasis (see 3.00K), documented by imaging (see 3.00D2) with exacerbations or complications requiring three hospitalizations within a 12-month period and at least 30 days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization.

3.08 [Reserved]

3.09 Chronic pulmonary hypertension due to any cause (see 3.00L) lasting or expected to last at least 12 months, documented while medically stable (see 3.00E2a) by A or B:

A. Mean pulmonary artery pressure equal to or greater than 40 mm Hg as determined by cardiac catheterization.

OR

B. Systolic pulmonary artery pressure equal to or greater than 65 mm Hg as determined by echocardiogram.

3.10 [Reserved]

3.11 Lung transplantation (see 3.00M). Consider under a disability for 3 years from the date of the transplant; after that, evaluate the residual impairment(s).

3.12 [Reserved]

3.13 [Reserved]

3.14 Respiratory failure (see 3.00N) resulting from any underlying chronic respiratory disorder except CF, requiring continuous assisted (mechanical) ventilation for at least 48 hours, or for at least 72 hours if postoperatively, and with two episodes within a 12-month period. The episodes must be at least 30 days apart. (For CF, see 3.04D.)

* * * * *

5. Amend part B of appendix 1 to subpart P of part 404 by revising the body

system name for section 103.00 in the table of contents to read as follows:

Part B

* * * * *

103.00 Respiratory Disorders.

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6. Revise section 103.00 in part B of appendix 1 to subpart P of part 404 to read as follows:

103.00 RESPIRATORY DISORDERS

A. What disorders do we evaluate in this body system?

1. We evaluate respiratory disorders that result in obstruction (difficulty moving air out of the lungs) or restriction (difficulty moving air into the lungs), or that interfere with diffusion (gas exchange) across cell membranes in the lungs. Examples of such disorders and the listings we use to evaluate them include chronic obstructive pulmonary disease (103.02), chronic lung disease of infancy (previously known as bronchopulmonary dysplasia) (103.02C and 103.02E), pulmonary fibrosis (103.02), asthma (103.02 and 103.03), and cystic fibrosis (103.04). We also use listings in this

body system to evaluate recurrent episodes of respiratory failure (103.04E2 and 103.14) and lung transplantation (103.11).

2. We evaluate cancers affecting the respiratory system under the malignant neoplastic diseases listings in 113.00. We evaluate neuromuscular disorders affecting the respiratory system under the neurological listings in 111.00 or under the immune system disorders listings in 114.00.

B. What are common signs and symptoms of respiratory disorders? Common signs and symptoms of respiratory disorders are shortness of breath, coughing, wheezing, sputum production, hemoptysis (coughing up blood from the respiratory tract), and chest pain.

C. What abbreviations do we use in this body system?

1. BTPS means body temperature and ambient pressure, saturated with water vapor.

2. CF means cystic fibrosis.

3. CFRD means CF-related diabetes.

4. CLD means chronic lung disease of infancy.

5. FEV_1 means forced expiratory volume in the first second of a forced expiratory maneuver.

6. FVC means forced vital capacity.

7. L means liter.

D. What documentation do we need to evaluate your respiratory disorder?

1. We need medical evidence to assess the effects of your respiratory disorder. Medical evidence should include your medical history, physical examination findings, the results of imaging (see 103.00D2), spirometry if age appropriate (see 103.00E), other relevant laboratory tests, and descriptions of any prescribed treatment and your response to it. We may not need all of this information depending upon your particular respiratory disorder and its effects on you.

2. Imaging refers to medical imaging techniques, such as x-ray, computerized tomography, and echocardiography. The imaging must be consistent with the prevailing state of medical knowledge and clinical practice as the proper technique to support the evaluation of the disorder.

3. Spirometry must be conducted in accordance with the most recently published

standards of the American Thoracic Society (ATS).

E. What is spirometry, and what are our requirements for an acceptable test and report?

1. Spirometry measures how well you move air into and out of your lungs. In accordance with ATS testing standards, spirometry involves at least three forced expiratory maneuvers. A forced expiratory maneuver is a maximum inhalation followed by a forced maximum exhalation, and measures exhaled volumes of air over time. The volume of air you exhale in the first second of the forced expiratory maneuver is the FEV_1. The total volume of air that you exhale during the entire forced expiratory maneuver is the FVC. We use your highest FEV_1 value to evaluate your respiratory disorder under 103.02A and 103.04A. We use your highest FVC value to evaluate your respiratory disorder under 103.02B.

2. We have the following requirements for spirometry under these listings:

a. You must be medically stable at the time of the test. Examples of when we would not consider you to be medically stable include when you are:

(i) Within 2 weeks of a change in your prescribed respiratory medication.

(ii) Experiencing, or within 30 days of completion of treatment for, a lower

respiratory tract infection.

(iii) Experiencing, or within 30 days of completion of treatment for, an acute exacerbation (temporary worsening) of a chronic respiratory disorder. Chronic wheezing by itself does not indicate that you are not medically stable.

b. During testing, if your FEV_1 is less than 70 percent of your predicted normal value, we require repeat spirometry after inhalation of a bronchodilator to evaluate your respiratory disorder under these listings, unless it is medically contraindicated. If you used a bronchodilator before the test and your FEV_1 is less than 70 percent of your predicted normal value, we still require a post-bronchodilator test unless the supervising physician determines that it is not safe for you to take a bronchodilator again. If you do not have post-bronchodilator spirometry, the test report must explain why. We can use the results of spirometry administered without bronchodilators when the use of bronchodilators is contraindicated.

c. We use the highest of at least three FEV_1 values and the highest of at least three FVC values obtained during the same test session, regardless of whether the highest FEV_1 value and the highest FVC value are from the same forced expiratory maneuver or different forced expiratory maneuvers. If the results of your spirometry include only one FEV_1 value and one FVC value, we will presume each reported value is the highest value from the test session, unless we have evidence to the contrary and subject to the post-bronchodilator requirements in 103.00E2b.

3. The spirometry report must include the following information:

a. The date of the test and your name, age or date of birth, gender, and height without shoes. (We will assume that your recorded height on the date of the test is without shoes, unless we have evidence to the contrary.) If your spine is abnormally curved (for example, you have kyphoscoliosis), we will substitute the longest distance between your outstretched fingertips with your arms abducted 90 degrees in place of your height when this measurement is greater than your standing height without shoes.

b. Any factors, if applicable, that can affect the interpretation of the test results (for example, your lack of cooperation or effort in doing the test).

4. If you have attained age 6, we may need to purchase spirometry to determine whether your disorder meets a listing, unless we can make a fully favorable determination or decision on another basis. We will not purchase spirometry for children who have not attained age 6 or any other pulmonary function tests for children of any age.

5. Before we purchase spirometry for a child age 6 or older, a medical consultant (see §416.1016 of this chapter), preferably one with experience in the care of children with respiratory disorders, must review your case record to determine if we need the test. The medical source we designate to administer the test is solely responsible for deciding whether it is safe for you to do the test and for how to administer it.

F. What is CLD, and how do we evaluate it?

1. CLD, previously known as bronchopulmonary dysplasia, or BPD, is scarring of the immature lung. CLD may develop as a complication of assisted ventilation and oxygen therapy for infants with significant neonatal respiratory problems. Within the first 6 months of life, most infants with CLD are successfully weaned from assisted ventilation, and then weaned from oxygen supplementation. Two listings apply to children under age 2 with CLD: 103.02C and 103.02E.

2. We will evaluate your CLD under 103.02C if you are at least 6 months old and need 24-hour-per-day oxygen supplementation. If you were born prematurely, we use your corrected chronological age. See §416.924b(b) of this chapter. We will use 103.02C if you were not weaned off oxygen supplementation by the time you were 6 months old, or were weaned off oxygen supplementation but needed it again by the time you were 6 months old or older.

3. If you have CLD, are not yet 6 months old, and need 24-hour-per-day oxygen supplementation, we will not adjudicate your case under 103.02C until you are 6 months old. Depending on the evidence in your case record, we may make a favorable determination or decision under other rules before you are 6 months old.

4. We use 103.02E if you are any age from birth to the attainment of age 2 and

have recurrent CLD exacerbations or related complications (for example, wheezing, lower respiratory tract infections, or acute respiratory distress) that require hospitalization. For the purpose of 103.02E, we will count your initial birth hospitalization as one hospitalization.

5. After you have attained age 2, we will evaluate your CLD under 103.03.

G. What is asthma, and how do we evaluate it?

1. Asthma is a chronic inflammatory disorder of the lung airways that we evaluate under 103.02 or 103.03.

2. Under 103.03:

a. The phrase "consider under a disability for 1 year" explains how long your asthma can meet the requirements of the listing. It does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your asthma continues to meet a listing or is otherwise disabling.

b. We will determine the onset of your disability based on the facts of your case, but it will be no later than the admission date of your first of three hospitalizations that satisfy the criteria of 103.03.

H. What is CF, and how do we evaluate it?

1. CF, which we evaluate under 103.04, is a genetic disorder that results in abnormal functioning of the cells lining the lung airways and of the cells in other body systems. We need the evidence described in 103.00H2, 103.00H3, or 103.00H4 to establish that you have CF.

2. A report signed by a physician showing both a. and b.:

a. One of the following:

(i) A positive newborn screen for CF; or

(ii) A history of CF in a sibling; or

(iii) Documentation of at least one specific CF phenotype or clinical criterion (for example, chronic sino-pulmonary disease with persistent colonization or infections with typical CF pathogens, pancreatic insufficiency, or salt-loss syndromes); and

b. One of the following definitive laboratory tests:

(i) An elevated sweat chloride concentration equal to or greater than 60 millimoles per L; or

(ii) The identification of two CF gene mutations affecting the cystic fibrosis transmembrane conductance regulator (CFTR); or

(iii) Characteristic abnormalities in ion transport across the nasal epithelium.

3. When we have the report described in 103.00H2 but it is not signed by a physician, we also need a report from a physician stating that you have CF.

4. When we do not have the report described in 103.00H2, we need a report from a physician that is persuasive that a positive diagnosis was confirmed by appropriate laboratory analysis or another method. To be persuasive, this report must state that you had the appropriate definitive laboratory study or studies for diagnosing CF and provide the results or explain how your diagnosis was established by other methods consistent with the prevailing state of medical knowledge and clinical practice.

5. In 103.04D, examples of exacerbations or complications of CF that may result in hospitalizations include increased cough and sputum production, hemoptysis, increased shortness of breath, increased fatigue, and reduction in pulmonary function.

6. For 103.04E, you must have at least two complications from the list of complications in 103.04E1 through 103.04E6 occurring within a 12-month period. You may have two of the same complications or two different ones.

a. If you have two of the acute complications we describe in 103.04E1 (spontaneous pneumothorax), 103.04E2 (respiratory failure), and 103.04E3 (pulmonary hemorrhage), there must be at least 30 days between the two complications; for example, between an episode of spontaneous pneumothorax and an episode of respiratory failure or between two episodes of respiratory failure.

b. The chronic complications we describe in 103.04E4 through 103.04E6 can occur at the same time as any of the other complications in 103.04E. For example, your CF meets 103.04E if you have the weight loss we describe in 103.04E5 and the CFRD we describe in 103.04E6 even if they do not occur 30 days apart. Your CF also meets 103.04E if you have the weight loss we describe in 103.04E5 and the spontaneous pneumothorax we describe in 103.04E1 even if the spontaneous pneumothorax occurs during the same 90-day period we describe in 103.04E5.

c. Your CF also meets 103.04E if you have two episodes of one of the chronic complications in 103.04E4 through 103.04E6.

7. CF may also affect the growth, digestive, and endocrine body systems. We evaluate CF-related growth failure under 100.00 or 105.00. We evaluate nonpulmonary CF-related digestive disorders that are not covered by 103.04E under 105.00. We evaluate CFRD under 103.04E, under 109.00, or under a body system affected by the diabetes.

I. How do we evaluate lung transplantation? If you receive a lung transplant (or a lung transplant simultaneous with other organs, such as the heart), we will consider you to be disabled under 103.11 for 3 years from the date of the transplant. After that, we will evaluate your residual impairment(s) by considering the adequacy of your post-transplant function, the frequency and severity of rejection episodes you have, complications in other body systems, and adverse treatment effects. Children who receive organ transplants generally have impairments that meet our definition of disability before they undergo transplantation. We will determine the onset of your disability based on the facts of your case.

J. What is respiratory failure, and how do we evaluate it? Respiratory failure is the inability of the lungs to perform their basic function of gas exchange. We use 103.04E2 if you have CF-related respiratory failure. We use 103.14 if you have respiratory failure due to any other respiratory disorder. Respiratory therapy that only increases air pressure in your throat, such as continuous positive airway pressure (CPAP) or bi-level positive airway pressure (BiPAP), does not meet the criterion for continuous assisted (mechanical) ventilation in 103.04E2 or 103.14.

K. How do we evaluate growth failure due to any chronic respiratory disorder? We evaluate linear growth failure under a growth impairment listing in 100.00. If your growth failure does not meet or medically equal the criteria of a listing in 100.00, we will consider whether your respiratory disorder meets or medically equals the criteria of a

listing in another body system. For example, if your respiratory disorder has resulted in weight loss or a combination of weight loss and linear growth failure, we will evaluate your impairment under a digestive system listing in 105.00.

L. How do we evaluate episodic respiratory disorders? Some respiratory disorders listings require a specific number of events within a 12-month period. See 103.02E, 103.03, 103.04D, 103.04E, and 103.14. When we use such criteria, the 12-month period must occur within the period we are considering in connection with your application or continuing disability review.

M. How do we evaluate respiratory disorders that do not meet one of these listings?

1. These listings are only examples of common respiratory disorders that we consider severe enough to result in marked and severe functional limitations. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that meets the criteria of a listing in another body system. For example, if your CF has resulted in chronic pancreatic or hepatobiliary disease, we will evaluate your impairment under the digestive system listings in 105.00.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. See §416.926 of this chapter. Respiratory disorders may be associated with disorders in other

body systems, and we consider the combined effects of multiple impairments when we determine whether they medically equal a listing. If your impairment(s) does not meet or medically equal a listing, we will also consider whether it functionally equals the listings. See §416.926a of this chapter. We use the rules in §416.994a of this chapter when we decide whether you continue to be disabled.

103.01 Category of Impairments, Respiratory Disorders

103.02 Chronic respiratory disorders due to any cause except cystic fibrosis (see 103.04), with:

A. FEV_1 (see 103.00E1) less than or equal to the value in Table I-A or I-B for your age, gender, and height without shoes (see 103.00E3a).

Table I: FEV_1 Criteria for 103.02A

Table I-A			Table I-B			
Age 6 to attainment of age 13 (For both females and males)			Age 13 to attainment of age 18			
Height without shoes (centimeters) < means less than	Height without shoes (inches) < means less than	FEV_1 less than or equal to (L, BTPS)	Height without shoes (centimeters) < means less than	Height without shoes (inches) < means less than	Females FEV_1 less than or equal to (L, BTPS)	Males FEV_1 less than or equal to (L, BTPS)
<123.0	<48.50	0.70	<153.0	<60.25	1.30	1.40

123.0 to <129.0	48.50 to <50.75	0.80	153.0 to <159.0	60.25 to <62.50	1.40	1.50
129.0 to <134.0	50.75 to <52.75	0.90	159.0 to <164.0	62.50 to <64.50	1.50	1.60
134.0 to <139.0	52.75 to <54.75	1.00	164.0 to <169.0	64.50 to <66.50	1.60	1.70
139.0 to <144.0	54.75 to <56.75	1.10	169.0 to <174.0	66.50 to <68.50	1.70	1.80
144.0 to <149.0	56.75 to <58.75	1.20	174.0 to <180.0	68.50 to <70.75	1.80	1.90
149.0 or more	58.75 or more	1.30	180.0 or more	70.75 or more	1.90	2.00

OR

B. FVC (see 103.00E1) less than or equal to the value in Table II-A or II-B for your age, gender, and height without shoes (see 103.00E3a).

Table II: FVC Criteria for 103.02B

Table II-A			Table II-B			
Age 6 to attainment of age 13 (For both females and males)			Age 13 to attainment of age 18			
Height without shoes (centimeters) < means less than	Height without shoes (inches) < means less than	FVC less than or equal to (L, BTPS)	Height without shoes (centimeters) < means less than	Height without shoes (inches) < means less than	Females FVC less than or equal to (L, BTPS)	Males FVC less than or equal to (L, BTPS)
<123.0	<48.50	0.95	<153.0	<60.25	1.55	1.65

123.0 to <129.0	48.50 to <50.75	1.05	153.0 to <159.0	60.25 to <62.50	1.65	1.75
129.0 to <134.0	50.75 to <52.75	1.15	159.0 to <164.0	62.50 to <64.50	1.75	1.85
134.0 to <139.0	52.75 to <54.75	1.25	164.0 to <169.0	64.50 to <66.50	1.85	1.95
139.0 to <144.0	54.75 to <56.75	1.35	169.0 to <174.0	66.50 to <68.50	1.95	2.05
144.0 to <149.0	56.75 to <58.75	1.45	174.0 to <180.0	68.50 to <70.75	2.05	2.15
149.0 or more	58.75 or more	1.55	180.0 or more	70.75 or more	2.15	2.25

OR

C. Hypoxemia with the need for at least 1.0 L/min of continuous (24 hours per day) oxygen supplementation for at least 90 consecutive days.

OR

D. The presence of a tracheostomy, with one of the following:

1. For children who have not attained age 3, consider under a disability until the attainment of age 3; after that, evaluate under 103.02D2, or evaluate the residual impairment(s); or

2. For children age 3 to the attainment of age 18, documented need for assisted (mechanical) ventilation via a tracheostomy for at least 4 hours per day and for at least 90 consecutive days.

OR

E. For children who have not attained age 2, CLD with exacerbations or related complications requiring three hospitalizations within a 12-month period (see 103.00F4). Each hospitalization must be at least 30 days apart. Consider under a disability for 1 year from the discharge date of the last hospitalization or until the attainment of age 2, whichever is later. After that, evaluate the impairment(s) under 103.03 or as otherwise appropriate.

103.03 Asthma, for children of any age, with exacerbations (see 103.00G) requiring three hospitalizations within a 12-month period and at least 30 days apart. Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization. Consider under a disability for 1 year from the discharge date of the last hospitalization; after that, evaluate the residual impairment(s).

103.04 Cystic fibrosis (documented as described in 103.00H), with:

A. FEV_1 (see 103.00E1) less than or equal to the value in Table III-A or Table III-

B for your age, gender, and height without shoes (see 103.00E3a).

Table III: FEV_1 Criteria for 103.04A

Table III-A			Table III-B			
Age 6 to attainment of age 13 (For both females and males)			Age 13 to attainment of age 18			
Height without shoes (centimeters) < means less than	Height without shoes (inches) < means less than	FEV_1 less than or equal to (L, BTPS)	Height without shoes (centimeters) < means less than	Height without shoes (inches) < means less than	Females FEV_1 less than or equal to (L, BTPS)	Males FEV_1 less than or equal to (L, BTPS)
<123.0	<48.50	0.95	<153.0	<60.25	1.55	1.65
123.0 to <129.0	48.50 to <50.75	1.05	153.0 to <159.0	60.25 to <62.50	1.65	1.75
129.0 to <134.0	50.75 to <52.75	1.15	159.0 to <164.0	62.50 to <64.50	1.75	1.85
134.0 to <139.0	52.75 to <54.75	1.25	164.0 to <169.0	64.50 to <66.50	1.85	1.95
139.0 to <144.0	54.75 to <56.75	1.35	169.0 to <174.0	66.50 to <68.50	1.95	2.05
144.0 to <149.0	56.75 to <58.75	1.45	174.0 to <180.0	68.50 to <70.75	2.05	2.15
149.0 or more	58.75 or more	1.55	180.0 or more	70.75 or more	2.15	2.25

OR

B. For children who have not attained age 6, findings on imaging (see 103.00D2)

of thickening of the proximal bronchial airways, nodular-cystic lesions, segmental or lobular atelectasis, or consolidation, and documentation of one of the following:

1. Shortness of breath with activity; or

2. Accumulation of secretions as manifested by repetitive coughing; or

3. Bilateral rales or rhonchi, or reduction of breath sounds.

OR

C. Hypoxemia with the need for at least 1.0 L/min of continuous (24 hours per day) oxygen supplementation for at least 90 consecutive days.

OR

D. Exacerbations or complications of CF (see 103.00H5) requiring three hospitalizations of any length within a 12-month period and at least 30 days apart.

OR

E. Any two of the following complications of CF that occur within a 12-month period. There must be at least 30 days between the acute complications in 103.04E1,

103.04E2, and 103.04E3 (see 103.00H6).

1. Spontaneous pneumothorax requiring chest tube treatment.

2. Respiratory failure (see 103.00J) requiring continuous assisted (mechanical) ventilation for at least 48 hours, or for at least 72 hours if postoperatively.

3. Pulmonary hemorrhage requiring vascular embolization to control bleeding.

4. Hypoxemia with the need for at least 1.0 L/min of oxygen supplementation for at least 4 hours per day and for at least 90 consecutive days.

5. Weight loss requiring daily supplemental enteral nutrition via a gastrostomy for at least 90 consecutive days or parenteral nutrition via a central venous catheter for at least 90 consecutive days.

6. CFRD requiring daily insulin therapy for at least 90 consecutive days.

103.05 [Reserved]

103.06 [Reserved]

103.07 [Reserved]

103.08 [Reserved]

103.09 [Reserved]

103.10 [Reserved]

103.11 Lung transplantation (see 103.00I). Consider under a disability for 3 years from the date of the transplant; after that, evaluate the residual impairment(s).

103.12 [Reserved]

103.13 [Reserved]

103.14 Respiratory failure (see 103.00J) resulting from any underlying chronic respiratory disorder except CF, requiring continuous assisted (mechanical) ventilation for at least 48 hours, or for at least 72 hours if postoperatively, and with two episodes within a 12-month period. The episodes must be at least 30 days apart. (For CF, see 103.04E2.)

PART 416 — SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart I — [Amended]

7. The authority citation for subpart I of part 416 continues to read as follows:

Authority: Secs. 221(m), 702(a)(5), 1611, 1614, 1619, 1631(a), (c), (d)(1), and (p), and 1633 of the Social Security Act (42 U.S.C. 421(m), 902(a)(5), 1382, 1382c, 1382h, 1383(a), (c), (d)(1), and (p), and 1383b); secs. 4(c) and 5, 6(c)-(e), 14(a), and 15, Pub. L. 98-460, 98 Stat. 1794, 1801, 1802, and 1808 (42 U.S.C. 421 note, 423 note, and 1382h note).

8. Amend §416.926a by removing paragraph (m)(1) and redesignating paragraphs (m)(2) through (m)(8) as (m)(1) through (m)(7).

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