information requirements should direct their comments to the Office of Management and Budget, Attention: Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Washington, DC 20503, and send a copy of the comments to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090, with reference to File No. S7–09–16. Requests for materials submitted to the OMB by us with regard to these collections of information should be in writing, refer to File No. S7–09–16 and be submitted to the Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington DC 20549–0213. Interested persons are encouraged to send comments to the OMB by July 11, 2016.

VI. Statutory Authority

The amendment contained in this release is being adopted under the authority set forth in Sections 3, 12, 13, 15(d), and 23(a) of the Exchange Act, and Section 72001 of the FAST Act.

List of Subjects in 17 CFR Part 249

Reporting and recordkeeping requirements, Securities.

Text of the Interim Final Amendment

For the reasons set out in the preamble, the Commission is amending Title 17, Chapter II of the Code of Federal Regulations as follows:

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

■ 1. The authority citation for part 249 is revised to read as follows:

Authority: 15 U.S.C. 78a *et seq.* and 7201 *et seq.;* 12 U.S.C. 5461 *et seq.;* 18 U.S.C. 1350; Sec. 953(b), Pub. L. 111–203, 124 Stat. 1904; Sec. 102(a)(3), Pub. L. 112–106, 126 Stat. 309 (2012); Sec. 107, Pub. L. 112–106, 126 Stat. 313 (2012), and Sec. 72001, Pub. L. 114–94, 129 Stat. 1312 (2015), unless otherwise noted.

Section 249.220f is also issued under secs. 3(a), 202, 208, 302, 306(a), 401(a), 401(b), 406 and 407, Pub. L. 107–204, 116 Stat. 745.

Section 249.240f is also issued under secs. 3(a), 202, 208, 302, 306(a), 401(a), 406 and 407, Pub. L. 107–204, 116 Stat. 745.

Section 249.308 is also issued under 15 U.S.C. 80a–29 and 80a–37.

Section 249.308a is also issued under secs. 3(a) and 302, Pub. L. 107–204, 116 Stat. 745.

Section 249.308b is also issued under secs. 3(a) and 302, Pub. L. 107–204, 116 Stat. 745.

Section 249.310 is also issued under secs. 3(a), 202, 208, 302, 406 and 407, Pub. L. 107–204, 116 Stat. 745.

Section 249.326(T) also issued under section 13(f)(1) (15 U.S.C. 78m(f)(1)).

Section 249.330 is also issued under secs. 3(a), 406, and 407, Pub. L. 107–204, 116 Stat. 745.

Section 249.331 is also issued under 15 U.S.C. 78j–1, 7202, 7233, 7241, 7264, 7265; and 18 U.S.C. 1350.

Section 249.617 is also issued under Pub. L. 111–203, § 939, 939A, 124. Stat. 1376 (2010) (15 U.S.C. 78c, 15 U.S.C. 78*o*–7 note).

Section 249.819 is also issued under 12 U.S.C. 5465(e).

Section 249.1400 is also issued under sec. 943, Pub. L. 111–203, 124 Stat. 1376.

Section 249.1800 is also issued under Pub. L. 111.203, § 922(a), 124 Stat 1841 (2010).

Section 249.1801 is also issued under Pub. L. 111.203, § 922(a), 124 Stat 1841 (2010).

■ 2. Amend Form 10–K (referenced in § 249.310) by adding new Item 16 to Part IV to read as follows:

Note: The text of Form 10–K does not, and this amendment will not, appear in the Code of Federal Regulations.

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10–K

* * * * *

Part IV

* * * * *

Item 16. Form 10–K Summary.

Registrants may, at their option, include a summary of information required by this form, but only if each item in the summary is presented fairly and accurately and includes a hyperlink to the material contained in this form to which such item relates, including to materials contained in any exhibits filed with the form.

Instruction: The summary shall refer only to Form 10–K disclosure that is included in the form at the time it is filed. A registrant need not update the summary to reflect information required by Part III of Form 10–K that the registrant incorporates by reference from a proxy or information statement filed after the Form 10–K, but must state in the summary that the summary does not include Part III information because that information will be incorporated by reference from a later filed proxy or information statement involving the election of directors.

* * * * *

By the Commission.

Dated: June 1, 2016.

Brent J. Fields,

Secretary.

[FR Doc. 2016–13328 Filed 6–8–16; 8:45 am]

BILLING CODE 8011–01–P

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: Final rule.

SUMMARY: We are revising 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 revisions reflect our program experience and advances in medical knowledge since we last comprehensively revised this body system in 1993, as well as comments we received from medical experts and the public.

DATES: These final rules are effective October 7, 2016.

FOR FURTHER INFORMATION CONTACT: Cheryl A. Williams, Office of Disability Policy, 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:

Background

We are revising and making final the rules for evaluating respiratory disorders we proposed in a Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** on February 4, 2013 (78 FR 7968). The preamble to the NPRM provided an explanation of the changes from the current rules and our reasons for proposing those changes. To the extent that we are adopting the proposed rules as published, we are not repeating that information here. You can view the NPRM by visiting *www.regulations.gov* and searching for document ''SSA–2006–0149–0024.'' We are making a number of changes because of public comments we received in response to the NPRM. We explain those changes in our summary of public comments and our responses later in this preamble. We are also making minor editorial changes for clarity throughout these final rules.

Why are we revising the listings for evaluating respiratory disorders?

We are revising the listings for evaluating respiratory disorders to

reflect our program experience and advances in medical knowledge since we last comprehensively revised the listings for this body system, and comments we received from medical experts and the public at an outreach policy conference, in response to an Advance Notice of Proposed Rulemaking (ANPRM), and in response to an NPRM. 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] Since that time, we have revised the introductory text for children, revised some testing requirements, added adult and child listings for lung transplants, removed criterion C from listing 3.09, added listing 103.06 and corresponding introductory text, and extended the effective date of the rules.[2]

When will we begin to use these final rules?

We will begin to use these final rules on their effective date. We will continue to use the current listings until the date these final rules become effective. We will apply the final rules to new applications filed on or after the effective date of these final rules and to claims that are pending on or after the effective date.[3] These final rules will remain in effect for 3 years after the date they become effective, unless we extend them, or revise and issue them again.

Public Comments on the NPRM

In the NPRM, we provided the public with a 60-day comment period that ended on April 5, 2013. We received 212 comments. The commenters included advocacy groups, legal services organizations, State agencies that make disability determinations for us, medical organizations, and people who have respiratory disorders or have relatives with respiratory disorders.

We carefully considered all of the comments that were relevant to this rulemaking. We have tried to present the commenters' concerns and suggestions accurately and completely, and we have responded to all significant issues that were within the scope of these rules. We provide our reasons for adopting or not adopting the recommendations in the summaries of the comments and our responses. We also received several comments supporting our proposed changes. We appreciate those comments; however, we did not include them in our discussion of the rules below.

As part of the rulemaking process, we held an informational teleconference with the public on May 10, 2013, during which we discussed general background information on the disability program, information for people with cystic fibrosis who either apply for Social Security disability benefits or are currently receiving disability benefits, information we received from medical experts and members of the public, and proposed criteria in listings 3.04 and 103.04.[4] We did not accept public comments during the teleconference. We have included information related to the teleconference in the rulemaking docket for these rules under Docket ID number SSA–2006–0149–0237.[5]

Pulmonary Function Testing

Comment: One commenter suggested that we not refer to arterial blood gas (ABG) tests and pulse oximetry as pulmonary function tests (PFTs) because they are monitoring devices.

Response: We are not adopting this recommendation because we use the results of these tests to document the severity of respiratory disorders and we believe it is appropriate, for this purpose, to refer to ABG tests and pulse oximetry as PFTs.

Comment: Many commenters did not support removing the requirement for spirometry tracings of the forced expiratory maneuvers used to determine a person's highest forced expiratory volume in the first second (FEV_1) and forced vital capacity (FVC). Some commenters explained that the tracings allow us to confirm that the American Thoracic Society (ATS) testing standards were met. One commenter stated that requiring tracings will enhance the quality of the test and ensure confidence in the disability decision-making process for respiratory disorders. Another commenter agreed with us that accepting providers' interpretations of spirometry results without requiring tracings might reduce the number of tests that we purchase, but stated that not also requiring tracings might result in inappropriate allowances. One commenter suggested that, if we do not require tracings, we should require flow-volume loops to ensure the integrity of the test.

Response: We are adopting the recommendation that we continue to require spirometry tracings. In the proposed rule, we indicated that we believed it would be appropriate to trust the professional who supervises the test and for us to use the resulting spirometry values *without* corresponding tracings to assess the severity of a person's respiratory disorder. The public commenters (including medical experts who use the results of spirometry in their treatment of people with respiratory disorders, and disability examiners), however, disagreed with us.

In its public comment, the ATS recommended that we continue to require documentation of three acceptable tracings. We agree with that comment.

For most claims involving respiratory disorders and in which spirometry results are available, the evidence we receive usually does not include the spirometry tracings. By requiring tracings, we may need to recontact the medical source to seek the tracings or, if we know from experience that the source either cannot or will not provide the tracings, we may need to purchase consultative examinations to obtain spirometry results with tracings, unless we can make a fully favorable determination or decision on another basis. We will provide guidance to our adjudicators on when it is appropriate to purchase a PFT when we conduct training on the final rules.

Comment: Some commenters recommended that we continue to require documentation of equipment calibration for spirometry.

Response: We are not adopting these recommendations because, in our program experience, recorded calibrations that we receive almost invariably establish spirometer accuracy. We do not believe it is necessary to continue to require proof of equipment calibration. We expect the professional who supervises the test to comply with the professional standards for equipment calibrations. If, however, we have reason to believe that the equipment was not calibrated, we may then request calibration logs from the medical source.

Comment: Several commenters explained that the spirometry values

[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 54747 (2000), 65 FR 57946 (2000), 67 FR 20018 (2002), 67 FR 43537 (2002), 68 FR 36911 (2003), 70 FR 35028 (2005), 71 FR 2312 (2006), 72 FR 33662 (2007), 73 FR 31025 (2008), 75 FR 33166 (2010), 77 FR 35264 (2012), 79 FR 10661 (2014), 80 FR 1 (2015), and 80 FR 19522 (2015).

[3] This means that we will use these final rules on and after their effective date, in any case in which we make a determination or decision. We expect that Federal courts will review our final decisions using the rules that were in effect at the time we issued the decisions. If a court reverses our final decision and remands a case for further administrative proceedings after the effective date of these final rules, we will apply these final rules to the entire period at issue in the decision we make after the court's remand.

[4] See 78 FR 26681 (2013).

[5] *See http://www.regulations.gov/#!documentDetail;D=SSA-2006-0149-0237.*

(FEV_1 and FVC) for several listings (proposed 3.02A, 3.02B, 3.02C4, 3.03A, 3.04A, 3.04B, 103.02A, 103.02B, 103.04A, and 103.04B) include too much variability in percent predicted between females and males, as well as between different height and age categories.

Response: We agree with these commenters. While we based the values in the spirometry tables on reference values from Hankinson, *et al.*,[6] as noted in the NPRM, we agree that there was too much variability between categories (age, gender, and height). In these final rules, the percent predicted values (from which we derive the spirometry values that we use in final 3.02A, 3.02B, 3.03A, 3.04A, 103.02A, 103.02B, and 103.04A) by height are all within three percentage points of one another for a given age and gender cohort.

Comment: Some commenters recommended that we include percent predicted values in our rules rather than tables of absolute values for measurement of lung function.

Response: We did not adopt these recommendations. We believe that both percent predicted values and absolute values accurately represent the severity of a person's respiratory disorder. While the percent predicted values represent the percentage of lung function remaining, the absolute values of FEV_1 and FVC represent the *actual* volumes of air that a person exhales during a forced expiratory maneuver.

Comment: Two commenters suggested that we use the Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health (CDC/NIOSH) calculator, which calculates percent predicted values, to determine the severity of a person's respiratory disorder.[7]

Response: We did not adopt these recommendations because the calculator is intended for use with a NIOSH spirometry training course and the Food and Drug Administration has not approved the calculator for clinical use.

Comment: One commenter agreed with using diffusing capacity of the lungs for carbon monoxide (DLCO) to measure respiratory function but recommended that we use percent predicted values rather than absolute values to more accurately capture condition severity.

Response: We did not adopt this recommendation. DLCO test results include both the actual (absolute) and percent predicted values for the measurement. Both values represent the ability of the lungs to transfer gases across the alveolar-capillary membrane. Neither value is more accurate than the other value because they both represent the same DLCO measurement.

Comment: One commenter had three concerns with the use of pulse oximetry in proposed 3.02C4a. First, requiring pulse oximetry and spirometry decreases the utility of the listing. Second, the key finding on a 6-minute walk test (6MWT) is whether desaturation occurs with exertion and not the baseline or post-6MWT results. Lastly, requiring printouts of pulse oximetry will dramatically reduce the availability of pulse oximetry evidence that we can use. This commenter suggested that the listing require desaturation with exercise independent of spirometry.

Response: We partially adopted these recommendations. We revised proposed 3.02C4, final 3.02C3, to require only pulse oximetry. We believe that the percent of oxygen saturation of blood hemoglobin measured by pulse oximetry required in 3.02C3 demonstrates a chronic gas exchange defect of listing-level severity. If resting pulse oximetry does not establish listing-level severity, we may use pulse oximetry during or after a 6MWT. We require a printout of the pulse wave during measurement because we use it to verify that perfusion to the area covered by the probe is adequate and that the probe is positioned properly, and because motion artifact may limit the accuracy of pulse oximetry *during* the 6MWT. Furthermore, to be consistent with this revision to final 3.02C3, we combined proposed 3.02C2, which required two resting ABG tests to document a chronic gas exchange defect of listing-level severity, and proposed 3.02C3, which required one exercise ABG test, into final 3.02C2 requiring one ABG test, either resting or during steady state exercise.

Comment: One commenter recommended that a clinical evaluation accompany the pulse oximetry measurement in proposed 3.02C4 because a pulse oximetry measurement should not be considered a primary diagnostic tool.

Response: We agree with the commenter, but did not make any changes as a result. Proposed and final 3.00D1 explain that we need a person's medical history, physical examination findings, the results of imaging, and pulmonary function tests to document and assess the severity of a person's respiratory disorder. Consequently, the rules already require the type of clinical evaluation of a person's respiratory disorder that the commenter suggested.

Comment: One commenter suggested that we require pulse oximetry be performed while the person is breathing room air or on oxygen supplementation. This commenter also suggested that we include a requirement that nail polish is removed prior to testing and that, if finger circulation is not good, we accept ear lobe pulse oximetry.

Response: We did not adopt these recommendations because the purpose of the pulse oximetry measurement is to determine oxygen (O_2) saturation on room air and not with oxygen supplementation. We do not require that a finger probe be used. It is the responsibility of the professional supervising the test to choose the most appropriate probe (for example, finger or ear) and to also ensure that proper testing protocol (including removal of nail polish) is followed.

Asthma

Comment: One commenter suggested that we remove the requirement for reduced lung function between asthma exacerbations (that is, baseline obstruction).

Response: We did not propose to change this requirement and, therefore, are not adopting this recommendation. We currently require baseline obstruction (current 3.00C) established by spirometry while the person is medically stable to document listing-level asthma. We continued to include this requirement in final 3.00I2a and 3.03A.

Comment: One commenter asked us to continue to consider adherence to therapy for asthma.

Response: We agree with the commenter, but did not make any changes as a result. We consider any hospitalization for an exacerbation of asthma lasting at least 48 hours to be despite prescribed therapy, unless we have evidence to the contrary.

Comment: One commenter suggested that we add a criterion to proposed 103.03 for the need for endotracheal intubation, which is a type of treatment for respiratory failure.

Response: We did not adopt this recommendation because we do not believe we need to specify the types of treatments we consider under 103.03 when a child is hospitalized for asthma. We did, however, add guidance in final 3.00I1 and 103.00G1 to explain that we evaluate respiratory failure resulting from chronic asthma under final 3.14 or 103.14.

[6] 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.

[7] The CDC/NIOSH calculator is available at *http://www.cdc.gov/niosh/topics/spirometry/refcalculator.html.*

Cystic Fibrosis

Comment: Many commenters recommended that we continue to consider treatment for cystic fibrosis (CF) outside of the hospital. The commenters stated that physicians treat CF pulmonary exacerbations in a variety of ways including hospitalization and through use of intravenous antibiotics and inhaled nebulized therapies outside of the hospital setting. Some commenters explained that treatment at home for CF pulmonary exacerbations indicates the same severity of illness as a hospitalization for CF and is increasingly the method preferred by treating physicians.

Response: We adopted these recommendations. We included a criterion in final 3.04G and 103.04G that requires 10 consecutive days of intravenous antibiotic treatment, without specifying where (for example, in a hospital) the treatment occurs, for CF pulmonary exacerbations. We also added guidance in final 3.00J3 and 103.00H3 to explain that treatment for CF exacerbations usually includes intravenous antibiotics and intensified airway clearance therapy (for example, increased frequencies of chest percussion or increased use of inhaled nebulized therapies, such as bronchodilators or mucolytics). We want to assure the commenters that we are able to evaluate CF under the criteria in final listings 3.04 and 103.04, using medical equivalence, the functional equivalence rules for children, or at other steps in our sequential evaluation process.

Comment: Multiple commenters suggested that we revise proposed 3.04D and 103.04E, which required any two of six listed CF exacerbations and complications. Some commenters explained that four of the listed exacerbations and complications (spontaneous pneumothorax, respiratory failure, pulmonary hemorrhage, and hypoxemia) are serious health issues for people with CF. The commenters recommended that we revise the list to more accurately reflect the progression of CF and that we require only one of these four exacerbations or complications to establish that a person is disabled.

Response: We adopted these recommendations by adding standalone listing criteria for spontaneous pneumothorax in final 3.04C and 103.04D, respiratory failure in final 3.04D and 103.04E, pulmonary hemorrhage requiring vascular embolization in final 3.04E and 103.04F, and hypoxemia measured by pulse oximetry in final 3.04F.

Comment: One commenter stated that ABG tests in proposed 3.04B do not correlate well to disability for people with CF, and that ABG tests are not generally used in most specialized CF care centers.

Response: We adopted this recommendation and removed proposed 3.04B that required ABG test results to evaluate the severity of CF in the final rule.

Comment: One commenter said that proposed 103.04C for hypoxemia with the need for at least 1.0 liter per minute of oxygen supplementation for at least 4 hours per day for at least 90 consecutive days is ''significantly too strict'' for children with CF. The commenter stated that any child whose CF meets the proposed listing would already be on a lung transplant list.

Response: We adopted this recommendation and have not included proposed 103.04C in the final rule. While being on a lung transplant list is not a listing criterion, we believe children with CF whose impairment would have met proposed 103.04C will have an impairment that meets the requirements in one of the listings for CF included in the final rule.

Comment: Multiple commenters objected to the proposed lower spirometry values for evaluating CF in proposed 3.04A and 103.04A.

Response: We adopted these comments and modified the spirometry values in proposed 3.04A and 103.04A. Our revisions to *all* spirometry values to minimize variability, as we described above, in addition to the fact that people with CF are disabled at a comparatively higher level of lung function than people who do not have CF, resulted in none of the values in final 3.04A and 103.04A being lower than the corresponding values in current 3.04A and 103.04A.

Pulmonary Hypertension

Comment: Multiple commenters recommended that we not use echocardiograms to evaluate the severity of chronic pulmonary hypertension in proposed 3.09B. One commenter stated that results from echocardiograms do not accurately reflect the presence of moderate pulmonary hypertension that causes marked functional limitations. Another commenter stated that only cardiac catheterization should be used to evaluate disability for pulmonary hypertension in proposed 3.09A.

Response: We adopted these recommendations and removed the echocardiography requirement from final 3.09. We also removed echocardiography from the list of examples of medical imaging techniques in proposed 3.00D2 (final 3.00D3).

Comment: One commenter suggested that we add listing criteria to proposed 3.09A, which requires only cardiac catheterization for chronic pulmonary hypertension.

Response: We did not adopt this recommendation because adding the suggested listing criteria to 3.09 increases the severity level of the listing. We believe final 3.09 is medically appropriate and represents an inability to perform any gainful activity. When we have the results of cardiac catheterization and those results meet the requirements of the listing, we do not need additional criteria to support listing-level severity. Adding listing criteria creates an unnecessary evidence burden on claimants.

Respiratory Failure

Comment: One commenter suggested that we exclude asthma and obesity as underlying conditions for respiratory failure in proposed 3.14 and 103.14.

Response: We did not adopt this recommendation. Final 3.14 and 103.14 require that we evaluate respiratory failure resulting from any chronic respiratory disorder except CF. Obesity is not a ''chronic respiratory disorder'' and, therefore, respiratory failure cannot be evaluated under these listings if obesity is the person's only impairment. (We address how to consider the effects of obesity combined with a respiratory disorder in final 3.00O.) We believe it is appropriate to evaluate respiratory failure resulting from chronic asthma under these listings.

Comment: One commenter recommended that we consider noninvasive ventilation as an alternative to invasive ventilation for treatment of respiratory failure resulting from CF.

Response: We adopted this recommendation because ventilatory support in respiratory failure associated with any underlying chronic respiratory disorder, including CF, while traditionally provided by invasive ventilation, is now often provided by noninvasive ventilation. In either case, cyclical positive pressure is applied to the airway to assist ventilation and reduce the work of breathing. We believe it is reasonable to count the total ventilatory support time, whether it be invasive or noninvasive ventilation, for our purposes, so we added this alternative to final 3.04D, 3.14, 103.04E, and 103.14.

Other Comments

Comment: One commenter suggested that we include a listing for people with

respiratory disorders who are dependent on oxygen supplementation.

Response: We are not adopting this recommendation because the use of supplemental oxygen does not, by itself, indicate an impairment of listing-level severity. In proposed 3.00D1 and final 3.00D2 and 103.00D2, we explain that if a person uses supplementation oxygen, we still need medical evidence to establish the severity of his or her respiratory disorder.

Comment: One commenter suggested that we include a criterion in 3.02 that requires three hospitalizations within a 12-month period for any chronic respiratory disorder except CF.

Response: We adopted this recommendation in final 3.02D because we agree that three hospitalizations of 48 hours or longer, 30 days or more apart, within a 12-month period that we are considering in connection with an application or continuing disability review for exacerbations or complications of a chronic respiratory disorder will prevent a person from engaging in any gainful activity and, therefore, represents listing-level severity.

Additionally, we are able to evaluate chronic respiratory disorders resulting in fewer than three hospitalizations in a consecutive 12-month period using medical equivalence, under other listing criteria, or at other steps in our sequential evaluation process. For example, if a claimant's chronic respiratory disorder does not precisely meet the hospitalization requirements in final 3.02D, we may find that the disorder is medically equivalent to that listing, if the disorder is at least medically equal in severity and duration to the listing criteria. Our medical equivalence rules permit us to find that a disorder is medically equivalent to a listing at step 3 if there are other findings related to the disorder that are at least of equal medical significance to the listing criteria (see §§ 404.1526 and 416.926).

Although some of our listings include criteria for repeated hospitalizations (3.02D, 3.03B, 3.04B, 3.07, 103.02E, 103.03, and 103.04C), our medical equivalence policy accommodates recent trends in clinical care that emphasize quality of, rather than quantity of, medical treatment. The medical equivalence policy also accommodates claimants' varying level of access to medical care (as well as the preference of some medical providers to reduce the use of emergency department and hospital-level medical interventions). This accommodation accounts for differences in medical care people with similar disorders receive depending on the medical resources available to them. The medical equivalence policy provides some flexibility in determining whether a claimant is disabled at step 3 of the sequential evaluation process by allowing us to consider whether the claimant's impairment meets the listed criteria or is at least equal in severity and duration to the criteria of any listed impairment. The final listings do not provide substantive instructions to our adjudicators for determining such equivalence because we can better provide this information through operating instructions and training

If we are not able to find that a person's impairment due to a chronic respiratory disorder is disabling using our listings, we may still find the person disabled at the final steps of the sequential evaluation process.

Comment: One commenter suggested that we include a criterion in 3.02 for persistent chronic lung infections that are refractory to treatment or provide guidance in our internal operating instructions for how to evaluate these cases.

Response: We did not adopt this recommendation because we explain in final 3.00Q that we evaluate limitations in respiratory function resulting from chronic lung infections under 3.02. We will, however, provide guidance to our adjudicators on how to evaluate chronic lung infections that are resistant to treatment when we conduct training on these final rules.

Comment: One commenter suggested that we include a listing for prolonged, active infectious periods of mycobacterium tuberculosis (MTB) lasting longer than 12 months.

Response: We did not adopt this recommendation because prolonged, active infectious periods of MTB lasting longer than 12 months are extremely rare. MTB is generally treatable with a 6-month course of antibiotics. If, however, active infectious periods associated with resistance to, or intolerance of, multiple antibiotics last longer than 12 months, we will evaluate the impairment under an appropriate listing.

Comment: One commenter suggested that we place the tables in Part A directly following the listings for which they are used, similar to how the tables appear in Part B.

Response: We adopted this recommendation because we agree that it is easier for an adjudicator to use a table when it is located directly following its listing.

Other Changes

In proposed 3.00O and 103.00L, we included guidance explaining that, for listings that require a specific number of events within a 12-month period, the 12-month period must occur within the period we are considering in connection with the application or continuing disability review. We did not, however, provide a reference to proposed 3.00O and 103.00L in each proposed listing. In these final rules, we include this guidance in each listing (final 3.02D, 3.03B, 3.04B, 3.04F, 3.04G, 3.07, 3.14, 103.02E, 103.03, 103.04C, 103.04G, and 103.14) and, as a result, it is unnecessary to also include the same guidance in the introductory text.

In proposed 3.00D3 and 103.00D3, we included a requirement that pulmonary function testing be conducted in accordance with the most recently published standards of the ATS. We do not include this statement in these final rules because we now include in final 3.00E and 103.00E (for spirometry) and in final 3.00F (for DLCO) the specific ATS testing standards that we require to evaluate respiratory disorders. The ATS may revise its testing standards at any time, in which case we would review any new standards and, if appropriate, publish proposed changes to our requirements for public comment before revising the rules.

In these final rules, we are redesignating current 103.00F as 103.00K and revising the reference to 103.00F in listing 103.06 to 103.00K. We are not revising the introductory text or the listing requirements, both of which we added to the respiratory body system in 2015.[8]

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

The Act authorizes us to make rules and regulations and to establish necessary and appropriate procedures to implement them. Sections 205(a), 702(a)(5), and 1631(d)(1) of the Act.

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 final rules meet the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB reviewed them.

[8] See 80 FR 19522.

Regulatory Flexibility Act

We certify that these final rules will not have a significant economic impact on a substantial number of small entities because they affect individuals only. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

Paperwork Reduction Act

This final rule does not create any new or affect any existing collections and, therefore, does not require OMB approval under the Paperwork Reduction Act.

(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).

Carolyn W. Colvin,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, we are amending 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—Determining Disability and Blindness

■ 1. The authority citation for subpart P of part 404 continues 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:
■ a. Revising item 4 of the introductory text before part A;
■ b. Revising the body system name for section 3.00 in the table of contents;
■ c. Revising section 3.00 in part A;
■ d. Revising in part B the body system name for section 103.00 in the table of contents; and
■ e. Revising section 103.00 in part B.

The revisions read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

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4. Respiratory Disorders (3.00 and 103.00): October 7, 2019.

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Part A

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3.00 Respiratory Disorders.

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3.00 RESPIRATORY DISORDERS

A. *Which 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 (chronic bronchitis and emphysema, 3.02), pulmonary fibrosis and pneumoconiosis (3.02), asthma (3.02 or 3.03), cystic fibrosis (3.04), and bronchiectasis (3.02 or 3.07). We also use listings in this body system to evaluate respiratory failure (3.04D or 3.14), chronic pulmonary hypertension (3.09), and lung transplantation (3.11).

2. We evaluate cancers affecting the respiratory system under the listings in 13.00. We evaluate the pulmonary effects of neuromuscular and autoimmune disorders under these listings or under the listings in 11.00 or 14.00, respectively.

B. *What are the symptoms and signs of respiratory disorders?* Symptoms and signs of respiratory disorders include dyspnea (shortness of breath), chest pain, coughing, wheezing, sputum production, hemoptysis (coughing up blood from the respiratory tract), use of accessory muscles of respiration, and tachypnea (rapid rate of breathing).

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

1. *ABG* means arterial blood gas.
2. *BiPAP* means bi-level positive airway pressure ventilation.
3. *BTPS* means body temperature and ambient pressure, saturated with water vapor.
4. *CF* means cystic fibrosis.
5. *CFRD* means CF-related diabetes.
6. *CFTR* means CF transmembrane conductance regulator.
7. *CO* means carbon monoxide.
8. *COPD* means chronic obstructive pulmonary disease.
9. *DLCO* means diffusing capacity of the lungs for carbon monoxide.
10. *FEV_1* means forced expiratory volume in the first second of a forced expiratory maneuver.
11. *FVC* means forced vital capacity.
12. *L* means liter.
13. *mL CO (STPD)/min/mmHg* means milliliters of carbon monoxide at standard temperature and pressure, dry, per minute, per millimeter of mercury.
14. *P_aO_2* means arterial blood partial pressure of oxygen.
15. *P_aCO_2* means arterial blood partial pressure of carbon dioxide.
16. *S_pO_2* means percentage of oxygen saturation of blood hemoglobin measured by pulse oximetry.
17. *6MWT* means 6-minute walk test.
18. *VI* means volume of inhaled gas during a DLCO test.

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

1. We need *medical evidence* to document and assess the severity of your respiratory disorder. Medical evidence should include your medical history, physical examination findings, the results of imaging (see 3.00D3), pulmonary function tests (see 3.00D4), other relevant laboratory tests, and descriptions of any prescribed treatment and your response to it. We may not need all of this evidence depending on your particular respiratory disorder and its effects on you.

2. If you use *supplemental oxygen,* we still need medical evidence to establish the severity of your respiratory disorder.

3. *Imaging* refers to medical imaging techniques, such as x-ray and computerized tomography. 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.

4. *Pulmonary function tests* include *spirometry* (which measures ventilation of the lungs), *DLCO* tests (which measure gas diffusion in the lungs), *ABG* tests (which measure the partial pressure of oxygen, P_aO_2, and carbon dioxide, P_aCO_2, in the arterial blood), and *pulse oximetry* (which measures oxygen saturation, S_pO_2, of peripheral blood hemoglobin).

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

1. Spirometry, which measures how well you move air into and out of your lungs, involves at least three forced expiratory maneuvers during the same test session. 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, 3.03A, and 3.04A, and your highest FVC value to evaluate your respiratory disorder under 3.02B, regardless of whether the values are from the same forced expiratory maneuver or different forced expiratory maneuvers.

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. Wheezing by itself does not indicate that you are not medically stable.

(iv) Hospitalized, 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 repeat spirometry after inhalation of a bronchodilator unless the supervising physician determines that it is not safe for you to take a bronchodilator again (in which case we may need to reschedule the test). 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 medically contraindicated.

c. Your forced expiratory maneuvers must be satisfactory. We consider a forced expiratory maneuver to be satisfactory when you exhale with maximum effort following a full inspiration, and when the test tracing has a sharp takeoff and rapid rise to peak flow, has a smooth contour, and either lasts for at least 6 seconds or maintains a plateau for at least 1 second.

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 cooperation or effort in doing the test).

c. Legible tracings of your forced expiratory maneuvers in a volume-time format showing your name and the date of the test for each maneuver.

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 the average of two of your unadjusted (that is, uncorrected for hemoglobin concentration) DLCO measurements 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 your FVC from programmatically acceptable spirometry administered within 90 days of 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 cooperation or effort in doing the test).

c. Legible 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. At least two acceptable (see 3.00F2) DLCO measurements 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 favorable 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 or an exercise ABG measurement to evaluate your respiratory disorder under 3.02C2.

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 a resting ABG test to determine whether your disorder meets 3.02C2 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 favorable determination or decision on another basis.

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.

b. 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, you generally must have exercised for at least 4 minutes at a grade and speed providing oxygen (O_2) consumption of approximately 17.5 milliliters per kilogram per minute (mL/kg/min) or 5.0 metabolic equivalents (METs). If you were tested on a cycle ergometer, you generally must have exercised for at least 4 minutes at an exercise equivalent of 5.0 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.

c. 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. *What is pulse oximetry, and what are our requirements for an acceptable test and report?*

1. Pulse oximetry measures S_pO_2, the percentage of oxygen saturation of blood hemoglobin. We use a pulse oximetry measurement (either at rest, during a 6MWT, or after a 6MWT) to evaluate your respiratory disorder under 3.02C3 or, if you have CF, to evaluate it under 3.04F.

2. We have the following requirements for pulse oximetry under 3.02C3:

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 must be stable. By ''stable,'' we mean that the range of S_pO_2 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 S_pO_2 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 more than one measurement (for example, at rest and after a 6MWT), we will use the measurement with the lowest S_pO_2 value.

e. The pulse oximetry 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) A graphical printout showing your S_pO_2 value and a concurrent, acceptable pulse wave. 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).

f. We may need to purchase pulse oximetry at rest to determine whether your disorder meets 3.02C3 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 favorable determination or decision on another basis. We may purchase pulse oximetry during and after a 6MWT if your S_pO_2 value at rest is greater than the value in Table V.

g. 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.

3. We have the following requirements for pulse oximetry under 3.04F:

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. If you have had more than one measurement (for example, at rest and after a 6MWT), we will use the measurement with the lowest S_pO_2 value.

d. The pulse oximetry report must include your name, the date of the test, and either the altitude or both the city and State of the test site. If you have CF, we do not require a graphical printout showing your S_pO_2 value and a concurrent, acceptable pulse wave.

I. *What is asthma and how do we evaluate it?*

1. *Asthma* is a chronic inflammatory disorder of the lung airways that we evaluate under 3.02 or 3.03. If you have respiratory failure resulting from chronic asthma (see 3.00N), we will evaluate it under 3.14.

2. For the purposes of 3.03:

a. We need evidence showing that you have listing-level (see Table VI in 3.03A) airflow obstruction at baseline while you are medically stable.

b. The phrase ''consider under a disability for 1 year'' in 3.03B 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 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. *General.* We evaluate *CF,* a genetic disorder that results in abnormal salt and water transport across cell membranes in the lungs, pancreas, and other body organs, under 3.04. We need the evidence described in 3.00J2 to establish that you have CF.

2. *Documentation of CF.* We need a report signed by a physician (see §§ 404.1513(a) and 416.913(a) of this chapter) 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 CFTR; or

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

c. When we have the report showing a and b, but it is not signed by a physician, we also need a report from a physician stating that you have CF.

d. When we do not have the report showing a and b, we need a report from a physician that is persuasive that a positive diagnosis of CF was confirmed by an appropriate definitive laboratory test. To be persuasive, this report must include a statement by the physician that you had the appropriate definitive laboratory test for diagnosing CF. The report must provide the test results or explain how your diagnosis was established that is consistent with the prevailing state of medical knowledge and clinical practice.

3. *CF pulmonary exacerbations.* Examples of CF pulmonary exacerbations include increased cough and sputum production, hemoptysis, increased shortness of breath, increased fatigue, and reduction in pulmonary function. Treatment usually includes intravenous antibiotics and intensified airway clearance therapy (for example, increased frequencies of chest percussion or increased use of inhaled nebulized therapies, such as bronchodilators or mucolytics).

4. For 3.04G, we require any two exacerbations or complications from the list in 3.04G1 through 3.04G4 within a 12-month period. You may have two of the same exacerbation or complication or two different ones.

a. If you have two of the acute exacerbations or complications we describe in 3.04G1 and 3.04G2, there must be at least 30 days between the two.

b. If you have one of the acute exacerbations or complications we describe in 3.04G1 and 3.04G2 and one of the chronic complications we describe in 3.04G3 and 3.04G4, the two can occur during the same time. For example, your CF meets 3.04G if you have the pulmonary hemorrhage we describe in 3.04G2 and the weight loss we describe in 3.04G3 even if the pulmonary hemorrhage occurs during the 90-day period in 3.04G3.

c. Your CF also meets 3.04G if you have both of the chronic complications in 3.04G3 and 3.04G4.

5. CF may also affect other body systems such as digestive or endocrine. If your CF, including pulmonary exacerbations and nonpulmonary complications, does not meet or medically equal a respiratory disorders listing, we may evaluate your CF-related impairments under the listings in the affected body system.

K. *What is bronchiectasis and how do we evaluate it?* Bronchiectasis is a chronic respiratory disorder that is characterized by abnormal and irreversible dilatation (enlargement) of the airways below the trachea, which may be associated with the accumulation of mucus, bacterial infections, and eventual airway scarring. We require imaging (see 3.00D3) to document this disorder. We evaluate your bronchiectasis under 3.02, or under 3.07 if you are having exacerbations or complications (for example, acute bacterial infections, increased shortness of breath, or coughing up blood) that require hospitalization.

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

1. Chronic pulmonary hypertension is an increase in the blood pressure of the blood vessels of the lungs. If pulmonary hypertension is not adequately treated, it can eventually result in right heart failure. We evaluate chronic pulmonary hypertension due to any cause under 3.09.

2. Chronic pulmonary hypertension is usually diagnosed by catheterization of the

pulmonary artery. We will not purchase cardiac catheterization.

M. *How do we evaluate lung transplantation?* If you receive a lung transplant (or a lung transplant simultaneously 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 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. The phrase ''consider under a disability for 3 years'' in 3.11 does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We 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 evaluate respiratory failure under 3.04D if you have CF-related respiratory failure, or under 3.14 if you have respiratory failure due to any other *chronic* respiratory disorder. Continuous positive airway pressure does not satisfy the criterion in 3.04D or 3.14, and cannot be substituted as an equivalent finding, for invasive mechanical ventilation or noninvasive ventilation with BiPAP.

O. *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 respiratory disorders. Obesity makes it harder for the chest and lungs to expand, which can compromise the ability of the respiratory system to supply adequate oxygen to the body. The combined effects of obesity with a respiratory disorder can be greater than the effects of each of the impairments considered separately. We consider any additional and cumulative effects of your obesity when we determine whether you have a severe respiratory disorder, a listing-level respiratory disorder, a combination of impairments that medically equals the severity of a listed impairment, and when we assess your residual functional capacity.

P. *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, which 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 or other complications.

2. We evaluate the complications of sleep-related breathing disorders under the listings in 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. We will not purchase polysomnography (sleep study).

Q. *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.

R. *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 evaluate your impairment under the 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 CF (for CF, see 3.04) with A, B, C, or D:

A. FEV_1 (see 3.00E) 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).

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*		*Table I–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	1.20	1.45	1.05	1.20
153.0 to <159.0	60.25 to <62.50	1.30	1.55	1.15	1.35
159.0 to <164.0	62.50 to <64.50	1.40	1.65	1.25	1.40
164.0 to <169.0	64.50 to <66.50	1.45	1.75	1.35	1.50
169.0 to <174.0	66.50 to <68.50	1.55	1.85	1.45	1.60
174.0 to <180.0	68.50 to <70.75	1.65	2.00	1.55	1.75
180.0 to <185.0	70.75 to <72.75	1.75	2.10	1.65	1.85
185.0 or more	72.75 or more	1.80	2.15	1.70	1.90

OR

B. FVC (see 3.00E) 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).

TABLE II—FVC CRITERIA FOR 3.02B

Height without shoes (centimeters) < means *less than*	Height without shoes (inches) < means *less than*	*Table II–A*		*Table II–B*	
		Age 18 to attainment of age 20		Age 20 or older	
		Females FVC less than or equal to (L, BTPS)	Females 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	1.35	1.65	1.30	1.50
153.0 to <159.0	60.25 to <62.50	1.50	1.80	1.40	1.65
159.0 to <164.0	62.50 to <64.50	1.60	1.90	1.50	1.75
164.0 to <169.0	64.50 to <66.50	1.70	2.05	1.60	1.90
169.0 to <174.0	66.50 to <68.50	1.80	2.20	1.70	2.00
174.0 to <180.0	68.50 to <70.75	1.90	2.35	1.85	2.20
180.0 to <185.0	70.75 to <72.75	2.05	2.50	1.95	2.30
185.0 or more	72.75 or more	2.10	2.60	2.00	2.40

OR

C. Chronic impairment of gas exchange demonstrated by 1, 2, or 3:

1. Average of two unadjusted, single-breath DLCO measurements (see 3.00F) less than or equal to the value in Table III for your gender and height without shoes (see 3.00F3a); or

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 CO (STPD)/min/mmHg)	Males DLCO less than or equal to (mL CO (STPD)/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

2. Arterial P_aO_2 and P_aCO_2 measured concurrently by an ABG test, while at rest or during steady state exercise, breathing room air (see 3.00G3b), less than or equal to the applicable values in Table IV–A, IV–B, or IV–C; or

Tables IV–A, IV–B, and IV–C—ABG Criteria for 3.02C2

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

TABLE IV–C—Continued

[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)
32	53
33	52
34	51
35	50
36	49
37	48
38	47
39	46
40 or above	45

3. S_pO_2 measured by pulse oximetry (see 3.00H2) either at rest, during a 6MWT, or after a 6MWT, less than or equal to the value in Table V.

TABLE V—S_pO_2 CRITERIA FOR 3.02C3

Test site altitude (feet above sea level)	S_pO_2 less than or equal to
Less than 3,000	87 percent.
3,000 through 6,000	85 percent.
Over 6,000	83 percent.

OR

D. Exacerbations or complications requiring three hospitalizations within a 12-month period and at least 30 days apart (the 12-month period must occur within the period we are considering in connection with your application or continuing disability review). Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization.

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 VI–A or VI–B for your age, gender, and height without shoes (see 3.00E3a) measured within the same 12-month period as the hospitalizations in 3.03B.

TABLE VI—FEV_1 CRITERIA FOR 3.03A

Height without shoes (centimeters) < means *less than*	Height without shoes (inches) < means *less than*	*Table VI–A*		*Table VI–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	1.65	1.90	1.45	1.60
153.0 to <159.0	60.25 to <62.50	1.75	2.05	1.55	1.75
159.0 to <164.0	62.50 to <64.50	1.85	2.15	1.65	1.90
164.0 to <169.0	64.50 to <66.50	1.95	2.30	1.75	2.00
169.0 to <174.0	66.50 to <68.50	2.05	2.45	1.85	2.15
174.0 to <180.0	68.50 to <70.75	2.20	2.60	2.00	2.30
180.0 to <185.0	70.75 to <72.75	2.35	2.75	2.10	2.45
185.0 or more	72.75 or more	2.40	2.85	2.20	2.55

AND

B. Exacerbations or complications requiring three hospitalizations within a 12-month period and at least 30 days apart (the 12-month period must occur within the period we are considering in connection with your application or continuing disability review). 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) under 3.03 or another appropriate listing.

3.04 *Cystic fibrosis* (documented as described in 3.00J2) with A, B, C, D, E, F, or G:

A. FEV_1 (see 3.00E) 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	1.65	1.90	1.45	1.60
153.0 to <159.0	60.25 to <62.50	1.75	2.05	1.55	1.75
159.0 to <164.0	62.50 to <64.50	1.85	2.15	1.65	1.90
164.0 to <169.0	64.50 to <66.50	1.95	2.30	1.75	2.00
169.0 to <174.0	66.50 to <68.50	2.05	2.45	1.85	2.15
174.0 to <180.0	68.50 to <70.75	2.20	2.60	2.00	2.30
180.0 to <185.0	70.75 to <72.75	2.35	2.75	2.10	2.45
185.0 or more	72.75 or more	2.40	2.85	2.20	2.55

OR

B. Exacerbations or complications (see 3.00J3) requiring three hospitalizations of any length within a 12-month period and at least 30 days apart (the 12-month period must occur within the period we are considering in connection with your application or continuing disability review).

OR

C. Spontaneous pneumothorax, secondary to CF, requiring chest tube placement.

OR

D. Respiratory failure (see 3.00N) requiring invasive mechanical ventilation, noninvasive ventilation with BiPAP, or a combination of both treatments, for a continuous period of at least 48 hours, or for a continuous period of at least 72 hours if postoperatively.

OR

E. Pulmonary hemorrhage requiring vascular embolization to control bleeding.

OR

F. S_pO_2 measured by pulse oximetry (see 3.00H3) either at rest, during a 6MWT, or after a 6MWT, less than or equal to the value in Table VIII, *twice* within a 12-month period and at least 30 days apart (the 12-month period must occur within the period we are considering in connection with your application or continuing disability review).

TABLES VIII—S_pO_2 CRITERIA FOR 3.04F

Test site altitude (feet above sea level)	S_pO_2 less than or equal to
Less than 3,000	89 percent.
3,000 through 6,000	87 percent.
Over 6,000	85 percent.

OR

G. Two of the following exacerbations or complications (either two of the same or two different, see 3.00J3 and 3.00J4) within a 12-month period (the 12-month period must

occur within the period we are considering in connection with your application or continuing disability review):

1. Pulmonary exacerbation requiring 10 consecutive days of intravenous antibiotic treatment.

2. Pulmonary hemorrhage (hemoptysis with more than blood-streaked sputum but not requiring vascular embolization) requiring hospitalization of any length.

3. 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.

4. 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 3.00D3), with exacerbations or complications requiring three hospitalizations within a 12-month period and at least 30 days apart (the 12-month period must occur within the period we are considering in connection with your application or continuing disability review). 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) documented by mean pulmonary artery pressure equal to or greater than 40 mm Hg as determined by cardiac catheterization while medically stable (see 3.00E2a).

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 (for CF, see 3.04D), requiring invasive mechanical ventilation, noninvasive ventilation with BiPAP, or a combination of both treatments, for a continuous period of at least 48 hours, or for a continuous period of at least 72 hours if postoperatively, *twice* within a 12-month period and at least 30 days apart (the 12-month period must occur within the period we are considering in connection with your application or continuing disability review).

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Part B

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103.00 Respiratory Disorders.

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103.00 Respiratory Disorders

A. *Which 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 (also known as bronchopulmonary dysplasia, 103.02C or 103.02E), pulmonary fibrosis (103.02), asthma (103.02 or 103.03), and cystic fibrosis (103.04). We also use listings in this body system to evaluate respiratory failure resulting from an underlying chronic respiratory disorder (103.04E or 103.14) and lung transplantation (103.11).

2. We evaluate cancers affecting the respiratory system under the listings in 113.00. We evaluate the pulmonary effects of neuromuscular and autoimmune disorders under these listings or under the listings in 111.00 or 114.00, respectively.

B. *What are the symptoms and signs of respiratory disorders?* Symptoms and signs of respiratory disorders include dyspnea (shortness of breath), chest pain, coughing, wheezing, sputum production, hemoptysis (coughing up blood from the respiratory tract), use of accessory muscles of respiration, and tachypnea (rapid rate of breathing).

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

1. *BiPAP* means bi-level positive airway pressure ventilation.

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

3. *CF* means cystic fibrosis.

4. *CFRD* means CF-related diabetes.

5. *CFTR* means CF transmembrane conductance regulator.

6. *CLD* means chronic lung disease of infancy.

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

8. *FVC* means forced vital capacity.

9. *L* means liter.

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

1. We need *medical evidence* to document and assess the severity of your respiratory disorder. Medical evidence should include your medical history, physical examination findings, the results of imaging (see 103.00D3), spirometry (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 evidence depending on your particular respiratory disorder and its effects on you.

2. If you use *supplemental oxygen,* we still need medical evidence to establish the severity of your respiratory disorder.

3. *Imaging* refers to medical imaging techniques, such as x-ray and computerized tomography. 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.

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

1. Spirometry, which measures how well you move air into and out of your lungs, involves at least three forced expiratory maneuvers during the same test session. 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, and your highest FVC value to evaluate your respiratory disorder under 103.02B, regardless of whether the values are from the same forced expiratory maneuver or different forced expiratory maneuvers. We will not purchase spirometry for children who have not attained age 6.

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. 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 repeat spirometry after inhalation of a bronchodilator unless the supervising physician determines that it is not safe for you to take a bronchodilator again (in which case we may need to reschedule the test). 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 medically contraindicated.

c. Your forced expiratory maneuvers must be satisfactory. We consider a forced expiratory maneuver to be satisfactory when you exhale with maximum effort following a full inspiration, and when the test tracing has a sharp takeoff and rapid rise to peak flow, has a smooth contour, and either lasts for at least 6 seconds (for children age 10 and older) or for at least 3 seconds (for children who have not attained age 10), or maintains a plateau for at least 1 second.

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 cooperation or effort in doing the test).

c. Legible tracings of your forced expiratory maneuvers in a volume-time format showing your name and the date of the test for each maneuver.

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.

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. 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 CLD and how do we evaluate it?*

1. *CLD,* also known as bronchopulmonary dysplasia, or BPD, is scarring of the immature lung. CLD may develop as a complication of mechanical 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 mechanical ventilation, and then weaned from oxygen supplementation. We evaluate CLD under 103.02C, 103.02E, or if you are age 2 or older, under 103.03 or another appropriate listing.

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

3. We evaluate your CLD under 103.02C if you are at least 6 months old and you 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 also evaluate your CLD under 103.02C if you were weaned off oxygen supplementation but needed it again by the time you were 6 months old or older.

4. We evaluate your CLD under 103.02E if you are any age from birth to the attainment of age 2 and have CLD exacerbations or complications (for example, wheezing, lower respiratory tract infections, or acute respiratory distress) that require hospitalization. For the purpose of 103.02E, we count your initial birth hospitalization as one hospitalization. The phrase ''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'' in 103.02E does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling.

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. If you have respiratory failure resulting from chronic asthma (see 103.00J), we will evaluate it under 103.14.

2. For the purposes of 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 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. *General.* We evaluate *CF,* a genetic disorder that results in abnormal salt and water transport across cell membranes in the lungs, pancreas, and other body organs, under 103.04. We need the evidence described in 103.00H2 to establish that you have CF.

2. *Documentation of CF.* We need a report signed by a physician (see § 416.913(a) of this chapter) 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 CFTR; or

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

c. When we have the report showing a and b, but it is not signed by a physician, we also need a report from a physician stating that you have CF.

d. When we do not have the report showing a and b, we need a report from a physician that is persuasive that a positive diagnosis of CF was confirmed by an appropriate definitive laboratory test. To be persuasive, this report must include a statement by the physician that you had the appropriate definitive laboratory test for diagnosing CF. The report must provide the test results or explain how your diagnosis was established that is consistent with the prevailing state of medical knowledge and clinical practice.

3. *CF pulmonary exacerbations.* Examples of CF pulmonary exacerbations include increased cough and sputum production, hemoptysis, increased shortness of breath, increased fatigue, and reduction in pulmonary function. Treatment usually includes intravenous antibiotics and intensified airway clearance therapy (for example, increased frequencies of chest percussion or increased use of inhaled nebulized therapies, such as bronchodilators or mucolytics).

4. For 103.04G, we require any two exacerbations or complications from the list in 103.04G1 through 103.04G4 within a 12-month period. You may have two of the same exacerbation or complication or two different ones.

a. If you have two of the acute exacerbations or complications we describe in 103.04G1 and 103.04G2, there must be at least 30 days between the two.

b. If you have one of the acute exacerbations or complications we describe in 103.04G1 and 103.04G2 and one of the chronic complications we describe in 103.04G3 and 103.04G4, the two can occur during the same time. For example, your CF meets 103.04G if you have the pulmonary hemorrhage we describe in 103.04G2 and the weight loss we describe in 103.04G3 even if the pulmonary hemorrhage occurs during the 90-day period in 103.04G3.

c. Your CF also meets 103.04G if you have both of the chronic complications in 103.04G3 and 103.04G4.

5. CF may also affect other body systems such as digestive or endocrine. If your CF, including pulmonary exacerbations and nonpulmonary complications, does not meet or medically equal a respiratory disorders listing, we may evaluate your CF-related impairments under the listings in the affected body system.

I. *How do we evaluate lung transplantation?* If you receive a lung transplant (or a lung transplant simultaneously 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 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. Children who receive organ transplants generally have impairments that meet our definition of disability before they undergo transplantation. The phrase ''consider under a disability for 3 years'' in 103.11 does not refer to the date on which your disability began, only to the date on which we must reevaluate whether your impairment(s) continues to meet a listing or is otherwise disabling. We 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 evaluate respiratory failure under 103.04E if you have CF-related respiratory failure, or under 103.14 if you have respiratory failure due to any other *chronic* respiratory disorder. Continuous positive airway pressure does not satisfy the criterion in 103.04E or 103.14, and cannot be substituted as an equivalent finding, for invasive mechanical ventilation or noninvasive ventilation with BiPAP.

K. *How do we evaluate growth failure due to any chronic respiratory disorder?*

1. To evaluate growth failure due to any chronic respiratory disorder, we require documentation of the oxygen supplementation described in 103.06A and the growth measurements in 103.06B within

the same consecutive 12-month period. The dates of oxygen supplementation may be different from the dates of growth measurements.

2. Under 103.06B, we use the appropriate table(s) under 105.08B in the digestive system to determine whether a child's growth is less than the third percentile.

a. For children from birth to attainment of age 2, we use the weight-for-length table corresponding to the child's gender (Table I or Table II).

b. For children age 2 to attainment of age 18, we use the body mass index (BMI)-for-age table corresponding to the child's gender (Table III or Table IV).

c. BMI is the ratio of a child's weight to the square of his or her height. We calculate BMI using the formulas in 105.00G2c.

L. *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 evaluate your impairment under the 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 CF (for CF, see 103.04), with A, B, C, D, or E:

A. FEV_1 (see 103.00E) 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	0.80	<153.0	<60.25	1.35	1.40
123.0 to <129.0	48.50 to <50.75	0.90	153.0 to <159.0	60.25 to <62.50	1.45	1.50
129.0 to <134.0	50.75 to <52.75	1.00	159.0 to <164.0	62.50 to <64.50	1.55	1.60
134.0 to <139.0	52.75 to <54.75	1.10	164.0 to <169.0	64.50 to <66.50	1.65	1.70
139.0 to <144.0	54.75 to <56.75	1.20	169.0 to <174.0	66.50 to <68.50	1.75	1.85
144.0 to <149.0	56.75 to <58.75	1.30	174.0 to <180.0	68.50 to <70.75	1.85	2.00
149.0 or more	58.75 or more	1.40	180.0 or more	70.75 or more	1.95	2.10

OR

B. FVC (see 103.00E) 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	0.85	<153.0	<60.25	1.65	1.65
123.0 to <129.0	48.50 to <50.75	1.00	153.0 to <159.0	60.25 to <62.50	1.70	1.80
129.0 to <134.0	50.75 to <52.75	1.10	159.0 to <164.0	62.50 to <64.50	1.80	1.95
134.0 to <139.0	52.75 to <54.75	1.30	164.0 to <169.0	64.50 to <66.50	1.95	2.10
139.0 to <144.0	54.75 to <56.75	1.40	169.0 to <174.0	66.50 to <68.50	2.05	2.25
144.0 to <149.0	56.75 to <58.75	1.55	174.0 to <180.0	68.50 to <70.75	2.20	2.45
149.0 or more	58.75 or more	1.70	180.0 or more	70.75 or more	2.30	2.55

OR

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

OR

D. The presence of a tracheostomy.

1. Consider under a disability until the attainment of age 3; or

2. Upon the attainment of age 3, documented need for 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 (see 103.00F) with exacerbations or complications requiring three hospitalizations within a 12-month period and at least 30 days apart (the 12-month period must occur within the period we are considering in connection with your application or continuing disability review).

Each hospitalization must last at least 48 hours, including hours in a hospital emergency department immediately before the hospitalization. (A child's initial birth hospitalization when CLD is first diagnosed counts as one hospitalization.) 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 another appropriate listing.

103.03 *Asthma* (see 103.00G) with exacerbations or complications requiring three hospitalizations within a 12-month period and at least 30 days apart (the 12-month period must occur within the period we are considering in connection with your application or continuing disability review). 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) under 103.03 or another appropriate listing.

103.04 *Cystic fibrosis* (documented as described in 103.00H), with A, B, C, D, E, F, or G:

A. FEV_1 (see 103.00E) 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	1.00	<153.0	<60.25	1.75	1.85
123.0 to <129.0	48.50 to <50.75	1.15	153.0 to <159.0	60.25 to <62.50	1.85	2.05
129.0 to <134.0	50.75 to <52.75	1.25	159.0 to <164.0	62.50 to <64.50	1.95	2.15
134.0 to <139.0	52.75 to <54.75	1.40	164.0 to <169.0	64.50 to <66.50	2.10	2.30
139.0 to <144.0	54.75 to <56.75	1.50	169.0 to <174.0	66.50 to <68.50	2.25	2.45
144.0 to <149.0	56.75 to <58.75	1.70	174.0 to <180.0	68.50 to <70.75	2.35	2.60
149.0 or more	58.75 or more	1.80	180.0 or more	70.75 or more	2.50	2.70

OR

B. For children who have not attained age 6, findings on imaging (see 103.00D3) 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. Exacerbations or complications (see 103.00H3) requiring three hospitalizations of any length within a 12-month period and at least 30 days apart (the 12-month period must occur within the period we are considering in connection with your application or continuing disability review).

OR

D. Spontaneous pneumothorax, secondary to CF, requiring chest tube placement.

OR

E. Respiratory failure (see 103.00J) requiring invasive mechanical ventilation, noninvasive ventilation with BiPAP, or a combination of both treatments, for a continuous period of at least 48 hours, or for a continuous period of at least 72 hours if postoperatively.

OR

F. Pulmonary hemorrhage requiring vascular embolization to control bleeding.

OR

G. Two of the following exacerbations or complications (either two of the same or two different, see 103.00H3 and 103.00H4) within a 12-month period (the 12-month period must occur within the period we are considering in connection with your application or continuing disability review):

1. Pulmonary exacerbation requiring 10 consecutive days of intravenous antibiotic treatment.

2. Pulmonary hemorrhage (hemoptysis with more than blood-streaked sputum but not requiring vascular embolization) requiring hospitalization of any length.

3. 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.

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

103.05 [Reserved]

103.06 *Growth failure due to any chronic respiratory disorder* (see 103.00K), documented by:

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

AND

B. Growth failure as required in 1 or 2:

1. *For children from birth to attainment of age 2,* three weight-for-length measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile on the appropriate weight-for-length table under 105.08B1; or

2. *For children age 2 to attainment of age 18,* three BMI-for-age measurements that are:

a. Within a consecutive 12-month period; and

b. At least 60 days apart; and

c. Less than the third percentile on the appropriate BMI-for-age table under 105.08B2.

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 (for CF, see 103.04E), requiring invasive mechanical ventilation, noninvasive ventilation with BiPAP, or a combination of both treatments, for a continuous period of at least 48 hours, or for a continuous period of at least 72 hours if postoperatively, *twice* within a 12-month period and at least 30 days apart (the 12-month period must occur within the period we are considering in connection with your application or continuing disability review).

* * * * *

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

Subpart I—Determining Disability and Blindness

■ 3. 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).

§ 416.926a [Amended]

■ 4. Amend § 416.926a by removing paragraph (m)(1) and redesignating paragraphs (m)(2) through (6) as (m)(1) through (5).

[FR Doc. 2016–13275 Filed 6–8–16; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA–2016–N–0001]

Advisory Committee; Transmissible Spongiform Encephalopathies Advisory Committee; Termination

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination of the Transmissible Spongiform Encephalopathies Advisory Committee. This document removes the Transmissible Spongiform Encephalopathies Advisory Committee from the Agency's list of standing advisory committees.

DATES: This rule is effective June 9, 2016.

FOR FURTHER INFORMATION CONTACT: Bryan Emery, Division of Scientific Advisors and Consultants, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6132, Silver Spring, MD 20993–0002, 240–402–8054, FAX: 301–595–1307, or *bryan.emery@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Transmissible Spongiform Encephalopathies Advisory Committee (the Committee) was established on June 9, 1995 (60 FR 31311, June 14, 1995; 21 CFR 14.100 erroneously lists the date of establishment as June 21, 1995). The Committee reviews and evaluates available scientific data concerning the safety of products that may be a risk for transmission of spongiform encephalopathies having an impact on the public health as determined by the Commissioner of Food and Drugs. The Committee makes recommendations to the Commissioner regarding the regulation of such products. In recent years, the number of issues requiring Committee advice has declined, and the Committee has met very infrequently. Therefore, the effort and expense of maintaining this advisory committee is no longer justified. Any relevant Transmissible Spongiform Encephalopathy issues in the future could be addressed by the Agency's other advisory committees, such as the Agency's Blood Products Advisory Committee, with additional augmentation of expertise by appropriate subject matter experts serving as temporary members on the committee.

The Committee is no longer needed and will be terminated on June 9, 2016.

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40 (d) and (e), the Agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule merely removes the name of the Transmissible Spongiform Encephalopathies Advisory Committee from the list of standing advisory committees in 21 CFR 14.100.

Therefore, the Agency is amending 21 CFR 14.100(b) as set forth in the regulatory text of this document.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 1. The authority citation for part 14 continues to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461, 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107–109; Pub. L. 108–155.

§ 14.100 [Amended]

■ 2. In § 14.100, redesignate paragraph (b)(5) as (b)(4) and remove paragraph (b)(6).

Dated: June 6, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2016–13705 Filed 6–8–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE INTERIOR

Office of Natural Resources Revenue

30 CFR Part 1241

[Docket No. ONRR–2016–0002; DS63644000 DR2PS0000.CH7000167D0102R2]

RIN 1012–AA17

Civil Monetary Penalties Inflation Adjustment

AGENCY: Office of the Secretary, Office of Natural Resources Revenue, Interior.

ACTION: Interim final rule.

SUMMARY: The Office of Natural Resources Revenue (ONRR) publishes this interim final rule to adjust the amount of our civil monetary penalties (CMPs) for inflation with an initial ''catch-up'' adjustment under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and Office of Management and Budget (OMB) guidance.

DATES: This rule is effective July 11, 2016. Comments will be accepted until August 8, 2016.

ADDRESSES: You may submit comments to ONRR by one of the following three methods. (Please reference the Regulation Identifier Number (RIN) 1012–AA17 in your comments.). See also Public Availability of Comments under Procedural Requirements.

1. Electronically, go to *www.regulations.gov.* In the entry titled ''Enter Keyword or ID,'' enter ''ONRR–2016–0002,'' and then click ''Search.'' Follow the instructions to submit public comments. ONRR will post all comments.

2. Mail comments to Luis Aguilar, Regulatory Specialist, ONRR, P.O. Box 25165, MS 64400B, Denver, Colorado 80225.

3. Hand-carry comments, or use an overnight courier service to the Office of Natural Resources Revenue, Building 53, Entrance E–20, Denver Federal Center, West 6th Ave. and Kipling St., Denver, Colorado 80225.

FOR FURTHER INFORMATION CONTACT: For comments or questions on procedural issues, contact Luis Aguilar, Regulatory Specialist, by telephone at (303) 231–3418 or email to *luis.aguilar@onrr.gov.* For questions on technical issues, contact Geary Keeton, Chief of Enforcement, by telephone at (303) 231–3096 or email to *geary.keeton@onrr.gov.*

SUPPLEMENTARY INFORMATION: