SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

RIN 0960–AD48

Revised Medical Criteria for Evaluating Cardiovascular Impairments

AGENCY: Social Security Administration.

ACTION: Final rules.

SUMMARY: We are revising the criteria in the Listing of Impairments (the listings) that we use to evaluate claims involving cardiovascular impairments. We apply these criteria when you claim benefits based on disability under title II and title XVI of the Social Security Act (the Act). The revisions reflect advances in medical knowledge, treatment, and methods of evaluating cardiovascular impairments.

DATES: These rules are effective April 13, 2006.

Electronic Version

The electronic file of this document is available on the date of publication in the **Federal Register** at *http://www.gpoaccess.gov/fr/index.html*.

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SUPPLEMENTARY INFORMATION: We are revising and making final the rules we proposed for evaluating cardiovascular impairments in the Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** on September 16, 2004 (69 FR 55874).

We provide a summary of the provisions of the final rules below, with an explanation of the changes we have made from the text in the NPRM. We then provide summaries of the public comments and our reasons for adopting or not adopting the recommendations in those comments in the section ''Public Comments.'' The final rule language follows the Public Comments section.

What Programs Do These Final Regulations Affect?

These final regulations affect disability determinations and decisions that we make under title II and title XVI of the Act. In addition, to the extent that Medicare entitlement and Medicaid eligibility are based on whether you qualify for disability benefits under title II and title XVI, these final regulations also affect the Medicare and Medicaid programs.

Who Can Get Disability Benefits?

Under title II of the Act, we provide for the payment of disability benefits if you are disabled and belong to one of the following three groups:

- Workers insured under the Act.
- Children of insured workers.
- Widows, widowers, and surviving divorced spouses (see § 404.336) of insured workers.

Under title XVI of the Act, we provide for Supplemental Security Income (SSI) payments on the basis of disability if you are disabled and have limited income and resources.

How Do We Define Disability?

Under both the title II and title XVI programs, disability must be the result of any medically determinable physical or mental impairment or combination of impairments that is expected to result in death or which has lasted or can be expected to last for a continuous period of at least 12 months. Our definitions of disability are shown in the following table:

If you file a claim under . . .	And you are . . .	Disability means you have a medically determinable impairment(s) as described above that results in . . .
title II	an adult or a child	the inability to do any substantial gainful activity (SGA).
title XVI	an individual age 18 or older	the inability to do any SGA.
title XVI	an individual under age 18	marked and severe functional limitations.

How Do We Decide Whether You Are Disabled?

If you are seeking benefits under title II of the Act, or if you are an adult seeking benefits under title XVI of the Act, we use a five-step ''sequential evaluation process'' to decide whether you are disabled. We describe this five-step process in our regulations at §§ 404.1520 and 416.920. We follow the five steps in order and stop as soon as we can make a determination or decision. The steps are:

1. Are you working and is the work you are doing substantial gainful activity? If you are working and the work you are doing is substantial gainful activity, we will find that you are not disabled, regardless of your medical condition or your age, education, and work experience. If you are not, we will go on to step 2.

2. Do you have a ''severe'' impairment? If you do not have an impairment or combination of impairments that significantly limits your physical or mental ability to do basic work activities, we will find that you are not disabled. If you do, we will go on to step 3.

3. Do you have an impairment(s) that meets or medically equals the severity of an impairment in the listings? If you do, and the impairment(s) meets the duration requirement, we will find that you are disabled. If you do not, we will go on to step 4.

4. Do you have the residual functional capacity to do your past relevant work? If you do, we will find that you are not disabled. If you do not, we will go on to step 5.

5. Does your impairment(s) prevent you from doing any other work that exists in significant numbers in the national economy, considering your residual functional capacity, age, education, and work experience? If it does, and it meets the duration requirement, we will find that you are disabled. If it does not, we will find that you are not disabled.

We use a different sequential evaluation process for children who apply for payments based on disability under title XVI of the Act. We describe that sequential evaluation process in § 416.924 of our regulations. If you are already receiving benefits, we also use a different sequential evaluation process when we decide whether your disability continues. See §§ 404.1594, 416.994, and 416.994a of our regulations. However, all of these processes include steps at which we consider whether your impairment meets or medically equals one of our listings.

What Are the Listings?

The listings are examples of impairments that we consider severe enough to prevent you as an adult from doing any gainful activity. If you are a child seeking SSI benefits based on disability, the listings describe impairments that we consider severe

enough to result in marked and severe functional limitations. Although the listings are contained only in appendix 1 to subpart P of part 404 of our regulations we incorporate them by reference in the SSI program in § 416.925 of our regulations, and apply them to claims under both title II and title XVI of the Act.

How Do We Use the Listings?

The listings are in two parts. There are listings for adults (part A) and for children (part B). If you are an individual age 18 or over, we apply the listings in part A when we assess your claim, and we do not use the listings in part B.

If you are an individual under age 18, we first use the criteria in part B of the listings. If the listings in part B do not apply, and the specific disease process(es) has a similar effect on adults and children, we then use the criteria in part A. (See §§ 404.1525 and 416.925.)

If your impairment(s) does not meet any listing, we will also consider whether it medically equals any listing; that is, whether it is as medically severe as an impairment in the listings. (See §§ 404.1526 and 416.926.)

What If You Do Not Have an Impairment(s) That Meets or Medically Equals a Listing?

We use the listings only to decide that individuals are disabled or that they are still disabled. We will not deny your claim because your impairment(s) does not meet or medically equal a listing. If you are not doing work that is substantial gainful activity, and you have a severe impairment(s) that does not meet or medically equal any listing, we may still find you disabled based on other rules in the ''sequential evaluation process'' described above. Likewise, we will not decide that your disability has ended only because your impairment(s) does not meet or medically equal a listing.

Also, when we conduct reviews to determine whether your disability continues, we will not find that your disability has ended because we have changed a listing. Our regulations explain that, when we change our listings, we continue to use our prior listings when we review your case, if you had qualified for disability benefits or SSI payments based on our determination or decision that your impairment(s) met or medically equaled a listing. In these cases, we determine whether you have experienced medical improvement, and if so, whether the medical improvement is related to the ability to work. If your condition(s) has medically improved so that you no longer meet or medically equal the prior listing, we evaluate your case further to determine whether you are currently disabled. We may find that you are currently disabled, depending on the full circumstances of your case. See §§ 404.1594(c)(3)(i) and 416.994(b)(2)(iv)(A). If you are a child who is eligible for SSI payments, we follow a similar rule when we decide whether you have experienced medical improvement in your condition(s). See § 416.994a(b)(2).

Why Are We Revising the Listings for Cardiovascular Impairments?

We are revising these listings to update our medical criteria for evaluating cardiovascular impairments and to provide more information about how we evaluate them. On April 24, 2002, we published final rules in the **Federal Register** (67 FR 20018) that included technical revisions to some of the listings for cardiovascular impairments. Prior to this, we last published final rules making comprehensive revisions to the listings for cardiovascular impairments in the **Federal Register** on February 10, 1994 (59 FR 6468). Because we have not comprehensively revised the listings for this body system since 1994, we believe that we need to update the rules.

What Do We Mean by ''Final Rules'' and ''Prior Rules''?

Even though these rules will not go into effect until 90 days after publication of this notice, for clarity, we refer to the changes we are making here as the ''final rules'' and to the rules that will be changed by these final rules as the ''prior rules.''

When Will We Start To Use These Final Rules?

We will start to use these final rules on their effective date. We will continue to use our prior rules until the effective date of these final rules. When these final rules become effective, we will apply them to new applications filed on or after the effective date of these rules and to claims pending before us, as we describe below.

As is our usual practice when we make changes to our regulations, we will apply these final rules on or after their effective date when we make a determination or decision, including those claims in which we make a determination or decision after remand to us from a Federal court. With respect to claims in which we have made a final decision, and that are pending judicial review in Federal court, we expect that the court's review of the Commissioner's final decision would be made in accordance with the rules in effect at the time of the administrative law judge's (ALJ) decision, if the ALJ's decision is the final decision of the Commissioner. If the court determines that the Commissioner's final decision is not supported by substantial evidence, or contains an error of law, we would expect that the court would reverse the final decision, and remand the case for further administrative proceedings pursuant to the fourth sentence of section 205(g) of the Act, except in those few instances in which the court determines that it is appropriate to reverse the final decision and award benefits without remanding the case for further administrative proceedings. In those cases decided by a court after the effective date of the rules, where the court reverses the Commissioner's final decision and remands the case for further administrative proceedings, on remand, we will apply the provisions of these final rules to the entire period at issue in the claim.

How Long Will These Final Rules Be Effective?

These rules will no longer be effective 5 years after the date on which they become effective, unless we extend them or revise and issue them again.

What General Changes Are We Making That Affect Both the Adult and Childhood Listings for Cardiovascular Impairments?

We are reorganizing and expanding the evaluation guidance we provide in the introductory text and improving its logical presentation. We are also removing reference listings from this body system. Reference listings are listings that are met by satisfying the criteria of another listing. For example, prior listing 4.08, for cardiomyopathies, was a reference listing that required evaluation under listings 4.02, Chronic heart failure, 4.04, Ischemic heart disease, 4.05, Recurrent arrhythmias, or 11.04, Central nervous system vascular accident. Instead of using reference listings, we are providing guidance in the introductory text stating that these impairments should be evaluated under the criteria for the affected body system. Where appropriate, we also provide references to specific listings. For example, in final section 104.00F4, we indicate that valvular heart disease should be evaluated under the criteria in 4.04 in part A, 104.02, 104.05, 104.06, or an appropriate neurological listing under 111.00ff.

How Are We Changing the Introductory Text to the Listings for Evaluating Cardiovascular Impairments in Adults?

4.00 Cardiovascular Impairments

We are expanding and reorganizing the introductory text to these listings to present the information in a more logical order, to provide additional guidance, and to reflect the new listings. The following is a detailed explanation of this material.

4.00A—General

In this section, we provide general information on what we mean by the term ''a cardiovascular impairment'' and what we consider when we evaluate cardiovascular impairments. Final section 4.00A1 incorporates the information found in prior 4.00B, with some minor editing. Final section 4.00A2 is taken from the first sentence of the first paragraph of prior 4.00A.

Final section 4.00A3 is a new section containing definitions of major terms we use in these final listings. In a nonsubstantive editorial revision to the NPRM text, we clarified the definition of a ''consecutive 12-month period'' to explain better when the 12-month period must occur.

4.00B—Documenting Cardiovascular Impairment

Final section 4.00B1 is based on the first sentence of prior section 4.00C and the second sentence of prior section 4.00A. In it, we provide information on the basic documentation that we need to evaluate cardiovascular impairments under the listings. Final sections 4.00B2–4.00B3 are based on the second and third paragraphs of prior section 4.00A. They include a discussion of the importance of longitudinal records and what we will do when a longitudinal record is not available because you have not received ongoing medical treatment. In final sections 4.00B4–4.00B6, we explain when we will wait for your condition to become stable before we ask for more evidence to help us evaluate the severity and duration of your impairment, explain when we may decide to purchase studies, and specify what studies we will not purchase. Much of this information is taken from prior sections 4.00C and 4.00D, with some rephrasing to clarify our meaning. For example:

- Final section 4.00B4a is based on prior section 4.00D1, and the examples in final sections 4.00B4a(i) and 4.00B4a(ii) are based on the first sentence of prior section 4.00D2.
- Final section 4.00B5 is based on the second sentence of prior section 4.00C2a and the third and sixth sentences of prior section 4.00C3.
- Final section 4.00B6 is based on information in prior section 4.00C4.

4.00C—Using Cardiovascular Test Results

In this section, we discuss various specialized cardiovascular tests and how we evaluate their results. In final section 4.00C1, we explain what an electrocardiogram (ECG) is. Our specifications for ECG tracings from prior section 4.00C1 are given in final section 4.00C2. In final section 4.00C3, we explain what the different kinds of exercise tests are and discuss their uses; the section includes information from various provisions throughout prior sections 4.00C and E, but we have also included additional guidance and definitions. Exercise testing is the most widely used testing for identifying the presence of myocardial ischemia and for estimating maximal aerobic capacity. However, as we state throughout the introductory text, we will consider all the relevant evidence and will not rely solely on the results of one type of test. In final section 4.00C4, we discuss the limitations of exercise tolerance tests (ETTs) as evidence for disability evaluation. We repeat our longstanding policy that ETTs estimate your ability to walk on a grade, bicycle, or move your arms in an environmentally controlled setting, so they do not correlate with the ability to perform other types of exertional activities and do not provide an estimate of your ability to perform activities required for work in all possible work environments or throughout a workday. Final section 4.00C5 is based on the second paragraph of prior section 4.00C3. In it, we explain what ETTs with measurement of maximal or peak oxygen uptake are and how they differ from other ETTs. We also explain what METs (metabolic equivalents) are and how they are calculated when not given in the report of an ETT with measurement of maximal or peak oxygen uptake.

In final section 4.00C6, we explain when we will consider purchasing an exercise test for case evaluation. Like final section 4.00B5, it is based on the second sentence of prior section 4.00C2a. As a result of a comment we describe below, we revised the language we proposed to clarify that we purchase an exercise test only when we need one to make a determination or decision.

In final section 4.00C7, we explain what we must do before we purchase an exercise test. The final rule combines a number of related provisions that were not grouped together in our prior rules and also adds a provision that provides additional safeguards for individuals that we ask to go for stress testing that we purchase.

In final section 4.00C7a, as in the third sentence of prior section 4.00C2a and the second sentence of prior section 4.00C2c, we continue to require that a medical consultant (MC), preferably one with experience in the care of patients with cardiovascular disease, review the evidence to determine whether performing an exercise test would put you at significant risk, or if there is some other medical reason not to do the test. (When an administrative law judge or an administrative appeals judge at the Appeals Council decides that a consultative examination is appropriate, the administrative law judge or the administrative appeals judge will ask the State agency to arrange for the examination. In this situation, an MC will still assess whether a consultative examination that includes exercise testing would involve a significant risk to you. This is the same procedure that we followed under our prior rules.)

Final section 4.00C7b corresponds to the fourth sentence of prior section 4.00C2e(1). In it, we explain that if you are under the care of a treating source for your cardiovascular impairment, this source has not performed an exercise test, and there are no reported significant risks to testing, we will request a statement from the source explaining why an exercise test was not done.

Final section 4.00C7c explains that an MC will generally give ''great weight'' to your treating source's opinion about the risk of exercise testing to you and will generally not override such an opinion; this policy was in the third sentence of prior section 4.00C2c. As in the NPRM, we are also including the provision that was in the fourth sentence of prior section 4.00C2c to require that in the rare situation in which the MC does override a treating source's opinion the MC must provide a written rationale documenting the reasons for overriding the opinion.

Final section 4.00C7d corresponds to the last sentence of prior section 4.00C2e(1). It explains that if you do not have a treating source or we cannot obtain a statement from your treating source, the MC is responsible for assessing the risk of exercise testing to you.

Final section 4.00C7e is new in our cardiovascular listings. It explains that, when we purchase an exercise test, we must send copies of your records to the medical source who conducts the test for us if he or she does not already have them. We also provide that this individual has the ultimate

responsibility for determining whether you would be at risk if you take the test.

In final section 4.00C8, we reorganize and modify the information on ''significant risk'' from the first sentence of prior section 4.00C2c. We are doing this because some of the so-called risk factors identified in the prior rule were not risks *per se*, but factors that affect proper interpretation of the tracings or situations that only temporarily preclude exercise testing. We identify several different categories that explain the various circumstances under which we will not purchase an ETT or will defer purchasing one. We base much of these provisions on the list of contraindications to exercise testing in the *Guidelines for Exercise Testing* published jointly by the American College of Cardiology (ACC) and the American Heart Association (AHA) in 1997 and updated in 2002. (See citations in the NPRM, 69 FR 55874, 55881–55882.) In response to a comment discussed in the public comments section of this preamble below, we have added a provision in the final rules, final section 4.00C8c, explaining that we will not purchase an ETT to document the presence of a cardiac arrhythmia. Final section 4.00C8d (proposed section 4.00C8c) is based on the first and second sentences of prior section 4.00C2d, the paragraph that explained when we will wait following specific cardiac events before we purchase an exercise test. Final section 4.00C8e corresponds to the last sentence of prior paragraph 4.00C2d; it explains that we will wait an appropriate period of time before we purchase an exercise test if you are deconditioned after an extended period of bedrest or inactivity. As in the NPRM, we removed the example of ''2 weeks'' from the prior rule to avoid any suggestion that a 2-week recovery period will generally be sufficient. The amount of time we may need to wait will depend on the particular facts of your case.

In final section 4.00C9, we explain when we consider exercise test results to be ''timely.'' Final section 4.00C9a corresponds to the last sentence of prior section 4.00C2a, explaining that we consider exercise test results to be timely for 12 months after the date they are performed, provided there has been no change in your clinical status that may alter the severity of your cardiovascular impairment. In final 4.00C9b and 4.00C9c, we are expanding this topic to explain how we consider tests that are not timely.

Final section 4.00C10 discusses the performance requirements of tests that we purchase, while final section 4.00C11 discusses how we evaluate all ETT results. We retained these provisions from prior sections 4.00C2b and the first three sentences of prior section 4.00C2e(1). In final section 4.00C10a, we added a sentence that we did not include in the NPRM. The sentence explains that exercise tests may also be performed using echocardiography to detect stress-induced ischemia and left ventricular dysfunction. This additional guidance will make more complete our explanation of the types of ETTs we may purchase in appropriate cases.

We explain when ETTs are done with imaging and when we will consider purchasing such tests in final sections 4.00C12–4.00C13; the provisions are based on prior section 4.00C3. We provide new guidance on drug-induced stress tests, what they are, how they are used, and when we may purchase them, in final section 4.00C14.

Final section 4.00C15 includes the information found in prior section 4.00C4 on two types of cardiac catheterization reports, the details that these reports should contain, and what we consider when evaluating these reports. Final sections 4.00C16 and 4.00C17 describe Doppler exercise tests and when we will purchase them. In response to a comment described below, we revised final section 4.00C16 to clarify which details are required in reports of exercise Doppler studies and what information should be obtained. We specify that the tracings should be included with the report and that they must be annotated with the standardization used by the testing facility. In final section 4.00C17, as in the NPRM, we changed the requirement in the third paragraph of prior section 4.00E4 for walking on a ''10 or 12 percent grade'' to a ''12 percent grade.'' This change makes our rules consistent with how the test is generally done. In a nonsubstantive editorial revision to the NPRM text, we have also clarified that you must exercise for ''up to 5 minutes'' to recognize that some individuals will be unable to exercise for a full 5 minutes. The language we proposed in the NPRM could have been misread to mean that we require everyone to exercise for 5 minutes even if they are unable to do so. We also provide that, because this is an exercise test, we must evaluate whether such testing would put you at significant risk, in accordance with the guidance found in 4.00C6, 4.00C7, and 4.00C8. Finally, in a technical clarification, we revised the heading of final section 4.00C17 from the proposed heading to change the word ''should'' to ''must.'' This is because the final rule (like the NPRM) specifies what we require in any exercise Doppler test we purchase.

In final sections 4.00D–4.00H, we provide general medical information on the various cardiovascular impairments and information on how we evaluate each of them using the final listing criteria. We incorporate information found in prior section 4.00E and guidance we have provided to our adjudicators in instructions that were not in the prior listings. We also add some new information, as described below.

4.00D—Evaluating Chronic Heart Failure

In final section 4.00D1, for chronic heart failure, we explain what chronic heart failure is and the differences between the two main types of chronic heart failure—systolic and diastolic. Final section 4.00D1b is based on prior section 4.00E1. We explain that we will now evaluate cor pulmonale under respiratory system listing 3.09, rather than listing 4.02, as it is a heart condition resulting from a respiratory disorder. (In a related change, described later in this preamble, we are also removing a cross-reference to the cardiovascular listings from listing 3.09.)

In final sections 4.00D2 and 4.00D3, we describe the evidence that we need for evaluating chronic heart failure and explain how ETTs may be used to evaluate individuals with known chronic heart failure. We added a reference in final section 4.00D3 to the section on when we will consider the purchase of an ETT (final section 4.00C6). In response to a comment on the last sentence of proposed section 4.00D3, we revised the sentence to clarify our intent, that ST segment changes from digitalis use in the treatment of chronic heart failure do not preclude the purchase of an ETT in cases involving chronic heart failure.

In the NPRM, proposed section 4.00D4 was a single paragraph that explained what we mean by ''periods of stabilization'' in listing 4.02B2. In the final rules, we have changed the heading of the section to ''How do we evaluate CHF using 4.02?'' and expanded the section to include four subparagraphs. The changes are not substantive, but only clarify generally how we use listing 4.02. They also explain how we use a criterion that is common to listings 4.02B3c and 4.04A3: In the NPRM, we explained how the criterion applies in listing 4.04A3 but inadvertently did not include the same explanation for listing 4.02B3c.

In final section 4.00D4a, and consistent with the provisions of final

section 4.00D2, we explain that we need objective evidence of chronic heart failure. In final section 4.00D4b, we repeat the requirement of final listing 4.02 that your impairment must satisfy one of the criteria in both A and B of that listing to meet the listing. Neither of these new sections provides any additional substantive guidance that was not already inherent in the proposed rules; however, they do explain more clearly how to use final listing 4.02.

Final section 4.00D4c corresponds to proposed section 4.00D4. Based on a suggestion from a commenter, we changed the duration of the periods of stabilization from 5 days to 2 weeks to allow for variability during medication titrations. We discuss the comment and our reasons for making the change in the public comments section later in this preamble.

Final section 4.00D4d addresses the criterion that is common to final listings sections 4.02B3c and 4.04A3: a requirement for a 10 mmHg decrease in systolic blood pressure below the baseline systolic blood pressure. We provided a detailed explanation of this provision in proposed section 4.00E9e, which addressed ischemic heart disease, but inadvertently omitted the same explanation for the virtually identical provision for CHF. Therefore, in these final rules, we moved the text of proposed section 4.00E9e to final section 4.00D4d because it comes first in the introductory text. In final section 4.00E9e, we now include only a cross-reference to the provisions we moved to final 4.00D4d instead of repeating the entire paragraph.

4.00E—Evaluating Ischemic Heart Disease

In final section 4.00E, for ischemic heart disease (IHD), we incorporate most of the information in prior section 4.00E3. We explain what IHD is and what causes chest discomfort of myocardial origin in final sections 4.00E1 and 4.00E2. We move and revise slightly the material on chest discomfort of myocardial ischemic origin from prior section 4.00E3e to final section 4.00E2 and explain that individuals with IHD may experience manifestations other than typical angina pectoris. We also deleted the final sentence in prior section 4.00E3e as it was not useful adjudicative guidance. We discuss the characteristics of typical angina pectoris in final section 4.00E3. This section is based on and incorporates material from prior section 4.00E3a. In final section 4.00E4, we include a definition of, and information on, atypical angina, which we included in our discussion of anginal equivalent in prior section 4.00E3b. We discuss anginal equivalent in final section 4.00E5. The material on anginal equivalent is based on prior section 4.00E3b, but we explain that it is essential to establish objective evidence of myocardial ischemia in order to differentiate anginal equivalent shortness of breath (dyspnea) that results from myocardial ischemia from dyspnea that results from non-ischemic or non-cardiac causes. Final section 4.00E6, on variant angina, is based on prior section 4.00E3c, but we discuss in greater detail what variant angina is, how it is diagnosed and treated, and how we will evaluate it. We also state that vasospasm that is catheter-induced during coronary angiography is not variant angina.

In final section 4.00E7, we expand the discussion of silent ischemia that appeared in prior section 4.00E3d. We explain what silent ischemia is and why it may occur. We describe the situations in which it most often occurs, how it may be documented using ambulatory ECG monitoring (Holter) equipment, and how we evaluate it. We move the material on chest discomfort of non-ischemic origin from prior section 4.00E3f to final section 4.00E8. We add acute anxiety or panic attacks to the examples of noncardiac conditions that may produce symptoms mimicking myocardial ischemia since we recognize that mental disorders may produce physical symptoms.

In final section 4.00E9, we explain how we evaluate IHD using the criteria in listing 4.04. In a nonsubstantive editorial change from the NPRM text, we specify in final section 4.00E9b how ischemia is confirmed in possible false-positive test situations, to conform to the language in final section 4.00E9d. We changed the reference to ''appropriate medically acceptable imaging techniques'' to ''radionuclide or echocardiogram confirmation'' because these are the appropriate medically acceptable imaging techniques for diagnosing ischemia in possible false-positive situations. We also added a reference to final sections 4.00C12 and 4.00C13, which discuss ETTs done with imaging.

In the next-to-last sentence of the final section 4.00E9d, we also added a reference to echocardiography in addition to the reference to radionuclide testing we had already included in the NPRM. Again, radionuclide and echocardiogram confirmation are the appropriate medically acceptable imaging techniques for diagnosing ischemia in possible false-positive situations. We also added a reference to final sections 4.00C12 and 4.00C13; this will make final sections 4.00D4b and 4.00D4d consistent with each other. As already noted, we moved the text we included in proposed section 4.00E9e to final section 4.00D4d because final listing sections 4.02B3c and 4.04A3 are identical. Instead of repeating the same provisions in final sections 4.00D4d and 4.00E9e, we abbreviate the explanation of the 10 mmHg decrease in systolic blood pressure required in final listing 4.04A3 and add a reference to the detailed discussion in final section 4.00D4d.

We also clarified and moved the explanation of what we mean by ''nonbypassed'' from proposed section 4.00E9g into a new section, final section 4.00E9h, because it is a different subject from what is addressed in final section 4.00E9g.

4.00F—Evaluating Arrhythmias

In final section 4.00F, we provide information on evaluating arrhythmias. We explain what arrhythmias are and discuss the different types in final sections 4.00F1–4.00F2. We made a nonsubstantive editorial revision, rearranging the NPRM material by combining the provisions of proposed sections 4.00F3 and 4.00F4 in final section 4.00F3 under the heading ''How do we evaluate arrhythmias under 4.05?'' Thus, final section 4.00F3a corresponds to proposed section 4.00F4, on the use of listing 4.05 when there is an implanted cardiac defibrillator, and final sections 4.00F3b and 4.00F3c correspond to proposed section 4.00F3. In final section 4.00F3b, we explain what we mean by ''near syncope'' in final listing 4.05. In final section 4.00F3c, we add information on the evidence we need to document the required association between your syncope or near syncope and your cardiac arrhythmia. Because of a comment that tilt-table testing is frequently used to establish the presence of arrhythmia, we reexamined our position on tilt-table testing. In the final rules, we removed the proposed prohibition for the use of tilt-table testing as acceptable documentation of arrhythmia and included new guidance for using such testing. We specify that the tilt-table testing must be done concurrently with an ECG, and that the symptom of syncope or near syncope must be associated with the arrhythmia.

We redesignated proposed section 4.00F5 as final section 4.00F4, in which we provide information on implantable cardiac defibrillators and how we will evaluate arrhythmias if you have an implanted cardiac defibrillator, to

reflect the foregoing reorganization of the proposed provisions.

4.00G—Evaluating Peripheral Vascular Disease

In final section 4.00G, the section on peripheral vascular disease (PVD), we incorporate the information in prior section 4.00E4 and provide additional information and guidance on the evaluation of PVD based on questions we have received in the past. Final section 4.00G1 explains what we mean by PVD and describes its usual effects. In a nonsubstantive editorial revision, we rearranged the third sentence and added a description of the effects of advanced PVD. In final section 4.00G2, we explain how we assess the limitations resulting from PVD. This section is based on prior section 4.00E4, and explains that we will evaluate limitations based on your symptoms, together with physical findings, Doppler studies, other appropriate non-invasive studies, or angiographic findings. We also explain that we will evaluate amputations resulting from PVD under the musculoskeletal body system listings.

In final section 4.00G3, we define ''brawny edema'' and explain how it is different from pitting edema, adding to the NPRM language a brief explanation of the term ''pit.'' As in the NPRM, we also clarify that pitting edema does not satisfy the requirements of listing 4.11A. In a nonsubstantive editorial revision, we combined proposed sections 4.00G4 and 4.00G5, on what lymphedema is and what causes it, and the guidance on the evaluation of lymphedema into one section devoted to lymphedema, final section 4.00G4. The final rules provide that we will evaluate lymphedema under the listing for the underlying cause or consider whether the condition medically equals a cardiovascular listing, such as listing 4.11, or a musculoskeletal listing in 1.00. We also explain how we evaluate the condition in cases in which the listings are not met or medically equaled.

In the final rules, we rearranged proposed sections 4.00G6–4.00G12 to present the information more logically and to follow the order of final listings 4.11 and 4.12 more closely. We moved proposed section 4.00G8, on when we will obtain exercise Doppler studies for the evaluation of peripheral arterial disease (PAD), which we took from prior section 4.00E4, to final section 4.00G5. We moved proposed section 4.00G11 to final section 4.00G6. That section describes other studies that are helpful in evaluating PAD, particularly the recording ultrasonic Doppler unit, and the value of reviewing pulse wave tracings from these studies when evaluating individuals with diabetes mellitus or other diseases with the potential for similar vascular changes.

In final section 4.00G7, we combine proposed sections 4.00G6, 4.00G7, and 4.00G9 to describe how we evaluate PAD under final listing 4.12. In final section 4.00G7a (proposed section 4.00G6), we clarify how we consider blood pressures taken at the ankle. We will use the higher of the posterior tibial or dorsalis pedis systolic blood pressures measured at the ankle, because the higher pressure is more significant in assessing the extent of arterial insufficiency.

In final section 4.00G7b (proposed section 4.00G7), we take information from the third paragraph of prior section 4.00E4 on how the ankle/brachial ratio is determined for purposes of evaluating a claim under final listing 4.12. We also explain that the ankle and brachial pressures do not have to be taken on the same side of the body because we will use the higher brachial pressure measured, and we provide information on the various techniques used for obtaining ankle systolic blood pressures. For medical accuracy, we removed ''duplex scanning with color imaging'' from the NPRM's list of techniques for obtaining ankle systolic blood pressures because, although it is done in conjunction with testing, it does not measure pressures. We also specify that we will request any available tracings from those listed techniques, so that we can review them.

In final section 4.00G7c (proposed section 4.00G9), we add guidance on the use of toe pressures for evaluating intermittent claudication in individuals with abnormal arterial calcification or small vessel disease, as may happen if you have diabetes mellitus or certain other diseases. In the presence of abnormal arterial calcification or small vessel disease, the blood pressure at the ankle may be misleadingly high, but the toe pressure is seldom affected by these vascular changes. We also add two new criteria in final listing 4.12 using toe pressure and toe/brachial pressure ratio.

We redesignated the remaining sections of proposed 4.00G because of the foregoing reorganization. In final section 4.00G8 (proposed section 4.00G10), we explain how toe pressures are measured. In final section 4.00G9 (proposed section 4.00G12), we discuss the similarities between peripheral grafting and coronary grafting and explain how we will evaluate cases involving peripheral grafting.

4.00H—Evaluating Other Cardiovascular Impairments

In final section 4.00H, we provide guidance on evaluating other cardiovascular impairments. In final section 4.00H1, we discuss the evaluation of hypertension, rephrasing material found in prior section 4.00E2. We explain what congenital heart disease is and provide guidance on how we will evaluate symptomatic congenital heart disease in final section 4.00H2, combining proposed sections 4.00H2 and 4.00H3 in a nonsubstantive editorial revision. In final section 4.00H3 (proposed section 4.00H4), we provide guidance on what cardiomyopathy is and how we will evaluate it. We provide guidance on the evaluation of valvular heart disease in final section 4.00H4 (proposed section 4.00H5). We discuss the evaluation of heart transplant recipients in final section 4.00H5 (proposed section 4.00H6). In final section 4.00H6 (proposed section 4.00H7), we explain when an aneurysm has ''dissection not controlled by prescribed treatment'' as required under final listing 4.10. We add guidance on what hyperlipidemia is and how we will evaluate it in final section 4.00H7 (proposed section 4.00H8).

Because of a comment described below in the public comments section of this preamble, we added a new section, final section 4.00H8, to discuss Marfan syndrome and how we evaluate its manifestations.

4.00I—Other Evaluation Issues

In this section, we provide guidance on a variety of issues. In final section 4.00I1, we explain the evaluation of obesity's effect on the cardiovascular system. The guidance in this section is taken from prior section 4.00F, with minor edits, and incorporates additional guidance we included in Social Security Ruling 02–1p (''Titles II and XVI: Evaluation of Obesity,'' 67 FR 57859 (2002)). Final section 4.00I2 explains how we relate treatment to functional status. This section is based on prior section 4.00D; we have deleted some language that dealt with listing-level impairment from the prior section and made nonsubstantive editorial changes. If the anticipated improvement might affect the determination or decision in the case, we will wait an appropriate length of time in order to evaluate the results of the treatment. Finally, in final section 4.00I3, we explain how we evaluate cardiovascular impairments that do not meet a cardiovascular listing. This section is based on the fourth paragraph of prior section 4.00A.

How Are We Changing the Listings for Evaluating Cardiovascular Impairments in Adults?

4.01—Category of Impairments, Cardiovascular System

We are deleting the following current cardiovascular listings because they are reference listings that direct adjudicators to evaluate these impairments and their effects under other listings: 4.02C, Cor pulmonale; 4.03, Hypertensive cardiovascular disease; 4.06C, Symptomatic congenital heart disease with chronic heart failure; 4.06D, Symptomatic congenital heart disease with recurrent arrhythmias; 4.07, Valvular heart disease or other stenotic defects, or valvular regurgitation; 4.08, Cardiomyopathies; 4.10B, Aneurysm of aorta or major branches with chronic heart failure; 4.10C, Aneurysm of aorta or major branches with renal failure; and 4.10D, Aneurysm of aorta or major branches with neurological complications. As we have done with other body system listings, we are deleting these reference listings because they are redundant. However, we provide guidance in the introductory text of the listing on how we will evaluate these impairments using other listings.

The following is a detailed explanation of the final listing criteria.

4.02—Chronic heart failure

We change the format of prior listing 4.02, creating two new sections, 4.02A and 4.02B. For the listing to be met, both the 4.02A and 4.02B requirements must be satisfied. We move the required imaging findings that are generally associated with the clinical diagnosis of heart failure from prior listings 4.02A and 4.02B to final listings 4.02A1 and 4.02A2 and revise them to reflect the anatomical changes associated with systolic and diastolic dysfunction, respectively; in a minor edit, we replaced the reference we included in proposed sections 4.02A1 and 4.02A2 with a brief explanation of what we mean by ''a period of stability.'' The prior listing had different criteria for heart failure in sections 4.02A and 4.02B and did not provide criteria for both systolic and diastolic failure. Additionally, because the criterion in prior listing 4.02A of 5.5 cm is generally considered the high end of normal for heart size, we change the left ventricular diastolic diameter to left ventricular end diastolic dimensions greater than 6.0 cm. This change more clearly establishes an enlarged heart that would result in the signs and symptoms associated with listing-level severity.

We also redesignate prior listing 4.02A as final listing 4.02B1 and revise the criteria. The prior listing included a description of heart failure and referred to the ''inability to carry on any physical activity,'' which implied that the individual must be bedridden. Our program experience shows that this listing was set at too high a level of severity and was little used. We have removed the description of heart failure and rephrased the criteria in final listing 4.02B1 to describe an ''extreme'' limitation; that is, an impairment that very seriously limits your ability to independently initiate, sustain, or complete activities of daily living. This is modeled after our other rules that define listing-level severity in terms of an ''extreme'' limitation; for example, the definition of ''inability to ambulate effectively'' in the musculoskeletal listings, section 1.00A2b(1). This listing may be used only if the performance of an exercise test would present a significant risk to you.

We add a new criterion in final listing 4.02B2 to include individuals who have frequent acute episodes of heart failure, showing that the heart failure is not well-controlled by the prescribed treatment. This also provides another avenue that allows us to make favorable determinations or decisions in certain cases without ETTs.

We redesignate prior listing 4.02B1 as final listing 4.02B3. We also revise it by specifying in final listing 4.02B3a the symptoms of chronic heart failure that might cause termination of an ETT. This change makes it clear that the inability to exercise at a workload equivalent to 5 METs could be due to symptoms, as well as the signs listed in final 4.02B3b through 4.02B3d. We change the ''three or more multiform beats'' in prior listing 4.02B1a to ''increasing frequency of ventricular ectopy with at least 6 premature ventricular contractions per minute'' in final listing 4.02B3b. This provides broader criteria for terminating the test on account of exercise-induced (and potentially dangerous) ventricular ectopy (an arrhythmia in which the heartbeat is being triggered inappropriately by the ventricle, causing premature ventricular contraction).

In final listing 4.02B3c, we eliminate the criterion for ''[f]ailure to increase systolic blood pressure by 10 mmHg,'' from prior listing 4.02B1b because your blood pressure might be temporarily elevated at ''baseline'' due to anxiety, and the blood pressure response could be blunted by medications. Instead, we specify only an amount of decrease from the baseline systolic blood pressure or the preceding systolic pressure measured during exercise, due to left ventricular dysfunction, despite an increase in workload, at which the test should be terminated. In the final rule, we made minor revisions to the language of listings 4.02B3c and 4.04A3, which were slightly different from each other, to make them match exactly as we originally intended. These revisions do not substantively change either of the criteria, but are only for language consistency. We redesignate prior listing 4.02B1c, for signs attributable to inadequate cerebral perfusion, as final listing 4.02B3d, but make no other changes to it. We remove prior listing 4.02B2, the functional criterion that calls for ''marked limitation of physical activity,'' because it is unnecessary. If you satisfy one of the final listing 4.02A criteria and one of the final listing 4.02B3 criteria, a very seriously limited level of physical activity is implied, so it is not necessary to have a criterion describing this limitation.

4.04—Ischemic Heart Disease

In the header text, we change ''chest discomfort'' to ''symptoms'' because some individuals have discomfort in other parts of their body, such as an arm, their back, or their neck, or have other symptoms, such as shortness of breath (dyspnea), associated with ischemia. In final listing 4.04A1, we remove the phrase ''and that have a typical ischemic time course of development and resolution (progression of horizontal or downsloping ST depression with exercise)'' which appeared in prior listing 4.04A1 because we believe it is unnecessary. We also eliminate the prior listing 4.04A2 criterion. The ACC/AHA *Guidelines for Exercise Testing* indicate that an upsloping ST junction depression, as described in the prior criterion, has less specificity (more false-positive results) and favors the more commonly used horizontal or downsloping ST depression. We redesignate the subsequent criteria.

In final listing 4.04A2 (prior listing 4.04A3), we specify that the ST elevation must occur in ''non-infarct'' leads; that is, leads that do not reflect previous injury due to an infarction. This is because ST elevation during exercise commonly occurs with a ventricular aneurysm resulting from an infarction, without ischemia being present. We also reduce the requirement for the ST elevation during recovery from ''3 or more minutes'' to ''1 or more minutes.'' We believe that this ST elevation in non-infarct leads is of such significance that ST elevation for 1 minute or more during recovery is sufficient to show an impairment of listing-level severity. In listing 4.04A3

(prior listing 4.04A4), we eliminate the phrase ''[f]ailure to increase systolic pressure by 10 mmHg'' for the reasons previously discussed under the explanation of listing 4.02B3c. We also specify that there must be a decrease of 10 mmHg below baseline or the preceding systolic pressure measured during exercise due to left ventricular dysfunction, despite an increase in workload, because exercise normally raises blood pressure and a decrease during exercise reflects the presence of ischemia. As already noted, we made minor revisions to the language of final listing 4.04A3 to make it the same as final listing 4.02B3c.

We revise prior listing 4.04A5, but make no substantive changes to it, to make clear that the ''perfusion defect'' represents ischemia and to provide for use of imaging techniques other than radionuclide perfusion scans. We also redesignate it as final listing 4.04A4.

We are adding a new listing 4.04B criterion. The new criterion provides that your impairment meets the listing if you have three separate ischemic episodes, each requiring revascularization (angioplasty or bypass surgery) or not amenable to revascularization, within a consecutive 12-month period. Because this is a new, additional listing criterion, it will permit us to allow some cases more quickly.

In the header text for final listing 4.04C, we added the phrase ''or other appropriate medically acceptable imaging'' because this area of technology is rapidly improving. Thus, we are providing for the likelihood that imaging other than angiography will soon be able to identify the extent of blockage resulting from coronary artery disease. We also change the phrase ''evaluating program physician'' from the prior listing to ''MC'' to be consistent with our terminology throughout these final rules and in other regulations. Because not everyone who has the cited findings has ischemia, we add that this listing can be used only ''in the absence of a timely exercise tolerance test or a timely normal drug-induced stress test.''

We also revise the prior listing 4.04C1e criterion, ''[t]otal obstruction of a bypass graft vessel,'' to change it from ''total obstruction'' to ''70 percent or more narrowing.'' This conforms to the criterion in prior listing 4.04C1b for a nonbypassed coronary artery, which we are not changing. When we originally published the prior rule, it was not possible to tell how obstructed bypass graft vessels were. Imaging techniques have improved, making it possible to identify lesser degrees of obstruction of a bypass graft vessel. In the final rules, we revise the prior listing 4.04C2 criterion for functional limitations using substantively the same language as in final listing section 4.02B1.

4.05—Recurrent Arrhythmias

We change the requirement for ''uncontrolled repeated episodes of cardiac syncope or near syncope'' to ''uncontrolled recurrent episodes'' using the same definitions for the terms ''uncontrolled'' and ''recurrent'' in final section 4.00A3 that we use throughout these final rules. We remove the phrase ''and arrhythmia'' that followed ''near syncope'' in prior listing 4.05, because it was redundant; listing 4.05 is for ''[r]ecurrent arrhythmias.'' We also add language that allows documentation ''by other appropriate medically acceptable testing, coincident with the occurrence of syncope or near syncope'' to provide for the use of any appropriate medically acceptable tests developed for arrhythmia in the future, and refer to final section 4.00F3c, the paragraph that describes how we consider test findings in cases of arrhythmia.

4.06—Symptomatic Congenital Heart Disease

Because we are eliminating prior reference listings 4.06C and 4.06D, we redesignate prior listing 4.06E as final listing 4.06C. In final listing 4.06C, we no longer refer to ''mean'' pulmonary artery pressure, as it is the relationship between the pulmonary artery pressure and the systemic arterial pressure that is important. We also clarify that the systolic pressures are to be used.

4.09—Heart Transplant

We change the name from ''Cardiac transplantation'' to ''Heart transplant'' consistent with terminology in our other listings. We also change the phrase ''reevaluate residual impairment'' to ''evaluate residual impairment,'' as more accurate, since we would not have evaluated the residual impairment earlier than the end of the 12-month period following the transplant. In addition, we remove the guidance in the prior listing to evaluate the residual impairment under listings ''4.02 to 4.08,'' and substitute the phrase ''the appropriate listing.'' This clarifies that other listings besides listings 4.02 through 4.08 may apply, including listings in other body systems.

4.10—Aneurysm of Aorta or Major Branches

As we have already noted, we remove listings 4.10B through 4.10D because they are reference listings. We incorporate prior listing 4.10A into the header text, because it was the sole remaining listing. Because dissection of an aorta must be either acute or chronic, we remove those descriptors as unnecessary in this context. We also change the description of treatment to ''prescribed treatment,'' which includes both medical and surgical methods, and include a cross-reference to final section 4.00H6, the section that explains what a dissecting aneurysm is and when we consider that it is not controlled by prescribed treatment.

4.11—Chronic Venous Insufficiency

In final listing 4.11A, we add language to clarify what we mean by ''extensive'' brawny edema. We provide that brawny edema is ''extensive'' if it involves at least two-thirds of the leg between the ankle and knee. In response to a comment, we removed the word ''approximately'' from this criterion and added an additional descriptor, ''or the distal one-third of the lower extremity between the ankle and hip'' for further clarity. In final listing 4.11B, as in the NPRM, we refer only to ''prescribed treatment,'' which includes both medical and surgical methods. This is a clarification of the prior listing, which used the phrase ''prescribed medical or surgical therapy.'' These changes also help to clarify that the phrase ''that has not healed following at least 3 months of prescribed treatment'' applies only to ''persistent'' ulceration.

4.12—Peripheral Arterial Disease

In final listing 4.12, we remove prior listing 4.12A because arteriograms are generally used to determine when and where surgical intervention is needed and, if surgery is performed, it is unlikely that the duration requirement would be met. If intermittent claudication continues following surgery, we will evaluate it under the remaining criteria of this listing. We redesignate prior listings 4.12B1 and 4.12B2 as final listings 4.12A and 4.12B. (Note: We removed prior listing 4.12C, amputation, when we published the final musculoskeletal rules, which were effective February 19, 2002. See 66 FR 58010.)

We also revise the criteria on the methods for establishing peripheral arterial disease by substituting the phrase ''appropriate medically acceptable imaging'' for the prior reference to ''Doppler studies.'' In final listing 4.12B (prior listing 4.12B2), we eliminate the phrase ''at the ankle'' following ''pre-exercise level'' because it is redundant.

We also add two new listings, final listings 4.12C and 4.12D, for the use of resting toe systolic blood pressures and

resting toe/brachial systolic blood pressure ratios. As we explained under the discussion of final section 4.00G7c, ankle pressures can be misleadingly high when you have a disease that results in abnormal arterial calcification or small vessel disease, but the toe pressure is seldom affected by these vascular changes.

How Are We Changing the Introductory Text to the Listings for Evaluating Cardiovascular Impairments in Children?

We expand and reorganize the introductory material in 104.00 to provide additional guidance and to reflect the final listings. Because of the extensive information and guidance included in the introductory text for the listings, and as in the adult listings in part A, we group information on various subjects and related issues together in separate sections. Except for minor changes to refer to children, we have repeated much of the introductory text of final 4.00 in the introductory text to final 104.00. This is because the same basic rules for establishing and evaluating the existence and severity of cardiovascular impairments in adults also apply to children. Because we have already described these provisions and revisions under the explanation of 4.00, the following discussions describe only those provisions or revisions that are unique to the childhood rules or that require further explanation.

104.00A—General

In final section 104.00A3, we explain the same terms and phrases as in final section 4.00A4, but also include an explanation of the phrase ''currently present,'' which appears only in the childhood listings for reasons we explain below.

104.00B—Documenting Cardiovascular Impairments

In final section 104.00B5, we specify that ''[w]e will make a reasonable effort to obtain any additional studies from a qualified medical source in an office or center experienced in pediatric cardiac assessment.'' In final sections 104.00B7a and 104.00B7b, we include the discussion, with some nonsubstantive editorial changes, on the use of exercise testing in children that was found in the third and fourth paragraphs of prior section 104.00B. In final section 104.00B7c, we include a cross-reference to the guidance on ETT requirements and usage found in final section 4.00C in part A. We did not repeat that section in part B because it addresses cardiovascular tests used mainly for the diagnosis and evaluation of ischemia, which is rare in children. However, if a child has IHD, documentation and evaluation are the same as for an adult. (See 20 CFR 416.925(b)(1).)

104.00C—Evaluating Chronic Heart Failure

In final section 104.00C1, we do not differentiate between systolic and diastolic dysfunction, as we do with adults in final section 4.00D1a, because in children it is unlikely that a specific type of dysfunction will be clearly identified. For children, certain laboratory findings of cardiac functional and structural abnormality in support of the diagnosis of CHF are sufficient. In final section 104.00C2a, we also update the findings that represent cardiomegaly or ventricular dysfunction in children. We use the phrase ''fractional shortening'' rather than ''shortening fraction'' in the discussion of left ventricular dysfunction and explain what it is. We retain in final section 104.00C2a(i)(*C*) the chest x-ray findings cited in the second paragraph of prior section 104.00E. In final section 104.00C2b, we include the information found in the first and third paragraphs of prior section 104.00E with some rephrasing for clarity but no substantive changes.

104.00D—Evaluating Congenital Heart Disease

In final section 104.00D, we move the list of examples of congenital heart defects from the second paragraph of prior section 104.00A to final section 104.00D1, with some minor edits. We make a nonsubstantive editorial revision in final section 104.00D2, combining proposed sections 104.00D2, 104.00D3, and 104.00D4 into a discussion of how we will evaluate symptomatic congenital heart disease. In final section 104.00D2a (proposed section 104.00D4), we repeat the discussion of symptomatic congenital heart disease in final section 4.00H3 with minor changes to address children. We delete the information contained in the third paragraph of prior section 104.00D, which discusses pulmonary vascular obstructive disease, because it is rarely seen due to the improved diagnosis and treatment of congenital heart disease. In final section 104.00D2b (proposed section 104.00D2), we state that we will accept pulse oximetry measurements instead of arterial O_2 values when evaluating children under final listing 104.06A2. However, if the arterial O_2 values are available, they are preferred because they are the most accurate. In final section 104.00D2c (proposed section 104.00D3) we list examples of congenital heart defects that we will evaluate under final listing 104.06D. We took this material from the first and second paragraphs of prior section 104.00D.

104.00E—Evaluating Arrhythmias

This section is substantively identical to the corresponding section in the final adult listing, 4.00F, with minor editorial changes that refer specifically to children.

104.00F—Evaluating Other Cardiovascular Impairments

In final section 104.00F, we address other cardiovascular impairments that may affect children and that are not already discussed in previous sections, such as chronic rheumatic fever or rheumatic heart disease, omitting some that are more often seen in adults, such as peripheral vascular disease. If necessary, the effects of any such cardiovascular impairment on a child can be evaluated using the part A listings, as we explain in § 416.925(b) of our regulations and in the introductory paragraph to the table of contents in part A of the listings.

Final section 104.00F contains much of the same information found in final section 4.00H, with the following differences.

We address ischemia only briefly in section 104.00F1, instead of discussing it in detail as in the adult rules, because it is rare in children. Because the documentation and evaluation are the same as for adults, we refer to final section 4.00E and final listing 4.04 in part A. As we have already noted, these provisions are also applicable to ischemia in children. Final section 104.00F2, on how we will evaluate hypertension, is similar to final section 4.00H1, but we have modified it to reflect the particular effects of hypertension in children.

In the preamble to the NPRM, we listed the reference listings that we proposed to remove as redundant and said that we were including guidance on how to evaluate the affected impairments in the introductory text. See 69 FR 55880. However, we inadvertently omitted a discussion of cardiomyopathies (included in prior listing 104.08) from the proposed introductory text. To correct this oversight, we have added a section on cardiomyopathy, final section 104.00F3. The final rule is the same as the corresponding adult section, final section 4.00H3, with minor changes to refer to children.

In final section 104.00F6, we include the information on chronic rheumatic fever and rheumatic heart disease found in prior section 104.00G. We refer to the

appropriate cardiovascular listings for the evaluation of chronic heart failure and arrhythmias associated with rheumatic heart disease. In section 104.00F8, we discuss how we will evaluate Kawasaki disease (formerly called Kawasaki syndrome), which usually develops before age 5. We have also added a section on Marfan syndrome in final section 104.00F10; it is the same as final section 4.00H8 in part A.

How Are We Changing the Listings for Evaluating Cardiovascular Impairments in Children?

104.01 Category of Impairments, Cardiovascular System

We are deleting the following prior listings: 104.02C, Chronic heart failure with recurrent arrhythmias; 104.02D3, Chronic heart failure with growth disturbance as described under the criteria in 100.00; 104.03, Hypertensive cardiovascular disease; 104.06B, Congenital heart disease with chronic heart failure with evidence of ventricular dysfunction; 104.06C, Congenital heart disease with recurrent arrhythmias; 104.06E, Congenital heart disease with congenital valvular or other stenotic defects, or valvular regurgitation; 104.06G, Congenital heart disease with growth failure; 104.07, Valvular heart disease or other stenotic defects, or valvular regurgitation; 104.08, Cardiomyopathies; 104.13B, Chronic rheumatic fever or rheumatic heart disease with evidence of chronic heart failure; 104.13C, Chronic rheumatic fever or rheumatic heart disease with recurrent arrhythmias; 104.14, Hyperlipidemia; and 104.15, Kawasaki syndrome. With the exception of listings 104.07B, 104.14B, 104.14C, 104.14D and 104.15A, these are reference listings that we are deleting because they are redundant. However, we provide guidance in the introductory text of the listing on how we will evaluate these impairments using other listings.

We are deleting prior listing 104.07B, Critical aortic stenosis in newborn, because treatment has improved such that this condition would not usually be expected to result in limitations of listing-level severity for 12 months. When necessary, this impairment can be evaluated using final listing 104.06D. We also are deleting the prior hyperlipidemia listings that are not reference listings, prior listings 104.14B, 104.14C, and 104.14D, because there is better treatment now available for hyperlipidemia making it less likely to result in limitations of listing-level severity. We will evaluate hyperlipidemia's effect on a child under a listing for the affected body system when appropriate. We also delete prior listing 104.15A, Kawasaki syndrome with major coronary artery aneurysm, because generally such an aneurysm would be producing symptoms of heart failure or ischemia, which can be evaluated under the appropriate listings for those effects.

The following is a detailed explanation of the final listing criteria.

104.02—Chronic Heart Failure

We add language to the header text to clarify that the heart failure must occur ''while on a regimen of prescribed treatment.'' Final listings 104.02A and 104.02B and their associated tables are the same as the prior listings. Because we deleted prior reference listing 104.02C, Recurrent arrhythmias, which refers the adjudicator to listing 104.05, we are redesignating prior listing 104.02D, Growth disturbance, as final listing 104.02C. We also add language to the first two growth disturbance criteria to clarify that the weight loss must be currently present and have persisted for 2 months or longer. This is to clarify that we will not find that a child is disabled under this listing simply because of a short-term growth disturbance that occurred sometime in the past. We also specify that we will use the current growth charts issued by the National Center for Health Statistics in the Centers for Disease Control and Prevention. This is consistent with the growth impairment listings in 100.00. The current growth charts are available online at: *http://www.cdc.gov/growthcharts/.*

104.05—Recurrent Arrhythmias

We use the same language as in final listing 4.05.

104.06—Congenital Heart Disease

In the header text of this section, we add language on documentation by appropriate medically acceptable imaging or cardiac catheterization, to make it parallel to the adult listing. In final listing 104.06A1, we revise the language on the frequency of the hematocrit finding to better capture persistence of the finding. Because we remove prior reference listings 104.06B and 104.06C, we redesignate prior listing 104.06D as final listing 104.06B. In this listing, we no longer refer to ''mean'' pulmonary artery pressure, for the reason discussed under the explanation of final listing 4.06. We also clarify that we will use the systolic pressures for purposes of this listing. We remove prior listing 104.06E, because it was a reference listing, and redesignate prior listing 104.06F as final listing 104.06C. We also revise the language of prior listing 104.06C to reflect the definition of an ''extreme'' limitation, found in § 416.926a(e)(3) of our regulations.

Finally, we remove prior reference listing 104.06G, redesignate prior listing 104.06H as final listing 104.06D and remove the references to two specific cardiovascular listings to allow for reference to any appropriate listing in any body system. Also in final listing 104.06D, we change the language that previously directed that a child should be considered disabled until the later of 1 year of age or 12 months after surgery for a life-threatening congenital heart impairment. Instead, we specify that the child should be considered disabled until at least 1 year of age. This is because, if the condition is truly life threatening, the surgical treatment would generally be done within the first few months after birth and, at the age of 1 year, an assessment of the child's residual impairment would generally be possible. We further specify that the listing applies only when the impairment is expected to be disabling (because of residual impairment following surgery, the recovery time required, or both) until the attainment of at least 1 year of age. The listing will not apply to surgery for congenital heart impairments that routinely result in prompt recovery or less severe residual impairment.

104.09—Heart Transplant

We use the same language as in final listing 4.09.

104.13—Rheumatic Heart Disease

We change the heading by removing the reference to ''[c]hronic rheumatic fever'' because the impairment is related to the resulting heart disease, not the ''fever.'' We also include prior listing 104.13A with the prior header text, with some reorganization of the material. We remove listings 104.13B and 104.13C because they are reference listings.

What Other Revisions Are We Making?

As we have already noted in our explanation of final section 4.00D1, cor pulmonale will be evaluated under the respiratory listings, as it is a heart condition resulting from a respiratory disorder. Thus, we also revise prior listing 3.09 by removing reference listing 3.09C, which referred to listing 4.02.

Throughout these final rules, we are also making nonsubstantive editorial changes to language we proposed in the NPRM for clarity, consistency, medical accuracy, and readability. For example:

• In the NPRM, we used ''order'' and ''purchase'' interchangeably in referring to consultative examinations or special testing we need to purchase to complete our evaluation of your case. To make it clear that we are paying for these examinations, we have changed ''order'' to ''purchase'' throughout these final listings.

• In final sections 4.00B3b and 104.00B3b, we added a reference to ''duration'' to the second sentence to clarify that we may need to purchase a consultative examination to help us establish severity and duration of your impairment.

We have also simplified the language of several of the provisions we proposed, corrected unintentional inconsistencies between part A and part B, and corrected other minor errors in the NPRM. As we have already explained, we also reorganized some of the paragraphs we proposed in the introductory text of both part A and part B to group them more logically. In some cases, this necessitated redesignation of subsequent paragraphs. Throughout, we also made minor editorial changes to simplify and clarify the language we proposed. We do not intend any of these revisions to change the meaning of the proposed rules.

Public Comments

In the NPRM we published in the **Federal Register** on September 16, 2004 (69 FR 55874), we provided the public with a 60-day comment period that ended on November 15, 2004.

In response to the notice, we received comments from six commenters. These commenters included a legal services organization, an advocacy organization for people with Marfan syndrome, State agencies that make disability determinations for us, an organization representing individuals who make disability determinations for us, and a private individual. Most of the commenters raised more than one issue. We carefully considered all of the comments.

A number of the comments were quite long and detailed, requiring us to condense, summarize, or paraphrase them. We believe we have accurately presented the views of the commenters, and we are responding to all of the significant issues within the scope of the proposed rulemaking raised by the commenters. Some comments simply agreed with specific proposed changes and do not require a response, and we did not summarize them here. We provide our reasons for adopting or not adopting the comments in our responses below.

Exercise Tolerance Tests (ETTs)

Comment: One commenter had several concerns about the ETT provisions in the proposed rules. The commenter believed that the proposed listings would require many more claimants to get SSA-purchased testing. The commenter believed that the proposed rules took a much more aggressive approach to testing than the prior rules and ''actually established a protocol for testing claimants using stress tests and exercise tolerance tests.'' The commenter also noted the requirement for review by a State agency medical consultant to determine whether there was risk before we purchased an ETT. Finally, the commenter said that the proposed rules did not allow for a consulting physician to examine a claimant or to talk to either the claimant or the claimant's treating physician in determining whether there was risk. The commenter said that this was ''a marked departure from previous policy.''

Another commenter believed that proposed section 4.00C6d would have required the purchase of an ETT to evaluate aerobic capacity even when there was sufficient information in the record to adequately assess residual functional capacity.

Response: Except for a few minor technical changes, the testing requirements in section 4.00C of the proposed listings and these final rules are the same as the requirements in section 4.00C of the prior rules; we primarily reorganized and clarified those provisions. For example, the provisions about what we need to evaluate electrocardiogram (ECG) reports in proposed and final section 4.00C2 were in prior section 4.00C1.

Likewise, the final rules for MC review and treating physician contact are based on the prior rules, although we expanded them somewhat to provide even more protection for claimants. We took the rules in final (and proposed) section 4.00C7a, which describe how an MC will review the evidence to determine whether an ETT would pose a significant risk to you, from section 4.00C2 of the prior rules. As in the fourth sentence of prior section 4.00C2e(1), we continue to require in final section 4.00C7b that our adjudicators ask for a statement from the treating source for your cardiac impairment why an ETT was not done or should not be done when we believe that we need to purchase an ETT. In final section 4.00C7c, as in the NPRM, we include the provision from the last sentence of prior section 4.00C2c and the fifth sentence of prior section 4.00C2e(1) that it will be a ''rare situation'' in which an MC will override a treating source's opinion that an ETT should not be performed. We also include the provision from the last sentence of prior section 4.00C2c that requires the MC to provide a written rationale documenting the reasons for overriding the opinion in those rare circumstances. In addition, we added a new provision in final section 4.00C7e explaining that the physician who conducts the ETT (and therefore who examines the claimant) must be provided with the background medical evidence and is ultimately responsible for assessing risk before performing a test we purchase.

In response to the second commenter, it was not our intent to require the purchase of ETTs under the circumstances described in the comment letter, but we are clarifying the final rule in response to this comment. Our intent in proposed section 4.00C6d was to clarify the statement in section 4.00C2a of our prior rules that ''[p]urchase of an exercise test may be appropriate when * * * there is insufficient evidence in the record to evaluate aerobic capacity, and the claim cannot otherwise be favorably decided.'' Like prior section 4.00C2a, final section 4.00C6 provides that we will purchase an ETT only when we need one to make a determination or decision. If we have sufficient evidence to evaluate your residual functional capacity, we will not purchase an ETT. We do not expect an increase in the number of purchased exercise tests.

Comment: One commenter agreed with our statement in proposed section 4.00D3 that digitalis would not prevent application of listing 4.02B3. However, the commenter said that digitalis raises the risk of performing an ETT and that the clinical findings of jugular venous distention, rales, S3 gallop, and peripheral edema in a claimant with chronic heart failure on digitalis should be adequate to assess these cases without the risk of an ETT.

Response: We clarified the rule in response to this comment. We believe that the commenter was referring to our statement in the NPRM that digitalis use ''is not a factor'' when considering ETT purchase in cases involving chronic heart failure. Although it is true that digitalis alone does not increase the risk of performing an ETT, it is certainly an indication that the individual is being treated for a heart condition and is one piece of information, along with the other factors presented in the commenter's remarks, that we would consider when we determine whether to purchase an ETT. As we have already

noted, and as we explain in final section 4.00C6, we do not require ETTs in any case in which there is already sufficient evidence to make a determination or decision.

In the final rules, we are clarifying what we originally intended; only that digitalis use *by itself* does not preclude the purchase of an ETT in cases involving CHF. We are also adding a cross-reference in section 4.00D3 to section 4.00C6 as a reminder that we do not need to purchase ETTs in all cases.

Other Cardiovascular Tests

Comment: A commenter was concerned that in proposed section 4.00C16 we seemed to require our adjudicators to obtain a copy of the plethysmographic tracings that support a report of a Doppler study in every case, including when we obtain the report from your treating source or another existing medical source. The commenter pointed out that these tracings are not always available and asked whether the proposed rule would require the purchase of new studies just so that we could get tracings.

Response: We clarified the final rule in response to this comment. To distinguish what we must have from what we would like to have in evidence we receive from treating sources and other existing medical sources, we indicate in final section 4.00C16 that we ''should'' have the tracings but that we ''must'' have the other information we include in the final rule. Although we prefer to get the tracings when they are available, we do not require them in reports from treating sources or other existing medical sources for the reasons given by the commenter and we would not always require retesting just to obtain the tracings. We do require the other information we note in the paragraph because we need it to properly evaluate the results of the Doppler study. We also require plethysmographic tracings when we purchase a Doppler study as part of a consultative examination.

Comment: One commenter objected to our exclusion of tilt-table testing for evaluating arrhythmias and syncope/near syncope.

Response: As noted in the summary of the changes above, we rethought our position on this and have decided to accept tilt-table testing for establishing arrhythmias as the cause for syncope/near syncope in appropriate circumstances. Final sections 4.00F3c and 104.00E3 require that the testing be done concurrently with an ECG and that the arrhythmias are coincident with the occurrence of syncope/near syncope, similar to the Holter requirements.

The Listing Criteria

Comment: We received extensive comments from an organization that provides support, advocacy, and education for and about people who have Marfan syndrome. The commenter noted that Marfan syndrome is rare and that, with improvements in diagnosis and treatment, people with Marfan syndrome are living longer. However, these individuals are experiencing more medical problems that affect other body systems in addition to the cardiovascular system. These other medical problems were not seen as frequently when people with Marfan syndrome did not live as long. The commenter noted that we did include Marfan syndrome under proposed listing 4.10. However, the commenter requested that we also add a separate listing for Marfan syndrome that would recognize the multiple body system effects of the syndrome, and suggested criteria for such a listing. The commenter also asked us to include Marfan syndrome under prior listing 4.07, Valvular heart disease. Finally, the commenter expressed concern about the difficulty that some individuals with Marfan syndrome have in obtaining disability benefits from us.

Response: We did not adopt the specific comments, but we added a section to the introductory text of part A and part B to address the commenter's concern. We did not add a new listing specifically for Marfan syndrome in these final rules because, as the commenter noted, Marfan syndrome is a genetic connective tissue disorder that affects multiple body systems; therefore, we do not believe it is appropriate to add a listing for this disorder in the cardiovascular listings. Also, we did not adopt the comment regarding prior listing 4.07, because we have removed it. We explained in the preamble to the NPRM (69 FR 55877) that we were removing all reference listings—listings that cross-refer to other listings—from the cardiovascular system.

However, in response to this comment we have added final sections 4.00H8 and 104.00F10. The new sections briefly describe Marfan syndrome and explain that we will evaluate your Marfan syndrome manifestations under the appropriate body system criteria.

Comment: One commenter provided several comments about the functional criteria in the proposed rules. The commenter said that the proposed listings did not mention the New York Heart Association (NYHA) standards for assessing functional loss in cardiovascular impairments. The commenter also said that, while the immune system and mental disorders listings put a great deal of emphasis on functional loss, the proposed cardiovascular listings made ''relatively little mention of function.''

The commenter also believed that when the proposed listings did mention functional loss, the standard of ''a very serious limit on ability to initiate or sustain activities of daily living'' appeared too high. Another commenter thought this standard was vague and hard to apply and preferred the prior terms, ''normal activities'' and ''at rest.''

A third commenter considered ''the changes to the requirements for heart failure to be more consistent with NYHA'' classifications.

Response: In the 1991 NPRM for the prior rules, we proposed to include NYHA functional criteria in the cardiovascular listings. (See 56 FR 31266, July 9, 1991.) We received several comments opposing this proposal, and because we agreed with the comments, we removed those references when we promulgated the prior rules in 1994. Among other concerns, commenters pointed out that the NYHA criteria are too vague for our purposes, that treating sources do not use the classifications, that the definitions of the NYHA classifications may be changed, and that the classifications are not useful when the level of an individual's functional limitations fluctuates over time. In responding to these comments, we said that we agreed with the commenters that there were a number of real problems in using the NYHA classifications in an adjudicatory context, and that the most straightforward approach would be simply to state exactly what we require in the listings. (See 59 FR 6468, at 6479–6480, February 10, 1994.) We believe that this explanation still holds true, especially since the final rules are not significantly different from the prior rules.

The phrase ''very serious limitations in the ability to independently initiate, sustain, or complete activities of daily living'' and similar phrases in these final rules convey our standard for an ''extreme'' limitation; that is, a limitation of listing-level severity. We use this standard for functional loss in other listings; for example, sections 1.00B2b and 1.00B2c in the musculoskeletal body system and section 8.00C in the skin body system in part A of our listings. We also use it in other regulations; see § 416.926a(e)(3). The standard describes limitations in all of an individual's day-to-day activities, so it includes limitations from

cardiovascular symptoms both during normal activities and at rest.

Comment: One commenter said that the proposed listings referred to medical procedures that are not ''fully embraced,'' that may become out-of-date in the near future, and that are not necessarily widely available, especially to people with low incomes. As an example, the commenter pointed to proposed new listing 4.04B for ischemic heart disease with three ischemic episodes requiring revascularization procedures within a 12-month period. The commenter said that it would be highly unlikely that a Medicaid patient could be scheduled for three procedures in such a short period of time.

Response: The medical procedures we include in the final rules are generally well-established and widely used. Therefore, we do not agree with the commenter that they are likely to become out-of-date in the near future. Also, we provide in these final rules that these rules will no longer be effective 5 years after the date on which they become effective, unless we extend them or revise and issue them again. This will allow us to update the medical procedures cited, if appropriate. Individuals with the very serious cardiovascular impairments described in these listings generally receive the kinds of tests and treatments described in these final rules because of urgent medical need.

Moreover, as we explained in the preamble to the proposed rules, final listing 4.04B is a new, *additional* listing criterion that ''will permit us to decide some cases more quickly.'' (69 FR 55878) In other words, it does not add any additional requirement that must be met, but provides another way in which a person can be found disabled under the listing.

Comment: One commenter approved of our addition of recurrent bouts of decompensation to the evaluation of chronic heart failure in proposed section 4.00D4, but suggested that we change the definition of ''periods of stabilization'' from at least 5 days between episodes to 30 days between episodes to avoid variability during medication titrations. This commenter also suggested that we include a reference to left ventricular ''fractional shortening'' on echocardiograms, as the fractional shortening parameter is being used with increasing frequency to assess left ventricular function.

Response: We partially adopted the comment on the number of days between episodes of decompensation by extending the required length of the ''periods of stabilization'' from the proposed 5 days to 2 weeks. Our intent is to set the minimum number of days that would denote separate episodes. We believe that 30 days is too long and that 2 weeks is sufficient for this purpose.

We use fractional shortening in the childhood listing as evidence of chronic heart failure, but cannot add fractional shortening to the adult listing. Ejection fraction, which we use in the adult listing, represents the mean of the fractional shortening of the left ventricle; therefore, it is more accurate than fractional shortening measured at a single point. This is especially important if there is a segmental wall motion abnormality, which is often seen in claimants with coronary artery disease, a more common condition in adults than in children.

Comment: One commenter suggested that we change the description of brawny edema in proposed listing 4.11A from ''approximately'' two-thirds of the leg between the ankle and the knee to ''at least'' two-thirds or ''above mid-tibia level.''

Response: We adopted the comment. We proposed to say ''approximately'' because physicians generally will estimate the extent of the edema, rather than actually measure it. However, we agree that the commenter's suggestion of ''at least'' is clearer and better expresses our intent. In response to this comment, we also added an alternate descriptor of ''the distal one-third of the lower extremity between the ankle and hip'' to provide for those situations where the amount of brawny edema is given as a fraction of the entire lower extremity.

Comment: One commenter was reluctant to support the elimination of all reference listings, citing valvular heart disease as an example of an impairment unique enough to merit a listing. The commenter conceded that we discussed the listings we proposed to eliminate in the introductory text, but felt that it is easier for adjudicators to identify the need to evaluate these impairments if they are also included in the listings. It was also this commenter's opinion that this would offer assurance to the public and to their treating sources that these specific impairments have been considered.

Response: We did not adopt the comment. We do not agree that any prior reference listing would be especially helpful to adjudicators. All people who could qualify under any of the provisions of our prior reference listings will continue to qualify under other listings or the rules for medical equivalence or, in children, functional equivalence. Also, as we have already noted, we are removing reference listings from all the body systems as we revise them because reference listings are redundant; therefore, retaining one reference listing in this body system would be anomalous. Our adjudicators are aware that the listings do not include all possible disabling impairments, so they review allegations and the medical evidence obtained from treating or examining sources to identify all of the impairments we will evaluate.

However, in reviewing the NPRM in connection with this comment, we realized that we had inadvertently omitted a discussion of cardiomyopathies (prior listing 104.08) in the introductory text to part B. As noted above, we have corrected this oversight by adding final section 104.00F3. The text of the final rule is essentially identical to the corresponding rule in part A, final section 4.00H3, with minor changes to refer to children.

Regulatory Procedures

Executive Order 12866

We have 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 amended by Executive Order 13258. Thus, they were subject to OMB review.

Regulatory Flexibility Act

We certify that these final rules do not have a significant economic impact on a substantial number of small entities because they affect only individuals. Thus, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

The Paperwork Reduction Act (PRA) of 1995 says that no persons are required to respond to a collection of information unless it displays a valid OMB control number. In accordance with the PRA, SSA is providing notice that the Office of Management and Budget has approved the information collection requirements contained in sections 4.00B, 4.00C, 4.00D, 4.00E, 4.00F, 4.00G, 4.02A, 104.00B, 104.00C, 104.00E, and 104.06 of these final rules. The OMB Control Number for these collections is 0960–0642, expiring March 31, 2008.

(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 in 20 CFR Part 404

Administrative practice and procedure, Death benefits, Blind,

Disability benefits, Old-Age, Survivors, and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: October 14, 2005.

Jo Anne B. Barnhart,

Commissioner of Social Security.

■ For the reasons set forth in the preamble, subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations is amended as set forth below:

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

■ 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) and (i), 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) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

Appendix 1 to Subpart P of Part 404—Listings of Impairments [Amended]

■ 2. Item 5 of the introductory text before part A of appendix 1 is revised to read as follows:

* * * * *

5. Cardiovascular System (4.00 and 104.00): January 13, 2011.

* * * * *

■ 3. Listing 3.09 of part A of appendix 1 is amended by removing the semi-colon at the end of B, replacing it with a period, and removing the remainder of the listing.

■ 4. Section 4.00 of appendix 1 to subpart P of part 404 is revised to read as follows:

* * * * *

Part A

* * * * *

4.00 CARDIOVASCULAR SYSTEM

A. General

1. *What do we mean by a cardiovascular impairment?*

a. We mean any disorder that affects the proper functioning of the heart or the circulatory system (that is, arteries, veins, capillaries, and the lymphatic drainage). The disorder can be congenital or acquired.

b. Cardiovascular impairment results from one or more of four consequences of heart disease:

(i) Chronic heart failure or ventricular dysfunction.

(ii) Discomfort or pain due to myocardial ischemia, with or without necrosis of heart muscle.

(iii) Syncope, or near syncope, due to inadequate cerebral perfusion from any cardiac cause, such as obstruction of flow or disturbance in rhythm or conduction resulting in inadequate cardiac output.

(iv) Central cyanosis due to right-to-left shunt, reduced oxygen concentration in the arterial blood, or pulmonary vascular disease.

c. Disorders of the veins or arteries (for example, obstruction, rupture, or aneurysm) may cause impairments of the lower extremities (peripheral vascular disease), the central nervous system, the eyes, the kidneys, and other organs. We will evaluate peripheral vascular disease under 4.11 or 4.12 and impairments of another body system(s) under the listings for that body system(s).

2. *What do we consider in evaluating cardiovascular impairments?* The listings in this section describe cardiovascular impairments based on symptoms, signs, laboratory findings, response to a regimen of prescribed treatment, and functional limitations.

3. *What do the following terms or phrases mean in these listings?*

a. *Medical consultant* is an individual defined in §§ 404.1616(a) and 416.1016(a). This term does not include medical sources who provide consultative examinations for us. We use the abbreviation ''MC'' throughout this section to designate a medical consultant.

b. *Persistent* means that the longitudinal clinical record shows that, with few exceptions, the required finding(s) has been present, or is expected to be present, for a continuous period of at least 12 months, such that a pattern of continuing severity is established.

c. *Recurrent* means that the longitudinal clinical record shows that, within a consecutive 12-month period, the finding(s) occurs at least three times, with intervening periods of improvement of sufficient duration that it is clear that separate events are involved.

d. *Appropriate medically acceptable imaging* means that the technique used is the proper one to evaluate and diagnose the impairment and is commonly recognized as accurate for assessing the cited finding.

e. *A consecutive 12-month period* means a period of 12 consecutive months, all or part of which must occur within the period we are considering in connection with an application or continuing disability review.

f. *Uncontrolled* means the impairment does not adequately respond to standard prescribed medical treatment.

B. Documenting Cardiovascular Impairment

1. *What basic documentation do we need?* We need sufficiently detailed reports of history, physical examinations, laboratory studies, and any prescribed treatment and response to allow us to assess the severity and duration of your cardiovascular impairment. A longitudinal clinical record covering a period of not less than 3 months of observations and treatment is usually necessary, unless we can make a determination or decision based on the current evidence.

2. *Why is a longitudinal clinical record important?* We will usually need a longitudinal clinical record to assess the severity and expected duration of your impairment(s). If you have a listing-level impairment, you probably will have received medically prescribed treatment. Whenever there is evidence of such treatment, your longitudinal clinical record should include a description of the ongoing management and evaluation provided by your treating or other medical source. It should also include your response to this medical management, as well as information about the nature and severity of your impairment. The record will provide us with information on your functional status over an extended period of time and show whether your ability to function is improving, worsening, or unchanging.

3. *What if you have not received ongoing medical treatment?*

a. You may not have received ongoing treatment or have an ongoing relationship with the medical community despite the existence of a severe impairment(s). In this situation, we will base our evaluation on the current objective medical evidence and the other evidence we have. If you do not receive treatment, you cannot show an impairment that meets the criteria of most of these listings. However, we may find you disabled because you have another impairment(s) that in combination with your cardiovascular impairment medically equals the severity of a listed impairment or based on consideration of your residual functional capacity and age, education, and work experience.

b. Unless we can decide your claim favorably on the basis of the current evidence, a longitudinal record is still important. In rare instances where there is no or insufficient longitudinal evidence, we may purchase a consultative examination(s) to help us establish the severity and duration of your impairment.

4. *When will we wait before we ask for more evidence?*

a. We will wait when we have information showing that your impairment is not yet stable and the expected change in your impairment might affect our determination or decision. In these situations, we need to wait to properly evaluate the severity and duration of your impairment during a stable period. Examples of when we might wait are:

(i) If you have had a recent acute event; for example, a myocardial infarction (heart attack).

(ii) If you have recently had a corrective cardiac procedure; for example, coronary artery bypass grafting.

(iii) If you have started new drug therapy and your response to this treatment has not yet been established; for example, beta-blocker therapy for dilated congestive cardiomyopathy.

b. In these situations, we will obtain more evidence 3 months following the event before we evaluate your impairment. However, we will not wait if we have enough information to make a determination or decision based on all of the relevant evidence in your case.

5. *Will we purchase any studies?* In appropriate situations, we will purchase studies necessary to substantiate the diagnosis or to document the severity of your impairment, generally after we have evaluated the medical and other evidence we already have. We will not purchase studies involving exercise testing if there is significant risk involved or if there is another medical reason not to perform the test. We will follow sections 4.00C6, 4.00C7, and 4.00C8 when we decide whether to purchase exercise testing.

6. *What studies will we not purchase?* We will not purchase any studies involving cardiac catheterization, such as coronary angiography, arteriograms, or electrophysiological studies. However, if the results of catheterization are part of the existing evidence we have, we will consider them together with the other relevant evidence. See 4.00C15a.

C. Using Cardiovascular Test Results

1. *What is an ECG?*

a. *ECG* stands for *electrocardiograph* or *electrocardiogram.* An electrocardiograph is a machine that records electrical impulses of your heart on a strip of paper called an electrocardiogram or a *tracing.* To record the ECG, a technician positions a number of small contacts (or *leads*) on your arms, legs, and across your chest to connect them to the ECG machine. An ECG may be done while you are resting or exercising.

b. The ECG tracing may indicate that you have a heart abnormality. It may indicate that your heart muscle is not getting as much oxygen as it needs (ischemia), that your heart rhythm is abnormal (arrhythmia), or that there are other abnormalities of your heart, such as left ventricular enlargement.

2. *How do we evaluate ECG evidence?* We consider a number of factors when we evaluate ECG evidence:

a. An original or legible copy of the 12-lead ECG obtained at rest must be appropriately dated and labeled, with the standardization inscribed on the tracing. Alteration in standardization of specific leads (such as to accommodate large QRS amplitudes) must be identified on those leads.

(i) Detailed descriptions or computer-averaged signals without original or legible copies of the ECG as described in listing 4.00C2a are not acceptable.

(ii) The effects of drugs or electrolyte abnormalities must be considered as possible noncardiac causes of ECG abnormalities of ventricular repolarization; that is, those involving the ST segment and T wave. If available, the predrug (especially digitalis glycosides) ECG should be submitted.

b. ECGs obtained in conjunction with treadmill, bicycle, or arm exercise tests should meet the following specifications:

(i) ECG reports must include the original calibrated ECG tracings or a legible copy.

(ii) A 12-lead baseline ECG must be recorded in the upright position before exercise.

(iii) A 12-lead ECG should be recorded at the end of each minute of exercise.

(iv) If ECG documentation of the effects of hyperventilation is obtained, the exercise test should be deferred for at least 10 minutes because metabolic changes of hyperventilation may alter the physiologic and ECG-recorded response to exercise.

(v) Post-exercise ECGs should be recorded using a generally accepted protocol consistent with the prevailing state of medical knowledge and clinical practice.

(vi) All resting, exercise, and recovery ECG strips must have the standardization inscribed on the tracing. The ECG strips should be labeled to indicate the date, the times recorded and the relationship to the stage of the exercise protocol. The speed and grade (treadmill test) or work rate (bicycle or arm ergometric test) should be recorded. The highest level of exercise achieved, heart rate and blood pressure levels during testing, and the reason(s) for terminating the test (including limiting signs or symptoms) must be recorded.

3. *What are exercise tests and what are they used for?*

a. Exercise tests have you perform physical activity and record how your cardiovascular system responds. Exercise tests usually involve walking on a treadmill, but other forms of exercise, such as an exercise bicycle or an arm exercise machine, may be used. Exercise testing may be done for various reasons; such as to evaluate the severity of your coronary artery disease or peripheral vascular disease or to evaluate your progress after a cardiac procedure or an acute event, like a myocardial infarction (heart attack). Exercise testing is the most widely used testing for identifying the presence of myocardial ischemia and for estimating maximal aerobic capacity (usually expressed in METs—metabolic equivalents) if you have heart disease.

b. We include exercise tolerance test (ETT) criteria in 4.02B3 (chronic heart failure) and 4.04A (ischemic heart disease). To meet the ETT criteria in these listings, the ETT must be a sign- or symptom-limited test in which you exercise while connected to an ECG until you develop a sign or symptom that indicates that you have exercised as much as is considered safe for you.

c. In 4.12B, we also refer to exercise testing for peripheral vascular disease. In this test, you walk on a treadmill, usually for a specified period of time, and the individual who administers the test measures the effect of exercise on the flow of blood in your legs, usually by using ultrasound. The test is also called an exercise Doppler test. Even though this test is intended to evaluate peripheral vascular disease, it will be stopped for your safety if you develop abnormal signs or symptoms because of heart disease.

d. Each type of test is done in a certain way following specific criteria, called a *protocol.* For our program, we also specify certain aspects of how any exercise test we purchase is to be done. See 4.00C10 and 4.00C17.

4. *Do ETTs have limitations?* An ETT provides an estimate of aerobic capacity for walking on a grade, bicycling, or moving one's arms in an environmentally controlled setting. Therefore, ETT results do not correlate with the ability to perform other types of exertional activities, such as lifting and carrying heavy loads, and do not provide an estimate of the ability to perform activities required for work in all possible work environments or throughout a workday. Also, certain medications (such as beta blockers) and

conduction disorders (such as left or right bundle branch blocks) can cause false-negative or false-positive results. Therefore, we must consider the results of an ETT together with all the other relevant evidence in your case record.

5. *How does an ETT with measurement of maximal or peak oxygen uptake VO_2) differ from other ETTs?* Occasionally, medical evidence will include the results of an ETT with VO_2. While ETTs without measurement of VO_2 provide only an estimate of aerobic capacity, measured maximal or peak oxygen uptake provides an accurate measurement of aerobic capacity, which is often expressed in METs (metabolic equivalents). The MET level may not be indicated in the report of attained maximal or peak VO_2 testing, but can be calculated as follows: 1 MET = 3.5 milliliters (ml) of oxygen uptake per kilogram (kg) of body weight per minute. For example, a 70 kg (154 lb.) individual who achieves a maximal or peak VO_2 of 1225 ml in 1 minute has attained 5 METs (1225 ml/70 kg/1 min = 17.5 ml/kg/min. 17.5/3.5 = 5 METs).

6. *When will we consider whether to purchase an exercise test?*

a. We will consider whether to purchase an exercise test when:

(i) There is a question whether your cardiovascular impairment meets or medically equals the severity of one of the listings, or there is no timely test in the evidence we have (see 4.00C9), and we cannot find you disabled on some other basis; or

(ii) We need to assess your residual functional capacity and there is insufficient evidence in the record to make a determination or decision.

b. We will not purchase an exercise test when we can make our determination or decision based on the evidence we already have.

7. *What must we do before purchasing an exercise test?*

a. Before we purchase an exercise test, an MC, preferably one with experience in the care of patients with cardiovascular disease, must review the pertinent history, physical examinations, and laboratory tests that we have to determine whether the test would present a significant risk to you or if there is some other medical reason not to purchase the test (see 4.00C8).

b. If you are under the care of a treating source (see §§ 404.1502 and 416.902) for a cardiovascular impairment, this source has not performed an exercise test, and there are no reported significant risks to testing, we will request a statement from that source explaining why it was not done or should not be done before we decide whether we will purchase the test.

c. The MC, in accordance with the regulations and other instructions on consultative examinations, will generally give great weight to the treating source's opinion about the risk of exercise testing to you and will generally not override it. In the rare situation in which the MC does override the treating source's opinion, the MC must prepare a written rationale documenting the reasons for overriding the opinion.

d. If you do not have a treating source or we cannot obtain a statement from your treating source, the MC is responsible for assessing the risk to exercise testing based on a review of the records we have before purchasing an exercise test for you.

e. We must also provide your records to the medical source who performs the exercise test for review prior to conducting the test if the source does not already have them. The medical source who performs the exercise test has the ultimate responsibility for deciding whether you would be at risk.

8. *When will we not purchase an exercise test or wait before we purchase an exercise test?*

a. We will not purchase an exercise test when an MC finds that you have one of the following significant risk factors:

(i) Unstable angina not previously stabilized by medical treatment.

(ii) Uncontrolled cardiac arrhythmias causing symptoms or hemodynamic compromise.

(iii) An implanted cardiac defibrillator.

(iv) Symptomatic severe aortic stenosis.

(v) Uncontrolled symptomatic heart failure.

(vi) Aortic dissection.

(vii) Severe pulmonary hypertension (pulmonary artery systolic pressure greater than 60 mm Hg).

(viii) Left main coronary stenosis of 50 percent or greater that has not been bypassed.

(ix) Moderate stenotic valvular disease with a systolic gradient across the aortic valve of 50 mm Hg or greater.

(x) Severe arterial hypertension (systolic greater than 200 mm Hg or diastolic greater than 110 mm Hg).

(xi) Hypertrophic cardiomyopathy with a systolic gradient of 50 mm Hg or greater.

b. We also will not purchase an exercise test when you are prevented from performing exercise testing due to another impairment affecting your ability to use your arms and legs.

c. We will not purchase an ETT to document the presence of a cardiac arrhythmia.

d. We will wait to purchase an exercise test until 3 months after you have had one of the following events. This will allow for maximal, attainable restoration of functional capacity.

(i) Acute myocardial infarction.

(ii) Surgical myocardial revascularization (bypass surgery).

(iii) Other open-heart surgical procedures.

(iv) Percutaneous transluminal coronary angioplasty with or without stenting.

e. If you are deconditioned after an extended period of bedrest or inactivity and could improve with activity, or if you are in acute heart failure and are expected to improve with treatment, we will wait an appropriate period of time for you to recuperate before we purchase an exercise test.

9. *What do we mean by a ''timely'' test?*

a. We consider exercise test results to be timely for 12 months after the date they are performed, provided there has been no change in your clinical status that may alter the severity of your cardiovascular impairment.

b. However, an exercise test that is older than 12 months, especially an abnormal one, can still provide information important to our adjudication. For example, a test that is more than 12 months old can provide evidence of ischemic heart disease or peripheral vascular disease, information on decreased aerobic capacity, or information about the duration or onset of your impairment. Such tests can be an important component of the longitudinal record.

c. When we evaluate a test that is more than 12 months old, we must consider the results in the context of all the relevant evidence, including why the test was performed and whether there has been an intervening event or improvement or worsening of your impairment.

d. We will purchase a new exercise test only if we cannot make a determination or decision based on the evidence we have.

10. *How must ETTs we purchase be performed?*

a. The ETT must be a sign- or symptom-limited test characterized by a progressive multistage regimen. It must be performed using a generally accepted protocol consistent with the prevailing state of medical knowledge and clinical practice. A description of the protocol that was followed must be provided, and the test must meet the requirements of 4.00C2b and this section. A radionuclide perfusion scan may be useful for detecting or confirming ischemia when resting ECG

abnormalities, medications, or other factors may decrease the accuracy of ECG interpretation of ischemia. (The perfusion imaging is done at the termination of exercise, which may be at a higher MET level than that at which ischemia first occurs. If the imaging confirms the presence of reversible ischemia, the exercise ECG may be useful for detecting the MET level at which ischemia initially appeared.) Exercise tests may also be performed using echocardiography to detect stress-induced ischemia and left ventricular dysfunction (see 4.00C12 and 4.00C13).

b. The exercise test must be paced to your capabilities and be performed following the generally accepted standards for adult exercise test laboratories. With a treadmill test, the speed, grade (incline), and duration of exercise must be recorded for each exercise test stage performed. Other exercise test protocols or techniques should use similar workloads. The exercise protocol may need to be modified in individual cases to allow for a lower initial workload with more slowly graded increments than the standard Bruce protocol.

c. Levels of exercise must be described in terms of workload and duration of each stage; for example, treadmill speed and grade, or bicycle ergometer work rate in kpm/min or watts.

d. The exercise laboratory's physical environment, staffing, and equipment must meet the generally accepted standards for adult exercise test laboratories.

11. *How do we evaluate ETT results?* We evaluate ETT results on the basis of the work level at which the test becomes abnormal, as documented by onset of signs or symptoms and any ECG or imaging abnormalities. The absence of an ischemic response on an ETT alone does not exclude the diagnosis of ischemic heart disease. We must consider the results of an ETT in the context of all of the other evidence in your case record.

12. *When are ETTs done with imaging?* When resting ECG abnormalities preclude interpretation of ETT tracings relative to ischemia, a radionuclide (for example, thallium-201 or technetium-99m) perfusion scan or echocardiography in conjunction with an ETT provides better results. You may have resting ECG abnormalities when you have a conduction defect—for example, Wolff-Parkinson-White syndrome, left bundle branch block, left ventricular hypertrophy—or when you are taking digitalis or other antiarrhythmic drugs, or when resting ST changes are present. Also, these techniques can provide a reliable estimate of ejection fraction.

13. *Will we purchase ETTs with imaging?* We may purchase an ETT with imaging in your case after an MC, preferably one with experience in the care of patients with cardiovascular disease, has reviewed your medical history and physical examination, any report(s) of appropriate medically acceptable imaging, ECGs, and other appropriate tests. We will consider purchasing an ETT with imaging when other information we have is not adequate for us to assess whether you have severe ventricular dysfunction or myocardial ischemia, there is no significant risk involved (see 4.00C8a), and we cannot make our determination or decision based on the evidence we already have.

14. *What are drug-induced stress tests?* These tests are designed primarily to provide evidence about myocardial ischemia or prior myocardial infarction, but do not require you to exercise. These tests are used when you cannot exercise or cannot exercise enough to achieve the desired cardiac stress. Drug-induced stress tests can also provide evidence about heart chamber dimensions and function; however, these tests do not provide information about your aerobic capacity and cannot be used to help us assess your ability to function. Some of these tests use agents, such as Persantine or adenosine, that dilate the coronary arteries and are used in combination with nuclear agents, such as thallium or technetium (for example, Cardiolyte or Myoview), and a myocardial scan. Other tests use agents, such as dobutamine, that stimulate the heart to contract more forcefully and faster to simulate exercise and are used in combination with a 2-dimensional echocardiogram. We may, when appropriate, purchase a drug-induced stress test to confirm the presence of myocardial ischemia after a review of the evidence in your file by an MC, preferably one with experience in the care of patients with cardiovascular disease.

15. *How do we evaluate cardiac catheterization evidence?*

a. We will not purchase cardiac catheterization; however, if you have had catheterization, we will make every reasonable effort to obtain the report and any ancillary studies. We will consider the quality and type of data provided and its relevance to the evaluation of your impairment. For adults, we generally see two types of catheterization reports: Coronary arteriography and left ventriculography.

b. For coronary arteriography, the report should provide information citing the method of assessing coronary arterial lumen diameter and the nature and location of obstructive lesions. Drug treatment at baseline and during the procedure should be reported. Some individuals with significant coronary atherosclerotic obstruction have collateral vessels that supply the myocardium distal to the arterial obstruction so that there is no evidence of myocardial damage or ischemia, even with exercise. When the results of quantitative computer measurements and analyses are included in your case record, we will consider them in interpreting the severity of stenotic lesions.

c. For left ventriculography, the report should describe the wall motion of the myocardium with regard to any areas of hypokinesis (abnormally decreased motion), akinesis (lack of motion), or dyskinesis (distortion of motion), and the overall contraction of the ventricle as measured by the ejection fraction. Measurement of chamber volumes and pressures may be useful. Quantitative computer analysis provides precise measurement of segmental left ventricular wall thickness and motion. There is often a poor correlation between left ventricular function at rest and functional capacity for physical activity.

16. *What details should exercise Doppler test reports contain?* The reports of exercise Doppler tests must describe the level of exercise; for example, the speed and grade of the treadmill settings, the duration of exercise, symptoms during exercise, and the reasons for stopping exercise if the expected level of exercise was not attained. They must also include the blood pressures at the ankle and other pertinent sites measured after exercise and the time required for the systolic blood pressure to return toward or to the pre-exercise level. The graphic tracings, if available, should also be included with the report. All tracings must be annotated with the standardization used by the testing facility.

17. *How must exercise Doppler tests we purchase be performed?* When we purchase an exercise Doppler test, you must exercise on a treadmill at 2 mph on a 12 percent grade for up to 5 minutes. The reports must include the information specified in 4.00C16. Because this is an exercise test, we must evaluate whether such testing would put you at significant risk, in accordance with the guidance found in 4.00C6, 4.00C7, and 4.00C8.

D. Evaluating Chronic Heart Failure

1. *What is chronic heart failure (CHF)?*

a. *CHF* is the inability of the heart to pump enough oxygenated blood to body tissues. This syndrome is characterized by symptoms and signs of pulmonary or systemic congestion (fluid retention) or limited cardiac output. Certain laboratory findings of cardiac functional and structural abnormality support the diagnosis of CHF. There are two main types of CHF:

(i) *Predominant systolic dysfunction* (the inability of the heart to contract normally and expel sufficient blood), which is characterized by a dilated, poorly contracting left ventricle and reduced ejection fraction (abbreviated EF, it represents the percentage of the blood in the ventricle actually pumped out with each contraction), and

(ii) *Predominant diastolic dysfunction* (the inability of the heart to relax and fill normally), which is characterized by a thickened ventricular muscle, poor ability of the left ventricle to distend, increased ventricular filling pressure, and a normal or increased EF.

b. CHF is considered in these listings as a single category whether due to atherosclerosis (narrowing of the arteries), cardiomyopathy, hypertension, or rheumatic, congenital, or other heart disease. However, if the CHF is the result of primary pulmonary hypertension secondary to disease of the lung (cor pulmonale), we will evaluate your impairment using 3.09, in the respiratory system listings.

2. *What evidence of CHF do we need?*

a. Cardiomegaly or ventricular dysfunction must be present and demonstrated by appropriate medically acceptable imaging, such as chest x-ray, echocardiography (M-Mode, 2-dimensional, and Doppler), radionuclide studies, or cardiac catheterization.

(i) Abnormal cardiac imaging showing increased left ventricular end diastolic diameter (LVEDD), decreased EF, increased left atrial chamber size, increased ventricular filling pressures measured at cardiac catheterization, or increased left ventricular wall or septum thickness, provides objective measures of both left ventricular function and structural abnormality in heart failure.

(ii) An LVEDD greater than 6.0 cm or an EF of 30 percent or less measured during a period of stability (that is, not during an episode of acute heart failure) may be associated clinically with systolic failure.

(iii) Left ventricular posterior wall thickness added to septal thickness totaling 2.5 cm or greater with left atrium enlarged to 4.5 cm or greater may be associated clinically with diastolic failure.

(iv) However, these measurements alone do not reflect your functional capacity, which we evaluate by considering all of the relevant evidence. In some situations, we may need to purchase an ETT to help us assess your functional capacity.

(v) Other findings on appropriate medically acceptable imaging may include increased pulmonary vascular markings, pleural effusion, and pulmonary edema. These findings need not be present on each report, since CHF may be controlled by prescribed treatment.

b. To establish that you have *chronic* heart failure, your medical history and physical examination should describe characteristic symptoms and signs of pulmonary or systemic congestion or of limited cardiac output associated with the abnormal findings on appropriate medically acceptable imaging. When an acute episode of heart failure is triggered by a remediable factor, such as an arrhythmia, dietary sodium overload, or high altitude, cardiac function may be restored and a chronic impairment may not be present.

(i) Symptoms of congestion or of limited cardiac output include easy fatigue, weakness, shortness of breath (dyspnea), cough, or chest discomfort at rest or with activity. Individuals with CHF may also experience shortness of breath on lying flat (orthopnea) or episodes of shortness of breath that wake them from sleep (paroxysmal nocturnal dyspnea). They may also experience cardiac arrhythmias resulting in palpitations, lightheadedness, or fainting.

(ii) Signs of congestion may include hepatomegaly, ascites, increased jugular venous distention or pressure, rales, peripheral edema, or rapid weight gain. However, these signs need not be found on all examinations because fluid retention may be controlled by prescribed treatment.

3. *Is it safe for you to have an ETT, if you have CHF?* The presence of CHF is not necessarily a contraindication to an ETT, unless you are having an acute episode of heart failure. Measures of cardiac performance are valuable in helping us evaluate your ability to do work-related activities. Exercise testing has been safely used in individuals with CHF; therefore, we may purchase an ETT for evaluation under 4.02B3 if an MC, preferably one experienced in the care of patients with cardiovascular disease, determines that there is no significant risk to you. (See 4.00C6 for when we will consider the purchase of an ETT. See 4.00C7–4.00C8 for what we must do before we purchase an ETT and when we will not purchase one.) ST segment changes from digitalis use in the treatment of CHF do not preclude the purchase of an ETT.

4. *How do we evaluate CHF using 4.02?*

a. We must have objective evidence, as described in 4.00D2, that you have chronic heart failure.

b. To meet the required level of severity for this listing, your impairment must satisfy the requirements of one of the criteria in A and one of the criteria in B.

c. In 4.02B2, the phrase *periods of stabilization* means that, for at least 2 weeks between episodes of acute heart failure, there must be objective evidence of clearing of the pulmonary edema or pleural effusions and evidence that you returned to, or you were medically considered able to return to, your prior level of activity.

d. Listing 4.02B3c requires a decrease in systolic blood pressure below the baseline level (taken in the standing position immediately prior to exercise) or below any systolic pressure reading recorded during exercise. This is because, normally, systolic blood pressure and heart rate increase gradually with exercise. Decreases in systolic blood pressure below the baseline level that occur during exercise are often associated with ischemia-induced left ventricular dysfunction resulting in decreased cardiac output. However, a blunted response (that is, failure of the systolic blood pressure to rise 10 mm Hg or more), particularly in the first 3 minutes of exercise, may be drug-related and is not necessarily associated with left ventricular dysfunction. Also, some individuals with increased sympathetic responses because of deconditioning or apprehension may increase their systolic blood pressure and heart rate above their baseline level just before and early into exercise. This can be associated with a drop in systolic pressure in early exercise that is not due to left ventricular dysfunction. Therefore, an early decrease in systolic blood pressure must be interpreted within the total context of the test; that is, the presence or absence of symptoms such as lightheadedness, ischemic changes, or arrhythmias on the ECG.

E. Evaluating Ischemic Heart Disease

1. *What is ischemic heart disease (IHD)? IHD* results when one or more of your coronary arteries is narrowed or obstructed or, in rare situations, constricted due to vasospasm, interfering with the normal flow of blood to your heart muscle (ischemia). The obstruction may be the result of an embolus, a thrombus, or plaque. When

heart muscle tissue dies as a result of the reduced blood supply, it is called a myocardial infarction (heart attack).

2. *What causes chest discomfort of myocardial origin?*

a. Chest discomfort of myocardial ischemic origin, commonly known as angina pectoris, is usually caused by coronary artery disease (often abbreviated CAD). However, ischemic discomfort may be caused by a noncoronary artery impairment, such as aortic stenosis, hypertrophic cardiomyopathy, pulmonary hypertension, or anemia.

b. Instead of typical angina pectoris, some individuals with IHD experience atypical angina, anginal equivalent, variant angina, or silent ischemia, all of which we may evaluate using 4.04. We discuss the various manifestations of ischemia in 4.00E3–4.00E7.

3. *What are the characteristics of typical angina pectoris?* Discomfort of myocardial ischemic origin (angina pectoris) is discomfort that is precipitated by effort or emotion and promptly relieved by rest, sublingual nitroglycerin (that is, nitroglycerin tablets that are placed under the tongue), or other rapidly acting nitrates. Typically, the discomfort is located in the chest (usually substernal) and described as pressing, crushing, squeezing, burning, aching, or oppressive. Sharp, sticking, or cramping discomfort is less common. Discomfort occurring with activity or emotion should be described specifically as to timing and usual inciting factors (type and intensity), character, location, radiation, duration, and response to nitrate treatment or rest.

4. *What is atypical angina? Atypical angina* describes discomfort or pain from myocardial ischemia that is felt in places other than the chest. The common sites of cardiac pain are the inner aspect of the left arm, neck, jaw(s), upper abdomen, and back, but the discomfort or pain can be elsewhere. When pain of cardiac ischemic origin presents in an atypical site in the absence of chest discomfort, the source of the pain may be difficult to diagnose. To represent atypical angina, your discomfort or pain should have precipitating and relieving factors similar to those of typical chest discomfort, and we must have objective medical evidence of myocardial ischemia; for example, ECG or ETT evidence or appropriate medically acceptable imaging.

5. *What is anginal equivalent?* Often, individuals with IHD will complain of shortness of breath (dyspnea) on exertion without chest pain or discomfort. In a minority of such situations, the shortness of breath is due to myocardial ischemia; this is called *anginal equivalent.* To represent anginal equivalent, your shortness of breath should have precipitating and relieving factors similar to those of typical chest discomfort, and we must have objective medical evidence of myocardial ischemia; for example, ECG or ETT evidence or appropriate medically acceptable imaging. In these situations, it is essential to establish objective evidence of myocardial ischemia to ensure that you do not have effort dyspnea due to non-ischemic or non-cardiac causes.

6. *What is variant angina?*

a. *Variant angina* (Prinzmetal's angina, vasospastic angina) refers to the occurrence of anginal episodes at rest, especially at night, accompanied by transitory ST segment elevation (or, at times, ST depression) on an ECG. It is due to severe spasm of a coronary artery, causing ischemia of the heart wall, and is often accompanied by major ventricular arrhythmias, such as ventricular tachycardia. We will consider variant angina under 4.04 only if you have spasm of a coronary artery in relation to an obstructive lesion of the vessel. If you have an arrhythmia as a result of variant angina, we may consider your impairment under 4.05.

b. Variant angina may also occur in the absence of obstructive coronary disease. In this situation, an ETT will not demonstrate ischemia. The diagnosis will be established by showing the typical transitory ST segment changes during attacks of pain, and the absence of obstructive lesions shown by catheterization. Treatment in cases where there is no obstructive coronary disease is limited to medications that reduce coronary vasospasm, such as calcium channel blockers and nitrates. In such situations, we will consider the frequency of anginal episodes despite prescribed treatment when evaluating your residual functional capacity.

c. Vasospasm that is catheter-induced during coronary angiography is not variant angina.

7. *What is silent ischemia?*

a. Myocardial ischemia, and even myocardial infarction, can occur without perception of pain or any other symptoms; when this happens, we call it *silent ischemia.* Pain sensitivity may be altered by a variety of diseases, most notably diabetes mellitus and other neuropathic disorders. Individuals also vary in their threshold for pain.

b. Silent ischemia occurs most often in:

(i) Individuals with documented past myocardial infarction or established angina without prior infarction who do not have chest pain on ETT, but have a positive test with ischemic abnormality on ECG, perfusion scan, or other appropriate medically acceptable imaging.

(ii) Individuals with documented past myocardial infarction or angina who have ST segment changes on ambulatory monitoring (Holter monitoring) that are similar to those that occur during episodes of angina. ST depression shown on the ambulatory recording should not be interpreted as positive for ischemia unless similar depression is also seen during chest pain episodes annotated in the diary that the individual keeps while wearing the Holter monitor.

c. ST depression can result from a variety of factors, such as postural changes and variations in cardiac sympathetic tone. In addition, there are differences in how different Holter monitors record the electrical responses. Therefore, we do not consider the Holter monitor reliable for the diagnosis of silent ischemia except in the situation described in 4.00E7b(ii).

8. *What other sources of chest discomfort are there?* Chest discomfort of nonischemic origin may result from other cardiac impairments, such as pericarditis. Noncardiac impairments may also produce symptoms mimicking that of myocardial ischemia. These impairments include acute anxiety or panic attacks, gastrointestinal tract disorders, such as esophageal spasm, esophagitis, hiatal hernia, biliary tract disease, gastritis, peptic ulcer, and pancreatitis, and musculoskeletal syndromes, such as chest wall muscle spasm, chest wall syndrome (especially after coronary bypass surgery), costochondritis, and cervical or dorsal spine arthritis. Hyperventilation may also mimic ischemic discomfort. Thus, in the absence of documented myocardial ischemia, such disorders should be considered as possible causes of chest discomfort.

9. *How do we evaluate IHD using 4.04?*

a. We must have objective evidence, as described under 4.00C, that your symptoms are due to myocardial ischemia.

b. Listing-level changes on the ECG in 4.04A1 are the classically accepted changes of horizontal or downsloping ST depression occurring both during exercise and recovery. Although we recognize that ischemic changes may at times occur only during exercise or recovery, and may at times be upsloping with only junctional ST depression, such changes can be false positive; that is, occur in the absence of ischemia.

Diagnosis of ischemia in this situation requires radionuclide or echocardiogram confirmation. See 4.00C12 and 4.00C13.

c. Also in 4.04A1, we require that the depression of the ST segment last for at least 1 minute of recovery because ST depression that occurs during exercise but that rapidly normalizes in recovery is a common false-positive response.

d. In 4.04A2, we specify that the ST elevation must be in non-infarct leads during both exercise and recovery. This is because, in the absence of ECG signs of prior infarction, ST elevation during exercise denotes ischemia, usually severe, requiring immediate termination of exercise. However, if there is baseline ST elevation in association with a prior infarction or ventricular aneurysm, further ST elevation during exercise does not necessarily denote ischemia and could be a false-positive ECG response. Diagnosis of ischemia in this situation requires radionuclide or echocardiogram confirmation. See 4.00C12 and 4.00C13.

e. Listing 4.04A3 requires a decrease in systolic blood pressure below the baseline level (taken in the standing position immediately prior to exercise) or below any systolic pressure reading recorded during exercise. This is the same finding required in 4.02B3c. See 4.00D4d for full details.

f. In 4.04B, each of the three ischemic episodes must require revascularization or be not amenable to treatment. *Revascularization* means angioplasty (with or without stent placement) or bypass surgery. However, reocclusion that occurs after a revascularization procedure but during the same hospitalization and that requires a second procedure during the same hospitalization will not be counted as another ischemic episode. Not amenable means that the revascularization procedure could not be done because of another medical impairment or because the vessel was not suitable for revascularization.

g. We will use 4.04C only when you have symptoms due to myocardial ischemia as described in 4.00E3–4.00E7 while on a regimen of prescribed treatment, you are at risk for exercise testing (see 4.00C8), and we do not have a timely ETT or a timely normal drug-induced stress test for you. See 4.00C9 for what we mean by a timely test.

h. In 4.04C1 the term *nonbypassed* means that the blockage is in a vessel that is potentially bypassable; that is, large enough to be bypassed and considered to be a cause of your ischemia. These vessels are usually major arteries or one of a major artery's major branches. A vessel that has become obstructed again after angioplasty or stent placement and has remained obstructed or is not amenable to another revascularization is considered a nonbypassed vessel for purposes of this listing. When you have had revascularization, we will not use the pre-operative findings to assess the current severity of your coronary artery disease under 4.04C, although we will consider the severity and duration of your impairment prior to your surgery in making our determination or decision.

F. Evaluating Arrhythmias

1. *What is an arrhythmia?* An *arrhythmia* is a change in the regular beat of the heart. Your heart may seem to skip a beat or beat irregularly, very quickly (tachycardia), or very slowly (bradycardia).

2. *What are the different types of arrhythmias?*

a. There are many types of arrhythmias. Arrhythmias are identified by where they occur in the heart (atria or ventricles) and by what happens to the heart's rhythm when they occur.

b. Arrhythmias arising in the cardiac atria (upper chambers of the heart) are called atrial or supraventricular arrhythmias. Ventricular arrhythmias begin in the ventricles (lower chambers). In general, ventricular arrhythmias caused by heart disease are the most serious.

3. *How do we evaluate arrhythmias using 4.05?*

a. We will use 4.05 when you have arrhythmias that are not fully controlled by medication, an implanted pacemaker, or an implanted cardiac defibrillator and you have uncontrolled recurrent episodes of syncope or near syncope. If your arrhythmias are controlled, we will evaluate your underlying heart disease using the appropriate listing. For other considerations when we evaluate arrhythmias in the presence of an implanted cardiac defibrillator, see 4.00F4.

b. We consider *near syncope* to be a period of altered consciousness, since syncope is a loss of consciousness or a faint. It is not merely a feeling of light-headedness, momentary weakness, or dizziness.

c. For purposes of 4.05, there must be a documented association between the syncope or near syncope and the recurrent arrhythmia. The recurrent arrhythmia, not some other cardiac or non-cardiac disorder, must be established as the cause of the associated symptom. This documentation of the association between the symptoms and the arrhythmia may come from the usual diagnostic methods, including Holter monitoring (also called ambulatory electrocardiography) and tilt-table testing with a concurrent ECG. Although an arrhythmia may be a coincidental finding on an ETT, we will not purchase an ETT to document the presence of a cardiac arrhythmia.

4. *What will we consider when you have an implanted cardiac defibrillator and you do not have arrhythmias that meet the requirements of 4.05?*

a. Implanted cardiac defibrillators are used to prevent sudden cardiac death in individuals who have had, or are at high risk for, cardiac arrest from life-threatening ventricular arrhythmias. The largest group at risk for sudden cardiac death consists of individuals with cardiomyopathy (ischemic or non-ischemic) and reduced ventricular function. However, life-threatening ventricular arrhythmias can also occur in individuals with little or no ventricular dysfunction. The shock from the implanted cardiac defibrillator is a unique form of treatment; it rescues an individual from what may have been cardiac arrest. However, as a consequence of the shock(s), individuals may experience psychological distress, which we may evaluate under the mental disorders listings in 12.00ff.

b. Most implantable cardiac defibrillators have rhythm-correcting and pacemaker capabilities. In some individuals, these functions may result in the termination of ventricular arrhythmias without an otherwise painful shock. (The shock is like being kicked in the chest.) Implanted cardiac defibrillators may deliver inappropriate shocks, often repeatedly, in response to benign arrhythmias or electrical malfunction. Also, exposure to strong electrical or magnetic fields, such as from MRI (magnetic resonance imaging), can trigger or reprogram an implanted cardiac defibrillator, resulting in inappropriate shocks. We must consider the frequency of, and the reason(s) for, the shocks when evaluating the severity and duration of your impairment.

c. In general, the exercise limitations imposed on individuals with an implanted cardiac defibrillator are those dictated by the underlying heart impairment. However, the exercise limitations may be greater when the implanted cardiac defibrillator delivers an inappropriate shock in response to the increase in heart rate with exercise, or when there is exercise-induced ventricular arrhythmia.

G. Evaluating Peripheral Vascular Disease

1. *What is peripheral vascular disease (PVD)?* Generally, *PVD* is any impairment that affects either the arteries (peripheral arterial disease) or the veins (venous insufficiency) in the extremities, particularly the lower extremities. The usual effect is blockage of the flow of blood either from the heart (arterial) or back to the heart (venous). If you have peripheral arterial disease, you may have pain in your calf after walking a distance that goes away when you rest (intermittent claudication); at more advanced stages, you may have pain in your calf at rest or you may develop ulceration or gangrene. If you have venous insufficiency, you may have swelling, varicose veins, skin pigmentation changes, or skin ulceration.

2. *How do we assess limitations resulting from PVD?* We will assess your limitations based on your symptoms together with physical findings, Doppler studies, other appropriate non-invasive studies, or angiographic findings. However, if the PVD has resulted in amputation, we will evaluate any limitations related to the amputation under the musculoskeletal listings, 1.00ff.

3. *What is brawny edema? Brawny edema* (4.11A) is swelling that is usually dense and feels firm due to the presence of increased connective tissue; it is also associated with characteristic skin pigmentation changes. It is not the same thing as pitting edema. Brawny edema generally does not pit (indent on pressure), and the terms are not interchangeable. Pitting edema does not satisfy the requirements of 4.11A.

4. *What is lymphedema and how will we evaluate it?*

a. *Lymphedema* is edema of the extremities due to a disorder of the lymphatic circulation; at its worst, it is called elephantiasis. Primary lymphedema is caused by abnormal development of lymph vessels and may be present at birth (congenital lymphedema), but more often develops during the teens (lymphedema praecox). It may also appear later, usually after age 35 (lymphedema tarda). Secondary lymphedema is due to obstruction or destruction of normal lymphatic channels due to tumor, surgery, repeated infections, or parasitic infection such as filariasis. Lymphedema most commonly affects one extremity.

b. Lymphedema does not meet the requirements of 4.11, although it may medically equal the severity of that listing. We will evaluate lymphedema by considering whether the underlying cause meets or medically equals any listing or whether the lymphedema medically equals a cardiovascular listing, such as 4.11, or a musculoskeletal listing, such as 1.02A or 1.03. If no listing is met or medically equaled, we will evaluate any functional limitations imposed by your lymphedema when we assess your residual functional capacity.

5. *When will we purchase exercise Doppler studies for evaluating peripheral arterial disease (PAD)?* If we need additional evidence of your PAD, we will generally purchase exercise Doppler studies (see 4.00C16 and 4.00C17) when your resting ankle/brachial systolic blood pressure ratio is at least 0.50 but less than 0.80, and only rarely when it is 0.80 or above. We will not purchase exercise Doppler testing if you have a disease that results in abnormal arterial calcification or small vessel disease, but will use your resting toe systolic blood pressure or resting toe/brachial systolic blood pressure ratio. (See 4.00G7c and 4.00G8.) There are no current medical standards for evaluating exercise toe pressures. Because any exercise test stresses your entire cardiovascular system, we will purchase exercise Doppler studies only after an MC, preferably one with experience in the care of patients with cardiovascular disease, has determined that the test would not present a significant risk to you and that there is no other medical reason not to purchase the test (see 4.00C6, 4.00C7, and 4.00C8).

6. *Are there any other studies that are helpful in evaluating PAD?* Doppler studies done using a recording ultrasonic Doppler unit and strain-gauge plethysmography are other useful tools for evaluating PAD. A recording Doppler, which prints a tracing of the arterial pulse wave in the femoral, popliteal, dorsalis pedis, and posterior tibial arteries, is an excellent evaluation tool to compare wave forms in normal and compromised peripheral blood flow. Qualitative analysis of the pulse wave is very helpful in the overall assessment of the severity of the occlusive disease. Tracings are especially helpful in assessing severity if you have small vessel disease related to diabetes mellitus or other diseases with similar vascular changes, or diseases causing medial calcifications when ankle pressure is either normal or falsely high.

7. *How do we evaluate PAD under 4.12?*

a. The ankle blood pressure referred to in 4.12A and B is the higher of the pressures recorded from the posterior tibial and dorsalis pedis arteries in the affected leg. The higher pressure recorded from the two sites is the more significant measurement in assessing the extent of arterial insufficiency. Techniques for obtaining ankle systolic blood pressures include Doppler (See 4.00C16 and 4.00C17), plethysmographic studies, or other techniques. We will request any available tracings generated by these studies so that we can review them.

b. In 4.12A, the ankle/brachial systolic blood pressure ratio is the ratio of the systolic blood pressure at the ankle to the systolic blood pressure at the brachial artery; both taken at the same time while you are lying on your back. We do not require that the ankle and brachial pressures be taken on the same side of your body. This is because, as with the ankle pressure, we will use the higher brachial systolic pressure measured. Listing 4.12A is met when your resting ankle/brachial systolic blood pressure ratio is less than 0.50. If your resting ankle/brachial systolic blood pressure ratio is 0.50 or above, we will use 4.12B to evaluate the severity of your PAD, unless you also have a disease causing abnormal arterial calcification or small vessel disease, such as diabetes mellitus. See 4.00G7c and 4.00G8.

c. We will use resting toe systolic blood pressures or resting toe/brachial systolic blood pressure ratios (determined the same way as ankle/brachial ratios, see 4.00G7b) when you have intermittent claudication and a disease that results in abnormal arterial calcification (for example, Monckeberg's sclerosis or diabetes mellitus) or small vessel disease (for example, diabetes mellitus). These diseases may result in misleadingly high blood pressure readings at the ankle. However, high blood pressures due to vascular changes related to these diseases seldom occur at the toe level. While the criteria in 4.12C and 4.12D are intended primarily for individuals who have a disease causing abnormal arterial calcification or small vessel disease, we may also use them for evaluating anyone with PAD.

8. *How are toe pressures measured?* Toe pressures are measured routinely in most vascular laboratories through one of three methods: most frequently, photoplethysmography; less frequently, plethysmography using strain gauge cuffs; and Doppler ultrasound. Toe pressure can also be measured by using any blood pressure cuff that fits snugly around the big toe and is neither too tight nor too loose. A neonatal cuff or a cuff designed for use on fingers or toes can be used in the measurement of toe pressure.

9. *How do we use listing 4.12 if you have had a peripheral graft?* Peripheral grafting serves the same purpose as coronary grafting; that is, to bypass a narrow or obstructed arterial segment. If intermittent claudication recurs or persists after peripheral grafting, we may purchase Doppler studies to assess the flow of blood through the bypassed vessel and to establish the current severity of the peripheral arterial impairment. However, if you have had peripheral grafting done for your PAD, we will not use the findings from before the surgery to assess the current severity of your impairment, although we will consider the severity and duration of your impairment prior to your surgery in making our determination or decision.

H. Evaluating Other Cardiovascular Impairments

1. *How will we evaluate hypertension?* Because *hypertension* (high blood pressure) generally causes disability through its effects on other body systems, we will evaluate it by reference to the specific body system(s) affected (heart, brain, kidneys, or eyes) when we consider its effects under the listings. We will also consider any limitations imposed by your hypertension when we assess your residual functional capacity.

2. *How will we evaluate symptomatic congenital heart disease? Congenital heart disease* is any abnormality of the heart or the major blood vessels that is present at birth. Because of improved treatment methods, more children with congenital heart disease are living to adulthood. Although some types of congenital heart disease may be corrected by surgery, many individuals with treated congenital heart disease continue to have problems throughout their lives (symptomatic congenital heart disease). If you have congenital heart disease that results in chronic heart failure with evidence of ventricular dysfunction or in recurrent arrhythmias, we will evaluate your impairment under 4.02 or 4.05. Otherwise, we will evaluate your impairment under 4.06.

3. *What is cardiomyopathy and how will we evaluate it? Cardiomyopathy* is a disease of the heart muscle. The heart loses its ability to pump blood (heart failure), and in some instances, heart rhythm is disturbed, leading to irregular heartbeats (arrhythmias). Usually, the exact cause of the muscle damage is never found (idiopathic cardiomyopathy). There are various types of cardiomyopathy, which fall into two major categories: *Ischemic* and *nonischemic* cardiomyopathy. Ischemic cardiomyopathy typically refers to heart muscle damage that results from coronary artery disease, including heart attacks. Nonischemic cardiomyopathy includes several types: Dilated, hypertrophic, and restrictive. We will evaluate cardiomyopathy under 4.02, 4.04, 4.05, or 11.04, depending on its effects on you.

4. *How will we evaluate valvular heart disease?* We will evaluate valvular heart disease under the listing appropriate for its effect on you. Thus, we may use 4.02, 4.04, 4.05, 4.06, or an appropriate neurological listing in 11.00ff.

5. *What do we consider when we evaluate heart transplant recipients?*

a. After your heart transplant, we will consider you disabled for 1 year following the surgery because there is a greater likelihood of rejection of the organ and infection during the first year.

b. However, heart transplant patients generally meet our definition of disability before they undergo transplantation. We will determine the onset of your disability based on the facts in your case.

c. We will not assume that you became disabled when your name was placed on a transplant waiting list. This is because you may be placed on a waiting list soon after diagnosis of the cardiac disorder that may eventually require a transplant. Physicians recognize that candidates for transplantation often have to wait months or even years before a suitable donor heart is found, so they place their patients on the list as soon as permitted.

d. When we do a continuing disability review to determine whether you are still disabled, we will evaluate your residual impairment(s), as shown by symptoms, signs, and laboratory findings, including any side effects of medication. We will consider any remaining symptoms, signs, and laboratory findings indicative of cardiac dysfunction in deciding whether medical improvement (as defined in §§ 404.1594 and 416.994) has occurred.

6. *When does an aneurysm have ''dissection not controlled by prescribed treatment,'' as required under 4.10?* An aneurysm (or bulge in the aorta or one of its major branches) is *dissecting* when the inner lining of the artery begins to separate from the arterial wall. We consider the dissection not controlled when you have persistence of chest pain due to progression of the dissection, an increase in the size of the aneurysm, or compression of one or more branches of the aorta supplying the heart, kidneys, brain, or other organs. An aneurysm with dissection can cause heart failure, renal (kidney) failure, or neurological complications. If you have an aneurysm that does not meet the requirements of 4.10 and you have one or more of these associated conditions, we will evaluate the condition(s) using the appropriate listing.

7. *What is hyperlipidemia and how will we evaluate it? Hyperlipidemia* is the general term for an elevation of any or all of the lipids (fats or cholesterol) in the blood; for example, hypertriglyceridemia, hypercholesterolemia, and hyperlipoproteinemia. These disorders of lipoprotein metabolism and transport can cause defects throughout the body. The effects most likely to interfere with function are those produced by atherosclerosis (narrowing of the arteries) and coronary artery disease. We will evaluate your lipoprotein disorder by considering its effects on you.

8. *What is Marfan syndrome and how will we evaluate it?*

a. Marfan syndrome is a genetic connective tissue disorder that affects multiple body systems, including the skeleton, eyes, heart, blood vessels, nervous system, skin, and lungs. There is no specific laboratory test to diagnose Marfan syndrome. The diagnosis is generally made by medical history, including family history, physical examination, including an evaluation of the ratio of arm/leg size to trunk size, a slit lamp eye examination, and a heart test(s), such as an echocardiogram. In some cases, a genetic analysis may be useful, but such analyses may not provide any additional helpful information.

b. The effects of Marfan syndrome can range from mild to severe. In most cases, the disorder progresses as you age. Most individuals with Marfan syndrome have abnormalities associated with the heart and blood vessels. Your heart's mitral valve may leak, causing a heart murmur. Small leaks may not cause symptoms, but larger ones may cause shortness of breath, fatigue, and palpitations. Another effect is that the wall of the aorta may be weakened and abnormally stretch (aortic dilation). This aortic dilation may tear, dissect, or rupture, causing serious heart problems or sometimes sudden death. We will evaluate the manifestations of your Marfan syndrome under the appropriate body system criteria, such as 4.10, or if necessary, consider the functional limitations imposed by your impairment.

I. Other Evaluation Issues

1. *What effect does obesity have on the cardiovascular system and how will we evaluate it?* Obesity is a medically determinable impairment that is often associated with disorders of the cardiovascular system. Disturbance of

this system can be a major cause of disability if you have obesity. Obesity may affect the cardiovascular system because of the increased workload the additional body mass places on the heart. Obesity may make it harder for the chest and lungs to expand. This can mean that the respiratory system must work harder to provide needed oxygen. This in turn would make the heart work harder to pump blood to carry oxygen to the body. Because the body would be working harder at rest, its ability to perform additional work would be less than would otherwise be expected. Thus, the combined effects of obesity with cardiovascular impairments can be greater than the effects of each of the impairments considered separately. We must consider any additional and cumulative effects of obesity when we determine whether you have a severe cardiovascular impairment or a listing-level cardiovascular impairment (or a combination of impairments that medically equals the severity of a listed impairment), and when we assess your residual functional capacity.

2. *How do we relate treatment to functional status?* In general, conclusions about the severity of a cardiovascular impairment cannot be made on the basis of type of treatment rendered or anticipated. The amount of function restored and the time required for improvement after treatment (medical, surgical, or a prescribed program of progressive physical activity) vary with the nature and extent of the disorder, the type of treatment, and other factors. Depending upon the timing of this treatment in relation to the alleged onset date of disability, we may need to defer evaluation of the impairment for a period of up to 3 months from the date treatment began to permit consideration of treatment effects, unless we can make a determination or decision using the evidence we have. See 4.00B4.

3. *How do we evaluate impairments that do not meet one of the cardiovascular listings?*

a. These listings are only examples of common cardiovascular impairments that we consider severe enough to prevent you from doing any gainful activity. If your severe impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

b. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairments(s) medically equals a listing. (See §§ 404.1526 and 416.926.) If you have a severe impairment(s) that does not meet or medically equal the criteria of a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. Therefore, we proceed to the fourth and, if necessary, the fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920. If you are an adult, we use the rules in §§ 404.1594 or 416.994, as appropriate, when we decide whether you continue to be disabled.

4.01 Category of Impairments, Cardiovascular System

4.02 *Chronic heart failure* while on a regimen of prescribed treatment, with symptoms and signs described in 4.00D2. The required level of severity for this impairment is met when the requirements in *both A and B* are satisfied.

A. Medically documented presence of one of the following:

1. Systolic failure (see 4.00D1a(i)), with left ventricular end diastolic dimensions greater than 6.0 cm or ejection fraction of 30 percent or less during a period of stability (not during an episode of acute heart failure); or

2. Diastolic failure (see 4.00D1a(ii)), with left ventricular posterior wall plus septal thickness totaling 2.5 cm or greater on imaging, with an enlarged left atrium greater than or equal to 4.5 cm, with normal or elevated ejection fraction during a period of stability (not during an episode of acute heart failure);

AND

B. Resulting in one of the following:

1. Persistent symptoms of heart failure which very seriously limit the ability to independently initiate, sustain, or complete activities of daily living in an individual for whom an MC, preferably one experienced in the care of patients with cardiovascular disease, has concluded that the performance of an exercise test would present a significant risk to the individual; or

2. Three or more separate episodes of acute congestive heart failure within a consecutive 12-month period (see 4.00A3e), with evidence of fluid retention (see 4.00D2b(ii)) from clinical and imaging assessments at the time of the episodes, requiring acute extended physician intervention such as hospitalization or emergency room treatment for 12 hours or more, separated by periods of stabilization (see 4.00D4c); or

3. Inability to perform on an exercise tolerance test at a workload equivalent to 5 METs or less due to:

a. Dyspnea, fatigue, palpitations, or chest discomfort; or

b. Three or more consecutive premature ventricular contractions (ventricular tachycardia), or increasing frequency of ventricular ectopy with at least 6 premature ventricular contractions per minute; or

c. Decrease of 10 mm Hg or more in systolic pressure below the baseline systolic blood pressure or the preceding systolic pressure measured during exercise (see 4.00D4d) due to left ventricular dysfunction, despite an increase in workload; or

d. Signs attributable to inadequate cerebral perfusion, such as ataxic gait or mental confusion.

4.04 *Ischemic heart disease*, with symptoms due to myocardial ischemia, as described in 4.00E3–4.00E7, while on a regimen of prescribed treatment (see 4.00B3 if there is no regimen of prescribed treatment), with one of the following:

A. Sign-or symptom-limited exercise tolerance test demonstrating at least one of the following manifestations at a workload equivalent to 5 METs or less:

1. Horizontal or downsloping depression, in the absence of digitalis glycoside treatment or hypokalemia, of the ST segment of at least −0.10 millivolts (−1.0 mm) in at least 3 consecutive complexes that are on a level baseline in any lead other than aVR, and depression of at least −0.10 millivolts lasting for at least 1 minute of recovery; or

2. At least 0.1 millivolt (1 mm) ST elevation above resting baseline in non-infarct leads during both exercise and 1 or more minutes of recovery; or

3. Decrease of 10 mm Hg or more in systolic pressure below the baseline blood pressure or the preceding systolic pressure measured during exercise (see 4.00E9e) due to left ventricular dysfunction, despite an increase in workload; or

4. Documented ischemia at an exercise level equivalent to 5 METs or less on appropriate medically acceptable imaging, such as radionuclide perfusion scans or stress echocardiography.

OR

B. Three separate ischemic episodes, each requiring revascularization or not amenable to revascularization (see 4.00E9f), within a consecutive 12-month period (see 4.00A3e).

OR

C. Coronary artery disease, demonstrated by angiography (obtained independent of Social Security disability evaluation) or other appropriate medically acceptable imaging, and in the absence of a timely exercise tolerance test or a timely

normal drug-induced stress test, an MC, preferably one experienced in the care of patients with cardiovascular disease, has concluded that performance of exercise tolerance testing would present a significant risk to the individual, with both 1 and 2:

1. Angiographic evidence showing:

a. 50 percent or more narrowing of a nonbypassed left main coronary artery; or

b. 70 percent or more narrowing of another nonbypassed coronary artery; or

c. 50 percent or more narrowing involving a long (greater than 1 cm) segment of a nonbypassed coronary artery; or

d. 50 percent or more narrowing of at least two nonbypassed coronary arteries; or

e. 70 percent or more narrowing of a bypass graft vessel; and

2. Resulting in very serious limitations in the ability to independently initiate, sustain, or complete activities of daily living.

4.05 *Recurrent arrhythmias*, not related to reversible causes, such as electrolyte abnormalities or digitalis glycoside or antiarrhythmic drug toxicity, resulting in uncontrolled (see 4.00A3f), recurrent (see 4.00A3c) episodes of cardiac syncope or near syncope (see 4.00F3b), despite prescribed treatment (see 4.00B3 if there is no prescribed treatment), and documented by resting or ambulatory (Holter) electrocardiography, or by other appropriate medically acceptable testing, coincident with the occurrence of syncope or near syncope (see 4.00F3c).

4.06 *Symptomatic congenital heart disease* (cyanotic or acyanotic), documented by appropriate medically acceptable imaging (see 4.00A3d) or cardiac catheterization, with one of the following:

A. Cyanosis at rest, and:

1. Hematocrit of 55 percent or greater; or

2. Arterial O_2 saturation of less than 90 percent in room air, or resting arterial PO_2 of 60 Torr or less.

OR

B. Intermittent right-to-left shunting resulting in cyanosis on exertion (*e.g.*, Eisenmenger's physiology) and with arterial PO_2 of 60 Torr or less at a workload equivalent to 5 METs or less.

OR

C. Secondary pulmonary vascular obstructive disease with pulmonary arterial systolic pressure elevated to at least 70 percent of the systemic arterial systolic pressure.

4.09 *Heart transplant.* Consider under a disability for 1 year following surgery; thereafter, evaluate residual impairment under the appropriate listing.

4.10 *Aneurysm of aorta or major branches*, due to any cause (*e.g.*, atherosclerosis, cystic medial necrosis, Marfan syndrome, trauma), demonstrated by appropriate medically acceptable imaging, with dissection not controlled by prescribed treatment (see 4.00H6).

4.11 *Chronic venous insufficiency* of a lower extremity with incompetency or obstruction of the deep venous system and one of the following:

A. Extensive brawny edema (see 4.00G3) involving at least two-thirds of the leg between the ankle and knee or the distal one-third of the lower extremity between the ankle and hip.

OR

B. Superficial varicosities, stasis dermatitis, and either recurrent ulceration or persistent ulceration that has not healed following at least 3 months of prescribed treatment.

4.12 *Peripheral arterial disease*, as determined by appropriate medically acceptable imaging (see 4.00A3d, 4.00G2, 4.00G5, and 4.00G6), causing intermittent claudication (see 4.00G1) and one of the following:

A. Resting ankle/brachial systolic blood pressure ratio of less than 0.50.

OR

B. Decrease in systolic blood pressure at the ankle on exercise (see 4.00G7a and 4.00C16–4.00C17) of 50 percent or more of pre-exercise level and requiring 10 minutes or more to return to pre-exercise level.

OR

C. Resting toe systolic pressure of less than 30 mm Hg (see 4.00G7c and 4.00G8).

OR

D. Resting toe/brachial systolic blood pressure ratio of less than 0.40 (see 4.00G7c).

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■ 5. Section 104.00 of appendix 1 to subpart P of part 404 is revised to read as follows:

Part B

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104.00 CARDIOVASCULAR SYSTEM

A. General

1. *What do we mean by a cardiovascular impairment?*

a. We mean any disorder that affects the proper functioning of the heart or the circulatory system (that is, arteries, veins, capillaries, and the lymphatic drainage). The disorder can be congenital or acquired.

b. Cardiovascular impairment results from one or more of four consequences of heart disease:

(i) Chronic heart failure or ventricular dysfunction.

(ii) Discomfort or pain due to myocardial ischemia, with or without necrosis of heart muscle.

(iii) Syncope, or near syncope, due to inadequate cerebral perfusion from any cardiac cause, such as obstruction of flow or disturbance in rhythm or conduction resulting in inadequate cardiac output.

(iv) Central cyanosis due to right-to-left shunt, reduced oxygen concentration in the arterial blood, or pulmonary vascular disease.

c. Disorders of the veins or arteries (for example, obstruction, rupture, or aneurysm) may cause impairments of the lower extremities (peripheral vascular disease), the central nervous system, the eyes, the kidneys, and other organs. We will evaluate peripheral vascular disease under 4.11 or 4.12 in part A, and impairments of another body system(s) under the listings for that body system(s).

2. *What do we consider in evaluating cardiovascular impairments?* The listings in this section describe cardiovascular impairments based on symptoms, signs, laboratory findings, response to a regimen of prescribed treatment, and functional limitations.

3. *What do the following terms or phrases mean in these listings?*

a. *Medical consultant* is an individual defined in §§ 404.1616(a) and 416.1016(a). This term does not include medical sources who provide consultative examinations for us. We use the abbreviation ''MC'' throughout this section to designate a medical consultant.

b. *Persistent* means that the longitudinal clinical record shows that, with few exceptions, the required finding(s) has been present, or is expected to be present, for a continuous period of at least 12 months, such that a pattern of continuing severity is established.

c. *Recurrent* means that the longitudinal clinical record shows that, within a consecutive 12-month period, the finding(s) occurs at least three times, with intervening periods of improvement of sufficient duration that it is clear that separate events are involved.

d. *Appropriate medically acceptable imaging* means that the technique used is the proper one to evaluate and diagnose the impairment and is commonly recognized as accurate for assessing the cited finding.

e. *A consecutive 12-month period* means a period of 12 consecutive months, all or part of which must occur within the period we are considering in connection with an application or continuing disability review.

f. *Currently present* means that the finding is present at the time of adjudication.

g. *Uncontrolled* means the impairment does not respond adequately to standard prescribed medical treatment.

B. Documenting Cardiovascular Impairment

1. *What basic documentation do we need?* We need sufficiently detailed reports of history, physical examinations, laboratory studies, and any prescribed treatment and response to allow us to assess the severity and duration of your cardiovascular impairment. A longitudinal clinical record covering a period of not less than 3 months of observations and treatment is usually necessary, unless we can make a determination or decision based on the current evidence.

2. *Why is a longitudinal clinical record important?* We will usually need a longitudinal clinical record to assess the severity and expected duration of your impairment(s). If you have a listing-level impairment, you probably will have received medically prescribed treatment. Whenever there is evidence of such treatment, your longitudinal clinical record should include a description of the ongoing management and evaluation provided by your treating or other medical source. It should also include your response to this medical management, as well as information about the nature and severity of your impairment. The record will provide us with information on your functional status over an extended period of time and show whether your ability to function is improving, worsening, or unchanging.

3. *What if you have not received ongoing medical treatment?*

a. You may not have received ongoing treatment or have an ongoing relationship with the medical community despite the existence of a severe impairment(s). In this situation, we will base our evaluation on the current objective medical evidence and the other evidence we have. If you do not receive treatment, you cannot show an impairment that meets the criteria of these listings. However, we may find you disabled because you have another impairment(s) that in combination with your cardiovascular impairment medically equals the severity of a listed impairment or that functionally equals the listings.

b. Unless we can decide your claim favorably on the basis of the current evidence, a longitudinal record is still important. In rare instances where there is no or insufficient longitudinal evidence, we may purchase a consultative examination(s) to help us establish the severity and duration of your impairment.

4. *When will we wait before we ask for more evidence?*

a. We will wait when we have information showing that your impairment is not yet stable and the expected change in your impairment might affect our determination or decision. In these situations, we need to wait to properly evaluate the severity and duration of your impairment during a stable period. Examples of when we might wait are:

(i) If you have had a recent acute event; for example, acute rheumatic fever.

(ii) If you have recently had a corrective cardiac procedure; for example, open-heart surgery.

(iii) If you have started new drug therapy and your response to this treatment has not yet been established; for example, beta-blocker therapy for dilated congestive cardiomyopathy.

b. In these situations, we will obtain more evidence 3 months following the event before we evaluate your impairment. However, we will not wait if we have enough information to make a determination or decision based on all of the relevant evidence in your case.

5. *Will we purchase any studies?* In appropriate situations, we will purchase studies necessary to substantiate the diagnosis or to document the severity of your impairment, generally after we have evaluated the medical and other evidence we already have. We will not purchase studies involving exercise testing if there is significant risk involved or if there is another medical reason not to perform the test. We will follow sections 4.00C6, 4.00C7, 4.00C8, and 104.00B7 when we decide whether to purchase exercise testing. We will make a reasonable effort to obtain any additional studies from a qualified medical source in an office or center experienced in pediatric cardiac assessment. (See § 416.919g.)

6. *What studies will we not purchase?* We will not purchase any studies involving cardiac catheterization, such as coronary angiography, arteriograms, or electrophysiological studies. However, if the results of catheterization are part of the existing evidence we have, we will consider them together with the other relevant evidence. See 4.00C15a in part A.

7. *Will we use exercise tolerance tests (ETTs) for evaluating children with cardiovascular impairment?*

a. ETTs, though increasingly used, are still less frequently indicated in children than in adults, and can rarely be performed successfully by children under 6 years of age. An ETT may be of value in the assessment of some arrhythmias, in the assessment of the severity of chronic heart failure, and in the assessment of recovery of function following cardiac surgery or other treatment.

b. We will purchase an ETT in a childhood claim only if we cannot make a determination or decision based on the evidence we have and an MC, preferably one with experience in the care of children with cardiovascular impairments, has determined that an ETT is needed to evaluate your impairment. We will not purchase an ETT if you are less than 6 years of age. If we do purchase an ETT for a child age 12 or younger, it must be performed by a qualified medical source in a specialty center for pediatric cardiology or other facility qualified to perform exercise tests of children.

c. For full details on ETT requirements and usage, see 4.00C in part A.

C. Evaluating Chronic Heart Failure

1. *What is chronic heart failure (CHF)?*

a. *CHF* is the inability of the heart to pump enough oxygenated blood to body tissues. This syndrome is characterized by symptoms and signs of pulmonary or systemic congestion (fluid retention) or limited cardiac output. Certain laboratory findings of cardiac functional and structural abnormality support the diagnosis of CHF.

b. CHF is considered in these listings as a single category whether due to atherosclerosis (narrowing of the arteries), cardiomyopathy, hypertension, or rheumatic, congenital, or other heart disease. However, if the CHF is the result of primary pulmonary hypertension secondary to disease of the lung (cor pulmonale), we will evaluate your impairment using 3.09 in the respiratory system listings in part A.

2. *What evidence of CHF do we need?*

a. Cardiomegaly or ventricular dysfunction must be present and demonstrated by appropriate medically acceptable imaging, such as chest x-ray, echocardiography (M-Mode, 2-dimensional, and Doppler), radionuclide studies, or cardiac catheterization.

(i) Cardiomegaly is present when:

(*A*) Left ventricular diastolic dimension or systolic dimension is greater than 2 standard deviations above the mean for the child's body surface area;

(*B*) Left ventricular mass is greater than 2 standard deviations above the mean for the child's body surface area; or

(*C*) Chest x-ray (6 foot PA film) is indicative of cardiomegaly if the cardiothoracic ratio is over 60 percent at 1 year of age or less, or 55 percent or greater at more than 1 year of age.

(ii) Ventricular dysfunction is present when indices of left ventricular function, such as fractional shortening or ejection fraction (the percentage of the blood in the ventricle actually pumped out with each contraction), are greater than 2 standard deviations below the mean for the child's age. (Fractional shortening, also called shortening fraction, reflects the left ventricular systolic function in the absence of segmental wall motion abnormalities and has a linear correlation with ejection fraction. In children, fractional shortening is more commonly used than ejection fraction.)

(iii) However, these measurements alone do not reflect your functional capacity, which we evaluate by considering all of the relevant evidence.

(iv) Other findings on appropriate medically acceptable imaging may include increased pulmonary vascular markings, pleural effusion, and pulmonary edema. These findings need not be present on each report, since CHF may be controlled by prescribed treatment.

b. To establish that you have *chronic* heart failure, your medical history and physical examination should describe characteristic symptoms and signs of pulmonary or systemic congestion or of limited cardiac output associated with the abnormal findings on appropriate medically acceptable imaging. When an acute episode of heart failure is triggered by a remediable factor, such as an arrhythmia, dietary sodium overload, or high altitude, cardiac function may be restored and a chronic impairment may not be present.

(i) Symptoms of congestion or of limited cardiac output include easy fatigue, weakness, shortness of breath (dyspnea), cough, or chest discomfort at rest or with activity. Children with CHF may also experience shortness of breath on lying flat (orthopnea) or episodes of shortness of breath that wake them from sleep (paroxysmal nocturnal dyspnea). They may also experience cardiac arrhythmias resulting in palpitations, lightheadedness, or fainting. Fatigue or exercise intolerance in an infant may be manifested by prolonged feeding time, often associated with excessive respiratory effort and sweating.

(ii) During infancy, other manifestations of chronic heart failure may include failure to gain weight or involuntary loss of weight and repeated lower respiratory tract infections.

(iii) Signs of congestion may include hepatomegaly, ascites, increased jugular venous distention or pressure, rales, peripheral edema, rapid shallow breathing (tachypnea), or rapid weight gain. However, these signs need not be found on all examinations because fluid retention may be controlled by prescribed treatment.

D. Evaluating Congenital Heart Disease

1. *What is congenital heart disease?* Congenital heart disease is any abnormality of the heart or the major blood vessels that is present at birth. Examples include:

a. *Abnormalities of cardiac septation,* including ventricular septal defect or atrioventricular canal;

b. *Abnormalities resulting in cyanotic heart disease,* including tetralogy of Fallot or transposition of the great arteries;

c. *Valvular defects or obstructions to ventricular outflow,* including pulmonary or aortic stenosis or coarctation of the aorta; and

d. *Major abnormalities of ventricular development,* including hypoplastic left heart syndrome or pulmonary tricuspid atresia with hypoplastic right ventricle.

2. *How will we evaluate symptomatic congenital heart disease?*

a. Because of improved treatment methods, more children with congenital heart disease are living longer. Although some types of congenital heart disease may be corrected by surgery, many children with treated congenital heart disease continue to have problems throughout their lives (symptomatic congenital heart disease). If you have congenital heart disease that results in chronic heart failure with evidence of ventricular dysfunction or in recurrent arrhythmias, we will evaluate your impairment under 104.02 or 104.05. Otherwise, we will evaluate your impairment under 104.06.

b. For 104.06A2, we will accept pulse oximetry measurements instead of arterial O_2, but the arterial O_2 values are preferred, if available.

c. For 104.06D, examples of impairments that in most instances will require life-saving surgery or a combination of surgery and other major interventional procedures (for example, multiple ''balloon'' catheter procedures) before age 1 include, but are not limited to, the following:

(i) Hypoplastic left heart syndrome,

(ii) Critical aortic stenosis with neonatal heart failure,

(iii) Critical coarctation of the aorta, with or without associated anomalies,

(iv) Complete atrioventricular canal defects,

(v) Transposition of the great arteries,

(vi) Tetralogy of Fallot,

(vii) Pulmonary atresia with intact ventricular septum,

(viii) Single ventricle,

(ix) Tricuspid atresia, and

(x) Multiple ventricular septal defects.

E. Evaluating Arrhythmias

1. *What is an arrhythmia?* An *arrhythmia* is a change in the regular beat of the heart. Your heart may seem to skip a beat or beat irregularly, very quickly (tachycardia), or very slowly (bradycardia).

2. *What are the different types of arrhythmias?*

a. There are many types of arrhythmias. Arrhythmias are identified by where they occur in the heart (atria or ventricles) and by what happens to the heart's rhythm when they occur.

b. Arrhythmias arising in the cardiac atria (upper chambers of the heart) are called atrial or supraventricular arrhythmias. Ventricular arrhythmias begin in the ventricles (lower chambers). In general, ventricular arrhythmias caused by heart disease are the most serious.

3. *How do we evaluate arrhythmias using 104.05?*

a. We will use 104.05 when you have arrhythmias that are not fully controlled by medication, an implanted pacemaker, or an implanted cardiac defibrillator and you have uncontrolled recurrent episodes of syncope or near syncope. If your arrhythmias are controlled, we will evaluate your underlying heart disease using the appropriate listing. For other considerations when we evaluate arrhythmias in the presence of an implanted cardiac defibrillator, see 104.00E4.

b. We consider *near syncope* to be a period of altered consciousness, since syncope is a loss of consciousness or a faint. It is not merely a feeling of light-headedness, momentary weakness, or dizziness.

c. For purposes of 104.05, there must be a documented association between the syncope or near syncope and the recurrent arrhythmia. The recurrent arrhythmia, not some other cardiac or non-cardiac disorder, must be established as the cause of the associated symptom. This documentation of the association between the symptoms and the

arrhythmia may come from the usual diagnostic methods, including Holter monitoring (also called ambulatory electrocardiography) and tilt-table testing with a concurrent ECG. Although an arrhythmia may be a coincidental finding on an ETT, we will not purchase an ETT to document the presence of a cardiac arrhythmia.

4. *What will we consider when you have an implanted cardiac defibrillator and you do not have arrhythmias that meet the requirements of 104.05?*

a. Implanted cardiac defibrillators are used to prevent sudden cardiac death in children who have had, or are at high risk for, cardiac arrest from life-threatening ventricular arrhythmias. The largest group of children at risk for sudden cardiac death consists of children with cardiomyopathy (ischemic or non-ischemic) and reduced ventricular function. However, life-threatening ventricular arrhythmias can also occur in children with little or no ventricular dysfunction. The shock from the implanted cardiac defibrillator is a unique form of treatment; it rescues a child from what may have been cardiac arrest. However, as a consequence of the shock(s), children may experience psychological distress, which we may evaluate under the mental disorders listings in 112.00ff.

b. Most implantable cardiac defibrillators have rhythm-correcting and pacemaker capabilities. In some children, these functions may result in the termination of ventricular arrhythmias without an otherwise painful shock. (The shock is like being kicked in the chest.) Implanted cardiac defibrillators may deliver inappropriate shocks, often repeatedly, in response to benign arrhythmias or electrical malfunction. Also, exposure to strong electrical or magnetic fields, such as from MRI (magnetic resonance imaging), can trigger or reprogram an implanted cardiac defibrillator, resulting in inappropriate shocks. We must consider the frequency of, and the reason(s) for, the shocks when evaluating the severity and duration of your impairment.

c. In general, the exercise limitations imposed on children with an implanted cardiac defibrillator are those dictated by the underlying heart impairment. However, the exercise limitations may be greater when the implanted cardiac defibrillator delivers an inappropriate shock in response to the increase in heart rate with exercise, or when there is exercise-induced ventricular arrhythmia.

F. Evaluating Other Cardiovascular Impairments

1. *What is ischemic heart disease (IHD) and how will we evaluate it in children? IHD* results when one or more of your coronary arteries is narrowed or obstructed or, in rare situations, constricted due to vasospasm, interfering with the normal flow of blood to your heart muscle (ischemia). The obstruction may be the result of an embolus, a thrombus, or plaque. When heart muscle tissue dies as a result of the reduced blood supply, it is called a myocardial infarction (heart attack). Ischemia is rare in children, but when it occurs, its effects on children are the same as on adults. If you have IHD, we will evaluate it under 4.00E and 4.04 in part A.

2. *How will we evaluate hypertension?* Because *hypertension* (high blood pressure) generally causes disability through its effects on other body systems, we will evaluate it by reference to the specific body system(s) affected (heart, brain, kidneys, or eyes) when we consider its effects under the listings. We will also consider any limitations imposed by your hypertension when we consider whether you have an impairment that functionally equals the listings.

3. *What is cardiomyopathy and how will we evaluate it? Cardiomyopathy* is a disease of the heart muscle. The heart loses its ability to pump blood (heart failure), and in some instances, heart rhythm is disturbed, leading to irregular heartbeats (arrhythmias). Usually, the exact cause of the muscle damage is never found (idiopathic cardiomyopathy). There are various types of cardiomyopathy, which fall into two major categories: *Ischemic* and *nonischemic* cardiomyopathy. Ischemic cardiomyopathy typically refers to heart muscle damage that results from coronary artery disease, including heart attacks. Nonischemic cardiomyopathy includes several types: Dilated, hypertrophic, and restrictive. We will evaluate cardiomyopathy under 4.04 in part A, 104.02, 104.05, or 111.06, depending on its effects on you.

4. *How will we evaluate valvular heart disease?* We will evaluate valvular heart disease under the listing appropriate for its effect on you. Thus, we may use 4.04 in part A, 104.02, 104.05, 104.06, or an appropriate neurological listing in 111.00ff.

5. *What do we consider when we evaluate heart transplant recipients?*

a. After your heart transplant, we will consider you disabled for 1 year following the surgery because there is a greater likelihood of rejection of the organ and infection during the first year.

b. However, heart transplant patients generally meet our definition of disability before they undergo transplantation. We will determine the onset of your disability based on the facts in your case.

c. We will not assume that you became disabled when your name was placed on a transplant waiting list. This is because you may be placed on a waiting list soon after diagnosis of the cardiac disorder that may eventually require a transplant. Physicians recognize that candidates for transplantation often have to wait months or even years before a suitable donor heart is found, so they place their patients on the list as soon as permitted.

d. When we do a continuing disability review to determine whether you are still disabled, we will evaluate your residual impairment(s), as shown by symptoms, signs, and laboratory findings, including any side effects of medication. We will consider any remaining symptoms, signs, and laboratory findings indicative of cardiac dysfunction in deciding whether medical improvement (as defined in § 416.994a) has occurred.

6. *How will we evaluate chronic rheumatic fever or rheumatic heart disease?* The diagnosis should be made in accordance with the current revised Jones criteria for guidance in the diagnosis of rheumatic fever. We will evaluate persistence of rheumatic fever activity under 104.13. If you have evidence of chronic heart failure or recurrent arrhythmias associated with rheumatic heart disease, we will use 104.02 or 104.05.

7. *What is hyperlipidemia and how will we evaluate it? Hyperlipidemia* is the general term for an elevation of any or all of the lipids (fats or cholesterol) in the blood; for example, hypertriglyceridemia, hypercholesterolemia, and hyperlipoproteinemia. These disorders of lipoprotein metabolism and transport can cause defects throughout the body. The effects most likely to interfere with function are those produced by atherosclerosis (narrowing of the arteries) and coronary artery disease. We will evaluate your lipoprotein disorder by considering its effects on you.

8. *How will we evaluate Kawasaki disease?* We will evaluate Kawasaki disease under the listing appropriate to its effects on you, which may include major coronary artery aneurysm or heart failure. A major coronary artery aneurysm may cause ischemia or arrhythmia, which we will evaluate under 4.04 in part A or 104.05. We will

evaluate chronic heart failure under 104.02.

9. *What is lymphedema and how will we evaluate it?*

a. *Lymphedema* is edema of the extremities due to a disorder of the lymphatic circulation; at its worst, it is called elephantiasis. Primary lymphedema is caused by abnormal development of lymph vessels and may be present at birth (congenital lymphedema), but more often develops during the teens (lymphedema praecox). Secondary lymphedema is due to obstruction or destruction of normal lymphatic channels due to tumor, surgery, repeated infections, or parasitic infection such as filariasis. Lymphedema most commonly affects one extremity.

b. Lymphedema does not meet the requirements of 4.11 in part A, although it may medically equal the severity of that listing. We will evaluate lymphedema by considering whether the underlying cause meets or medically equals any listing or whether the lymphedema medically equals a cardiovascular listing, such as 4.11, or a musculoskeletal listing, such as 101.02A or 101.03. If no listing is met or medically equaled, we will evaluate any functional limitations imposed by your lymphedema when we consider whether you have an impairment that functionally equals the listings.

10. *What is Marfan syndrome and how will we evaluate it?*

a. Marfan syndrome is a genetic connective tissue disorder that affects multiple body systems, including the skeleton, eyes, heart, blood vessels, nervous system, skin, and lungs. There is no specific laboratory test to diagnose Marfan syndrome. The diagnosis is generally made by medical history, including family history, physical examination, including an evaluation of the ratio of arm/leg size to trunk size, a slit lamp eye examination, and a heart test(s), such as an echocardiogram. In some cases, a genetic analysis may be useful, but such analyses may not provide any additional helpful information.

b. The effects of Marfan syndrome can range from mild to severe. In most cases, the disorder progresses as you age. Most individuals with Marfan syndrome have abnormalities associated with the heart and blood vessels. Your heart's mitral valve may leak, causing a heart murmur. Small leaks may not cause symptoms, but larger ones may cause shortness of breath, fatigue, and palpitations. Another effect is that the wall of the aorta may be weakened and stretch (aortic dilation). This aortic dilation may tear, dissect, or rupture, causing serious heart problems or sometimes sudden death. We will evaluate the manifestations of your Marfan syndrome under the appropriate body system criteria, such as 4.10 in part A, or if necessary consider the functional limitations imposed by your impairment.

G. Other Evaluation Issues

1. *What effect does obesity have on the cardiovascular system and how will we evaluate it?* Obesity is a medically determinable impairment that is often associated with disorders of the cardiovascular system. Disturbance of this system can be a major cause of disability in children with obesity. Obesity may affect the cardiovascular system because of the increased workload the additional body mass places on the heart. Obesity may make it harder for the chest and lungs to expand. This can mean that the respiratory system must work harder to provide needed oxygen. This in turn would make the heart work harder to pump blood to carry oxygen to the body. Because the body would be working harder at rest, its ability to perform additional work would be less than would otherwise be expected. Thus, the combined effects of obesity with cardiovascular impairments can be greater than the effects of each of the impairments considered separately. We must consider any additional and cumulative effects of obesity when we determine whether you have a severe cardiovascular impairment or a listing-level cardiovascular impairment (or a combination of impairments that medically equals a listing), and when we determine whether your impairment(s) functionally equals the listings.

2. *How do we relate treatment to functional status?* In general, conclusions about the severity of a cardiovascular impairment cannot be made on the basis of type of treatment rendered or anticipated. The amount of function restored and the time required for improvement after treatment (medical, surgical, or a prescribed program of progressive physical activity) vary with the nature and extent of the disorder, the type of treatment, and other factors. Depending upon the timing of this treatment in relation to the alleged onset date of disability, we may need to defer evaluation of the impairment for a period of up to 3 months from the date treatment began to permit consideration of treatment effects, unless we can make a determination or decision using the evidence we have. See 104.00B4.

3. *How do we evaluate impairments that do not meet one of the cardiovascular listings?*

a. These listings are only examples of common cardiovascular disorders that we consider severe enough to result in marked and severe functional limitations. If your severe impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that satisfies the criteria of a listing in another body system.

b. 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.) If you have a severe impairment(s) that does not meet or medically equal the criteria of a listing, we will consider whether it functionally equals the listings. (See § 416.926a.) When we decide whether you continue to be disabled, we use the rules in § 416.994a.

104.01 Category of Impairments, Cardiovascular System

104.02. *Chronic heart failure* while on a regimen of prescribed treatment, with symptoms and signs described in 104.00C2, and with one of the following:

A. Persistent tachycardia at rest (see Table I);

OR

B. Persistent tachypnea at rest (see Table II) or markedly decreased exercise tolerance (see 104.00C2b);

OR

C. Growth disturbance with:

1. An involuntary weight loss or failure to gain weight at an appropriate rate for age, resulting in a fall of 15 percentiles from an established growth curve (on current NCHS/CDC growth chart) which is currently present (see 104.00A3f) and has persisted for 2 months or longer; or

2. An involuntary weight loss or failure to gain weight at an appropriate rate for age, resulting in a fall to below the third percentile from an established growth curve (on current NCHS/CDC growth chart) which is currently present (see 104.00A3f) and has persisted for 2 months or longer.

TABLE I.—TACHYCARDIA AT REST

Age	Apical heart rate (beats per minute)
Under 1 yr	150
1 through 3 yrs	130
4 through 9 yrs	120
10 through 15 yrs	110
Over 15 yrs	100

TABLE II.—TACHYPNEA AT REST

Age	Respiratory rate over (per minute)
Under 1 yr	40
1 through 5 yrs	35
6 through 9 yrs	30
Over 9 yrs	25

104.05 *Recurrent arrhythmias,* not related to reversible causes such as electrolyte abnormalities or digitalis glycoside or antiarrhythmic drug toxicity, resulting in uncontrolled (see 104.00A3g), recurrent (see 104.00A3c) episodes of cardiac syncope or near syncope (see 104.00E3b), despite prescribed treatment (see 104.00B3 if there is no prescribed treatment), and documented by resting or ambulatory (Holter) electrocardiography, or by other appropriate medically acceptable testing, coincident with the occurrence of syncope or near syncope (see 104.00E3c).

104.06 *Congenital heart disease,* documented by appropriate medically acceptable imaging (see 104.00A3d) or cardiac catheterization, with one of the following:

A. Cyanotic heart disease, with persistent, chronic hypoxemia as manifested by:

1. Hematocrit of 55 percent or greater on two evaluations 3 months or more apart within a consecutive 12-month period (see 104.00A3e); or

2. Arterial O_2 saturation of less than 90 percent in room air, or resting arterial PO_2 of 60 Torr or less; or

3. Hypercyanotic spells, syncope, characteristic squatting, or other incapacitating symptoms directly related to documented cyanotic heart disease; or

4. Exercise intolerance with increased hypoxemia on exertion.

OR

B. Secondary pulmonary vascular obstructive disease with pulmonary arterial systolic pressure elevated to at least 70 percent of the systemic arterial systolic pressure.

OR

C. Symptomatic acyanotic heart disease, with ventricular dysfunction interfering very seriously with the ability to independently initiate, sustain, or complete activities.

OR

D. For infants under 12 months of age at the time of filing, with life-threatening congenital heart impairment that will require or already has required surgical treatment in the first year of life, and the impairment is expected to be disabling (because of residual impairment following surgery, or the recovery time required, or both) until the attainment of at least 1 year of age, consider the infant to be under disability until the attainment of at least age 1; thereafter, evaluate impairment severity with reference to the appropriate listing.

104.09 *Heart transplant.* Consider under a disability for 1 year following surgery; thereafter, evaluate residual impairment under the appropriate listing.

104.13 *Rheumatic heart disease,* with persistence of rheumatic fever activity manifested by significant murmurs(s), cardiac enlargement or ventricular dysfunction (see 104.00C2a), and other associated abnormal laboratory findings; for example, an elevated sedimentation rate or ECG findings, for 6 months or more in a consecutive 12-month period (see 104.00A3e). Consider under a disability for 18 months from the established onset of impairment, then evaluate any residual impairment(s).

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