SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Regulation No. 4]

RIN 0960–AF48

Revised Medical Criteria for Evaluating Cardiovascular Impairments

AGENCY: Social Security Administration.

ACTION: Proposed rules.

SUMMARY: We propose to revise 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 proposed revisions reflect our program experience and advances in medical knowledge, treatment, and methods of evaluating cardiovascular disorders.

DATES: To be sure your comments are considered, we must receive them by November 15, 2004.

ADDRESSES: You may give us your comments by: using our Internet site facility (*i.e.,* Social Security Online) at: *http://policy.ssa.gov/pnpublic.nsf/LawsRegs* or the Federal eRulemaking Portal at: *http://www.regulations.gov;* e-mail to *regulations@ssa.gov*; telefax to (410) 966–2830; or letter to the Commissioner of Social Security, P.O. Box 17703, Baltimore, Maryland 21235–7703. You may also deliver them to the Office of Regulations, Social Security Administration, 100 Altmeyer Building, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, between 8 a.m. and 4:30 p.m. on regular business days. Comments are posted on our Internet site at *http://policy.ssa.gov/pnpublic.nsf/LawsRegs* or you may inspect them on regular business days by making arrangements with the contact person shown in this preamble.

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.* It is also available on the Internet site for SSA (*i.e.,* Social Security Online): *http://policy.ssa.gov/pnpublic.nsf/LawsRegs.*

FOR FURTHER INFORMATION CONTACT: Fran O. Thomas, Social Insurance Specialist, Office of Disability and Income Security Programs, Social Security Administration, 100 Altmeyer, 6401 Security Boulevard, Baltimore, Maryland 21235–6401, (410) 966–9822 or TTY (410) 966–5609. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet Web site, *Social Security Online*, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION:

What Programs Would These Proposed Regulations Affect?

These proposed regulations would 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 or title XVI, these proposed regulations would 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, and
- Widows, widowers, and surviving divorced spouses (*see* 20 CFR 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 is 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 and that results in . . .
Title II	An adult or a child	The inability to do any substantial gainful activity (SGA).
Title XVI	a person age 18 or older	The inability to do any SGA.
Title XVI	A person under age 18	Marked and severe functional limitations.

What Are the Listings?

The listings are examples of impairments that we consider severe enough to prevent an individual from doing any gainful activity or that result in ''marked and severe functional limitations'' in children seeking SSI payments under title XVI of the Act. Although we publish the listings only in appendix 1 to subpart P of part 404 of our rules, 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 never 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. (*See* §§ 404.1526 and 416.926.)

We use the listings only to decide that individuals are disabled or that they are still disabled. We will never deny your claim or decide that you no longer qualify for benefits because your impairment(s) does not meet or medically equal a listing. If 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'' that we use to evaluate all disability claims. (*See* §§ 404.1520, 416.920, and 416.924.)

Also, when we conduct reviews to determine whether your disability continues, we will not find that your disability has ended based only on any changes in the listings. Our regulations explain that, when we change our listings, we continue to use our prior

listings when we review your case, if you qualified for disability benefits or SSI payments based on our determination or decision that your impairment(s) met or medically equaled the listings. 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 after we decide that you have experienced medical improvement in your condition(s). *See* § 416.994a(b)(2).

Why Are We Proposing To Revise the Listings for Cardiovascular Impairments?

We last published final rules revising the listings for the cardiovascular body system in the **Federal Register** on February 10, 1994 (59 FR 6468). In that notice, we said that those rules would be effective for 4 years unless we extended them, or revised and issued them again. The current listings for the cardiovascular system will no longer be effective on July 1, 2005, unless we extend them, or revise and issue them again.

We are proposing these revisions because we decided to update the medical criteria and provide more information about how we evaluate cardiovascular impairments.

When Will We Start To Use These Rules?

We will not use these rules until we evaluate the public comments we receive on them, determine whether to issue them as final rules, and issue final rules in the **Federal Register**. If we publish final rules, we will explain in the preamble how we will apply them, and summarize and respond to the major public comments. Until the effective date of any final rules, we will continue to use our current rules.

How Long Would These Proposed Rules Be Effective?

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

How Are We Proposing To Change the Introductory Text to the Adult Cardiovascular Listings?

We propose to expand and reorganize the introductory material in current section 4.00 to provide additional guidance and to reflect the new listings. Because of the extensive information and guidance included in the introductory text to the listings, we propose to provide separate sections that are devoted to specific issues. The following is an explanation of the proposed material.

Proposed 4.00A—General

In this proposed section, we provide general information on what we mean by a cardiovascular impairment and what we consider when we evaluate cardiovascular impairments. Proposed section 4.00A1 incorporates the information found in current 4.00B, with some minor editing. Proposed section 4.00A2 is taken from the first paragraph of current 4.00A. Proposed section 4.00A3 is a new section containing definitions of some terms we use in these proposed listings.

Proposed 4.00B—Documenting Cardiovascular Impairments

In 4.00B1, we propose to provide information on the basic documentation that we need to evaluate cardiovascular impairments under the listings. In proposed sections 4.00B2–4.00B3, we 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 proposed 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 order studies, and specify what studies we will not order. Much of this information is taken from the current sections 4.00A and 4.00C, with some rephrasing to clarify our meaning.

Proposed 4.00C—Using Cardiovascular Test Results

In this proposed section, we discuss various specialized cardiovascular tests and how we evaluate their results. In 4.00C1, we explain what an electrocardiogram (ECG) is. Our specifications for ECG tracings from current section 4.00C1 are given in proposed section 4.00C2. In proposed section 4.00C3, we explain what the different kinds of exercise tests are and discuss their uses. Exercise testing is the most widely used testing for identifying the presence of myocardial ischemia and for estimating maximal aerobic capacity if you have heart disease. 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 proposed section 4.00C4, we discuss what limitations exercise tolerance tests (ETTs) have. We also explain, in proposed section 4.00C5, what ETTs with measurement of maximal or peak oxygen uptake are and how they differ from other ETTs.

In proposed sections 4.00C6–4.00C7, we explain when we will consider ordering an exercise test for case evaluation and what we must do before ordering one. We will 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 follow under our current rules.) We also send copies of your records to the physician conducting the exercise test for us, if he or she does not already have them, as the examining physician has the ultimate responsibility for determining whether you would be at risk. We also propose, in section 4.00C8, to reorganize and modify the information on ''significant risk'' in current section 4.00C2c. We are doing this because some of the so-called risk factors identified in the current section are not risks *per se*, but are factors that affect proper interpretation of the tracings or are situations that only temporarily preclude exercise testing. We propose to identify several different categories that explain the various circumstances under which we will not order an ETT or will defer ordering one. We propose to 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 at the end of this preamble.)

In proposed section 4.00C9, we explain when we consider exercise test results to be timely. In proposed sections 4.00C10–4.00C11, we outline the criteria for evaluating how ETTs we order should be performed (taken from current section 4.00C2b) and explain how we evaluate ETT results (taken from current section 4.00C2e). We explain when ETTs are done with imaging and when we will consider ordering such tests in proposed sections 4.00C12–4.00C13, which are based on the guidance given in current section 4.00C3. We provide new guidance on drug-induced stress tests, what they are, and how they are used, in proposed section 4.00C14.

In proposed section 4.00C15, we placed the information found in current section 4.00C4 on two types of cardiac catheterization reports and the details that the reports should contain and what we consider when evaluating these reports. In proposed sections 4.00C16–4.00C17, we placed the information found in current section 4.00E4 on the details that exercise Doppler studies should contain and how any such studies we order should be performed. We propose to change the requirement in the third paragraph of current section 4.00E4 for walking on a 10 or 12 percent grade to a 12 percent grade. This proposed change would make our rules consistent with how the test is generally done. 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 proposed 4.00C7 and 4.00C8. We also specify that the tracings should be included with the report and that they should be annotated with the standardization used by the testing facility.

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

Proposed 4.00D—Evaluating Chronic Heart Failure

In proposed 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. We also propose to evaluate *cor pulmonale* under the respiratory system listing 3.09, rather than listing 4.02, as it is a heart condition resulting from a respiratory disorder. In proposed 4.00D2 and 4.00D3, we describe the evidence of chronic heart failure that we need and explain how ETTs are used to evaluate individuals with known chronic heart failure. We also explain, in proposed 4.00D4, the phrase ''periods of stabilization,'' which we use in proposed listing 4.02B2.

Proposed 4.00E—Evaluating Ischemic Heart Disease

In proposed section 4.00E, for ischemic heart disease (IHD), we would incorporate most of the information in current section 4.00E3. We explain what IHD is and what causes chest discomfort of myocardial origin in proposed sections 4.00E1 and 4.00E2. We propose to move unchanged the material on chest discomfort of myocardial ischemic origin from current section 4.00E3e to proposed section 4.00E2 and to explain that individuals with IHD may experience manifestations other than typical angina pectoris. We discuss the characteristics of typical angina pectoris in proposed section 4.00E3. This section is based on and incorporates material from current section 4.00E3a. In proposed section 4.00E4, we include a definition of, and information on, atypical angina, which we include in our discussion of anginal equivalent in current section 4.00E3b. We discuss anginal equivalent in proposed section 4.00E5. The material on anginal equivalent is based on current 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. Proposed section 4.00E6 on variant angina is based on current 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 proposed section 4.00E7, we would expand the discussion of silent ischemia that appears in current 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 monitoring (Holter) equipment, and how we evaluate it. We propose to move the material on chest discomfort of non-ischemic origin from current section 4.00E3f to proposed section 4.00E8. We propose to 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 proposed section 4.00E9, we explain how we evaluate IHD using the criteria in proposed listing 4.04.

Proposed 4.00F—Evaluating Arrhythmias

In proposed section 4.00F, we provide information on evaluating arrhythmias. We explain what arrhythmias are and discuss the different types in proposed sections 4.00F1–4.00F2. In proposed section 4.00F3, we explain what we mean by ''near syncope'' in listing 4.05. In proposed sections 4.00F4 and 4.00F5, we would add information on implantable cardiac defibrillators and how we will evaluate arrhythmias if you have a defibrillator implanted.

Proposed 4.00G—Evaluating Peripheral Vascular Disease

In the proposed section on peripheral vascular disease (PVD), 4.00G, we would incorporate the information in current 4.00E4 and provide additional information and guidance on the evaluation of PVD, based on questions we have received in the past. Proposed section 4.00G1 explains what we mean by PVD and describes its usual effects. In proposed section 4.00G2, we explain how we assess the limitations resulting from PVD. This section is based on current 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.

We explain in proposed section 4.00G3 what brawny edema is to distinguish it from pitting edema and clarify that pitting edema does not satisfy the requirements of listing 4.11. We also propose to explain what lymphedema is and what causes it in proposed section 4.00G4. We also add guidance on the evaluation of lymphedema in section 4.00G5. We propose to evaluate lymphedema either under the listing for the underlying cause, or to 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 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 the more reliable. In proposed section 4.00G7, we take information from the third paragraph of current section 4.00E4 on how the ankle/brachial ratio is determined for purposes of evaluating a claim under 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. We also specify that we will request any available tracings from those techniques, so that we can review them.

We would move and rephrase somewhat for clarity the information on when we will obtain exercise Doppler studies for the evaluation of peripheral arterial disease from current section 4.00E4 to proposed section 4.00G8, but make no substantive changes. We add guidance in proposed section 4.00G9 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 are also proposing two new criteria in listing 4.12 using toe pressure and toe/brachial pressure ratio. Then, in proposed section 4.00G10, we explain how toe pressures are measured. In proposed section 4.00G11, we describe other studies helpful in evaluating PVD, 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 similar vascular changes. We close our discussion of the evaluation of PVD with section 4.00G12, which discusses the similarities between peripheral grafting and coronary grafting and explains how we will evaluate cases involving peripheral grafting.

Proposed 4.00H—Evaluating Other Cardiovascular Impairments

In proposed section 4.00H, we provide guidance on evaluating other cardiovascular impairments. In proposed section 4.00H1, we discuss the evaluation of hypertension, rephrasing material found in current section 4.00E2. We explain what congenital heart disease is in proposed section 4.00H2 and provide guidance on how we will evaluate symptomatic congenital heart disease in proposed 4.00H3. In proposed 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 proposed 4.00H5. We discuss the evaluation of heart transplant recipients in proposed section 4.00H6. Finally, we explain when an aneurysm has ''dissection not controlled by prescribed treatment'' as required under listing 4.10, in proposed section 4.00H7. We propose to add guidance on what hyperlipidemia is and how we will evaluate it in proposed section 4.00H8.

Proposed 4.00I—Other Evaluation Issues

In this section, we would provide guidance on a variety of issues. In proposed section 4.00I1, we explain the evaluation of obesity's effect on the cardiovascular system. The guidance in this section is taken from current section 4.00F and incorporates additional guidance we included in Social Security Ruling 02–1p (''Titles II and XVI: Evaluation of Obesity,'' 67 FR 57859 (2002)). Proposed section 4.00I2 explains how we relate treatment to functional status. This section is based on current section 4.00D; we have deleted some language that dealt with listing-level impairment from the current section and made non-substantive editorial changes. If the anticipated improvement might affect the determination or decision on the case, we will wait an appropriate length of time in order to evaluate the results of the treatment. Finally, in proposed 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 current section 4.00A. We propose to make non-substantive editorial changes in the current language.

How Are We Proposing To Change the Criteria in the Listings for Evaluating Cardiovascular Impairments in Adults?

Proposed 4.01—Category of Impairments, Cardiovascular System

We propose to delete 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 propose to delete these reference listings from our 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 proposed listing criteria.

Proposed 4.02—Chronic Heart Failure

We propose to change the format of current listing 4.02, creating two new sections, 4.02A and 4.02B, with subsections. For the listing to be met, both the 4.02A and 4.02B requirements must be satisfied. We propose to move the required imaging findings that are generally associated with the clinical diagnosis of heart failure from current subsections 4.02A and 4.02B to new subsections 4.02A1 and 4.02A2 and to revise them to reflect the anatomical changes associated with systolic and diastolic dysfunction, respectively. The current listing has different criteria for heart failure in sections 4.02A and 4.02B and does not provide criteria for both systolic and diastolic failure. Additionally, because the criteria in current listing 4.02A of 5.5 cm is generally considered the high end of normal for heart size, we propose to change the left ventricular diastolic diameter to left ventricular end diastolic dimensions greater than 6.0 cm. This change would more clearly establish an enlarged heart that would result in the signs and symptoms associated with listing-level severity.

We also propose to redesignate current listing 4.02A as 4.02B1 and revise the criteria language. The current listing includes a description of heart failure and refers to the ''inability to carry on any physical activity,'' which implies that the individual must be bedridden. Our program experience shows that this listing is set at too high a level of severity and is little used. We have removed the description of heart failure and rephrased the proposed criteria in listing 4.02B1 to describe an extreme limitation in that you have an impairment that very seriously limits

your ability to independently initiate, sustain, or complete activities of daily living. This is modeled after the definition of ''inability to ambulate effectively'' in the musculoskeletal listings, section 1.00A2b(1). We believe this reflects the proper listing level of severity. This listing may only be used if exercise testing presents a significant risk to you.

We propose to add a new criterion in listing 4.02B2 to include individuals who have frequent acute attacks of heart failure, showing that the heart failure is not well-controlled by the prescribed treatment. This also would provide another avenue that would allow us to make favorable determinations or decisions in certain cases without exercise tolerance test documentation.

We propose to redesignate current 4.02B1 as listing 4.02B3. We also propose to revise it, by specifying in proposed listing 4.02B3a the symptoms of chronic heart failure that might cause termination of an ETT. This proposed 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 proposed 4.02B3b through 4.02B3d. We propose to change the ''three or more multiform beats'' in the current listing 4.02B1a to ''increasing frequency of ventricular ectopy with at least 6 premature ventricular contractions per minute'' in proposed 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 proposed listing 4.02B3c, we propose to eliminate the criterion for ''[f]ailure to increase systolic blood pressure by 10 mmHg,'' from current 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 propose to specify only an amount of decrease from the ''baseline'' systolic blood pressure due to left ventricular dysfunction or the preceding systolic pressure measured during exercise at which the test should be terminated. We would redesignate current listing 4.02B1c, for signs attributable to inadequate cerebral perfusion, as proposed listing 4.02B3d, but would make no other changes to it. We would remove current listing 4.02B2, the functional criterion that calls for ''marked limitation of physical activity,'' because it is unnecessary. If you satisfy one of the proposed 4.02A criteria and one of the proposed 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.

Proposed 4.04—Ischemic Heart Disease

In the header text, we propose to change ''chest discomfort'' to ''symptoms'' because some individuals have discomfort in other parts of their body, such as an arm, back, or neck, or have other symptoms, such as shortness of breath (dyspnea), associated with ischemia. In proposed listing 4.04A1, we would 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 appears in current listing 4.04A1 because we believe it is unnecessary. We also propose to eliminate the current listing 4.04A2 criterion. The ACC/AHA *Guidelines for Exercise Testing* indicated that an upsloping ST junction depression, as described in the current criterion, has less specificity (more false-positive results) and they favored the more commonly used horizontal or downsloping ST depression. We would redesignate the subsequent criteria.

In proposed listing 4.04A2 (current listing 4.04A3), we would 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 propose to reduce the requirement for the ST elevation during recovery from 3 or more minutes to 1 or more minutes. This ST elevation in non-infarct leads is of such significance, we believe persistence of the ST elevation for 1 or more minutes of recovery to be sufficient for listing-level severity. In proposed listing 4.04A3 (current listing 4.04A4), we would eliminate the phrase ''failure to increase systolic pressure by 10 mmHg'' for the reasons previously discussed under the explanation of proposed listing 4.02B3c. We also would specify a decrease of 10 mmHg below baseline due to left ventricular dysfunction, or the preceding systolic pressure measured during exercise, despite an increase in workload, because exercise normally raises blood pressure and a decrease during exercise reflects the presence of ischemia.

We propose to revise current listing 4.04A5, but would 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 would also redesignate it as listing 4.04A4.

We propose a new listing 4.04B criterion. The new criterion would provide that you would meet the listing if you have three separate ischemic episodes, each requiring revascularization (angioplasty or bypass surgery) or be not amenable to revascularization, within a consecutive 12-month period. This will permit us to decide some cases more quickly.

In the header text for listing 4.04C, we propose to change the phrase ''evaluating program physician'' to ''MC'' to be consistent with our terminology throughout these proposed rules and in other regulations. Because not everyone who has the cited findings has ischemia, we propose to add that this criterion can be used only ''in the absence of a timely exercise tolerance test or a timely normal drug-induced stress test.''

We also propose to revise the current 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 would conform to the criterion in current listing 4.04C1b for a nonbypassed coronary artery, which we are not proposing to change. When we originally published the current 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. We propose to revise the 4.04C2 criterion, using substantively the same language that appears in proposed 4.02B1.

Proposed 4.05—Recurrent Arrhythmias

We propose to 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 proposed 4.00A3 that we use throughout these proposed rules. We propose to remove the phrase ''and arrhythmia'' that follows near syncope in current 4.05, because it is redundant. Listing 4.05 is for ''recurrent arrhythmias.'' We also propose to 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 electrophysiological studies or any appropriate medical tests developed for arrhythmia in the future.

Proposed 4.06—Symptomatic Congenital Heart Disease

Because we propose to eliminate current reference listings 4.06C and 4.06D, we would redesignate current listing 4.06E as 4.06C. In proposed listing 4.06C, we would 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.

Proposed 4.09—Heart Transplant

We propose to change the name from ''Cardiac transplantation'' to ''Heart transplant'' consistent with terminology in our other listings. We also propose to 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 propose to remove the cross-reference to listings 4.02 to 4.08, which we explain we may use when we reevaluate an individual a year after the transplant, and to substitute the phrase ''the appropriate listing.'' This will clarify that other listings besides listings 4.02 through 4.08 may apply, including listings in other body systems.

Proposed 4.10—Aneurysm of Aorta or Major Branches

As we have already noted, we propose to remove listings 4.10B through 4.10D because they are reference listings. We would incorporate the criteria from current listing 4.10A into the header text, because it would be the sole remaining criterion. Because dissection of an aorta must be either acute or chronic, we propose to remove those descriptors as unnecessary in this context. We also propose to change the description of treatment to ''prescribed treatment,'' which includes both medical and surgical methods, and to include a cross-reference to proposed section 4.00H7. That paragraph explains what a dissecting aneurysm is and when we consider that it is not controlled for purposes of this listing.

Proposed 4.11—Chronic Venous Insufficiency

In listing 4.11A, we propose to add language to clarify what we mean by ''extensive'' brawny edema. We provide that, for purposes of this proposed listing, the brawny edema is ''extensive'' if it involves approximately two-thirds of the leg between the ankle and knee. In listing 4.11B, we propose to refer only to ''prescribed treatment,'' which includes both medical and surgical methods. This is a non-substantive change from the current listing, which uses the phrase ''prescribed medical or surgical therapy.'' We have also clarified that the phrase ''that has not healed following at least 3 months of prescribed treatment'' applies only to ''persistent'' ulceration.

Proposed 4.12—Peripheral Arterial Disease

In listing 4.12, we propose to remove current 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. Following surgery, if intermittent claudication continued, it would be evaluated under the remaining criteria. We would redesignate current listings 4.12B1 and 4.12B2 as 4.12A and 4.12B. (**Note:** We removed prior 4.12C, amputation, when we published the final musculoskeletal rules, which were effective February 19, 2002. *See* 66 FR 58010.)

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

We also propose two new 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 proposed 4.00G8, ankle pressures can be misleadingly high when you have a disease that results in abnormal arterial calcification or small vessel disease.

How Are We Proposing To Change the Introductory Text to the Listings for Evaluating Cardiovascular Impairments in Children?

We propose to expand and reorganize the introductory material in 104.00 to provide additional guidance and reflect the new listings. As with the adult listings, because of the extensive information and guidance included in the introductory text for the listings, we propose to 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 proposed 4.00 in the introductory text to proposed 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 under the explanation of proposed 4.00, the following discussions describe only those provisions that are unique to the childhood rules or that require further explanation.

Proposed 104.00A—General

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

Proposed 104.00B—Documenting Cardiovascular Impairments

In proposed 104.00B5, we specify that ''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.'' In proposed section 104.00B7a and 104.00B7b, we include the discussion, with some non-substantive editorial changes, on the use of exercise testing in children found in the third and fourth paragraphs of current section 104.00B. In proposed section 104.00B7c, we include a cross-reference to the guidance on ETT requirements and usage found in proposed section 4.00C. We did not repeat that section in the childhood listing because it addresses cardiovascular tests used mainly for the diagnosis and evaluation of ischemia, which is rare in children, but if present, the documentation and evaluation are the same as for adults.

Proposed 104.00C—Evaluating Chronic Heart Failure

In proposed section 104.00C1, we do not differentiate between systolic and diastolic dysfunction, as we do with adults in proposed section 4.00D1a, because in children, it is unlikely that we will have a specific type of dysfunction clearly identified. For children, certain laboratory findings of cardiac functional and structural abnormality in support of the diagnosis of chronic heart failure are sufficient. In proposed 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 proposed 104.00C2a(1)(c) the chest x-ray findings cited in the second paragraph of current section 104.00E. In

proposed section 104.00C2b, we include the information found in the first and third paragraphs of current 104.00E, with some rephrasing for clarity, but no substantive changes.

Proposed 104.00D—Evaluating Congenital Heart Disease

In the proposed congenital heart disease section, we would move the list of examples of congenital heart defects from the second paragraph of current section 104.00A to proposed section 104.00D1. In proposed section 104.00D2, we state that we will accept pulse oximetry measurements instead of arterial O_2 values when evaluating children under proposed listing 104.06A2. However, if the arterial O_2 values are available, they are preferred because they are the most accurate. Proposed section 104.00D3 lists examples of congenital heart defects that we would evaluate under proposed listing 104.06D. This material was taken from the first and second paragraphs of current section 104.00D. The discussion of symptomatic congenital heart disease found in proposed section 4.00H3 is repeated in proposed 104.00D4, with minor changes to address children. We propose to delete the information contained in the third paragraph of current 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.

Proposed 104.00E—Evaluating Arrhythmias

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

Proposed 104.00F—Evaluating Other Cardiovascular Impairments

In proposed section 104.00F, we address cardiovascular impairments that are most likely to affect children and that are not already discussed in previous sections, omitting those 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 adult listings. We include discussions of cardiovascular impairments that are more likely to be seen in children, such as chronic rheumatic fever or rheumatic heart disease. This proposed section contains much of the same information found in the proposed section 4.00H, with the following differences.

We address ischemia in proposed section 104.00F1 instead of a separate section (like in the adult rules) because it is rare in children. Because the documentation and evaluation are the same as for adults, we refer to the adult sections 4.00E and listing 4.04 for the evaluation of ischemic heart disease in children. Proposed section 104.00F2, on how we will evaluate hypertension, is similar to proposed section 4.00H1, but has been modified to reflect its effects on children. In proposed section 104.00F5, we include the information on chronic rheumatic fever and rheumatic heart disease found in current 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 proposed section 104.00F7, we discuss how we will evaluate Kawasaki Disease (formerly called Kawasaki syndrome), which usually develops before you are 5 years old.

Proposed 104.00G—Other Evaluation Issues

This proposed section corresponds to the proposed adult section 4.00I, with minor editorial changes to refer to children.

How Are We Proposing To Change the Criteria in the Listings for Evaluating Cardiovascular Impairments in Children?

Proposed 104.01—Category of Impairments, Cardiovascular System

We propose to delete the following current 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 propose to delete 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 propose to delete current 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 proposed listing 104.06D. We also propose to delete the current Hyperlipidemia listings that are not reference listings, 104.14B, 104.14C, and 104.14D. We propose to delete these listings because there is better treatment now available for hyperlipidemia, making it less likely to result in limitations of listing-level severity. If necessary, hyperlipidemia's effect on a child can be evaluated under a listing for the affected body system. We propose to delete current 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.

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

Proposed 104.02—Chronic Heart Failure

We propose to add language to the header text to clarify that the heart failure must occur ''while on a regimen of prescribed treatment.'' Listings 104.02A and 104.02B and their associated tables will remain the same. Because we propose to delete current listing 104.02C, Recurrent arrhythmias, which refers the adjudicator to listing 104.05, we would redesignate the current listing 104.02D, Growth disturbance, as 104.02C. We also propose to 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 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 at 100.00. The current growth charts are available on-line at: *www.cdc.gov/growthcharts/*.

Proposed 104.05—Recurrent Arrhythmias

We propose to use the same language as in proposed listing 4.05.

Proposed 104.06—Congenital Heart Disease

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

Finally, we propose to remove the current reference listing 104.06G, redesignate current listing 104.06H as 104.06D and to remove the references to specific listings from it. Also in proposed listing 104.06D, we would change the language that currently directs 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 would 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 would 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 would not apply to surgery for congenital heart impairments that routinely result in prompt recovery or less severe residual impairment.

Proposed Listing 104.09—Heart Transplant

We propose to use the same language as in proposed listing 4.09.

Proposed Listing 104.13—Rheumatic Heart Disease

We propose to change the name by removing ''Chronic rheumatic fever'' because the impairment is related to the resulting heart disease, rather than the fever activity. We also propose to include current listing 104.13A with the current header text, with some reorganization of the material. We would remove listings 104.13B and 104.13C because they are reference listings.

What Other Revision Are We Proposing?

We propose that *Cor pulmonale* be evaluated under the respiratory listings, as it is a heart condition resulting from a respiratory disorder. Thus, we also propose to revise current listing 3.09 by removing the reference listing 3.09C, which refers to listing 4.02.

Clarity of These Proposed Rules

Executive Order 12866 requires each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make these proposed rules easier to understand. For example:

- Have we organized the material to suit your needs?
- Are the requirements in the rules clearly stated?
- Do the rules contain technical language or jargon that is not clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rules easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?

Regulatory Procedures

Executive Order (E.O.) 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these proposed rules meet the requirements for a significant regulatory action under E.O. 12866, as amended by E.O. 13258. Thus, they were subject to OMB review.

Regulatory Flexibility Act

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

Paperwork Reduction Act

These proposed rules contain reporting requirements at 4.00B, 4.00C, 4.00D, 4.00E, 4.00F, 4.00G, 4.02A, 104.00B, 104.00C, 104.00E, and 104.06. The public reporting burden is accounted for in the Information Collection Requests for the various forms that the public uses to submit the information to SSA. Consequently, a 1-hour placeholder burden is being assigned to the specific reporting requirement(s) contained in these rules. We are seeking clearance of the burden referenced in these rules because the rules were not considered during the clearance of the forms. An Information Collection Request has been submitted to OMB. We are soliciting comments on the burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility and clarity; and on ways to minimize the burden on respondents, including the use of automated collection techniques or other forms of information technology. Comments should be submitted and/or faxed to the Office of Management and Budget and to the Social Security Administration at the following addresses/numbers:

Office of Management and Budget, Attn: Desk Officer for SSA, Fax Number: (202) 395–6974.

Social Security Administration, Attn: SSA Reports Clearance Officer, Rm: 1338 Annex Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–6400.

Comments can be received for up to 60 days after publication of this notice and will be most useful if received within 30 days of publication. To receive a copy of the OMB clearance package, you may call the SSA Reports Clearance Officer on (410) 965–0454.

References

A list of the sources we consulted when developing these proposed rules include the following:

1. Gibbons RJ, Balady GJ, Beasley JW, Bricker JT, Duvernoy WFC, Froelicher VF, Mark DB, Marwick TH, McCallister BD, Thompson PD, Winters WL Jr, Yanowitz FG. ACC/AHA guidelines for exercise testing: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Exercise Testing). *J Am Coll Cardiol.* 1997; 30:260–315.

2. Gibbons RJ, Balady GJ, Bricker JT, Chaitman BR, Fletcher GF, Froelicher VF, Mark DB, McCallister BD, Mooss AN, O'Reilly MG, Winters WL Jr. ACC/AHA 2002 guideline update for exercise testing: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on Exercise Testing). 2002. American College of

Cardiology Web site. Available at: *www.acc.org/clinical/guidelines/exercise/dirIndex.htm*.

3. Braddom, RL, ed., *Physical Medicine and Rehabilitation,* 2nd ed., Philadelphia: W.B. Saunders Co., 2000, pp. 665–686.

4. Canto, JG, *et al.*, ''Prevalence, Clinical Characteristics, and Mortality Among Patients With Myocardial Infarction Presenting Without Chest Pain.'' *Journal of the American Medical Association*, June 28, 2000, Vol. 283, No. 24, pp. 3223–3229.

5. ''Diastolic Heart Failure—No Time to Relax.'' *The New England Journal of Medicine*, January 4, 2001, Vol. 344, No. 1, pp. 56–58.

6. National Heart, Lung, and Blood Institute, National Institutes of Health. ''Facts About Heart Failure.'' NIH Publication No. 97–923, Reprinted May 1997. Available on-line at: *www.nhlbi.nih.gov/health/public/heart/other/hrtfail.htm*.

7. Pinkowish, MD, ''Revascularization in the 21st century.'' *Patient Care*, January 15, 2001, pp. 82–98.

8. ''Syncope.'' *The New England Journal of Medicine*, December 21, 2000, Vol. 343, No. 25, pp. 1856–1862.

9. ''Guidelines for the Diagnosis of Rheumatic Fever, Jones Criteria, 1992 Update.'' *The Journal of the American Medical Association*, October 21, 1992, Vol. 268, No. 15, pp. 2069–2073.

10. National Heart, Lung, and Blood Institute, National Institutes of Health. ''Facts About Arrhythmias/Rhythm Disorders.'' NIH Publication No. 95–2264, Reprinted September 1995. Available on-line at: *www.nhlbi.nih.gov/health/public/heart/other/arrhyth.htm*.

11. Anthony S. Fauci, *et al.*, eds., *Harrison's Principles of Internal Medicine*, 14th ed., New York: McGraw-Hill, 1998, pp.1405–1406.

12. P. J. Palumbo, MD, and L. Joseph Melton III, MD, ''Peripheral Vascular Disease and Diabetes,'' *Diabetes in America*, 2nd ed., National Diabetes Data Group, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, NIH Publication No. 95–1468, 1995, chapter 17, pp. 401–408. Available on-line at: *www.niddk.nih.gov/health/diabetes/dia/chpt17.pdf*.

13. Jamie D. Santilli, MD, and Steven M. Santilli, MD, PhD, ''Chronic Critical Limb Ischemia: Diagnosis, Treatment and Prognosis,'' *American Family Physician*, April 1, 1999, pp. 1899–1910. Available on-line at: *www.aafp.org/afp/990401ap/1899.html*.

14. Jeffrey W. Olin, DO, ''Clinical Evaluation and Office-Based Detection of Peripheral Arterial Disease,'' Monograph from Continuing Medical Education, Part I: *The Epidemiology and Practical Detection of PAD*, Society of Vascular Medicine and Biology.

15. Michael R. Jaff, DO, FACP, FACC, ''Severe Peripheral Arterial Disease and Critical Limb Ischemia: Incidence, Pathophysiology, Presentation, Methods of Diagnosis,'' Monograph from Continuing Medical Education, Part III: *Severe PAD: Limb Salvage and Revascularization Failure*, Society of Vascular Medicine and Biology.

16. National Heart, Lung, and Blood Institute, National Institutes of Health. ''Facts About Cardiomyopathy.'' NIH Publication No. 97–3082, Revised July 1997. Available on-line at: *www.nhlbi.nih.gov/health/public/heart/other/cardiomy.htm*.

These references are included in the rulemaking record for these proposed rules and are available for inspection by interested individuals by making arrangements with the contact person shown in this preamble.

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

Dated: June 10, 2004.

Jo Anne B. Barnhart,

Commissioner of Social Security.

For the reasons set out in the preamble, we propose to amend subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations as set forth below:

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

Subpart P—[Amended]

1. The authority citation for subpart P of part 404 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—[Amended]

2. Appendix 1 to subpart P of part 404 is amended as follows:

a. Item 5 of the introductory text before part A of appendix 1 is revised as set forth below.

b. Listing 3.09 of part A of appendix 1 is amended by removing ''; Or'' at the end of paragraph B, replacing it with a period, and removing paragraph C.

c. Sections 4.00 and 104.00 of appendix 1 to subpart P of part 404 are revised to read as follows:

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

* * * * *

5. Cardiovascular System (4.00 and 104.00): (Insert date 5 years from the date of publication of the final rules in the **Federal Register**.)

* * * * *

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 either the heart or the circulatory system (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:

(1) Chronic heart failure or ventricular dysfunction.

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

(3) 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.

(4) 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, eyes, kidneys, and other organs. We will evaluate peripheral vascular disease under this body system 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 impairments of the cardiovascular system 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* must occur within the period we are considering in connection with an application or continuing disability review.

f. *Uncontrolled* means the condition 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 on 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 there is no longitudinal record because 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 such cases, 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, you may have another impairment(s) that, in combination with your cardiovascular impairment, medically equals a listed impairment, or you may be found disabled based on consideration of your residual functional capacity and age, education, and work experience.

b. Unless your claim can be decided 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 any necessary examination(s) to establish the severity 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 condition might affect our determination or decision. In these cases, 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:

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

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

(3) 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 order any studies?* In appropriate cases, we will order additional studies necessary to substantiate the diagnosis or to document the severity of your impairment after we have evaluated the medical and other evidence we already have. We will order studies involving exercise testing only if there is no significant risk involved or if there is no other medical reason not to perform the test. We will follow sections 4.00C7 and 4.00C8 when we decide whether to order these studies.

6. *What studies will we not order?* We will not order 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.

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.

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

(2) 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 (see 4.00C4–4.00C14) should meet the following specifications:

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

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

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

(4) 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.

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

(6) 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 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 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 exercise Doppler testing. Even though this test is intended to evaluate peripheral vascular disease, if you develop abnormal signs or symptoms because of heart disease, it will be stopped for your safety.

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, throughout a workday, activities required for work in all possible work environments. Also, certain medications (such as beta blockers) and conduction disorders (such as left or right bundle branch blocks) can result in false negatives or false positives. Therefore, we must consider the results of an ETT together with all the other relevant evidence.

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 milliliter (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 ordering an exercise test for case evaluation?* We will consider ordering an exercise test when:

a. We cannot find you disabled on some other basis; and

b. There is no timely test in the evidence we have (see 4.00C9); and

c. There is a question whether a cardiovascular impairment meets or medically equals the severity of one of the listings; or

d. We need to assess your residual functional capacity and there is insufficient evidence in the record to evaluate your aerobic capacity or the effect of exercise on blood flow in your legs.

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

a. Before we order 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 order the test (*see* 4.00C8).

b. If you are under the care of a treating source (*see* § 404.1502) for a cardiac 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 order the test.

c. In defining risk, the MC, in accordance with the regulations and other instructions on consultative examinations, will generally give great weight to the treating source's opinions and will generally not override them. 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 ordering 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 order or wait before we order an exercise test?*

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

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

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

(3) An implantable cardiac defibrillator.

(4) Symptomatic severe aortic stenosis.

(5) Uncontrolled symptomatic heart failure.

(6) Aortic dissection.

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

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

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

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

(11) Hypertrophic cardiomyopathy with a systolic gradient of 50 mm Hg or greater; or

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

c. We will wait to order an exercise test when you have had one of the following within the last 3 months. In these situations, we will defer ordering the ETT until 3 months after the event to allow for maximal, attainable restoration of functional capacity:

(1) Acute myocardial infarction.

(2) Surgical myocardial revascularization (bypass surgery).

(3) Other open-heart surgical procedures.

(4) Percutaneous transluminal coronary angioplasty with or without stenting; or

d. 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 order 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, whether there has been an intervening event or improvement or worsening of your condition. We will also consider the purpose of the test.

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

10. *How should ETTs we order be performed?*

a. The ETT should 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.)

b. The exercise test should 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 should 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 should 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. Examples of such resting ECG abnormalities include conduction defects—Wolff-Parkinson-White syndrome, left bundle branch block, left ventricular hypertrophy—or you are taking digitalis or other antiarrhythmic drugs or resting ST changes are present. Also, these techniques can provide a reliable estimate of ejection fraction.

13. *Will we order ETTs with imaging?* We may order 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 ordering 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 decide your claim in your favor on another basis.

14. *What are drug-induced stress tests?* These are tests 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 (simulating exercise) and are used in combination with a 2-dimensional echocardiogram. We may, when necessary, order 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. Although we will not purchase cardiac catheterization, if you have had catheterization, we will make a 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 available, we will consider quantitative computer measurements and analyses 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. When available, 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 should 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 should 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 should also be included with the report. All tracings should be annotated with the standardization used by the testing facility.

17. *How should exercise Doppler tests we order be performed?* When we order an exercise Doppler test, you must exercise on a treadmill at 2 mph on a 12 percent grade for 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 4.00C7 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:

(1) 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

(2) Predominant diastolic dysfunction (the inability 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 use 3.09 under 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.

(1) 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.

(2) 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.

(3) 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.

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

(5) 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, there should also be characteristic symptoms and signs of pulmonary or systemic congestion, or limited cardiac output described in the medical history and on physical examinations, 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.

(1) 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 waking them from sleep (paroxysmal nocturnal dyspnea). They may also experience cardiac arrhythmias resulting in palpitations, lightheadedness, or fainting.

(2) 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 perform 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 to evaluate your ability to do work-related activities. Exercise testing has been safely used in individuals with CHF, and we may order 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 4.00C7–4.00C8 for what we must do before we order an ETT and when we will not order one.) Since the presence of possible ischemic ST segment abnormality on exercise is not critical for application of 4.02B3, digitalis use is not a factor when considering ETT purchase in cases involving CHF.

4. *What do we mean by ''periods of stabilization'' in 4.02B2?* We mean that, for at least 5 days between episodes of acute heart failure, there must be some objective evidence of clearing of the pulmonary edema or pleural effusions and that you returned to or you were medically considered able to return to your prior level of activity.

E. Evaluating Ischemic Heart Disease

1. *What is ischemic heart disease (IHD)?* IHD results when one or more of the coronary arteries is narrowed or obstructed or, in rare cases, constricted due to vasospasm, interfering with the normal flow of blood to the 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 condition, such as critical aortic stenosis, hypertrophic cardiomyopathy, pulmonary hypertension, or anemia.

b. Instead of typical angina pectoris, some individuals with IHD may experience atypical angina, anginal equivalent, variant angina, or even 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 establish that this symptom represents atypical angina, the discomfort or pain should have similar precipitating and relieving factors as with 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 cardiac disease will complain of shortness of breath (dyspnea) on exertion without chest pain or discomfort. In a minority of such cases, the shortness of breath is due to myocardial ischemia and this is called anginal equivalent. To establish that this symptom represents anginal equivalent, the shortness of breath should have similar precipitating and relieving factors as with typical chest discomfort and we must have objective medical evidence of myocardial ischemia; such as, ECG or ETT evidence or appropriate medically acceptable imaging. It is essential to establish objective evidence of myocardial ischemia in order to differentiate these cases from those presenting with effort dyspnea due to non-ischemic or non-cardiac causes.

6. *What is variant angina?*

a. Variant angina (Prinzmetal's, vasospastic angina) refers to the occurrence of anginal episodes at rest, accompanied by transitory ST segment elevation (or, at times, ST depression) on 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, which we may evaluate using 4.05. Spasm of a coronary artery may occur in relation to an obstructive lesion of the vessel of varying degree and is the only situation in which we will consider variant angina under 4.04.

b. Variant angina may also occur in the absence of obstructive coronary disease. In this situation, the ETT will not demonstrate ischemia, and diagnosis will depend on documenting the typical transitory ST segment changes during attacks of pain, and the absence of obstructive lesions at 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 cases, we will consider the frequency of anginal episodes despite prescribed treatment.

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:

(1) 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 or perfusion imaging.

(2) 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. The ambulatory recording may show ST depression that 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(2).

8. *What other sources of chest discomfort are there?* Chest discomfort of nonischemic origin may result from other cardiac conditions such as pericarditis. Noncardiac conditions may also produce symptoms mimicking that of myocardial ischemia. These conditions 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 during both exercise and recovery. Although we recognize that ischemic changes may at times be confined only to exercise or only to recovery, and may at times be upsloping with only junctional ST depression, such changes can also occur in the absence of ischemia; that is, a ''false positive'' ECG response. Such situations may

require appropriate medically acceptable imaging for clarification.

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 occurring during exercise 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 confirmation.

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 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 (because of deconditioning or apprehension) with increased sympathetic responses 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.

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, requiring 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 health condition or the vessel was not suitable for revascularization.

g. For 4.04C to apply, you must be at risk for exercise testing (see 4.00C9) and we must not have a timely ETT or timely normal drug-induced stress test for you. For purposes of 4.04C, 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 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 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, 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 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. *What do we mean by ''near syncope'' in 4.05?* 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. For purposes of 4.05, there has to be a documented association between the symptom and the medically determinable arrhythmia to satisfy the requirements of the listing and it must be recurrent arrhythmia causing the recurrent episodes of syncope or near syncope. The arrhythmia, not some other cardiac or non-cardiac disorder, must be established as the cause of the symptom. Thus, for purposes of this listing, tilt table findings are not acceptable, as they may provoke syncope or near syncope not related to a cardiac condition.

4. *Will we evaluate arrhythmias under 4.05 when an implantable cardiac defibrillator is present?* If you have arrhythmias that are not fully controlled by drug or implantable cardiac defibrillator treatment such that you have uncontrolled recurrent episodes of syncope or near syncope, we will evaluate the arrhythmias under 4.05. 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 implantable cardiac defibrillator, see 4.00F5.

5. *What will we consider when we evaluate arrhythmias that do not meet 4.05 and an implantable cardiac defibrillator is present?*

a. Implantable 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 implantable cardiac defibrillator is a unique form of treatment; it rescues an individual from what may have been cardiac arrest. As a consequence of the shock(s), individuals may experience psychological distress, which we may evaluate under the mental disorders listings.

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.) Implantable 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 an MRI (magnetic resonance imaging), can trigger or reprogram an implantable 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 implantable cardiac defibrillator are those dictated by the underlying heart condition. However, the exercise limitations may be lowered further when the implantable 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, for our purposes, PVD is any condition 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). You may have pain in the calf of your leg after walking a distance (intermittent claudication) if you have peripheral arterial disease. If you have venous insufficiency, you may have swelling, varicose veins, or skin changes.

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 usually dense and feels firm, due to the presence of increased connective tissue, and is associated with characteristic skin pigmentation changes. It is not the same thing as ''pitting edema.'' Brawny edema generally does not ''pit,'' and the terms are not interchangeable. Pitting edema does not satisfy the requirements of 4.11A.

4. *What is lymphedema?* Edema of the extremities due to a disorder of the lymph circulation is called lymphedema or, at its worst, 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.

5. *How do we evaluate lymphedema?* 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. If no listing is met or medically equaled, we will evaluate any functional limitations imposed by the lymphedema when we assess your residual functional capacity.

6. *Which ankle blood pressure is referred to in 4.12, the posterior tibial or the dorsalis pedis?* The ankle blood pressure referred to in 4.12 is the higher recorded pressure, either from the posterior tibial or dorsalis pedis. The higher pressure recorded from either site is the more reliable measurement.

7. *What is an ankle/brachial ratio and how do we use it under 4.12A?* The requirements for evaluating peripheral arterial disease in 4.12A are based on 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. Techniques for obtaining ankle systolic blood pressures include Doppler, plethysmographic studies, duplex scanning with color imaging, or other techniques. We will request any available tracings generated by these studies so that we can review them. (*See* 4.00C16 and 4.00C17.) 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 peripheral arterial disease, unless you also have a disease causing abnormal arterial calcification or small vessel disease. *See* 4.00G9 and 4.00G10.

8. *When will we purchase exercise Doppler studies for evaluating peripheral arterial disease?* We will decide whether to purchase exercise Doppler studies by evaluating the existing clinical evidence. If we need additional evidence of your peripheral arterial disease, we will generally order exercise studies (*see* 4.00C16 and 4.00C17) when your resting ankle/brachial systolic blood pressure ratio is at least 0.50 or above, but less than 0.80, and only rarely when it is 0.80 or above. We will not order 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* 4.00G9.) There are no current medical standards for evaluating exercise toe pressures. Because any exercise test stresses your entire cardiovascular system, we will order exercise Doppler studies only after an MC, preferably one with experience in the care of patients with cardiovascular disease, has determined that none of the situations listed in 4.00C8 apply to you.

9. *When will we use toe systolic blood pressures for evaluating peripheral arterial disease under 4.12?* 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* 4.00G7) when you have 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. Therefore, if you have intermittent claudication and arterial calcification or small vessel disease, we will use your resting toe systolic blood pressure or resting toe/brachial systolic blood pressure ratio when we evaluate your impairment. While the criteria in 4.12C and 4.12D are intended primarily for use when you have a disease causing abnormal arterial calcification or small vessel disease, we may also use them for evaluating anyone with peripheral arterial disease.

10. *How are toe pressures measured?* Toe pressures are measured routinely in most vascular laboratories through one of three methods: Doppler ultrasound; plethysmography using strain gauge cuffs; and photoplethysmography. 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 (digicuffs) can be used in the measurement of toe pressure.

11. *Are there any other studies that are helpful in evaluating PVD?* Doppler studies done using a recording ultrasonic Doppler unit and strain-gauge plethysmography are other useful tools for evaluating PVD. 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.

12. *How do we use the PVD listings 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 vascular impairment. However, if you have had peripheral grafting done for your PVD, 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 the effects of hypertension under the listings. We will also consider any limitations imposed by your hypertension when we assess your residual functional capacity.

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

3. *How will we evaluate symptomatic congenital heart disease?* Because of improved treatment methods, more individuals with congenital heart disease are living longer. Although some types of congenital heart disease may be corrected through 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.

4. *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.

5. *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, or the appropriate neurological listing in 11.00ff.

6. *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 actual 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 §§ 404.1579(b)(1) and 404.1579(c)(1), 404.1594(b)(1) and 404.1594(c)(1), or 416.994(b)(1)(i) and 416.994(b)(2)(i), as appropriate) has occurred.

7. *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 associated dissection can cause heart failure, renal (kidney) failure, or neurological complications. We will evaluate these conditions using the appropriate listing.

8. *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/cholesterol) in the blood; for example, hypertriglyceridemia, hypercholesterolemia, and hyperlipoproteinemia. These disorders of lipoprotein metabolism and transport can cause defects in various organs. The effects most likely to interfere with function are those produced by atherosclerosis (narrowing of the arteries) and coronary artery disease. Treatment of all of these disorders has improved, which lessens or delays the resulting functional limitations. We will evaluate all of these lipoprotein disorders under the listing appropriate to its effects on you, which may include myocardial ischemia, arterial stenosis, liver transplant (as a form of treatment), pancreatitis, or joint effusions.

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. If you have obesity, when we determine whether you have a listing-level cardiovascular impairment (or a combination of impairments that medically equals the severity of a listed impairment), and when assessing your claim at other steps of the sequential evaluation process, including when assessing your residual functional capacity, we must consider any additional and cumulative effects of obesity.

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 the impairments(s) medically equals a listing. (See §§ 404.1526 and 416.926.) If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. In that situation, 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. Left ventricular end diastolic dimensions greater than 6.0 cm or ejection fraction of 30 percent or less during a period of stability (see 4.00D2a(2)) (systolic failure); or

2. 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 (see 4.00D2a(2)) (diastolic 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(2)) from clinical and imaging methods 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 4.00D4); or

3. Inability to perform on an exercise tolerance test at a workload equivalent to 5 METs or less (see 4.00C2b and 4.00C10) 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 below the baseline systolic blood pressure due to left ventricular dysfunction or the preceding systolic pressure measured during exercise; 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 in systolic pressure below the baseline blood pressure due to left ventricular dysfunction or the preceding systolic pressure measured during exercise (see 4.00E9e) 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 (see 4.00E9f), each requiring revascularization or not amenable (see 4.00E9f) to revascularization, within a consecutive 12-month period (see 4.00A3e); or

C. Coronary artery disease, demonstrated by angiography (obtained independent of Social Security disability evaluation), 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 revealing:

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 2 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 4.00F3), 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.

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 4.00H7).

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 involving approximately two-thirds of the leg between the ankle and knee; 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, and 4.00G11), 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 4.00G6–4.00G7 and 4.00C13–4.00C14) 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 4.00G9); or

D. Resting toe/brachial systolic blood pressure ratio of less than 0.40 (see 4.00G9).

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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 either the heart or the circulatory system (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:

(1) Chronic heart failure or ventricular dysfunction.

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

(3) 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.

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

c. Disorders of the veins and arteries (for example, obstruction, rupture, or aneurysm) may cause impairments of the lower extremities (peripheral vascular disease), the central nervous system, eyes, 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 impairments of the cardiovascular system 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* 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 condition 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 on 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 there is no longitudinal record because 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 such cases, 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, you may have another impairment(s) that, in combination with your cardiovascular impairment, medically equals a listed impairment or that functionally equals the listings.

b. Unless your claim can be decided 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 any necessary examination(s) to establish the severity 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 condition might affect our determination or decision. In these cases, 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:

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

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

(3) 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 order any studies?* In appropriate cases, we will order additional studies necessary to substantiate the diagnosis or to document the severity of your impairment after we have evaluated the medical and other evidence we already have. We will order studies involving exercise testing only if there is no significant risk involved or if there is no other medical reason not to perform the test. We will follow sections 4.00C7 and 4.00C8 when we decide whether to order these studies. 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 §§ 404.1519g and 416.919g.)

6. *What studies will we not order?* We will not order 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.

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 successfully performed in 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 testing for children.

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

C. Evaluating Chronic Heart Failure

1. *What is chronic heart failure (CHF)?* 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. 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 use 3.09 under 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.

(1) 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.

(2) 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.)

(3) 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, there should also be characteristic symptoms and signs of pulmonary or systemic congestion, or limited cardiac output described in the medical history and on physical examinations, 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.

(1) 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 waking 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.

(2) 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.

(3) Signs of congestion may include hepatomegaly, ascites, increased jugular venous distention or pressure, rales, peripheral edema, quick 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,* such as ventricular septal defect or atrioventricular canal;

b. *Abnormalities resulting in cyanotic heart disease,* such as tetralogy of Fallot or transposition of the vessels;

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. *Will we accept pulse oximetry measurements for use under 104.06A2?* We will accept pulse oximetry measurements instead of arterial O_2, but if the arterial O_2 values are available, they are preferred.

3. *What congenital heart defects will we evaluate under 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:

a. Hypoplastic left heart syndrome;

b. Critical aortic stenosis with neonatal heart failure;

c. Critical coarctation of the aorta, with or without associated anomalies;

d. Complete atrioventricular canal defects;

e. Transposition of the great arteries;

f. Tetralogy of Fallot;

g. Pulmonary atresia with intact ventricular septum;

h. Single ventricle;

i. Tricuspid atresia, and

j. Multiple ventricular septal defects.

4. *How will we evaluate symptomatic congenital heart disease?* Because of improved treatment methods, more children with congenital heart disease are living longer. Although some types of congenital heart disease may be corrected through 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 either 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.

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, 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 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. *What do we mean by ''near syncope'' in 104.05?* 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. For purposes of 104.05, there has to be a documented association between the symptom and the medically determinable arrhythmia to satisfy the requirements of the listing and it must be recurrent arrhythmia causing the recurrent episodes of syncope or near syncope. The arrhythmia, not some other cardiac or non-cardiac disorder, must be established as the cause of the symptom. Thus, for purposes of this listing, tilt table findings are not acceptable, as they may provoke syncope or near syncope not related to a cardiac condition.

4. *Will we evaluate arrhythmias under 104.05 when an implantable cardiac defibrillator is present?* If you have arrhythmias that are not fully controlled by drug or implantable cardiac defibrillator treatment such that you have uncontrolled recurrent episodes of syncope or near syncope, we will evaluate the arrhythmias under 104.05. 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 implantable cardiac defibrillator, see 104.00E5.

5. *What will we consider when we evaluate arrhythmias that do not meet 104.05 and an implantable cardiac defibrillator is present?*

a. Implantable 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 implantable cardiac defibrillator is a unique form of treatment; it rescues a child from what may have been cardiac arrest. As a consequence of the shock(s), children may experience psychological distress, which we may evaluate under the mental disorders listings.

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.) Implantable 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 an MRI (magnetic resonance imaging), can trigger or reprogram an implantable 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 implantable cardiac defibrillator are those dictated by the underlying heart condition. However, the exercise limitations may be lowered further when the implantable 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 and how will we evaluate it in children?* Ischemic heart disease results when one or more of the coronary arteries is narrowed or obstructed or, in rare cases, constricted due to vasospasm, interfering with the normal flow of blood to the 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 and its effects on children and adults are the same. We will evaluate it in children using the guidance and criteria found in 4.00E and 4.04.

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 the effects of hypertension under the listings. If you are a child seeking supplemental security income payments based on disability, we will also consider your hypertension when we consider whether you have an impairment that functionally equals the listings.

3. *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 104.02, 104.05, 104.06, 4.04, or the appropriate neurological listing under 111.00ff or 11.00ff.

4. *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 actual 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(c)) has occurred.

5. *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.

6. *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/cholesterol) in the blood; for example, hypertriglyceridemia, hypercholesterolemia, and hyperlipoproteinemia. These disorders of lipoprotein metabolism and transport can cause defects in various organs. The effects most likely to interfere with function are those produced by atherosclerosis (narrowing of the arteries) and coronary artery disease. Treatment of all of these disorders has improved, which lessens or delays the resulting functional limitations. We will evaluate all of these lipoprotein disorders under the listing appropriate to its effects on you, which may include myocardial ischemia, arterial stenosis, liver transplant (as a form of treatment), pancreatitis, or joint effusions.

7. *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 or 104.05. We will evaluate heart failure under 104.02.

8. *What is lymphedema?* Edema of the extremities due to a disorder of the lymph circulation is called lymphedema or, at its worst, 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.

9. *How do we evaluate lymphedema?* 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. If you are a child seeking supplemental security income payments based on disability, we will also consider your lymphedema when we consider whether you have an impairment that functionally equals the listings.

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. If you have 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 or, as appropriate, functionally equals the listings), we must consider any additional and cumulative effects of obesity.

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. In the case of a claim for SSI payments, if your impairment(s) does not meet or medically equal a listing, we will consider whether it functionally equals the listings. (See §§ 404.1526, 416.926, and 416.926a.) If you are receiving SSI payments, 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 104.00E3), despite prescribed treatment (see 104.00B3 if there is no prescribed treatment), and documented by resting or ambulatory (Holter) electrocardiography, or by other appropriate medical testing, coincident with the occurrence of syncope or near syncope.

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.

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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