Signed at Washington, DC this 16th day of August, 2002.

John L. Henshaw,

Assistant Secretary of Labor.

[FR Doc. 02–21449 Filed 8–21–02; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900–AL26

Schedule for Rating Disabilities; Guidelines for Application of Evaluation Criteria for Certain Respiratory and Cardiovascular Conditions; Evaluation of Hypertension With Heart Disease

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the Department of Veterans Affairs (VA) Schedule for Rating Disabilities, in order to provide guidance in the evaluation of certain respiratory and cardiovascular conditions, and to explain that hypertension will be evaluated separately from hypertensive and other types of heart diseases. The intended effect of this amendment is to clarify the use of the current criteria for evaluating respiratory and cardiovascular conditions, particularly in cases where alternative criteria are provided, in order to ensure that veterans receive consistent evaluations and are not required to undergo unnecessary tests.

DATES: Comments must be received on or before October 21, 2002.

ADDRESSES: Mail or hand-deliver written comments to: Director, Office of Regulations Management (02D), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1154, Washington, DC 20420; or fax comments to (202) 273–9289; or e-mail comments to *OGCRegulations@mail.va.gov*. Comments should indicate that they are submitted in response to ''RIN 2900–AL26.'' All comments received will be available for public inspection in the Office of Regulations Management, Room 1158, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays).

FOR FURTHER INFORMATION CONTACT: Caroll McBrine, M.D., Consultant, Regulations Staff (211A), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Ave., NW., Washington, DC 20420, (202) 273–7210.

SUPPLEMENTARY INFORMATION:

Evaluation of Certain Respiratory Conditions

Since revised evaluation criteria for respiratory conditions were established in 1996, the evaluation of most respiratory conditions has been based primarily on the results of specific pulmonary function tests (PFT's). Conditions evaluated on that basis include chronic bronchitis (diagnostic code 6600), pulmonary emphysema (diagnostic code 6603), chronic obstructive pulmonary disease (diagnostic code 6604), interstitial lung disease (diagnostic codes 6825–6833), and restrictive lung disease (diagnostic codes 6840–6845). In some cases, the rating schedule provides alternative evaluation criteria that may be used instead of PFT's. These include measures of the maximum exercise capacity; the presence of pulmonary hypertension (documented by echocardiogram or cardiac catheterization), cor pulmonale, or right ventricular hypertrophy; episode(s) of respiratory failure; and a requirement for outpatient oxygen therapy. Alternative criteria were established in order to provide more than one route to reach a particular level of evaluation and, at the same time, avoid requiring that veterans undergo additional invasive, risky, costly, or time-consuming tests when one or more objective and reliable tests or findings suitable for evaluation purposes are already of record.

Applying the PFT results can be difficult in some cases. We therefore propose to add provisions that would clarify the use of PFT's in evaluating respiratory conditions to 38 CFR 4.96 as paragraph (d), titled ''Special provisions for the application of evaluation criteria for diagnostic codes 6600, 6603, 6604, 6825–6833, and 6840–6845.'' We developed these provisions after consultation with the Pulmonary/Critical Care Advisory Committee of the Veterans Health Administration.

Chronic bronchitis (diagnostic code 6600) is an example of a respiratory condition that is evaluated primarily on the basis of PFT's but also has alternative evaluation criteria. The criteria for a 100-percent evaluation are FEV–1 (Forced Expiratory Volume in one second) less than 40 percent of predicted value, the ratio of FEV–1 to FVC (Forced Vital Capacity) less than 40 percent, DLCO (SB) (Diffusion Capacity of the Lung for Carbon Monoxide by the Single Breath Method) less than 40-percent predicted, maximum exercise capacity less than 15 ml/kg/min oxygen consumption (with cardiac or respiratory limitation), cor pulmonale (right heart failure), right ventricular hypertrophy, pulmonary hypertension (shown by echocardiogram or cardiac catheterization), episode(s) of acute respiratory failure, or a requirement for outpatient oxygen therapy. The criteria for a 60-percent evaluation are FEV–1 of 40- to 55-percent predicted, FEV–1/FVC of 40 to 55 percent, DLCO (SB) of 40- to 55-percent predicted, or maximum oxygen consumption of 15 to 20 ml/kg/min (with cardiorespiratory limit). The criteria for a 30-percent evaluation are FEV–1 of 56- to 70-percent predicted, FEV–1/FVC of 56 to 70 percent, or DLCO (SB) 56- to 65-percent predicted. The criteria for a 10-percent evaluation are FEV–1 of 71- to 80-percent predicted, FEV–1/FVC of 71 to 80 percent, or DLCO (SB) 66- to 80-percent predicted.

For the first provision, we propose to state when pulmonary function testing is not needed for disability evaluation purposes. The first instance would be when there is a maximum exercise capacity of record that is 20 ml/kg/min or less (which would result in a 60- or 100-percent evaluation). Although this test is not routinely done, and not all facilities have the necessary equipment to conduct the test, if available, it is a reliable and precise way to assess respiratory disability, so it may be used to evaluate when it is available and is reported at levels that would warrant a 60- or 100-percent evaluation. If not of record, however, evaluation will be based on alternative criteria. The second instance would be when pulmonary hypertension (documented by an echocardiogram or cardiac catheterization), cor pulmonale, or right ventricular hypertrophy has been diagnosed. Any of these would result in a 100-percent evaluation. The third instance would be when there is a history of one or more episodes of acute respiratory failure, and the fourth instance would be when there is a requirement for outpatient oxygen therapy, because either of these also establishes entitlement to a 100-percent evaluation.

Routine pulmonary function testing may or may not include a measurement of DLCO (SB) (Diffusion Capacity of the Lung for Carbon Monoxide by the Single Breath Method). The DLCO (SB) is not useful or valid in assessing every respiratory condition (for example, it is not valid in cases where the lung volume is decreased), so it is up to the examiner to assess whether it would provide useful information in a particular case. We therefore propose to add a second provision that would state that if the DLCO (SB) is not of record, evaluation will be based on alternative

criteria as long as the examiner states why the DLCO (SB) would not be useful or valid in a particular case.

The third provision directs that when the PFT's are not consistent with the clinical findings, evaluation will be based on the PFT's unless the examiner states why they are not a valid indication of respiratory functional impairment in a particular case. The rationale for this is that PFT's are reliable, objective tests, and the respiratory system evaluation criteria have been revised in part to remove subjective assessment criteria, such as self-reported symptoms, in order to ensure consistent ratings. The PFT-based criteria are similar to the method of assessing impairment due to respiratory disease used by the American Thoracic Society and the American Medical Association *Guides to the Evaluation of Permanent Impairment,* 5th ed. (2001).

The fourth provision states that post-bronchodilator studies are required when PFT's are done for disability evaluation purposes except when the results of pre-bronchodilator pulmonary function tests are normal or when an examiner determines that post-bronchodilator studies should not be done and states why (for example, because the patient is allergic to the bronchodilator). The American Lung Association/American Thoracic Society Component Committee on Disability Criteria recommends testing for pulmonary function after optimum therapy.

The fifth provision also applies to post-bronchodilator studies and states that when evaluating based on PFT's, the post-bronchodilator results (rather than pre-bronchodilator results) will be used in applying the evaluation criteria in the rating schedule unless the post-bronchodilator results were poorer than the pre-bronchodilator results. In those cases, the pre-bronchodilator values will be used. The American Lung Association/American Thoracic Society Component Committee on Disability Criteria recommends testing for pulmonary function after optimum therapy. The best possible pulmonary function (which is ordinarily post-bronchodilator functioning) is the basis of standards for pulmonary function testing. If the bronchodilator has a contrary effect, the best pulmonary function would be the pre-bronchodilator functioning.

The sixth provision addresses cases in which there is a disparity between the results of different PFT's (FEV–1, FVC, etc.), so that the level of evaluation would differ depending on which test result is used to evaluate. In such cases, the test result that the examiner states most accurately reflects the level of disability would be used to evaluate.

The seventh provision states that a decreased FEV–1/FVC ratio will be considered normal if the FEV–1 is greater than 100 percent. In that case, both the FVC and the FEV–1 would be high (better than normal), so a decreased ratio would not indicate pathology.

Evaluation of Certain Cardiovascular Conditions

In 38 CFR 4.104 (Schedule of ratings—cardiovascular system), diagnostic codes 7000 (valvular heart disease), 7001 (endocarditis), 7002 (pericarditis), 7003 (pericardial adhesions), 7004 (syphilitic heart disease), 7005 (arteriosclerotic heart disease), 7006 (myocardial infarction), 7007 (hypertensive heart disease), 7011 (ventricular arrhythmias (sustained)), 7015 (atrioventricular block), 7016 (heart valve replacement), 7017 (coronary bypass surgery), 7018 (implantable cardiac pacemakers), 7019 (cardiac transplantation), and 7020 (cardiomyopathy) have almost identical evaluation criteria. As in the case of respiratory conditions, there are alternative criteria for evaluation at some levels, and some criteria are based on the results of special tests. For example, the evaluation criteria for diagnostic code 7000, valvular heart disease, are, in part, as follows: for a 100-percent evaluation, chronic congestive heart failure, workload of 3 METs (metabolic equivalents) or less results in dyspnea, fatigue, angina, dizziness, or syncope, or left ventricular dysfunction with an ejection fraction of less than 30 percent; for a 60-percent evaluation, more than one episode of acute congestive heart failure in the past year, workload of greater than 3 METs but not greater than 5 METs results in dyspnea, fatigue, angina, dizziness, or syncope, or left ventricular dysfunction with an ejection fraction of 30 to 50 percent; for a 30—percent evaluation, workload of greater than 5 METs but not greater than 7 METs results in dyspnea, fatigue, angina, dizziness, or syncope, or evidence of cardiac hypertrophy or dilatation on electro-cardiogram, echocardiogram, or X-ray; and for a 10-percent evaluation, workload of greater than 7 METs but not greater than 10 METs results in dyspnea, fatigue, angina, dizziness, or syncope, or continuous medication required.

There are many tests that can assess cardiac function, as the presence of alternative criteria at various levels indicates. Which ones are done in a clinical situation for a particular patient, however, depends on many criteria, such as the type of heart disease, the clinical status of the patient, the clinician's preference, the local availability of certain tests, etc. The alternative criteria we provide at a particular level of evaluation are meant to closely approximate one another in the degree of cardiac disability they represent. For example, a National Institutes of Health publication titled ''Heart Failure: Evaluation and Care of Patients With Left-Ventricular Systolic Dysfunction'' (*http://text.nlm.nih.gov/ahcpr/lvd/www/lvdctxt.html*) states that the majority of patients with heart failure have moderate-to-severe left-ventricular systolic dysfunction and ejection fractions of less than 35–40 percent. Therefore, if congestive heart failure is present, the condition can be evaluated on that basis, with no need for a ventricular ejection fraction study to be conducted for rating purposes. The rating schedule requires that a diagnosis of cardiac enlargement or hypertrophy be supported by either X-ray, EKG, or echocardiogram, but it does not require that all 3 tests be done in every case simply for rating purposes. Our intent in providing alternative criteria was to avoid the need for a veteran to undergo additional tests that might be invasive, risky, costly, or time-consuming, if one or more objective and reliable tests or findings suitable for evaluation purposes are already of record. Although it was not our intent to require that a veteran undergo every test listed in the criteria, some individuals have interpreted the regulation as requiring that every veteran undergoing evaluation for one of these heart conditions have X-rays, an echocardiogram, a ventricular ejection fraction test (which can be done either by means of echocardiography or radionuclide ventriculography (MUGA scan)), and METs measurement (by exercise stress testing), in order to be certain that a higher evaluation based on one of the alternative criteria is not warranted. This regulation is proposed in order to clarify the application of these criteria.

We propose to add a new § 4.100, to be titled ''Application of the evaluation criteria for diagnostic codes 7000–7007, 7011, and 7015–7020,'' to VA's Schedule for Rating Disabilities. This section would contain three provisions guiding the evaluation of specified cardiovascular conditions. The first provision would require the evaluator to ascertain in all cases whether or not cardiac hypertrophy or dilatation (documented by electrocardiogram, echocardiogram, or X-ray) is present and whether or not there is a need for

continuous medication. Either of these would establish entitlement to a minimum evaluation level, and it is therefore essential to know whether either is present.

A second provision would indicate that even if the requirement for a 10% (based on the need for continuous medication) or 30% (based on the presence of cardiac hypertrophy or dilatation) evaluation is met, METs testing is always required except in the following cases: (1) When there is a medical contraindication, (2) when the left ventricular ejection fraction has been measured and is 50% or less, (3) when chronic congestive heart failure is present or there has been more than one episode of congestive heart failure within the past year, or (4) when a 100% evaluation can be assigned on another basis (such as during the three-month period following myocardial infarction). The rationale for this provision is that cardiac disability may warrant a higher evaluation on some other basis, such as the METs level, than the minimum evaluations assigned for continuous medication, or cardiac enlargement or hypertrophy. For example, even if a veteran with disability due to arteriosclerotic heart disease with angina requires continuous medication warranting a 10-percent evaluation, the METs level might warrant a higher evaluation.

The left ventricular ejection fraction (LVEF) is an objective measure of left ventricular function, that is, of the heart's ability to pump blood throughout the body. Decreased left ventricular function is a good indicator of the level of severity, prognosis, response to treatment, etc., of many heart problems. It has no value for rating purposes, however, unless it is decreased, because serious cardiac disability may be present even though the left ventricular function is normal. Whether an LVEF study is needed must be determined in a clinical setting. For rating purposes, the LVEF test is not necessary if there is a clinical diagnosis of either chronic congestive heart failure or a history of more than one episode of congestive heart failure within the past year because congestive heart failure of this degree establishes eligibility for a total (100-percent) evaluation. The LVEF test is also not usually necessary if METs testing, another very good indicator of the overall cardiovascular functional capacity, is available. We therefore propose that a third provision state that if LVEF testing is not of record, evaluation will be based on alternative criteria unless the examiner states that the LVEF test is needed in a particular case because the available medical information does not sufficiently reflect the severity of the veteran's cardiovascular disability.

These provisions will clarify the method of evaluation of these heart conditions.

Evaluation of Hypertension and Hypertensive Heart Disease

Before the cardiovascular system was revised in 1997, the evaluation criteria for hypertensive heart disease (diagnostic code 7007 in § 4.104 of 38 CFR), a condition that means the heart is enlarged or hypertrophied due to hypertension, were based in part on blood pressure readings. Hypertension itself was also evaluated primarily on the basis of blood pressure readings. Separately evaluating hypertension and hypertensive heart disease at that time was therefore prohibited because it would have meant evaluating two different conditions based on the same findings (or evaluating the same disability under two diagnoses), a process prohibited by 38 CFR 4.14, Avoidance of pyramiding. Since 1997, hypertensive heart disease has been evaluated on the same basis as most other types of heart disease, namely, the results of exercise testing expressed in METs, the presence of congestive heart failure, the ventricular ejection fraction, etc. It is no longer evaluated on the basis of blood pressure readings. Therefore, hypertension and hypertensive heart disease may now be separately evaluated because each has separate and independent evaluation criteria that do not overlap. There is therefore no conflict with § 4.14. The rating schedule changes left some confused about whether or not separate evaluations for hypertension and hypertensive heart disease are now appropriate. To eliminate the confusion, we propose to add a new note (3) under diagnostic code 7101, hypertensive vascular disease, in § 4.104, stating that hypertension will be separately evaluated from hypertensive heart disease and other types of heart disease.

Unfunded Mandates

The Unfunded Mandates Reform Act requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of $100 million or more in any given year. This rule would have no consequential effect on State, local, or tribal governments.

Executive Order 12866

This regulatory amendment has been reviewed by the Office of Management and Budget under the provisions of Executive Order 12866, Regulatory Planning and Review, dated September 30, 1993.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3520).

Regulatory Flexibility Act

The Secretary hereby certifies that this regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. The reason for this certification is that this amendment would not directly affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this amendment is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program numbers are 64.104 and 64.109.

List of Subjects in 38 CFR Part 4

Disability benefits, Pensions, Veterans.

Approved: June 26, 2002.

Anthony J. Principi,

Secretary of Veterans Affairs.

For the reasons set out in the preamble, 38 CFR part 4 (subpart B) is proposed to be amended as set forth below:

PART 4—SCHEDULE FOR RATING DISABILITIES

Subpart B—Disability Ratings

1. The authority citation for part 4 continues to read as follows:

Authority: 38 U.S.C. 1155, unless otherwise noted.

2. Section 4.96 is amended by adding paragraph (d) preceding the authority citation at the end of the section to read as follows:

§ 4.96 Special provisions regarding evaluation of respiratory conditions.

* * * * *

(d) *Special provisions for the application of evaluation criteria for diagnostic codes 6600, 6603, 6604, 6825–6833, and 6840–6845.* (1) Pulmonary function tests (PFT's) are

required to evaluate these conditions except:

(i) When the results of a maximum exercise capacity test are of record and are 20 ml/kg/min or less. If a maximum exercise capacity test is not of record, evaluate based on alternative criteria.

(ii) When pulmonary hypertension (documented by an echocardiogram or cardiac catheterization), cor pulmonale, or right ventricular hypertrophy, has been diagnosed.

(iii) When there have been one or more episodes of acute respiratory failure.

(iv) When outpatient oxygen therapy is required.

(2) If the DLCO (SB) (Diffusion Capacity of the Lung for Carbon Monoxide by the Single Breath Method) test is not of record, evaluate based on alternative criteria as long as the examiner states why the test would not be useful or valid in a particular case.

(3) When the PFT's are not consistent with clinical findings, evaluate based on the PFT's unless the examiner states why they are not a valid indication of respiratory functional impairment in a particular case.

(4) Post-bronchodilator studies are required when PFT's are done for disability evaluation purposes except when the results of pre-bronchodilator pulmonary function tests are normal or when the examiner determines that post-bronchodilator studies should not be done and states why.

(5) When evaluating based on PFT's, use post-bronchodilator results in applying the evaluation criteria in the rating schedule unless the post-bronchodilator results were poorer than the pre-bronchodilator results. In those cases, use the pre-bronchodilator values for rating purposes.

(6) When there is a disparity between the results of different PFT's (FEV–1 (Forced Expiratory Volume in one second), FVC (Forced Vital Capacity), etc.), so that the level of evaluation would differ depending on which test result is used, use the test result that the examiner states most accurately reflects the level of disability.

(7) Consider a decreased FEV–1/FVC ratio to be normal if the FEV–1 is greater than 100 percent.

* * * * *

3. Section 4.100 is added to read as follows:

§ 4.100 Application of the evaluation criteria for diagnostic codes 7000–7007, 7011, and 7015–7020.

(a) Whether or not cardiac hypertrophy or dilatation (documented by electrocardiogram, echocardiogram, or X-ray) is present and whether or not there is a need for continuous medication must be ascertained in all cases.

(b) Even if the requirement for a 10% (based on the need for continuous medication) or 30% (based on the presence of cardiac hypertrophy or dilatation) evaluation is met, METs testing is required in all cases except:

(1) When there is a medical contraindication.

(2) When the left ventricular ejection fraction has been measured and is 50% or less.

(3) When chronic congestive heart failure is present or there has been more than one episode of congestive heart failure within the past year.

(4) When a 100% evaluation can be assigned on another basis.

(c) If left ventricular ejection fraction (LVEF) testing is not of record, evaluate based on the alternative criteria unless the examiner states that the LVEF test is needed in a particular case because the available medical information does not sufficiently reflect the severity of the veteran's cardiovascular disability.

4. Section 4.104, diagnostic code 7101 is amended by adding a Note 3 to read as follows:

§ 4.104 Schedule of ratings—cardiovascular system.

DISEASES OF THE HEART

	Rating
* * * * *	
7101 Hypertensive vascular disease (hypertension and isolated systolic hypertension):	
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Note (3): Evaluate hypertension separately from hypertensive heart disease and other types of heart disease.

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[FR Doc. 02–21366 Filed 8–21–02; 8:45 am]

BILLING CODE 8320–01–P

POSTAL SERVICE

39 CFR Part 111

Simplified Address Format for Letter-Size and Flat-Size Standard Mail and Periodicals

AGENCY: Postal Service.

ACTION: Proposed rule.

SUMMARY: This proposal would amend some of the standards and identification procedures for Standard Mail and Periodicals letter-size and flat-size mail using the simplified address format as provided in *Domestic Mail Manual* (DMM) A040.4.0. This proposal would improve the processing and distribution of such mail and would also clarify and expand the standards for identifying this mail that does not bear a specific delivery address.

DATES: Comments must be received on or before September 23, 2002.

ADDRESSES: Mail or deliver written comments to the manager, Mail Preparation and Standards, Postal Service Headquarters, 1735 N Lynn Street, Suite 3025, Arlington, Virginia 22209–6038. Copies of all written comments will be available for inspection and photocopying between 9 a.m. and 4 p.m., Monday through Friday, at Postal Service Headquarters Library, 475 L'Enfant Plaza SW., 11th Floor North, Washington, DC. Comments may also be submitted via fax to 703–292–4058, ATTN: O.B. Akinwole.

FOR FURTHER INFORMATION CONTACT: OB Akinwole at (703) 292–3643.

SUPPLEMENTARY INFORMATION: Some mailers elect to use the simplified form of address for their mass mailings. Simplified address is an alternate-addressing format that allows mailers to prepare mailpieces without using individual names and addresses within very specific requirements. Instead of using individual addresses, the mailpieces are simply addressed as ''Postal Customer'' (or a similar designation as permitted). Eligibility to use the simplified address format is determined by the type of route selected for distribution, and in some instances by the type of mailer, as follows:

- Rural Routes, Highway Contract Routes, and Post Office Boxes. Any mailer may use simplified address format for the distribution of mail to rural routes, highway contract routes, and Post Office boxes at offices without city carrier service. Distribution of such mail is made to each boxholder on a rural route or highway contract route, each family on a rural route or highway contract route (at any Post Office), or all Post Office boxholders at a Post Office without city carrier service.
- City Routes and Post Office Boxes. Only certain authorized governmental entities may use the simplified address format for the distribution of mail to city routes or to Post Office boxes at Post Offices with city carrier service. Authorized governmental entities include U.S. Congress and Federal Government agencies or state, county, or municipal governments, and the governments of the District of Columbia, the Commonwealth of Puerto Rico, and any U.S. territory or possession listed in *Domestic Mail Manual* (DMM) G010.