Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900-AQ67

Schedule for Rating Disabilities: The Cardiovascular System

AGENCY: Department of Veterans Affairs. **ACTION:** Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend the section of the VA Schedule for Rating Disabilities (VASRD or Rating Schedule) that addresses the cardiovascular system. The proposed changes incorporate medical advances that have occurred since the last review, update medical terminology, and clarify evaluation criteria where necessary.

Where changes to the scientific and/or medical nature of a given condition have been proposed, VA has cited the published, publicly-available sources for these changes. The proposed changes are not a reflection of any particular expert's comments or recommendations, but were based on published, peer-reviewed materials. Materials from the public forum, held in 2011, are available for public inspection at the Office of Regulation Policy and Management (see the ADDRESSES section of this rulemaking), and other deliberative materials are cited herein.

DATES: VA must receive comments on or before September 30, 2019.

ADDRESSES: Submit written comments through www.Regulations.gov; by mail or hand-delivery to the Director, Office of Regulations Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Ave. NW, Room 1064, Washington, DC 20420; or by fax to (202) 273–9026. Comments should indicate that they are submitted in response to RIN 2900–AQ67—Schedule for Rating Disabilities: The Cardiovascular System. Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management,

Room 1068, between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 461–4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, please view comments online through the Federal Docket Management System (FDMS) at www.Regulations.gov.

FOR FURTHER INFORMATION CONTACT: Gary Reynolds, MD, Medical Officer, Regulations Staff (211D), Compensation Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–9700. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: As part of VA's ongoing revision of the VA Schedule for Rating Disabilities (VASRD or Rating Schedule), VA proposes changes to 38 Code of Federal Regulations (CFR) §§ 4.100 and 4.104, which pertain to the cardiovascular system. The proposed changes will: (1) Update the medical terminology of certain conditions; (2) add medical conditions not currently in the Rating Schedule; (3) refine evaluation criteria based on medical advances that have occurred since the last revision; and (4) incorporate current understanding of functional changes associated with, or resulting from, cardiovascular disease or injury (pathophysiology).

I. § 4.100 Application of the Evaluation Criteria for Diagnostic Codes 7000–7007, 7011, and 7015–7020

In almost all cases, the current § 4.100 specifically requires testing for metabolic equivalent of tasks when evaluating heart diseases. Medical literature more commonly refers to metabolic equivalent of tasks as simply metabolic equivalents, or METs. Exceptions to METs testing for rating purposes occur when medically contraindicated, when the left ejection fraction is 50 percent or less, with chronic congestive heart failure, when more than one episode of heart failure occurred in the past year, or when VA may assign a 100 percent evaluation on another basis. 38 CFR 4.100(b). As explained below, this proposed rule will eliminate considering ejection fractions or congestive heart failure when evaluating cardiovascular disability. Therefore, for clarity and simplicity, VA proposes to delete paragraphs (b)(2),

(b)(3), and (c), and redesignate paragraphs (b)(4) as (b)(2) of this section.

II. General Rating Formula for Diseases of the Heart

VA proposes to revise § 4.104 to include a new General Rating Formula for Diseases of the Heart (General Formula). VA will use this new General Formula to clarify and standardize the evaluation of many cardiovascular diseases. As discussed below, it will provide a more timely, efficient, and accurate method of evaluating these diseases.

The proposed General Formula reflects current concepts in cardiovascular disability. The Institute of Medicine (now called the National Academy of Medicine) stated, "It is important for the Rating Schedule to be as up-to-date as possible in current medical approaches and terminology to serve veterans with disabilities most effectively. This ensures that the criteria in the Rating Schedule are based on concepts and terms used by medical personnel who provide medical evidence, and that evolving understanding of, or recognition of, new disabling conditions are reflected." Institute of Medicine, Committee on Medical Evaluation of Veterans for Disability Compensation, "A 21st Century System for Evaluating Veterans for Disability Benefits," 5 (Michael McGeary et al. eds. 2007).

As in the current Rating Schedule, the proposed General Formula is based primarily on Metabolic equivalents (METs), which objectively and accurately measure the cardiac work capacity and which clinicians routinely obtain for all patients with heart disease. The examiner eliminates spurious results by considering various parameters, such as age and expected maximal heart rate achieved when factors other than heart disease are present. In situations where a person is unable to walk, or walk well, the patient may test on a bicycle or with the use of certain medications.

VA notes that a number of diagnostic codes (DCs) within current § 4.104, including DCs 7000–7007, 7011, 7015–7017, and 7019–7020, already utilize METs in evaluating their respective cardiovascular conditions. Specifically, each level of evaluation (10, 30, 60, and 100 percent) outlines a range of METs, as well as a list of associated symptoms,

within which an individual must fall to warrant that particular evaluation. Additionally, VA may assign higher ratings (e.g., 60 and 100 percent) for congestive heart failure or left ventricular dysfunction as demonstrated by ejection fraction. Finally, VA may also assign a 30 percent evaluation with evidence on electrocardiogram, echocardiogram, or X-ray of cardiac hypertrophy or dilatation. Lastly, VA may assign a 10 percent evaluation if the condition requires continuous medication.

VA proposes to rely on METs as the primary indicator of cardiac ability and eliminate other indicators currently found in the VASRD, such as ejection fractions or the number of any episodes of acute congestive heart failure in the past year. These latter indicators are less reliable in assessing cardiac function. Congestive heart failure may be due to poor conditioning, salt consumption, poor medication compliance, body weight, additional disease burden, or a variety of other factors not associated with the underlying cardiovascular disease itself. See Joshi, Mohanan et al., "Factors precipitating Congestive Heart Failure—role of patient noncompliance," 47 J. Assoc. Physicians India 294-95 (Mar. 1999) (emphasizing "the importance of patient noncompliance with prescribed therapy as a leading precipitating factor for congestive heart failure . . . which can be prevented by appropriate cost saving strategies aimed to improve patient compliance.") Similarly, ejection fractions are unreliable because factors unrelated to cardiovascular disability, such as fluid intake, salt ingestion, and exercise, may influence them. See Ramachandran S. Vasan, MD, et al., "Congestive heart failure in subjects with normal versus reduced left ventricular ejection fraction," 33(7) 1948-55 (1999). Conversely, METs form the most reliable basis of cardiac capability, even after heart disease weakens the ability of the heart to function at full capacity. See Charles K. Morris, MD, et al., "Nomogram based on metabolic equivalents and age for assessing aerobic exercise capacity in men," 22(1) J. Am. College of Cardiology, 175–82 (1993).

The heart is often described as the pump of the human body, and, as such, requires power to function. Power is the rate that energy is consumed to work. Various types of energy employ different measures of rate (power), such as kW (kilowatts) for electrical energy; Btu/hr (British Thermal Units per hour) for heat energy; hp (horsepower) for mechanical energy; and, for our

purposes, METs (metabolic equivalent of tasks) for cardiac energy.

In evaluating cardiovascular disabilities, METs refer to the intensity of activities. For example, an activity with a MET of 2, such as walking at a slow pace (e.g., 2 mph), would require twice the energy that an average person consumes at rest (e.g., sitting quietly), which requires 1 MET. See "The Compendium of Physical Activities," Arnold School of Public Health-Prevention Research Center, available at http://prevention.sph.sc.edu/tools/ compendium.htm. VA does not propose any alteration to the ranges of METs provided in the current VASRD, nor will it eliminate the references to dyspnea, fatigue, angina, dizziness, or syncope. Instead, VA proposes to state that these symptoms may represent heart failure. VA also proposes to use the more common term "breathlessness" for the more obscure term "dyspnea," and to expand the list of common findings associated with congestive heart failure to include arrhythmia and palpitations. See "Congestive Heart Failure," Johns Hopkins Medicine, available at http:// www.hopkinsmedicine.org/heart vascular institute/conditions treatments/conditions/congestive heart failure.html (last visited Apr. 30, 2014). Although VA proposes to eliminate the use of congestive heart failure and ejection fraction as indicators for evaluation, it will retain the non-MET criteria provided in the current 10 and 30 percent evaluations because these criteria remain valid. Id.

VA proposes to apply the General Formula to those DCs within § 4.104 that instruct rating personnel to consider METs (among other indicators). The DCs using METS as the primary rating criteria include 7003, 7004, 7005, 7007, 7015, and 7020. On the other hand, DCs 7000, 7001, 7002, 7006, 7011, 7016, 7017, and 7019 have 100 percent evaluation criteria unique to each particular DC. VA does not intend to disturb the 100 percent evaluations currently prescribed in these DCs; rather, it proposes to apply the General Formula following the total evaluations. To ensure clarity and consistency in applying the General Formula, VA intends to instruct personnel to rate disabilities under § 4.104 using the General Formula unless otherwise directed.

With respect to DCs 7010, 7011, 7015, and newly proposed DC 7009, regardless of the DC, the resulting impairment and disability are essentially indistinguishable. To offer more than one evaluation under those circumstances would be contrary to

§ 4.14 (pyramiding). VA will provide an instruction immediately before DC 7009 which states "For DCs 7009, 7010, 7011, and 7015, a single evaluation will be assigned under the diagnostic code which reflects the predominant disability picture."

The discussion that follows explains the changes to each DC affected by the General Formula, and explains additional changes to these DCs (e.g., title changes, note changes, etc.).

A. Diagnostic Code 7000

DC 7000 currently provides a 100 percent evaluation during active infection with valvular heart damage and for three months following the cessation of treatment for the active infection. VA proposes no change to this provision. Following the three months, VA will evaluate residual cardiac disability using the General Rating Formula for Diseases of the Heart.

B. Diagnostic Codes 7001 and 7002

The current DCs 7001 and 7002 (endocarditis and pericarditis, respectively) provide a 100 percent evaluation during active infection with cardiac involvement, and for three months following the cessation of treatment for the active infection. VA proposes no change to these provisions. Following the three months, VA will evaluate any residual cardiac disability using the General Rating Formula for Diseases of the Heart.

C. Diagnostic Codes 7003, 7004, 7005, 7007, and 7020

VA proposes to evaluate disability due to these conditions (pericardial adhesions, syphilitic heart disease, arteriosclerotic heart disease, hypertensive heart disease, and cardiomyopathy, respectively) using the General Rating Formula.

D. Diagnostic Code 7006

The current DC 7006 provides a 100 percent evaluation during, and for three months following, a documented myocardial infarction. VA proposes no change to this provision. Following the three months, VA proposes to evaluate residual disability under the General Rating Formula.

E. Diagnostic Code 7011

VA does not propose any change to the current DC 7011 provisions establishing a 100 percent evaluation for sustained ventricular arrhythmia or ventricular aneurysmectomy from the date of hospital admission. However, VA proposes to apply the General Rating Formula following the mandatory examination provided six months after discharge to determine residual disability rating.

Additionally, DC 7011 currently includes a note indicating VA will conduct a mandatory examination six months following discharge and therapy for a sustained arrhythmia or ventricular aneurysmectomy. The intent is to monitor the extent of disability following inpatient hospitalization for surgical intervention and therapy. VA proposes to add the phrase "discharge from inpatient hospitalization" to the note to clarify that the timing for mandatory re-examination is based upon discharge from inpatient hospitalization, rather than discharge from an outpatient treatment program. This proposed clarification does not represent a change in VA policy.

F. Diagnostic Code 7015

VA proposes to update this DC to reflect modern treatment and to more accurately evaluate impairment by separating the various forms of atrioventricular block into two specific categories: benign and non-benign *i.e.*, the latter requiring immediate treatment. "Types of Heart Block," National Heart, Lung, and Blood Institute (July 9, 2012), http://www.nhlbi.nih.gov/health/healthtopics/topics/hb/types.html (last visited April 22, 2014).

The benign, or less severe, category of atrioventricular block includes firstdegree heart block (first-degree) and second-degree heart block, type I (second-degree type I). First-degree (seen as a delayed or prolonged P-R interval on electrocardiogram), involves the slowing of the heart's electrical signals, often without any symptoms and, therefore, without requiring any treatment. Id. In second-degree type I, the electrical signals are slowed more and more with each heartbeat until the heart eventually skips a beat. An occasional, transitory, and mild symptom may be associated with second-degree type I heart block. Id. No specific therapy is required for seconddegree type I heart block. Ali A. Sovari, "Second-Degree Atrioventricular Block Treatment & Management," Medscape-Reference (May 9, 2013) http:// emedicine.medscape.com/article/ 161919-treatment (last visited April 22. 2014). VA proposes to evaluate the benign form of atrioventricular block under the General Rating Formula.

The non-benign, or more severe, category of atrioventricular block include second-degree heart block, type II (second-degree type II) and third-degree heart block (third-degree). In second-degree type II, some of the heart's electrical signals do not reach

the ventricles, which may result in symptoms of dizziness, lightheadedness, or syncope. In addition, individuals with second degree may experience chest pain, hypoperfusion, and hypotension. Ali A. Sovari, "Second-Degree Atrioventricular Block Clinical Presentation," Medscape-Reference (May 9, 2013), http:// emedicine.medscape.com/article/ 161919-clinical (last visited April 22, 2014). Second-degree type II presents a much more immediate medical risk as it may progress rapidly to complete heart block. As a result, affected individuals may receive permanent pacemakers. Third-degree heart block occurs when none of the heart's electrical signals reach the ventricles, which often requires emergency treatment because it can result in cardiac arrest or death. Like second-degree type II, this severe type of atrioventricular block requires pacemaker implantation. Based on this treatment, VA proposes to evaluate the non-benign categories of atrioventricular block (second-degree, type II and thirddegree) under DC 7018, implantable cardiac pacemakers. Given the proposed amendments to DC 7015, the note that currently follows is no longer relevant. The VA proposes to remove the note following DC 7015.

G. Diagnostic Code 7016

VA does not propose any change to the current DC 7016 provisions establishing a 100 percent evaluation for heart valve replacement (prosthesis). However, VA proposes to apply the General Rating Formula following the mandatory examination provided six months after discharge to determine residual disability rating.

Additionally, DC 7016 currently includes a note indicating VA will examine this disability six months following discharge. The intent is to monitor the extent of the disability following hospitalization for surgery. Similar to DC 7011, VA proposes to link the evaluation with discharge from inpatient hospitalization for this particular dysrhythmia. This clarification does not represent a change in VA policy.

H. Diagnostic Code 7017

DC 7017 currently provides a 100 percent evaluation for three months following hospital admission for coronary bypass surgery. VA proposes no change to this provision. Following the three months, VA proposes to evaluate any residual cardiac disability under the General Rating Formula.

I. Diagnostic Code 7019

Currently, DC 7019 provides a 100 percent evaluation from the date of hospital admission for cardiac transplantation, continuing for "an indefinite period." The current note also states, however, that one year following discharge, VA should examine the individual to determine the appropriate disability rating, assigning a minimum evaluation of 30 percent. VA applies 38 CFR 3.105(e) to any change in evaluation. VA proposes no changes to this process or the minimum evaluation of 30 percent. However, VA proposes to eliminate the phrase "for an indefinite period" and replace it with "for a minimum of one year." This will eliminate any confusion as to whether the Veteran's 100 percent evaluation may be subject to reduction during the year following transplantation. Practically, a Veteran will receive a 100 percent evaluation for at least one vear plus hospitalization time as VA will not re-evaluate the Veteran until one year following hospital discharge. In addition to this change, VA proposes to evaluate residual cardiac disability under the General Rating Formula.

Additionally, DC 7019 currently includes a note indicating VA will examine this disability one year following discharge. The note's intent is to assess the extent of residual cardiac disability following hospitalization for surgery. VA proposes to add the phrase "discharge from inpatient hospitalization" to clarify when the point at which the timing for mandatory examination begins. Discharge from an outpatient treatment program does not activate this provision. This clarification does not represent a change in VA policy.

III. Proposed Changes to Diagnostic Codes Not Rated Under the General Formula

A. Diagnostic Code 7008

The DC 7008 addresses hyperthyroid heart disease. This DC was amended with the final publication of 82 FR 50804, Schedule for Rating Disabilities; The Endocrine System, effective December 10, 2017. VA's update of the endocrine system (38 CFR 4.117) revised the evaluation criteria for hyperthyroidism under DC 7900. See RIN 2900-AO44. Specifically, VA eliminated any current rating criteria in DC 7900 that referred to cardiovascular findings. Instead, VA evaluates any hyperthyroid heart disease under DC 7008, which directs rating personnel to evaluate any cardiovascular findings according to the appropriate DC. The

VA does not propose any additional changes for DC 7008 at this time.

B. Diagnostic Code 7010

VA proposes to change the name of the current DC 7010 from supraventricular arrhythmias to the more modern and accurate supraventricular tachycardia. Arrhythmia generally refers to an irregular heartbeat and includes a heartbeat that is too fast, too slow, or irregular. "What Is an Arrhythmia?" National Heart, Lung, and Blood Institute (July 1, 2011), http:// www.nhlbi.nih.gov/health/healthtopics/topics/arr/ (last visited April 22, 2014). Supraventricular tachycardia is an irregularly fast heartbeat that originates above or within the atrioventricular node 18 or in the upper part of the heart. Id. The various forms of supraventricular tachycardia include, but are not limited to, atrial fibrillation, atrial flutter, sinus tachycardia, sinoatrial nodal reentrant tachycardia, atrioventricular nodal reentrant tachycardia, atrioventricular reentrant tachycardia, atrial tachycardia, junctional tachycardia, and multifocal atrial tachycardia. Id. VA proposes to add an explanatory Note 1 to provide a non-exhaustive list of examples of supraventricular tachycardia. VA proposes to use tachycardia, rather than arrhythmia, in the title to clarify that rating personnel should use this DC to evaluate individuals with abnormally fast heartbeats.

VA also proposes to update the evaluation criteria for supraventricular tachycardia, utilizing hospitalization as a more accurate measure of disability. The current criteria in DC 7010 assign evaluations based on the number of episodes of supraventricular arrhythmias documented by electrocardiogram (ECG or EKG) or Holter monitor, without considering the need for hospital treatment. Supraventricular tachycardia is usually non-lethal and does not result in disabling symptoms in otherwise healthy individuals. See "Paroxysmal supraventricular tachycardia" in "A.D.A.M. Medical Encyclopedia," PubMed Health, U.S. National Library of Medicine (June 18, 2012), http:// www.nlm.nih.gov/medlineplus/ency/ article/000183.htm (last visited Apr. 30, 2014). For example, some patients with supraventricular tachycardias have many short episodes throughout the day and remain asymptomatic. Id. Others may have atrial fibrillation on a permanent basis, also without symptoms. These non-disabling episodes do not require hospitalization or treatment, but may be recorded

incidentally by an ECG or Holter monitor without any other findings. Id. Therefore, the mere presence of episodes of supraventricular tachycardia, as well as their number, is unrelated to symptomatology or disability.

However, some episodes of supraventricular tachycardia result in hypotension, shortness of breath, dizziness, or chest pain in patients who are older or have underlying cardiac disorders. Id. These symptomatic episodes typically require a controlled medical setting to monitor and treat heart rate control, anticoagulation, cardioversion, electrophysiological studies, or catheter-based arrhythmia ablation. Id. Medical intervention for supraventricular tachycardia more accurately indicates impairment, as the purpose of treatment is to eliminate or reduce any disabling symptoms. As mentioned previously, the mere documentation of supraventricular tachycardia on an ECG or Holter monitor does not confirm the existence of symptoms or impairment.

As such, VA proposes to replace the current reference to episodes documented by ECG or Holter monitor in DC 7010 with treatment interventions. For the purposes of this DC, a treatment intervention occurs whenever a symptomatic patient requires intravenous pharmacologic adjustment, cardioversion, and/or ablation for symptom relief. For clarity, VA proposes to add Note 2 to identify when a treatment occurs. VA will assign a 10 percent evaluation for supraventricular tachycardia, documented by ECG, with one to four treatment interventions per year; VA will assign a 30 percent evaluation with five or more treatment interventions per year. VA proposes the number of interventions annually because benign, non-disabling episodes may occur throughout the year. However, only episodes that require treatment interventions are most likely disabling, because they require treatment within a controlled medical setting and typically prevent an individual from working.

C. Diagnostic Code 7018

DC 7018 currently provides a 100 percent evaluation for two months following hospital admission for implantation or reimplantation of a cardiac pacemaker. Following these two months, VA evaluates the disability under DC 7010, 7011, or 7015, with a minimum evaluation of 10 percent. Advances in surgical methods and medical technology have drastically reduced the recovery time following implantation of a cardiac pacemaker.

Surgical techniques for cardiac pacemakers have changed and improved drastically over the past several years and recovery currently requires less than 30 days. According to the National Institutes of Health (NIH), hospitalization following surgical implantation of a pacemaker usually lasts one to two days. "What to Expect After Pacemaker Surgery," NIH-National Heart, Lung, and Blood Institute (February 28, 2012), http:// www.nhlbi.nih.gov/health/healthtopics/topics/pace/after.html (last visited April 14, 2014). NIH also indicates that mild pain, swelling, and tenderness at the site of pacemaker implantation may continue from a few days to a few weeks. Id. While healthcare providers may instruct patients to avoid vigorous activity, including heavy lifting, for up to one month following surgery, most patients may return to their normal activity level within a few days. Id. VA proposes to reduce the period of 100 percent evaluation from two months to one month. Additionally, VA proposes to add a second note to this DC, crossreferencing DC 7009, which will be addressed in greater detail below. VA proposes no other changes to this DC.

D. Diagnostic Code 7110

The current DC 7110 addresses impairment due to aortic aneurysm. VA proposes to change the name of the code to "Aortic aneurysm: ascending, thoracic, or abdominal" to clarify the location of aortic aneurysm that this DC will evaluate.

VA proposes to eliminate the 60 percent evaluation for an aortic aneurysm that precludes exertion while expanding the criteria for a 100 percent evaluation to include symptomatic aneurysm (e.g., precludes exertion). VA proposes to omit the 60 percent category as it is does not provide an adequate evaluation for a symptomatic aneurysm in which exertion may hasten rupture. See Emile R. Mohler III, MD, "Patient information: Abdominal aortic aneurysm (Beyond the Basics)," Up-todate (Aug. 21, 2013), http:// www.uptodate.com/contents/ abdominal-aortic-aneurysm-beyond-thebasics#H4 (last visited May 2, 2014). A symptomatic aneurysm presents a medical emergency and requires surgical treatment to prevent the aneurysm from rupturing. Id. Under the proposed criteria, VA will grant a total evaluation when a patient becomes a surgical candidate and is unable to exert him/herself.

Additionally, if a person cannot exert him/herself due to aortic aneurysm but is unable to undergo surgery due to a co-

morbid medical condition (e.g., kidney dysfunction requiring dialysis), VA will grant a total evaluation. Jeffrey Jim, MD and Robert W. Thompson, MD, "Management of symptomatic (nonruptured) and ruptured abdominal aortic aneurysm," UpToDate (Feb. 12, 2013), http://www.uptodate.com/ contents/management-of-symptomaticnon-ruptured-and-ruptured-abdominalaortic-aneurysm?source=see link&anchor=H53322839#H53322839 (last visited May 5, 2014). "Although there are rare reports of patient survival following ruptured abdominal aortic aneurysm (AAA) without repair, in general, expectant management of ruptured AAA is nearly uniformly fatal. Thus, when ruptured AAA is identified, repair should be undertaken emergently to give the patient the best chance for survival." Id. As such, expanding the 100 percent evaluation to the date a physician recommended surgical correction will include Veterans who have severely disabling aneurysms but, due to co-morbid medical conditions or other reasons, cannot undergo surgical intervention. This 100 percent evaluation will continue for six months following hospital discharge.

In addition, VA proposes to add a 0 percent rating if an aneurysm is present but does not meet the requirements for surgical correction. Asymptomatic aneurysms may expand rapidly until they require surgical correction, so they need close medical follow-up. This provision allowing service connection for aneurysms not requiring surgery eliminates barriers to frequent medical check-ups by VA to monitor the progress of those aneurysms.

VA will also add a directive for raters to evaluate non-cardiovascular residuals according to the body systems affected. This is done to take into acount any disabling residuals related to surgical correction (e.g., infection, bowel adhesions, kidney failure, and so forth).

The current DC 7110 also includes a note indicating that VA will assign the 100 percent rating as of the date of admission for surgical correction. VA will re-evaluate the condition after a mandatory examination six months following discharge. VA proposes to add the phrase "discharge from inpatient hospitalization" to clarify that the starting point to calculate the mandatory re-examination begins with discharge from inpatient hospitalization. VA also proposes to clarify in the rating criteria for a 100 percent evaluation that it shall assign the 100 percent evaluation as of the date a physician recommends surgical correction. This practice will allow VA to assign 100 percent evaluations to individuals who require

surgical correction but, due to comorbid medical conditions or other reasons, cannot undergo surgical procedures.

E. Diagnostic Code 7111

The current DC 7111 provides 100 percent evaluations for aneurysms of large arteries which are symptomatic. It also provides 100 percent evaluations for indefinite periods of time from the date of hospital admission for surgical corrections. VA proposes to amend the latter criteria to provide a 100 percent evaluation from the date a physician recommends surgical correction, rather than the date of hospital admission. Aneurysms of any large artery are known to spontaneously rupture, which, depending on its location, can lead to death if not immediately addressed by surgery.

This expansion to the 100 percent evaluation criteria requires that VA amend the note in DC 7111. Currently, VA assigns the 100 percent rating as of the date of admission for surgical correction, and VA assesses any residual disability by a mandatory examination six months following discharge. VA proposes to add the phrase "discharge from inpatient hospitalization" in the criteria note to clarify that the timing for the mandatory re-examination is based upon discharge from inpatient hospitalization. Additionally, VA proposes to clarify that it shall assign the 100 percent evaluation beginning from the date a physician recommends surgical correction, in the event individuals who require surgical correction cannot undergo it due to comorbid medical conditions or other reasons. The 100 percent evaluation shall continue for six months following hospital discharge for surgical correction.

The current DC 7111 provides rating criteria following surgical intervention that is based on the ankle-brachial index, claudication on walking certain distances, and other symptoms related to poor blood flow to the extremities. These criteria provide for evaluations ranging from 20 to 100 percent; notes (1) and (2) provide additional information when evaluating post-surgical large artery aneurysms. The residual disabilities after post-surgical repair of large artery aneurysms are similar to those under DC 7114. For greater ease of use and simplicity, VA therefore proposes to remove these criteria and notes and replace them with instructions to evaluate post-surgical residuals under DC 7114. The section of the preamble below specifically addressing DC 7114 discusses any

changes related to these criteria and notes.

F. Diagnostic Code 7113

DC 7113, arteriovenous (AV) fistula, traumatic, currently includes the phrase "with edema" as one of the disabling symptoms present at the 50, 40, 30, and 20 percent levels. However, such wording does not distinguish between chronic and transitory edema, resulting in evaluations that may be based on symptoms that are unrelated to arteriovenous fistula or do not adequately represent its chronic residual disability. Transitory edema may occur following prolonged standing, prolonged sitting during travel, the wearing of tight hosiery, taking certain medications, consuming excessive salt, or being pregnant. Transitory edema due to these causes is non-disabling and typically resolves without complication.

However, edema due to an AV fistula requires medical treatment and may impair function. Therefore, VA proposes to clarify that evaluations at the 50, 40, 30, and 20 percent levels under DC 7113 must involve "chronic edema" to better comply with 38 CFR 4.1, which states the accurate application of the VASRD requires an emphasis upon "the limitation of activity imposed by the disabling condition."

G. Diagnostic Code 7114

The current DC 7114, titled "Arteriosclerosis obliterans," addresses impairment of the lower extremities due to narrowing and hardening of the arteries. The term "arteriosclerosis" is also used in current note (2). VA proposes to replace the term "arteriosclerosis obliterans" with "peripheral arterial disease" to conform to current medical terminology. Peter Libby et al., "Braunwald's Heart Disease: A Textbook of Cardiovascular Medicine," 1491–1515 (8th ed. 2007).

The evaluation criteria of the current DC 7114 include the ankle/brachial index (ABI), associated examination findings and symptoms, or claudication (pain in the extremities) upon walking certain distances. The current criteria, however, have two major shortcomings: (1) They do not account for veterans with non-compressible arteries (these veterans have either a normal or elevated ABI, which would be noncompensable); and (2) they rely in large part on claudication, which is an inconsistent measure of disability. To that end, VA will employ a more objective approach as outlined below.

VA will create evaluation criteria based on a modified version of the ischemia scoring table found in J. Mills, "The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: Risk stratification based on Wound, Ischemia, and foot Infection (WIfI)" J Vasc Surg; vol 59, pg 226. 2014. This table uses the ABI, as well as ankle pressure (AP), toe pressure (TP) and transcutaneous oximetry (T_cPO₂) to describe four different levels of impairment. The ABI is the ratio of the systolic blood pressure measured at the ankle to that measured at the antecubital fossa. For VA disability compensation purposes, normal is greater than or equal to 0.80. The reason this normal value is used, rather than normal values cited in the 2016 ACC/ AHA Guidelines is that an ABI between 0.90 and 0.81 is not consistently associated with objective signs of disability beyond symptomatic complaints (e.g., wounds or infections). The AP is the systolic blood pressure measured at the ankle. Normal is greater than or equal to 100 mm Hg. The TP is the systolic blood pressure measured at the great toe. Normal is greater than or equal to 60 mm Hg. T_cPO₂ is measured at the first intercostal space on the foot. Normal is greater than or equal to 60 mm Hg. See also M. Kalani "Transcutaneous Oxygen Tension and Toe Blood Pressure as Predictors for Outcome of Diabetic Foot Ulcers,' Diabetes Care, vol. 22, Pgs 147–52. 1999. The levels of impairment as described in the previously referenced ischemia scoring table directly correlate to levels of disability (i.e., evaluation levels). VA will slightly modify this table to describe four levels of disability (and thus, evaluation levels) consistent with these criteria, while preserving the 20, 40, 60, and 100 percent evaluation

Turning to the three notes associated with DC 7114, VA will make two significant revisions. First, VA will revise Note (1) to add definitions and normal values for ABI, AP, TP, and T_cPO₂. Next, VA will redesignate current Note (2) as Note (3), and current Note (3) as Note (4). Finally, VA will then add a new Note (2), which directs the rater to select the value (ABI, AP, TP, or T_cPO₂) which yields the highest level of impairment for evaluation.

H. Diagnostic Code 7115

DC 7115 currently uses lower extremity findings to evaluate thromboangiitis obliterans (Buerger's Disease). VA proposes new criteria for the evaluation of upper extremity disease because Buerger's Disease can affect either upper or lower extremities. Buerger's disease is a nonatherosclerotic segmental inflammatory disease that affects the small and medium-sized

arteries, veins, and nerves of the arms, legs, and rarely elsewhere. See Topol, E.J., Textbook of Cardiovascular Medicine Chap. 108, Pg 1535. (2007). DC 7115 currently evaluates impairment of the lower extremity using the ankle/ brachial index (ABI) or associated signs and symptoms upon examination (as found in current DC 7114). For the reasons discussed above in DC 7114, VA proposes to clarify the evaluation criteria by using objective signs, with the ABI as the primary criteria for the lower extremities. VA proposes to delete claudication on walking from all evaluation criteria as it inaccurately measures the extent of this disability. VA also proposes to remove current Note (1), as DC 7115 will now direct rating personnel to evaluate lower extremities under DC 7114 and the information regarding the ABI is contained in that diagnostic code. With elimination of current Note (1), VA proposes to rename existing Note (2) as Note (1) with clarification similar to that proposed in Note (3) DC 7114 (as explained above). Additionally, a new Note (2) is proposed to give raters examples of trophic changes so it will be easier to recognize when encountered in clinical documentation.

I. Diagnostic Code 7117

Currently, DC 7117 addresses impairment due to Raynaud's syndrome, in which cold or stress abnormally reduces blood flow in the extremities. Raynaud's syndrome (also called secondary Raynaud's phenomenon) is often confused with Raynaud's disease (also called primary Raynaud's phenomenon or primary Raynaud's), which is different in terms of etiology and severity. While both conditions present with vasospasm, Raynaud's disease (primary Raynaud's phenomenon) has few, if any, long term residuals. In contrast, Raynaud's syndrome (secondary Raynaud's phenomenon) is associated with another illness, most commonly an autoimmune disease. The residuals tend to be permanent, more extensive, and more disabling. To improve clarity, ensure more accurate evaluations, and promote consistency and usability of the VASRD, VA proposes to focus DC 7117 on Ravnaud's syndrome (secondary Raynaud's phenomenon) only, while creating a new DC 7124 for Raynaud's disease (primary Raynaud's phenomenon or primary Raynaud's). In addition, VA proposes to use the existing note to emphasize that DC 7117 is only for evaluating Raynaud's syndrome (secondary Raynaud's phenomenon), and add a note emphasizing that Raynaud's disease

(primary Raynaud's phenomenon) should be rated under DC 7124.

As stated, Raynaud's syndrome (secondary Raynaud's phenomenon) and Raynaud's disease (primary Raynaud's phenomenon) are unrelated in both etiology and severity. According to the NIH's National Heart, Lung, and Blood Institute, Raynaud's syndrome (secondary Raynaud's phenomenon) is typically caused by autoimmune diseases such as scleroderma, lupus, rheumatoid arthritis, atherosclerosis, or polycythemia. "Raynaud Phenomenon." Medscape (September 6, 2017), http:// emedicine.medscape.com/article/ 331197-overview (last visited September 12, 2017).

On the other hand, the cause of Raynaud's disease (primary Raynaud's phenomenon) is not known. Id. Raynaud's disease (primary Raynaud's phenomenon) is more common and tends to be less severe than Raynaud's syndrome (secondary Raynaud's phenomenon). Ray W. Gifford, Jr. & Edgar A. Hines, Jr., "Raynaud's Disease Among Women and Girls," 16 Circulation 1012, 1019 (1957). VA discusses how to properly evaluate Raynaud's disease (primary Raynaud's phenomenon) below in the section proposing the new DC 7124. No other changes are proposed to DC 7117.

J. Diagnostic Code 7120

DC 7121 currently evaluates postphlebitic syndrome of any etiology, with its rating criteria identical to that used in DC 7120, Varicose veins. VA currently maintains separate DCs for these disabilities to monitor in the Veteran population the incidence and outcome of claims for these specific and separate diagnoses. However, for clarity, consistency, and improved ease of use, VA proposes to delete the duplicative rating criteria and instruct rating personnel to evaluate DC 7120, Varicose veins, under DC 7121, Post-phlebitic syndrome. VA does not propose any changes to the content of DC 7121 itself.

K. Diagnostic Code 7122

VA last amended the rating criteria for DC 7122, Cold injury residuals, in 1998. 63 FR 37778. In the time since, medicine has documented new chronic residuals of cold injury. Therefore, VA proposes to update the criteria to include the findings specifically noted by the Veterans Health Initiative, Department of Veterans Affairs, "Cold Injury: Diagnosis and Management of Long-Term Sequelae," revised in March 2002. https://www.publichealth.va.gov/docs/vhi/coldinjury.pdf

This study collected medical and anecdotal information on cold injury

residuals from veterans. The study indicated that the effects of cold weather injuries may be irreversible and worsen with age. Id. at 15. The residuals of cold injuries include residual pain, numbness, cold sensitivity, tissue loss, nail abnormalities, color changes, locally impaired sensation, hyperhidrosis, x-ray abnormalities, anhydrosis, muscle atrophy, muscle fibrosis, deformity in flexion and/or extension of certain joints, loss of fat pads in the fingers and toes, bone death, skin ulcers, and carpal or tarsal tunnel syndrome. Id. at 24-25. VA proposes to include these updated residuals of cold injuries within this DC, which assigns evaluations based on the number of cold injury residuals present.

IV. Proposed New Diagnostic Codes

VA proposes to add a new DC 7009,

titled "Bradycardia (Bradyarrhythmia),

A. New Diagnostic Code 7009

symptomatic, requiring permanent pacemaker implantation," to account for impairment in the Veteran population due to this condition. Individuals generally have a normal resting heart rate ranging from 60 to 100 beats per minute. Individuals with bradycardia, however, have a resting heart rate of less than 60 beats per minute. "Bradycardia," Harvard Health Topic at Drugs.com, http://www.drugs.com/ health-guide/bradycardia.html (last visited May 5, 2014). Notably, asymptomatic bradycardia occurs normally in individuals when sleeping and in many healthy, athletic adults. Id. See also "Bradycardia (Slow Heart Rate)—Topic Overview," WebMD (Nov. 21, 2011), http://www.webmd.com/ heart-disease/tc/bradvcardia-slowheart-rate-overview (last visited May 5, 2014). It should be noted that asymptomatic bradycardia is a medical finding, does not require medical intervention, and is not subject to service-connected compensation.

Symptomatic bradycardia can be caused by changes due to aging, certain medications, diseases, and infections, all of which can damage the heart and slow its electrical impulses. See Amy Scholten, MPH, "Bradycardia (Bradyarrhythmia)," NYU Langone Cardiac and Vascular Institute, 2–3 (Feb. 2008). When medical management for symptomatic bradycardia is not effective, a pacemaker implant is the treatment of choice. Id. at 3. Implantation of a pacemaker aids in normalizing the heart rate and returning the individual to baseline cardiac function. VA proposes to evaluate this condition at 100 percent for one month following hospitalization for

implantation or re-implantation. Following the initial month, the disability will be evaluated using the General Rating Formula. To assist rating personnel in understanding and evaluating bradycardia, VA also proposes to include a note under DC 7009 which defines bradycardia and describes the five general classes of bradyarrhythmias.

B. New Diagnostic Code 7124

VA proposes to add a new DC 7124, titled "Raynaud's disease (also known as primary Raynaud's phenomenon or primary Raynaud's):." The VASRD currently evaluates Raynaud's disease using the criteria under DC 7117, which is for "Raynaud's syndrome," a different and more severe disability. Therefore, VA proposes a new DC to specifically evaluate Raynaud's disease. This DC will also include notes to define characteristic attacks as well as to emphasize rating Raynaud's syndrome (Raynaud's phenomenon, Secondary Raynaud's) under DC 7117.

As stated previously, Raynaud's disease is more common and tends to be less severe than Raynaud's syndrome. The Mayo Clinic performed a study involving 474 women and girls with Raynaud's disease. Follow-up information obtained from 307 of those who received conservative treatment confirmed the benign nature of the disease, with no deaths attributed to it and extremely little disability. The study found that uncomplicated Raynaud's disease may be inconvenient because of the need to protect the extremities from cold and trauma, but it is not disabling.

Raynaud's disease, the less severe form of Raynaud's, rarely involves trophic changes because it involves brief spasms of the arteries rather than occlusion of the peripheral arteries. See "What is Raynaud's?" National Heart, Lung, and Blood Institute (Mar. 21, 2014), https://www.nhlbi.nih.gov/ health/health-topics/topics/raynaud/ (last visited May 5, 2014). Furthermore, when trophic changes are present, they are limited to the distal skin of the digits. "Raynaud's disease," Mayo Clinic (Oct. 20, 2011), http:// www.mavoclinic.org/diseasesconditions/raynauds-disease/basics/ complications/con-20022916 (last visited May 5, 2014). Therefore, VA proposes a non-compensable evaluation when Raynaud's disease manifests without lasting impairment in the form of trophic changes. VA proposes a 10 percent evaluation with residual trophic changes (e.g., skin changes such as thinning, atrophy fissuring, ulceration, scarring, absence of hair; nail changes

(clubbing, deformities).) VA proposes the addition of a note to provide examples of trophic changes for clarification purposes, consistent with other proposed changes.

VA also proposes to include a note to clarify and assist assigning evaluations under this DC by defining a characteristic attack of Raynaud's disease. As with DC 7117, this note will also indicate that evaluations under this code are for the disease as a whole. To further promote clarity and consistency, another proposed note would emphasize that the purpose of DC 7124 is to evaluate only Raynaud's disease, as opposed to Raynaud's syndrome. A veteran cannot receive simultaneous ratings under both DC 7117 and DC 7124, because Raynaud's disease and Ravnaud's syndrome cannot be comorbid conditions.

Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this proposed rulemaking, would represent VA's implementation of its legal authority on this subject. Other than future amendments to these regulations or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this proposed rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits. reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a "significant regulatory action," which requires review by the Office of Management and Budget (OMB), as "any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious

inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order."

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined and it has been determined to be a significant regulatory action under Executive Order 12866, because it raises novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. VA's impact analysis can be found as a supporting document at http:// www.regulations.gov, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's website at http:// www.va.gov/orpm by following the link for VA Regulations Published from FY 2004 through Fiscal Year to Date. This proposed rule is not expected to be subject to the requirements of EO13771 because this proposed rule is expected to result in no more than de minimis

Paperwork Reduction Act

This regulatory action contains provisions constituting a collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

The information collection requirements for 38 CFR 3.151 are associated with this rule, but do not constitute a new or revised collection of information; OMB has already approved these requirements under control number 2900–0747.

Regulatory Flexibility Act

The Secretary hereby certifies that the adoption of this rule would 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. This rule would not directly affect any small entities; only individuals could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any 1 year. This rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program numbers and titles for this rule are 64.104, Pension for Non-Service-Connected Disability for Veterans; 64.109, Veterans Compensation for Service-Connected Disability; and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

List of Subjects in 38 CFR Part 4

Disability benefits, Pensions, Veterans.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to submit it to the Office of the Federal Register for electronic publication as an official document of the Department of Veterans Affairs. Robert L. Wilkie, Secretary, Department of Veterans Affairs, approved this document on April 10, 2019, for publication.

Dated: July 23, 2019.

Jeffrey M. Martin,

Assistant Director, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons set out in the preamble, VA proposes to amend 38 CFR part 4 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. Revise § 4.100 paragraph (b) to read as follows:

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

* * * * * *

- (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 a 100% evaluation can be assigned on another basis.

(Authority: 38 U.S.C. 1155)

- 3. Amend § 4.104 by:
- a. Adding the General Rating Formula for Diseases of the Heart
- b. Adding the instruction to DCs 7000, 7001, 7002, 7006, 7017 to evaluate disability using the General Rating Formula to evaluate residual disability after three months
- c. Adding the instruction to DCs 7003, 7004, 7005, 7007, and 7020 to evaluate disability using the General Rating Formula
- d. Adding the instruction to DCs 7011, 7016 to evaluate disability using the General Rating Formula by mandatory examination six months after discharge
- e. Revising the evaluation criteria for DC 7015
- f. Revising the evaluation criteria for DC 7019
- g. Retitling and revise the evaluation criteria for DC 7010
- h. Revising the evaluation criteria for DC 7018
- i. Retitling and revise the evaluation criteria for DC 7110
- $lue{}$ j. Revising the evaluation criteria for DC 7111
- k. Revising DC 7113 to add explanatory information
- l. Revising the evaluation criteria for DC 7114
- m. Revising the evaluation criteria for DC 7115
- n. Revising the evaluation criteria for DC 7117
- o. Revising the evaluation criteria for DC 7120
- p. Revising the evaluation criteria for DC 7122
- q. Adding new DC 7009
- r. Adding new DC 7124.

The revisions and additions read as follows:

§ 4.104 Schedule of ratings—cardiovascular system.

Rating Diseases of the Heart Unless otherwise directed, use this general rating formula to evaluate diseases of the heart. Note (1): Evaluate cor pulmonale, which is a form of secondary heart disease, as part of the pulmonary condition that causes it. Note (2): One MET (metabolic equivalent) is the energy cost of standing quietly at rest and represents an oxygen uptake of 3.5 milliliters per kilogram of body weight per minute. When the level of METs at which breathlessness, fatigue, angina, dizziness, or syncope develops is required for evaluation, and a laboratory determination of METs by exercise testing cannot be done for medical reasons, a medical examiner may estimate the level of activity (expressed in METs and supported by specific examples, such as slow stair climbing or shoveling snow) that results in those symptoms. Note (3): For this general formula, heart failure symptoms include, but are not limited to, breathlessness, fatigue, angina, dizziness, arrhythmia, palpitations, or syncope. General Rating Formula for Diseases of the Heart: Workload of 3.0 METs or less results in heart failure symptoms 100 Workload of 3.1–5.0 METs results in heart failure symptoms 60 Workload of 5.1-7.0 METs results in heart failure symptoms; or evidence of cardiac hypertrophy or dilatation confirmed by echocardiogram or equivalent (e.g., multigated acquisition scan or magnetic resonance imaging) 30 Workload of 7.1-10.0 METs results in heart failure symptoms; or continuous medication required for control 10 7000 Valvular heart disease (including rheumatic heart disease), 7001 Endocarditis, or 7002 Pericarditis: During active infection with cardiac involvement and for three months following cessation of therapy for the active infection 100 Thereafter, with diagnosis confirmed by findings on physical examination and either echocardiogram, Doppler echocardiogram, or cardiac catheterization, use the General Rating Formula. 7003 Pericardial adhesions. 7004 Syphilitic heart disease: Note: Evaluate syphilitic aortic aneurysms under DC 7110 (Aortic aneurysm: Ascending, thoracic, abdominal). 7005 Arteriosclerotic heart disease (coronary artery disease). Note: If non-service-connected arteriosclerotic heart disease is superimposed on service-connected valvular or other nonarteriosclerotic heart disease, request a medical opinion as to which condition is causing the current signs and symptoms. 7006 Myocardial infarction: During and for three months following myocardial infarction, confirmed by laboratory tests 100 Thereafter, use the General Rating Formula. 7007 Hypertensive heart disease. 7008 Hyperthyroid heart disease: Rate under the appropriate cardiovascular diagnostic code, depending on particular findings. For DCs 7009, 7010, 7011, and 7015, a single evaluation will be assigned under the diagnostic code which reflects the predominant disability picture. 7009 Bradycardia (Bradyarrhythmia), symptomatic, requiring permanent pacemaker implantation: For one month following hospital discharge for implantation or re-implantation 100 Thereafter, use the General Rating Formula. Note (1): Bradycardia (bradyarrhythmia) refers to conduction abnormalities that produce a heart rate less than 60 beats/ min. There are five general classes of bradyarrhythmias: Sinus bradycardia, including sinoatrial block; —Atrioventricular (AV) junctional (nodal) escape rhythm; -AV heart block (second or third degree) or AV dissociation; -Atrial fibrillation or flutter with a slow ventricular response; and -Idioventricular escape rhythm. Note (2): Asymptomatic bradycardia (bradyarrhythmia) is a medical finding which does not require medical intervention, thus, it is not entitled to service connection. 7010 Supraventricular tachycardia: Confirmed by ECG, with five or more treatment interventions per year 30 Confirmed by ECG, with one to four treatment interventions per year 10 Note (1): Examples of supraventricular tachycardia include, but are not limited to, atrial fibrillation, atrial flutter, sinus tachycardia, sinoatrial nodal reentrant tachycardia, atrioventricular nodal reentrant tachycardia, atrioventricular reentrant tachycardia, atrial tachycardia, junctional tachycardia, and multifocal atrial tachycardia. Note (2): For the purposes of this diagnostic code, a treatment intervention occurs whenever a symptomatic patient requires intravenous pharmacologic adjustment, cardioversion, and/or ablation for symptom relief. 7011 Ventricular arrhythmias (sustained): For an indefinite period from the date of hospital admission for initial medical therapy for a sustained ventricular arrhythmia; or for an indefinite period from the date of hospital admission for ventricular aneurysmectomy; or with an automatic implantable cardioverter-defibrillator (AICD) in place 100 Thereafter, use the General Rating Formula. Note: Six months following discharge from inpatient hospitalization for sustained ventricular arrhythmia or for ventricular aneurysmectomy, disability evaluation shall be conducted by mandatory VA examination using the General Rating Formula. Apply the provisions of § 3.105(e) of this chapter to any change in evaluation based upon that or any subsequent examination. 7015 Atrioventricular block: Benign (First-Degree and Second-Degree, Type I): Evaluate under the General Rating Formula. Non-Benign (Second-Degree, Type II and Third-Degree): Evaluate under DC 7018 (implantable cardiac pacemakers). 7016 Heart valve replacement (prosthesis): For an indefinite period following date of hospital admission for valve replacement 100 Thereafter, use the General Rating Formula.

	Rating
Note: Six months following discharge from inpatient hospitalization, disability evaluation shall be conducted by mandatory VA examination using the General Rating Formula. Apply the provisions of §3.105(e) of this chapter to any change in evaluation based upon that or any subsequent examination.	
7017 Coronary bypass surgery:. For three months following hospital admission for surgery	100
7018 Implantable cardiac pacemakers: For one month following hospital discharge for implantation or re-implantation	100
Thereafter: Evaluate as supraventricular tachycardia (DC 7010), ventricular arrhythmias (DC 7011), or atrioventricular block (DC 7015).	
Minimum	10
For a minimum of one year from the date of hospital admission for cardiac transplantation	100
Evaluate under the General Rating Formula. Minimum	30
Note: One year following discharge from inpatient hospitalization, determine the appropriate disability rating by mandatory VA examination. Apply the provisions of §3.105(e) of this chapter to any change in evaluation based upon that or any subsequent examination. 7020 Cardiomyopathy.	
Diseases of the Arteries and Veins	
7110 Aortic aneurysm: Ascending, thoracic, or abdominal: If 5 centimeters (cm) or larger in diameter; or, if symptomatic (e.g., precludes exertion) and a physician recommends surgical correction, for the period beginning on the date a physician recommends surgical correction and continuing for six months following hospital discharge for surgical correction (including any type of graft insertion) If less than 5 cm in diameter; or, surgical correction not recommended	100 0
Note: Six months following discharge from inpatient hospitalization for surgery, disability evaluation shall be determined by mandatory VA examination of cardiovascular residuals using the General Rating Formula for Diseases of the Heart. Any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of §3.105(e) of this chapter. 7111 Aneurysm, any large artery: If symptomatic; or, for the period beginning on the date a physician recommends surgical correction and continuing for six	
months following discharge from inpatient hospital admission for surgical correction	100
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7113 Arteriovenous fistula, traumatic: With high-output heart failure	100 60
Lower extremity	50 40
Without cardiac involvement but with chronic edema or stasis dermatitis: Lower extremity	30
Upper extremity	20
sure less than 30 mm Hg; or transcutaneous oxygen tension less than 30 mm Hg	100
mm Hg; or transcutaneous oxygen tension of 30–39 mm Hg	60 40
At least one of the following: Ankle/brachial index of 0.67–0.79; ankle pressure of 84–99 mm Hg; toe pressure of 50–59 mm Hg; or transcutaneous oxygen tension of 50–59 mm Hg	20
Note (1): The ankle/brachial index (ABI) is the ratio of the systolic blood pressure at the ankle divided by the simultaneous brachial artery systolic blood pressure. For the purposes of this diagnostic code, normal ABI will be greater than or equal to 0.80. The ankle pressure (AP) is the systolic blood pressure measured at the ankle. Normal AP is greater than or equal to 100 mm Hg. The toe pressure (TP) is the systolic blood pressure measured at the great toe. Normal TP is greater than or equal to 60 mm Hg. Transcutaneous oxygen tension (T _c PO ₂) is measured at the first intercostal space on the foot. Normal T _c PO ₂ is greater than or equal to 60 mm Hg. All measurements must be determined by objective testing.	
Note (2): Select the highest impairment value of ABI, AP, TP, or T _c PO ₂ for evaluation. Note (3): Evaluate residuals of aortic and large arterial bypass surgery or arterial graft as peripheral arterial disease. Note (4): These evaluations involve a single extremity. If more than one extremity is affected, evaluate each extremity separately and combine (under § 4.25), using the bilateral factor (§ 4.26), if applicable. 7115 Thrombo-angiitis obliterans (Buerger's Disease):	

	Rating					
Lower extremity: Rate under DC 7114.						
Upper extremity: Deep ischemic ulcers and necrosis of the fingers with persistent coldness of the extremity, trophic changes with pains						
in the hand during physical activity, and diminished upper extremity pulses						
Persistent coldness of the extremity, trophic changes with pains in the hands during physical activity, and diminished						
upper extremity pulses Trophic changes with numbness and paresthesia at the tips of the fingers, and diminished upper extremity pulses	6 4					
Diminished upper extremity pulses	2					
Note (1): These evaluations involve a single extremity. If more than one extremity is affected, evaluate each extremity sep-						
arately and combine (under § 4.25), using the bilateral factor (§ 4.26), if applicable.						
Note (2): Trophic changes include, but are not limited to, skin changes (thinning, atrophy, fissuring, ulceration, scarring, absence of hair) as well as nail changes (clubbing, deformities).						
117 Raynaud's syndrome (also known as secondary Raynaud's phenomenon or secondary Raynaud's).						
With two or more digital ulcers plus auto-amputation of one or more digits and history of characteristic attacks	10					
With two or more digital ulcers and history of characteristic attacks	6					
Characteristic attacks occurring at least daily	4					
Characteristic attacks occurring one to three times a week	1					
Note (1): For purposes of this section, characteristic attacks consist of sequential color changes of the digits of one or more extremities lasting minutes to hours, sometimes with pain and paresthesias, and precipitated by exposure to cold or by						
emotional upsets. These evaluations are for Raynaud's syndrome as a whole, regardless of the number of extremities involved or whether the nose and ears are involved.						
Note (2): This section is for evaluating Raynaud's syndrome (secondary Raynaud's phenomenon or secondary Raynaud's). For evaluation of Raynaud's disease (primary Raynaud's phenomenon, or primary Raynaud's), see DC 7124.						
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120 Varicose veins: Evaluate under diagnostic code 7121.						
* * * * * * * * * * * * * * * * * * *	*					
With the following in affected parts: Arthralgia or other pain, numbness, or cold sensitivity plus two or more of the following: Tissue loss, nail abnormalities, color changes, locally impaired sensation, hyperhidrosis, anhydrosis, X-ray abnormalities (osteoporosis, subarticular punched-out lesions, or osteoarthritis), atrophy or fibrosis of the affected musculature, flexion or extension deformity of distal joints, volar fat pad loss in fingers or toes, avascular necrosis of bone, chronic ulceration, carpal or tarsal tunnel syndrome Arthralgia or other pain, numbness, or cold sensitivity plus one of the following: Tissue loss, nail abnormalities, color changes, locally impaired sensation, hyperhidrosis, anhydrosis, X-ray abnormalities (osteoporosis, subarticular punched-out lesions, or osteoarthritis), atrophy or fibrosis of the affected musculature, flexion or extension deformity of distal joints, volar fat pad loss in fingers or toes, avascular necrosis of bone, chronic ulceration, carpal or tarsal tunnel syndrome Arthralgia or other pain, numbness, or cold sensitivity	2					
Note (1): Separately evaluate amputations of fingers or toes, and complications such as squamous cell carcinoma at the site of a cold injury scar or peripheral neuropathy, under other diagnostic codes. Separately evaluate other disabilities diagnosed as the residual effects of cold injury, such as Raynaud's syndrome (which is otherwise known as secondary Raynaud's phenomenon), muscle atrophy, etc., unless they are used to support an evaluation under diagnostic code 7122. Note (2): Evaluate each affected part (e.g., hand, foot, ear, nose) separately and combine the ratings in accordance with						
§§ 4.25 and 4.26.	*					
124 Raynaud's disease (also known as primary Raynaud's phenomenon or primary Raynaud's):.						
Characteristic attacks associated with trophic change(s), such as tight, shiny skin	1					
Note (1): For purposes of this section, characteristic attacks consist of intermittent and episodic color changes of the digits of one or more extremities, lasting minutes or longer, with occasional pain and paresthesias, and precipitated by exposure to cold or by emotional upsets. These evaluations are for the disease as a whole, regardless of the number of ex-						
tremities involved or whether the nose and ears are involved. Note (2): Trophic changes include, but are not limited to, skin changes (thinning, atrophy, fissuring, ulceration, scarring, absence of hair) as well as nail changes (clubbing, deformities).						
Note (3): This section is for evaluating Raynaud's disease (primary Raynaud's phenomenon or primary Raynaud's). For evaluation of Raynaud's syndrome (also known as secondary Raynaud's phenomenon, or secondary Raynaud's), see DC 7117.						

(Authority: 38 U.S.C. 1155)

- 4. Amend Appendix A to Part 4 by:
- a. Adding an entry for the General Rating Formula for Diseases of the Heart to 4.104;
- b. Revising the entries for diagnostic codes 7000 through 7008;
- c. Adding, in numerical order, an entry for diagnostic code 7009;
- d. Revising the entries for diagnostic codes 7010, 7011, 7015 through 7020,

7110 through 7111, 7113 through 7115, 7117, and 7121 through 7122; and

■ e. Adding, in numerical order, an entry for diagnostic code 7124.

The revisions and additions read as follows:

APPENDIX A TO PART 4—TABLE OF AMENDMENTS AND EFFECTIVE DATES SINCE 1946 Diagnostic Sec. code No. General Rating Formula for Diseases of the Heart [Effective date of final rule]. 4.104 7000 Evaluation July 6, 1950; evaluation September 22, 1928, evaluation January 12, 1998; criterion [Effective date of final rule]. 7001 Evaluation January 12, 1998; criterion [Effective date of final rule]. 7002 Evaluation January 12, 1998; criterion [Effective date of final rule]. Evaluation January 12, 1998; criterion [Effective date of final rule]. 7003 Criterion September 22, 1978; evaluation January 12, 1998; criterion [Effective date of final rule]. 7004 7005 Evaluation September 9, 1975; evaluation September 22, 1978; evaluation January 12, 1998; criterion [Effective date of final rule]. 7006 Evaluation January 12, 1998; criterion [Effective date of final rule] Evaluation September 22, 1978; evaluation January 12, 1998; criterion [Effective date of final rule]. 7007 7008 Evaluation January 12, 1998; evaluation [Effective date of final rule]. 7009 Added [Effective date of final rule]. Evaluation January 12, 1998; title, criterion [Effective date of final rule]. 7010 Evaluation January 12, 1998; note, criterion [Effective date of final rule]. Evaluation September 9, 1975; criterion January 12, 1998; criterion [Effective date of final rule]. 7015 7016 Added September 9, 1975; criterion January 12, 1998; note, criterion [Effective date of final rule]. Added September 22, 1978; evaluation January 12, 1998; criterion [Effective date of final rule]. Added January 12, 1998; criterion [Effective date of final rule]. 7018 7019 Added January 12, 1998; note, criterion [Effective date of final rule]. 7020 Added January 12, 1998; criterion [Effective date of final rule]. Evaluation September 9, 1975; evaluation January 12, 1998; title, criterion, note [Effective date of final rule]. 7110 Criterion September 9, 1975; evaluation January 12, 1998; note, criterion [Effective date of final rule]. Evaluation January 12, 1998; criterion [Effective date of final rule]. 7113 Added June 9, 1952; evaluation January 12, 1998; title, criterion, note [Effective date of final rule]. Added June 9, 1952; evaluation January 12, 1998; note, criterion, evaluation [Effective date of final rule]. 7117 Added June 9, 1952; evaluation January 12, 1998; title, note [Effective date of final rule]. 7121 Criterion July 6, 1950; evaluation March 10, 1976; evaluation January 12, 1998; criterion [Effective date of Last sentence of Note following July 6, 1950; evaluation January 12, 1998; criterion August 13, 1998; criterion 7122 [Effective date of final rule]. 7124 Added [Effective date of final rule]. ■ 5. Amend Appendix B to Part 4, ■ b. Revising diagnostic codes 7010, The revisions and additions read as § 4.104 by: 7110, 7114, and 7117; and follows: a. Adding, in numerical order, an ■ c. Adding, in numerical order, an entry for diagnostic code 7009; entry for diagnostic code 7124. APPENDIX B TO PART 4—NUMERICAL INDEX OF DISABILITIES Diagnostic code No. The Cardiovascular System—Diseases of the Heart

7009 Bradycardia (Bradyarrhythmia), symptomatic, requiring permanent pacemaker implantation.

APPENDIX B TO PART 4—NUMERICAL INDEX OF DISABILITIES—Continued

Diagnostic code No.								
*	*	*	*	*	*	*		
7010	Supraventricular tachy	cardia.						
*	*	*	*	*	*	*		
7110	Aortic aneurysm: asce	nding, thoracic, abdo	minal.					
*	*	*	*	*	*	*		
7114	Peripheral arterial dise	ease.						
*	*	*	*	*	*	*		
7117	Raynaud's syndrome (secondary Raynaud's phenomenon).							
*	*	*	*	*	*	*		
7124	Raynaud's disease (pr	imary Raynaud's phe	nomenon, primary Ra	aynaud's).				
*	*	*	*	*	*	*		

- 6. Revise Appendix C to Part 4, § 4.104 by:
- a. Revising the entry for Aneurysm: Aortic: ascending, thoracic, abdominal;
- b. Adding, in alphabetical order, under the entry for Bones an entry for Bradycardia (Bradyarrhthmia), symptomatic, requiring permanent pacemaker implantation;
- c. Revising the entries for Hypertension (isolated systolic, diastolic, or combined systolic and diastolic hypertension) and Peripheral arterial disease;
- d. Adding, in alphabetical order, under the entry for Pyelonephritis, chronic, an entry for Raynaud's disease

(primary Raynaud's phenomenon, primary Raynaud's); and

■ e. Revising the entries for Raynaud's syndrome (Raynaud's phenomenon, secondary Raynaud's) and Supraventricular tachycardia.

The revisions and additions read as follows:

APPENDIX C TO PART 4—ALPHABETICAL INDEX OF DISABILITIES

						Diagnostic code No.
*	*	*	*	*	*	*
Aneurysm:						
Aortic: ascending	g, thoracic, abdomina	al				7110
• •						
Small artery						7118
*	*	*	*	*	*	*
Arrhythmia: Ventricular						7011
*	*	*	*	*	*	*
Bones: Bradycardia (Bradyarrhythmia	ı), symptomatic, requ	uiring permanent pac	emaker implantation.			7009
*	*	*	*	*	*	*
Peripheral arterial dis	ease					7114
*	*	*	*	*	*	*
Raynaud's disease (primary Raynaud's)						
Raynaud's syndrome	(Raynaud's phenom	nenon, secondary Ra	ynaud's)			7117
*	*	*	*	*	*	*
Supraventricular tach	ycardia					7010

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R03-OAR-2019-0277; FRL-9997-70-Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Virginia; Source-Specific Reasonably Available Control Technology Determinations for 2008 Ozone National Ambient Air Quality Standard

AGENCY: Environmental Protection

Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve three state implementation plan (SIP) revisions submitted by the Commonwealth of Virginia. These revisions address reasonably available control technology (RACT) requirements under the 2008 ozone national ambient air quality standard (NAAQS) for three facilities in Northern Virginia through source-specific determinations. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before September 3, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R03-OAR-2019-0277 at https:// www.regulations.gov, or via email to spielberger.susan@epa.gov. For comments submitted at Regulations.gov, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (i.e. on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the FOR FURTHER INFORMATION CONTACT section. For the

full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit http://www2.epa.gov/dockets/commenting-epa-dockets.

FOR FURTHER INFORMATION CONTACT:

Emlyn Vélez-Rosa, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2038. Ms. Vélez-Rosa can also be reached via electronic mail at *velezrosa.emlyn@epa.gov*.

SUPPLEMENTARY INFORMATION: On February 1, 14, and 15, 2019, the Virginia Department of Environmental Quality (VADEQ) submitted three separate revisions to its SIP addressing RACT under the 2008 ozone NAAQS for three facilities in Northern Virginia. The SIP revisions consist of source-specific RACT determinations for each facility.

I. Background

RACT is an important strategy for reducing oxides of nitrogen (NO_X) and volatile organic compounds (VOC) emissions from major stationary sources within areas not meeting the ozone NAAQS. Since the 1970's, EPA has consistently defined "RACT" as the lowest emission limit that a particular source is capable of meeting by the application of the control technology that is reasonably available considering technological and economic feasibility.¹

Section 172(c)(1) of the CAA provides that SIPs for nonattainment areas must include reasonably available control measures (RACM) for demonstrating attainment of all NAAQS, including emissions reductions from existing sources through adoption of RACT. In addition, Section 182 of the CAA sets forth additional RACT requirements for the ozone NAAOS for moderate, serious or severe nonattainment areas. Section 182 requires states to implement RACT for VOC sources in the area covered by a control technique guideline (CTG) document issued by EPA, all other major stationary sources of VOCs that are located in the area, and major stationary sources of NO_X. The section 182 RACT requirements are usually referred to as CTG RACT, major non-CTG VOC RACT, and major NO_X RACT.

Further, section 184(b)(1)(B) of the CAA requires states to implement RACT

in any areas located within ozone transport regions established pursuant to section 184. This requirement is referred to as OTR RACT. A single ozone transport region (the OTR) has been established under section 184(a), which comprises of 12 States, including the District of Columbia, the Northern portion of Virginia, and portions of Maryland as part of the Consolidated Metropolitan Statistical Area (CMSA). The Northern portion of Virginia (hereafter Northern Virginia) consists of the Arlington County, Fairfax County, Loudoun County, Prince William County, Alexandria City, Fairfax City, Falls Church City, Manassas City, Manassas Park City, and Strafford County. The three facilities which are the subject of this Notice of Proposed Rulemaking are located in Northern Virginia, and thus subject to OTR RACT.

On March 12, 2008, EPA revised the 8-hour ozone standards, by lowering the standard to 0.075 parts per million (ppm) averaged over an 8-hour period (2008 ozone NAAQS). See 73 FR 16436. On May 21, 2012, EPA designated the Washington, DC-MD-VA area as a marginal ozone nonattainment area for the 2008 ozone NAAQS. The Washington, DC-MD-VA marginal ozone nonattainment area includes all cities and counties in the Northern portion of Virginia that are part of the OTR, with exception of the Strafford County. See 77 FR 30088 and 40 CFR 81.347.

On March 6, 2015, EPA issued its final rule for implementing the 2008 ozone NAAQS ("the 2008 Ozone SIP Requirements Rule").² In addressing RACT requirements, the 2008 Ozone SIP Requirements Rule is consistent with existing policy and EPA's previous ozone implementation rule. For 2008 ozone NAAQS, only Northern Virginia is subject to RACT due to its location in the OTR, as no moderate nonattainment areas were designated by EPA under the standard.

II. Summary of SIP Revision and EPA Analysis

Virginia's February 1, 14, and 15, 2019 SIP revisions address NO_X and/or VOC RACT for the following facilities: Virginia Electric and Power Company—Possum Point Power Station, Covanta Alexandria/Arlington, Inc., and Covanta Fairfax, Inc. VADEQ is adopting as part of these SIP revisions additional NO_X control requirements for these three facilities to meet RACT under the 2008 ozone NAAQS, all of which are implemented via Federally enforceable permits issued by VADEQ. These RACT permits, as listed on Table 1, have been

¹ See December 9, 1976 memorandum from Roger Strelow, Assistant Administrator for Air and Waste Management, to Regional Administrators, "Guidance for Determining Acceptability of SIP Regulations in Non-Attainment Areas," and also 44 FR 53762; September 17, 1979.

² 80 FR 12264 (March 6, 2015).