

because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone in the navigable waters around the loading, staging, transit, and display of fireworks near Pier 50 and Pier 27 in San Francisco Bay. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.2.

■ 2. Add § 165.T11–067 to read as follows:

§ 165.T11–067 Safety Zone; Pier 27 Fireworks Display, San Francisco Bay, San Francisco, CA.

(a) *Location.* The following area is a safety zone: all navigable waters of San Francisco Bay, from surface to bottom, within a circle formed by connecting all points 100 feet out from the fireworks barge during loading and staging at Pier 50 in San Francisco, as well as transit and arrival at Pier 27, San Francisco, CA. Between 9:20 p.m. and 10:30 p.m. on October 1, 2021, the safety zone will expand to all navigable waters, from surface to bottom, within a circle formed by connection all points 500 feet out from the fireworks barge in approximate position 37°48′23.0″ N, 122°23′51.1″ W (NAD 83) or as announced via Broadcast Notice to Mariners.

(b) *Definitions.* As used in this section, “designated representative” means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel, or a Federal, State, or Local officer designated by or assisting the Captain of the Port San Francisco (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) Under the general safety zone regulations in subpart C of this part, you may not enter the safety zone described in paragraph (a) of this section unless authorized by the COTP or the COTP’s designated representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP or the COTP’s designated representative.

(3) Vessel operators desiring to enter or operate within the safety zone must contact the COTP or the COTP’s designated representative to obtain permission to do so. Vessel operators given permission to enter or operate in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP’s designated representative. Persons and vessels may request permission to enter the safety zone on VHF–23A or through

the 24-hour Command Center at telephone (415) 399–3547.

(d) *Enforcement period.* This section will be enforced from 9 a.m. until 10:30 p.m. on October 1, 2021.

(e) *Information broadcasts.* The COTP or the COTP’s designated representative will notify the maritime community of periods during which this zone will be enforced, in accordance with § 165.7.

Dated: September 22, 2021.

Taylor Q. Lam,

Captain, U.S. Coast Guard, Captain of the Port, San Francisco.

[FR Doc. 2021–21098 Filed 9–29–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900–AQ71

Schedule for Rating Disabilities; The Genitourinary Diseases and Conditions

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) Schedule for Rating Disabilities (VASRD) by revising the portion of the schedule that addresses the genitourinary system. This action ensures that the rating schedule uses current medical terminology and provides detailed and updated criteria for evaluation of genitourinary conditions for disability rating purposes.

DATES: This final rule is effective November 14, 2021.

FOR FURTHER INFORMATION CONTACT: Ioulia Vvedenskaya, M.D., M.B.A., Medical Officer, VASRD Program Office (210), Compensation Service (21C), Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461–9752. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: On October 15, 2019, VA published the proposed rule for Schedule of Rating Disabilities; The Genitourinary Diseases and Conditions in the **Federal Register**. See 84 FR 55086. VA received 12 comments during the 60-day comment period. VA appreciates the comments submitted in response to the proposed rule. Based on the rationale stated in the proposed rule and in this document, the proposed rule is adopted as a final rule with minor changes noted below.

I. Comments of General Support

One commenter welcomed the proposed changes to 38 CFR 4.115a, including the replacement of a vague term (“intermittent intensive management”) with a more specific reference (“suppressive drug therapy”) in the urinary tract infection (UTI) criteria. The commenter supported VA’s proposal to eliminate subjective terms such as “markedly,” “some,” and “slight” in the renal dysfunction criteria and to replace them with specific, objective laboratory findings, such as the glomerular filtration rate (GFR) and albumin/creatinine ratio (ACR). The commenter noted that these revisions will likely result in a more efficient application of the rating schedule of disabilities and will benefit many veterans with kidney diseases. VA appreciates the commenter’s support and makes no changes based on this comment.

Another commenter supported VA’s proposal to update medical terminology and 38 CFR 4.115a. The commenter noted that the proposed changes include more specific, objective laboratory findings such as GFR. The commenter also noted that the National Kidney Foundation indicated that an estimated glomerular filtration (eGFR) is the best test to measure the level of kidney function and to determine the stage of the kidney disease. VA appreciates the commenter’s support and makes no changes based on this comment.

II. Comments Regarding 38 CFR 4.115a

One commenter expressed an opinion that the GFR values in a previously proposed rule, which was published on July 28, 2017, are more in line with National Kidney Foundation standards. See 82 FR 35140. However, that July 2017 proposal was formally withdrawn through notice published in the **Federal Register** on March 5, 2019. See 84 FR 7844. Although the commenter asserted that the July 2017 proposal’s GFR values more accurately reflected disease progression, VA found during its internal review that the renal dysfunction rating criteria proposed in July 2017 contained erroneous values and units of measure for ACR and GFR. These erroneous proposed values were not in line with the National Kidney Foundation guidelines and would have resulted in erroneous disability evaluations for multiple renal disabilities. In contrast, the October 2019 proposed rule cited corrected GFR values aligned with the National Kidney Foundation’s definition and classification of chronic kidney disease. Nat’l Kidney Found., “KDIGO 2012

Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease,” 3(1) *Kidney Int’l Suppl.* 5 (Jan. 2013), available at https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_GL.pdf (last viewed May 15, 2020) [hereinafter “KDIGO”]. Therefore, VA makes no changes based on this comment.

Another commenter stated that a recent study showed that an overestimation of renal function was correlated with patients’ post-amputation status. The commenter stated that this study suggested that a cystatin C test would be a more accurate measure of kidney function in patients who have had amputations. According to the National Kidney Foundation, a blood test for cystatin C can be helpful in some instances, but it is not the usual or regular way to estimate a GFR. National Kidney Foundation, “Cystatin C,” <https://www.kidney.org/atoz/content/cystatinC> (last viewed May 15, 2020). A recently published study examined the accuracy of kidney function estimates when prescribing renally-eliminated medications in non-traumatic amputees. Aakjaer et al., “Differences in Kidney Function Estimates Based on Creatinine and/or Cystatin C in Non-Traumatic Amputation Patients and Their Impact on Drug Prescribing,” 8(1) *J Clin Med.* 89 (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6351924/> (last viewed May 15, 2020). The conclusions of this study highlighted the fact that a non-traumatic amputation of a lower extremity has a significant effect on both eGFR and cystatin C. Furthermore, there are significant differences between eGFR and cystatin C (both before and after amputation) and these differences impact how renally-eliminated medications should be prescribed. VA appreciates this comment. However, the VA rating schedule for disabilities is not used for diagnosis and treatment of medical conditions; it is used to evaluate disabilities in accord with average earnings loss. VA has determined that, for VA disability evaluation purposes, GFR, eGFR, and ACR values present adequate measurements of functional impairment due to kidney disease. VA makes no changes based on this comment.

Another commenter disagreed with the changes made in 38 CFR 4.115a by stating that decreasing the required GFR for the 80, 60 and 30 percent rating criteria would disqualify many veterans with chronic kidney disease from future increases in their disability rating if their conditions worsen. However, VA did not propose a decrease in GFR

values; rather, VA replaced subjective terms such as “markedly,” “some,” and “slight” in the current evaluation criteria with specific, objective laboratory findings, such as GFR and ACR. To the extent that the comment was intended to suggest that VA should use the GFR values in the proposed rule published in July 2017 and later withdrawn, VA has determined, as stated above, that the GFR values proposed in October 2019 are more accurate and better aligned with the National Kidney Foundation’s definition and classification of chronic kidney disease. VA makes no changes based on this comment.

The same commenter was concerned that, under the proposed GFR values, a veteran would have to be at the point of getting a kidney transplant in order to reach an 80 percent disability evaluation. VA proposed an 80 percent evaluation for individuals with a GFR between 15 and 29 mL/min/1.73 m² for at least three consecutive months. This aligned VA’s functional impairment evaluation with the most current clinical guidelines. Nat’l Kidney Found., “Managing Your Adult Patients Who Have a Kidney Transplant,” at 2 (2011), available at https://www.kidney.org/sites/default/files/02-50-4079_ABB_ManagingTransRecipBk_PC.pdf (last viewed May 15, 2020) [hereinafter “Managing”]. According to the National Kidney Foundation guidelines, only patients with kidney failure (GFR value <15 or dialysis) are considered for kidney replacement therapy (kidney transplant). *Id.* For patients with severely decreased kidney function (GFR between 15 and 29 mL/min/1.73 m²), a referral to a nephrologist for evaluation of chronic kidney disease progression is recommended. *Id.* Such evaluation would include a range of activities in preparation for kidney replacement therapy such as patient and family education, dialysis access, and preemptive transplant. *Id.* VA makes no changes based on this comment.

Another commenter referenced a study that showed a link between kidney disease and/or kidney failure and prolonged use of proton pump inhibitors such as Prilosec and Nexium. The commenter suggested that the overuse and/or prolonged use of proton pump inhibitors during military service and the medications’ side effects should be included in the schedule for rating disabilities. VA appreciates this comment. The comment appears directed more toward establishment of service connection for a condition resulting in disability than to rating the level of disability attributable to the

condition. Nonetheless, to ensure that the full range of relevant factors is adequately addressed, VA intends to establish a work group that will consider this issue at a future time. Upon consideration and assessment of the work group's findings, VA will determine whether any additional amendments to the criteria are necessary; if so, they would be addressed in a future proposal. At this time, however, VA makes no changes based on this comment.

Another commenter expressed concern that the proposed rule did not make clear how the stages of chronic kidney disease (CKD) translate into the proposed rating criteria for renal dysfunction. To be clear, VA proposed 100, 80, 60, 30, and 0 percent evaluations based on the stages of CKD according to most current clinical guidelines, specifically, those of the National Kidney Foundation. See KDIGO at 8. The National Kidney Foundation guidelines distinguish between patients with kidney failure (that is, GFR value <15 or dialysis), severely decreased kidney function (GFR value 15 to 29), moderately to severely decreased kidney function (GFR value 30 to 44), mildly to moderately decreased kidney function (GFR value 45 to 59), and mildly decreased kidney function (GFR value 60 to 89). *Id.* VA's proposed (and now final) rating criteria for renal dysfunction provide the same staging. VA makes no changes based on this comment.

Another commenter welcomed VA's decision to base its disability evaluations for renal dysfunction on GFR and ACR laboratory findings, but was concerned that VA would use only these laboratory findings without taking into consideration other available evidence in the claims file. By law, VA must consider all available evidence when determining whether the criteria for a particular a disability evaluation are met. 38 U.S.C. 5107(b). As noted above, the GFR and ACR laboratory findings are an objective, accurate, and standard method for measuring renal dysfunction. Other relevant evidence in the claims file may implicate broader issues such as separate ratings or secondary service connection in a given case but, for the renal dysfunction rating specifically, the GFR and ACR laboratory findings will govern. VA makes no changes based on this comment.

The same commenter referenced a National Institutes of Health (NIH) study and alleged that renal dysfunction due to cold injury-related venous congestion cannot be rated based on GFR values.

VA disagrees. The NIH report does not appear to make such an allegation; indeed, it used GFR values to measure renal impairment. Mullens et al., "Importance of Venous Congestion for Worsening of Renal Function in Advanced Decompensated Heart Failure," 53(7) J Am Coll Cardiol. 589–596 (2009), available at <https://pubmed.ncbi.nlm.nih.gov/19215833/> (last visited May 19, 2020). According to the National Kidney Foundation, GFR is widely accepted as the best overall index of kidney function, KDIGO at 19, and the commenter does not appear to present an alternative measure. VA makes no changes based on this comment.

The same commenter stated that basing the renal dysfunction rating on GFR values would exclude combat veterans with warm water immersion foot and paddy foot injuries from receiving VA disability compensation. VA disagrees. To the extent that these injuries cause renal dysfunction, that dysfunction can be measured through GFR, and compensation can be provided based on the GFR value. VA makes no changes based on this comment.

The same commenter proposed the addition of new diagnostic codes for kidney dysfunction due to the warm water immersion foot and paddy foot injuries. VA appreciates this comment. To ensure that the full range of relevant factors is adequately addressed, VA intends to establish a work group that will consider this issue at a future time. Upon consideration and assessment of the work group's findings, VA will determine whether any additional amendments to the criteria are necessary; if so, they would be addressed in a future proposal. At this time, however, VA makes no changes based on this comment.

Based on its internal review, however, VA makes one change to the general rating formula for renal dysfunction: Adding the word "eligible" to the 100 percent evaluation that describes a kidney transplant recipient. This addition is made to ensure that all veterans with service-connected renal disease who are eligible to receive a kidney transplant will be entitled to a 100 percent evaluation as soon as they are deemed eligible for a kidney transplant, whether or not the transplant has been scheduled.

III. Comments Regarding Diagnostic Codes 7520 Through 7522

VA received several comments regarding the proposed changes to DCs 7520 through 7522, which address removal and deformity of the penis.

One commenter asked VA to provide a rationale for its decision to remove the ability to rate the removal of the penis or glans as voiding dysfunction. Under most circumstances, the removal of the penis or glans does not result in voiding dysfunction. Most commonly, the loss of penis or glans will affect the ability to void while standing, which is not considered a compensable functional impairment under the criteria for voiding dysfunction in 38 CFR 4.115a. Santucci et al., "Penile Fracture and Trauma," Medscape (updated 2019), <https://emedicine.medscape.com/article/456305-overview> (last visited May 15, 2020). Furthermore, if, in the course of penis or glans surgical removal, there is associated urethral trauma resulting in voiding dysfunction, it should be separately rated under DC 7518, which addresses the stricture of the urethra. For these reasons, VA does not find it appropriate to direct rating personnel to reference the voiding dysfunction criteria of 38 CFR 4.115a when evaluating DCs 7520 and 7521. VA therefore makes no changes based on this comment.

The same commenter recognized that erectile dysfunction alone may not equate to a reduction in earning capacity, but nevertheless asserted that VA should acknowledge that erectile dysfunction could lead to mental distress, such as depression and anxiety, and could impact a veteran's ability to work. The commenter recommended that VA grant compensation for any secondary condition that is related to erectile dysfunction that causes a reduction in earning capacity. VA agrees with the commenter's assessment that a mental disorder related to service-connected erectile dysfunction could warrant secondary service connection. That mental disorder would require its own diagnosis, service connection, and a disability evaluation under 38 CFR 4.130, which governs ratings for mental disorders. VA already recognizes this concept in 38 CFR 3.310(a), which directs that any disability which is proximately due to or the result of a service-connected disability shall be service-connected. VA makes no changes based on this comment.

Another commenter disagreed with the proposed changes to DC 7522, which addresses erectile dysfunction and penile deformity. The commenter expressed concern that, by removing a compensable evaluation for penis deformity, VA will unreasonably deprive certain veterans of benefits, specifically, veterans with Peyronie's disease. The commenter listed several signs and symptoms of Peyronie's disease to include scar tissue, a

significant bend to the penis, erection problems, shortening of the penis, pain with or without erection, and mental health disorders due to stress and anxiety. The commenter indicated that the severity of the overall impact of Peyronie's disease on male veterans is evidenced by the prevalence of mental health disorders associated with it. The commenter expressed an opinion that the functional impairment due to Peyronie's disease affects veterans' ability to function under the ordinary conditions of life and work. Additionally, the commenter stated that, though disabilities relating to creative organs may not affect earning capacity directly, they impact non-economic factors such as personal inconvenience, social inadaptability, or psychological factors. The commenter proposed the addition of a diagnostic code and specific rating criteria for Peyronie's disease, including penile deformity and pain.

Moreover, two commenters asked VA to provide a rationale for its decision to exclude Peyronie's disease from ratable conditions. The commenters expressed concern that Peyronie's disease may be caused by trauma as a result of an in-service injury and, in some cases, prevent a veteran from having sexual intercourse or make it difficult to get or maintain an erection.

Peyronie's disease is typically associated with painful erections or intercourse or a curve in the penis that prevents sexual intercourse. According to the NIH, and based on studies of men who reported having symptoms of Peyronie's disease, researchers estimate that Peyronie's disease affects more than one in 10 men. "Penile Curvature (Peyronie's Disease)," National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), NIH, <https://www.niddk.nih.gov/health-information/urologic-diseases/penile-curvature-peyronies-disease> (last viewed May 15, 2020). The etiology of Peyronie's disease remains partially understood. More recently, Peyronie's disease has been thought to result from vascular trauma or injury to the penis that causes scarring and deformity of the penis. Lizza et al., "Peyronie's Disease," *Medscape* (2018), <https://emedicine.medscape.com/article/456574-overview#a7> (last visited May 15, 2020).

VA agrees with the commenters that penile trauma as a result of an in-service injury should be recognized under DC 7522. Accordingly, VA in this final rule is adding a note under DC 7522 to clarify how rating personnel should evaluate disabling effects of penile trauma or disease, to include Peyronie's disease. The note states that, for the

purpose of VA disability evaluation, a disease or traumatic injury of the penis resulting in scarring or deformity shall be rated under DC 7522. With this clarification, VA ensures that a traumatic injury or disease of the penis will be recognized by the VASRD. VA would review any mental health disorders associated with erectile dysfunction or Peyronie's disease under 38 CFR 4.125, 4.126, and 4.130. Furthermore, DC 7522's footnote regarding consideration of special monthly compensation for loss of use of a creative organ, where warranted, will apply for both erectile dysfunction or Peyronie's disease.

Nevertheless, as noted in the preamble to the proposed rule, VA provides disability compensation for conditions based on the average impairment of earning capacity pursuant to 38 U.S.C. 1155. Erectile dysfunction, with or without penile deformity, is not associated directly with reductions in earning capacity, which is why VA proposed to provide a noncompensable evaluation for erectile dysfunction under DC 7522. Similarly, the potentially painful erections and intercourse associated with Peyronie's disease do not, on average, impair earning capacity at a compensable level. To the extent these conditions impact social or psychological factors, VA has a variety of mental health and counseling services available for service-connected veterans. But the law specifically links disability compensation to impairment of earning capacity. 38 U.S.C. 1155. VA thanks the commenters for their input.

IV. Comments Regarding Diagnostic Code 7542

One commenter expressed concern with VA's proposal to rate neurogenic bladder as voiding dysfunction or urinary tract infection, whichever is predominant. The commenter asserted that VA would fail to adequately compensate a veteran who suffers from both effects. Historically, 38 CFR 4.115a has recognized that "[d]iseases of the genitourinary system generally result in disabilities related to renal or voiding dysfunctions, infections, or a combination of these." Further, § 4.115a directs rating personnel to evaluate such disabilities on the "predominant area of dysfunction." VA's proposal for DC 7542 to evaluate neurogenic bladder conditions based on voiding dysfunction or urinary tract infection mirrors the instructions in § 4.115a, which instruct that only the predominant area of dysfunction shall be considered when evaluating genitourinary conditions. Moreover,

§ 4.14 directs that the evaluation of the same disability under various diagnoses is to be avoided. Both urinary tract infections and voiding dysfunctions affect urinary tract functioning, specifically, urination. Consequently, these dysfunctions do not lend themselves to distinct and separate disability evaluations without violating the fundamental principle relating to pyramiding as outlined in § 4.14. VA declines to make any changes based on this comment.

V. Comments Regarding Diagnostic Code 7543

One commenter expressed concern that the noncompensable disability rating for varicocele and hydrocele under proposed DC 7543 does not provide proper compensation for individuals with severe cases of varicocele or hydrocele that result in acute pain during walking or driving. The commenter suggested a 10 percent disability rating for such severe cases of varicocele or hydrocele. However, the evidence indicates that varicoceles are often asymptomatic and hydroceles are usually painless and disappear without treatment. *See* Junnile, J. and Lassen, P., "Testicular Masses," 57(4) *Am Fam Physician* 685–692 (1998), available at <https://www.aafp.org/afp/1998/0215/p685.html> (last viewed May 15, 2020). While these conditions may cause a decrease in fertility, or the existence of infertility, neither cause a reduction in earning capacity that would warrant a compensable rating. However, where varicocele or hydrocele causes pain that necessitates surgery, a rating under an appropriate diagnostic code may be available for post-surgery residuals. Also, in any instance in which a veteran has loss of use of a creative organ due to a service-connected condition, VA provides special monthly compensation for this functional loss. *See* 38 CFR 3.350(a). VA makes no changes based on these comments.

VI. Comments Beyond the Scope of This Rulemaking

One commenter stated that many combat veterans are unknowingly and silently enduring cold injury kidney dysfunction, and VA neglected to notify 1.7 million combat veterans of the long-term sequelae of warm water immersion foot injuries. These aspects of the comment relate to notice and education for veterans, not the rating criteria used in the evaluation of service-connected genitourinary conditions. Therefore, these issues are not within the scope of this rulemaking. VA makes no changes based on these comments.

The same commenter stated that physicians at VA medical centers do not know and have no reasonable means to ascertain information related to the disability rating criteria associated with immersion foot injuries and related kidney dysfunction, in order to properly treat disabled veterans. Furthermore, the commenter discussed in detail his medical conditions and claims' adjudication process. VA appreciates these comments; however, the comments relate to diagnosis and treatment of cardiovascular and renal conditions rather than disability evaluations in the rating schedule. Therefore, these issues are not within the scope of this rulemaking. VA makes no changes based on these comments.

VII. Proposed Changes to § 4.115

In its proposed rule, VA deemed the first three sentences of § 4.115 unnecessary and proposed to remove them. However, during its internal review and additional considerations of such removal, VA realized that further study of this action is warranted to account for complex relationships between cardiovascular and genitourinary disabilities.

Currently, VA does not assign separate evaluations for heart disease and any form of nephritis due to its close interrelationship with cardiovascular disabilities. However, VA can separately evaluate non-nephritis renal disease and cardiovascular disease (e.g., diabetic nephropathy and coronary artery disease) when complications do not overlap.

VA proposed new terminology for § 4.115, but did not clearly define renal disease and its relationship with cardiovascular conditions. Thus, if the proposed changes were to be made effective, they might be interpreted as precluding separate evaluations for non-nephritis renal disease and cardiovascular disabilities. This was not an intended consequence of this rulemaking, and would be disadvantageous to veterans who suffer from service-connected renal and cardiovascular conditions.

Therefore, VA withdraws its proposal to revise § 4.115. VA will review and update § 4.115 during its next revision of the VA Rating Schedule for Disabilities.

VII. Technical Correction

In the proposed rule, VA updated its general rating formula for renal dysfunction by replacing subjective criteria with specific, objective laboratory findings, such as the GFR and ACR. Upon further review, VA realized

that it inadvertently omitted a reference to the period of evaluation for the GFR and ACR values. VA makes a clarifying change in the text for the 100, 80, 60, 30, and 0 percent disability evaluations by adding the reference "during the past 12 months" to "Chronic kidney disease with GFR . . . for at least 3 consecutive months." This change to the language does not result to any substantive changes to the criteria in the general rating formula for renal dysfunction.

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. The Office of Information and Regulatory Affairs has determined that this rule is a significant regulatory action under Executive Order 12866. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at www.regulations.gov.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule 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 certification is based on the fact that small entities or businesses are not affected by revisions to the VASRD. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

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 one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This final rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program numbers and titles affected by this document are 64.009, Veterans Medical Care Benefits; 64.104, Pension for Non-Service-Connected Disability for Veterans; 64.109, Veterans Compensation for Service-Connected Disability.

List of Subjects in 38 CFR Part 4

Disability benefits, Pensions, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved this document on June 22, 2021, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

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 of this rule and the proposed rule, the Department of Veterans Affairs amends 38 CFR part 4 as follows:

PART 4—SCHEDULE FOR RATING DISABILITIES

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

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

Subpart B—Disability Ratings

■ 2. Amend § 4.115a by revising the introductory text and the table entries for "Renal dysfunction" and "Urinary tract infection" to read as follows:

§ 4.115a Ratings of the genitourinary system—dysfunctions.

Diseases of the genitourinary system generally result in disabilities related to renal or voiding dysfunctions, infections, or a combination of these. The following section provides descriptions of various levels of disability in each of these symptom

areas. Where diagnostic codes refer the decision maker to these specific areas of dysfunction, only the predominant area of dysfunction shall be considered for rating purposes. Distinct disabilities may be evaluated separately under this section, pursuant to § 4.14, if the symptoms do not overlap. Since the areas of dysfunction described below do not cover all symptoms resulting from genitourinary diseases, specific diagnoses may include a description of symptoms assigned to that diagnosis.

| | Rating |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| Renal dysfunction: | |
| Chronic kidney disease with glomerular filtration rate (GFR) less than 15 mL/min/1.73 m ² for at least 3 consecutive months during the past 12 months; or requiring regular routine dialysis; or eligible kidney transplant recipient | 100 |
| Chronic kidney disease with GFR from 15 to 29 mL/min/1.73 m ² for at least 3 consecutive months during the past 12 months | 80 |
| Chronic kidney disease with GFR from 30 to 44 mL/min/1.73 m ² for at least 3 consecutive months during the past 12 months | 60 |
| Chronic kidney disease with GFR from 45 to 59 mL/min/1.73 m ² for at least 3 consecutive months during the past 12 months | 30 |
| GFR from 60 to 89 mL/min/1.73 m ² and either recurrent red blood cell (RBC) casts, white blood cell (WBC) casts, or granular casts for at least 3 consecutive months during the past 12 months; or | |
| GFR from 60 to 89 mL/min/1.73 m ² and structural kidney abnormalities (cystic, obstructive, or glomerular) for at least 3 consecutive months during the past 12 months; or | |
| GFR from 60 to 89 mL/min/1.73 m ² and albumin/creatinine ratio (ACR) ≥30 mg/g for at least 3 consecutive months during the past 12 months | 0 |
| Note: GFR, estimated GFR (eGFR), and creatinine-based approximations of GFR will be accepted for evaluation purposes under this section when determined to be appropriate and calculated by a medical professional. | |
| * * * * * | |
| Urinary tract infection: | |
| Poor renal function: Rate as renal dysfunction. | |
| Recurrent symptomatic infection requiring drainage by stent or nephrostomy tube; or requiring greater than 2 hospitalizations per year; or requiring continuous intensive management | 30 |
| Recurrent symptomatic infection requiring 1–2 hospitalizations per year or suppressive drug therapy lasting six months or longer | 10 |
| Recurrent symptomatic infection not requiring hospitalization, but requiring suppressive drug therapy for less than 6 months | 0 |

- 3. Amend § 4.115b by:
 - a. Revising the entry for diagnostic code 7508;
 - b. Removing the entry for diagnostic code 7510;
 - c. Revising the entries for diagnostic codes 7520, 7521, 7522, 7524, 7525,
- 7527, 7533, 7534, 7537, 7539, 7541, and 7542; and
- d. Adding entries in numerical order for diagnostic codes 7543, 7544, and 7545.
- The revisions and additions read as follows:
- § 4.115b Ratings of the genitourinary system—diagnoses.**

| | Rating |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| * * * * * | |
| 7508 Nephrolithiasis/Ureterolithiasis/Nephrocalcinosis: | |
| Rate as hydronephrosis, except for recurrent stone formation requiring invasive or non-invasive procedures more than two times/year | 30 |
| * * * * * | |
| 7520 Penis, removal of half or more | 130 |
| 7521 Penis, removal of glans | 120 |
| 7522 Erectile dysfunction, with or without penile deformity | 10 |
| Note: For the purpose of VA disability evaluation, a disease or traumatic injury of the penis resulting in scarring or deformity shall be rated under diagnostic code 7522. | |
| * * * * * | |
| 7524 Testis, removal: | |
| Both | 130 |
| One | 10 |
| Note: In cases of the removal of one testis as the result of a service-incurred injury or disease, other than an undescended or congenitally undeveloped testis, with the absence or nonfunctioning of the other testis unrelated to service, an evaluation of 30 percent will be assigned for the service-connected testicular loss. Testis, undescended, or congenitally undeveloped is not a ratable disability. | |
| 7525 Prostatitis, urethritis, epididymitis, orchitis (unilateral or bilateral), chronic only: | |
| Rate as urinary tract infection. | |
| For tubercular infections: Rate in accordance with §§ 4.88b or 4.89, whichever is appropriate. | |
| 7527 Prostate gland injuries, infections, hypertrophy, postoperative residuals, bladder outlet obstruction: | |
| Rate as voiding dysfunction or urinary tract infection, whichever is predominant. | |

| | | | | | | | Rating |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|---|---|---|---|---|--------|
| * | * | * | * | * | * | * | * |
| 7533 Cystic diseases of the kidneys: Rate as renal dysfunction. Note: Cystic diseases of the kidneys include, but are not limited to, polycystic disease, uremic medullary cystic disease, medullary sponge kidney, and similar conditions such as Alport's syndrome, cystinosis, primary oxalosis, and Fabry's disease. | | | | | | | |
| 7534 Atherosclerotic renal disease (renal artery stenosis, atheroembolic renal disease, or large vessel disease, unspecified): Rate as renal dysfunction. | | | | | | | |
| * | * | * | * | * | * | * | * |
| 7537 Interstitial nephritis, including gouty nephropathy, disorders of calcium metabolism: Rate as renal dysfunction. | | | | | | | |
| * | * | * | * | * | * | * | * |
| 7539 Renal amyloid disease: Rate as renal dysfunction. Note: This diagnostic code pertains to renal involvement secondary to all glomerulonephritis conditions, all vasculitis conditions and their derivatives, and other renal conditions caused by systemic diseases, such as Lupus erythematosus, systemic lupus erythematosus nephritis, Henoch-Schonlein syndrome, scleroderma, hemolytic uremic syndrome, polyarthritis, Wegener's granulomatosis, Goodpasture's syndrome, and sickle cell disease. | | | | | | | |
| * | * | * | * | * | * | * | * |
| 7541 Renal involvement in diabetes mellitus type I or II: Rate as renal dysfunction. | | | | | | | |
| 7542 Neurogenic bladder: Rate as voiding dysfunction or urinary tract infection, whichever is predominant. | | | | | | | |
| 7543 Varicocele/Hydrocele | | | | | | | 10 |
| 7544 Renal disease caused by viral infection such as human immunodeficiency virus (HIV), Hepatitis B, and Hepatitis C: Rate as renal dysfunction. | | | | | | | |
| 7545 Bladder, diverticulum of: Rate as voiding dysfunction or urinary tract infection, whichever is predominant. | | | | | | | |

¹ Review for entitlement to special monthly compensation under § 3.350 of this chapter.

- 4. Amend appendix A to part 4 by:
 - a. Revising the entry for § 4.115a;
 - b. Under the entry for § 4.115b, revising the entries for diagnostic codes 7500, 7501, 7502, 7504, 7507, 7508, 7509, 7510, 7511, 7516, 7520, 7521, 7522, 7524, 7525, 7527, 7528, 7529,
 - 7530, 7531, 7532, 7533, 7534, 7535, 7536, 7537, 7538, 7539, 7540, 7541, and 7542; and
 - c. Under the entry for § 4.115b, adding in numerical order entries for diagnostic codes 7543 through 7545.
- The revisions and additions read as follows:
- Appendix A to Part 4—Table of Amendments and Effective Dates Since 1946**

| Sec. | Diagnostic code No. | |
|--------|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| * | * | * |
| 4.115a | | Re-designated and revised as § 4.115b; new § 4.115a "Ratings of the genitourinary system-dysfunctions" added February 17, 1994; revised November 14, 2021. |
| 4.115b | 7500 | Note July 6, 1950; evaluation February 17, 1994, criterion September 8, 1994; criterion November 14, 2021. |
| | 7501 | Evaluation February 17, 1994; criterion November 14, 2021. |
| | 7502 | Evaluation February 17, 1994; criterion November 14, 2021. |
| * | * | * |
| | 7504 | Evaluation February 17, 1994; criterion November 14, 2021. |
| * | * | * |
| | 7507 | Evaluation February 17, 1994; criterion November 14, 2021. |
| | 7508 | Evaluation February 17, 1994; title, criterion November 14, 2021. |
| | 7509 | Evaluation February 17, 1994; criterion November 14, 2021. |
| | 7510 | Evaluation February 17, 1994; removed November 14, 2021. |
| | 7511 | Evaluation February 17, 1994; criterion November 14, 2021. |
| * | * | * |
| | 7516 | Evaluation February 17, 1994; criterion November 14, 2021. |
| * | * | * |
| | 7520 | Criterion February 17, 1994; criterion, footnote November 14, 2021. |
| | 7521 | Criterion February 17, 1994; criterion, footnote November 14, 2021. |
| | 7522 | Criterion September 8, 1994; title, criterion, note November 14, 2021. |
| * | * | * |
| | 7524 | Note July 6, 1950; evaluation February 17, 1994; evaluation September 8, 1994; note November 14, 2021. |
| | 7525 | Criterion March 11, 1969; evaluation February 17, 1994; title and criterion November 14, 2021. |

| Sec. | Diagnostic code No. |
|------|------------------------------------------------------------------------------------------|
| * | * |
| | 7527 Criterion February 17, 1994; title and criterion November 14, 2021. |
| | 7528 Criterion March 10, 1976; criterion February 17, 1994; criterion November 14, 2021. |
| | 7529 Evaluation February 17, 1994; criterion November 14, 2021. |
| | 7530 Added September 9, 1975; evaluation February 17, 1994; criterion November 14, 2021. |
| | 7531 Added September 9, 1975; criterion February 17, 1994; criterion November 14, 2021. |
| | 7532 Evaluation February 17, 1994; criterion November 14, 2021. |
| | 7533 Added February 17, 1994; title, criterion, and note November 14, 2021. |
| | 7534 Added February 17, 1994; title and criterion November 14, 2021. |
| | 7535 Evaluation February 17, 1994; criterion November 14, 2021. |
| | 7536 Evaluation February 17, 1994; criterion November 14, 2021. |
| | 7537 Added February 17, 1994; title and criterion November 14, 2021. |
| | 7538 Evaluation February 17, 1994; criterion November 14, 2021. |
| | 7539 Added February 17, 1994; note and criterion November 14, 2021. |
| | 7540 Evaluation February 17, 1994; criterion November 14, 2021. |
| | 7541 Added February 17, 1994; title and criterion November 14, 2021. |
| | 7542 Added February 17, 1994; criterion November 14, 2021. |
| | 7543 Added November 14, 2021. |
| | 7544 Added November 14, 2021. |
| | 7545 Added November 14, 2021. |
| * | * |

■ 5. Amend appendix B to part 4 by:
 ■ a. Revising the entries for diagnostic codes 7508, 7522, 7525, 7527, 7533, 7534, 7537, and 7541;

■ b. Removing the entry for diagnostic code 7510; and
 ■ c. Adding in numerical order entries for diagnostic codes 7543 through 7545.

The revisions and additions read as follows:
Appendix B to Part 4—Numerical Index of Disabilities

| Diagnostic code No. | |
|---------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| The Genitourinary System | |
| * | * |
| 7508 | Nephrolithiasis/Ureterolithiasis/Nephrocalcinosis. |
| * | * |
| 7522 | Erectile dysfunction, with or without penile deformity. |
| * | * |
| 7525 | Prostatitis, urethritis, epididymitis, orchitis (unilateral or bilateral), chronic only. |
| 7527 | Prostate gland injuries, infections, hypertrophy, postoperative residuals, bladder outlet obstruction. |
| * | * |
| 7533 | Cystic diseases of the kidneys. |
| 7534 | Atherosclerotic renal disease (renal artery stenosis, atheroembolic renal disease, or large vessel disease, unspecified). |
| * | * |
| 7537 | Interstitial nephritis, including gouty nephropathy, disorders of calcium metabolism. |
| * | * |
| 7541 | Renal involvement in diabetes mellitus type I or II. |
| * | * |
| 7543 | Varicocele/Hydrocele. |
| 7544 | Renal disease caused by viral infection such as HIV, Hepatitis B, and Hepatitis C. |
| 7545 | Bladder, diverticulum of. |
| * | * |

■ 6. Amend appendix C to part 4 by:
 ■ a. Under the heading “Bladder,” adding in alphabetical order an entry for “Diverticulum of” (diagnostic code 7545);

■ b. Revising the entry for “Interstitial nephritis” (diagnostic code 7537);
 ■ c. Revising the entry for “Nephrolithiasis” (diagnostic code 7508);

■ d. Under the heading “Penis,” removing the entry for “Deformity, with loss of erectile power” (diagnostic code 7522), and adding an entry for “Erectile dysfunction” in its place;

- e. Revising the entry for “Prostate gland” (diagnostic code 7527);
- f. Under the heading “Renal,” adding in alphabetical order an entry for “Disease caused by viral infection such as HIV, Hepatitis B, and Hepatitis C” (diagnostic code 7544);
- g. Under the heading “Renal,” removing the entry for “Involvement in systemic diseases” (diagnostic code

- 7541), and adding an entry for “Involvement in diabetes mellitus type I or II” in its place;
- h. Removing the entry for “Ureterolithiasis” (diagnostic code 7510);
- i. Removing the entry for “Epididymo-orchitis” (diagnostic code 7525);
- j. Adding in alphabetical order an entry for “Prostatitis, urethritis,

- epididymitis, orchitis (unilateral or bilateral), chronic only” (diagnostic code 7525); and
- k. Adding in alphabetical order an entry for “Varicocele/Hydrocele” (diagnostic code 7543).

The additions and revisions read as follows:

Appendix C to Part 4—Alphabetical Index of Disabilities

| | Diagnostic code No. |
|-------------------------------------------------------------------------------------------------------------|---------------------|
| Bladder: | |
| Calculus in | 7515 |
| Diverticulum of | 7545 |
| Fistula in | 7516 |
| Injury of | 7517 |
| Neurogenic | 7542 |
| Interstitial nephritis, including gouty nephropathy, disorders of calcium metabolism | 7537 |
| Nephrolithiasis/Ureterolithiasis/Nephrocalcinosis | 7508 |
| Penis: | |
| Erectile dysfunction | 7522 |
| Removal of glans | 7521 |
| Removal of half or more | 7520 |
| Prostate gland injuries, infections, hypertrophy, postoperative residuals, bladder outlet obstruction | 7527 |
| Prostatitis, urethritis, epididymitis, orchitis (unilateral or bilateral), chronic only | 7525 |
| Renal: | |
| Amyloid disease | 7539 |
| Disease, chronic | 7530 |
| Disease caused by viral infection such as HIV, Hepatitis B, and Hepatitis C | 7544 |
| Involvement in diabetes mellitus type I or II | 7541 |
| Tubular disorders | 7532 |
| Varicocele/Hydrocele | 7543 |

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900–AQ67

Schedule for Rating Disabilities: The Cardiovascular System

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) Schedule for Rating Disabilities

(“VASRD” or “rating schedule”) by revising the portion of the rating schedule that addresses the cardiovascular system. The purpose of this revision is to ensure that this portion of the rating schedule uses current medical terminology and provides detailed and updated criteria for the evaluation of cardiovascular disabilities by incorporating medical advances that have occurred since the last review.

DATES: This rule is effective November 14, 2021.

FOR FURTHER INFORMATION CONTACT: Gary Reynolds, M.D., 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 number.)

SUPPLEMENTARY INFORMATION: VA published a proposed rule in the **Federal Register** at 84 FR 37594 on August 1, 2019, to amend the regulations involving the cardiovascular system. VA provided a 60-day public comment period and invited interested persons to submit written comments, suggestions, or objections on or before September 30, 2019. VA received comments from National Organization of Veterans’ Advocates (NOVA), Military Disability Made Easy (two comments), Veterans of Foreign Wars (VFW), National Veterans Legal Services