

the beginning point, proceed east in a straight line for 3.71 miles to the intersection of two unnamed, unimproved roads north of Rancho San Juan; then

(2) Proceed east-southeast in a straight line for approximately 1.2 miles to an unnamed hilltop with a marked elevation of 1,424 feet in the La Laguna Grant; then

(3) Proceed southwest in a straight line for approximately 1.7 miles, crossing onto the Zaca Creek map, to a point designated "Oil," adjacent to the north fork of San Antonio Creek and the intersection of three unnamed light-duty roads in the Cañada del Comasa, La Laguna Grant; then

(4) Proceed west-southwest in a straight line for approximately 1.56 miles to the intersection of the north fork of San Antonio Creek and the 800-foot elevation contour in the Cañada del Comasa, La Laguna Grant; then

(5) Proceed west in a straight line 1.95 miles to an unnamed rectangular structure northeast of the terminus of an unnamed, unimproved road north of U.S. Highway 101 and BM 684 in the La Laguna Grant; then

(6) Proceed northwesterly in a straight line 0.32 mile to the intersection of Alisos Canyon Road and an unnamed, unimproved road east of the Cañada de los Coches in the La Laguna Grant; then

(7) Proceed north-northwest in a straight line for 1.68 miles, crossing onto the Foxen Canyon map, to an unnamed hilltop with a marked elevation of 997 feet in the La Laguna Grant; then

(8) Proceed northeast in a straight line for 0.5 mile to return to the beginning point.

Signed: August 6, 2019.

Mary G. Ryan

Acting Administrator.

Approved: September 23, 2019.

Timothy E. Skud,

Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).

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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: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend the portion of the Schedule for Rating Disabilities that addresses the genitourinary system. The purpose of this change is to update current medical terminology, incorporate medical advances that have occurred since the last review, and provide well-defined criteria in accordance with actual, standard medical clinical practice. In fashioning this proposed rule, VA considered the most up-to-date medical knowledge and clinical practice of nephrology and urology specialties. Contact information for that office is noted in the **ADDRESSES** section of this proposed rule.

DATES: Comments must be received on or before December 16, 2019.

ADDRESSES: Written comments may be submitted through www.Regulations.gov; by mail or hand-delivery to Director, Office of Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue 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-AQ71—Schedule for Rating Disabilities; The Genitourinary Diseases and Conditions." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1064, 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, comments may be viewed online through the Federal Docket Management System at www.Regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Ioulia Vvedenskaya, M.D., M.B.A., Medical Officer, Part 4 VASRD Regulations Staff (211D), Compensation Service, 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: As part of VA's ongoing revision of the Schedule for Rating Disabilities (VASRD), VA proposes changes to the portion of the VASRD that addresses the genitourinary system, which was last revised in 1994. See 59 FR 2523 (Jan. 18, 1994); see also 59 FR 46338 (Sep. 8, 1994). Through this revision, VA aims to eliminate ambiguities, include medical conditions not currently in the rating schedule,

implement current, well-refined medical criteria, and update terminology to reflect the most recent medical advances. For this proposed rule, VA considered the most up-to-date medical knowledge and clinical practice of nephrology and urology specialties, as well as feedback from a public forum held on January 27-28, 2011. Please email at 21_EXECASST.VBACO@va.gov for a copy of the public forum transcript.

I. Proposed Changes to § 4.115

Currently, 38 CFR 4.115 ("Nephritis") does not adequately reflect current concepts of renal and urinary tract diseases and conditions. Regardless of specific disease pathology, kidney conditions generally produce the same symptomatology and lead to the same functional impairment. Therefore, for rating purposes, analysis of pathology, such as is currently presented in the first three sentences of § 4.115, is unnecessary and VA proposes to remove this language.

However, VA proposes to retain the remainder of the language in § 4.115, which addresses the assignment of ratings when both renal and cardiovascular conditions are present, but to replace the reference to "nephritis" in the first sentence of the proposed revised section with "renal disease" to more accurately reflect the applicability of the provision. VA proposes to retitle this provision as "Co-existence of renal and cardiovascular conditions" to better address the amended content.

II. Proposed Changes to § 4.115a

Under the current VASRD, diseases of the genitourinary system are listed at 38 CFR 4.115b with instructions directing rating personnel to various rating criteria found at 38 CFR 4.115a, when appropriate. The rating criteria in § 4.115a address impairment of the genitourinary system, including renal dysfunction, voiding dysfunction, and infections.

The introductory paragraph in § 4.115a states that when the VASRD refers a decision-maker to these areas of dysfunction, only the predominant area of dysfunction will be considered for rating purposes. VA proposes clarifying this statement by noting that distinct disabilities may be assigned separate evaluations under this section, consistent with the anti-pyramiding provisions in § 4.14. This statement is intended to reflect that when a particular diagnostic code refers to multiple dysfunctions, only the predominant dysfunction will be evaluated for that diagnostic code.

Distinct disabilities resulting in non-overlapping symptoms may be assigned separate evaluations, however.

VA also proposes to make changes to the rating criteria found in § 4.115a; these proposed changes are discussed below.

A. Renal Dysfunction

Currently, VA evaluates renal dysfunction as follows:

A 100 percent evaluation is assigned for any of the following: Requiring regular dialysis, or precluding more than sedentary activity from one of the following: Persistent edema and albuminuria; or, BUN more than 80 mg%; or, creatinine more than 8 mg%; or, markedly decreased function of kidney or other organ systems, especially cardiovascular.

An 80 percent evaluation is assigned for any of the following: Persistent edema and albuminuria with BUN 40 to 80 mg%; or, creatinine 4 to 8 mg%; or, generalized poor health characterized by lethargy, weakness, anorexia, weight loss, or limitation of exertion.

A 60 percent evaluation is assigned for any of the following: Constant albuminuria with some edema; or, definite decrease in kidney function; or, hypertension at least 40 percent disabling under diagnostic code 7101.

A 30 percent evaluation is assigned for any of the following: Albumin constant or recurring with hyaline and granular casts or red blood cells; or, transient or slight edema or hypertension at least 10 percent disabling under diagnostic code 7101.

A 0 percent evaluation is assigned for either albumin and casts with a history of acute nephritis; or, hypertension non-compensable under diagnostic code 7101.

Subjective terms such as “markedly,” “some,” and “slight” in the current evaluation criteria contribute to inconsistent evaluation of genitourinary disabilities rated under these criteria. Therefore, VA proposes to replace these subjective criteria with specific, objective laboratory findings, such as the glomerular filtration rate (GFR) and albumin/creatinine ratio (ACR). Modern medicine states that the “[GFR] is widely accepted as the best overall measure of kidney function in health and 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.* 19 (Jan. 2013), available at https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_GL.pdf (last viewed Jan. 4, 2019). In clinical practice, subject matter experts have noted an inverse

correlation between GFR and functional impairment (*i.e.*, lower GFRs correspond to greater impairment), and individuals with GFRs less than 60 mL/min/1.73 m² are considered to have chronic kidney disease. *Id.* A GFR less than 15 mL/min/1.73 m² is also a sign of renal failure. *Id.* In addition to using the GFR for evaluation purposes, VA also proposes adding a note to the evaluation criteria specifying that GFR, estimated GFR (eGFR), and creatinine based approximations are acceptable for evaluation purposes, as each has been shown to be an adequate indicator of the stage of chronic kidney disease. The GFR used must be medically appropriate and calculated by a medical professional.

Based on the level of kidney function generally associated with a specific GFR, VA proposes assigning a 100 percent evaluation for chronic kidney disease with GFR less than 15 mL/min/1.73 m² for at least three consecutive months; an 80 percent evaluation for a GFR between 15 and 29 mL/min/1.73 m² for at least three consecutive months; a 60 percent evaluation for a GFR between 30 and 44 mL/min/1.73 m² for at least three consecutive months; and a 30 percent evaluation for a GFR between 45 and 59 mL/min/1.73 m² for at least three consecutive months. Additionally, a 100 percent evaluation would still be assigned for chronic kidney disease requiring regular routine dialysis. VA intends to also extend this evaluation to individuals who are the recipients of a kidney transplant.

VA proposes assigning a 0 percent evaluation for certain markers of kidney damage for at least three consecutive months: A GFR between 60 and 89 mL/min/1.73 m² and the presence of recurrent red blood cell (RBC) casts, white blood cell (WBC) casts, granular casts, structural kidney abnormalities (cystic, obstructive, or glomerular), or increased secretion of protein in the urine (proteinuria). Proteinuria, as measured by increased urinary excretion of albumin, is an early and sensitive marker of kidney damage and is reflected by an albumin/creatinine ratio (ACR) of 30 mg/g or greater.

These levels of evaluation correlate to a modified staging classification of chronic kidney disease by the National Kidney Foundation. At the 100 percent evaluation, the designated GFR is associated with kidney failure and, at the 0 percent evaluation, the designated GFR and proteinuria are associated with an increased risk of kidney damage even without a diagnosis of chronic kidney disease. Intermediate levels of evaluation at the 30, 60, and 80 percent

levels correspond to the remaining stages of chronic kidney disease as they increase in severity as manifest by declining GFR.

B. Urinary Tract Infection

VA proposes to preserve the existing rating criteria for urinary tract infection with little change. VA does, however, propose to clarify the criteria for a 30 percent evaluation by specifying that drainage would be by stent or nephrostomy tube. This differentiates drainage via catheterization. Stent or nephrostomy tube insertion are surgical procedures and require more intensive medical management than drainage via catheterization. Catheterization is not medically consistent with the remainder of the criteria required for a 30 percent evaluation because the need for catheterization is not generally accompanied by frequent hospitalization (greater than two times/year) or continuous intensive management.

For the 10 percent evaluation, VA proposes to replace the ambiguous phrase “intermittent intensive management” with “suppressive drug therapy lasting six months or longer.” Antibiotic and suppressive medications are typically the treatment used to treat urinary tract infections. Charles Kodner et al., “Recurrent Urinary Tract Infections in Women: Diagnosis and Management,” 82(6) *Am. Family Physician* 638–43 (2010); B. Lee et al., “Methenamine hippurate for preventing urinary tract infections,” *The Cochrane Library* (Oct. 17, 2012), <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003265.pub3/abstract> (last visited April 10, 2019). However, the term “intensive management” suggests something beyond short-term courses of antibiotic treatment for urinary tract infections; this is not clear from the current definition. As such, VA intends to replace “intermittent intensive management” with the objective criterion of “suppressive drug therapy lasting six months or longer.” As for the length of time selected, suppressive therapy is more appropriate for a chronic infection. B. Lee, *supra*. Recurrent, or chronic, infections are generally defined as two or more infections in six months, and the recommended treatment is six to twelve months of suppressive drug therapy. Kodner, *supra*. Therefore, VA proposes a 10 percent evaluation when there are one to two hospitalizations per year for urinary tract infections, or suppressive drug therapy lasting six months or longer is required.

The addition of a 0 percent evaluation is also proposed and would be

applicable if a Veteran has recurrent urinary tract infections that require suppressive drug therapy for less than six months. Under this evaluation, drug suppressive therapy lasting six months or longer is not required. This proposed evaluation would cover cases that are responsive to treatment and/or are not severe enough to require suppressive drug therapy for six months or more. It would also ease field application by specifying non-compensable criteria that can be compared to the criteria warranting a compensable evaluation.

III. Proposed Changes to § 4.115b

A. Diagnostic Codes (DCs) 7508 and 7510

VA proposes to amend these DCs based on a better understanding of the disease process and the impact of treatment. When imbalances occur in the body, substances in urine can form solid pieces within the urinary tract. These pieces are commonly referred to as stones. Nephrolithiasis, to which diagnostic code 7508 currently applies, is another name for kidney stones. Ureterolithiasis (current DC 7510) refers to stones in the ureter, which is the tube that carries urine from the kidney to the bladder.

Regardless of whether the stone is in the kidney or the ureter, symptoms may include abdominal and/or back pain and blood in the urine. This shared symptomology leads to similar functional impairment. Therefore, VA proposes to delete existing DC 7510 and to evaluate stones in either the kidney or the ureter under diagnostic code 7508.

Nephrocalcinosis, a disorder in which excess calcium accumulates in the kidneys, does not result in symptoms. Rather, if the accumulation of calcium leads to the creation of stones, the stones themselves may cause symptoms. This condition is commonly evaluated under DC 7508 as analogous to nephrolithiasis, and VA proposes that it continue to be evaluated under this code, but that it be expressly added to the diagnostic code for ease of field application. Therefore, to better express the conditions to be evaluated under DC 7508, VA proposes to rename it as “Nephrolithiasis/Ureterolithiasis/Nephrocalcinosis.”

Proposed DC 7508 would provide a 30-percent rating for recurrent stone formation requiring invasive or non-invasive procedures more than two times per year, as current DC 7508 does, but would no longer require diet or drug therapy, because such therapies have no specific relationship to these disabilities and are widely recommended for the

majority of medical diseases and conditions.

B. DCs 7520 Through 7522

Current DCs 7520 and 7521 provide compensation for actual physical removal of the penis or glans. An evaluation of 30 percent is provided when there is removal of half or more of the penis under DC 7520. In addition, a 20 percent evaluation is assigned when there is removal of the glans under DC 7521. Current DCs 7520 and 7521 also permit rating these conditions alternatively as voiding dysfunction in § 4.115a. VA proposes to no longer rate these conditions as voiding dysfunction, which pertains to issues of leakage and frequency and the use of an appliance or absorbent materials. VA also proposes to revise DCs 7520 and 7521 to include a footnote reference to consider entitlement to Special Monthly Compensation (SMC) for loss of a creative organ under § 3.350. This is meant to correct the omission of this note from previous versions of the VASRD. Removal of half or more of the penis, or removal of the glans, may result in loss of a creative organ. Therefore, although consideration of SMC is considered with application of these diagnostic codes under current policy, this change would ensure consistent consideration of SMC for loss of a creative organ.

VA proposes to revise DC 7522 to encompass erectile dysfunction (ED), regardless of etiology. In making this change, VA intends to retitle this diagnostic code, “Erectile dysfunction, with or without penile deformity.” ED can occur with or without deformity of the penis, and is a symptom of many systemic, psychological, and metabolic diseases. W. Ludwig, “Organic causes of erectile dysfunction in men under 40,” 92(1) *Urologia Internationalis* 1–6 (2014).

VA proposes to no longer provide a 20-percent rating for this condition, whether with or without penile deformity. VA provides disability compensation for conditions that result in reduced earning capacity. 38 U.S.C. 1155. Erectile dysfunction, with or without penile deformity, is not associated with reductions in earning capacity. Therefore, VA proposes to provide a 0 percent evaluation for this condition. Section 4.115b’s footnote regarding consideration of SMC for loss of use a creative organ where warranted would continue to apply to DC 7522. Similarly, 38 CFR 4.116, DC 7632, provides a 0 percent evaluation for female Veterans with service-connected female sexual arousal disorder (FSAD) without physical damage to female

genitalia, with a note directing rating personnel to consider eligibility for SMC.

C. DC 7524

VA does not propose any substantive changes to current DC 7524. However, it does intend to correct a typographical error in the last sentence of the existing note, which refers to “underscended” rather than “undescended” testis.

D. DCs 7525, 7527, 7533, 7534, and 7537

Currently, each of these diagnostic codes identifies one or more conditions that have similar symptomatology and functional impairment. The conditions identified are not an exclusive list; therefore, other conditions are often rated as analogous to one of these diagnostic codes. To assist the field in ensuring that the appropriate diagnostic criteria is used to evaluate other conditions not currently listed, VA proposes to rename each of these diagnostic codes and/or include a note identifying those conditions not currently listed.

First, VA proposes to rename DC 7525 as “Prostatitis, urethritis, epididymitis, orchitis (unilateral or bilateral), chronic only,” as these diagnoses all refer to urinary tract infections that do not involve the kidneys and have similar symptoms. Prostatitis would not be included in proposed revised DC 7527, “Prostate gland injuries, infections, hypertrophy, postoperative residuals, bladder outlet obstruction,” because it is rarely caused by a bacterial infection and generally results in repeated bladder infections. J. Stevermer et al., “Treatment of Prostatitis,” 61(10) *Am. Family Physician* 3015–22 (2000). The diagnoses contained in DC 7527 are not consistent with non-bacterial prostatitis. In addition, the symptoms caused by prostatitis—recurrent bladder infections—are more similar to the diagnoses contained in DC 7525. There is no change to the evaluation criteria for this DC.

VA also proposes to rename DC 7527 to include bladder outlet obstruction, which has the same functional impairment and symptomatology as the other conditions currently encompassed in this code. Bladder outlet obstruction is not included in current DC 7517, “Bladder, injury of,” because this condition is not caused by an injury to the bladder, but is generally caused by another condition, such as benign prostatic hypertrophy (BPH), which is addressed in DC 7527. R. Dmochowski, “Bladder Outlet Obstruction: Etiology and Evaluation,” 7(Supp. 6) *Reviews in Urology* S3–S13 (2005). In addition, the

symptomatology for this condition may include urinary tract infections, rather than only voiding dysfunction, as contemplated by DC 7517. There is no change to the evaluation criteria for this DC.

VA proposes to add a note to DC 7533 to identify some of the most common cystic kidney diseases seen in the Veteran population, to include polycystic disease, uremic medullary cystic disease, medullary sponge kidney, and similar conditions such as Alport's syndrome, cystinosis, primary oxalosis, and Fabry's disease. M. Biscaglia et al., "Renal cystic diseases: a review," 13(1) *Advances in Anatomic Pathology* 26–56 (2006). These diseases are being added as a medical update and would ensure proper field application of this DC. There is no change to the evaluation criteria for this DC.

Regarding DC 7534, which deals with atherosclerotic renal disease, VA proposes to specifically identify another atherosclerotic renal disease—large vessel disease, unspecified. Renal Failure: Diagnosis and Treatment 65 (J. Gary Abuelo ed. 1995). This disease is being added as a medical update and would ensure proper field application of this DC. There is no change to the evaluation criteria.

Finally, VA proposes to retitle DC 7537 to identify the most common forms of interstitial nephritis resulting from the high prevalence of the disease, including gouty nephropathy and disorders of calcium metabolism. There is no change to the evaluation criteria.

E. DCs 7539 and 7541

VA proposes to move all conditions contained in DC 7541 over to DC 7539, with the exception of renal involvement in diabetes mellitus, to encompass all systemic conditions that impact the kidneys. All of these conditions are, as amyloid diseases, systemic diseases with renal involvement and therefore are more appropriately evaluated under a single DC. For clarity and ease of field application, VA proposes to add a note to DC 7539 to identify all forms of glomerulonephritis, nephritis, and renal vasculitis encountered with systemic diseases. There is no change to the evaluation criteria.

As for renal involvement in diabetes mellitus (e.g., diabetic nephropathy), VA proposes to continue rating this condition separately under DC 7541. Although this condition would also be rated as renal dysfunction, VA finds there is a need to track this particular condition given its incidence and prevalence in the Veteran population, especially with regard to claims related to Agent Orange exposure.

F. DC 7542

Based on modern clinical findings, neurogenic bladder should continue to be rated as a voiding dysfunction. However, due to high rate of urinary tract infections, VA proposes that this condition may be rated as voiding dysfunction or urinary tract infection, whichever is predominant. D. Sauerwein, "Urinary tract infection in patients with neurogenic bladder dysfunction," 19(6) *Int'l J. of Antimicrobial Agents* 592–97 (2002).

G. New Proposed DC 7543

VA proposes the introduction of new DC 7543, "Varicocele/Hydrocele," to reflect related conditions of the urinary tract that have not previously been recognized for disability evaluation purposes. Varicocele is a dilatation of the veins along the cord that receives blood from the testicles. Hydrocele is a collection of fluid in the scrotum.

The medical community now recognizes that these conditions may be associated with a decrease in fertility and, in rare instances, may be associated with infertility. Center for Male Reproductive Medicine and Vasectomy Reversal, "Varicocele Repair," <http://www.malereproduction.com/male-infertility/treatment/varicocele-repair.php> (last accessed April 9, 2019). As a decrease in fertility, or the existence of infertility, does not cause a reduction in earning capacity, VA proposes to assign a 0 percent evaluation to these conditions. In instances where there is a clinical finding of infertility, these conditions may support eligibility for SMC due to loss of use of a creative organ. Therefore, to best administer this benefit, VA proposes a diagnostic code for these conditions that provides a 0 percent evaluation. Section 4.115b's footnote directing consideration of SMC would apply to DC 7543, consistent with the other DCs in the VASRD addressing a creative organ.

H. New Proposed DC 7544

VA proposes the introduction of new DC 7544, "Renal disease caused by viral infection such as human immunodeficiency virus (HIV), Hepatitis B, and Hepatitis C," to reflect renal dysfunctions associated with HIV and hepatitis because of increasing prevalence and incidence of diseases caused by these viruses. Perico Norberto et al., "Hepatitis C Infection and Chronic Renal Diseases," 4(1) *Clinical J. Am. Soc'y of Nephrology* 207–20 (2009). Hepatitis A, an acute liver disease, does not cause chronic renal disease and is therefore not included in this DC.

VA proposes to evaluate this DC as renal dysfunction under § 4.115a because, when the liver is damaged due to Hepatitis B or C infection, the accumulation of toxins in the blood can damage the kidneys, causing renal dysfunction. HIV-associated renal dysfunctions have several different etiologies, but can include direct HIV infection of the kidney, kidney damage caused by drugs used to treat HIV, and fluid loss caused by various processes associated with the advanced disease process. Moro O. Salifu, "HIV-Associated Nephropathy," *Medscape*, <http://emedicine.medscape.com/article/246031-overview> (Vecihi Batuman ed., 2013) (last accessed April 10, 2019).

I. New Proposed DC 7545

VA proposes the introduction of new DC 7545, "Bladder, diverticulum of." Currently, there is no DC for diverticulum of the bladder and, as such, it is generally evaluated in the field as analogous to fistula of the bladder. A bladder fistula is an abnormal connection between the bladder and another organ of the body (e.g., the bowel). A bladder diverticulum is an abnormal pouch or sac due to weakness in the bladder's muscular wall that allows a portion of the bladder to protrude. Urology Care Foundation, "What is Bladder Diverticulum?" <https://www.urologyhealth.org/urologic-conditions/bladder-diverticulum> (last accessed April 9, 2019). The two conditions have dissimilar symptomatology and result in dissimilar functional impairment. A bladder fistula allows urine to escape the confines of the bladder into another space such as the rectum, or externally, causing urinary leakage. A bladder diverticulum allows urine to remain in the bladder longer, often resulting in infection as well as voiding dysfunction.

The proposed addition of this new DC would ensure that the condition is more appropriately rated. VA proposes to rate DC 7545 as voiding dysfunction or urinary tract infection, whichever is predominant, because these criteria best capture the functional impairment associated with this condition.

Executive Orders 12866, 13563, and 13771

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. VA's impact analysis can be found as a supporting document at www.regulations.gov, usually within 48 hours after the rulemaking document is published. Additionally, a copy of this rulemaking and its impact analysis are available on VA's website at www.va.gov/orpm/, by following the link for VA Regulations Published from FY 2004 Through Fiscal Year to Date. This rule is not expected to be subject to the requirements of Executive Order 13771 because this rulemaking is expected to result in no more than de minimis costs.

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed 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 VA is the only entity involved with the provisions of this rulemaking. There are no outside or small entities involved, impacted and/or affiliated with VA's authorization to evaluate and revise disability compensation criteria. Therefore, VA is exempt from the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 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

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

Paperwork Reduction Act

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

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

The Secretary of Veterans Affairs approved this document 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. Robert L. Wilkie, Secretary, Department of Veterans Affairs, approved this document on June 4, 2019, for publication.

Dated: October 4, 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, the Department of Veterans Affairs proposes to amend 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. Revise § 4.115 to read as follows:

§ 4.115 Co-Existence of renal and cardiovascular conditions.

Separate ratings are not to be assigned for disability from disease of the heart and any form of renal disease, on account of the close interrelationships of cardiovascular diseases. If, however, absence of a kidney is the sole renal disability, even if removal was required because of nephritis, the absent kidney and any hypertension or heart disease will be separately rated. Also, in the event that chronic renal disease has progressed to the point where regular dialysis is required, any coexisting hypertension or heart disease will be separately rated.

■ 3. 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; or requiring regular routine dialysis; or 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	80
Chronic kidney disease with GFR from 30 to 44 mL/min/1.73 m ² for at least 3 consecutive months	60
Chronic kidney disease with GFR from 45 to 59 mL/min/1.73 m ² for at least 3 consecutive 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 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 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	0
<i>Note:</i> 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:	

	Rating
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

- 4. Amend § 4.115b by:
- a. Removing diagnostic code 7510.
- b. Revising diagnostic codes 7508, 7520, 7521, 7522, 7524, 7525, 7527, 7533, 7534, 7537, 7539, 7541, and 7542.

- c. Adding 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
7524 Testis, removal: Both	130
One	10
<i>Note:</i> 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.	
7533 Cystic diseases of the kidneys: Rate as renal dysfunction. <i>Note:</i> 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. <i>Note:</i> 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:	

Rating

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.

- 5. Amend Appendix A to Part 4 by:
 - a. Adding § 4.115.
 - b. Revising § 4.115a.
 - c. In § 4.115b,
 - i. Revising the entries for diagnostic codes 7508, 7510, 7520 through 7522, 7524, 7525, 7527, 7533, 7534, 7537, 7539, 7541, and 7542.
 - ii. Adding diagnostic codes 7543 through 7545.
The additions and revisions to read as follows:

APPENDIX A TO PART 4—TABLE OF AMENDMENTS AND EFFECTIVE DATES SINCE 1946

Sec.	Diagnostic Code No.	
*	*	*
4.115		Retitled and revised [<i>Effective date of final rule</i>].
4.115a		Re-designated and revised as § 4.115b; new § 4.115a "Ratings of the genitourinary system-dysfunctions" added February 17, 1994; revised [<i>Effective date of final rule</i>].
4.115b	7500	Note July 6, 1950; evaluation February 17, 1994, criterion September 8, 1994; criterion [<i>Effective date of final rule</i>].
	7501	Evaluation February 17, 1994; criterion [<i>Effective date of final rule</i>].
	7502	Evaluation February 17, 1994; criterion [<i>Effective date of final rule</i>].
*	*	*
	7504	Evaluation February 17, 1994; criterion [<i>Effective date of final rule</i>].
*	*	*
	7507	Evaluation February 17, 1994; criterion [<i>Effective date of final rule</i>].
	7508	Evaluation February 17, 1994; title, criterion [<i>Effective date of final rule</i>].
	7509	Evaluation February 17, 1994; criterion [<i>Effective date of final rule</i>].
	7510	Evaluation February 17, 1994; removed [<i>Effective date of final rule</i>].
*	*	*
	7516	Evaluation February 17, 1994; criterion [<i>Effective date of final rule</i>].
*	*	*
	7520	Criterion February 17, 1994; criterion, footnote [<i>Effective date of final rule</i>].
	7521	Criterion February 17, 1994; criterion, footnote [<i>Effective date of final rule</i>].
	7522	Criterion September 8, 1994; title, criterion [<i>Effective date of final rule</i>].
*	*	*
	7524	Note July 6, 1950; evaluation February 17, 1994; evaluation September 8, 1994; note [<i>Effective date of final rule</i>].
	7525	Criterion March 11, 1969; evaluation February 17, 1994; title and criterion [<i>Effective date of final rule</i>].
	7527	Criterion February 17, 1994; title and criterion [<i>Effective date of final rule</i>].
	7528	Criterion March 10, 1976; criterion February 17, 1994; criterion [<i>Effective date of final rule</i>].
	7529	Evaluation February 17, 1994; criterion [<i>Effective date of final rule</i>].
	7530	Added September 9, 1975; evaluation February 17, 1994; criterion [<i>Effective date of final rule</i>].
	7531	Added September 9, 1975; criterion February 17, 1994; criterion [<i>Effective date of final rule</i>].
	7532	Evaluation February 17, 1994; criterion [<i>Effective date of final rule</i>].
	7533	Added February 17, 1994; title, criterion, and note [<i>Effective date of final rule</i>].
	7534	Added February 17, 1994; title and criterion [<i>Effective date of final rule</i>].
	7535	Evaluation February 17, 1994; criterion [<i>Effective date of final rule</i>].
	7536	Evaluation February 17, 1994; criterion [<i>Effective date of final rule</i>].
	7537	Added February 17, 1994; title and criterion [<i>Effective date of final rule</i>].
	7538	Evaluation February 17, 1994; criterion [<i>Effective date of final rule</i>].
	7539	Added February 17, 1994; note and criterion [<i>Effective date of final rule</i>].
	7540	Evaluation February 17, 1994; criterion [<i>Effective date of final rule</i>].
	7541	Added February 17, 1994; title and criterion [<i>Effective date of final rule</i>].
	7542	Added February 17, 1994; criterion [<i>Effective date of final rule</i>].
	7543	Added [<i>Effective date of final rule</i>].
	7544	Added [<i>Effective date of final rule</i>].
	7545	Added [<i>Effective date of final rule</i>].
*	*	*

- 6. Amend Appendix B to Part 4 by:
 - a. Revising diagnostic codes 7508, 7522, 7525, 7527, 7533, 7534, 7537, and 7541.
 - b. Removing diagnostic code 7510;
 - c. Adding 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 human immunodeficiency viruses (HIV), Hepatitis B, and Hepatitis C.
7545	Bladder, diverticulum of.

■ 7. Amend Appendix C to Part 4 by:
 ■ a. Revising the entries for diagnostic codes 7508, 7522, 7525, 7527, 7533, 7537, and 7541.

■ b. Removing the reference to diagnostic code 7510;
 ■ c. Adding diagnostic codes 7543 through 7545.

The revisions and additions read as follows:

APPENDIX C TO PART 4—ALPHABETICAL INDEX OF DISABILITIES

	Diagnostic code No.
Bladder:	
Diverticulum of	7545
Erectile dysfunction, with or without penile deformity	7522
Interstitial nephritis, including gouty nephropathy, disorders of calcium metabolism	7537
Kidney:	
Cystic diseases of the	7533
Nephrolithiasis/Ureterolithiasis/Nephrocalcinosis	7508
Prostate gland injuries, infections, hypertrophy, postoperative residuals, bladder outlet obstruction	7527
Prostatitis, urethritis, epididymitis, orchitis (unilateral or bilateral), chronic only	7525

APPENDIX C TO PART 4—ALPHABETICAL INDEX OF DISABILITIES—Continued

	Diagnostic code No.
Renal:	
Disease caused by viral infection such as HIV, Hepatitis B, and Hepatitis C	7544
Involvement in diabetes mellitus type I or II	7541
Varicocele/Hydrocele	7543

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2018–0810, FRL–10001–04–Region 10]

Air Plan Approval; AK: Infrastructure Requirements for the 2015 Ozone Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: Whenever a new or revised National Ambient Air Quality Standard is promulgated, the Clean Air Act requires states to submit plans for the implementation, maintenance, and enforcement of such standard, commonly referred to as infrastructure requirements. On October 25, 2018, the State of Alaska submitted such a plan for the ozone standard revised on October 1, 2015. In this action, the Environmental Protection Agency (EPA) is proposing to approve the Alaska plan as meeting applicable infrastructure requirements.

DATES: Comments must be received on or before November 14, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2018–0810, at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not electronically submit any information you consider to be Confidential Business Information (CBI) or other information the disclosure of which 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. The 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, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

FOR FURTHER INFORMATION CONTACT: Kristin Hall, (206) 553–6357, hall.kristin@epa.gov, or Attn: Kristin Hall (15–H13), Air and Radiation Division, EPA Region 10, 1200 6th Avenue (Suite 155), Seattle, WA 98101.

SUPPLEMENTARY INFORMATION: Throughout this document wherever “we,” “us,” or “our” is used, it refers to the EPA.

Table of Contents

- I. Background
- II. Infrastructure Elements
- III. EPA Approach To Review of Infrastructure SIP Submissions
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I. Background

On October 1, 2015, the Environmental Protection Agency (EPA) revised the existing ozone National Ambient Air Quality Standard (NAAQS), lowering the level of both the primary and secondary standards from 0.075 parts per million (ppm) to 0.070 ppm, among other changes.¹ The revision triggered the Clean Air Act

¹ National Ambient Air Quality Standards for Ozone, Final rule (October 26, 2015, 80 FR 65292).

(CAA) requirement for states to submit State Implementation Plans (SIPs) addressing basic infrastructure elements required to implement, maintain, and enforce the 2015 ozone NAAQS. On October 25, 2018, the Alaska Department of Environmental Conservation (ADEC) made such a submission.²

II. Infrastructure Elements

The CAA provides the procedure and timing for infrastructure SIP submissions and lists the required elements, set forth at sections 110(a)(1) and (2), respectively. The EPA has issued guidance to help states address these requirements, most recently on September 13, 2013 (2013 Guidance).³ The elements and corresponding CAA subsections are listed below:

- 110(a)(2)(A): Emission limits and other control measures.
- 110(a)(2)(B): Ambient air quality monitoring/data system.
- 110(a)(2)(C): Program for enforcement of control measures.
- 110(a)(2)(D): Interstate transport.
- 110(a)(2)(E): Adequate resources.
- 110(a)(2)(F): Stationary source monitoring system.
- 110(a)(2)(G): Emergency episodes.
- 110(a)(2)(H): Future SIP revisions.
- 110(a)(2)(I): Areas designated nonattainment and applicable requirements of part D.

² Alaska’s October 25, 2018 submission not only addresses infrastructure requirements, but also requests EPA approval of regulatory updates and permitting rule revisions. The EPA approved the regulatory updates and permitting rule revisions in a separate rulemaking on August 29, 2019 (84 FR 45419).

³ Stephen D. Page, Director, Office of Air Quality Planning and Standards. “Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2).” Memorandum to EPA Air Division Directors, Regions 1–10, September 13, 2013. The 2013 Guidance is available in the docket for this action and at <https://www.epa.gov/air-quality-implementation-plans/infrastructure-sip-requirements-and-guidance>.