

and complete to the best of the individual's knowledge, information, and belief, and is made in good faith.

(iii) Submission of an opt-out notice does not constitute agreement by the rights owner or the individual submitting the opt-out notice that the proposed use is in fact noncommercial. The submitter may choose to comment upon whether the rights owner agrees that the proposed use is noncommercial use, but failure to do so does not constitute agreement that the proposed use is in fact noncommercial.

(3) *Multiple rights owners.* Where a pre-1972 sound recording has multiple rights owners, only one rights owner needs to file an opt-out notice for purposes of 17 U.S.C. 1401(c)(5).

(4) *Effect of opting out.* If a rights owner files a timely opt-out notice under paragraph (e)(1) of this section, the user must wait one year before filing another notice of noncommercial use proposing the same or similar use of the same pre-1972 sound recording(s).

(5) *Legal sufficiency.* The Copyright Office does not review opt-out notices submitted under paragraph (e)(1) of this section for legal sufficiency. The Office's review is limited to whether the procedural requirements established by the Office (including payment of the proper filing fee) have been met. Rights owners are therefore cautioned to review and scrutinize opt-out notices to assure their legal sufficiency before submitting them to the Office.

(6) *Filing date.* The date of filing of an opt-out notice is the date when a proper submission, including the prescribed fee, is received in the Copyright Office.

(7) *Fee.* The filing fee to submit an opt-out notice pursuant to this section is prescribed in § 201.3(c).

(f) *Fraudulent filings.* If the Register becomes aware of abuse or fraudulent filings under this section by or from a certain filer or user, she shall have the discretion to reject all submissions from that filer or user under this section for up to one year.

Dated: January 30, 2019.

Regan A. Smith,

General Counsel and Associate Register of Copyrights.

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 4

RIN 2900-AQ43

Schedule for Rating Disabilities: Infectious Diseases, Immune Disorders, and Nutritional Deficiencies

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend the section of the VA Schedule for Rating Disabilities (VASRD or Rating Schedule) that addresses infectious diseases and immune disorders. The purpose of these changes is to incorporate medical advances since the last revision, update medical terminology, and clarify evaluation criteria. The proposed rule considers comments from experts and the public during a forum held from January 31 to February 1, 2011, on revising this section of the VASRD.

DATES: Comments must be received by VA on or before April 8, 2019.

ADDRESSES: Written comments may be submitted through www.regulations.gov; by mail or hand-delivery to Director, Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Ave. NW, Room 1063B, Washington, DC 20420; or by fax to (202) 273-9026. (This is not a toll free number.) Comments should indicate that they are submitted in response to "RIN 2900-AQ43—Schedule for Rating Disabilities: Infectious Diseases, Immune Disorders, and Nutritional Deficiencies." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 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 (FDMS) at www.Regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Ioulia Vvedenskaya, M.D., M.B.A., Medical Officer, Part 4 VASRD Regulations Staff (211C), Compensation Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (202) 461-9700. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: As part of its ongoing revision of the VASRD, VA proposes changes to 38 CFR 4.88a,

which pertains to chronic fatigue syndrome (CFS), and 38 CFR 4.88b, which pertains to the schedule of ratings for infectious diseases and immune disorders (we note that the proposed changes for § 4.88b exclude the schedule of ratings for nutritional deficiencies—diagnostic codes (DC) 6313, 6314, and 6315). VA last updated the schedule of ratings in § 4.88b on July 31, 1996 (*see* 61 FR 39875) and updated § 4.88a on July 19, 1995 (*see* 60 FR 37012).

VA proposes to: (1) Update the medical terminology and definition of certain infectious diseases and immune disorders; (2) add medical conditions not currently in the Rating Schedule; (3) refine evaluation criteria based on medical advances that have occurred since the last revision; and (4) incorporate current understanding of functional changes associated with or resulting from disease (pathophysiology).

A panel of independent experts convened by the Institute of Medicine (IOM) in February 2015 proposed an updated set of diagnostic criteria for infectious disease and immune disorders. This updated revision also included changing the name of CFS to "Systemic Exertion Intolerance Disease (SEID)/Chronic Fatigue Syndrome (CFS)."

VA has clear authority to make this regulatory change because of its broad authority to "prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by [VA] and are consistent with those laws." 38 U.S.C. 501(a); *see also* 38 U.S.C. 1155 (VA's authority to adopt and apply schedule for rating disabilities).

§ 4.88a Chronic Fatigue Syndrome

Currently, § 4.88a specifies older diagnostic criteria for the diagnosis of CFS and uses outdated terminology to refer to this complex disease. VA proposes to update the nomenclature for this disease, which is also known as systemic exertion intolerance disease (SEID) or myalgic encephalomyelitis (ME), by changing the diagnostic code name to "Systemic Exertion Intolerance Disease (SEID)/Chronic Fatigue Syndrome (CFS)." This new name captures a central characteristic of the disease that reflects negative effects of any exertion (physical, cognitive, or emotional) on patients' many organ systems. IOM (Institute of Medicine), *Beyond Myalgic Encephalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness* (2015), <http://www.nationalacademies.org/hmd/~media/Files/Report%20Files/2015/>

MECFS/MECFScliniciansguide.pdf (last accessed August 30, 2018).

VA is also proposing to revise the current diagnostic criteria for SEID/CFS to adhere to evidence-based criteria which were adopted by the Centers for Disease Control and Prevention (CDC). *IOM Report on ME/CFS* (2015) (updated July 3, 2017), <https://www.cdc.gov/me-cfs/symptoms-diagnosis/diagnosis.html> (last accessed July 17, 2018). According to the 2015 IOM Report, up to 2.5 million Americans suffer from this disease which is characterized by profound fatigue, cognitive dysfunction, sleep abnormalities, pain, autoimmune manifestations, and a variety of other symptoms that are made worse by exertion of any sort. New diagnostic criteria will take into consideration whether this severe chronic fatigue significantly interferes with daily activities and work, if the affected individual concurrently has four or more of the eight symptoms as outlined in CDC evidence-based criteria and whether these symptoms first appeared before the fatigue, have persisted or recurred during six or more consecutive months of illness, and were due to ongoing exertion or other medical conditions associated with fatigue.

The CDC mandates a thorough medical history, physical examination, mental status examination, and laboratory tests to identify underlying or contributing conditions that require treatment. CDC recognizes and identifies several conditions that do not exclude a diagnosis of SEID/CFS. Currently, § 4.88b lists 19 DCs encompassing infectious diseases and immune disorders. VA proposes to revise these codes to reflect current terminology, advances in medical knowledge, recommendations from the 2015 IOM Report on ME/CFS and a 2007 IOM Report on evaluating veterans for disability benefits, IOM, *A 21st Century System For Evaluating Veterans for Disability Benefits* (2007), <https://www.nap.edu/read/11885/chapter/1> (last accessed July 17, 2018).

Schedule of Ratings—Infectious Diseases, Immune Disorders, and Nutritional Deficiencies

Proposed General Rating Formula for § 4.88b

Currently, each infectious disease listed under § 4.88b has its own prescribed rating criteria. In most cases, each specific infectious disease warrants a 100 percent evaluation during an active period of the disease. Thereafter, any residual functional impairment from the infectious disease determines the level of disability. These evaluation

principles are generally consistent with the clinical presentation of infectious diseases.

VA proposes one General Rating Formula for § 4.88b. This approach is based on the association between clinical resolution or stabilization of an infectious disease and elimination or complete suppression of the causative infectious agent. Regardless of whether resolution occurs spontaneously or because of treatment, long-term disability in such situations results from residual functional impairment of the body systems affected by the infectious disease, rather than the infection itself. Sheila Davey, World Health Organization, *World Health Organization Report on Infectious Diseases: Removing Obstacles to Healthy Development* (1999).

Therefore, VA's proposal to use a General Rating Formula does not substantively change the current evaluation criteria so much as their organization. This rulemaking proposes to restructure rating criteria by creating one General Rating Formula applicable to multiple infectious diseases, regardless of etiology. A General Rating Formula for infectious diseases would ensure consistency in rating these conditions and be similar to the use of a General Rating Formula in other sections of the VASRD, such as in §§ 4.97, 4.116, 4.130, and others. This formula would be a familiar concept for Veterans Benefits Administration (VBA) employees and minimize the risk for error by providing one criterion applicable to multiple diagnostic codes. Although each specific infectious disease has a different etiology and natural history, once the active disease phase is over, disability would be rated on residuals. VA would assign a 100 percent disability rating during the variable length of each specific disease's active phase. For most infectious diseases manifesting acutely, the length of the active disease phase (*i.e.*, the time between disease onset and resolution or stabilization) is at most usually six to eight weeks. VA proposes to assign a 100 percent evaluation during the active disease phase. VA recognizes that some infectious diseases, such as tuberculosis, may have a longer than average active disease phase. Therefore, VA proposes that the General Rating Formula apply only in those cases where specific rating criteria are not otherwise provided. Diagnostic codes in § 4.88b that would not follow the General Rating Formula would be 6301, 6302, 6310, 6311, 6312, 6313, 6314, 6315, 6325, 6326, 6351, and 6354.

After the disease becomes inactive, VA proposes to assign a 0 percent

evaluation. However, even though advancements in antimicrobial therapy have significantly lessened the occurrence of residuals of infectious diseases, they continue to occur. Therefore, VA generally proposes to append each diagnostic code with a note describing the most common residuals associated with a given infection. See below for additional details. As a list of every residual would be impractical, these notes would clearly indicate that they are not exhaustive. Where ascertainable residuals exist, VA proposes to assign evaluations for those residuals under the appropriate body system(s).

Certain infectious conditions are prone to relapse and require laboratory evaluation for confirmation. L. Joseph Wheat et al., *Clinical Practice Guidelines for the Management of Patients with Histoplasmosis: 2007 Update by the Infectious Diseases Society of America*, 45 *Clinical Infectious Diseases* 807, 807–25 (2007). Oftentimes, non-specific constitutional symptoms (weakness, tiredness, insomnia, weight loss, etc.) occur following the active phase of an infectious disease. However, such symptoms may be due to other causes than the infection. Therefore, to ensure VA assigns the most appropriate evaluations for relapsing infections, VA proposes to include a note in the rule requiring that relapses be confirmed by pathogen-specific testing using appropriate microbiologic, serologic, biochemical (*e.g.*, nucleic acid detection) histopathologic methods.

Finally, although VA proposes using a General Rating Formula for most infectious diseases, VA notes that each infectious disease has a different long-term impact. For those that have longer active phases and/or are commonly associated with relapse and residuals, VA proposes to require VA examination once the disease is no longer active so that a medical professional can evaluate the individual's condition. In these cases, VA also proposes to apply the provisions of § 3.105(e) that require VA to send beneficiaries notice of any proposed reduction in evaluation and provide an opportunity to respond before it becomes effective.

Proposed Changes to Existing Diagnostic Codes

As discussed above, VA proposes to apply a General Rating Formula for infectious diseases unless otherwise noted. Additionally, VA proposes to provide notes identifying common residuals associated with particular diseases and instructions to rating personnel regarding the level of medical

review necessary following cessation of treatment and infection. These specific proposed changes are discussed below.

Diagnostic Code 6300

Currently, DC 6300 is titled “Cholera, Asiatic” referring only to infection with toxigenic strains of *Vibrio cholerae*; it does not reflect infections due to other species within the genus *Vibrio*. Non-cholera *Vibrio* species cause diarrheal diseases, as well as wound infections and septicemia. To reflect the total array of diseases caused by *Vibrio* species, VA proposes to rename this DC “Vibriosis (cholera, non-cholera), to encompass conditions caused by *V. cholerae* and by non-cholera *Vibrio* organisms.

Cholera due to *V. cholerae* and gastroenteritis due to other *Vibrio* species are associated with severe diarrhea of relatively short duration. Hoi Ho et al., *Vibrio Infections*, *Medscape.com* (July 24, 2018), <http://emedicine.medscape.com/article/232038-overview>. Including the incubation period, cholera usually lasts 7 to 10 days and results in total remission, or, in 5 to 10 percent of cases, death if left untreated. Therefore, the proposed General Rating Formula would be appropriate for both cholera and non-cholera gastroenteritis due to other *Vibrio* species, and VA would remove the existing provision for a separate three-month convalescence period as it would no longer be necessary.

VA proposes to use a note to provide information about common residual disability of cholera and non-cholera *Vibrio* infection, including renal failure, skin, and musculoskeletal conditions, such as necrotizing fasciitis. VA proposes no changes to the evaluation criterion for this DC except eliminating the three-month convalescence and adding a note to address rating of residual disability.

Diagnostic Code 6301

VA evaluates DC 6301, visceral leishmaniasis, at 100 percent for six months following cessation of treatment, after which a VA examination helps determine residual disability. VA proposes only minor changes to this rating criteria, but proposes to change the note regarding rating residual disability. VA would generally identify those residuals commonly associated with post-infection or post-treatment residuals that may warrant evaluation. Currently, DC 6301 lists lymphadenopathy as one such residual disability. However, lymphadenopathy follows numerous diseases and is a frequent physical finding which, even when permanent, is

otherwise without symptoms or disability that would warrant evaluation. Robert Ferrer, *Lymphadenopathy: Differential Diagnosis and Evaluation*, 58 a.m. Fam. Physician 1313, 1313–20 (Oct. 15, 1998). In many cases, it may constitute a normal physical finding, Vikramjit S. Kanwar, *Lymphadenopathy*, *Medscape.com* (Feb. 1, 2018), <http://emedicine.medscape.com/article/956340-overview>.

As lymphadenopathy is often associated with other diseases and, regardless of origin, commonly presents without symptoms or disability warranting evaluation, VA proposes to remove it from the note in DC 6301. VA notes that the list of possible residuals in proposed DC 6301 would not be exhaustive. Thus, if a veteran presents with lymphadenopathy as a residual of visceral leishmaniasis that results in chronic, functional impairment, VA would consider an evaluation under the appropriate system.

In addition to the above revision, VA proposes to amend the existing Note 1 to inform that the residual effects of infection include bone marrow diseases. *Parasites—Leishmaniasis*, CDC (Jan. 10, 2013), <https://www.cdc.gov/parasites/leishmaniasis/index.html>. This note would also refer to the residuals listed in 38 CFR 3.317(d), “Long-term health effects potentially associated with infectious diseases.”

Finally, VA proposes to add a new Note 2 to address the use of culture, histopathology, and other diagnostic testing to confirm relapses. Clinicians rely on such diagnostic testing, which has increased steadily in accuracy and availability, to determine whether symptoms are due to leishmaniasis or some other disease. Shyam Sundar & M. Rai, “Laboratory Diagnosis of Visceral Leishmaniasis,” 9 *Clinical and Diagnostic Laboratory Immunology* 951, 951–58 (2002). VA also proposes to retitle the existing note as Note 1 to account for the addition of this second note.

Diagnostic Code 6302

VA would not change the rating criteria for leprosy (Hansen’s disease), but proposes to amend the current Note under DC 6302 by adding amputations as a residual in the proposed Note. The neurologic impairment in leprosy involves sensory and motor deficits/loss in the extremities that may lead to auto-amputation. Preenon Bagchi et al., *Bacterio-Informatics: Identifying the Cause of Hansen’s Disease and Establish [sic] a Remedy for the Same*, 2 *Int’l J. of Bioinformatics Res. and Applications* 15, 15–19 (2010).

Diagnostic Code 6304

VA proposes to evaluate DC 6304, malaria, using the General Rating Formula because it is an acute, debilitating disease with predictable clinical presentation.

VA proposes to amend an existing note and to add one new note. Note 1 would explicitly state that VA requires diagnostic confirmation for both the initial diagnosis and any relapse. To reflect advances in malarial testing, VA also proposes to refer to other specific diagnostic tests such as antigen detection, immunologic (immunochromatographic) tests, and molecular testing, such as polymerase chain reaction tests. *Malaria Diagnosis (United States)*, CDC (Nov. 19, 2015), https://www.cdc.gov/malaria/diagnosis_treatment/diagnosis.html.

Note 2 would recognize potential nervous system residuals because severe forms of malaria affect the brain as an encephalopathy. Pralay Sarkar et al., “Critical care aspects of malaria,” 25 *J. of Intensive Care Med.* 93, 93–103 (2010). In addition, this note would also refer to the residuals listed in § 3.317(d).

Diagnostic Code 6305

VA proposes to amend the title of this DC, currently “Lymphatic filariasis,” to include the term elephantiasis, which is another name commonly associated with the chronic form of this condition. *Lymphatic Filariasis Fact Sheet No. 102*, World Health Organization (May 11, 2018), <http://www.who.int/mediacentre/factsheets/fs102/en/>.

The new General Rating Formula would provide 100 percent evaluation for the acute phase of active infection for lymphatic filariasis. The proposed General Rating Formula would be appropriate for use in this acute infection. However, no actual changes in the evaluation criteria would result from this organizational change intended to help rating personnel easily apply the VASRD.

VA proposes to add information to more adequately address the range of potential residuals, which include lymphedema (permanent swelling) and lymphatic obstruction. *Parasites—Lymphatic Filariasis*, CDC (June 14, 2013), <http://www.cdc.gov/parasites/lymphaticfilariasis/disease.html>. VA proposes a new Note to instruct rating personnel to evaluate under the appropriate body system residuals such as epididymitis, lymphangitis, lymphatic obstruction, or lymphedema affecting extremities, genitals, and/or breasts.

Diagnostic Code 6306

Bartonellosis, currently evaluated under DC 6306, generally resolves within two months with appropriate treatment. Kassem A. Hammoud et al., *Bartonellosis*, Medscape.com (Oct. 17, 2012), <http://emedicine.medscape.com/article/213169-overview>. Therefore, VA proposes to rate active bartonellosis under the General Rating Formula at 100 percent, and VA would remove the existing provision for a separate three-month convalescence period as it would no longer be necessary.

VA also proposes to update the residual disability to include endocarditis, which occurs when the bloodstream may carry this bacterium to the heart valves. John L. Bruschi et al., *Infective Endocarditis—Pathophysiology*, Medscape.com (Dec. 17, 2013), <http://emedicine.medscape.com/article/216650-overview#a0104>.

Diagnostic Code 6307

VA proposes to evaluate DC 6307, plague, which is an acute, debilitating disease of short duration, using the General Rating Formula.

Use of modern antibiotics renders residual disability from the infection itself extremely rare. Therefore, VA proposes to delete the existing note regarding specific residuals and replace it with a note stating that VA would rate any residual disability under the appropriate body system. Again, lymphadenopathy is a frequent physical finding following numerous diseases, often permanent and without disabling symptoms. Robert Ferrer, *Lymphadenopathy: Differential Diagnosis and Evaluation*, 58 Am.Fam. Physician at 1313–20. VA proposes removing lymphadenopathy as a residual because it may be a normal physical finding. Vikramjit S. Kanwar, *Lymphadenopathy*, Medscape.com (July 10, 2015), <http://emedicine.medscape.com/article/956340-overview>; *Plague*, CDC (Nov. 28, 2012), <http://www.cdc.gov/plague/>.

Diagnostic Code 6308

VA proposes to evaluate DC 6308, relapsing fever, which is an acute, debilitating disease of short duration, using the General Rating Formula.

Modern treatment helps most patients recover from this disease within a few days, with little incidence of splenic damage. Long-term sequelae of relapsing fever are rare, but include iritis, uveitis, cranial nerve, and other neuropathies. *Tick-borne Relapsing Fever (TBRF)*, CDC (Jan. 8, 2016), <http://www.cdc.gov/relapsing-fever/clinicians/>. Therefore,

VA proposes a new Note adding iritis and uveitis as residual disabilities and retaining the remainder of the existing information without substantive change.

VA does not propose any changes to the evaluation criteria for this DC.

Diagnostic Code 6309

VA proposes to evaluate DC 6309, rheumatic fever, which is an acute, febrile disease typically lasting less than a month, using the General Rating Formula. The existing note regarding residuals would remain substantively unchanged.

Diagnostic Code 6310

VA does not propose substantive change to the criteria under diagnostic code 6310 for syphilis and other treponemal infections. However, for consistency with the remainder of this section, VA proposes to replace the term “complications” with the term “residual disability,” which VA would rate under the appropriate body system.

Additionally, VA proposes to remove specific references to the names associated with each DC identified in this note because future revisions of the rating schedule would retitle several of them.

Diagnostic Code 6311

Currently, DC 6311, miliary tuberculosis, provides a 100 percent evaluation during active infection. Under § 4.88c, the 100 percent is continued for one year following the date of inactivity. Active infection may last for months to years, and, if undiagnosed or untreated, may result in death. The standard treatment for drug-susceptible miliary tuberculosis is six to nine months with a combination of anti-tuberculosis drugs. If the meninges are involved, treatment will last for 9 to 12 months, but may occasionally require longer a treatment duration. Nahid, P., et al., “Executive Summary: Official American Thoracic Society/Centers for Disease Control and Prevention/ Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis,” 63 *Clinical Infectious Diseases* 853, 853–867 (Oct. 2016), <https://www.nidcd.nih.gov/health/balance/pages/meniere.aspx> (last visited January 22, 2019). Relapses are common when medication is not taken for the full time prescribed and/or not taken in the appropriate combination. Generally, most relapses occur within the first 12 months of treatment completion. *Tuberculosis (TB) Guidelines*. CDC (May 4, 2016), <https://www.cdc.gov/tb/publications/guidelines/treatment.htm>.

To ensure that individuals are entitled to any resumption or continuation of the 100 percent evaluation after the initial active disease, VA proposes to add a Note requiring confirmation of relapse by culture, histopathology, or other diagnostic laboratory testing.

VA also proposes Note 2 addressing residuals which may be found under § 4.88c. Infection residuals include, but are not limited to, chronic diagnosed disabilities affecting such body systems as the skin and respiratory, central nervous, musculoskeletal, ocular, gastrointestinal, and genitourinary systems. VA would rate them under the appropriate body system. J.J. van der Harst & G.J. Luijckx, *Treatment of Central Nervous System Tuberculosis Infections and Neurological Complications of Tuberculosis Treatment*, 17 *Current Pharmaceutical Design* 2940, 2940–47 (2011).

Diagnostic Code 6316

VA proposes to evaluate DC 6316, brucellosis, an acute, debilitating disease of short duration usually lasting several weeks or less, using the General Rating Formula. Brucellosis is easily treated with antibiotics, but, if untreated, brucellosis may become chronic and leave significant residuals. VA proposes no changes to the evaluation criteria.

As the correct diagnosis is essential in determining if symptoms are due to brucellosis or some other disease entity, VA proposes to add a new Note 1 directing that culture, serologic testing, or both must confirm both the initial diagnosis and any relapse of active infection. Wafa Al-Nassir, *Brucellosis*, Medscape.com (June 16, 2017), <http://emedicine.medscape.com/article/213430-overview>.

VA proposes to amend the existing note as Note 2 and expand the list of residuals in light of advances in medicine and early treatment. Note 2 would reflect the residuals most commonly associated with this infection, including meningitis, and liver, spleen, or musculoskeletal conditions. *Brucellosis*, CDC (Sept. 13, 2017) <http://www.cdc.gov/brucellosis/index.html>. As this condition is a presumptive disease related to Gulf War service, this note would also refer to the many specific residuals of brucellosis listed in § 3.317(d).

Diagnostic Code 6317

Currently, DC 6317 represents scrub typhus, an acute debilitating rickettsial disease lasting for several weeks or less. If untreated, a high mortality rate results. Antibiotic treatment rapidly eradicates the disease and significantly

reduces the chances of complications. Therefore, VA proposes to evaluate DC 6317 using the General Rating Formula. VA proposes to rename this DC to encompass all forms of rickettsial and similar ehrlichial and *Anaplasma* infections. These infections are not specific to the veteran population as they afflict travelers and field scientists as well. Renaming this DC would mean rating personnel need not further clarify the type of typhus infecting a veteran.

VA is not proposing any changes to the evaluation criteria except to use the General Rating Formula. VA would also remove the existing provision for a separate three-month convalescence period as it would no longer be necessary.

VA proposes to update the existing note to include such residuals frequently associated with DC 6317 as involvement of bone marrow and the central nervous system, in addition to the current list of spleen damage or skin conditions.

Rickettsial, ehrlichial, and *Anaplasma* infections cause similar nonspecific influenza-like illness in humans, including but not limited to, scrub typhus, Rocky Mountain spotted fever, African tick-borne fever, ehrlichiosis, and anaplasmosis. Therefore, VA also proposes to add a second note to list other rickettsial infections, including infections by *Ehrlichia* and *Anaplasma* species (members of the order Rickettsiales) to account for its occurrence in the U.S. veteran population. Johan S. Bakken & J. Stephen Dumler, *Ehrlichiosis and Anaplasmosis*, *Medscape.com* (2004), https://www.medscape.com/viewarticle/490468_4.

Diagnostic Code 6318

Currently, DC 6318 represents melioidosis, an acute debilitating bacterial disease lasting several weeks or less, which, if left untreated, may result in mortality. VA proposes no changes to the evaluation criteria, except use of the General Rating Formula.

As accuracy is essential in diagnosing melioidosis, VA proposes to add Note 1 directing that culture or other specific diagnostic laboratory tests must confirm both the initial diagnosis and any relapse or chronic activity of infection.

VA would retain the existing information regarding common residuals and the instruction to rate residuals under the appropriate body system under Note 2.

Diagnostic Code 6319

VA currently assigns a 100 percent evaluation for DC 6319, Lyme disease,

when it is active. Lyme disease is an acute illness, usually lasting several weeks or less. Therefore, VA proposes to rate Lyme disease under the General Rating Formula, without changes to the actual evaluation criteria. VA also proposes to amend the existing note associated with this DC to account for residuals such as Bell's palsy, radiculopathy, ocular, and cognitive dysfunction, in addition to arthritis.

Diagnostic Code 6320

Currently, DC 6320 represents "Parasitic diseases otherwise not specified." VA proposes no changes to the evaluation criteria except to use the General Rating Formula. VA also proposes to amend the existing note associated with this DC with general instructions to rate any residuals of this infection under the appropriate body system.

Diagnostic Code 6351

VA proposes a number of changes to DC 6351, which pertains to human immunodeficiency virus (HIV) related illness. Currently, VA provides a 100 percent evaluation for "AIDS with recurrent opportunistic infections or with secondary diseases affecting multiple body systems; HIV-related illness with debility and progressive weight loss, without remission, or few or brief remissions." VA proposes to remove the statement about remission because the CDC considers AIDS a chronic condition, and the diagnosis continues once a person is properly diagnosed, regardless of improvements in that person's condition.

When VA last revised the evaluation criteria, the medical community considered oral hairy leukoplakia (OHL) a distinctive clinical marker of HIV infection. Since then, measurement of the peripheral CD4 cell count and HIV viral load have become the standard method for evaluating a patient's stage of HIV infection. Sowmya Nanjappa, *Anti-retroviral Therapy in Treatment-Naïve Patients*, *Medscape.com* (June 3, 2016), <https://emedicine.medscape.com/article/2041458-overview>. In addition, OHL by itself rarely, if ever, requires specific treatment in patients receiving anti-retroviral therapy. James Cade, *Hairy Leukoplakia Treatment and Management*, *Medscape.com* (December 19, 2018), <https://emedicine.medscape.com/article/279269-overview>. VA proposes to remove reference to OHL in the criteria for a 30 percent evaluation.

Similarly, VA proposes to modify the reference of oral candidiasis to esophageal and lower respiratory tract

candidiasis for the criteria for a 30 percent evaluation. In the past, oral candidiasis was strongly associated with HIV infection. However, the increased use of antiretroviral medications has greatly reduced the incidence of this condition in HIV-positive individuals. C. Frezzini et al., *Current Trends of HIV Disease of the Mouth*, 34 *J. of Oral Pathology & Med.* 513, 513-31 (2005).

For clarification, VA proposes to replace the phrase "definite medical symptoms" in the criteria for a 10 percent evaluation with "HIV-related constitutional symptoms." VA would not change the remainder of the criteria for a 10 percent evaluation. The criteria for a 0 percent evaluation would not change.

Existing Note 1 would continue to provide that "medications prescribed as part of a research protocol at an accredited medical institution" are to be considered "approved medication" within the context of the evaluation criteria. VA proposes to add a reference to treatment regimens as part of a research protocol at an accredited medical institution because some research protocols use not only new medications but also new regimens for already FDA approved medications.

Existing Note 2 would continue to provide for separate evaluation of various manifestations of HIV infection under the appropriate diagnostic codes. VA proposes to retain the instruction to evaluate on the basis of psychiatric or central nervous system manifestations, opportunistic infections, and neoplasms, rather than based on this diagnostic code, if a higher overall evaluation results. However, VA proposes to substitute the term "diagnosed psychiatric condition" for the phrase "psychiatric manifestations." VA recognizes that a veteran may exhibit psychiatric symptoms, such as depression, which do not rise to the level of a diagnosed disability. Such symptoms are more appropriately rated under DC 6351 as 10 percent disabling, provided there is evidence of activity limitations. Note 2, however, would refer to diagnosed, disabling acquired psychiatric illness.

VA also proposes the addition of a new Note 3 to assist rating personnel in applying these revised evaluation criteria. Note 3 would include a list of current opportunistic infections, which includes the following conditions: Candidiasis of the bronchi, trachea, esophagus, or lungs; invasive cervical cancer; coccidioidomycosis; cryptococcosis; cryptosporidiosis; cytomegalovirus (particularly CMV retinitis); HIV-related encephalopathy; herpes simplex-chronic ulcers of greater

than one month's duration, or bronchitis, pneumonia, or esophagitis; histoplasmosis; isosporiasis (chronic intestinal); Kaposi's sarcoma; lymphoma; *Mycobacterium avium* complex; tuberculosis; *Pneumocystis jirovecii* (carinii) pneumonia; pneumonia, recurrent; progressive multifocal leukoencephalopathy; *Salmonella* septicemia, recurrent; toxoplasmosis of the brain; and wasting syndrome due to HIV. *AIDS and Opportunistic Infections*, CDC (July 23, 2018), <https://www.cdc.gov/hiv/basics/livingwithhiv/opportunisticinfections.html>.

Diagnostic Code 6354

VA is proposing no change to the rating criteria for this DC other than to update the name from chronic fatigue syndrome (CFS) to systemic exertion intolerance disease/chronic fatigue syndrome (CFS). VA would, however, clarify the note to indicate that incapacitation requires that a licensed physician must prescribe both bed rest and treatment, which would be consistent with current VA practice.

Proposed New Diagnostic Codes

As discussed above, in addition to updating existing DCs, VA proposes to add medical conditions not currently listed in the Rating Schedule:

Proposed New Diagnostic Code 6312

VA proposes to add a new DC 6312 for "Nontuberculosis mycobacterial infection" (NTM). NTM lung infection occurs when a person inhales the organism from the environment. Most people do not become ill but some susceptible individuals require prolonged treatment of one to two years. Without treatment, many people, but not all, will develop a progressive lung infection characterized by cough, fatigue, and often weight loss. However, death directly related to NTM lung disease is relatively rare in immunocompetent individuals.

Systemic infection, which is the most severe form, is most often seen in individuals with other underlying conditions, especially those that inhibit immune function. Arry Dieudonne, *Atypical Mycobacterium Infection*, *Medscape.com* (Feb. 7, 2018), <http://emedicine.medscape.com/article/972708-overview>.

Similar to other infectious diseases found in the Rating Schedule, VA proposes to assign a 100 percent evaluation during active infection, after which a mandatory VA evaluation would be conducted to determine the appropriate evaluation based on residuals, if any. Therefore, VA

proposes a Note 1 to this effect and instructs that any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e). Furthermore, the note would instruct rating personnel to rate on residuals if there is no relapse.

Establishing the correct diagnosis is essential in determining if symptoms are due to NTM or some other disease entity. Diagnostic testing has become more accurate and readily available over the years. Therefore, VA proposes a Note 2, requiring diagnostic confirmation for subsequent relapses.

VA proposes to include Note 3, which would identify common residuals to assist rating personnel in assigning evaluations following cessation of the 100 percent evaluation. Residuals of infection identified in Note 3 would include skin conditions and conditions of the respiratory, central nervous, musculoskeletal, ocular, gastrointestinal, and genitourinary systems.

Proposed New Diagnostic Code 6325

VA proposes to add new DC 6325 which applies to hyperinfection syndrome or disseminated strongyloidiasis. Because strongyloidiasis is not an acute, self-limited disease, VA would not use the General Rating Formula. Similar to other severe infectious diseases, VA proposes to assign a 100 percent evaluation during active disease followed by a mandatory VA evaluation to determine the appropriate evaluation based on any residuals. Systemic infection, which is the most severe form of strongyloidiasis, with a mortality rate approaching 90 percent, is most often seen in individuals with other underlying conditions, especially those with compromised immune function. *Parasites—Strongyloides, Resources for Health Professionals*, CDC (Jan. 6, 2012), <http://www.cdc.gov/parasites/strongyloides/>. VA is not proposing to list the most common residuals because their number is so vast.

Proposed New Diagnostic Code 6326

VA proposes a new diagnostic code for schistosomiasis, the second most common parasitic disease in the world. *Parasites—Schistosomiasis*, CDC (Apr. 30, 2018), <http://www.cdc.gov/parasites/schistosomiasis/>. While the parasite is not found in the United States, it is sufficiently prevalent in tropical regions that VA may presume service connection if records indicate service in such regions. See 38 CFR 3.309(b). VA is proposing to add a distinct DC for schistosomiasis because it otherwise lacks a means to accurately track such

claims and can evaluate them only by analogy.

Most people who contract schistosomiasis are asymptomatic and have subclinical disease during both acute and chronic stages of infection. Persons with acute infection (also known as Katayama syndrome) may present with mild symptoms such as rash, fever, headache, myalgia, and respiratory symptoms that are not disabling.

Chronic disease results from host immune responses to schistosome eggs: *S. mansoni* and *S. japonicum*. These eggs most commonly lodge in the blood vessels of the liver or intestine with chronic inflammation leading to bowel wall ulceration, hyperplasia, and polyposis and, with heavy infections, to liver fibrosis and portal hypertension.

S. haematobium eggs tend to lodge in the urinary tract and the female genital tract. Female genital schistosomiasis can affect the cervix, fallopian tubes, and vagina.

Central nervous system lesions, such as in the spinal cord or brain and inflammatory reactions, may cause the formation of granulomas that act as space-occupying lesions.

VA proposes to evaluate DC 6326 by assigning a 0 percent evaluation for acute and asymptomatic chronic infections. Additionally, VA proposes to note common residuals of infection, such as liver and genitourinary tract conditions. VA would rate residual disability in the appropriate system.

Proposed New Diagnostic Code 6329

VA proposes new DC 6329 to encompass hemorrhagic fevers, including dengue, yellow fever, and others. While these fevers are uncommon in the United States, they are prevalent in tropical regions and, therefore, associated with military deployments. David C. Pigott, *CBRNE—Viral Hemorrhagic Fevers*, *Medscape.com* (Mar. 16, 2017), <https://emedicine.medscape.com/article/830594-overview>. VA may presume service connection for hemorrhagic fever if records indicate service in certain regions. See 38 CFR 3.309(b). VA is proposing to add a distinct DC for hemorrhagic fever because it otherwise lacks a means to accurately track such claims and can evaluate them only by analogy.

VA proposes to apply the General Rating Formula and assign a 100 percent evaluation for active disease because hemorrhagic fever is associated with a debilitating, acute, febrile illness that often lasts for several weeks at most. VA also proposes to include a note listing common residual disabilities of central

nervous system, liver, or kidney conditions.

Proposed New Diagnostic Code 6330

VA proposes new DC 6330 for infections caused by *Campylobacter jejuni*. In 2010, VA issued a regulation establishing that *Campylobacter jejuni* is subject to presumptive service connection for certain veterans because it is (1) prevalent in Southwest Asia, (2) has been diagnosed among U.S. troops serving in the Persian Gulf/Southwest Asia Theater of operations, and (3) is known to cause long-term adverse health effects. See 75 FR 59968 and 38 CFR 3.317. To monitor claims for this infection, VA proposes a diagnostic code specifically for *Campylobacter jejuni*.

VA proposes to rate *Campylobacter jejuni* infection under the General Rating Formula, meaning that it would receive a 100 percent evaluation during active infection. The symptoms of *Campylobacter jejuni* infection consist of diarrhea, cramping, abdominal pain, and fever within two to five days after exposure to the bacteria. The diarrhea may be bloody and can be accompanied by nausea and vomiting. The illness typically lasts about one week. *Campylobacter (Campylobacteriosis)*, CDC (Aug. 30, 2017), <https://www.cdc.gov/campylobacter/index.html>.

Thereafter, VA would rate the condition based on residuals listed in § 3.317(d), “Long-Term Health Effects Potentially Associated With Infectious Diseases,” such as Guillain-Barre syndrome, reactive arthritis, and uveitis.

Proposed New Diagnostic Code 6331

VA proposes a new diagnostic code to encompass infections caused by *Coxiella burnetii*. In 2010, VA issued a regulation establishing that infection due to *Coxiella burnetii* (Q fever) is subject to presumptive service connection for certain veterans because it is (1) prevalent in Southwest Asia, (2) has been diagnosed among U.S. troops serving in the Persian Gulf/Southwest Asia theater of operations, and (3) is known to cause long-term adverse health effects. See 75 FR 59968 and 38 CFR 3.317. To track claims for this infection, VA proposes a diagnostic code specifically for *Coxiella burnetii* infection (Q fever).

VA proposes assigning a 100 percent evaluation during active infection according to the General Rating Formula. Thereafter, VA would rate the condition based on residuals listed in § 3.317(d), such as chronic hepatitis, endocarditis, osteomyelitis, post Q-fever

chronic fatigue syndrome, and vascular infections.

Proposed New Diagnostic Code 6333

VA proposes a new diagnostic code to encompass infections caused by nontyphoidal *Salmonella*. In 2010, VA issued a regulation establishing that nontyphoidal salmonellosis is subject to presumptive service connection for certain veterans. See 75 FR 59968 and 38 CFR 3.317. To track claims decisions regarding this infection and to more consistently rate it, VA proposes a diagnostic code specifically for nontyphoidal salmonellosis.

VA proposes to assign a 100 percent evaluation during active infection according to the General Rating Formula. Thereafter, VA would rate the condition based on residuals, including those listed in § 3.317(d), such as reactive arthritis.

Proposed New Diagnostic Code 6334

VA proposes a new diagnostic code to encompass infections caused by *Shigella*, which would be rated under the General Rating Formula. In 2010, VA issued a regulation presuming service connection for *Shigella* infection in certain veterans. See 75 FR 59968 and 38 CFR 3.317. To allow for better tracking of decisions on claims for this infection and to more consistently rate it, VA proposes a diagnostic code specifically for *Shigella* infection.

VA would rate the condition based on residuals, including those listed in § 3.317(d), such as hemolytic-uremic syndrome, and reactive arthritis.

Proposed New Diagnostic Code 6335

VA proposes a new diagnostic code to encompass infections caused by West Nile virus. In 2010, VA issued a regulation presuming service connection for West Nile virus in certain veterans. See 75 FR 59968. To better track claims decisions regarding this infection, VA proposes a separate diagnostic code for West Nile virus, which would be rated under the General Rating Formula.

VA would rate the condition based on residuals, including those listed in § 3.317(d), such as variable physical, functional, or cognitive disability.

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. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” which requires review by the Office of Management and Budget (OMB), as “any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in this Executive Order.”

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined, and it has been determined not to be a significant regulatory action under E.O. 12866. VA’s impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of this rulemaking and its impact analysis are available on VA’s website at <http://www.va.gov/orpm/>, by following the link for “VA Regulations Published From FY 2004 Through Fiscal Year to Date.”

This rule is not an E.O. 13771 regulatory action because this rule is not significant under E.O. 12866.

Regulatory Flexibility Act

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

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any given year. This proposed rule would 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).

Catalog of Federal Domestic Assistance Numbers and Titles

The Catalog of Federal Domestic Assistance program numbers and titles for this rule are 64.102, Compensation for Service-Connected Deaths for Veterans' Dependents; 64.105, Pension to Veterans, Surviving Spouses, and Children; 64.109, Veterans Compensation for Service-Connected Disability; and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

List of Subjects in 38 CFR Part 4

Disability benefits, Pensions, Veterans.

Signing Authority

The Secretary of Veterans Affairs 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 January 29, 2019, for publication.

Dated: January 29, 2019.

Jeffrey M. Martin,

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

For the reasons stated in the preamble, the Department of Veterans

Affairs proposes to amend 38 CFR part 4 as set forth below:

PART 4—SCHEDULE FOR RATING DISABILITIES

Subpart B—Disability Ratings

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

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

■ 2. Revise § 4.88a to read as follows:

§ 4.88a Systemic exertion intolerance disease/chronic fatigue syndrome (CFS).

(a) For VA purposes, the diagnosis of Systemic Exertion Intolerance Disease/Chronic Fatigue Syndrome (CFS) must meet the following conditions:

- (1) A severe chronic fatigue that significantly interferes with daily activities and work.
- (2) The individual concerned concurrently has four or more of the following eight symptoms:
 - (i) Post-exertion malaise lasting more than 24 hours
 - (ii) Unrefreshing sleep
 - (iii) Significant impairment of short-term memory or concentration
 - (iv) Muscle pain
 - (v) Pain in the joints without swelling or redness
 - (vi) Headaches of a new type, pattern, or severity
 - (vii) Tender lymph nodes in the neck or armpit
 - (viii) Sore throat that is frequent or recurring
- (3) These symptoms:
 - (i) Cannot have first appeared before the fatigue
 - (ii) Have persisted or recurred during six or more consecutive months of illness, and
 - (iii) Are not due to ongoing exertion or other medical conditions associated with fatigue, as ruled out by a physician who administered relevant diagnostic tests.

(b) Several past or current medical conditions exclude the diagnosis of systemic exertion intolerance disease/ CFS to include:

(1) Any active condition that may explain the presence of chronic fatigue, such as untreated hypothyroidism, sleep

apnea, narcolepsy, and iatrogenic conditions such as side effects of medication.

(2) Some illnesses, including some types of cancers and chronic cases of hepatitis B or C virus infection, which could explain the presence of chronic fatigue, and which have not clearly and completely resolved.

(3) Any past or current diagnosis of: major depressive disorder with psychotic or melancholic features, bipolar affective disorders, anorexia nervosa, bulimia nervosa, or any subtype of schizophrenia, delusional disorders, or dementias.

(4) Alcohol or other substance abuse, occurring within two years of the onset of chronic fatigue and any time afterwards.

(5) Severe obesity, defined as having a body mass index equal to or greater than 45. [Body mass index = weight in kilograms ÷ (height in meters)²].

(6) Examination or testing detects any abnormality that strongly suggests an exclusionary condition that needs to be treated or resolved before attempting further diagnosis. Once fully treated, diagnose accordingly if the individual still meets criteria for Systemic Exertion Intolerance Disease (SEID)/Chronic Fatigue Syndrome (CFS).

■ 3. Amend § 4.88b by:

- a. Revising the entries for diagnostic codes 6300 through 6302 and 6304 through 6311;
- b. Adding in numerical order an entry for diagnostic code 6312;
- c. Revising the entries for diagnostic codes 6316 through 6320;
- d. Adding in numerical order entries for diagnostic codes 6325, 6326, 6329 through 6331, and 6333 through 6335; and
- e. Revising the entries for diagnostic codes 6351 and 6354.

The revisions and additions read as follows:

§ 4.88b Schedule of ratings-infectious diseases, immune disorders, and nutritional deficiencies.

Rating

General Rating Formula for Infectious Diseases:

For active disease 100
 After active disease has resolved, rate at 0 percent for infection. Rate any residual disability of infection within the appropriate body system.

6300 Vibriosis (Cholera, Non-cholera):

Evaluate under the General Rating Formula.

Note: Rate residuals of cholera and non-cholera *Vibrio* infections, such as renal failure, skin, and musculoskeletal conditions, within the appropriate body system.

		Rating
6301	<p>Visceral leishmaniasis: As active disease 100 <i>Note 1:</i> Continue a 100 percent evaluation beyond the cessation of treatment for active disease. Six months after discontinuance of such treatment, determine the appropriate disability rating by mandatory VA examination. Any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter. Thereafter, rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, liver damage, bone marrow disease, and those residuals listed in § 3.317(d) of this chapter. <i>Note 2:</i> Confirm the recurrence of active infection by culture, histopathology, or other diagnostic laboratory testing.</p>	100
6302	<p>Leprosy (Hansen's disease): As active disease 100 <i>Note:</i> Continue a 100 percent evaluation beyond the cessation of treatment for active disease. Six months after discontinuance of such treatment, determine the appropriate disability rating by mandatory VA examination. Any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter. Thereafter, rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, skin lesions, peripheral neuropathy, or amputations.</p>	100
6304	<p>Malaria: Evaluate under the General Rating Formula. <i>Note 1:</i> The diagnosis of malaria, both initially and during relapse, depends on the identification of the malarial parasites in blood smears or other specific diagnostic laboratory tests such as antigen detection, immunologic (immunochromatographic) tests, and molecular testing such as polymerase chain reaction tests. <i>Note 2:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, liver or splenic damage, central nervous system conditions, and those residuals listed in § 3.317(d) of this chapter.</p>	
6305	<p>Lymphatic filariasis, to include elephantiasis: Evaluate under the General Rating Formula. <i>Note:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, epididymitis, lymphangitis, lymphatic obstruction, or lymphedema affecting extremities, genitals, and/or breasts.</p>	
6306	<p>Bartonellosis: Evaluate under the General Rating Formula. <i>Note:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, endocarditis or skin lesions.</p>	
6307	<p>Plague: Evaluate under the General Rating Formula. <i>Note:</i> Rate under the appropriate body system any residual disability of infection.</p>	
6308	<p>Relapsing Fever: Evaluate under the General Rating Formula. <i>Note:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, liver or spleen damage, iritis, uveitis, or central nervous system involvement.</p>	
6309	<p>Rheumatic fever: Evaluate under the General Rating Formula. <i>Note:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, heart damage.</p>	
6310	<p>Syphilis, and other treponemal infections: <i>Note :</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, diseases of the nervous system, vascular system, eyes, or ears (see DC 7004, DC 8013, DC 8014, DC 8015, and DC 9301).</p>	
6311	<p>Tuberculosis, miliary: As active disease 100 Inactive disease: See §§ 4.88c and 4.89. <i>Note 1:</i> Confirm the recurrence of active infection by culture, histopathology, or other diagnostic laboratory testing. <i>Note 2:</i> Rate under the appropriate body system any residual disability of infection which includes, but is not limited to, skin conditions and conditions of the respiratory, central nervous, musculoskeletal, ocular, gastrointestinal, and genitourinary systems and those residuals listed in § 4.88c of this chapter.</p>	100
6312	<p>Nontuberculosis mycobacterial infection: As active disease 100 <i>Note 1:</i> Continue the rating of 100 percent for the duration of treatment for active disease followed by a mandatory VA exam. If there is no relapse, rate on residuals. Any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter. <i>Note 2:</i> Confirm the recurrence of active infection by culture, histopathology, or other diagnostic laboratory testing. <i>Note 3:</i> Rate under the appropriate body system any residual disability of infection which includes, but is not limited to, skin conditions and conditions of the respiratory, central nervous, musculoskeletal, ocular, gastrointestinal, and genitourinary systems and those residuals listed in § 4.88c of this chapter.</p>	100
* * * * *		
6316	<p>Brucellosis: Evaluate under the General Rating Formula. <i>Note 1:</i> Culture, serologic testing, or both must confirm the initial diagnosis and recurrence of active infection. <i>Note 2:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, meningitis, liver, spleen and musculoskeletal conditions, and those residuals listed in § 3.317(d) of this chapter.</p>	
6317	<p>Rickettsial, ehrlichial, and Anaplasma infections: Evaluate under the General Rating Formula. <i>Note 1:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, bone marrow, spleen, central nervous system, and skin conditions. <i>Note 2:</i> This diagnostic code includes, but is not limited to, scrub typhus, Rickettsial pox, African tick-borne fever, Rocky Mountain spotted fever, ehrlichiosis, or anaplasmosis.</p>	
6318	<p>Melioidosis:</p>	

		Rating
	Evaluate under the General Rating Formula. <i>Note 1:</i> Confirm by culture or other specific diagnostic laboratory tests the initial diagnosis and any relapse or chronic activity of infection. <i>Note 2:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, arthritis, lung lesions, or meningitis.	
6319	Lyme disease: Evaluate under the General Rating Formula. <i>Note:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, arthritis, Bell's palsy, radiculopathy, ocular, or cognitive dysfunction.	
6320	Parasitic diseases otherwise not specified: Evaluate under the General Rating Formula. <i>Note:</i> Rate under the appropriate body system any residual disability of infection.	
	* * * * *	
6325	Hyperinfection syndrome or disseminated strongyloidiasis: As active disease <i>Note:</i> Continue the rating of 100 percent through active disease followed by a mandatory VA exam. If there is no relapse, rate on residual disability. Any change in evaluation based upon that or any subsequent examination shall be subject to the provisions of § 3.105(e) of this chapter.	100
6326	Schistosomiasis: As acute or asymptomatic chronic disease <i>Note:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, conditions of the liver, intestinal system, female genital tract, genitourinary tract, or central nervous system.	0
6329	Hemorrhagic fevers, including dengue, yellow fever, and others: Evaluate under the General Rating Formula. <i>Note:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, conditions of the central nervous system, liver, or kidney.	
6330	<i>Campylobacter jejuni</i> infection: Evaluate under the General Rating Formula. <i>Note:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, Guillain-Barre syndrome, reactive arthritis, or uveitis as specified in § 3.317(d) of this chapter.	
6331	<i>Coxiella burnetii</i> infection (Q fever): Evaluate under the General Rating Formula. <i>Note:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, chronic hepatitis, endocarditis, osteomyelitis, post Q-fever chronic fatigue syndrome, or vascular infections as specified in § 3.317(d) of this chapter.	
6333	Nontyphoid <i>Salmonella</i> infections: Evaluate under the General Rating Formula. <i>Note:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, reactive arthritis as specified in § 3.317(d) of this chapter.	
6334	<i>Shigella</i> infections: Evaluate under the General Rating Formula. <i>Note:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, hemolytic-uremic syndrome or reactive arthritis as specified in § 3.317(d) of this chapter.	
6335	West Nile virus infection: Evaluate under the General Rating Formula. <i>Note:</i> Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, variable physical, functional, or cognitive disabilities as specified in § 3.317(d) of this chapter.	
	* * * * *	
6351	HIV-related illness: AIDS with recurrent opportunistic infections (see Note 3) or with secondary diseases afflicting multiple body systems; HIV-related illness with debility and progressive weight loss Refractory constitutional symptoms, diarrhea, and pathological weight loss; or minimum rating following development of AIDS-related opportunistic infection or neoplasm Recurrent constitutional symptoms, intermittent diarrhea, and use of approved medication(s); or minimum rating with T4 cell count less than 200 Following development of HIV-related constitutional symptoms; T4 cell count between 200 and 500, and use of approved medication(s); or with evidence of depression or memory loss with employment limitations Asymptomatic, following initial diagnosis of HIV infection, with or without lymphadenopathy or decreased T4 cell count <i>Note 1:</i> In addition to standard therapies and regimens, the term "approved medication(s)" includes treatment regimens and medications prescribed as part of a research protocol at an accredited medical institution. <i>Note 2:</i> Diagnosed psychiatric illness, central nervous system manifestations, opportunistic infections, and neoplasms may be rated separately under the appropriate diagnostic codes if a higher overall evaluation results, provided the disability symptoms do not overlap with evaluations otherwise assignable above. <i>Note 3:</i> The following list of opportunistic infections are considered AIDS-defining conditions, that is, a diagnosis of AIDS follows if a person has HIV and one more of these infections, regardless of the CD4 count—candidiasis of the bronchi, trachea, esophagus, or lungs; invasive cervical cancer; coccidioidomycosis; cryptococcosis; cryptosporidiosis; cytomegalovirus (particularly CMV retinitis); HIV-related encephalopathy; herpes simplex-chronic ulcers for greater than one month, or bronchitis, pneumonia, or esophagitis; histoplasmosis; isosporiasis (chronic intestinal); Kaposi's sarcoma; lymphoma; <i>Mycobacterium avium</i> complex; tuberculosis; <i>Pneumocystis jirovecii</i> (<i>carinii</i>) pneumonia; pneumonia, recurrent; progressive multifocal leukoencephalopathy; <i>Salmonella</i> septicemia, recurrent; toxoplasmosis of the brain; and wasting syndrome due to HIV.	100 60 30 10 0
6354	Systemic exertional intolerance disease/chronic fatigue syndrome (CFS):	

	Rating
Debilitating fatigue, cognitive impairments (such as inability to concentrate, forgetfulness, or confusion), or a combination of other signs and symptoms:	
Which are nearly constant and so severe as to restrict routine daily activities almost completely and which may occasionally preclude self-care	100
Which are nearly constant and restrict routine daily activities to less than 50 percent of the pre-illness level; or which wax and wane, resulting in periods of incapacitation totaling at least six weeks per year	60
Which are nearly constant and restrict routine daily activities from 50 to 75 percent of the pre-illness level; or which wax and wane, resulting in periods of incapacitation totaling at least four but less than six weeks per year	40
Which are nearly constant and restrict routine daily activities by less than 25 percent of the pre-illness level; or which wax and wane, resulting in periods of incapacitation totaling at least two but less than four weeks per year	20
Which wax and wane but result in periods of incapacitation totaling at least one but less than two weeks per year; or symptoms controlled by continuous medication	10
<i>Note:</i> For the purpose of evaluating this disability, incapacitation exists only when a licensed physician prescribes bed rest and treatment.	

- 4. In appendix A to part 4 by:
 - a. Revising the entries for diagnostic codes 6300–6302, 6304–6311;
 - b. Adding in numerical order an entry for diagnostic code 6312;
 - c. Revising the entries for diagnostic codes 6316–6320;
 - d. Adding in numerical order entries for diagnostic codes 6325, 6326, 6329 through 6331, and 6333 through 6335; and
 - e. Revising the entries for diagnostic codes 6351 and 6354.
- The revisions and additions read as follows:

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

Sec.	Diagnostic code No.	
4.88a	6300	March 11, 1969; re-designated § 4.88b November 29, 1994; § 4.88a added to read “Chronic fatigue syndrome”; criterion November 29, 1994; title, criterion [insert <i>effective date of final rule</i>].
4.88b	6301	Added March 11, 1969; re-designated § 4.88c November 29, 1994; § 4.88a re-designated to § 4.88b November 29, 1994; General Rating Formula for Infectious Diseases added [insert <i>effective date of final rule</i>].
	6302	Criterion August 30, 1996; title, criterion, and note [insert <i>effective date of final rule</i>].
	6303	Criterion, note [insert <i>effective date of final rule</i>].
	6304	Criterion September 22, 1978; criterion August 30, 1996; criterion, note [insert <i>effective date of final rule</i>].
	6305	Evaluation August 30, 1996; criterion, note [insert <i>effective date of final rule</i>].
	6306	Criterion March 1, 1989; evaluation August 30, 1996; title, criterion, note [insert <i>effective date of final rule</i>].
	6307	Evaluation August 30, 1996; criterion, note [insert <i>effective date of final rule</i>].
	6308	Criterion May 13, 2018; criterion, note [insert <i>effective date of final rule</i>].
	6309	Criterion August 30, 1996; criterion, note [insert <i>effective date of final rule</i>].
	6310	Added March 1, 1963; criterion March 1, 1989; criterion August 30, 1996; criterion, note [insert <i>effective date of final rule</i>].
	6311	Criterion, note [insert <i>effective date of final rule</i>].
	6312	Added [insert <i>effective date of final rule</i>].
	6316	Evaluation March 1, 1989; evaluation August 30, 1996; criterion, note [insert <i>effective date of final rule</i>].
	6317	Criterion August 30, 1996; title, criterion, note [insert <i>effective date of final rule</i>].
	6318	Added March 1, 1989; criterion August 30, 1996; criterion, note [insert <i>effective date of final rule</i>].
	6319	Added August 30, 1996; criterion, note [insert <i>effective date of final rule</i>].
	6320	Added August 30, 1996; criterion, note [insert <i>effective date of final rule</i>].
	6325	Added [insert <i>effective date of final rule</i>].
	6326	Added [insert <i>effective date of final rule</i>].
	6329	Added [insert <i>effective date of final rule</i>].
	6330	Added [insert <i>effective date of final rule</i>].
	6331	Added [insert <i>effective date of final rule</i>].
	6333	Added [insert <i>effective date of final rule</i>].
	6334	Added [insert <i>effective date of final rule</i>].
	6335	Added [insert <i>effective date of final rule</i>].
	6351	Added March 1, 1989; evaluation March 24, 1992; criterion August 30, 1996; criterion, note [insert <i>effective date of final rule</i>].
	6354	Added November 29, 1994; criterion August 30, 1996; title, criterion, note [insert <i>effective date of final rule</i>].

- 5. Amend appendix B to part 4 by:
 - a. Revising the entries for diagnostic codes 6300 and 6305;
 - b. Adding in numerical order an entry for diagnostic code 6312;

- c. Revising the entry for diagnostic code 6317; and,
- d. Adding in numerical order entries for diagnostic codes 6325, 6326, 6329 through 6331, and 6333 through 6335.

The revisions and additions read as follows:

APPENDIX B TO PART 4—NUMERICAL INDEX OF DISABILITIES

Diagnostic code No.						
*	*	*	*	*	*	*
INFECTIOUS DISEASES, IMMUNE DISORDERS AND NUTRITIONAL DEFICIENCIES						
6300			Vibriosis (Cholera, Non-cholera).		
6305			Lymphatic filariasis, to include elephantiasis.		
6312			Nontuberculosis mycobacterial infection.		
6317			Rickettsial, erlichial, and <i>Anaplasma</i> infections.		
6325			Hyperinfection syndrome or disseminated strongyloidiasis.		
6326			Schistosomiasis.		
6329			Hemorrhagic fevers, including dengue, yellow fever, and others.		
6330			Campylobacter jejuni infection.		
6331			Coxiella burnetii infection (Q Fever).		
6333			Nontyphoid salmonella infections.		
6334			Shigella infections.		
6335			West Nile virus infection.		
6351			HIV-related infection.		
6356			Systemic exertional intolerance disease/chronic fatigue syndrome (CFS).		

- 6. Amend appendix C to part 4 by:
 - a. Adding in alphabetical order an entry for “Campylobacter jejuni infection”;
 - b. Removing the entry for “Cholera, Asiatic”;
 - c. Adding in alphabetical order entries for “Coxiella burnetii infection (Q Fever)”, “Hemorrhagic fevers, including

- dengue, yellow fever, and others”, and “Hyperinfection syndrome or disseminated strongyloidiasis”;
- d. Revise the entry for “Lymphatic filariasis”;
- e. Adding in alphabetical order entries for “Nontuberculosis mycobacterial infection”, “Nontyphoid salmonella infection”, “Rickettsial, erlichial, and

- Anaplasma* infections”, Shigella infections, and “Schistosomiasis”;
 - f. Removing the entry for “Typhus, scrub”; and
 - g. Adding in alphabetical order entries for “Vibriosis (Cholera, Non-cholera)” and “West Nile virus infection”
- The additions and revisions read as follows:

APPENDIX C TO PART 4—ALPHABETICAL INDEX OF DISABILITIES

	Diagnostic code No.
Campylobacter jejuni infection	6330
Coxiella burnetii infection (Q Fever)	6331
Hemorrhagic fevers, including dengue, yellow fever, and others)	6329
Hyperinfection syndrome or disseminated strongyloidiasis	6325
Lymphatic filariasis, to include elephantiasis	6305

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

	Diagnostic code No.
* * * * *	
Nontyphoid salmonella infection	6333
* * * * *	
Nontuberculosis mycobacterial infection	6312
* * * * *	
Rickettsial, erlichial, and <i>Anaplasma</i> Infections	6317
* * * * *	
Schistosomiasis	6326
* * * * *	
Shigella infections	6334
* * * * *	
Vibriosis (Cholera, Non-cholera)	6300
* * * * *	
West Nile virus infection	6335
* * * * *	

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 49 and 52

[EPA-R10-OAR-2017-0347; FRL-9988-88-Region 10]

Indian Country: Air Quality Planning and Management; Federal Implementation Plan for the Kalispel Indian Community of the Kalispel Reservation, Washington; Redesignation to a PSD Class I Area

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed rulemaking; reopening of comment period.

SUMMARY: The Environmental Protection Agency (EPA) is reopening the public comment period for the proposed rule “Indian Country: Air Quality Planning and Management; Federal Implementation Plan for the Kalispel Indian Community of the Kalispel Reservation, Washington; Redesignation to a PSD Class I Area” published on October 31, 2018. In the October 31, 2018, publication, the EPA proposed to approve the Kalispel Indian Community of the Kalispel Reservation’s request to redesignate certain lands within its reservation to a Class I area under the Prevention of Significant Deterioration

program and revise the Federal Implementation Plan for the Kalispel Reservation and State Implementation Plan for the State of Washington accordingly. A commenter requested additional time to review the proposal and prepare comments. In response to this request, the EPA is reopening the comment period.

DATES: The comment period for the proposed rule published October 31, 2018 (83 FR 54691), is reopened, and written comments must be received on or before February 20, 2019.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R10-OAR-2017-0347 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 submit electronically 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: Sandra Brozusky at (206) 553-5317, or brozusky.sandra@epa.gov.

SUPPLEMENTARY INFORMATION: On October 31, 2018, the EPA published a proposed rulemaking to approve the Kalispel Indian Community of the Kalispel Reservation’s request to redesignate certain lands within its reservation to a Class I area under the Prevention of Significant Deterioration program and revise the Federal Implementation Plan for the Kalispel Reservation (40 CFR part 49, subpart M) and State Implementation Plan for the State of Washington (40 CFR part 52, subpart WW) accordingly. (83 FR 54691). A commenter requested additional time to review the proposal and prepare comments. In response to this request, the EPA is reopening the comment period.

Dated: December 20, 2018.

Michelle L. Pirzadeh,

Acting Regional Administrator, Region 10.

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