

Dated: June 12, 2019.

Jeffrey W. Novak,

Captain, U.S. Coast Guard, Captain of the Port Detroit.

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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: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) Schedule for Rating Disabilities (VASRD) by revising the portion of the schedule that addresses infectious diseases, immune disorders, and nutritional deficiencies. The effect of this action is to ensure that the rating schedule uses current medical terminology and to provide detailed and updated criteria for evaluation of infectious diseases, immune disorders, and nutritional deficiencies for disability rating purposes.

DATES: *Effective Date:* This final rule is effective August 11, 2019.

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, Ioulia.Vvedenskaya@va.gov, (202) 461-9700 (This is not a toll-free telephone number).

SUPPLEMENTARY INFORMATION: VA published a proposed rule in the *Federal Register* at 84 FR 1678 on February 5, 2019, to amend 38 CFR 4.88a and 4.88b, the portion of the VASRD dealing with infectious diseases, immune disorders, and nutritional deficiencies. VA provided a 60-day public comment period, and interested persons were invited to submit written comments on or before April 8, 2019. VA received 32 comments.

One commenter supported VA's intent to eliminate obsolete terminology and substitute the most up-to-date terms and definitions for conditions such as Chronic Fatigue Syndrome. The commenter noted that this rule would help to achieve the important public

policy goal of clear, effective communication among veterans, their health care providers, and the Department. Additionally, the commenter observed that it is important that what appears to be "catch-all" language appended to the respective disease evaluation categories be correctly phrased to minimize the likelihood that deserving patients will be excluded from care. The commenter suggested that VA should consider identifying the "residual effects" categories explicitly so the rating decisions and appeals would be most favorable to the veterans seeking care. The commenter further suggested that VA consider expressly recognizing that any ambiguity in the rules regarding covered residual effects should be resolved in the veteran's favor. VA makes no changes based on these comments. The proposed diagnostic codes provided examples of common residuals of specific diseases, but also made clear that the instruction to rate "any residual disability" from a disease "includes, but is not limited to" the listed examples. We believe this language is sufficiently clear and broad to ensure that any residuals identified in individual cases may be appropriately evaluated. We do not believe it is necessary or advisable to seek to list in these regulations all of the conditions that may be found to be residuals of diseases in specific cases. Further, because these rules do not restrict the conditions that may be found in individual cases to be residuals of a disease, we do not believe the regulation is restrictive or ambiguous on that issue. We note also that the principle of resolving reasonable doubt in favor of veterans is established in 38 CFR 3.102 and 4.3.

One commenter expressed an opinion that this regulatory update can be viewed as a bureaucratic move to disenfranchise veterans eligible for unspecified services. The commenter did not offer any specific recommendations and did not propose any actions. VA makes no changes based on this comment.

One commenter stated that vector-borne diseases (VBD) are of major importance to human health both locally and globally. In addition, the commenter highlighted that the precise diagnoses of many of these diseases remains a major challenge because of the lack of comprehensive data available on accurate and reliable diagnostic methods, specifically for borreliosis (Lyme disease). The commenter did not offer a specific recommendation or a course of action. VA makes no changes based on this comment.

Two commenters were concerned that by implementing a General Rating Formula (GRF) for infectious diseases, VA would drastically change veterans' ratings from 100 percent to zero percent, dependent upon whether the disease is deemed active or resolved based upon a laboratory test. Commenters noted that there is considerable evidence that laboratory tests may not always be deemed reliable and that each laboratory may have differing reference ranges leading to improper reading of results. However, VA's proposed GRF did not alter the rating principles for infectious diseases, which currently provide—in individual diagnostic codes rather than a GRF—for evaluation of active diseases and residuals. Instead, we updated the format of the rating schedule to indicate that the GFR for infectious diseases would be consistent for rating these conditions and also be similar to the use of a GFR in other sections of the VASRD, such as in 38 CFR 4.97, 4.116, 4.130, and others. Currently, VA assigns a 100-percent evaluation for each specific infectious disease during an active period; thereafter, any residual functional impairment from the infectious disease determines the level of disability. VA pointed out that its proposed GFR 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 (DCs). Additionally, VA did not propose any laboratory testing in its GFR, but instead we proposed to confirm the recurrence of active infection for certain conditions (DCs 6301, 6304, 6311, 6312, 6316) with overlapping clinical symptoms such as pallor, fever and hepatosplenomegaly. By adding a specific reference to laboratory testing for each infection, we made an effort to distinguish one infection from another. VA makes no changes based on this comment.

Additionally, commenters were concerned that the proposed GRF would not consider veterans' ability to maintain gainful employment because many infectious diseases, even after negative laboratory test results, can cause long-lasting residual symptoms that may last up to eight weeks or longer and that lingering, residual symptoms would adversely affect a veteran's normal functioning and his/her ability to maintain gainful employment. The proposed GRF is designed to assess permanent functional impairment that resulted from long-lasting residual symptoms rather than rely solely on a specific laboratory test. The proposed

GFR directs rating personnel to rate any residual effect of acute and/or chronic infection and to determine the degree of disability within the appropriate body system using the same principles as they exist in the current rating schedule. VA's disability compensation benefits are based on the extent of average impairment of earning capacity from the service-connected injury or disease and this focus is reflected throughout the rating schedule. Therefore, VA makes no changes based on this comment.

One commenter expressed concern regarding West Nile Virus infection, stating infected individuals could experience headaches, body aches, joint pains, vomiting, diarrhea, or rash during an acute phase of the disease and that the residual symptoms could last for an extended period. The commenter specifically noted a severe complication of the West Nile Virus infection that affects the central nervous system in its acute phase and that such complications could become clinically permanent. The commenter proposed to list specific neuroinvasive diseases such as meningitis and encephalitis as residuals of West Nile Virus in § 4.88b and to be rated under the applicable DC code(s). The commenter further interpreted the note under DC 6335 that VA would rate West Nile virus infection residuals and residuals listed in § 3.317 together and was concerned that this approach would cause confusion and limit this DC to only a subset of Persian Gulf veterans who served in the Southwest Asia Theater of Operations and are entitled to presumptive service connection. VA clarifies that the note under DC 6335 concerning § 3.317 is intended solely to serve as a reference that provides guidance to the adjudicator in rating a disease under this DC. The reference to § 3.317 is not intended nor can it be read to restrict application of DC 6335 to veterans with Southwest Asia service. As West Nile infection and other similar infectious diseases have complex disability pictures that are not commonly seen by VA adjudicators, the inclusion of the § 3.317(d) reference under DC 6335 is specifically meant to assist our adjudicators in understanding the nature of the disease and, most critically, the usual residual disabilities of the disease. Referencing § 3.317(d) in the note for infectious diseases like the West Nile virus serves to impart understanding to VA adjudicators that such infectious diseases may result in various residuals or complications with physical, functional, or cognitive effects and enables adjudicators to accurately rate veterans with these diseases. In response and in order to minimize any

confusion, VA has removed the notes that reference 38 CFR 3.317(d) from the Infectious Diseases rating criteria for DCs 6301, 6304, 6316, 6330, 6331, 6333–6335. VA has added the reference to 38 CFR 3.317(d) as a note in a new introductory paragraph before the rating schedule for infectious diseases, immune disorders, and nutritional deficiencies in 38 CFR 4.88b.

Additionally, commenters expressed a concern that the proposed GRF will negatively affect veterans' care and treatment. VA appreciates commenters' concerns; however, VA's Rating Schedule for Disabilities does not regulate veterans' access to clinical care. Further, as explained above, the provisions in the proposed GRF for rating active diseases and residuals are consistent with the existing provisions under individual diagnostic codes in § 4.88b and will not significantly change how VA evaluates these conditions. VA makes no changes based on these comments.

One commenter supported the need for greater simplification of the rating schedule and disability determination process and was concerned that this proposed update to the schedule for infectious disease, immune disorders and nutritional deficiencies excludes nurse practitioners and their patients. Specifically, the commenter noted that the proposed criteria for determining incapacitation related to systemic exertion intolerance disease (SEID)/ chronic fatigue syndrome (CFS) require bed rest and treatment prescribed by a licensed physician and that a physician who administered diagnostic tests ruled out ongoing exertion or other medical conditions associated with fatigue. The commenter requested that the Veterans Health Administration (VHA) revise this proposed rating schedule update and add "or nurse practitioner" after the word "physician" in all sections. The commenter also asked that, in future revisions of the rating schedule, VHA recognize that thousands of veterans receive care from nurse practitioners and to include nurse practitioners in the language of the rating schedule. VA clarifies that this rulemaking pertains to the Veterans Benefits Administration (VBA) and addresses disability evaluations due to the functional impairment related to service-connected health conditions. This rulemaking does not address the scope of clinical practice for nurse practitioners. However, VBA will assess whether amendments to the list of qualifying health care providers are necessary and such amendments, if any, will be addressed in a future proposal. VA

makes no changes based on this comment.

One commenter stated that it is unfair that a National Guard soldier who was called to active duty and then immediately released upon return from the Middle East has to have manifested one of the infectious diseases listed in § 3.317 within one year from separation (aside from three exceptions), whereas an active duty soldier who redeploys from Iraq or Afghanistan and serves several more years on active duty only has to show the disease within a year after separation, which may be several years after service in Iraq or Afghanistan. This comment relates to the time period prescribed in 38 CFR 3.317(c)(3) for applying the presumption of service connection for infectious diseases in veterans who served in the Southwest Asia theater of operations during the Persian Gulf War. The proposed rules pertained only to the criteria for evaluating the severity of service-connected infectious diseases, immune disorders, and nutritional deficiencies. They did not propose to address matters concerning the establishment of service connection or the operation of presumptions of service connection for any diseases. Accordingly, the comment is beyond the scope of this rulemaking. VA makes no changes based on this comment.

Multiple commenters including individual veterans, Veterans Advocacy Organizations, Veterans Service Organizations, and other professional organizations expressed a wide range of concerns regarding the proposed changes to the definition of chronic fatigue syndrome (CFS) under § 4.88a and the name change for DC 6354. Commenters thought the name change of Chronic Fatigue Syndrome (CFS) to Systemic Exertion Intolerance Disease/Chronic Fatigue Syndrome (SEID/CFS) was unwarranted and that it would create unnecessary confusion among medical providers, including non-VA medical providers. Commenters also stated that the new name, Systemic Exertion Intolerance Disease (SEID), has not been adopted by any federal agency, nor by researchers and clinicians and that the CDC, National Institutes of Health (NIH), research publications, and materials for patients and health care providers all use the term ME/CFS. Commenters felt that VA's use of the term SEID/CFS would introduce confusion among medical providers and patients at VA and reduce VA's ability to coordinate with other federal agencies.

Commenters expressed that the proposed changes to the definition of CFS does not conform to the Kansas

Criteria (2000), the Centers for Disease Control (CDC) Chronic Multisymptom Illness (CMI) criteria, and to those used in VA-funded research into Gulf War Illness (GWI) and that the proposed definition is not compatible with the department of Defense (DoD) Congressionally Directed Medical Research Programs (CDMRP) for CMI. Commenters stated that VA's proposed combination of the Institute of Medicine (IOM) reevaluation of CFS as SEID with the 1994 Fukuda criteria for CFS presents an amalgamation that is not based in evidence nor discussed in any publications. The commenters expressed concern that VA did not follow any recommendations from the IOM, the Gulf War Research Advisory Committee (RAC), CDC, or other agencies and this combination is for an entirely new entity that is not known by World Health Organization, International Classification of Diseases, Tenth Revision (ICD-10) or other medical classification system and that the VA proposed definition is not compatible with the one mandated by DoD's CDMRP for CMI and the Kansas Criteria to qualify for GWI research funding.

Commenters noted that VA did not consult the RAC on these proposed changes and stated that the RAC is responsible for understanding the definitions and entirety of the condition. Commenters also were concerned that the proposed changes would leave those Gulf War veterans who receive care and services for CFS, vulnerable to VA manipulation of their care and services. The commenters suggested that CFS should be studied by the Gulf War research community, the veteran community, CFS researchers, the RAC, and independent medical professionals and that VA rely on the recommendations from these parties as a guide for new criteria updates and to ascertain if these changes are even warranted. Commenters also stated that VA would be directly and negatively impacting more than 300,000 Gulf War veterans suffering from Gulf War Illness by not relying on the studies from these parties and by combining, in whole or in part, the 2015 Systemic Exertion Intolerance Disease (SEID) and the 1994 Fukuda CDC criteria for Chronic Fatigue Syndrome (CFS) into what would be called SEID/CFS.

Commenters felt that VA's adoption of the Fukuda criteria is a step backwards that will perpetuate diagnostic inaccuracy and cause harm to Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) patients served by the VA. Commenters referenced the 2015 IOM Report to state that the

Fukuda criteria were overly broad because they do not require the hallmark symptom of post-exertional malaise and should not be used because of the possibility of misdiagnosing patients with other conditions. Commenters believed that VA's reliance on outdated Fukuda diagnostic criteria would cause harm to veterans with ME/CFS through misdiagnosis and cause a mismatch with the diagnostic criteria in use elsewhere. Commenters suggested that VA adopt ME/CFS or ME/CFS/SEID title for the illness to stay in alignment with the greater ME/CFS community, to include patients, doctors, and researchers. Commenters felt that VA's proposed revisions were based on financial reasons in order to revoke benefits from existing veterans and prevent other veterans from receiving this combined diagnosis of SEID/CFS.

Commenters also provided questions and recommended that VA adopt ME/CFS instead of SEID/CFS; reject the Fukuda criteria; and adopt the IOM diagnostic criteria.

Another recommendation was for VA to revise § 4.88a to more closely mirror the diagnostic standard endorsed by the IOM and CDC and eliminate the listed exclusions to allow the veterans' examining and/or treating physician to make a final determination as to the appropriate diagnosis for veterans. In addition, commenters recommended that VA should broaden the group of medical professionals authorized to prescribe bed rest and treatment to meet the incapacitation standard.

While VA received some support for updating its definition of CFS, VA considered these comments and concerns and concluded that this proposed update to § 4.88a is premature and that additional research is needed to provide a more comprehensive way to determine the disabling effects of CFS and associated conditions. Therefore, VA is withdrawing its proposal to amend § 4.88a Chronic Fatigue Syndrome. To ensure that the full range of relevant factors is adequately addressed, VA intends to establish a work group to specifically address this condition. Upon assessment of the work group's findings, VA will determine whether amendments to § 4.88a are necessary and such amendments, if any, will be addressed in a future proposal.

VA makes one clarifying change to the criteria for a 10 percent disability rating under DC 6351, HIV-related illness. In the proposed rule, VA proposed to replace the phrase "definite medical symptoms" with "HIV-related constitutional symptoms" but stated that we would otherwise make no change to the criteria for a 10 percent

evaluation. The prior criteria for a 10 percent evaluation read: "Following development of definite medical symptoms, T4 cells of 200 or more and less than 500, and on approved medication(s), or with evidence of depression or memory loss with employment limitations." We proposed to revise this to read: "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." In its review of the final rule, VA realized that the prior text for a 10 percent disability rating was unclear because it listed four criteria, separated by commas, but used "and" between the second and third criteria, while using "or" between the third and fourth criteria. The proposed text listed three criteria, separated by semicolons, with the second of those criteria encompassing both the second and third criteria of the prior text, joined by the word "and". We recognize that the combination of punctuation and conjunctions in both the prior and the proposed text could create confusion. Accordingly, VA revises the text for a 10 percent disability rating to read: "Following development of HIV-related constitutional symptoms; T4 cell count between 200 and 500; use of approved medication(s); or with evidence of depression or memory loss with employment limitations." This clarifies that the text includes four separate criteria, consistent with the prior text, but will eliminate the potential confusion caused by the term "and" between two of those criteria. This will ensure that the provision is implemented in the manner most consistent with VA's intent and most favorable to veterans. VA appreciates the comments submitted in response to the proposed rule. Based on the rationale stated in the proposed rule and in this document, the proposed rule is adopted as a final rule with the changes noted above.

Effective Date of Final Rule

VBA personnel utilize the Veterans Benefit Management System for Rating (VBMS-R) to process disability compensation claims that involve disability evaluations made under the VASRD. In order to ensure that there is no delay in processing veterans' claims, VA must coordinate the effective date of this final rule with corresponding VBMS-R system updates. As such, this final rule will apply effective August 11, 2019, the date VBMS-R system updates related to this final rule will be complete.

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 the 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 Executive Order 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 the rulemaking and its impact analysis are available on VA’s website at <http://www.va.gov/orpm> by following the link for VA Regulations Published from FY 2004 through FYTD. 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 final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612. This final rule will not affect any small entities. 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 one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

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

Catalog of Federal Domestic Assistance

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 May 20, 2019, for publication.

Dated: May 20, 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 amends 38 CFR part 4 as set forth below:

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.

■ 2. Amend § 4.88b by:

- a. Adding introductory text;
- b. Adding the entry “General Rating Formula for Infectious Diseases:” before the entry for diagnostic code 6300;
- c. Revising the entries for diagnostic codes 6300 through 6302 and 6304 through 6311;
- d. Adding in numerical order an entry for diagnostic code 6312;
- e. Revising the entries for diagnostic codes 6316 through 6320;
- f. Adding in numerical order entries for diagnostic codes 6325, 6326, 6329 through 6331, and 6333 through 6335; and
- g. Revising the entries for diagnostic codes 6351 and 6354.

The additions and revisions read as follows:

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

Note: Rate any residual disability of infection within the appropriate body system as indicated by the notes in the evaluation criteria. As applicable, consider the long-term health effects potentially associated with infectious diseases as listed in § 3.317(d) of this chapter, specifically Brucellosis, *Campylobacter jejuni*, *Coxiella burnetii* (Q fever), Malaria, *Mycobacterium Tuberculosis*, Nontyphoid *Salmonella*, *Shigella*, Visceral Leishmaniasis, and West Nile virus.

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. | |

| | Rating |
|--|--------|
| <i>Note:</i> Rate residuals of cholera and non-cholera vibrio infections, such as renal failure, skin, and musculoskeletal conditions, within the appropriate body system. | |
| 6301 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 and bone marrow disease. | |
| <i>Note 2:</i> Confirm the recurrence of active infection by culture, histopathology, or other diagnostic laboratory testing. | |
| 6302 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. | |
| 6304 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, and central nervous system conditions. | |
| 6305 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. | |
| 6306 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. | |
| 6307 Plague: | |
| Evaluate under the General Rating Formula. | |
| <i>Note:</i> Rate under the appropriate body system any residual disability of infection. | |
| 6308 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. | |
| 6309 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. | |
| 6310 Syphilis, and other treponema 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). | |
| 6311 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. | |
| 6312 Nontuberculosis mycobacterium 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. | |
| * * * * * | |
| 6316 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. | |
| 6317 Rickettsial, ehrlichia, 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. | |

- Note 2:* This diagnostic code includes, but is not limited to, scrub typhus, Rickettsial pox, African tick-borne fever, Rocky Mountain spotted fever, ehrlichiosis, or anaplasmosis.
- 6318 **Melioidosis:**
 Evaluate under the General Rating Formula.
Note 1: Confirm by culture or other specific diagnostic laboratory tests the initial diagnosis and any relapse or chronic activity of infection.
Note 2: 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.
Note: 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.
Note: Rate under the appropriate body system any residual disability of infection.
- 6325 **Hyperinfection syndrome or disseminated strongyloidiasis:**
 As active disease 100
Note: 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.
- 6326 **Schistosomiasis:**
 As acute or asymptomatic chronic disease 0
Note: 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.
- 6329 **Hemorrhagic fevers, including dengue, yellow fever, and others:**
 Evaluate under the General Rating Formula.
Note: 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 **Campylobacter jejuni infection:**
 Evaluate under the General Rating Formula.
Note: 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.
- 6331 **Coxiella burnetii infection (Q fever):**
 Evaluate under the General Rating Formula.
Note: 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.
- 6333 **Nontyphoid salmonella infections:**
 Evaluate under the General Rating Formula.
Note: Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, reactive arthritis.
- 6334 **Shigella infections:**
 Evaluate under the General Rating Formula.
Note: Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, hemolytic-uremic syndrome or reactive arthritis.
- 6335 **West Nile virus infection:**
 Evaluate under the General Rating Formula.
Note: Rate under the appropriate body system any residual disability of infection, which includes, but is not limited to, variable physical, functional, or cognitive disabilities.
- * * * * *
- 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 100
 Refractory constitutional symptoms, diarrhea, and pathological weight loss; or minimum rating following development of AIDS-related opportunistic infection or neoplasm 60
 Recurrent constitutional symptoms, intermittent diarrhea, and use of approved medication(s); or minimum rating with T4 cell count less than 200 30
 Following development of HIV-related constitutional symptoms; T4 cell count between 200 and 500; use of approved medication(s); or with evidence of depression or memory loss with employment limitations 10
 Asymptomatic, following initial diagnosis of HIV infection, with or without lymphadenopathy or decreased T4 cell count 0
Note 1: 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.
Note 2: 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.
Note 3: 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; 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.
- 6354 **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 of at least six weeks total duration 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 of at least four but less than six weeks total duration 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 of at least two but less than four weeks total duration per year | 20 |
| Which wax and wane but result in periods of incapacitation of at least one but less than two weeks total duration 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. | |

- 3. In appendix A to part 4, amend entry 4.88b by:
 - a. Revising the entry before the entry for diagnostic code 6300;
 - b. Revising the entry for diagnostic code 6300;
 - c. Adding in numerical order an entry for diagnostic code 6301;
 - d. Revising the entries for diagnostic codes 6302 and 6304 through 6309;
 - e. Adding in numerical order entries for diagnostic codes 6310 through 6312;
 - f. Revising the entries for diagnostic codes 6316 through 6320;
 - g. Adding in numerical order entries for diagnostic codes 6325, 6326, 6329 through 6331, and 6333 through 6335; and
 - h. 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. | |
|-------|---------------------|--|
| 4.88b | 6300 | 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 August 11, 2019. |
| | 6301 | Criterion August 30, 1996; title, criterion, and note August 11, 2019. |
| | 6302 | Criterion September 22, 1978; criterion August 30, 1996; criterion, note August 11, 2019. |
| | 6304 | Criterion August 30, 1996; title, criterion, and note August 11, 2019. |
| | 6305 | Evaluation August 30, 1996; criterion, note August 11, 2019. |
| | 6306 | Criterion March 1, 1989; evaluation August 30, 1996; title, criterion, note August 11, 2019. |
| | 6307 | Evaluation August 30, 1996; criterion, note August 11, 2019. |
| | 6309 | Criterion May 13, 2018; criterion, note August 11, 2019. |
| | 6308 | Criterion August 30, 1996; criterion, note August 11, 2019. |
| | 6310 | Added March 1, 1963; criterion March 1, 1989; criterion August 30, 1996; criterion, note August 11, 2019. |
| | 6311 | Criterion August 30, 1996; title, criterion, note August 11, 2019. |
| | 6312 | Criterion August 30, 1996; title, criterion, note August 11, 2019. |
| | 6316 | Added August 11, 2019. |
| | 6317 | Evaluation March 1, 1989; evaluation August 30, 1996; criterion, note August 11, 2019. |
| | 6318 | Criterion August 30, 1996; title, criterion, note August 11, 2019. |
| | 6319 | Added March 1, 1989; criterion August 30, 1996; criterion, note August 11, 2019. |
| | 6320 | Added August 30, 1996; criterion, note August 11, 2019. |
| | 6325 | Added August 30, 1996; criterion, note August 11, 2019. |
| | 6326 | Added August 11, 2019. |
| | 6329 | Added August 11, 2019. |
| | 6330 | Added August 11, 2019. |
| | 6331 | Added August 11, 2019. |
| | 6333 | Added August 11, 2019. |
| | 6334 | Added August 11, 2019. |
| | 6335 | Added August 11, 2019. |
| | 6351 | Added March 1, 1989; evaluation March 24, 1992; criterion August 30, 1996; criterion, note August 11, 2019. |
| | 6354 | Added November 29, 1994; criterion August 30, 1996; title, criterion, note August 11, 2019. |

- 4. 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 mycobacterium infection. | | | | |
| * | * | * | * | * | * | * |
| 6317 | | Rickettsial, ehrlichia, and anaplasma 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. | | | | |
| * | * | * | * | * | * | * |

- 5. 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. Removing the entry for “Lymphatic filariasis”;
- e. Adding in alphabetical order entries for “Lymphatic filariasis, to include elephantiasis”, “Nontuberculosis mycobacterium infection”, “Nontyphoid salmonella infection”, “Rickettsial, erlichial, and Anaplasma

- infections”, “Schistosomiasis” and “Shigella infections”;
 - 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. |
|--|---------------------|
| Nontuberculosis mycobacterium infection | 6312 |
| Nontyphoid salmonella infection | 6333 |
| Rickettsial, ehrlichia, and anaplasma 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 Part 180

[EPA-HQ-OPP-2014-0560; FRL-9994-90]

Bacillus amyloliquefaciens subspecies plantarum strain FZB42; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of *Bacillus amyloliquefaciens* subspecies *plantarum* strain FZB42 in or on all food commodities when used in accordance with label directions and good agricultural practices. Andermatt Biocontrol AG (c/o SciReg, Inc.) submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus amyloliquefaciens* subspecies *plantarum* strain FZB42 in or on all food commodities under FFDCA.

DATES: This regulation is effective June 18, 2019. Objections and requests for hearings must be received on or before August 19, 2019 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also

Unit I.C. of the SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0560, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: BPPDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers

determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0560 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before August 19, 2019. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please