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DEPARTMENT OF VETERANS AFFAIRS**38 CFR Part 4**

RIN 2900-AP27

Schedule for Rating Disabilities; Skin Conditions

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

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend the portion of the VA Schedule for Rating Disabilities (VASRD or Rating Schedule) that addresses skin conditions. The purpose of these changes is to incorporate medical advances that have occurred since the last review, update current medical terminology, and provide clear evaluation criteria. The proposed rule reflects advances in medical knowledge, recommendations from the Skin Disorders Work Group, which is comprised of subject matter experts from both the Veterans Benefits Administration and the Veterans Health Administration, and comments from experts and the public gathered as part of a public forum. The public forum, focusing on revisions to the skin conditions section of the VASRD, was held in January 2012.

DATES: *Comment Date:* Comments must be received by VA on or before October 11, 2016.

Applicability Date: The provisions of this rulemaking shall apply to all applications for benefits that are received by VA or that are pending before the agency of original jurisdiction on or after the effective date of the final rule. The Secretary does not intend for the provisions of this rulemaking to apply to claims that have been certified for appeal to the Board of Veterans' Appeals or are pending before the Board of Veterans' Appeals, the United States Court of Appeals for Veterans Claims, or the United States Court of Appeals for the Federal Circuit.

ADDRESSES: Written comments may be submitted through www.Regulations.gov; by mail or hand-delivery to Director, Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, 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-AP27-Schedule for Rating Disabilities;

Skin Conditions." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at www.Regulations.gov.

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

SUPPLEMENTARY INFORMATION: The National Defense Authorization Act For Fiscal Year 2004, sec. 1501-07, Public Law 108-136, 117 Stat. 1392, established the Veterans' Disability Benefits Commission (Commission). Section 1502 of Public Law 108-136 mandated the Commission to study ways to improve the disability compensation system for disabled military veterans. The Commission consulted with the Institute of Medicine (IOM) to review the medical aspects of the current disability compensation policies for veterans. In 2007, the IOM released its report titled, "A 21st Century System for Evaluating Veterans for Disability Benefits."

The IOM Report was notable in several respects. The IOM observed, in part, that the VASRD was inadequate at times because it contained obsolete information and did not sufficiently integrate current and accepted diagnostic procedures. In addition, the IOM observed that the current body system organization of the VASRD does not reflect current knowledge of the relationships between conditions and comorbidities. Institute of Medicine, Committee on Medical Evaluation of Veterans for Disability Compensation, "A 21st Century System for Evaluating Veterans for Disability Benefits," 113 (Michael McGeary et al. eds. 2007).

Following release of the IOM report, VA created a Skin Disorders Work Group (Work Group). The goals adopted by the Work Group were to: 1) improve and update the criteria that VA uses to assign levels of disability after service connection is granted; 2) improve the level of fairness in adjudication of benefits related to service connected disabilities of Veterans; and 3) invite public participation. The Work Group was led by co-chairs from the Veterans Health Administration (VHA) and

Veterans Benefits Administration (VBA). The workgroup was comprised of subject matter experts (SMEs) from within VA, DoD, and medical academia. In addition, members from several Veterans Service Organizations (VSOs) were invited to participate as representatives from the public. The Work Group held a public forum in New York City during January 2012, where several SMEs gave presentations focused on their particular area(s) of expertise.

After the public forum, the Work Group met periodically to continue the revision efforts. Participants from VBA, VHA, medical academia, and VSO representatives continued work within their areas of expertise. The regulation drafting phase began in September 2013, and continues through the publication of this proposed rule. The rule VA proposes is consistent with updating and improving criteria by using validated severity ratings specific to the skin for each of the disability rating levels. As discussed in more detail below, the newly adopted classifications are derived from current medical practice.

Schedule of Ratings—Skin Conditions**General Rating Formula for Skin Disorders**

Section 4.118 currently lists 30 diagnostic codes (DCs) encompassing conditions involving injury or disease of the skin. VA proposes to revise these codes, through addition, removal, or other revisions, to reflect current medical science, terminology, and functional impairment.

VA would delete the current introductory paragraph to § 4.118. VA added the current paragraph to explain the applicability of the 2008 amendments to § 4.118, DCs 7800, 7801, 7802, 7804, and 7805. This rulemaking would make further amendments and would render outdated the current introductory paragraph. VA would add an applicability date paragraph to the dates section to explain this rulemaking's applicability. The existing provisions in § 4.118 concerning review of ratings and effective dates merely reflect generally applicable principles that need not be restated in the rating schedule.

VA would add a new introductory paragraph to state that, for the purposes of § 4.118, systemic therapy is treatment that is administered through any route (orally, injection, suppository, intranasally) other than the skin, and topical therapy is treatment that is administered through the skin. On March 1, 2016, the United States Court

of Appeals for Veterans Claims (Veterans Court) found it “unambiguous” that the “use of a topical corticosteroid is systemic therapy within the meaning of Diagnostic Code 7806.” *Johnson v. McDonald*, 27 Vet. App. 497, 502, 504 (2016). Under this holding, repeated localized application of topical corticosteroid could entitle a veteran to a disability rating as high as sixty percent, even if the affected area is very small. *Johnson* creates a dramatic disconnect between the severity of the veteran’s disability and the corresponding rating. Therefore, VA is amending § 4.118 to clearly provide that VA does not intend for treatment administered through the skin (topical therapy) to constitute systemic therapy. VA notes that it is possible for topical treatments to have systemic effects if administered on a large enough scale. However, in these situations, a veteran can obtain a higher rating due to the percentage of the body affected, not the mode of administration for his or her treatment. For example, if more than 40 percent of a veteran’s body is covered in eczema and a veteran treats all affected areas with topical corticosteroid, the veteran will be entitled to a 60 percent rating due to the percentage of the body affected, not because he is taking systemic therapy.

VA proposes a General Rating Formula to evaluate several of the skin disorders: dermatitis or eczema (DC 7806), discoid lupus erythematosus (DC 7809), dermatophytosis (DC 7813), bullous disorders (DC 7815), psoriasis (DC 7816), infections of the skin not listed elsewhere (DC 7820), cutaneous manifestations of collagen-vascular diseases not listed elsewhere (DC 7821), papulosquamous disorders not listed elsewhere (DC 7822), and diseases of keratinization (DC 7824). Individually, each of the above referenced conditions involves similar superficial components of the skin. The severity of impairment for each condition increases as more skin is involved. All of the conditions have treatments which are applied directly to the skin, as well as taken systemically (e.g., by mouth). There are still more similarities with regard to which treatments are used, treatment dosages given, treatment routes of administration, and treatment duration. As a result, VA concluded it would be more efficient to rate under the same formula, rather than to prescribe individual rating criteria.

Similar to how these DCs are currently evaluated, this General Rating Formula accounts for percentages of areas affected, both of the entire body and exposed areas, as well as the level

of treatment required. The percentage evaluations assigned under the General Rating Formula mirror the percentage evaluations currently assigned for these DCs. Specifically, VA proposes a 60 percent evaluation when at least one of the following is present: More than 40 percent of the entire body or more than 40 percent of exposed areas affected, or; Constant or near-constant systemic therapy including, but not limited to, corticosteroids, phototherapy, retinoids, biologics, photochemotherapy, PUVA or other immunosuppressive drugs required per 12-month period. VA proposes a 30 percent evaluation when at least one of the following is present: 20 to 40 percent of the entire body or 20 to 40 percent of exposed areas affected, or; Systemic therapy including, but not limited to, corticosteroids, phototherapy, retinoids, biologics, photochemotherapy, PUVA or other immunosuppressive drugs required for a total duration of six weeks or more, but not constantly, per 12-month period. VA proposes a 10 percent evaluation when at least one of the following is present: At least 5 percent, but less than 20 percent of the entire body affected, or; At least 5 percent, but less than 20 percent of exposed areas affected, or; Intermittent systemic therapy including, but not limited to, corticosteroids, phototherapy, retinoids, biologics, photochemotherapy, PUVA or other immunosuppressive drugs required for a total duration of less than six weeks per 12-month period. VA proposes a zero percent evaluation when no more than topical therapy is required per 12-month period and at least one of the following is present: Less than 5 percent of the entire body affected, or; Less than 5 percent of exposed areas affected.

Additionally, VA proposes to maintain the current rating instruction for DCs 7806, 7809, 7813–7816, and 7820–7822 which allows for evaluation under disfigurement of the head, face, or neck (DC 7800) or scars (DCs 7801, 7802, 7804, or 7805), depending upon the predominant disability, in lieu of using the General Rating Formula. This rating instruction does not apply to current or new DC 7824, and therefore, VA proposes to add a clarifying sentence to that effect to this instruction.

As for the expanded list of systemic therapies identified in the General Rating Formula, VA notes that the current VASRD lists only “corticosteroids or other immunosuppressive drugs” as examples of systemic therapy. However, since the last review and update of the schedule of disability ratings for the skin, a number of new systemic therapies have

surfaced that are used to treat the conditions covered under the General Rating Formula. These include phototherapy, retinoids, biologics, photochemotherapy, and PUVA (e.g., ultraviolet therapy). See, e.g., Jennifer D. Peterson, MD, et al., “A Comprehensive Management Guide for Atopic Dermatitis,” 18:6 *Dermatology Nursing*, 531–42 (2006); “Psoriasis Medications,” WebMD, <http://www.webmd.com/skin-problems-and-treatments/psoriasis/psoriasis-medications> (last visited Aug. 25, 2015). To ensure consistent evaluation of these conditions, VA proposes to add these systemic therapies to the list of enumerated treatments.

In addition to creating the General Rating Formula and applying it to DCs 7806, 7809, 7813, 7815, 7816, 7820, 7821, 7822, and 7824, VA proposes to amend certain individual DCs within § 4.118. The particular changes affecting each DC immediately follow.

Diagnostic Codes 7801 and 7802

Each of these DCs pertains to types of scars which are, in part, characterized as “nonlinear.” To broaden application of these DCs, VA proposes to remove the reference to “nonlinear” from each DC title. In addition, VA proposes to include a more descriptive reference to whether the scar involves underlying soft tissue damage in place of the current terms “superficial” and “deep”—to assist rating personnel. This latter proposed change eliminates the need for current note (1) in each DC, as well as the last sentence in note (2) in each DC; therefore, VA proposes removal of those items.

Currently, if a scar runs in two or more separate areas of the body, note (2) for DCs 7801 and 7802 is intended to allow for the assignment of a separate evaluation for each affected zone and then to combine those evaluations under 38 CFR 4.25. See 73 FR 54708, 54709, Sept. 23, 2008. Although VA has been applying note (2) in this way, VA finds that the note could be written more clearly. Therefore, VA proposes to rewrite note (2) in a clearer and more concise manner and to add a new note (1) to be placed under both DCs 7801 and 7802 that would define the zones of the body. Specifically, note (1) would define the six zones of the body as each extremity, the anterior trunk, and the posterior trunk. VA also proposes to move the statement that the midaxillary line is what divides the anterior and posterior trunk from note (2) to note (1).

Additionally, VA proposes to add language to note (2) to allow for an alternative evaluation. Specifically, VA proposes to allow for a single evaluation

under DCs 7801 and 7802 if adding the entire affected zones of the body together would result in a higher evaluation. VA proposes this additional evaluation method in order to accurately reflect the level of disability present. In some circumstances, combining the scars from different zones under § 4.25 results in a lower compensation level than if the total scar area was added together without regard to the zone involved. For example, under DC 7801, if there is a single scar of 6 square inches total equally affecting both the anterior and posterior trunk, a compensable rating would not be warranted because the area affecting each zone would be less than 6 square inches total (e.g., 3 square inches on the anterior trunk and 3 square inches on the posterior trunk). However, when adding these scar segments together to consider the total square area (6 square inches), a 10 percent evaluation would be warranted. Similarly, under DC 7802, there may be scars in separate zones that are not each 144 square inches, but which add up to 144 square inches total. For example, a veteran may have a 100 square inch scar on the anterior trunk and a 100 square inch scar on the posterior trunk, which would not warrant a compensable rating under DC 7802. However, an evaluation of 10 percent would be warranted by adding the affected zones together for both scars, as they total to 200 square inches together.

Diagnostic Code 7803

This DC was deleted in October 2008. See 73 FR at 54710. However, several criteria reference this code. VA proposes to delete any and all references to DC 7803.

Diagnostic Code 7805

VA proposes to remove the reference to “linear” scars from DC 7805. The result of this change is that this DC applies to both linear and non-linear scars. As discussed above, VA proposes to remove the reference to “nonlinear” scars from DCs 7801 and 7802, expanding application of these codes to linear scars. Thus, the reference to linear scars should be removed from DC 7805 to avoid confusion by rating personnel.

Diagnostic Codes 7809 and 7821

VA proposes to retitle both DC 7809 and DC 7821 using current medical terminology. Current DC 7809 refers to “Discoid lupus erythematosus or subacute cutaneous lupus erythematosus.” VA proposes to remove the listed condition “subacute cutaneous lupus erythematosus” from

DC 7809 and add it to DC 7821. The proposed DC 7809 will read as “Discoid lupus erythematosus. Current DC 7809 also provides that a rating under DC 7809 should not be combined with a rating under DC 6350. In order to maintain this provision, we would add a note to DC 7809. The rationale for transferring subacute cutaneous lupus erythematosus from DC 7809 to DC 7821 is that subacute cutaneous lupus erythematosus is a distinctly different condition which is more analogous to collagen-vascular diseases not listed elsewhere (e.g., DC 7821) than it is to discoid lupus erythematosus. See Jean L. Bologna, John L. Jorizzo, et al. eds., “Dermatology,” 618–20 (3d ed. 2012). The proposed DC 7821 will read as “Cutaneous manifestations of collagen-vascular diseases not listed elsewhere (including scleroderma, calcinosis cutis, subacute cutaneous lupus erythematosus, and dermatomyositis).” There is no change in the evaluation criteria; both conditions would be rated under the General Rating Formula.

Diagnostic Code 7813

Current DC 7813 describes a number of variations of dermatophytosis, including tinea corporis, tinea capitis, tinea pedis, tinea barbae, tinea unguium, and tinea cruris. To update this DC title with current medical terminology, VA proposes to add “tinea versicolor” to this list as well as a parenthetical for tinea unguium—onychomycosis as these are also common variations of dermatophytosis seen in the veteran population. Id. at 1251–84. As previously discussed above, VA intends to rate conditions covered by DC 7813 under the General Rating Formula, which provides for similar evaluation criteria as are currently in effect.

Diagnostic Codes 7815 and 7816

Current medical practice indicates conditions rated under DC 7815 (bullous disorders) and DC 7816 (psoriasis) can affect additional areas beyond the skin (bullous disorders can affect mucosa of the ocular, oral, gastrointestinal, respiratory, and genitourinary tracts; psoriasis can affect oral mucosa, nails and the joints). Id. at 142, 148–55, 472–73, 482, and 487–89. Therefore, in addition to rating these conditions under the General Rating Formula, VA proposes a note for each of these DCs. The note to DC 7815 would instruct the rater to rate complications and residuals of mucosal involvement (ocular, oral, gastrointestinal, respiratory, and genitourinary) separately under the appropriate diagnostic code. The note to DC 7816

would instruct the rater to rate complications such as psoriatic arthritis and other clinical manifestations (oral mucosa, nails) under the appropriate diagnostic code.

Diagnostic Code 7817

VA proposes to retitle DC 7817, currently “Exfoliative dermatitis (erythroderma),” as “Erythroderma.” Erythroderma is the nomenclature being used in current medical practice. Id. at 171–81. In addition, it proposes to update the rating criteria to reflect up-to-date medical understanding of this condition. VA would also slightly reorganize the presentation of criteria for ease of field use. Currently, this condition is evaluated based upon level of involvement of the skin, presence of systemic manifestations, and the level of treatment required. VA does not propose any changes to the level of involvement of the skin, presence of systemic manifestations, or the level of treatment required. However, similar to the changes proposed in the General Rating Formula, the new rating criteria for DC 7817 would reflect additional systemic treatments appropriate for this condition. Currently, DC 7817 includes corticosteroids, immunosuppressive retinoids, PUVA (psoralen with long-wave ultraviolet-A light) or UVB (ultraviolet-B light) treatments, or electron beam therapy. VA proposes to add biologics to this list as several biological therapies have been approved for treatment of skin disorders in recent years. See M. Viguier, et al., “Efficacy and Safety of Biologics in Erythrodermic Psoriasis,” *The British J. of Dermatology* 167(2): 417–23 (2012). VA proposes that inclusion of this type of systemic therapy in the rating criteria would ensure consistent and accurate evaluations.

In addition to expanding the list of systemic therapies listed, VA proposes to include a criterion which considers an individual’s level of response to treatment for both the 60 percent and 100 percent evaluations. Under the new criteria, VA would provide a 100 percent rating when the veteran is not currently undergoing treatment due to a documented history of treatment failure with 2 or more treatment regimens and a 60 percent rating when the veteran is not currently undergoing treatment due to a documented history of treatment failure with 1 treatment regimen. Historically, there have been a significant number of veterans with this disorder who fail to respond to treatment (frequently, the condition is related to an underlying malignancy that is not treated successfully, hence the treatment failure).

To assist rating personnel in applying the new rating criteria, VA proposes to add a note to DC 7817 which defines “treatment failure.” Modeled after a formula developed to study the efficacy of treatment in erythrodermic cutaneous T-cell lymphoma, VA proposes to define “treatment failure” as either disease progression or less than a 25 percent reduction in the extent and severity of disease after four weeks of prescribed therapy, as documented by medical records. See Zackheim HS, Kashani-Sabet M, et al., “Low-dose methotrexate to treat erythrodermic cutaneous T-cell lymphoma: Results in twenty-nine patients,” *J. Am. Acad. of Dermatology* 34(4):626–31 (1996); see also Bolognia, supra at 181 (erythroderma usually improves within two to six weeks of initiation).

Diagnostic Code 7822

VA proposes to update the description in this code to reflect current medical practice. Specifically, the condition mycosis fungoides is added to the list of papulosquamous disorders. See Bolognia, 2019–2027. Currently, mycosis fungoides is not listed in the rating schedule and has caused confusion among VA rating specialists on how to account for this condition, leaving VA rating specialists to invoke § 4.20, analogous ratings. This approach could lead to inconsistent ratings for this condition. Therefore, adding mycosis fungoides under DC 7822 would eliminate the need for an analogous rating and provide a consistent basis for evaluating this condition.

Diagnostic Code 7825

Chronic urticaria, also known as chronic hives, is defined as continuous urticaria at least twice per week off treatment for a period of six weeks or more. See Bolognia at 295. It can be caused by a number of mechanisms (physical stimulus, or touch; autoimmune causes; pseudoallergenic, infection-related; vasculitis-related; and, idiopathic, or unknown). Id. at 296. Chronic urticaria is currently evaluated based on the frequency of “episodes” or “debilitating episodes” and type of treatment. Regarding “episodes” or “debilitating episodes,” VA believes this term is non-specific and not helpful to rating personnel in evaluating this condition. Therefore, VA proposes to replace this term with “documented urticarial attacks.” Furthermore, VA proposes to revise all of the rating criteria to indicate both a minimum specified frequency of documented urticarial attacks within a 12 month period and the type of treatment

required. VA proposes this approach to the criteria to introduce greater objectivity within the evaluation criteria based on current medical practice. VA acknowledges that an urticarial attack generally results in debilitation; however, this change makes it clear that the acute period of debilitation must be related to the service-connected skin disease itself rather than another condition.

Regarding the current 30 percent and 60 percent criteria, VA proposes to include examples of common “immunosuppressive therapy,” to include, but not limited to, cyclosporine or steroids. See Bolognia, supra at 300–05. For clarity and consistency, VA would replace the phrase occurring “at least four times during the past 12-month period” in the 30 and 60 percent criteria with “four or more times per 12-month period.”

VA also proposes to add two new sets of criteria under the 10 percent evaluation; the revised criteria would allow a 10 percent evaluation to be assigned in more circumstances based upon an individual’s level of response to treatment. A 10 percent evaluation would be assigned if there are recurrent documented urticarial attacks occurring one to three times during the past 12-month period and intermittent systemic immunosuppressive therapy is required for control. VA would also assign a 10 percent evaluation if there are recurrent documented urticarial attacks occurring four or more times during the past 12-month period and treatment with antihistamines or sympathomimetics (including, but not limited to an epipen or intramuscular epinephrine) is required or, if there are no recurrent documented urticarial attacks, but continuous systemic immunosuppressive therapy medication is required for control (including, but not limited to, cyclosporine, steroids). VA also proposes to reorganize how the various criteria are presented for ease of field use.

VA believes that a 10 percent evaluation is appropriate in each of these cases because the treatment measures may impose slight disability upon the individual. For example, long term treatment with antihistamines can result in drowsiness (even the non-sedating kinds) and autonomic nervous system dysfunction (e.g., urinary retention). Id. at 303. Similarly, continuous use of systemic medications may result in disabling effects, such as drowsiness with doxepin or weight gain, and increased risk of diabetes with long-term steroid use. See Manuchair Ebadi, “Desk Reference of Clinical Pharmacology,” 101, 113, 329, and 582

(2d ed. 2008); see also “Chronic hives (urticaria),” Mayo Clinic (Sept. 17, 2011), <http://www.mayoclinic.org/diseases-conditions/chronic-hives/basics/treatment/con-20031634> (last visited Apr. 23, 2014).

Diagnostic Code 7826

Similar to DC 7825, VA proposes to update the criteria under current DC 7826, “Vasculitis, primary cutaneous.” First, VA proposes to replace the term “debilitating episodes,” which is a non-specific term not defined in the VASRD with the term “documented vasculitic episodes.” This change in terminology is more consistent with current medical practice. Next, VA proposes to modify the criteria to specify the minimum frequency of documented vasculitic episodes, the type of treatment required and the effectiveness of that treatment. In turn, increased disability would be reflected in objective terms (e.g., increased frequency of vasculitic episodes, more intensive treatment or lack of treatment effectiveness). VA also proposes to reorganize how the various criteria are presented for ease of field use. These modifications incorporate current medical knowledge, enhance objectivity and are easier for rating personnel to utilize.

For the 60 percent level of compensation, VA proposes to remove the phrase “occurring at least four times during the past 12 month period” and replace the term “recurrent” with “persistent” and the term “despite” with the phrase “refractory to.” The phrase removal and term replacements are to more clearly differentiate between the 60 percent and 30 percent compensation levels. For the 30 percent evaluation, VA proposes to replace the phrase “. . . at least four times during the past 12-month period . . .” with the phrase “four or more times per 12-month period” to clearly delineate the minimal frequency requirement and ease of field use. For the 10 percent evaluation, VA proposes to replace the phrase “one to three times during the past 12-month period” with “one to three times per 12-month period” for ease of field use. Additionally for the 10 percent evaluation, VA proposes to add that the absence of recurrent documented vasculitic episodes but requiring continuous systemic medication for control would also warrant compensation. This proposed revision allows a 10 percent evaluation to be assigned in more circumstances, namely, when the disorder is controlled through the use of systemic medications, but there may be slight disabling effects as a result of such medication. See Ebadi, supra; see also

“Vasculitis,” Mayo Clinic (Oct. 8, 2011), <http://www.mayoclinic.org/diseases-conditions/vasculitis/basics/treatment/con-20026049> (last visited Apr. 23, 2014).

Diagnostic Code 7827

VA proposes to revise and update the criteria for DC 7827, “Erythema multiforme; Toxic epidermal necrolysis.” First, each evaluation level would reference the presence of mucosal (leading to impaired mastication, that is, chewing), palmar (leading to impaired handgrip), or plantar involvement (leading to impaired ambulation, that is, walking). See Bologna, supra at 320, 322, and 326–32. The mucosal, palmar, and/or plantar findings would be restricted to the past 12-month period for all evaluation levels. For clarity and consistency, VA would replace the phrase occurring “at least four times during the past 12-month period” in the 30 and 60 percent criteria with “four or more times per 12-month period.” For a 60 percent evaluation, recurrent mucosal, palmar, or plantar involvement impairing mastication, use of hands, or ambulation occurring four or more times per 12-month period despite ongoing immunosuppressive therapy would be required. For a 30 percent evaluation, recurrent mucosal, palmar, or plantar involvement not impairing mastication, use of hands, or ambulation occurring four or more times per 12-month period, and requiring intermittent systemic therapy would be required.

A 10 percent evaluation would be assigned for the following circumstances: (1) One to three episodes of mucosal, palmar, or plantar involvement not impairing mastication, use of hands, or ambulation occurring per 12-month period AND requiring intermittent systemic therapy, or (2) without recurrent episodes, but requiring continuous systemic medication for control. This allows a 10 percent evaluation to be assigned in more circumstances, based upon the level of response to treatment. Lastly, VA proposes to add a note at the end of DC 7827 defining, for the purposes of DC 7827 only, that systemic therapy may consist of one or more of the following treatment agents: Immunosuppressives, antihistamines, or sympathomimetics. See Ebadi, supra; see also Victor Cohen, PharmD, et al., “Toxic Epidermal Necrolysis Treatment & Management,” MEDSCAPE REFERENCE (Mar. 3, 2014), <http://emedicine.medscape.com/article/229698-treatment#a1156> (last visited Apr. 23, 2014).

Diagnostic Code 7828

VA proposes to update DC 7828, “Acne,” by removing the reference to “superficial cysts” in the zero percent rating criteria. This update is proposed based upon current medical terminology as the term “superficial cysts” is no longer used in the medical community. See Bologna, supra at 547–50 and 555–58.

Diagnostic Code 7829

Current DC 7829 instructs rating personnel to evaluate chloracne based, in part, on either the presence of deep or superficial acne. The current evaluation criteria instructs that either a 10 or 30 percent evaluation should be assigned depending upon whether more or less than 40 percent of the face and neck are involved; VA does not propose changes to these criteria. However, a 10 percent evaluation is also assigned when there is “deep acne other than on the face and neck.” VA proposes to clarify that a 10 percent evaluation should only be assigned when deep acne affects non-intertriginous areas of the body other than the face and neck or less than 40 percent of the face and neck. Intertriginous areas of the body include the axilla of the arm, the anogenital region, and skin folds of the breast or between digits. Samuel T. Selden, MD, “Intertrigo,” Medscape Reference (Mar. 27, 2012), <http://emedicine.medscape.com/article/1087691-overview> (last visited Apr. 23, 2014). Deep acne affecting these areas of the body results in greater functional impairment to the individual because these represent more sensitive areas of the body. Therefore, VA proposes to assign a higher 20 percent evaluation when deep acne affects the intertriginous areas of the body.

Additionally, for reasons previously discussed in DC 7828, VA proposes to remove the term “superficial cysts” from the rating criteria under the zero percent evaluation. See Bologna, supra at 547–50 and 555–58.

Technical Amendments

VA also proposes several technical amendments. We would update Appendix A, B, and C of part 4 to reflect the above noted proposed amendments.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages;

distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, 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 Web site at <http://www.va.gov/orpm/>, by following the link for “VA Regulations Published From FY 2004 Through Fiscal Year to Date.”

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 directly affect only individuals and would not directly affect 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

	Rating
Systemic therapy including, but not limited to, corticosteroids, phototherapy, retinoids, biologics, photochemotherapy, PUVA or other immunosuppressive drugs required for a total duration of six weeks or more, but not constantly, per 12-month period.	
At least one of the following At least 5 percent, but less than 20 percent of the entire body affected, or; At least 5 percent, but less than 20 percent of exposed areas affected, or; Intermittent systemic therapy including, but not limited to, corticosteroids, phototherapy, retinoids, biologics, photochemotherapy, PUVA or other immunosuppressive drugs required for a total duration of less than six weeks per 12-month period.	10
No more than topical therapy required per 12-month period and at least one of the following Less than 5 percent of the entire body affected, or; Less than 5 percent of exposed areas affected.	0
Or rate as disfigurement of the head, face or neck (DC 7800) or scars (DCs 7801, 7802, 7804, or 7805), depending upon the predominant disability. This rating instruction does not apply to DC 7824.	
7806 Dermatitis or eczema. Evaluate under the General Rating Formula for the Skin.	
* * * * *	
7809 Discoid lupus erythematosus. Evaluate under the General Rating Formula for the Skin. <i>Note:</i> Do not combine with ratings under DC 6350.	
* * * * *	
7813 Dermatophytosis (ringworm: of body, tinea corporis; of head, tinea capitis; of feet, tinea pedis; of beard area, tinea barbae; of nails, tinea unguium (onychomycosis); of inguinal area (jock itch), tinea cruris; tinea versicolor) Evaluate under the General Rating Formula for the Skin.	
7815 Bullous disorders (including pemphigus vulgaris, pemphigus foliaceus, bullous pemphigoid, dermatitis herpetiformis, epidermolysis bullosa acquisita, benign chronic familial pemphigus (Hailey-Hailey), and porphyria cutanea tarda). Evaluate under the General Rating Formula for the Skin. <i>Note:</i> Rate complications and residuals of mucosal involvement (ocular, oral, gastrointestinal, respiratory, and genitourinary) separately under the appropriate diagnostic code.	
7816 Psoriasis. Evaluate under the General Rating Formula for the Skin. <i>Note:</i> Rate complications such as psoriatic arthritis and other clinical manifestations (oral mucosa, nails) under the appropriate diagnostic code.	
7817 Erythroderma: Generalized involvement of the skin with systemic manifestations (such as fever, weight loss, and hypoproteinemia) AND one of the following: Constant or near-constant systemic therapy such as therapeutic doses of corticosteroids, immunosuppressive retinoids, PUVA (psoralen with long-wave ultraviolet-A light); UVB (ultraviolet-B light) treatments, biologics, or electron beam therapy required per 12-month period, or No current treatment due to a documented history of treatment failure with 2 or more treatment regimens	100
Generalized involvement of the skin without systemic manifestations and one of the following: Constant or near-constant systemic therapy such as therapeutic doses of corticosteroids, immunosuppressive retinoids, PUVA (psoralen with long-wave ultraviolet-A light); UVB (ultraviolet-B light) treatments, biologics, or electron beam therapy required per 12-month period, or No current treatment due to a documented history of treatment failure with 1 treatment regimen	60
Any extent of involvement of the skin, and any of the following therapies required for a total duration of six weeks or more, but not constantly, per 12-month period: Systemic therapy such as therapeutic doses of corticosteroids, immunosuppressive retinoids, PUVA (psoralen with long-wave ultraviolet-A light) or UVB (ultraviolet-B light) treatments, biologics, or electron beam therapy	30
Any extent of involvement of the skin, and any of the following therapies required for a total duration of less than six weeks per 12-month period: Systemic therapy such as therapeutic doses of corticosteroids, immunosuppressive retinoids, PUVA (psoralen with long-wave ultraviolet-A light) or UVB (ultraviolet-B light) treatments, biologics, or electron beam therapy	10
Any extent of involvement of the skin, and; no more than topical therapy required per 12-month period	0
<i>Note:</i> Treatment failure is defined as either disease progression, or less than a 25 percent reduction in the extent and severity of disease after four weeks of prescribed therapy, as documented by medical records.	
* * * * *	
7820 Infections of the skin not listed elsewhere (including bacterial, fungal, viral, treponemal and parasitic diseases). Evaluate under the General Rating Formula for the Skin.	
7821 Cutaneous manifestations of collagen-vascular diseases not listed elsewhere (including scleroderma, calcinosis cutis, subacute cutaneous lupus erythematosus, and dermatomyositis). Evaluate under the General Rating Formula for the Skin.	
7822 Papulosquamous disorders not listed elsewhere (including lichen planus, large or small plaque parapsoriasis, pityriasis lichenoides et varioliformis acuta (PLEVA), lymphomatoid papulosus, mycosis fungoides, and pityriasis rubra pilaris (PRP)). Evaluate under the General Rating Formula for the Skin.	
* * * * *	
7824 Diseases of keratinization (including ichthyoses, Darier's disease, and palmoplantar keratoderma). Evaluate under the General Rating Formula for the Skin.	
7825 Urticaria: Recurrent documented urticarial attacks occurring four or more times per 12-month period despite continuous immunosuppressive therapy (including, but not limited to, cyclosporine and steroids)	60

	Rating
Recurrent documented urticarial attacks occurring four or more times per 12-month period and requiring intermittent systemic immunosuppressive therapy (including, but not limited to, cyclosporine and steroids) for control	30
At least one of the following	10
Recurrent documented urticarial attacks occurring one to three times per 12-month period, and requiring intermittent systemic immunosuppressive therapy for control, or	
Recurrent documented urticarial attacks occurring four or more times per 12-month period, and requiring treatment with antihistamines or sympathomimetics (including, but not limited to an epipen or intramuscular epinephrine), or	
Without recurrent documented urticarial attacks, but requiring continuous systemic immunosuppressive therapy medication (including, but not limited to, cyclosporine and steroids) for control.	
7826 Vasculitis, primary cutaneous:	
Persistent documented vasculitis episodes refractory to continuous immunosuppressive therapy	60
All of the following	30
Recurrent documented vasculitic episodes occurring four or more times per 12-month period, and	
Requiring intermittent systemic immunosuppressive therapy for control.	
At least one of the following	10
Recurrent documented vasculitic episodes occurring one to three times per 12-month period, and requiring intermittent systemic immunosuppressive therapy for control, or	
Without recurrent documented vasculitic episodes but requiring continuous systemic medication for control.	
Or rate as disfigurement of the head, face, or neck (DC 7800) or scars (DC's 7801, 7802, 7804, or 7805), depending upon the predominant disability.	
7827 Erythema multiforme; Toxic epidermal necrolysis:	
Recurrent mucosal, palmar, or plantar involvement impairing mastication, use of hands, or ambulation occurring four or more times per 12-month period despite ongoing immunosuppressive therapy	60
All of the following	30
Recurrent mucosal, palmar, or plantar involvement not impairing mastication, use of hands, or ambulation occurring four or more times per 12-month period, and	
Requiring intermittent systemic therapy.	
At least one of the following	10
One to three episodes of mucosal, palmar, or plantar involvement not impairing mastication, use of hands, or ambulation occurring per 12-month period AND requiring intermittent systemic therapy, or	
Without recurrent episodes, but requiring continuous systemic medication for control.	
Or rate as disfigurement of the head, face, or neck (DC 7800) or scars (DC's 7801, 7802, 7804, or 7805), depending upon the predominant disability.	
Note: For the purposes of this DC only, systemic therapy may consist of one or more of the following treatment agents: Immunosuppressives, antihistamines, or sympathomimetics.	
7828 Acne:	
Deep acne (deep inflamed nodules and pus-filled cysts) affecting 40 percent or more of the face and neck	30
Deep acne (deep inflamed nodules and pus-filled cysts) affecting less than 40 percent of the face and neck, or; deep acne other than on the face and neck	10
Superficial acne (comedones, papules, pustules) of any extent	0
Or rate as disfigurement of the head, face, or neck (DC 7800) or scars (DC's 7801, 7802, 7804, or 7805), depending upon the predominant disability.	
7829 Chloracne:	
Deep acne (deep inflamed nodules and pus-filled cysts) affecting 40 percent or more of the face and neck	30
Deep acne (deep inflamed nodules and pus-filled cysts) affecting the intertriginous areas (the axilla of the arm, the anogenital region, skin folds of the breasts or between digits)	20
Deep acne (deep inflamed nodules and pus-filled cysts) affecting less than 40 percent of the face and neck; or, deep acne affecting non-intertriginous areas of the body (other than the face and neck)	10
Superficial acne (comedones, papules, pustules) of any extent	0
Or rate as disfigurement of the head, face, or neck (DC 7800) or scars (DC's 7801, 7802, 7804, or 7805), depending upon the predominant disability.	

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

■ 3. Amend appendix A to part 4, under the entry Sec. 4.118, by:

- a. Revising the entries for diagnostic codes 7801, 7802, 7805, 7806, 7809, 7813, 7815, 7816, and 7817;
- b. Removing the entry for 7820–7833;
- c. Adding entries for diagnostic codes 7820, 7821, 7822, 7823, 7824, 7825,

7826, 7827, 7828, 7829, 7830, 7831, 7832, and 7833.

The revisions and additions read as follows:

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

Section	Diagnostic Code No.						
4.118	7801	Criterion July 6, 1950; criterion August 30, 2002; criterion October 23, 2008; title, note 1, note 2 [effective date of final rule].					

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

Section	Diagnostic Code No.						
	7802	Criterion	September 22, 1978; criterion	August 30, 2002; criterion	October 23, 2008; title, note 1, note 2		
			[effective date of final rule].				
*	*	*	*	*	*	*	*
	7805	Criterion	October 23, 2008; title	[effective date of final rule].			
		General Rating Formula for DCs	7806, 7809, 7813—7816, 7820—7822, and 7824	added [effective date of final rule].			
	7806	Criterion	September 9, 1975; evaluation	August 30, 2002; criterion	[effective date of final rule].		
*	*	*	*	*	*	*	*
	7809	Criterion	August 30, 2002; title, criterion	[effective date of final rule].			
*	*	*	*	*	*	*	*
	7813	Criterion	August 30, 2002; title, criterion	[effective date of final rule].			
*	*	*	*	*	*	*	*
	7815	Evaluation	August 30, 2002; criterion, note	[effective date of final rule].			
	7816	Evaluation	August 30, 2002; criterion, note	[effective date of final rule].			
	7817	Evaluation	August 30, 2002; title, criterion, note	[effective date of final rule].			
*	*	*	*	*	*	*	*
	7820	Added	August 30, 2002; criterion	[effective date of final rule].			
	7821	Added	August 30, 2002; title, criterion	[effective date of final rule].			
	7822	Added	August 30, 2002; title, criterion	[effective date of final rule].			
	7823	Added	August 30, 2002; title, criterion	[effective date of final rule].			
	7824	Added	August 30, 2002; criterion	[effective date of final rule].			
	7825	Added	August 30, 2002; criterion	[effective date of final rule].			
	7826	Added	August 30, 2002; criterion	[effective date of final rule].			
	7827	Added	August 30, 2002; criterion	[effective date of final rule].			
	7828	Added	August 30, 2002; criterion	[effective date of final rule].			
	7829	Added	August 30, 2002; criterion	[effective date of final rule].			
	7830	Added	August 30, 2002; title, criterion	[effective date of final rule].			
	7831	Added	August 30, 2002; title, criterion	[effective date of final rule].			
	7832	Added	August 30, 2002; title, criterion	[effective date of final rule].			
	7833	Added	August 30, 2002; title, criterion	[effective date of final rule].			
*	*	*	*	*	*	*	*

■ 4. Amend appendix B to part 4, under the center heading The Skin., by revising the entries for diagnostic codes 7801, 7802, 7805, 7809, 7813, 7817, 7821, and 7822 to read as follows:

APPENDIX B TO PART 4—NUMERICAL INDEX OF DISABILITIES

Diagnostic Code No.							
*	*	*	*	*	*	*	*
THE SKIN							
7801	Burn scar(s) or scar(s) due to other causes, not of the head, face, or neck that are associated with underlying soft tissue damage.					
7802	Burn scar(s) or scar(s) due to other causes, not of the head, face, or neck that are not associated with underlying soft tissue damage.					
*	*	*	*	*	*	*	*
7805	Scars, other; and other effects of scars evaluated under diagnostic codes 7800, 7801, 7802, and 7804.					
*	*	*	*	*	*	*	*
7809	Discoid lupus erythematosus.					
*	*	*	*	*	*	*	*
7813	Dermatophytosis.					

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

Diagnostic Code No.	
7817	Erythroderma.
7821	Cutaneous manifestations of collagen-vascular diseases not listed elsewhere (including scleroderma, calcinosis cutis, subacute cutaneous lupus erythematosus, and dermatomyositis).
7822	Papulosquamous disorders not listed elsewhere.

- 5. Amend appendix C to part 4 by:
 - a. Removing the entry “Cutaneous manifestations of collagen-vascular diseases” and add in its place an entry for “Cutaneous manifestations of collagen-vascular diseases not listed elsewhere (including scleroderma, calcinosis cutis, subacute cutaneous lupus erythematosus, and dermatomyositis)”;
 - b. Adding in alphabetical order entries for “Discoid lupus erythematosus”, and “Erythroderma”; and
 - c. Revising the entries under “Scars.”
- The additions and revisions read as follows:

APPENDIX C TO PART 4—ALPHABETICAL INDEX OF DISABILITIES

	Diagnostic Code No.
Cutaneous manifestations of collagen-vascular diseases not listed elsewhere (including scleroderma, calcinosis cutis, subacute cutaneous lupus erythematosus, and dermatomyositis)	7821
Discoid lupus erythematosus	7809
Erythroderma	7817
Scars:	
Burn scar(s) of the head, face, or neck; scar(s) of the head, face, or neck due to other causes; or other disfigurement of the head, face, or neck	7800
Burn scar(s) or scar(s) due to other causes, not of the head, face, or neck that are associated with underlying soft tissue damage	7801
Burn scar(s) or scar(s) due to other causes, not of the head, face, or neck that are not associated with underlying soft tissue damage	7802
Retina	6011
Scars, other; and other effects of scars evaluated under diagnostic codes 7800, 7801, 7802, and 7804	7805
Unstable or painful	7804

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R10-OAR-2016-0394, FRL-9950-55-Region 10]

Approval and Promulgation of Implementation Plans; Washington: Updates to Incorporation by Reference and Miscellaneous Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) proposes to approve State Implementation Plan revisions submitted by the Washington State Department of Ecology (Ecology) on July 11, 2016. The revisions update the incorporation by reference of Federal provisions cited in Ecology’s general air quality regulations. The revisions also reflect changes to the primary and secondary National Ambient Air Quality Standards (NAAQS) for ozone, promulgated since Ecology’s last update. Ecology also made minor corrections to typographical errors and

non-substantive edits for clarity, such as standardizing the citation format.

DATES: Comments must be received on or before September 12, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R10-OAR-2016-0394 at <http://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 whose disclosure is