While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the FOR FURTHER INFORMATION CONTACT section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

# C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

# D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

#### E. Unfunded Mandates Reform Act

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

# F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023-01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321-4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone surrounding the vessels and machinery being used by personnel to repair the Wilsonville Wastewater Treatment Plant outfall. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 01. A **Record of Environmental Consideration** supporting this determination is available in the docket where indicated under ADDRESSES.

# G. Protest Activities

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

# List of Subjects in 33 CFR Part 165

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

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

# PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T13–0647 to read as follows:

# § 165.T13–0647 Safety Zone; Willamette River, Wilsonville, OR.

(a) Location. The following area is designated safety zone: All navigable waters of the Willamette River surrounding the Wilsonville Wastewater Treatment Plant outfall repair vessels and machinery located in Wilsonville, OR, encompassed by a line connecting these points:  $45^{\circ}17'33.1764''$  N,  $122^{\circ}46'17.3886''$  W;  $45^{\circ}17'31.1958''$  N,  $122^{\circ}46'18.1092''$  W;  $45^{\circ}17'32.1504''$  N,  $122^{\circ}46'8.9544''$  W; and  $45^{\circ}17'30.1956''$  N,  $122^{\circ}46'8.8746''$  W.

(b) *Regulations.* In accordance with the general regulations in part 165, subpart C, of this chapter, no person may enter or remain in the safety zone created in this section or bring, cause to be brought, or allow to remain in the safety zone created in this section any vehicle, vessel, or object unless authorized by the Captain of the Port or his designated representative.

(c) Enforcement period. This safety zone is in effect from July 9, 2018, until August 31, 2018. It will be subject to enforcement this entire period unless the COTP, Columbia River determines it is no longer needed. The Coast Guard will inform mariners of any change to this period of enforcement via Broadcast Notice to Mariners.

(d) *Enforcement.* Any Coast Guard commissioned, warrant, or petty officer may enforce the rules in this section.

Dated: July 6, 2018.

#### D.F. Berliner,

Captain, U.S. Coast Guard, Acting Captain of the Port, Sector Columbia River. [FR Doc. 2018–14983 Filed 7–12–18; 8:45 am]

BILLING CODE 9110-04-P

### DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 4

# RIN 2900-AP27

#### Schedule for Rating Disabilities: Skin

**AGENCY:** Department of Veterans Affairs. **ACTION:** Final rule.

**SUMMARY:** On August 12, 2016, VA published in the **Federal Register** the

proposed rule for Schedule for Rating Disabilities: Skin. VA received multiple responses during the 60-day comment period. This final rule implements the Secretary's proposed rule with limited revisions.

**DATES:** This rule is effective on August 13, 2018.

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:

#### Applicability

In reviewing the proposed rule to prepare for publication of the final rule, VA determined that the statements regarding the applicability date in the proposed rule should be revised in order to avoid potential misapplication of this final rule. In the proposed rule, VA stated that the provisions of the new regulations would apply to all applications for benefits received by VA or that are pending before the agency of original jurisdiction on or after the effective date of the final rule. VA has indeed structured some regulations this way in the past, due to the dynamics of the regulation in question. See "Schedule for Rating Disabilities-Mental Disorders and Definition of Psychosis for Certain VA Purposes," 80 FR 14308 (March 19, 2015). However, for this final rule, VA's intent is that the claims pending prior to the effective date will be considered under both old and new rating criteria, and whatever criteria is more favorable to the veteran will be applied. For applications filed on or after the effective date, only the new criteria will be applied.

### **Comments Received**

Ten different commenters (including two Veterans Service Organizations) submitted comments in response to the proposed rule. VA will address their comments within the topics below.

# Comments Warranting Revisions to the Proposed Rule

VA has made five changes to the proposed rule based on comments received. First, two commenters noted that additional guidance regarding coexistent skin conditions and pyramiding might be helpful. VA agrees and has added a clarifying note at the start of § 4.118(b) which states: "Two or more skin conditions may be combined in accordance with § 4.25 only if separate areas of skin are involved. If two or more skin conditions involve the same area of skin, then only the highest evaluation shall be used."

Second, two commenters felt that the proposed language "per 12-month period" in multiple diagnostic codes (DCs) was unclear about which 12month period would be used for evaluation purposes. VA concurs and has revised the criteria to specify that "over the past 12-month period" is the applicable time frame for these DCs.

Third, a commenter asserted that the evaluation criteria for eczema (DC 7806) should consider itching. Eczema (also known as atopic dermatitis) is often called "the itch that rashes." The intense itching (without lesions at first) leads to the scratching, resulting in the characteristic lesions. See "Dermatology" 210 (Jean Bolognia et al. eds., 3d ed. 2012). Thus, itching is part of the pathology in all eczema ratings, even though only involved areas (lesions, scars) are considered for compensation purposes. Based on this comment, VA has clarified that it is the area of lesions, not the itching, that forms the basis of a rating, by revising in this final rule each criteria level in the General Rating Formula for the Skin to include the phrase "Characteristic lesions involving. . . .

Fourth, a commenter expressed concern that a long-lasting urticarial attack with no breaks would qualify for a 10% rating, rather than a 60% rating under DC 7825 (Urticaria). VA understands this concern and has revised the criteria in this final rule to be based on the condition's response to required treatment. First, VA has retitled the diagnostic code, "Chronic urticaria" and added a definition for chronic urticaria, which is "continuous urticaria at least twice per week, off treatment, for a period of six weeks or more." A subset of patients has chronic urticaria that is unresponsive to first line treatment (antihistamines). If a patient is also unresponsive to second line treatment (*e.g.*, epinephrine, corticosteroids, aminosalicylates), it is considered refractory chronic urticaria. It was, and continues to be, VA's intent to have evaluation levels that clearly and distinctly reflect increasing disability. To that end, VA has revised the evaluation criteria to more clearly establish three distinct levels of disability: (1) Chronic urticaria requiring first line treatment for control, (2) chronic urticaria requiring second line treatment for control, and (3) chronic urticaria which is refractory to both first line and second line treatment. A non-exhaustive list of examples for first line, second line, and third line treatment is given with each evaluation level. This should ensure,

commensurate with the commenter's concern, that more severe and less controllable urticarial attacks receive higher ratings.

Fifth, a commenter asked if active psoriatic arthritis would be entitled to a 60% evaluation under DC 7816 (Psoriasis) and a 100% evaluation under DC 5009 (Arthritis, other types), allowing for special monthly compensation at the "s" level, i.e., housebound. To clarify that separate ratings are permissible, VA has added the term "separately" to the note in DC 7816. Special monthly compensation would be warranted under 38 CFR 3.350(i)(1), if the psoriasis and the arthritis constitute "separate and distinct" disabilities "involving different anatomical segments or bodily systems."

Beyond the changes made in response to comments, this final rule contains several technical and non-substantive amendments to the proposed rule.

## Comments Related to Systemic and Topical Therapy and *Johnson* v. *McDonald*

A total of six comments either disagreed with or questioned VA's proposal for defining topical and systemic therapy in light of the Johnson v. McDonald decision of the U.S. Court of Appeals for Veterans Claims (CAVC) in 2016. That decision found that any use of a topically-applied corticosteroid constituted "systemic therapy" pursuant to diagnostic code 7806. However, in July 2017, the U.S. Court of Appeals for the Federal Circuit (Federal Circuit) reversed the CAVC's interpretation. See Johnson v. Shulkin, 862 F.3d 1351 (Fed. Cir. 2017). The Federal Circuit held that the CAVC was incorrect to "read DC 7806 as unambiguously elevating any form of corticosteroid treatment, including any degree of topical corticosteroid treatment, to the level of 'systemic therapy." Id. at 1354.

Although VA's proposal for systemic and topical therapy was in part a reaction to the CAVC's now-reversed Johnson decision, its aim was also to provide clarity for raters adjudicating these claims. VA proposed to clarify that treatment administered through the skin is "topical therapy," while treatment administered through any route other than the skin (orally, injection, suppository, intranasally) is "systemic therapy." This final rule adopts VA's proposal. One theme of the comments was that topically-applied medications could be considered systemic therapy or could have systemic effects. In this regard, one commenter questioned why VA does not provide

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more information as to the potential systemic effects of topically-applied corticosteroids, and another asserted that topically-applied medications can cause heightened effects in elderly populations.

As noted in the supplementary information to the proposed rule, however, it creates a dramatic disconnect to rate a medication applied to the skin—affecting only the localized area to which it is applied—as "systemic therapy" that affects the entire body. Rather, the prevailing medical understanding is that "topical" therapy "pertain[s] to a particular surface area . . . and affect[s] only the area to which it is applied," while ''systemic'' therapy ''pertain[s] to or affect[s] the body as a whole." Dorland's Illustrated Medical Dictionary 1865, 1940 (32d ed. 2012). VA's proposal, adopted as a final rule here, sets clear guidelines in accordance with this understanding: creams applied to the skin are "topical therapy," and treatments applied in a way (orally, intranasally, etc.) that the medication circulates throughout the entire body and suppresses the immune system as a whole are "systemic therapy."

VA also acknowledged in the supplementary information that some medications applied to the skin, if administered on a large enough scale, could have a systemic effect; but in those situations the veteran can obtain a higher rating due to the percentage of the body affected. For example, a veteran who is required to apply a cream on his entire body is not subject to a noncompensable rating; even though he is not taking systemic therapy, he would obtain a compensable rating under this final rule based on the percentage of his body affected by the condition.

Overall, the aim of this rule is to clarify the terms used in the rating schedule, in order to distinguish between a condition that affects a large portion of the body or requires therapy affecting the entire body, and a condition that is localized and involves localized treatment. The former generally impairs earning capacity more than the latter. To the extent that topically-applied medications might affect different people (such as the elderly) in different ways, the rating schedule is based on the average impairment in earning capacity. 38 U.S.C. 1155. If there is an exceptional or unusual effect of applying corticosteroid cream, a claimant can submit argument for an extraschedular rating. 38 CFR 3.321(b)(1). VA can also raise the issue of an extraschedular rating on its own when the evidence of record suggests

such consideration is appropriate. This is why VA cannot provide more specific information on the potential systemic effects of topically-applied corticosteroids: the potency of the medication, the amount of skin affected, and the strength of the condition, will vary from veteran to veteran.

One comment on this topic advocated that VA should automatically assume that topical corticosteroids have systemic effects based on the benefit-ofthe-doubt standard. The benefit-of-thedoubt rule, however, applies to the adjudication of claims, not formulation of the rating schedule. 38 U.S.C. 5107(b). This commenter further stated that certain skin conditions cannot be cured, but only treated, and that the burden of applying medication with little effect is not taken into consideration in the proposed rule. To the contrary, frequency in application is a factor in the schedule for rating systemic therapy, but it remains VA's assessment that applying cream on the skin of less than 5% of the body reflects a condition that does not impair earning capacity at a compensable level.

Two additional commenters viewed the proposed rule as an attempt to circumvent or undermine the CAVC's ruling. These comments are obviated by the fact that the CAVC's ruling has been reversed. See Johnson v. Shulkin. supra. But even if it had not been reversed, it is well established that a judicial interpretation of regulatory language does not preclude an agency from revising that language (for prospective application) pursuant to its rulemaking authority. See Nat'l Org. of Veterans Advocates Inc., v. Sec'y of Veterans Affairs, 260 F.3d 1365, 1373 (Fed. Cir. 2001) (argument that CAVC holdings prevent revision of regulations seriously misunderstand[s] . . . the nature of the judicial function."). VA may clarify the rating schedule to accord with its original intent in promulgating these diagnostic codes. One of these commenters added that skin conditions can cause real pain and embarrassment and should not be devalued. We understand this concern. but the objective criteria of (1) percentage of body affected and (2) mode and frequency of therapy are better suited in determining average impairment of earning capacity than an individual's level of embarrassment.

Another commenter questioned the consistency of the proposed definition for systemic therapy with DC 6602 and the overall rating schedule. This rule is consistent with DC 6602—which defines "systemic" corticosteroids as "oral or parenteral," *i.e.*, the corticosteroids that circulate throughout the body and affect the entire immune system. We are unaware, and the commenter does not provide further information, as to how the rule is inconsistent with other portions of the rating schedule.

Finally, two commenters asserted that VA is emphasizing topical treatment in order to save money at the expense of quality care. This rule, however, should not affect how doctors treat conditions; rather, its aim is to clarify terms for raters adjudicating claims. We are not aware of any VA instruction that its doctors prescribe topical treatment to save money when it is not best for the patient.

# Comments Recommending Revisions to Evaluation Criteria

A number of comments recommended revisions to criteria within the proposed rule. VA received two comments regarding DC 7806, Dermatitis or eczema. One comment has been addressed above and prompted a revision to this final rule. The other comment requested that VA include biopsy results in the evaluation criteria, because eczema can occur sporadically over the year and a doctor might only take account of what is observable during the examination. VA declines to make changes based upon this comment. The General Rating Formula for the Skin employs two routes to compensation, based on either the extent of skin involvement or the intensity of treatment. If the condition requires constant or near-constant systemic therapy, then, regardless of the extent of skin involvement at the time of examination, the veteran would be entitled to the highest evaluation. It is unclear how criteria based on biopsy results would be more favorable to veterans than this scheme. Moreover, obtaining a biopsy for every ratable skin condition is not necessarily appropriate, and a service-connected veteran is free to request an additional examination if a skin disorder becomes more extensive than what was observed during a given examination. VA received two comments concerning DC 7817, Erythroderma. One comment asked why the "treatment failure" language was incorporated into the proposed criteria when the term "uncontrolled" in the evaluation criteria for diabetes (DC 7913) "was found to be problematic." VA incorporated language regarding "treatment failure" here because it is easily measured and can be applied by rating officials with consistent results. Treatment failure is a common occurrence with erythroderma, and we see no connection to the term "uncontrolled" in a diagnostic code for

a different condition (diabetes) that was revised over two decades ago. The second comment asked whether VA would use the new DC 7817 criteria for pending appeals. As explained above, VA will only apply the new criteria to pending appeals if it is advantageous to the appellant.

One comment addressed DC 7824, Diseases of keratinization. The commenter stated that we would be underrating diseases of keratinization by moving them to the General Rating Formula for the Skin, where it would not account for systemic manifestations. While VA concurs that the term "systemic manifestations" is not employed within the General Rating Formula for the Skin, this change does not adversely affect the veteran. Under the version of DC 7824 that is being revised by this final rule, a veteran needs both "systemic manifestations" and "systemic medication" for a 30% or 60% rating if there is not generalized cutaneous involvement. Now, under this final rule, a veteran with a disease of keratinization can receive such a rating for taking "systemic therapy" even without any systemic manifestations. This change simplifies the evaluation for veterans with diseases of keratinization.

Three comments requested changes to DC 7825, Urticaria, and DC 7826, Vasculitis, primary cutaneous. One comment has been addressed above, resulting in a revision to the final rule. Another comment asserted that the term "documented" in DC 7826 should not require evidence of a visit to a physician, clinic, or hospital, because those already on medication may not seek medical attention if they are used to managing their condition. That commenter requested that VA clarify that lay evidence fulfills the "documented" standard.

VA understands that lay evidence must be considered when VA adjudicators evaluate a claim, and nothing in this final rule is meant to undercut that principle. On the other hand, virtually the entire VA ratings schedule requires some kind of documentation or objective testing in order to gauge the severity of a disability. In that vein, this final rule requires that vasculitic episodes be "documented" for a higher rating. Though the rule does not state that the only acceptable documentation is a doctor's contemporaneous confirmation, a veteran whose disease is not under control and continues to prompt episodes would most likely see a provider multiple times within a 12month period.

The third commenter found it problematic that the criteria would allow mild, frequent attacks to be rated higher than more severe and longer attacks. This commenter also stated that a reliance on treatment modality is problematic, because biologics are impossible for veterans with weakened immune systems and others are prescribed unevenly.

VA's change to DC 7825 in this final rule obviates this comment, as the urticaria criteria are no longer reliant on the number of attacks. VA also disagrees that basing evaluation criteria on treatment modality is problematic. Each line of treatment for chronic urticaria (first line, second line, or third line) has more than one treatment option available, so the fact that one particular option is poorly tolerated does not imply that veterans will be inaccurately rated.

VA received three comments involving areas of affected skin, including requests to add forearms and lower legs as exposed areas. One of the commenters explained that, in summer temperatures, veterans cannot be expected to work with their forearms and lower legs covered. A second stated that there is no equitable definition of exposed skin, and doctors are commonly recommending more sunlight for psoriasis. The third suggested the work group identify which technique for measuring the area of involved skin would be best suited for evaluation purposes.

VA will not make any revisions to the final rule based on the above comments, as VA is unaware of any occupations that *require* exposed forearms or lower legs, *i.e.*, mandate such exposure as part of the job. Furthermore, dermatologists (who are the subject matter experts when it comes to conditions affecting the skin) have already decided how to calculate involved skin area and what constitutes a routinely exposed area; and the established medical practice in that field is to consider only the head, neck, and hands consistently and truly exposed, as long-sleeved shirts and fulllength pants have customarily been considered part of the typical clothing used in occupational settings. There is no justification, medical or otherwise, to change from established practice. Lastly, a treatment recommendation to get more sunlight for psoriatic skin neither precludes nor interferes with employment, and thus should have no bearing on the rating criteria.

VA received two comments about alopecia, specifically DC 7830, Scarring alopecia, and DC 7831, Alopecia areata. One comment asserted that DC 7831 should provide a compensable rating for

loss of scalp hair, since it is an exposed area. The other comment recommended a higher evaluation under DC 7830 for women, because this condition is more socially debilitating for women and, as a result, women incur a higher financial responsibility to deal with the condition. VA is sympathetic to these issues and understands the social aspects of hair loss. Nevertheless, the rating schedule is based on the loss of wage-earning capacity and no reliable evidence establishes significant occupational impairment with loss of body hair, or that occupational impairment is greater in women than in men with scarring alopecia. As such, VA will not revise the final rule based on these two comments.

As to the final comments, one requested a note adding consideration of the effect of disfigurement on the veteran's mental health. VA acknowledges that secondary service connection under 38 CFR 3.310 may be possible for a mental health disability that is found to be causally related to a service-connected skin disability. However, we believe this is clear from 38 CFR 3.310, such that a note is not necessary here. The second questioned why evaluation criteria do not comment on conditions caused by the failure of the immune system, such as lymphedema, which affect the skin and may require compression therapy. Although lymphedema may be evaluated under diagnostic codes pertaining to the skin if it disfigures and/or scars the skin, see 38 CFR 4.116, DC 7627–7628 (evaluating lymphedema "under the appropriate diagnostic code(s) within the appropriate body system"), it is ultimately a lymphatic condition, not a skin condition, such that its consideration would be outside the scope of both the proposed and final rules for the skin.

# **Comments Regarding Interplay of Regulations**

VA received a number of comments seeking clarification or guidance on the interplay between section 4.118 and other regulations.

Three comments implicated the relationship between part 3 regulations and section 4.118. One comment regarding multiple ratings for psoriatic arthritis has been addressed above, resulting in a revision in this final rule. Another comment asked if VA would service connect disabilities to other body systems resulting from the treatment of skin conditions. Generally, yes, VA may grant secondary service connection as long as the standards found in 38 CFR 3.310 are met.

A third comment questioned the consistency between the definition of chronic in 38 CFR 3.380 (diseases of allergic etiology) and the definition in DCs 7825 and 7826. No inconsistencies exist, as 38 CFR 3.380 addresses service connection, while DCs 7825 and 7826 address evaluation, and none of these provisions address the term ''chronic.'' This commenter continued by stating: "Confusion regarding 'service connection' and evaluation criteria applies to the 'continuous use' and 'disabling effects of medication' to suggest that VA will concede secondary service connection [38 CFR 3.310] in cases with facts similar to those described (or are these functional impairments simply acute and transitory or will this be pyramiding?)." VA finds this portion of the comment unclear and is unable to respond.

The remaining comments covered the relationship between section 4.118 and other part 4 regulations. One commenter assumed that combined ratings would result from DCs 7801 and 7802. To the contrary, the General Rating Formula for the Skin instructs the rater to use the relevant criteria or rate under DCs 7800, 7801, 7802, 7804, or 7805. Hence, the guidance precludes combining of disability criteria in this regard. Another comment asked about the difference between the six zones of the body in 38 CFR 4.118 and the five anatomic zones of 38 CFR 4.55(b). VA intends that the six zones in this final rule are specific for the skin and not intended to reflect a global standard to be applied for all body systems. Yet another comment asked about the difference between "anogenital region" (noted in DC 7829) and "pruritus ani" (DC 7337), and whether these ratings may be combined. "Anogenital region" is an anatomic area that may be affected by chloracne (DC 7829), whereas "pruritus ani" is an itching near the rectum. VA may separately evaluate these conditions and combine them in accordance with 38 CFR 4.25.

Still another assertion involving DC 7829 and other part 4 regulations was that "[i]ntertriginous areas and limitation of function are problematic. The axilla of the arm and the range of motion of the shoulder are similar to the facts in [Cullen v. Shinseki, 24 Vet. App. 74 (2010)]." We discern no problem in the language of DC 7829 or conflict with Cullen. VA may separately evaluate disability related to acne (skin) and a disability affecting the shoulder (musculoskeletal). One last question presented by this commenter asked if the reference to "skin folds of the breasts" in DC 7829 could be used to justify a 20 percent evaluation by

analogy under DC 7628, benign neoplasms. Because DC 7628 permits rating benign neoplasms as a skin condition, such a rating by analogy may be possible.

#### **Comments Recommending Additional Diagnostic Codes**

VA received four comments recommending additional diagnostic codes: One comment recommending additional codes generally to reduce analogous coding, and three other comments recommending codes for lymphedema (and/or skin conditions caused by immune system failure), pressure ulcers, actinic keratoses, and rosacea. VA finds these additions unnecessary. As noted above, VA may evaluate lymphedema which disfigures and/or scars the skin under DCs 7801, 7802, 7804, or 7805. Furthermore, pressure ulcers normally are not considered a skin condition warranting compensation. Actinic keratoses and rosacea are not occupationally significant. VA is willing to consider adding diagnostic codes for skin conditions that are occupationally significant.

# Comment Outside the Scope of the Proposed Rule

VA received a comment asking why the Food and Drug Administration could not find another manufacturer for EpiPen<sup>®</sup>. The EpiPen question is well outside the scope of this rule, so VA will not respond to it.

#### **Comment Regarding Public Access**

The last issue raised by a commenter dealt with public access to the materials developed by the Skin Disorders Work Group after a public forum in New York City in January 2012 but before the drafting of the proposed rule. Specifically, the commenter requested that the information developed and shared by the work group should be publicly available.

In the SUPPLEMENTARY INFORMATION to the proposed rule, VA included information about the Skin Disorders Work Group. See 81 FR 53353, 53353 (Aug. 12, 2016). As noted, the stated goals of the work group included improving and updating VA Schedule for Rating Disabilities (VASRD) criteria, and inviting public participation; this process included presentations on areas of expertise and interaction with the public at a public forum in January 2012. (A transcript of this public forum and all related materials are on file and available for public inspection in the Office of Regulation and Policy Management. Contact information for that office is noted in the ADDRESSES

section of the proposed rule. *See* 81 FR at 53358.) The work group served as an initial call to various subject matter experts and Veterans Service Organizations to provide a preliminary review of the VASRD from both internal and external stakeholders.

VA emphasizes that this review of the VASRD was not an opportunity for work group members to participate in the deliberative rulemaking process; the work group discussed the general topic of the VASRD body system and provided feedback on the areas that were subject to advances since the last major revision of the body system. To this end, where changes to the scientific and/or medical nature of a given condition were made in the proposed rule, VA cited the published, publiclyavailable source for these changes. Not only did this provide the public with access to the source for a given proposed change, it also confirmed that VA relied upon peer-reviewed scientific and medical information to support a given change. While similar information may have been presented by a work group member, VA relied upon the published document(s) as the primary source for a change and included such sources in the administrative record for this rulemaking. VA did not propose scientific and/or medical changes to the VASRD in the absence of publicly available, peer-reviewed sources.

Accordingly, references in the proposed rule to the work group serve as an explanatory background and introduction to the VASRD rewrite project; the changes made by this rulemaking are not a reflection of the work group or any work group member. All changes based on scientific and/or medical information are a reflection of cited, published materials which are available to the public. VA has made deliberative materials available (via citation in the rulemaking) and is providing access to materials from the public forum available for public inspection at the Office of Regulation Policy and Management.

#### **Effective Date of Final Rule**

Veterans Benefits Administration personnel utilize the Veterans Benefits 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 13, 2018, 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 this Executive Order.'

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined and it has been determined not to be a significant regulatory action under 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 "VĂ Regulations Published from FY 2004 through Fiscal Year to Date." This rule is not an Executive Order 13771 regulatory action because this rule is not significant under Executive Order 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 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 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 provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). Specifically, this final rule is associated with information collections related to the application for disability benefits (VA Form 21–526EZ), as well as **Disability Benefits Questionnaires** (DBQs), which enable a claimant to gather the necessary information from his or her treating physician as to the current symptoms and severity of a disability (VA Forms 21-0960F-1, Scars/Disfigurement DBQ, and 21-0960F-2, Skin Diseases DBQ). These information collections are currently approved by the Office of Management and Budget (OMB) and have been assigned OMB control numbers 2900-0749 (for the application) and 2900-0776 (for the DBQs). VA has reviewed the impact of this final rule on these information collections and determined that the incremental information collection burden for the first year of this rule is \$8,828.20.

## **Catalog of Federal Domestic Assistance**

The Catalog of Federal Domestic Assistance number and title for the program affected by this document is 64.109, Veterans Compensation for Service-Connected Disability.

#### **Signing Authority**

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to submit it to the Office of the Federal Register for electronic publication as an official document of the Department of Veterans Affairs. Jacquelyn Hayes-Byrd, Acting Chief of Staff, Department of Veterans Affairs, approved this document on June 28, 2018, for publication.

#### List of Subjects in 38 CFR Part 4

Disability benefits, Pensions, Veterans.

Dated: June 28, 2018.

# Jeffrey M. Martin,

Impact Analyst, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons set out in the preamble, the Department of Veterans Affairs amends 38 CFR part 4, subpart B, as follows:

# PART 4—SCHEDULE FOR RATING DISABILITIES

# Subpart B—Disability Ratings

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

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

■ 2. Amend § 4.118 as follows:

■ a. Remove the introductory text;

■ b. Add paragraphs (a) and (b) before the table;

■ c. Revise the entries for diagnostic codes 7801, 7802, and 7805;

■ d. Add an entry for "GENERAL RATING FORMULA FOR THE SKIN FOR DCs 7806, 7809, 7813–7816, 7820– 7822, AND 7824", to appear after the entry for diagnostic code 7805; and

■ e. Revise the entries for diagnostic codes 7806, 7809, 7813, 7815–7817, 7820–7822, and 7824–7829.

The revisions and additions read as follows:

## §4.118 Schedule of ratings-skin.

(a) For the purposes of this section, 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.

(b) Two or more skin conditions may be combined in accordance with § 4.25 only if separate areas of skin are involved. If two or more skin conditions involve the same area of skin, then only the highest evaluation shall be used.

						Ratin
*	*	*	*	*	*	*
damage:					with underlying soft tissue	
Area or areas of	144 square inches (929	sq. cm.) or greater			· · · · · · · · · · · · · · · · · · ·	
					.)	
Area or areas of	at least 12 square inche	(77  sq. cm) but less	than 12 square ind	(405  sq. cm.)		
					h extremity, anterior trunk,	
	unk. The midaxillary line					
Note (2): A separ	ate evaluation may be a	ssigned for each affe	cted zone of the bo	dy under this diagn	ostic code if there are mul-	
natively, if a hi	gher evaluation would r	esult from adding the			ations under §4.25. Alter- the body, a single evalua-	
	e assigned under this d					
J2 Burn scar(s) or lamage:	scar(s) due to other cal	ises, not of the head,	tace, or neck, that	are not associated	with underlying soft tissue	
	144 square inches (929	sa. cm.) or areater				
					h extremity, anterior trunk,	
	unk. The midaxillary line				-	
					ostic code if there are mul-	
					ations under §4.25. Alter- the body, a single evalua-	
	e assigned under this d		areas anected non	in multiple zones of	the body, a single evalua-	
*	*	*	*	*	*	*
)5 Scars. other: a	nd other effects of scars	evaluated under diad	nostic codes 7800.	7801, 7802, or 780	)4:	
					under an appropriate diag-	
	Ila For The Skin For DC	s 7806, 7809, 7813–7	'816, 7820–7822, a	nd 7824:		
At least one of th	e following					
					posed areas affected; or	
Constant or nea	r-constant systemic the	rapy including, but r	ot limited to, cortinated to, cortin	costeroids, phototh	erapy, retinoids, biologics, ve drugs required over the	
					ve drugs required over the	
Characteristic les	ions involving more thar	20 to 40 percent of t	he entire body or 20	0 to 40 percent of e	xposed areas affected; or	
					tochemotherapy, PUVA, or ly, over the past 12-month	
	e following					
	ions involving at least 5			entire body affected	l; or	
	t, but less than 20 perce			and the state of the state		
					ogics, photochemotherapy, e past 12-month period.	
					e past 12-month penod.	
	ions involving less than			one of the following		
	ions involving less than					
Or rate as disfigu	rement of the head, fac	e, or neck (DC 7800)	or scars (DCs 780	01, 7802, 7804, or 1	7805), depending upon the	
	sability. This rating instru	uction does not apply	to DC 7824.			
Of Dermatitis or e Evaluate under the	czema. ie General Rating Formi	la for the Skin				
* 09 Discoid lupus e	* anythematosus	*	*	*	*	*
	e General Rating Form	ila for the Skin				
	bine with ratings under					
	C .					
* Dormatophytor	* vic (ringworm: Of body d	* inco corporio: of booc	* tipop conitic: of fo	* at tinco podic: of h	eard area, tinea barbae; of	*
nails, tinea unguium	n (onychomycosis); of in	guinal area (jock itch),			eard area, linea barbae, or	
	e General Rating Form		ique foliaceous h	ullous nemphiaoid	, dermatitis herpetiformis,	
epidermolysis bullos	sa acquisita, benign chro	onic familial pemphigu				
	e General Rating Form		t (aquilar arcl	cintoctinal reactions	one or conitation and and	
	e appropriate diagnostic		i (ocular, oral, gasti	ontestinal, respirat	ory, or genitourinary) sepa-	
6 Psoriasis.	appropriate diagnostic					
	e General Rating Form	ula for the Skin.				
Note: Rate comp	lications such as psoria		clinical manifestatio	ons ( <i>e.g.,</i> oral muco	sa, nails) separately under	
	diagnostic code.					
7 Erythroderma:			, <b>.</b>			
Generalized invol	vement of the ekin with	svetemic manitactation	ne (such as tavar	weight lose or hur	oproteinemia) AND one of	

the following .....

	Rating
Constant or near-constant systemic therapy such as therapeutic doses of corticosteroids, other immunosuppressive drugs, retinoids, PUVA (psoralen with long-wave ultraviolet-A light), UVB (ultraviolet-B light) treatments, biologics, or electron beam therapy required over the past 12 month period; or	
No current treatment due to a documented history of treatment failure with 2 or more treatment regimens 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, other immunosuppressive drugs,	10
retinoids, PUVA, UVB treatments, biologics, or electron beam therapy required over the past 12-month period; or	6
Any extent of involvement of the skin, and any of the following therapies required for a total duration of 6 weeks or more, but not constantly, over the past 12-month period: systemic therapy such as therapeutic doses of corticosteroids, other immuno- suppressive drugs, retinoids, PUVA, UVB treatments, biologics, or electron beam therapy	3
Any extent of involvement of the skin, and any of the following therapies required for a total duration of less than 6 weeks over the past 12-month period: systemic therapy such as therapeutic doses of corticosteroids, other immunosuppressive drugs, retinoids, PUVA, UVB treatments, biologics, or electron beam therapy	1
Any extent of involvement of the skin, and no more than topical therapy required over the past 12-month period	
* * * * * * * * * * * * * * * * * * *	*
Evaluate under the General Rating Formula for the Skin. Biggin 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.	
* * * * * *	*
322 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.	
* * * * * *	*
324 Diseases of keratinization (including icthyoses, Darier's disease, and palmoplantar keratoderma). Evaluate under the General Rating Formula for the Skin. 325 Chronic urticaria:	
For the purposes of this diagnostic code, chronic urticaria is defined as continuous urticaria at least twice per week, off treat- ment, for a period of six weeks or more. Chronic refractory urticaria that requires third line treatment for control (e.g., plasmapheresis, immunotherapy, immunosuppressives) due to ineffectiveness with first and second line treatments	
Chronic urticaria that requires second line treatment (e.g., corticosteroids, sympathomimetics, leukotriene inhibitors, neutrophil inhibitors, thyroid hormone) for control	6
Chronic urticaria that requires first line treatment (antihistamines) for control	1
All of the following Recurrent documented vasculitic episodes occurring four or more times over the past 12-month period; and	3
Requiring intermittent systemic immunosuppressive therapy for control At least one of the following Recurrent documented vasculitic episodes occurring one to three times over the past 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 (DCs 7801, 7802, 7804, or 7805), depending upon the predominant disability. 327 Erythema multiforme; Toxic epidermal necrolysis:	
Recurrent mucosal, palmar, or plantar involvement impairing mastication, use of hands, or ambulation occurring four or more times over the past 12-month period despite ongoing immunosuppressive therapy	6
All of the following Recurrent mucosal, palmar, or plantar involvement not impairing mastication, use of hands, or ambulation, occurring four or more times over the past 12-month period; and requiring intermittent systemic therapy.	·
At least one of the following One to three episodes of mucosal, palmar, or plantar involvement not impairing mastication, use of hands, or ambulation, occur- ring over the past 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 (DCs 7801, 7802, 7804, or 7805), depending upon the predominant disability.	
<i>Note:</i> For the purposes of this DC only, systemic therapy may consist of one or more of the following treatment agents: immunosuppressives, antihistamines, or sympathomimetics. 328 Acne:	
Deep acne (deep inflamed nodules and pus-filled cysts) affecting 40 percent or more of the face and neck 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 uperficial acne (comedones, papules, pustules) of any extent 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.	

\*

	Rating
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 (DCs 7801, 7802, 7804, or 7805), depending upon the predominant disability.	
F	

■ 3. Amend appendix A to part 4 in the table under Sec. 4.118 by revising the entries for diagnostic codes 7801, 7802,

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\*

7805, 7806, 7809, 7813, 7815 through 7817, and 7820–7833 to read as follows:

\*

\*

Appendix A to Part 4—Table of Amendments and Effective Dates Since 1946

\*

Section	Diagnostic Code No.					
*		* *	*	*	*	*
.118	7800 7801 7802	Evaluation August 30, 2002; Criterion July 6, 1950; criterio Criterion September 22, 197 13, 2018.	n August 30, 2002;	criterion October 23, 20		
*		* *	*	*	*	*
	7805				d 7004 addad Aug	at 10, 0010
	7806	General Rating Formula for E Criterion September 9, 1975;				St 13, 2018.
*		* *	*	*	*	*
	7809	Criterion August 30, 2002; titl	e, criterion August 1	3, 2018.		
*		* *	*	*	*	*
	7813	Criterion August 30, 2002; titl	e, criterion August 1	3, 2018.		
*		* *	*	*	*	*
	7816	Evaluation August 30, 2002; Evaluation August 30, 2002; Evaluation August 30, 2002;	criterion, note Augus	t 13, 2018.		
*		* *	*	*	*	*
	7820 7821 7822 7823 7824 7825 7826 7826 7827 7828 7829 7830 7831 7832 7833	Added August 30, 2002; crite Added August 30, 2002; crite Added August 30, 2002; title, Added August 30, 2002; crite Added August 30, 2002; crite	criterion August 13, criterion August 13, rion August 13, 2018 rion August 13, 2018 criterion August 13, 2018 rion August 13, 2018	2018. 2018. 3. 2018. 3. 3. 3. 3. 3. 3. 3.		

■ 4. Amend appendix B to part 4 under the heading ''THE SKIN'' by revising the

entries for diagnostic codes 7801, 7802,

7805, 7809, 7813, 7817, 7821, 7822, and 7825 to read as follows:

Appendix B to Part 4—Numerical Index of Disabilities

Diagnostic Code No.						
*	*	*	*	*	*	*
			THE SKIN			
*	*	*	*	*	*	*
7801 7802	Burn scar(s) or scar(s) due Burn scar(s) or scar(s) due age.					
*	*	*	*	*	*	*
7805	Scars, other; and other effe	cts of scars evaluate	ed under diagnostic co	des 7800, 7801, 780	02, or 7804.	
*	*	*	*	*	*	*
7809	Discoid lupus erythematosu	IS.				
*	*	*	*	*	*	*
7813	Dermatophytosis.					
*	*	*	*	*	*	*
7817	Erythroderma.					
*	*	*	*	*	*	*
7821 7822	Cutaneous manifestations o Papulosquamous disorders			ewhere.		
*	*	*	*	*	*	*
7825	Chronic urticaria.					
*	*	*	*	*	*	*

■ 5. Amend appendix C to part 4 as follows:

■ a. Revise the entry for "Cutaneous manifestations of collagen-vascular diseases" (diagnostic code 7821); ■ b. Add in alphabetical order an entry for "Erythroderma";

■ c. Remove the entry for "Exfoliative dermatitis";

■ d. Revise the entry for "Scars"; and

■ e. Revise the entry for "Urticaria" (diagnostic code 7825). The revisions and addition read as follows:

# Appendix C to Part 4—Alphabetical Index of Disabilities

						Diagr Code	
*	*	*	*	*	*	*	
taneous manifest	ations of collagen-vas	cular diseases not liste	ed elsewhere				78
*	*	*	*	*	*	*	
throderma							78
*	*	*	*	*	*	*	
					r other disfigurement of		
the head, fac Burn scar(s) or damage Burn scar(s) or sue damage Retina Scars, other; ar	e, or neck scar(s) due to other scar(s) due to other ad other effects of sca	causes, not of the hea causes, not of the hea rs evaluated under dia	d, face, or neck th d, face, or neck tha gnostic codes 7800	at are associated wi t are not associated , 7801, 7802, or 780	r other disfigurement of th underlying soft tissue with underlying soft tis-		78 78 78 60 78 78
the head, fac Burn scar(s) or damage Burn scar(s) or sue damage Retina Scars, other; ar Unstable or pair	e, or neck scar(s) due to other scar(s) due to other and other effects of sca nful	causes, not of the hea causes, not of the hea rs evaluated under dia	d, face, or neck th d, face, or neck tha gnostic codes 7800	at are associated wi tt are not associated , 7801, 7802, or 780 *	th underlying soft tissue with underlying soft tis- 4		78 78 60 78
the head, fac Burn scar(s) or damage Burn scar(s) or sue damage Retina Scars, other; ar Unstable or pair	e, or neck scar(s) due to other scar(s) due to other and other effects of sca nful	causes, not of the hea causes, not of the hea rs evaluated under dia	d, face, or neck th d, face, or neck tha gnostic codes 7800	at are associated wi tt are not associated , 7801, 7802, or 780 *	th underlying soft tissue with underlying soft tis- 4		78 78 60 78