

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. For this action, the Office of Management and Budget has waived its review process required under Executive Order 12866.

We are proposing to remove Portugal from the list of regions where ASF exists. We are proposing this action because Portugal is now free of ASF. This action would relieve restrictions due to ASF on the importation of pork and pork products into the United States from Portugal. However, because Portugal is on the list of regions where hog cholera exists and the list of regions that are subject to certain restrictions because of their proximity to or trading relationships with rinderpest- or FMD-affected countries, Portugal would continue to be subject to certain restrictions regarding the importation into the United States of pork and pork products.

The following analysis addresses the economic effect of this rule on small entities, as required by the Regulatory Flexibility Act.

Entities in the United States likely to be affected by this proposed rule include those engaged in the production of swine and processed pork products. Since Portugal has never exported pork or pork products to the United States, we anticipate that this proposed rule would have no economic effect on U.S. swine importers, hog meat processors, hog producers, or any other entities, large or small. However, should Portugal commence the exportation of pork and pork products to the United States, restrictions on the importation of pork and pork products into the United States from Portugal would still be in place because Portugal is on the list of regions where hog cholera exists and the list of regions that are subject to certain restrictions because of their proximity to or trading relationships with rinderpest- or FMD-affected countries. Given those continuing restrictions, we believe any potential imports of processed pork and pork products from Portugal would be minimal. Likewise, because any potential increase in imports of processed pork and pork products from Portugal would be slight, the potential effect on U.S. swine producers and processors of pork is expected to be minimal.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. If this proposed rule is adopted: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings will not be required before parties may file suit in court challenging this rule.

Paperwork Reduction Act

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 94

Animal diseases, Imports, Livestock, Meat and meat products, Milk, Poultry and poultry products, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR part 94 as follows:

PART 94—RINDERPEST, FOOT-AND-MOUTH DISEASE, FOWL PEST (FOWL PLAGUE), EXOTIC NEWCASTLE DISEASE, AFRICAN SWINE FEVER, HOG CHOLERA, AND BOVINE SPONGIFORM ENCEPHALOPATHY: PROHIBITED AND RESTRICTED IMPORTATIONS

1. The authority citation for part 94 would continue to read as follows:

Authority: 7 U.S.C. 450, 7711, 7712, 7713, 7714, 7751, and 7754; 19 U.S.C. 1306; 21 U.S.C. 111, 114a, 134a, 134b, 134c, 134f, 136, and 136a; 31 U.S.C. 9701; 42 U.S.C. 4331 and 4332; 7 CFR 2.22, 2.80, and 371.4.

§ 94.8 [Amended]

2. In § 94.8, the introductory text of the section would be amended by removing the word "Portugal,".

Done in Washington, DC, this 4th day of December, 2001.

W. Ron DeHaven,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 01-30463 Filed 12-7-01; 8:45 am]

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SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Regulations No. 4 and 16]

RIN 0960-AF29

Revised Medical Criteria for Evaluating Skin Disorders

AGENCY: Social Security Administration.

ACTION: Proposed rules.

SUMMARY: We propose to revise the criteria in the Listing of Impairments (the listings) that we use to evaluate claims involving skin disorders. We apply these criteria when you claim benefits based on disability under title II and title XVI of the Social Security Act (the Act). The proposed revisions will reflect advances in medical knowledge, treatment, and methods of evaluating skin disorders.

DATES: To be sure your comments are considered, we must receive them by February 8, 2002.

ADDRESSES: You may give us your comments by using: our Internet site facility (*i.e.*, Social Security Online) at: <http://www.ssa.gov/regulations/>, e-mail to regulations@ssa.gov; telefax to (410) 966-2830; or by letter to the Commissioner of Social Security, P.O. Box 17703, Baltimore, Maryland 21235-7703.

You may also deliver them to the Office of Process and Innovation Management, Social Security Administration, L2109 West Low Rise Building, 6401 Security Boulevard, Baltimore, Maryland 21235-6401, between 8:00 a.m. and 4:30 p.m. on regular business days. Comments are posted on our Internet site, or you may inspect them physically on regular business days by making arrangements with the contact person shown in this preamble.

Electronic Version: The electronic file of this document is available on the date of publication in the **Federal Register** at <http://www.access.gpo.gov/su/docs/aces/aces140.html>. It is also available on the Internet site for SSA (*i.e.*, Social Security Online): <http://www.ssa.gov/regulations/>.

FOR FURTHER INFORMATION CONTACT: Suzanne DiMarino, Social Insurance Specialist, Office of Process and Innovation Management, Social Security Administration, L2109 West Low Rise, 6401 Security Boulevard, Baltimore, Maryland 21235-6401, (410) 965-1769 or TTY (410) 966-5609. For information on eligibility or filing for benefits, call our national toll-free number 1-800-772-1213 or TTY 1-800-325-0778, or visit our Internet web site, Social Security Online, at <http://www.ssa.gov>.

SUPPLEMENTARY INFORMATION:

What Programs Would These Proposed Regulations Affect?

These proposed regulations would affect disability determinations and decisions we make for you under title II and title XVI of the Act. In addition, to the extent that Medicare and Medicaid eligibility are based on entitlement to benefits under title II and eligibility for

benefits under title XVI, these proposed regulations would also affect the Medicare and Medicaid programs.

Who Can Get Disability Benefits?

Under title II of the Act, we provide for the payment of disability benefits if you are disabled and belong to one of the following three groups:

- Workers insured under the Act,
- Children of insured workers, and

• Widows, widowers, and surviving divorced spouses (see 20 CFR § 404.336) of insured workers.

Under title XVI of the Act, we provide for Supplemental Security Income (SSI) payments on the basis of disability if you have limited income and resources.

How Do We Define Disability?

Under both the title II and title XVI programs, disability must be the result

of any medically determinable physical or mental impairment or combination of impairments that can be expected to result in death or that has lasted or can be expected to last for a continuous period of at least 12 months. Our definitions of disability are shown in the following table:

If you file a claim under . . .	And you are . . .	Disability means you have a medically determinable impairment(s) that meets the statutory duration requirement and results in . . .
title II	an adult or child	the inability to do any substantial gainful activity (SGA).
title XVI	an adult	the inability to do any SGA.
title XVI	a child	marked and severe functional limitations.

What Are the Listings?

The listings contain examples of impairments that we consider severe enough to prevent you as an adult from doing any gainful activity. If you are a child seeking SSI benefits based on disability, the listings describe impairments that we consider severe enough to result in marked and severe functional limitations. Although the listings are contained only in appendix 1 to subpart P of part 404 of our rules, we incorporate them by reference in the SSI program in § 416.925 of our regulations, and apply them to claims under both title II and title XVI of the Act.

How Do We Use the Listings?

There are listings for adults (part A) and for children (part B). We apply the medical criteria in part A when we assess your claim if you are an adult, i.e., a person age 18 or over.

If you are a child, we first use the criteria in part B. If the B criteria do not apply, and the specific disease process(es) has a similar effect on adults and children, we then use the criteria in part A. (See §§ 404.1525, 404.1526, 416.925 and 416.926.)

We use the criteria in the listings only to make favorable findings of disability. We never deny a claim or find that disability has ceased because your impairment(s) does not meet or medically equal a listing.

Why Are We Proposing To Revise the Listings for Skin Impairments?

We are proposing these revisions to update the medical criteria and provide more information about how we evaluate skin impairments. We last published final rules containing comprehensive revisions to the skin listings in the **Federal Register** on March 27, 1979 (44 FR 18170). In subsequent rules published December 6,

1985 (50 FR 50068), we indicated that due to advances in medical treatment, technology, and program experience we would periodically review and update the listings. The current listings for the evaluation of skin impairments would no longer be effective on July 2, 2003 (66 FR 34361 (June 28, 2001)).

How Long Would These Proposed Rules Be Effective?

These proposed rules would remain in effect for 8 years from the date we publish them as final rules in the **Federal Register**, unless we extend them, or revise and issue them again.

We will continue to apply our current listings until we evaluate the public comments on these proposed rules and determine whether they should be issued as final rules. If we finalize these proposed rules, when any final rules become effective, we will apply them to new applications filed on or after the effective date of the final rules, and to cases that are pending in the administrative review process. In accordance with our usual practice, we would explain how we would apply any final rules in greater detail in the preamble to the final rules.

When we conduct reviews to determine whether your disability continues, we would not find that your disability has ended based only on any changes in the listings. Our regulations explain that we continue to use our prior listings when we review your case if you receive disability benefits or SSI payments based on our determination or decision that your impairment(s) met or equaled the listings. In these cases, we determine whether you have experienced medical improvement, and if so, whether the medical improvement is related to the ability to work. If your impairment(s) still meets or equals the same listing section that we used to make our most recent favorable

determination or decision, we will find the medical improvement is not related to the ability to work. If your condition has medically improved so that you no longer meet or equal the prior listing, we evaluate your case further to determine whether you are currently disabled. We may find that you are currently disabled, depending on the full circumstances of your case. See 20 CFR 404.1594(c)(3)(i), 416.994(b)(2)(iv)(A). If you are a child who is eligible for SSI payments, we follow a similar rule when we decide whether you have experienced medical improvement in your condition. 20 CFR 416.994a(b)(2).

What Revisions Are We Proposing To Make?

To present the skin listing criteria in part A of Appendix 1 in a more logical order, and make the listings easier to use, we propose to:

- Revise the titles to put them in plain language;
- Revise the order and update the diagnostic groupings of skin impairments;
- Add a listing for photosensitivity disorders;
- Provide a more uniform and clearly defined statement of severity required for a listing-level skin impairment;
- Expand the guidance in the introductory text to the listing; and
- Make nonsubstantive editorial changes.

In addition, we propose to add a set of childhood skin listings in part B of Appendix 1.

How Are We Proposing To Change the Introductory Text to the Adult Skin Listings?

We propose to change the heading title from 8.00 Skin to 8.00 Skin Disorders.

We propose to expand and significantly reorganize the introductory

text to the skin impairments listings in current 8.00A and 8.00B in order to provide additional guidance in applying the skin listings. In doing so, we propose to:

- Expand and supplement the first sentence of current 8.00A and move it into proposed 8.00C;
- Expand and supplement the second sentence of current 8.00A and move it into proposed 8.00F;
- Expand the third sentence of current 8.00A and move it into proposed 8.00C(3); and
- Expand the material in 8.00B and move it into proposed 8.00D.

We also propose to add new material in all the proposed sections of the introductory text. A detailed description of the new and modified paragraphs follows.

Proposed 8.00A—What Skin Impairments Do We Evaluate With These Listings?

This new section provides a detailed description of the more common impairments that may be disabling covered by the skin listings.

Proposed 8.00B—What Documentation Do We Need?

We propose to add a new section that discusses the documentation we require in evaluating skin impairment(s) cases. The proposed section explains the information we expect to find in a complete dermatologic case record in order to make a reasonable assessment of severity. It also explains the importance of diagnostic procedures, which produce laboratory findings or other evidence from generally acceptable methods, in accurately diagnosing skin impairments.

Proposed 8.00C—How Do We Determine if Your Skin Impairment(s) Prevents You From Doing Any Gainful Activity?

This section, which is partially new and partially based on modification to the first sentence of current 8.00A, will explain the three factors we consider when evaluating the severity of skin impairments. The proposed section consists of three subsections:

- Proposed 8.00C1 defines “extensive lesions”, a term in proposed listings 8.02 through 8.07. That definition explains that the term extensive not only refers to the amount of surface area affected, but also to the limitations resulting from the lesions. Hence, these listings require a qualitative, as well as a quantitative, evaluation of the effect of the skin lesions. This section also gives examples of extensive lesions. We will determine whether you can ambulate effectively or can perform fine and gross

movements effectively based on the medical and other evidence in the case record, generally without developing additional evidence about your ability to perform the specific activities listed as examples.

- Proposed 8.00C2 explains how we evaluate symptoms (including pain) consistent with our rules in §§ 404.1525(f) and 416.925(f) and §§ 404.1529 and 416.929.
- Proposed 8.00C3 explains that while skin impairments often respond to treatment, there is a wide variation in how people respond, including side effects to drug therapy. Therefore, we will consider each case on an individual basis.

Proposed 8.00D—How Do We Assess Impairments That Involve More Than One Body System?

This section modifies current 8.00B. It clarifies that other impairments, in addition to systemic ones, can involve the skin and explains how we evaluate such impairments under the listings. It also broadens the list of examples of impairments that affect skin and other body systems.

Proposed 8.00E—How Do We Evaluate Burns?

We propose to include this new section on burns in the introductory text to the skin listings in response to many inquiries that we receive on how we evaluate these injuries. This new paragraph notes that burns frequently affect more than one body system. It then explains that we evaluate the specific impairment resulting from burns using the criteria of the affected body system.

Proposed 8.00F—How Do We Determine if an Impairment Will Continue at a Disabling Level of Severity in Order to Meet the Duration Requirement?

We propose to add this section to explain how we will determine if the duration requirement is or will be met. This section is partially new and partially based on the second sentence of current 8.00A.

We state that the extensive skin lesions must persist for at least 3 months despite continuing treatment as prescribed in order for us to infer that the duration requirement will be met. Currently, each listing requires that the skin lesions not respond to prescribed treatment, but there is no statement of how long the lesions must last despite prescribed treatment before we can evaluate the skin impairment(s) under the listing criteria. Since most skin impairments improve significantly within 3 months after treatment begins,

we propose that skin lesions must have persisted for at least 3 months despite continuing treatment as prescribed. The proposed timeframe will allow us to predict, with a high degree of certainty, which impairments resulting in the inability to perform gainful activity will also satisfy the duration requirement of the Act. In addition, the proposed timeframe will help to ensure that we do not decide cases prematurely or unnecessarily delay making decisions.

Proposed 8.00G—How Do We Assess Impairments if There Is No Prescribed Treatment, or the Extensive Lesions Have Not Persisted for at Least 3 Months?

This section explains how we assess a skin impairment when there is no record of ongoing treatment, such treatment has lasted less than 3 months, or the extensive lesions have not yet persisted for at least 3 months. It describes how we continue through the sequential evaluation process if the listing(s) cannot be met due to insufficient longitudinal treatment records.

How Are We Proposing To Change the Criteria in the Listings for Evaluating Skin Impairments in Adults?

8.01 Category of Impairments, Skin

Most of the changes we propose to make to the skin listings are not significant. For instance, we propose to update the medical terminology and to broaden and reorganize the skin listings.

A significant change we do propose to make is to add a listing, 8.07, for photosensitivity disorders. Currently, such disorders may be found equivalent in severity to a listed skin impairment. We also propose to define “extensive lesions” and to add to each listing a requirement that the extensive lesions must persist, despite continuing treatment as prescribed, for a period of at least 3 months. This is explained in 8.00F of the introductory text.

The following is a detailed explanation of the proposed listing criteria.

Proposed Listing 8.02—Ichthyosis

We propose to revise the title of listing 8.02 to ichthyosis so that it covers the general group of disorders characterized by noninflammatory scaling of the skin. This prevents the need to also cite the inherited disorder ichthyosiform erythroderma, which we do not commonly see. We also propose to move exfoliative dermatitis to listing 8.05 with the other dermatitis disorders.

Proposed Listing 8.03—Bullous Disease (e.g., Pemphigus, Erythema Multiforme Bullosum, Epidermolysis Bullosa, Bullous Pemphigoid, Dermatitis Herpetiformis)

We propose to revise the title of listing 8.03 so that we can apply it to all types of bullous diseases. Then, through the use of examples, we propose to cite the four currently listed diseases and epidermolysis bullosa.

Proposed Listing 8.04—Chronic Infections of the Skin or Mucous Membranes

We propose to revise the title of listing 8.04 so that the listing will include infections other than deep mycotic (fungal) infections. In this listing we propose to use the words “fungating” (to grow exuberantly like a fungus or spongy growth) and “ulcerating” (a lesion through the skin or a mucous membrane resulting from loss of tissue, usually with inflammation) to modify the term “extensive lesions” because they are descriptive of the different types of lesions frequently associated with the more severe types of chronic infections. Listing-level severity is characterized by either fungating or ulcerating lesions.

Proposed Listing 8.05—Dermatitis (e.g., Psoriasis, Dyshidrosis, Atopic Dermatitis, Exfoliative Dermatitis, Allergic Contact Dermatitis)

We propose to revise the title of listing 8.05 so that we can use it to evaluate miscellaneous inflammatory conditions of the skin, rather than just the three conditions currently cited. The new title will allow us to use this listing to evaluate environmental skin conditions such as allergic contact dermatitis.

Proposed Listing 8.06—Hidradenitis Suppurativa

We propose to remove the reference to acne conglobata from listing 8.06 because it is not usually disabling and frequently responds well to current treatment. Also, we propose different severity criteria for this listing. We are taking out the condition of “not amenable to surgical treatment” since most lesions associated with hidradenitis suppurativa involve local inflammation of the apocrine glands and occur in the axillae, inguinal areas, or perineum. Due to advances in medical treatments, these conditions do not usually require surgery; but if surgery is needed, continuing treatment as prescribed includes any necessary surgical procedures.

Proposed Listing 8.07—Photosensitivity Disorders (e.g., Xeroderma Pigmentosum)

We propose to add a listing for evaluating photosensitivity disorders, such as xeroderma pigmentosum, in adults. Some individuals with these disorders are now surviving into adulthood and thus we believe it appropriate to have a separate listing for these disorders. For more information about this new listing disorder, we refer you to the following:

1. Photosensitivity (Section 15), in: Harper J, Oranje A, Prose N, (eds) *Textbook of Pediatric Dermatology*, vols 1 & 2, Oxford: Blackwell Science, 2000:895–936.
2. Roelandts R., The Diagnosis of Photosensitivity, *Arch Dermatol*, 2000:136:1152–7.
3. Epstein JH., Photosensitivity and Photoallergy, *Semin Cutan Med Surg.*, 1999:18:274–84.

Why Are We Proposing To Add Listings for Evaluating Skin Impairments in Children?

We propose to add new listings to evaluate claims filed by persons under age 18 who have skin impairments to maintain consistency with the other body system listings which have both adult and child criteria.

How Do the Skin Listings We Are Proposing for Children Differ From Those We Are Proposing for Adults?

The skin listings we are proposing for children are identical in content to those we are proposing for adults, except that we propose to include examples of erythropoietic porphyrias and hemangiomas in 108.00D, and not in 8.00D. We did this because the skin manifestations of these disorders are not likely to be the primary manifestations in adults. For example, most hemangiomas disappear spontaneously or are surgically removed in childhood. When the hemangiomas are associated with Kasabach-Merritt Syndrome, a rare condition in which the low number of blood platelets cause bleeding, the hemic manifestations are obvious in adults. Similarly, in erythropoietic porphyria, a rare metabolic disorder characterized by a deficiency of the enzyme ferrochelatase that is essential to the synthesis of hemoglobin, a major symptom in children is the hypersensitivity of their skin to sunlight and some types of artificial light. Generally, by adulthood, anemia is a prominent manifestation in the more severe cases, with possible complications related to liver and gallbladder function.

Clarity of These Proposed Rules

Executive Order 12866 requires each agency to write all rules in plain language. In addition to your substantive comments on these proposed rules, we invite your comments on how to make these proposed rules easier to understand.

For example:

- Have we organized the material to suit your needs?
- Are the requirements in the rules clearly stated?
- Do the rules contain technical language or jargon that is not clear?
- Would a different format (grouping and order of sections, use of headings, paragraphing) make the rules easier to understand?
- Would more (but shorter) sections be better?
- Could we improve clarity by adding tables, lists, or diagrams?
- What else could we do to make the rules easier to understand?

Regulatory Procedures

Executive Order (E.O.) 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these proposed rules meet the requirements for a significant regulatory action under E.O. 12866. Thus, they were subject to OMB review.

Regulatory Flexibility Act

We certify that these proposed rules would not have a significant economic impact on a substantial number of small entities because they affect only individuals. Thus, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

These proposed rules contain reporting requirements at 8.00B, 8.00C, 8.00D, 108.00B, 108.00C, and 108.00D. The public reporting burden is accounted for in the Information Collection Requests for the various forms that the public uses to submit the information to SSA. Consequently, a 1-hour placeholder burden is being assigned to the specific reporting requirement(s) contained in these rules. We are seeking clearance of the burdens referenced in these rules because they were not considered during the clearance of the forms. An Information Collection Request has been submitted to OMB. We are soliciting comments on the burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility and clarity; and on ways to minimize the burden on respondents, including the use of

automated collection techniques or other forms of information technology. Comments should be submitted to the Social Security Administration at the following address: Social Security Administration, Attn: SSA Reports Clearance Officer, Rm. 1-A-20 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235-6401.

Comments can be received for between 30 and 60 days after publication of this notice. Comments will be most useful if received by SSA within 30 days of publication.

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors, and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: December 3, 2001.

Jo Anne B. Barnhart,

Commissioner of Social Security.

For the reasons set out in the preamble, we propose to amend subpart P of part 404 of 20 CFR chapter III as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950—)

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)—(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)—(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104-193, 110 Stat. 2105, 2189.

Appendix 1 to Subpart P of Part 404—Listing of Impairments (Amended)

2. Item 9 of the introductory text before part A is amended by revising the heading title, revising the expiration date for section 8.00, and adding section 108.00 and its expiration date as follows:

* * * * *

9. Skin Disorders (8.00 and 108.00): (date 8 years from the date of publication of final rules in the **Federal Register**).

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3. The list of sections for part A of appendix 1 is amended by revising 8.00 to read “8.00 Skin Disorders”.

4. The list of sections for part B of appendix 1 is amended by revising of 108.00 to read “108.00 Skin Disorders”.

5. Section 8.00 in part A of appendix 1 is revised and section 108.00 in part B of appendix 1 is added to read as follows:

APPENDIX 1 TO SUBPART P OF PART 404—LISTING OF IMPAIRMENTS

* * * * *

Part A

* * * * *

8.00 Skin Disorders

A. *What skin impairments do we evaluate with these listings?* We use these listings to evaluate skin impairments that may result from hereditary, congenital, or acquired pathological processes. Examples of impairments covered by these listings include: ichthyosis, bullous diseases, chronic infections of the skin or mucous membranes, dermatitis, hidradenitis suppurativa, and photosensitivity disorders.

B. *What documentation do we need?* Your case record should include information about onset, duration, frequency of flare-ups, and prognosis; location, size, and appearance of lesions; and, when applicable: history of exposure to toxins, allergens, or irritants; familial incidence; seasonal variation; and stress factors. To confirm the diagnosis, we often need laboratory findings (e.g., biopsy or serological testing) or evidence from other medically acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

C. *How do we determine if your skin impairment(s) prevents you from doing any gainful activity?* We base our assessment of severity on whether your skin lesions are extensive, how your symptoms (including pain) limit you, the extent of your treatment, and how your treatment affects you.

(1) *Extensive skin lesions.* Extensive skin lesions are those that involve sufficient surface area over multiple body sites or involve critical body areas, and result in very serious limitations. Examples of extensive lesions that result in very serious limitations include:

(a) Skin lesions that interfere with motion of joints that very seriously limit your use of more than one extremity, i.e. two upper extremities, two lower extremities, or one upper and one lower extremity; or

(b) Skin lesions on the palms of the hands or the axillary areas that very seriously limit your ability to do fine and gross motor movements; or

(c) Skin lesions on the soles of the feet, the perineum, or the inguinal areas that very seriously limit your ability to ambulate.

(2) *Symptoms (including pain).* Symptoms (including pain) may be important factors contributing to the severity of your skin impairment(s). We assess the impact of symptoms as explained in §§ 404.1525(f), 404.1529, 416.925(f), and 416.929.

(3) *Treatment.* Skin impairments frequently respond to treatment, however response to treatment can vary widely, with some impairments becoming resistant to treatment.

(a) We assess the effects of treatment by determining if there is improvement in the symptoms, signs, and laboratory findings of the disorder, and if there are side effects that may result in functional limitations. We assess the effects of medication, therapy, surgery, or any other form of treatment you receive when determining the severity and

the duration of the impairment(s). An assessment of these issues may require:

- (i) a description of the treatment prescribed (e.g., the type, dosage, method and frequency of administration of medication or therapy);
- (ii) your response to the treatment;
- (iii) any adverse effects of such treatment;

or

- (iv) the expected duration of the treatment.

(b) Because treatment itself or the effects of treatment may be temporary, in most cases sufficient time must elapse to allow us to evaluate the impact and expected duration of treatment and side effects. You must follow prescribed treatment for at least 3 months before your impairment can be determined to meet a skin listing. We consider your specific response to treatment when we evaluate overall severity of your impairment.

D. *How do we assess impairments that involve more than one body system?* These listings are only examples of common skin disorders that we consider severe enough to prevent you from doing any gainful activity. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment that satisfies the criteria of a listing in another body system. Also, when your impairment involves more than one body system, we first evaluate the predominant feature under the appropriate body system. For example:

(1) Tuberous sclerosis has cutaneous manifestations, but the more dominant feature involves the brain, often resulting in seizures (11.02 and 11.03) and organic mental disorders (12.02);

(2) Malignant tumors of the skin (e.g., malignant melanoma) are neoplastic diseases and we first evaluate them under 13.00ff;

(3) Connective tissue disorders or immune system disorders (e.g., systemic lupus erythematosus or HIV infection) involve more than one body system. We first evaluate these disorders under 14.00ff;

(4) Scleroderma, although at times limited to skin only, usually involves other body systems as a part of generalized systemic sclerosis which we evaluate under listing 14.04. However, when it involves skin contractures restricting joint motion we also consider the appropriate criteria in 1.00ff;

(5) Facial disfigurement resulting from skin lesions may also be associated with physical functional loss such as impairment of sight, hearing, speech, and mastication, which we evaluate under the appropriate criteria in 2.00ff and 5.00ff. Facial disfigurement or any kind of physical deformity due to skin lesions may also result in psychological impairment(s) with socialization, mood, or other related limitations. We evaluate those impairments under the appropriate criteria in 12.00ff.

E. *How do we evaluate burns?* Electrical, chemical, or thermal traumatic burns frequently affect more than one body system (e.g., musculoskeletal, special senses, respiratory, cardiovascular, skin, renal, neurological, or mental). Consequently, we evaluate impairments that can result from severe burns under the criteria of the affected body systems. For example, we evaluate soft tissue injuries resulting from burns under the musculoskeletal system criteria in 1.00ff and

we evaluate renal failure resulting from burns under the genito-urinary system criteria in 6.00ff.

F. *How do we determine if an impairment will continue at a disabling level of severity in order to meet the duration requirement?* If you have extensive skin lesions, and they persist for at least 3 months despite continuing treatment as prescribed, these listings allow us to infer that they will continue at that level of severity for at least 12 months. By persist, we mean the longitudinal clinical record shows that, with few exceptions, the lesions have been at the level of severity specified in the listing and that this pattern could be expected to continue. Where adverse effects of treatment contribute to the impairment severity, the duration or expected duration of the treatment must be considered in assessing the duration of the impairment(s).

G. *How do we assess skin impairments if there is no prescribed treatment, or extensive lesions have not persisted for 3 months?*

(1) For your impairment to meet a skin listing, you must have extensive lesions that persist for at least 3 months despite continuing treatment as prescribed, and you must follow that treatment, unless you have an acceptable reason for failing to follow prescribed treatment (see §§ 404.1530 and 416.930).

(2) If you have not received ongoing treatment nor have an ongoing relationship with the medical community despite the existence of a severe impairment(s), or if your skin lesions have not persisted for at least 3 months, but you are undergoing continuing treatment as prescribed, you still may have an impairment(s) that medically equals the listings. An individual who has an impairment(s) that does not meet or medically equal the listings may or may not have the residual functional capacity to engage in substantial gainful activity. For such an individual, we proceed to the fourth, and if necessary, the fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920. When we decide whether an adult continues to be disabled, we use the rules in §§ 404.1594 and 416.994, as appropriate. We will base our evaluation on the current objective medical evidence and other available evidence. We will take into consideration your medical history, symptoms, and acceptable medical source opinions.

8.01 Category of Impairments, Skin

8.02 *Ichthyosis*, with extensive lesions that persist for at least 3 months despite continuing treatment as prescribed.

8.03 *Bullous disease* (e.g., *pemphigus*, *erythema multiforme bullosum*, *epidermolysis bullosa*, *bullous pemphigoid*, *dermatitis herpetiformis*), with extensive lesions that persist for at least 3 months despite continuing treatment as prescribed.

8.04 *Chronic infections of the skin or mucous membranes*, with extensive fungating, or extensive ulcerating lesions that persist for at least 3 months despite continuing treatment as prescribed.

8.05 *Dermatitis* (e.g., *psoriasis*, *dyshidrosis*, *atopic dermatitis*, *exfoliative dermatitis*, *allergic contact dermatitis*), with extensive lesions that persist for at least 3 months despite continuing treatment as prescribed.

8.06 *Hidradenitis suppurativa*, with extensive lesions involving the axillae, inguinal areas, or perineum that persist for at least 3 months despite continuing treatment as prescribed.

8.07 *Photosensitivity disorders* (e.g., *xeroderma pigmentosum*), with extensive lesions that persist for at least 3 months despite continuing treatment as prescribed.

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Part B

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108.00 Skin Disorders

A. *What skin impairments do we evaluate with these listings?* We use these listings to evaluate skin impairments that may result from hereditary, congenital, or acquired pathological processes. Examples of impairments covered by these listings include: ichthyosis, bullous diseases, chronic infections of the skin or mucous membranes, dermatitis, hidradenitis suppurativa, and photosensitivity disorders.

B. *What documentation do we need?* Your case record should include information about onset, duration, frequency of flare-ups, and prognosis; location, size, and appearance of lesions; and, when applicable: history of exposure to toxins, allergens, or irritants; familial incidence; seasonal variation; and stress factors. To confirm the diagnosis, we often need laboratory findings (e.g., biopsy or serological testing) or evidence from other medically acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

C. *How do we determine if your skin impairment(s) results in marked and severe limitations?* We base our assessment of severity on whether your skin lesions are extensive, how your symptoms (including pain) limit you, the extent of your treatment, and how your treatment affects you.

(1) *Extensive skin lesions.* Extensive skin lesions are those that involve sufficient surface area over multiple body sites or involve critical body areas, and result in very serious limitations. Examples of extensive lesions that result in very serious limitations include:

(a) Skin lesions that interfere with motion of joints that very seriously limit your use of more than one extremity, i.e. two upper extremities, two lower extremities, or one upper and one lower extremity; or

(b) Skin lesions on the palms of the hands or the axillary areas that very seriously limit your ability to do fine and gross motor movements; or

(c) Skin lesions on the soles of the feet, the perineum, or the inguinal areas that very seriously limit your ability to ambulate.

(2) *Symptoms (including pain).* Symptoms (including pain) may be important factors contributing to the severity of your skin impairment(s). We assess the impact of symptoms as explained in §§ 404.1525(f), 404.1529, 416.925(f) and 416.929.

(3) *Treatment.* Skin impairments frequently respond to treatment, however response to treatment can vary widely, with some impairments becoming resistant to treatment.

(a) We assess the effects of treatment by determining if there is improvement in the

symptoms, signs, and laboratory findings of the disorder, and if there are side effects that may result in functional limitations. We assess the effects of medication, therapy, surgery, or any other form of treatment you receive when determining the severity and the duration of the impairment(s). An assessment of these issues may require:

- (i) a description of the treatment prescribed (e.g., the type, dosage, method and frequency of administration of medication or therapy);
- (ii) your response to the treatment;
- (iii) any adverse effects of such treatment;

or

- (iv) the expected duration of the treatment.

(b) Because treatment itself or the effects of treatment may be temporary, in most cases sufficient time must elapse to allow us to evaluate the impact and expected duration of treatment and side effects. You must follow prescribed treatment for at least 3 months before your impairment can be determined to meet a skin listing. We consider your specific response to treatment when we evaluate overall severity of your impairment.

D. *How do we assess impairments that involve more than one body system?* These listings are only examples of common skin disorders that we consider severe enough to result in marked and severe functional limitations. If your impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment that satisfies the criteria of a listing in another body system. Also, when your impairment involves more than one body system, we first evaluate the predominant feature under the appropriate body system. For example:

(1) Tuberous sclerosis has cutaneous manifestations, but the more dominant feature involves the brain, often resulting in seizures (111.02 and 111.03) and organic mental disorders (112.02);

(2) Malignant tumors of the skin (e.g., malignant melanoma) are neoplastic diseases and we first evaluate them under 113.00ff;

(3) Connective tissue disorders or immune system disorders (e.g., systemic lupus erythematosus or HIV infection) involve more than one body system. We first evaluate these disorders under 114.00ff;

(4) Scleroderma, although at times limited to skin only, usually involves other body systems as a part of generalized systemic sclerosis which we evaluate under listing 114.04. However, when it involves skin contractures restricting joint motion we also consider the appropriate criteria in 101.00ff;

(5) Facial disfigurement resulting from skin lesions may also be associated with physical functional loss such as impairment of sight, hearing, speech, and mastication, which we evaluate under the appropriate criteria in 102.00ff and 105.00ff. Facial disfigurement or any kind of physical deformity due to skin lesions may also result in psychological impairment(s) with socialization, mood, or other related limitations. We evaluate those impairments under the appropriate criteria in 112.00ff;

(6) We evaluate erythropoietic porphyrias under 107.00ff;

(7) We evaluate hemangiomas associated with thrombocytopenia and hemorrhage (e.g., Kasabach-Merritt Syndrome) involving

coagulation defects, under 107.00ff. But, when hemangiomas impinge on vital structures or interfere with function or feeding, we evaluate them under the appropriate body system.

E. *How do we evaluate burns?* Electrical, chemical, or thermal traumatic burns frequently affect more than one body system (e.g., musculoskeletal, special senses, respiratory, cardiovascular, skin, renal, neurological, or mental). Consequently, we evaluate impairments that can result from severe burns under the criteria of the affected body systems. For example, we evaluate soft tissue injuries resulting from burns under the musculoskeletal system criteria in 101.00ff and we evaluate renal failure resulting from burns under the genito-urinary system criteria in 106.00ff.

F. *How do we determine if an impairment will continue at a disabling level of severity in order to meet the duration requirement?* If you have extensive skin lesions, and they persist for at least 3 months despite continuing treatment as prescribed, these listings allow us to infer that they will continue at that level of severity for at least 12 months. By persist, we mean the longitudinal clinical record shows that, with few exceptions, the lesions have been at the level of severity specified in the listing and that this pattern could be expected to continue. Where adverse effects of treatment contribute to the impairment severity, the duration or expected duration of the treatment must be considered in assessing the duration of the impairment(s).

G. *How do we assess skin impairments if there is no prescribed treatment, or extensive lesions have not persisted for 3 months?*

(1) For your impairment to meet a skin listing, you must have extensive lesions that persist for at least 3 months despite continuing treatment as prescribed, and you must follow that treatment, unless you have an acceptable reason for failing to follow prescribed treatment (see §§ 404.1530 and 416.930).

(2) If you have not received ongoing treatment nor have an ongoing relationship with the medical community despite the existence of a severe impairment(s), or if your skin lesions have not persisted for at least 3 months, but you are undergoing continuing treatment as prescribed, you still may have an impairment(s) that medically equals the listings or, in the case of a childhood claim for SSI payments under Title XVI, functionally equals the listings. (See §§ 404.1526, 416.926, and 416.926a.) When we decide whether a child receiving SSI payments continues to be disabled, we use the rules in § 416.994a. We will base our evaluation on the current objective medical evidence and other available evidence. We will take into consideration your medical history, symptoms, and acceptable medical source opinions.

108.01 Category of Impairments, Skin

108.02 *Ichthyosis*, with extensive lesions that persist for at least 3 months despite continuing treatment as prescribed.

108.03 *Bullous disease (e.g., pemphigus, erythema multiforme bullosum, epidermolysis bullosa, bullous pemphigoid, dermatitis herpetiformis)*, with extensive

lesions that persist for at least 3 months despite continuing treatment as prescribed.

108.04 *Chronic infections of the skin or mucous membranes*, with extensive fungating or extensive ulcerating lesions that persist for at least 3 months despite continuing treatment as prescribed.

108.05 *Dermatitis (e.g., psoriasis, dyshidrosis, atopic dermatitis, exfoliative dermatitis, allergic contact dermatitis)*, with extensive lesions that persist for at least 3 months despite continuing treatment as prescribed.

108.06 *Hidradenitis suppurativa*, with extensive lesions involving the axillae, inguinal areas, or perineum that persist for at least 3 months despite continuing treatment as prescribed.

108.07 *Photosensitivity disorders (e.g., xeroderma pigmentosum)*, with extensive lesions that persist for at least 3 months despite continuing treatment as prescribed.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 1

[USCG-2001-9175]

RIN 2115-AG15

Revised Options for Responding to Notices of Violations

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes changing the procedure for Notices of Violation when the recipient fails to either accept or decline it within 45 days. Instead of automatically converting the Notice of Violation to a marine violation case with its lengthier processing and potentially higher penalties, we would treat the Notice of Violation as a default and proceed with the civil penalty. Our proposal would not change the party's existing option to choose marine violation processing at any time during the 45-day response period.

DATES: Comments and related material must reach the Docket Management Facility on or before February 8, 2002.

ADDRESSES: To make sure that your comments and related material are not entered more than once in the docket, please submit them by only one of the following means:

(1) By mail to the Docket Management Facility (USCG-2001-9175), U.S. Department of Transportation, room PL-401, 400 Seventh Street SW., Washington, DC 20590-0001.

(2) By delivery to room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

(3) By fax to the Docket Management Facility at 202-493-2251.

(4) Electronically through the web site for the Docket Management System at <http://dms.dot.gov>.

The Docket Management Facility maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, will become part of this docket and will be available for inspection or copying at room PL-401 on the Plaza level of the Nassif Building, 400 Seventh Street SW., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. You may also find this docket on the Internet at <http://dms.dot.gov>.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call LCDR Scott Budka, Project Manager, Office of Investigations & Analysis (G-MOA), Coast Guard, telephone 202-267-2026. If you have questions on viewing or submitting material to the docket, call Dorothy Beard, Chief, Dockets, Department of Transportation, telephone 202-366-5149.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking (USCG-2001-9175), indicate the specific section of this document to which each comment applies, and give the reason for each comment. You may submit your comments and material by mail, hand delivery, fax, or electronic means to the Docket Management Facility at the address under **ADDRESSES**; but please submit your comments and material by only one means. If you submit them by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.