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DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 3

RIN 2900-AO32

Disease Associated With Exposure to Certain Herbicide Agents: Peripheral Neuropathy

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) adopts as a final rule its proposal to amend its adjudication regulations by clarifying and expanding the terminology regarding presumptive service connection for acute and subacute peripheral neuropathy associated with exposure to certain herbicide agents. This amendment implements a decision by the Secretary of Veterans Affairs based on findings from the National Academy of Sciences (NAS) Institute of Medicine report, Veterans and Agent Orange: Update 2010. It also amends VA's regulation governing retroactive awards for certain diseases associated with herbicide exposure as required by court orders in the class action litigation of Nehmer v. U.S. Department of Veterans Affairs.

DATES: Effective Date: This rule is effective [insert date of publication in the FEDERAL REGISTER].

Applicability Date: This final rule shall apply to claims received by VA on or after [insert date of publication in the FEDERAL REGISTER] and to claims pending before VA on that date. Additionally, VA will apply this rule in readjudicating certain previously denied claims as required by court orders in Nehmer v.

Department of Veterans Affairs.

FOR FURTHER INFORMATION CONTACT: Dr. Nick Olmos-Lau, Medical Officer, Regulations Staff (211D), or Nancy Copeland, Consultant, 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: As required by the Agent Orange Act of 1991, codified in part at 38 U.S.C. 1116, the Department of Veterans Affairs (VA) asks the National Academy of Sciences (NAS) to evaluate scientific literature regarding possible associations between the occurrence of a disease in humans and exposure to an herbicide agent. Congress mandated that NAS to the extent possible determine (1) Whether there is a statistical association between exposure to herbicide agents and the illness, taking into account the strength of the scientific evidence and the appropriateness of the scientific methodology used to detect the association; (2) the increased risk of illness among individuals exposed to herbicide agents during service in the Republic of Vietnam during the Vietnam era; and (3) whether a plausible biological mechanism or other evidence

of a causal relationship exists between exposure to the herbicides and the illness. That statute provides that whenever the Secretary determines, based on sound medical and scientific evidence, that a positive association (i.e., the credible evidence for the association is equal to or outweighs the credible evidence against the association) exists between an illness and exposure to herbicide agents in an herbicide used in support of U.S. military operations in the Republic of Vietnam, the Secretary will publish regulations establishing presumptive service connection for that illness. On August 10, 2012, VA published a proposed rule in the Federal Register (77 FR 47795), to amend its adjudication regulations regarding presumptive service connection for acute and subacute peripheral neuropathy associated with exposure to certain herbicide agents. Specifically, based on findings from the September 29, 2010 NAS report titled, Veterans and Agent Orange: Update 2010 (hereinafter “Update 2010”), which concluded that early-onset peripheral neuropathy associated with herbicide exposure is not necessarily a transient condition, we proposed replacing the terms “acute and subacute” in 38 CFR 3.307(a)(6)(ii) and 38 CFR 3.309(e) with the term “early-onset” and removing the Note to 38 CFR 3.309(e) requiring that the neuropathy be “transient.” This change would remove the requirement that acute and subacute peripheral neuropathy appear “within weeks or months” after exposure and that the condition resolve within two years of the date of onset in order for the presumption to apply.

This amendment clarifies that VA will not deny presumptive service connection for early-onset peripheral neuropathy solely because the condition persisted for more than two years after the date of the last herbicide exposure. However, it does not change the requirement that peripheral neuropathy must have become manifest to a degree of ten percent or more within one year after the veteran's last in-service exposure in order to qualify for the presumption of service connection. In Update 2010, NAS found that evidence did not support an association between herbicide exposure and delayed-onset peripheral neuropathy, which NAS defined as having its onset more than one year after exposure.

We also proposed amending 38 CFR 3.816(b)(2), the regulation governing retroactive awards for certain diseases associated with herbicide exposure as required by court orders in the class action litigation in Nehmer v. U.S. Veterans' Admin. 712 F. Supp. 1404 (N.D. Cal. 1989) (incorporating Final Stipulation and Order, May 14, 1991) (Nehmer I), enforced, Nehmer v. U.S. Veterans' Admin., 32 F. Supp. 2d 1175 (N.D. Cal. 1999) (Nehmer II), aff'd sub nom., Nehmer v. Veterans' Admin. of Gov't of U.S., 284 F.3d 1158 (9th Cir. 2002) (Nehmer III); Nehmer v. U.S. Dep't of Veterans Affairs, 494 F.3d 846, 850 (9th Cir. 2007) (Nehmer IV).

Currently, the regulation states that the Nehmer court orders apply to presumptions established before October 1, 2002, and lists the diseases covered by those presumptions, including “acute and subacute peripheral neuropathy.” The courts invalidated the date restriction and corresponding listing of presumptive conditions because they were not inclusive of all the conditions VA has determined to be presumptively service connected based on herbicide exposure under the Agent Orange Act of 1991. Rather than revising and maintaining separate lists of diseases covered, VA is removing the list of conditions in 38 CFR 3.816 and the October 1, 2002, date and inserting language clarifying that the Nehmer court orders apply to the presumptions listed in 38 CFR 3.309(e).

We provided a 60-day comment period and interested persons were invited to submit comments on or before October 9, 2012. We received 111 written comments, including 3 from Veterans Service Organizations and advocacy groups.

The majority of commenters expressed support for VA’s proposed amendments. However, many felt that the action does not go far enough and urged VA to eliminate the requirement that peripheral neuropathy manifest to a degree of at least ten percent disabling within the first year after the veteran’s last in-service exposure to herbicides. VA appreciates these comments. However, in

Update 2010, NAS concluded that there is inadequate or insufficient evidence to determine whether there is an association between exposure to herbicides (including Agent Orange) and delayed-onset chronic neuropathy. NAS reaffirmed the conclusion in each of its prior reports that there are no data to suggest that exposure to herbicides can lead to the development of delayed-onset chronic peripheral neuropathy many years after termination of exposure in those who did not originally experience early-onset neuropathy. NAS went on to state that “[t]he committee considers a neuropathy to be early onset if abnormalities appear within a year after external exposure has ended.”

Therefore, we make no changes based on these comments.

Several commenters advocated that VA expand the list of presumptive conditions for veterans exposed to Agent Orange. Some asserted that veterans exposed to Agent Orange during service should be granted entitlement to service connection for all disabilities they currently have and one commenter stated that all Vietnam era veterans should be automatically entitled to 100 percent compensation. A service organization urged that hypertension be added based on the benefit of the doubt doctrine. The organization contends that, because some studies link hypertension to herbicide exposure while others do not, the evidence is in equipoise and veterans should be given the benefit of the doubt. Another service organization asserted that VA’s proposed rule fails to provide the most favorable interpretation of the existing science.

In response, VA notes that the Agent Orange Act of 1991, codified at 38 U.S.C. 1116, established a deliberate process for determining when a disease should be added. Specifically, the Secretary must determine, based on sound medical and scientific evidence, that there is a “positive association” between an illness and exposure to herbicide agents used in support of U.S. military operations in the Republic of Vietnam. The Secretary must take into account reports from NAS and “all other sound medical and scientific information and analyses available to the Secretary.” In evaluating any study, the Secretary must “take into consideration whether the results are statistically significant, are capable of replication, and withstand peer review.” The law further provides that a positive association exists if “the credible evidence for the association is equal to or outweighs the credible evidence against the association.” VA adheres to this process. Following the issuance of Update 2010, VA issued a negative notice on August 10, 2012, explaining why no additional diseases were being added to its list of conditions associated with exposure to herbicides in Vietnam (77 FR 47924). This notice provided an explanation of VA’s decision to not create presumptions of service connection for a variety of other diseases, including hypertension. This rulemaking is limited to clarifying and expanding the terminology regarding presumptive service connection for acute and subacute peripheral neuropathy associated with exposure to certain herbicides. See 77 FR 47795. As such, the addition of diseases other than early-onset peripheral neuropathy to VA’s presumptive list is beyond the scope of this rulemaking. Therefore, we make no changes based on these comments.

Three commenters, including one service organization, urged VA to recognize chronic delayed-onset peripheral neuropathy as due to Agent Orange exposure when no other cause can be established. As explained earlier, NAS found that there are no data to suggest that exposure to herbicides can lead to the development of delayed-onset chronic peripheral neuropathy many years after termination of exposure in those who did not originally experience early-onset neuropathy. NAS also noted that some neuropathies are often labeled as idiopathic or of unknown or spontaneous origin because, in 30 percent of the cases of chronic neuropathies, there is no apparent cause. Therefore, we make no changes based on these comments.

We received many comments from veterans who served in the Republic of Vietnam regarding their individual claims for veterans benefits and comments from family members and friends in support of veterans who served in the Republic of Vietnam. These comments are beyond the scope of this rulemaking. Therefore, VA makes no changes based on these comments.

Some commenters, including one service organization, support the rule but advocate for more research and point to other entities and studies as additional resources. The service organization also urged VA to fund well-designed epidemiologic studies of Vietnam veterans. VA acknowledges the need for ongoing research and continues to carefully evaluate ongoing NAS

herbicide exposure studies, medical and scientific research findings, discoveries, and recommendations as they occur. In addition, VA conducts ongoing research on the health effects of herbicides and supports epidemiologic studies of Vietnam veterans through grants to outside scientists. We make no changes based on these comments.

One commenter disagreed with VA's proposed rule, stating that he is not a veteran and that he was diagnosed with peripheral neuropathy as the result of shingles. VA recognizes that peripheral neuropathy is not unique to veterans or exposure to Agent Orange. However, as explained above, pursuant to the Agent Orange Act of 1991, whenever the Secretary determines, based on sound medical and scientific evidence, that there is a positive association (i.e., the credible evidence for the association is equal to or outweighs the credible evidence against the association) between an illness and exposure to herbicide agents, the Secretary will publish regulations establishing presumptive service connection for that illness. Thus, VA makes no changes based on this comment.

One commenter suggested that VA should add a regulatory "discovery rule" to the current requirement that peripheral neuropathy become manifest to a degree of ten percent or more within one year after the veteran's last in-service exposure. The commenter clarified that his proposed "discovery rule" would provide for a tolling of the current one-year manifestation requirement until after the veteran is first diagnosed with peripheral neuropathy (i.e., the veteran first

“discovers” that he or she has peripheral neuropathy). The commenter asserted that adding a “discovery rule” to the one-year period would give relief to veterans with peripheral neuropathy whose symptoms were not recognized until many years after exposure while also balancing cost concerns. In response, VA notes that the existing statutory and regulatory framework governing the administration of VA compensation benefits does not limit the time period during which veterans may file claims for benefits. Moreover, whether a condition became manifest to a degree of ten percent or more within one year of the veteran’s last in-service exposure to herbicides is a factual determination that must be made on a case-by-case basis, considering all the available evidence. Additionally, even if a veteran is not able to avail himself of the presumption of service connection, he may still be able to establish service connection on a direct basis under 38 U.S.C. 1110 and 38 CFR 3.303(d). To the extent the comment recommends changes to VA’s overall scheme for administering benefits, such changes would require legislation which is beyond the scope of this rulemaking. Thus, VA makes no changes based on this comment.

One commenter stated that he had type 2 diabetes and asked why a time limit is being imposed on the onset of peripheral neuropathy, given that it may result from type 2 diabetes that arises many years after the initial diagnosis of that condition. Several other commenters also stated that they had diabetes and asserted that they should be able to receive compensation for both diabetes and peripheral neuropathy. These commenters may be confused as to how the

peripheral neuropathy presumption relates to cases where peripheral neuropathy arises secondary to service-connected type 2 diabetes. In such cases, service connection can be awarded under 38 CFR 3.310 if the peripheral neuropathy is found to be secondary to service-connected type 2 diabetes. As a result, the “early onset” time limitation contained in the amended 38 CFR 3.307(a)(6)(ii), would not apply to these cases.

One organization commented that there is a disparity between the law and actual practice and stated that the Board of Veterans’ Appeals has considered the latent nature of peripheral neuropathy and found in favor of disabled veterans on many occasions. Decisions of the Board are not considered precedential and are binding only with regard to the specific case addressed in each decision. Moreover, as discussed above, determinations regarding entitlement to service connection are made on an individual basis, dependent on the facts of each case. Even if a veteran is unable to avail himself of the presumption afforded by 38 U.S.C. 1116, he may still be able to establish entitlement on a direct basis. This is particularly important when there is an approximate balance of positive and negative evidence in a claimant’s particular case because a claimant is entitled to the benefit of the doubt. (38 U.S.C. 5107(b)) The fact that VA has made favorable determinations underscores its adherence to this principle when deciding the merits of each case. VA makes no changes based on this comment.

One organization stated that using the term “early-onset” in 38 CFR 3.307(a)(6)(ii) is unnecessary and confusing because the requirement in that regulation that the disease be manifest to a ten percent degree within one year of exposure is sufficient to indicate that the presumption applies only to early-onset peripheral neuropathy. However, we believe that using the term “early-onset peripheral neuropathy” is necessary and helpful in 38 CFR 3.309(e), which lists the diseases presumptively associated with herbicide exposure, and we believe that using consistent terminology in 38 CFR 3.307(a)(6)(ii) and 3.309(e) will minimize confusion rather than creating it. The commenter also asserted that the changes to 38 CFR 3.816(b)(2) are unrelated to NAS’ findings regarding peripheral neuropathy and that cross-referencing between 38 CFR 3.816 and 38 CFR 3.309 appears to obfuscate the diseases that receive a presumptive service connection and may serve to undermine the Agent Orange Act of 1991. We have considered the language used and believe it is clear and accurate. As explained in the proposed rule, we are revising 3.816(b)(2) to comport with the Nehmer court orders and believe that cross-referencing 38 CFR 3.816 and 38 CFR 3.309 will simplify updating the list of diseases covered. This revision will clarify that Nehmer court orders apply to all presumptive conditions covered by § 3.309(e). As such, we make no change based on these comments.

Based on the rationale set forth in the proposed rule and this document, we are adopting the proposed rule as a final rule with no changes.

Administrative Procedure Act

The Secretary finds good cause to dispense with the delayed-effective-date requirement of 5 U.S.C. 553(d) because 38 USC 1116 (c)(2) requires that final regulations establishing presumptions of service connection for diseases associated with exposure to certain herbicide agents “shall be effective on the date of issuance.”

Paperwork Reduction Act

This document contains no provisions constituting a new collection of information under the Paperwork Reduction Act (44 U.S.C. 3501-3521).

Regulatory Flexibility Act

The Secretary hereby certifies that this 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 will not affect any small entities. Only VA beneficiaries could be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Executive Order 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including

potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” 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 final rule have been examined and it has been determined to be a significant regulatory action under Executive Order 12866 because it raises novel legal or policy issues.

VA's impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's Web site at <http://www1.va.gov/orpm/>, by following the link for "VA Regulations Published."

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 year. This rule will have no such effect on State, local, and tribal governments, or on the private sector.

Catalog of Federal Domestic Assistance Numbers and Titles

The Catalog of Federal Domestic Assistance program number and title for this rule 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 sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Jose D. Rojas, Interim Chief of Staff, approved

this document on April 22, 2013, for publication.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Health care, Pensions, Radioactive materials, Veterans, Vietnam.

Dated: September 3, 2013

Robert C. McFetridge,
Director of Regulations Policy and Management,
Office of the General Counsel,
Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 38 CFR part 3 as follows:

PART 3 — ADJUDICATION

Subpart A-Pension, Compensation, and Dependency and Indemnity Compensation

1. The authority citation for part 3, subpart A continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.
2. In § 3.307(a)(6)(ii), remove the term "acute and subacute peripheral neuropathy" and add, in its place, "early-onset peripheral neuropathy".
3. Amend § 3.309(e) by:
 - a. Removing the term "Acute and subacute peripheral neuropathy" and adding, in its place, "Early-onset peripheral neuropathy".
 - b. Removing Note 2.
 - c. Redesignating Note 3 as Note 2.
4. Amend § 3.816 by:
 - a. In the introductory text of paragraph (b)(2), removing "before October 1, 2002."

b. In the introductory text of paragraph (b)(2), removing the period after "chloracne" and the phrase "Those diseases are:" and adding, in their place, ", as provided in § 3.309(e)."

c. Removing paragraphs (b)(2)(i) through (ix).

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