Peripheral Neuropathy Rule Change Communications Plan

Background

Under Secretary Shinseki's leadership, the Department of Veterans Affairs (VA) remains committed to ensuring Vietnam Veterans receive the benefits they have earned through their service. On August 31, 2010, the Department of Veterans Affairs (VA) amended its regulations to add ischemic heart disease, hairy cell leukemia and other chronic B-cell leukemias, and Parkinson's disease to the list of diseases presumed to be related to exposure to Agent Orange, and other herbicides used in Vietnam.

Currently, 14 diseases are on the presumptive list for Agent Orange, including Acute and Sub-acute peripheral neuropathy. On August 10, 2012, the Department of Veterans Affairs posted a Federal Register Notice which included a proposed rule that would relax the requirements of the presumptive conditions associated with exposure to <u>Agent Orange and</u> <u>other herbicides used in Vietnam</u> under 38 C.F.R. §3.309(e) from Acute or Sub-acute Peripheral Neuropathy to Early Onset Peripheral Neuropathy. A final rule implementing this change will be published in the Federal Register on September 6, 2013.

Previous Rule (in plain language): Peripheral neuropathy is presumed to be associated with exposure to Agent Orange or other herbicides used in Vietnam if it is diagnosed *within one year*¹ of the last exposure to such herbicides AND the condition resolves within two years of diagnosis.²

New Rule (in plain language): Peripheral neuropathy is presumed to be associated with exposure to Agent Orange or other herbicides used in Vietnam if there is evidence showing it was diagnosed within 1 year of the last exposure to such herbicides, *regardless of whether the condition resolves or persists*.

A Veteran who filed a claim for VA benefits based on peripheral neuropathy related to herbicide exposure in Vietnam under the previous rule most likely would not have received a favorable decision, as the rule requires the condition resolve within two years of onset. Stated another way, Veterans who filed a claim seeking benefits based on the previous rule would not be able to demonstrate that they currently had acute or sub-acute peripheral neuropathy at the time of their claim, so such a claim would likely be denied.

Under the new rule, a Veteran will need to show evidence that peripheral neuropathy was diagnosed within a year of herbicide exposure, or that there were symptoms within the first year that led to a diagnosis of peripheral neuropathy, and that peripheral neuropathy has persisted from the time of onset of symptoms to the present to gain service connection. The Institute of Medicine

¹ Although 3.309(e) defines the condition as arising within weeks or months of exposure, 3.307(a)(6) makes clear the presumption applies if PN is manifest within 1 year of exposure; this aspect of the rule is not a change.

² The previous rule is found at 38 C.F.R. §§§ 3.307(a)(6) and 3.309(e).

of the National Academies of Science (IOM) has not found any evidence that chronic peripheral neuropathy developing years after exposure to herbicides is associated with that exposure. VA estimates that a relatively small number of Veterans will be eligible for compensation benefits under the new rule.

The Federal Court decision in *Nehmer v. U.S. Dep't of Veterans Affairs* [herein *Nehmer*] will apply to previously denied claims. *Nehmer* holds that when VA adds a new presumptive condition, to the list of those conditions associated with exposure to herbicides used in Vietnam, it must readjudicate the claims of Veterans or eligible survivors who previously filed claims seeking benefits based on that condition, and, in appropriate cases pay benefits retroactive to the date of receipt of the denied claim.³ VA will apply *Nehmer* requirements to cases affected by this rule, which expands the type of peripheral neuropathy covered by the presumption.

VA believes there are approximately 67,800 Vietnam Veterans previously denied service connection for peripheral neuropathy, and approximately 58,000 of them are alive.⁴ Of the previously denied Veterans, approximately 10,700 are not currently receiving compensation for any condition. VA plans to use a contractor to screen claims to determine potential eligibility. The screened claims that are identified as qualifying for potential eligibility will then be forwarded to a VA facility for adjudication. VA adjudication staff will then review those claims to determine if Veterans or surviving dependents are eligible for benefits and, if so, determine the effective date and calculate any retroactive payment.

Risk/Opportunity

VA estimates that roughly 1,000 Veterans⁵ will be added to the compensation rolls and about 400⁶ Veterans currently receiving benefits will receive an increase in benefits. VA realizes that this change is not likely to result in benefits for a large number of Veterans but has determined it is important to do what is necessary to provide benefits to all eligible Veterans. VA understands that some Veterans who will not be eligible will still seek benefits based on the addition of this presumption, and that its addition will require VA to expend resources to comply with its *Nehmer* obligations. Further, stakeholders now have general knowledge of the impact of *Nehmer* on claims processing due to the most recent additions to the presumptive list of herbicide-related conditions, and will have concerns about this rule's effect on the claims backlog. To mitigate this risk, VA will need to explain that because of the very limited presumptive period, the new rule is expected to have a minimal impact on the backlog. While VBA staff will spend time readjudicating the affected claims, utilizing resources in this manner is the correct response to recent medical findings, as reported by the Institute of Medicine (IOM).

Goal and Objectives

Through this communications plan, VA will achieve the following goals:

• Ensure stakeholders are aware of the rule change and of its final publication

³ Nehmer v. Veterans' Admin., 284 F.3d 1158, 1161-62 (9th Cir.2002) (Nehmer III).

⁴ VA Office of Performance Analysis and Integrity (PA&I) data.

⁵ Impact Analysis for RIN 2900-A032, p. 5, first paragraph.

⁶ Impact Analysis for RIN 2900-A032, p. 3, second paragraph.

- Ensure Veterans, family members, and survivors, understand the criteria for entitlement under the new rule, and how VA will handle previously denied claims
- Inform stakeholders of impact on backlog and VBA Transformation

Audiences

Internal: VBA employees, specifically VSRs and RVSRs; OSVA, VSO liaisons (Kevin Secor and Julie Carrie); AFGE; General Counsel, OCLA, OPA, VHA

External: VSOs, especially Big 6 and Associates of Vietnam Veterans of America; SVAC; HVAC; Veterans, families and survivors; media; CVSO, State Departments of Veterans Affairs

Messaging

- (1) Secretary Shinseki remains committed to ensuring that Vietnam Veterans receive benefits that they have earned through their service. Changes to disability compensation rules are based on the most current medical science as reported by the Institute of Medicine (IOM) of the National Academies.
 - The IOM's 2010 update to its <u>Veterans and Agent Orange</u> report provided sufficient medical evidence to support a positive association for early-onset, chronic peripheral neuropathy.
 - VA is modifying its regulations so peripheral neuropathy that was diagnosed within one year of exposure and is persistent (chronic) is a condition that qualifies as a presumptive condition based on exposure to herbicides used in Vietnam.
- (2) While scientific study supports expanding what is covered as a presumptive condition following herbicide exposure, it is not expected to impact a significant number of Veterans.
 - Many Veterans who were exposed to herbicides in Vietnam are already in receipt of compensation benefits for peripheral neuropathy (many resulting from Type II Diabetes, which is already a presumptive condition).
 - Under the new rule, VA estimates that roughly 1,000 Veterans will be added to the roles for compensation and approximately 400 will receive an increase in their compensation benefits.
- (3) The new rule should not significantly impact the current backlog of claims.
 - The *Nehmer* cases will be processed in accordance with procedures formulated for processing other claims where a new disability has been added to the presumptive list. However, VA estimates the number of Veterans who will be affected by this rule change will be small.
- (4) The new rule should not impact VA's new initiative to expedite compensation claims decisions for Veterans who have waited one year or longer.

Statement

Under Secretary Shinseki's leadership, VA remains committed to ensuring Vietnam Veterans receive the benefits they have earned through their service. Based on the most current medical science as reported by the Institute of Medicine (IOM), VA has modified its disability compensation rules so that peripheral neuropathy qualifies as a presumptive condition if it was diagnosed within one year of exposure to Agent Orange or other herbicides used in Vietnam and is persistent (chronic). Many Veterans who were exposed to herbicides in Vietnam are already in receipt of compensation benefits for peripheral neuropathy (often as a secondary condition resulting from Type II Diabetes, which is already a presumptive condition).

Under the new rule, VA anticipates minimal impact with approximately 1,000 Veterans added to the roles for compensation and approximately 400 will receive an increase in their compensation benefits. As a result, VA expects minimal impact on its goal to process claims in less than 125 days with 98 percent accuracy in 2015.

Communication Timeline

VA plans to limit communication of this rule change to stakeholder notification and in response to queries.

Action Plan upon OMB Approval

Tuesday, September 3rd, 2013 before 2 PM

• Final rule sent to OMB

Wednesday, September 4th, 2013

- HVAC and SVAC, VSOs and State Department of Veterans Affairs are notified via Fact Sheet
- OCLA/OPIA staff are utilize RTQ Statement and Q&A to respond to queries

Thursday, September 5th, 2013

• Final rule is posted online (approximately 8:45 AM)

Friday, September 6th, 2013

• Final rule is published

Other facts:

- The Agent Orange Act of 1991 requires VA to obtain a report on the effects of Agent Orange every 2 years from the National Academy of Sciences (NAS).
- 14 diseases are currently on the presumptive list for Agent Orange, including Acute and Sub-acute peripheral neuropathy
 - AL amyloidosis
- Multiple myelomaNon-Hodgkin's
- ChloracneType II Diabetes
- Hodgkin's disease
- Chronic B-cell
- leukemias
- lymphoma

 Acute and sub-acute
- peripheral neuropathy
 Porphyria cutanea tarda
- Porphyria cutanea tarda
- Prostate Cancer
- Respiratory cancers
- Soft-tissue Sarcoma
- Ischemic heart disease
- Parkinson's disease
- This rule expands the definition or redefines "acute and sub-acute peripheral neuropathy" as "early onset and persistent (chronic) peripheral neuropathy."
- Based on the September 2010 Institute of Medicine (IOM) report on Agent Orange from the National Academies of Science, the Secretary of Veterans Affairs determined that there was sufficient evidence to support a positive association for early onset, persistent (chronic) peripheral neuropathy.
- In 2010, VA amended its regulations to add ischemic heart disease, hairy cell and chronic Bcell leukemias, and Parkinson's disease to the list of diseases presumed related to exposure to the herbicide used in Southeast Asia.
 - The 2010 rule amendment resulted in164,000 Veterans receiving retroactive VA compensation totaling more than \$4.5 billion.
- VA will review approximately 67,000 peripheral neuropathy claims that were previously denied to see which claims should be re-adjudicated under *Nehmer*. This will have significantly less impact than the 2010 amended rule, which yielded approximately 150,000 claims for re-adjudication.
- Many Veterans who were exposed to herbicides in Vietnam are already service connected for peripheral neuropathy, since peripheral neuropathy is often a condition associated with Type II Diabetes, which is already identified as a presumptive condition.
- Potentially newly eligible Veterans include those who were exposed based on duty or visitation in Vietnam or on its inland waterways between January 9, 1962, and May 7, 1975; exposed along the demilitarized zone in Korea between April 1, 1968, and August 31, 1971; or exposed due to herbicide tests and storage at military bases within and outside of the United States.

Questions and Answers

Q: What are the major differences between the previous rule and the new rule?

A: Previous Rule (in plain language):

Peripheral neuropathy is presumed to be associated with exposure to Agent Orange or other herbicides used in Vietnam if it is diagnosed *within 1 year* of the last exposure to Agent Orange AND the condition resolves within two years of diagnosis.⁷

New Rule (in plain language): Peripheral neuropathy is presumed to be associated with exposure to Agent Orange, or other herbicides used in Vietnam if there is evidence showing it was diagnosed within 1 year of the last exposure, regardless of whether the condition resolves or persists.

Q: How many Veterans are currently service-connected for PN due to Agent Orange Exposure to Herbicides used in Vietnam?

A: Under the previous rule, it would have been very difficult for Veterans to be service connected solely for acute and sub-acute peripheral neuropathy because the rule required that the condition resolve within two years after exposure, and service connection requires a current disability. However, VA does compensate Veterans for conditions that are caused by service-connected conditions. Often peripheral neuropathy is a condition caused by diabetes mellitus, which is already a presumptive condition associated with Agent Orange exposure. There are currently 145,682⁸ Veterans receiving compensation for peripheral neuropathy related to diabetes mellitus.

Q: How many Veterans does VA estimate will be eligible under the new rule change?

A: Based on the number of Vietnam Veterans who physically served in country or on its inland waterways, VA's rough estimate is that approximately 400 Veterans will receive an increase in their compensation benefits in the first year, plus an additional 1000 Veterans who were previously denied.

Q: How does this proposed rule change impact Blue Water Veterans?

A: Based on the analysis and conclusions in the IOM report, VA has determined that the evidence available at this time warrants no extension of a presumption of exposure to herbicides to Blue Water Navy Vietnam Veterans.

VA will continue to accept and review on a case-by-case basis all Blue Water Vietnam Veteran claims and will work to ensure that Veterans serving on Blue Water ships that operated on Vietnam's inland waterways or sent crewmembers ashore are identified as such.

⁷ The previous rule is found at 38 C.F.R. §§ 3.307(a)(6) and 3.309(e).

⁸ Impact Analysis for RIN 2900-A032, p. 5, first paragraph (There are 485,605 living Veterans currently receiving compensation for PN, Comp Service assumes 30 percent are Vietnam Veterans – 145,682

Q: What is VA's plan to address the cases that were previously denied?

A: Claims for peripheral neuropathy related to exposure in Vietnam that were previously denied fall under 38 C.F.R. 3.816 (*Nehmer processing*). Consistent with *Nehmer*, when VA issues a new presumptive condition, or changes the definition of a presumptive condition, it must re-adjudicate the claims of Veterans or eligible survivors who previously filed for compensation or death benefits and were denied and must compensate them retroactively to the date of receipt of the prior denied claim. VA plans to have the previously denied claims screened to determine which claims present a potential basis for entitlement to benefits based on the addition of this new presumption. Such claims will then be readjudicated using the *Nehmer* criteria.

Q: How will the new rule affect the current backlog of disability claims?

A: VA will act to quickly and accurately identify and re-adjudicate these claims to minimize the impact this new presumption will have on the backlog of disability claims.

Q: How many Veterans will receive increased monthly compensation?

A: There are approximately 67,000 Vietnam Veterans who were previously denied service connection for peripheral neuropathy. Of these, nearly 70 percent are already on VA's compensation rolls for service-connected disabilities. VA assumes the average rating for peripheral neuropathy will be 10 percent. Veterans who are already rated 50 to 100 percent for combined service connected disabilities and receive an average compensation rate for peripheral neuropathy will not see a difference in their monthly compensation. Veterans who are compensated at the 0 to 40 percent rates and receive the average compensation rate for peripheral neuropathy will see an increase in their monthly compensation rate. Approximately 400 Veterans will receive an increase in their compensation benefits in the first year, plus an additional 1,000 Veterans who were previously denied.

Q: How will VA assist the Veterans in developing their claims, considering the evidence required is from nearly 4 decades ago or longer?

A: Veterans who qualify for *Nehmer* processing will have their claims readjudicated based on evidence already in their file. VA will exercise its duty to assist Veterans who are applying for the first time the way it assists all Veterans. Further, VA will continue to give Veterans the benefit of the doubt when there is an approximate balance of positive and negative evidence regarding the matter.

Q: How will this new rule impact VA's recent initiative to expedite compensation claims decisions for Veterans who have waited one year or longer?

A: The new rule will have a minimal impact on VA's new initiative to expedite compensation claims decisions for Veterans who have waited one year or longer.

Q: What is the reasoning for the delay between IOM's findings and VA's final rule change?

A: The IOM made their recommendation in 2010. After any recommendation is made, the IOM working group forms and it makes their recommendation, working through concurrence to the Secretary of VA. Once the Secretary approves the recommendation to add a presumption, VA starts drafting the proposed rule. This process takes time, as several offices review the proposed content to ensure it is within sound legal standing. VA publishes the proposed rule in the Federal Register to allow the public to provide comments. VA then addresses each comment and may amend the rule accordingly. Once all comments are addressed, a final rule is published in the Federal Register.