

Proposed Rules

Federal Register

Vol. 73, No. 213

Monday, November 3, 2008

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900-AN01

Presumptive Service Connection for Disease Associated With Exposure to Certain Herbicide Agents: AL Amyloidosis

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

SUMMARY: The Department of Veterans Affairs (VA) is proposing to amend its adjudication regulations concerning presumptive service connection for a certain disease based on the most recent National Academy of Sciences (NAS) Institute of Medicine committee report, "Veterans and Agent Orange: Update 2006 (Update 2006)." This proposed amendment is necessary to implement a decision of the Secretary of Veterans Affairs that there is a positive association between exposure to herbicides used in the Republic of Vietnam during the Vietnam era and the subsequent development of AL amyloidosis. The intended effect of this proposed amendment is to establish presumptive service connection for AL amyloidosis based on herbicide exposure.

DATES: Comments must be received by VA on or before January 2, 2009.

ADDRESSES: Written comments may be submitted through <http://www.Regulations.gov>; by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue, NW., Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. (This is not a toll-free number.)

Comments should indicate that they are submitted in response to "RIN 2900-AN01—Disease Associated With Exposure to Certain Herbicide Agents: AL Amyloidosis." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B,

between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System at <http://www.Regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Rhonda F. Ford, Chief, Regulations Staff (211D), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461-9739. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: Section 3 of the Agent Orange Act of 1991, Public Law 102-4, 105 Stat. 11, directed the Secretary to seek to enter into an agreement with NAS to review and summarize the scientific evidence concerning the association between exposure to herbicides used in support of military operations in the Republic of Vietnam during the Vietnam era and each disease suspected to be associated with such exposure. Congress mandated that NAS determine, to the extent possible: (1) Whether there is a statistical association between the suspect diseases and herbicide exposure, taking into account the strength of the scientific evidence and the appropriateness of the methods used to detect the association; (2) the increased risk of disease among individuals exposed to herbicides during service in the Republic of Vietnam during the Vietnam era; and (3) whether there is a plausible biological mechanism or other evidence of a causal relationship between herbicide exposure and the suspect disease. Section 3 of Public Law 102-4 also required that NAS submit reports on its activities every 2 years (as measured from the date of the first report) for a 10-year period. The Veterans Education and Benefits Expansion Act of 2001 (Benefits Expansion Act), Public Law 107-103, § 201(d), extended through October 1, 2014, the period for submission of NAS reports.

Section 1116(b) of title 38, United States Code, as enacted by the Agent Orange Act of 1991, Public Law 102-4, 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 exposure of humans to an herbicide agent (i.e., a chemical in an herbicide used in support of the United States and allied military operations in the Republic of Vietnam during the Vietnam era) and a disease, the Secretary will publish regulations establishing presumptive service connection for that disease. If the Secretary determines that a presumption of service connection is not warranted, he is to publish a notice of that determination, including an explanation of the scientific basis for that determination. The Secretary's determination must be based on consideration of the NAS reports and all other sound medical and scientific information and analysis available to the Secretary.

Although 38 U.S.C. 1116(b) does not define "credible," it does instruct the Secretary to "take into consideration whether the results [of any study] are statistically significant, are capable of replication, and withstand peer review." Simply comparing the number of studies which report a positive relative risk to the number of studies which report a negative relative risk for a particular condition is not a valid method for determining whether the weight of evidence overall supports a finding that there is or is not a positive association between herbicide exposure and the subsequent development of the particular condition. Because of differences in statistical significance, confidence levels, control for confounding factors, bias, and other pertinent characteristics, some studies are clearly more credible than others, and the Secretary has given the more credible studies more weight in evaluating the overall weight of the evidence concerning specific diseases.

Section 2 of the Agent Orange Act of 1991, Public Law 102-4, provided that the congressional mandate that the Secretary establish presumptions of service connection under 38 U.S.C. 1116(b) would expire 10 years after the first day of the fiscal year in which the NAS transmitted its first report to VA. The first NAS report was transmitted to VA in July 1993, during the fiscal year that began on October 1, 1992. Accordingly, under the Agent Orange Act of 1991, Public Law 102-4, the mandate for VA to issue regulatory

presumptions as specified in section 1116(b) expired on September 30, 2002. In December 2001, however, Congress enacted the Benefits Expansion Act, section 201(d) of which extended the mandate under section 1116(b) through September 30, 2015. Pursuant to the Benefits Expansion Act, Public Law 107-103, VA must issue new regulations between October 1, 2002, and September 30, 2015, establishing additional presumptions of service connection for diseases that are found to be associated with exposure to an herbicide agent.

I. History of Agent Orange Presumptions

Pursuant to 38 U.S.C. 1116 and prior NAS reports received between July 1993 and March 2005, VA regulations contain presumptions of service connection for eleven categories of disease based on exposure to an herbicide agent. Those diseases are listed in 38 CFR 3.309(e) as follows: Chloracne or other acneform disease consistent with chloracne, Type 2 diabetes (also known as Type II diabetes mellitus or adult-onset diabetes), Hodgkin's disease, Chronic lymphocytic leukemia, Multiple myeloma, Non-Hodgkin's lymphoma, Acute and subacute peripheral neuropathy, Porphyria cutanea tarda, Prostate cancer, Respiratory cancers (cancer of the lung, bronchus, larynx, or trachea), and Soft-tissue sarcoma (other than osteosarcoma, chondrosarcoma, Kaposi's sarcoma, or mesothelioma).

If a veteran who was exposed to an herbicide agent in service subsequently develops one of the presumptive diseases, VA will presume the disease was caused by the exposure to an herbicide agent in service for purposes of establishing entitlement to service-connected benefits. To qualify for this presumption, chloracne, porphyria cutanea tarda, and acute and subacute peripheral neuropathy must become manifest to a degree of disability of 10 percent or more within 1 year after the date of last exposure. The other conditions are presumed service connected if they are manifest to a degree of disability of 10 percent or more at any time after exposure. 38 U.S.C. 1116(a)(2). VA presumes that any veteran who served in the Republic of Vietnam during the period beginning on January 9, 1962, and ending on May 7, 1975, was exposed to an herbicide agent during such service. 38 U.S.C. 1116(f).

II. Prior Actions Concerning AL Amyloidosis

VA identified AL amyloidosis as a concern after the publication of Veterans and Agent Orange: Update

1998. AL amyloidosis was considered by the NAS in its reports: Veterans and Agent Orange: Update 2000, Veterans and Agent Orange: Update 2002, and Veterans and Agent Orange: Update 2004. In these reports, NAS concluded that there was inadequate or insufficient evidence to determine whether there was an association between exposure to the compounds of interest and AL amyloidosis. After reviewing each of those reports, the Secretary determined that the credible evidence against an association between exposure to an herbicide agent and the occurrence of AL amyloidosis in exposed persons outweighed the credible evidence for such an association, and that a positive association therefore did not exist. 72 FR 32395, 32405 (June 12, 2007); 68 FR 27630, 27640 (May 20, 2003); 67 FR 42600, 42607-08 (June 24, 2002).

III. Latest NAS Review of AL Amyloidosis

In Update 2006, VA specifically requested a focused review of the evidence related to whether the occurrence of acute myeloid leukemia, tonsil cancer, AL amyloidosis, and lupus may be associated with exposure to the components of herbicides used by the military in Vietnam and requested explicit indication of the appropriate category of association for all forms of cancer. NAS issued its report, "Veterans and Agent Orange: Update 2006" on July 27, 2007. In pertinent part in that report, NAS concluded that "there is limited or suggestive evidence of an association between exposures to the compounds of interest and AL amyloidosis." The term "limited or suggestive evidence of an association," as explained in the NAS report, means that the evidence suggests an association between exposure to herbicides and the outcome considered, but the evidence is limited because chance, bias, and confounding could not be ruled out with confidence. For example, a well-conducted study showing a positive association combined with less compelling results from studies of populations with similar exposures could constitute such evidence.

In Update 2006, NAS re-categorized the section on AL amyloidosis from its position in the previous reports, where it was grouped with a variety of non-neoplastic health conditions, and placed it closer to related conditions, such as multiple myeloma and some types of B-cell lymphoma. The conditions share several biological features, most notably clonal hyperproliferation of B-cell-derived plasma cells and production of abnormal amounts of immunoglobulins.

NAS found that because AL amyloidosis is a rare condition, there is little epidemiologic literature. One study indicates that AL amyloidosis and non-Hodgkin's lymphoma are closely related. Another study reviewed the relationship between AL amyloidosis and other plasma cell disorders. It describes AL amyloidosis as a clonal plasma cell disorder characterized by low tumor burden but profound multisystemic disease. The observation of common chromosomal abnormalities in AL amyloidosis and multiple myeloma and of "progression" from AL amyloidosis to multiple myeloma support the biologic plausibility of linking AL amyloidosis with multiple myeloma. It is known that AL amyloidosis is associated with B-cell diseases and roughly 15-20 percent of the time it occurs with multiple myeloma. Other diagnoses associated with AL amyloidosis include B-cell lymphomas (which are types of non-Hodgkin's lymphoma), monoclonal gammopathies, agammaglobulinemia, and monoclonal gammopathy of undetermined significance. Thus, AL amyloidosis can result from such medical conditions as multiple myeloma and B-cell lymphomas for which there is evidence of association with exposure to the compounds of interest. The NAS committee's conclusion that there is limited or suggestive evidence of an association between herbicide exposure and AL amyloidosis is predicated primarily on the evidence of a pathophysiological association between AL amyloidosis and these other diseases, which have previously been found to be associated with herbicide exposure.

IV. The Secretary's Determination on AL Amyloidosis

After considering all of the evidence, the Secretary has determined that there is a positive association between exposure to herbicide agents and the occurrence of AL amyloidosis.

The biological and pathophysiological features of AL amyloidosis link it to multiple myeloma and some lymphomas that are associated with herbicide exposure in previous NAS reports. Establishing presumptive service connection for AL amyloidosis is consistent with existing VA recognition of multiple myeloma and some lymphomas as presumptively service connected based on exposure to an herbicide agent. Although there is relatively little direct epidemiological evidence concerning the relation of AL amyloidosis to herbicide exposure, the Secretary notes that NAS considered the evidence linking AL amyloidosis to

multiple myelomas and lymphomas to be significant, if indirect, evidence of an association. Therefore, the Secretary concludes that the credible evidence for an association between exposure to an herbicide agent and the occurrence of AL amyloidosis in humans outweighs the credible evidence against such an association. Accordingly, the Secretary has determined that a presumption of service connection for AL amyloidosis is warranted pursuant to 38 U.S.C. 1116(b).

This proposed rule does not reflect determinations concerning any disease other than AL amyloidosis. The Secretary's determinations concerning other diseases discussed in the Update 2006 report will be addressed in future documents published in the **Federal Register**.

Paperwork Reduction Act

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

Regulatory Flexibility Act

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

Executive Order 12866

Executive Order 12866 directs agencies to assess all 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, and other advantages; distributive impacts; and equity). The Executive Order classifies a "significant regulatory action," requiring 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 the Executive Order.

The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined and it has been determined to be a significant regulatory action under the Executive Order because it is likely to result in a rule that may raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

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 proposed rule would 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 numbers and titles for this proposed rule are 64.109, Veterans Compensation for Service-Connected Disability, and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

List of Subjects in 38 CFR Part 3

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

Approved: September 30, 2008.

Gordon H. Mansfield,

Deputy Secretary of Veterans Affairs.

For the reasons set out in the preamble, VA proposes to amend 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.

§ 3.309 [Amended]

2. In § 3.309(e) the listing of diseases is amended by adding "AL

amyloidosis" immediately preceding "Chloracne or other acneform disease consistent with chloracne."

[FR Doc. E8–26175 Filed 10–31–08; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AM81

Elimination of Co-Payment for Weight Management Counseling

AGENCY: Department of Veterans Affairs.

ACTION: Withdrawal of proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) is withdrawing VA's proposal published in the **Federal Register** at 73 FR 20579 on April 16, 2008, to amend our medical regulations to designate weight management counseling (individual and group sessions) as a service that is not subject to VA's co-payment requirements. VA received no significant adverse comments concerning the proposed rule or its companion substantially identical direct final rule published on the same date. In a companion document in this issue of the **Federal Register**, we are confirming that the direct final rule became effective on June 16, 2008. Accordingly, this document withdraws as unnecessary the proposed rule.

FOR FURTHER INFORMATION CONTACT:

Tony Guagliardo, Director, Business Policy, Chief Business Office (16), Veterans Health Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–1591 (this is not a toll-free number).

Approved: October 27, 2008.

Gordon H. Mansfield,

Deputy Secretary of Veterans Affairs.

[FR Doc. E8–26174 Filed 10–31–08; 8:45 am]

BILLING CODE 8320–01–P