

**DEPARTMENT OF VETERANS
AFFAIRS**

38 CFR Part 3

RIN 2900-AK63

**Disease Associated With Exposure to
Certain Herbicide Agents: Type 2
Diabetes**

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is amending its adjudication regulations concerning presumptive service connection for certain diseases for which there is no record during service. This amendment is necessary to implement a decision of the Secretary of Veterans Affairs under the authority granted by 38 U.S.C. 1116 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 Type 2 diabetes. The intended effect of this amendment is to establish presumptive service connection for that condition based on herbicide exposure.

DATES: *Effective Date:* July 9, 2001.

FOR FURTHER INFORMATION CONTACT: Bill Russo, Regulations Staff, Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, telephone (202) 273-7211.

SUPPLEMENTARY INFORMATION: VA published a proposal to amend 38 CFR 3.309(e) to establish presumptive service connection for Type 2 diabetes based on exposure to herbicides in the **Federal Register** of January 11, 2001 (66 FR 2376-80). Interested persons were invited to submit written comments concerning the proposal on or before March 12, 2001. We received 14 comments: one from the New York State Council of the Vietnam Veterans of America, one from the Wisconsin State Council of the Vietnam Veterans of America, and 12 from concerned individuals.

I. Comments on the Proposed Rule

Comments Supporting the Proposed Regulation

Three commenters stated that they supported the proposed regulation. One e-mail comment signed by 86 individuals also stated that they supported the proposed regulation. One commenter stated that he supported the proposed regulation and asked for swift implementation of the regulation.

Minimum 10% Rating

One commenter urged that all Vietnam veterans with Type 2 diabetes be awarded a minimum 10% disability rating.

This rule implements 38 U.S.C. 1116(c), which requires VA to establish a presumption of service connection when a positive association is found between exposure to certain herbicide agents and the subsequent development of a disease. The statute does not require VA to presume that such diseases result in any particular degree of disability. Further, under 38 CFR 3.307(a)(6)(ii), any disease must be manifest to a degree of disability of 10 percent or more before it may be presumed service connected based on herbicide exposure. In establishing presumptions of service connection for specific diseases based on herbicide exposure or other circumstances of service, Congress has consistently required that the disease be manifest to a degree of disability of 10 percent or more before the presumption applies. (See 38 U.S.C. 1116(a)(2)). We are aware of no justification for treating type 2 diabetes differently than other presumptive conditions in this regard. We therefore make no change based on this comment. We note that VA's rating schedule in 38 CFR 4.119, Diagnostic Code 7913, provides that a 10-percent rating will be assigned for diabetes which is "[m]anageable by restricted diet only."

Herbicide Exposure Outside Republic of Vietnam

One commenter urged that VA amend the proposed regulation to include veterans who did not serve in the Republic of Vietnam, but were exposed to herbicides during their military service.

Section 1116(a)(3) of title 38 of the United States Code establishes a presumption of exposure to certain herbicides for any veteran who served in the Republic of Vietnam between January 9, 1962 and May 7, 1975, and has one of the diseases on the list of diseases subject to presumptive service connection. However, if a veteran who did not serve in the Republic of Vietnam, but was exposed to an herbicide agent defined in 38 CFR 3.307(a)(6) during active military service, has a disease on the list of diseases subject to presumptive service connection, VA will presume that the disease is due to the exposure to herbicides. (See 38 CFR 3.309(e)). We therefore believe that there is no need to revise the regulation based on this comment.

Another commenter urged VA to use this rulemaking to define service in the Republic of Vietnam to include service in Vietnam's inland waterways or its territorial waters. The commenter asserted that U.S. military personnel were exposed to herbicides while serving in those locations.

Title 38 U.S.C. 1116 requires that a veteran have served "in the Republic of Vietnam" to be eligible for the presumption of exposure to herbicides. We believe that it is commonly recognized that this term includes the inland waterways.

With respect to offshore service, 38 CFR 3.307(a)(6)(iii) provides that "Service in the Republic of Vietnam" includes service in offshore waters or other locations only if the conditions of service involved duty or visitation within the Republic of Vietnam. In interpreting similar language in 38 U.S.C. 101(29)(A), VA's General Counsel has concluded that service in a deep-water vessel in waters offshore the Republic of Vietnam does not constitute service "in the Republic of Vietnam." (See VAOPGCPREC 27-97). VA's regulatory definition of "Service in the Republic of Vietnam" predates the enactment of section 1116(a)(3) (see former 38 CFR 3.311a(a)(1) (1990)), and we find no basis to conclude that Congress intended to broaden that definition. The commenter cited no authority for concluding that individuals who served in the waters offshore of the Republic of Vietnam were subject to the same risk of herbicide exposure as those who served within the geographic boundaries of the Republic of Vietnam, or for concluding that offshore service is within the meaning of the statutory phrase "Service in the Republic of Vietnam." We therefore make no change based on this comment.

Type 1 Diabetes

We received two comments urging VA to broaden the scope of this regulation to include Type 1 diabetes (also known as juvenile diabetes).

One commenter noted that VA's rating schedule (38 CFR 4.119, DC 7913) refers only to "diabetes mellitus" and does not distinguish between Type 1 and Type 2. He also noted that DC 7913 refers to ketoacidosis, and asserted that this condition only occurs with Type 1 diabetes.

VA's Schedule for Rating Disabilities (38 CFR part 4) is used to assess the level of disability caused by a disease or injury. It is not used to determine whether disabilities are service connected, nor is it considered when the Secretary determines whether there

is an association between herbicide exposure and a specific disease. Under 38 U.S.C. 1116, that decision is based on reports of the National Academy of Sciences (NAS) and all other sound medical and scientific information and analyses available to the Secretary.

Another commenter, an endocrinologist, stated that environmental toxins are well known triggers for the onset of Type 1 diabetes. However, this commenter cited no medical or scientific literature in support of this statement, nor did the commenter specify which environmental toxins (e.g., herbicides) are well known triggers for Type 1 diabetes.

The intent of the proposed regulation was to add only Type 2 diabetes to the list of diseases subject to presumptive service connection based on herbicide exposure in the Republic of Vietnam. Type 1 diabetes is a clinically distinct disease from Type 2 diabetes. As discussed extensively in "Veterans and Agent Orange: Herbicide/Dioxin Exposure and Type 2 Diabetes" (VAO: Diabetes), Appendix B, Type 1 is generally considered to be disease of insulin deficiency due to an immune disorder, while Type 2 diabetes is considered to be primarily a disease of insulin resistance. In its report, "Veterans and Agent Orange: Update 1998" (Update 1998), NAS concluded that there was "inadequate or insufficient evidence" to determine whether an association existed between exposure to herbicides and immune disorders. The Secretary determined "that the credible evidence against an association between immune system disorders and herbicide exposure outweighs the credible evidence for such an association, and [] determined that a positive association does not exist." Diseases Not Associated With Exposure to Certain Herbicide Agents, 64 FR 59232, 59241 (November 2, 1999).

The conclusion reached by NAS in VAO Diabetes was that "there is limited/suggestive evidence of an association between exposure to the herbicides used in Vietnam or the contaminant dioxin and Type 2 diabetes." This conclusion was based on NAS' thorough review of the published scientific literature on herbicide exposure and diabetes. The Secretary subsequently determined that there is a positive association between exposure to herbicides used in the Republic of Vietnam during the Vietnam era and the development of Type 2 diabetes.

Based on the reasons discussed above, VA finds no basis on which to expand the proposed regulation to include Type

1 diabetes, and we therefore make no change based on these comments.

Obesity and Type 2 Diabetes

One commenter asserted that several recent medical studies reported a significant increase in the incidence of diabetes, apparently resulting from an increase in obesity in the general population. The commenter stated that assuming these studies are valid, it is improper for VA to find a "statistically significant relationship" between diabetes and Agent Orange.

NAS was well aware that obesity is a significant risk factor in causing Type 2 diabetes. (VAO: Diabetes at 3). Nevertheless, after a thorough review of the scientific literature available on the subject, NAS concluded "there is limited/suggestive evidence of an association between exposure to the herbicides used in Vietnam or the contaminant dioxin and Type 2 diabetes."

The Secretary has not found a "statistically significant relationship" between herbicide exposure and diabetes, but rather a "positive association." Title 38 U.S.C. 1116(b)(3) provides that an association is "positive" if the credible evidence for the association is equal to or outweighs the credible evidence against the association. Once he has determined that a positive association exists between herbicide exposure and a particular disease, the Secretary must publish regulations establishing presumptive service connection for that disease.

The same commenter suggested that VA either reconsider whether to add Type 2 diabetes to the list of diseases subject to presumptive service connection based on herbicide exposure in the Republic of Vietnam or that it wait to publish the final rule until it reviewed these studies.

Title 38 U.S.C. 1116(c)(1) requires that the Secretary, not later than 60 days after the date on which he receives a report from NAS, determine whether a presumption of service connection is warranted for each disease covered by the report and, if the Secretary determines that a presumption is warranted, issue proposed regulations within 60 days thereafter. 38 U.S.C. 1116(c)(2) requires the Secretary to issue final regulations establishing presumptive service connection for any condition for which he determines there is a positive association with exposure of humans to an herbicide agent not later than 90 days after he has issued proposed regulations.

We believe that the NAS adequately took into consideration the recognized

relationship between obesity and type 2 diabetes, and the existence of additional studies concerning this risk factor does not warrant ignoring the time requirements of section 1116(c)(2). For reasons more fully explained in the proposal, the Secretary has concluded that presumptive service connection is warranted for Type 2 diabetes, and VA is, therefore, proceeding with publication of a final rule notwithstanding these comments.

Effective Dates

One commenter urged that the proposed rule be amended to state that awards granted under the rule will be retroactive to the date the claimant first submitted evidence of a diagnosis of Type 2 diabetes. Title 38 U.S.C. 1116(c)(2) clearly and unambiguously requires that regulations promulgated as a result of a decision of the Secretary of Veterans Affairs that a positive association exists between exposure to herbicides and a specified condition or disease "shall be effective on the date of issuance." The effective date established by this rule is in accordance with 38 U.S.C. 1116(c)(2) and 5 U.S.C. 801 et. seq. Under 38 U.S.C. 5110(g), when benefits are awarded based on a new regulation, the effective date of the award may not be earlier than the effective date of the regulation. In view of 38 U.S.C. 1116(c)(2) and 5110(g), VA does not have authority to provide in this rule for assignment of effective dates earlier than the date on which this rule is issued.

Another commenter asked how the court case *Nehmer v. U.S. Veterans' Admin.*, C.A. No. C-86-6160 (TEH) (N.D. Cal.), will apply to Type 2 diabetes claims under the proposed rule. The commenter asserted that it is unfair for a Vietnam veteran to not be compensated retroactively by VA.

Pursuant to a stipulation and order of the Federal district court in *Nehmer*, awards of disability compensation or dependency and indemnity compensation (DIC) made under VA's regulations issued pursuant to 38 U.S.C. 1116 may, in some circumstances, be made effective retroactive to the date of an earlier claim that was filed or denied before such regulations were issued. Thus, the *Nehmer* stipulation and order, when it applies, permits awards of retroactive benefits that would otherwise be prohibited by 38 U.S.C. 1116(c)(2) and 5110(g). The scope and application of the *Nehmer* stipulation and order is the subject of pending litigation and, until that litigation is resolved, we cannot say how the *Nehmer* stipulation and order will affect claims under this rule.

Nothing in this rule is intended to modify the *Nehmer* stipulation and order or to detract from rights existing under that document. The *Nehmer* stipulation and order applies to a specific class of claimants whose claims were previously filed or denied during a particular time period. This rule will apply to a broader class of claimants, including those whose claims were denied during periods not covered by the *Nehmer* stipulation and order, as well as those who file claims in the future. Individuals will continue to have specific rights under the terms of the *Nehmer* stipulation and order when it applies.

The final rule does not incorporate the effective-date provisions of the *Nehmer* stipulation and order because the scope and application of those provisions is the subject of current litigation and because VA lacks the authority to issue regulatory provisions that would be inconsistent with 38 U.S.C. 1116(c)(2) and 5110(g). (See 38 U.S.C. 501(a).)

VA appreciates the comments submitted in response to the proposed rule that is now adopted without change.

II. Compliance With the Congressional Review Act, the Regulatory Flexibility Act, and Executive Order 12866

We estimate that the five-year cost of this rule from appropriated funds would be \$3.3 billion in benefits costs and \$62 million in government operating expenses. Since it is likely that the adoption of the proposed rule may have an annual effect on the economy of \$100 million or more, the Office of Management and Budget has designated this rule as a major rule under the Congressional Review Act, 5 U.S.C. 802, and a significant regulatory action under Executive Order 12866, Regulatory Planning and Review. The following information is provided pursuant to E.O. 12866.

This rule is necessary to comply with 38 U.S.C. 1116, which requires VA to establish a presumption of service connection if the Secretary finds 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 any particular disease. As explained above, the Secretary found that there is such an association regarding Type 2 diabetes. There are no feasible alternatives to this rule, since section 1116 requires the Secretary to promulgate it once he finds the positive association described above. This rule would not interfere with state, local or

tribal governments in the exercise of their governmental functions.

Benefits Costs

Historical statistics indicate that the total number of veterans who served in the Republic of Vietnam or its surrounding waters was about 2.6 million. We estimate that about 2.3 million of these veterans are alive today. Using information gained from VAO: Diabetes and VA's Office of Planning and Analysis, VA applied a prevalence rate of 9% to the current population to determine the number of veterans who might have Type 2 diabetes today. VA assumes that over five years, about 90% of these same veterans would file a diabetes-related claim. We expect that 8 out of 10 claims will be made by first time applicants (original) and that 2 out of 10 will come from veterans already service connected for some other issue (reopened). The average monthly award made on account of diabetes or its ancillary conditions for original and reopened claims is estimated to be \$462 and \$786, respectively. These figures are based on average benefits to current beneficiaries for all conditions and include dependents' benefits and unemployment benefits where applicable. A moderate number of DIC and burial claims have also been factored into this estimate.

VA estimates the cumulative totals of benefits awards to claimants for years 2001–2005 as follows: 10,199, 80,526, 129,988, 159,198 and 178,356. Benefits costs (in \$ million) for years 2001–2005 are as follows: \$16.6, \$303, \$720.1, \$1,010.7, and \$1,205.3, for a total cost of \$3.3 billion over five years. This cost estimate also provides for a nominal number of DIC payments and burial awards. Anticipated cost-of-living allowances (COLA's), per current economic assumptions, were factored into this estimate; however, no retroactive payments were considered.

Administrative Costs

The administrative workload caused by this proposed rule is expected to be 13,361 claims filed in 2001 and more than 220,000 over five years. Full time employee resources devoted to processing claims in years one through five would be 128, 378, 311, 185, and 123, respectively. Administrative workloads assume that not all claims would be granted; it is probable that diabetes related claims will be received from veterans who never served in the Republic of Vietnam. GOE costs (in \$ million) for years 2001–2005 are as follows: \$6.4, \$18.6, \$16.5, \$11.9, and \$8.2, for a total GOE cost of \$62 million over five years.

The Unfunded Mandates Reform Act requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector of \$100 million or more in any given year. This rule would have no consequential effect on State, local, or tribal governments.

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3520).

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

(The Catalog of Federal Domestic Assistance program numbers are 64.100, 64.101, 64.104, 64.105, 64.106, 64.109, and 64.110).

List of Subjects in 38 CFR Part 3

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

Approved: April 19, 2001.

Anthony J. Principi,
Secretary of Veterans Affairs.

For the reasons set forth in the preamble, 38 CFR part 3 is amended 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 § 3.309, paragraph (e), the listing of diseases is amended by adding “Type 2 diabetes (also known as Type II diabetes mellitus or adult-onset diabetes)” between “Chloracne or other acneform disease consistent with chloracne” and “Hodgkin’s disease” to read as follows:

§ 3.309 Diseases subject to presumptive service connection.

* * * * *

(e) * * *

Type 2 diabetes (also known as Type II diabetes mellitus or adult-onset diabetes)

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[FR Doc. 01-11569 Filed 5-7-01; 8:45 am]

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GENERAL SERVICES ADMINISTRATION

41 CFR Parts 101-20, 101-21, and 102-85

RIN 3090-AG33

Pricing Policy for Occupancy in GSA Space

AGENCY: Office of Business Performance, Public Buildings Service.

ACTION: Interim rule.

SUMMARY: The General Services Administration (GSA) is revising the Federal Property Management Regulations (FPMR) by moving coverage of GSA's Rent program into the Federal Management Regulation (FMR). A cross-reference is added to the FPMR to direct readers to the coverage in the FMR. The FMR is written in plain language to provide agencies with updated regulatory material that is easy to read and understand. This interim rule establishes the pricing policy guidance for Occupancy Agreements between GSA and customer agencies. It also governs intra-governmental pricing of space and services.

DATES: *Effective Date:* May 8, 2001.

Comment Date: Comments should be submitted on or before July 9, 2001 to be considered in the formulation of a final rule.

ADDRESSES: Written comments should be submitted to: Mr. Michael Hopkins, Regulatory Secretariat (MVRS), Office of Governmentwide Policy, General Services Administration, 1800 F Street, NW., Washington, DC 20405.

E-mail comments submitted over the Internet should be addressed to RIN.3090-AG33@gsa.gov.

FOR FURTHER INFORMATION CONTACT: Mr. Ronald Kendall, Office of Portfolio Management, General Services Administration, at 202-501-0638, or Internet e-mail at ron.kendall@gsa.gov.

SUPPLEMENTARY INFORMATION:

A. Background

This interim rule changes the methods by which GSA-controlled space is identified and measured, eliminates the specific physical description of the components of standard level alterations, and

substitutes budget guidance for alterations, providing customer agencies flexibility in designing space to meet their mission needs.

The recommendations are being implemented to improve GSA's overall management of real property assets and the level of service and choices provided to its customer agencies.

As a result of the principles outlined in this rule:

(1) Federal agencies will have greater choice in using GSA to meet space needs;

(2) GSA will remain available to provide the benefits of centralized services desired by its customers; and

(3) GSA's relationship with its customers will more closely approximate landlord/customer relationships typical in the private sector, providing incentives to economize and speed program delivery.

The FMR, which replaces the FPMR, contains a refined and streamlined set of policies and regulatory requirements related to managing property and administrative services. Non-regulatory materials, such as guidance, procedures, and standards currently found in the FPMR, and new non-regulatory materials may become available in separate documents, such as customer guides.

B. Executive Order 12866

GSA has determined that this interim rule is a significant regulatory action for the purposes of Executive Order 12866 of September 30, 1993.

C. Regulatory Flexibility Act

The interim rule is not expected to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*

D. Paperwork Reduction Act

The Paperwork Reduction Act does not apply because this interim rule does not impose recordkeeping or information collection requirements, or the collection of information from offerors, contractors, or members of the public which require the approval of the Office of Management and Budget (OMB) under 44 U.S.C. 3501, *et seq.*

E. Small Business Regulatory Enforcement Fairness Act

This interim rule is also exempt from congressional review prescribed under 5 U.S.C. 801 since it relates solely to agency management and personnel.

F. Administrative Procedures Act

GSA finds good cause to make this rule effective upon publication of this

document in the **Federal Register** under the Administrative Procedure Act (APA) (5 U.S.C. 553(d)). This interim final rule does not impose any additional responsibilities on entities in the private sector. Instead, its purpose is to improve asset management practices that affect only Federal agencies that occupy real property owned or controlled by GSA.

List of Subjects in 41 CFR Parts 101-20, 101-21, and 102-85

Federal buildings and facilities, Government property and management.

For the reasons set forth in the preamble, 41 CFR parts 101-20, 101-21, and 102-85 are amended to read as follows:

CHAPTER 101—[AMENDED]

PART 101-20—MANAGEMENT OF BUILDINGS AND GROUNDS

1. The authority citation for part 101-20 continues to read as follows:

Authority: Sec. 205(c), 63 Stat. 390; 40 U.S.C. 486(c).

§ 101-20.102 [Amended]

2. Amend § 101-20.102 by removing and reserving paragraph (e).

3. Part 101-21 is revised to read as follows:

PART 101-21—FEDERAL BUILDINGS FUND

Authority: 40 U.S.C. 486(c); 40 U.S.C. 490(j) (The Federal Property and Administrative Services Act of 1949, as amended, Sec. 205(c) and 210(j), 63 Stat. 390 and 86 Stat. 219; 40 U.S.C. 486(c) and 40 U.S.C. 490(j), respectively).

§ 101-21.000 Cross-reference to the Federal Management Regulation (FMR) (41 CFR chapter 102, parts 102-1 through 102-220.)

For information previously contained in this part, see FMR part 85 (41 CFR part 102-85).

CHAPTER 102—[AMENDED]

4. Part 102-85 is added to subchapter C to read as follows:

PART 102-85—PRICING POLICY FOR OCCUPANCY IN GSA SPACE

Subpart A—Pricing Policy—General

Sec.

102-85.5 By what authority is the pricing policy in this part prescribed?

102-85.10 What is the scope of this part?

102-85.15 What are the basic policies for charging Rent for space and services?

102-85.20 What does an Occupancy Agreement (OA) do?

102-85.25 What is the basic principle governing OAs?