

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900-AN16

Presumption of Service Connection for Osteoporosis for Former Prisoners of War

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its adjudication regulation to establish a presumption of service connection for osteoporosis for former Prisoners of War (POWs) who were detained or interned for at least 30 days and whose osteoporosis is at least 10 percent disabling. The proposed amendment would implement a decision by the Secretary to establish such a presumption based on scientific studies.

DATES: Comments must be received by VA on or before February 13, 2009.

ADDRESSES: Written comments may be submitted through <http://www.Regulations.gov>; by mail or hand-delivery to the Director, Regulations Management (00REG), 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-AN16—Presumption of Service Connection for Osteoporosis for Former Prisoners of War." 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 (FDMS) at <http://www.Regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Nancy Copeland, Regulations Staff (211D), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461-9685.

SUPPLEMENTARY INFORMATION: The standard for creating a presumption of service connection for former POWs is set out in 38 CFR 1.18, "Guidelines for establishing presumptions of service connection for former prisoners of war." The Secretary may establish a presumption of service connection for a

disease where there is "at least limited/suggestive evidence that an increased risk of such disease is associated with service involving detention or internment as a prisoner of war and an association between such detention or internment and the disease is biologically plausible." 38 CFR 1.18(b). The term "limited/suggestive evidence" is defined in § 1.18(b)(1) to mean "evidence of a sound scientific or medical nature that is reasonably suggestive of an association between prisoner-of-war experience and the disease, even though the evidence may be limited because matters such as chance, bias, and confounding could not be ruled out with confidence or because the relatively small size of the affected population restricts the data available for study." Section 1.18(d) of title 38, Code of Federal Regulations, explains that "the requirement in paragraph (b) of this section that an increased risk of disease be 'associated' with prisoner-of-war service may be satisfied by evidence that demonstrates either a statistical association or a causal association."

This proposed rule would establish a presumption of service connection for osteoporosis for any former prisoner of war (POW) who was interned or detained for a period of at least 30 days while on active duty and develops osteoporosis that manifests to a degree of 10 percent or more at any time after discharge from active military, naval or air service even though there is no record of such disease during service.

Osteoporosis is a disease characterized by inadequate bone formation resulting in a decrease in bone mass and increased bone weakness. The Merck Manual of Diagnosis & Therapy 469 (17th ed. 1999). The major clinical manifestations of osteoporosis are bone fractures. *Id.* at 470. The cause of osteoporosis is generally related to a number of risk factors, including low calcium, phosphorus, and vitamin D intake, advanced age, hormone deficiency, genetic factors, and immobilization. *Id.*

On October 8, 2008, the Under Secretary for Health advised the Secretary of Veterans Affairs that "there is at least limited/suggestive evidence that an increased risk of osteoporosis is associated with service involving detention or internment as a POW" and recommended establishing a presumption of osteoporosis for former POWs. The Secretary of Veterans Affairs agrees that the following reports constitute evidence of a sound scientific or medical nature that is reasonably suggestive of an association between prisoner-of-war experience and osteoporosis.

The basis of the Under Secretary's recommendation regarding establishing a presumption of service connection for osteoporosis for former POWs was a study conducted by Dr. Stanley M. Garn, Ph.D. of the University of Michigan Center for Human Growth and Development that found that, while in captivity, U.S. Air Force personnel imprisoned in North Vietnam, who were subject to malnutrition, protein-deficiency, recurrent dysenteries, vitamin deficiencies, and a variety of infectious diseases, suffered from serious bone loss long after their release from captivity. Stanley M. Garn, "Researcher Says POWs Sustained Bone Loss," 23 U. of Mich. Hospital Star (Oct. 1975). Garn and his associates examined the skeletal x-rays of 108 former POWs and found that, although the POWs seemed to be in relative "good health" upon release from captivity, the POWs nonetheless had "far less bone structure than is usual for their age, with bone losses averaging 10 percent and going as high as 45.8 percent." *Id.* The study also found that many of the former male POWs ages 30 to 40 exhibited "a skeletal structure which might be expected in an 80-year old man." *Id.* Although not published in peer-reviewed literature, the study was presented as a paper on August 9, 1975, at the 10th International Congress of Nutrition, in Kyoto, Japan. *Id.*

The Under Secretary also cited a 2001 abstract of a study conducted at the Robert Mitchell Center for Prisoner of War Studies, Navy Personnel Command, that reported increased rates of osteopenia among former POWs with posttraumatic stress disorder (PTSD). Kenneth P. Sausen *et al.*, "The Relationship Between PTSD & Osteopenia," 63 Psychosomatic Medicine 144 (2001), <http://navmednpte.med.navy.mil/nomi/rpow/centcolresproj.cfm>. Study participants included 131 repatriated male POWs in an ongoing medical follow-up program. The study showed that POW participants with PTSD were twice as likely to be osteopenic as POW participants without PTSD. In addition, the study showed that, without proper identification and intervention, POWs with PTSD may be at risk for osteoporosis and its attendant physical disabilities. "The Relationship Between PTSD & Osteopenia," 63 Psychosomatic Medicine, at 144.

An unpublished study by M.R. Ambrose *et al.*, referenced by the Under Secretary showed increased rates of osteopenia in aviators who were POWs in Vietnam.

The Under Secretary's recommendation also cited an article,

Jerri W. Nieves, "Osteoporosis: the role of micronutrients," 81 Am. Journal of Clinical Nutrition 1232S (2005), reporting that "[o]steoporosis and low bone mass are currently estimated to be a major public health threat" for U.S. men and women age 50 and older. The article explored the significance of adequate nutrition in the prevention and treatment of osteoporosis and stated that calcium and vitamin D are the two key micronutrients of "greatest importance." *Id.* Nieves discussed the potential importance of Vitamin D in peak bone mass and recommended at least 600 International Units (IU) of vitamin D in persons over age 70 for optimal bone health. *Id.* at 1236S.

Another source cited by the Under Secretary for Health, the National Osteoporosis Foundation (NOF) Web site, states that calcium is a "building block of bone" and vitamin D helps the "body use calcium." <http://www.nof.org/prevention/risk.htm>. Without vitamin D, a person is "at much greater risk for bone loss and osteoporosis." *Id.* Although calcium and vitamin D are the two most significant nutrients related to bone development and prevention of bone loss, NOF also reports that magnesium, vitamin K, vitamin B6, and vitamin B12 are other key minerals that enhance bone health and may prevent bone loss. *Id.*

Dietary deficiencies have been recognized as a common feature of prisoner of war captivity across different conflicts. See H.R. Rep. No. 91-1166 (1970), *reprinted in* 1970 U.S.C.C.A.N. 3723, 3727-28 (noting prevalence of dietary deficiencies among POWs in World War II, the Korean Conflict, and the Vietnam War); *Acree v. Republic of Iraq*, 271 F. Supp. 2d 179, 185, 186 (D.D.C. (2003) (finding that U.S. POWs held by Iraq between January 17, 1991, and March 1991 "were systematically starved" and suffered nausea, severe weight loss, dysentery), *vacated* 370 F.3d 41 (D.C. Cir. 2004).

The Under Secretary for Health advised the Secretary of Veterans Affairs that osteoporosis has apparently not been a major health and disability issue among former POWs until recently, probably because this condition usually does not manifest as a major medical condition until later in life. Since most former POWs are now in their 80's, it is much more of a health problem among this cohort of veterans now than in the past. Undiagnosed and untreated osteoporosis may result in progressive bone loss and eventual fracture.

Finally, the Under Secretary relied on a 2003 World Health Organization (WHO) report on osteoporosis. World Health Org. Scientific Group, Technical

Rep. Series 921, "Prevention and Management of Osteoporosis" (2003). The report stated that "[e]arly osteoporosis is not usually diagnosed and remains asymptomatic; it does not become clinically evident until fractures occur." *Id.* at 2. WHO also stated that, "[u]ntil recently, osteoporosis was an under-recognized disease" and "[i]mprovements in diagnostic technology over the past decade now means that it is possible to detect the disease before fractures occur." *Id.* at 7.

The referenced studies are suggestive of a link between osteoporosis and internment or detention as a POW for a period sufficient to result in nutritional deficiency. Further, the fact that osteoporosis has been shown in the medical literature to be associated with nutritional deficiency establishes the biological plausibility of a link between osteoporosis and internment or detention as a POW. After careful consideration of the scientific evidence referenced above, the Secretary of Veterans Affairs believes there is limited/suggestive evidence that an increased risk of osteoporosis is associated with detention or internment as a POW and that an association between such detention or internment and osteoporosis is biologically plausible. The Secretary therefore is establishing a presumption of service connection for osteoporosis for former POWs who were interned or detained for not less than 30 days and whose osteoporosis is manifest to a degree of 10 percent or more at any time after discharge or release from active service. 38 CFR 1.18; 38 U.S.C. 501(a)(1).

Accordingly, this proposed rule would amend 38 CFR 3.309(c)(2) to add osteoporosis as a presumptive disease for former POWs who were interned or detained for not less than 30 days and whose osteoporosis is manifested to a degree of 10 percent or more at any time after discharge from active duty service. As a result of such presumption, osteoporosis would be considered to have been incurred in or aggravated by internment or detention for at least 30 days, even though there is not evidence of osteoporosis during such service. The requirement of internment for at least 30 days would conform to policies embodied in current statutes and regulations, which require at least 30 days of internment as a POW as a prerequisite for presumptive service connection for diseases associated with nutritional deficiencies, but require no minimum period of internment for presumptive service connection of diseases associated with acute physical or psychological trauma. 38 U.S.C. 1112(b); 38 CFR 3.309(c). As explained

above, nutritional deficiencies play a primary role in the incurrence of osteoporosis. The 1975 study finding increased bone loss among former POWs discussed the bone loss observed in persons who had been interred as POWs for periods of years and suggested that nutritional deficiencies over such periods may be the cause of the observed bone loss. VA has reviewed the scientific literature on osteoporosis and it does not disclose how long a period of malnutrition may cause the disease. Although we have no specific scientific information upon which to define the duration of malnutrition necessary to cause osteoporosis, we also have no scientific basis for distinguishing osteoporosis from the other nutrition-related disabilities identified in 1112(b)(3), for which Congress has determined that a 30-day period is appropriate. In the absence of evidence supporting a different result, treating osteoporosis the same as other nutrition-related disabilities is the fairest result. Therefore, VA proposes to set a 30-day internment requirement for this presumption. If new scientific evidence shows that a shorter or longer period of malnutrition may cause osteoporosis, VA reserves the right to change the required internment period. Accordingly, consistent with other presumptions for diseases associated with nutritional deficiencies, the presumption for osteoporosis would apply to periods of at least 30 days internment as a POW.

This presumption would be rebutted if there is affirmative evidence that osteoporosis was not incurred during or aggravated by such service or affirmative evidence that osteoporosis was caused by the veteran's own willful misconduct. 38 U.S.C. 1113; 38 CFR 3.307(d) and 3.309(c)(2)(ii).

Administrative Procedure Act

The Secretary has determined that there is good cause to limit the public comment period on this rule to 30 days. This proposed rule is necessary to implement the Secretary's decision to establish a presumption of service connection for osteoporosis for veterans who are former POWs. Due to the advanced age of many veterans who would benefit from this presumption, any delay in implementing this presumption would be contrary to the public interest. In April 2006, the VA Office of Policy and Planning identified 29,350 living POWs. Statistical data shows that development of osteoporosis is correlated to advanced age, thus any delay in implementation would be extremely detrimental particularly to former POWs of World War II, Korea,

and Vietnam, who are currently afflicted with osteoporosis. Therefore, in order to ensure that as many former POWs as possible benefit from this presumption, it is critical that VA take action as soon as practicable. Accordingly, the Secretary has provided a 30-day comment period for this rule.

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

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, 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 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 entitlement recipients; 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.

VA has examined the economic, interagency, budgetary, legal, and policy implications of this proposed rule and has concluded that it is a significant regulatory action under Executive Order 12866 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.

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (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.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program numbers and titles for this rule are as follows: 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, Pensions, Veterans, Vietnam.

Approved: November 5, 2008.

James B. Peake,

Secretary of Veterans Affairs.

For the reasons set forth 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.

2. Amend § 3.309(c)(2) by:

(a) In the list of diseases, adding "Osteoporosis." after "Cirrhosis of the liver."

(b) Revising the authority citation at the end of the paragraph.

The revision reads as follows:

§ 3.309 Disease subject to presumptive service connection.

* * * * *

(c) * * *

(2) * * *

Authority: 38 U.S.C. 501(a) and 1112(b).

[FR Doc. E9–587 Filed 1–13–09; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2007–1031; FRL–8754–6]

Approval and Promulgation of Air Quality Implementation Plans; Utah's Emission Inventory Reporting Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed Rule.

SUMMARY: EPA is proposing to approve State Implementation Plan (SIP) revisions submitted by the State of Utah on September 7, 1999, and December 1, 2003. The revisions add the requirements of EPA's Consolidated Emission Reporting Rule (CERR) to the State's SIP. The intended effect of this action is to approve only those portions from the State's submittals that add CERR requirements. This action is being taken under section 110 of the Clean Air Act.

In the "Rules and Regulations" section of this **Federal Register**, EPA is approving the State's SIP revisions as a direct final rule without prior proposal because the Agency views these as non-controversial SIP revisions and anticipates no adverse comments. A detailed rationale for taking this action is set forth in the preamble to the direct final rule. If EPA receives no adverse comments, EPA will not take further action on this proposed rule. If EPA receives adverse comments, EPA will withdraw the direct final rule and it will not take effect. EPA will address all public comments in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

DATES: Any written comments on this proposal must be received on or before February 13, 2009.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2007–1031, by one of the following methods: