

permitted by the Captain of the Port, Sector Lake Michigan, or his or her on-scene representative.

(3) The “designated representative” of the Captain of the Port, Sector Lake Michigan, is any Coast Guard commissioned, warrant or petty officer who has been designated by the Captain of the Port, Sector Lake Michigan, to act on his or her behalf. The designated representative of the Captain of the Port, Sector Lake Michigan, will be on land in the vicinity of the safety zone and will have constant communications with the involved safety vessels that will be provided by the contracting company, James McHugh Construction, and will have communications with a D8 Bridge Branch representative, who will be on scene as well.

(4) Vessel operators desiring to enter or operate within the safety zone shall contact the Captain of the Port, Sector Lake Michigan, or his or her designated representative to obtain permission to do so. The Captain of the Port, Sector Lake Michigan, or his or her designated representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the Captain of the Port, Sector Lake Michigan, or his or her designated representative.

Dated: July 1, 2011.

**M.W. Sibley,**

*Captain, U.S. Coast Guard, Captain of the Port, Sector Lake Michigan.*

[FR Doc. 2011-17802 Filed 7-14-11; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF VETERANS AFFAIRS

### 38 CFR Part 3

RIN 2900-AN83

#### **Presumptive Service Connection for Diseases Associated With Service in the Southwest Asia Theater of Operations During the Persian Gulf War: Functional Gastrointestinal Disorders**

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Final rule.

**SUMMARY:** The Department of Veterans Affairs (VA) adopts as a final rule the proposal to amend its adjudication regulations regarding presumptive service connection for medically unexplained chronic multisymptom illnesses associated with service in the Southwest Asia theater of operations for which there is no record during service. This amendment implements a decision

by the Secretary that there is a positive association between service in Southwest Asia during certain periods and the subsequent development of functional gastrointestinal disorders (FGIDs) and clarifies that FGIDs fall within the scope of the existing presumptions of service connection for medically unexplained chronic multisymptom illnesses.

**DATES:** This final rule is effective August 15, 2011.

**Applicability Date:** This final rule shall apply to claims pending before, filed with or remanded to VA on or after August 15, 2011.

#### **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. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** In a document published in the **Federal Register** on November 17, 2010 (75 FR 70162-65), VA proposed to amend its adjudication regulations regarding the presumption of service connection for medically unexplained chronic multisymptom illnesses. The amendment clarifies VA's interpretation that FGIDs fall within the scope of the existing presumption of service connection for medically unexplained chronic multisymptom illnesses. This clarification is based on available scientific and medical evidence presented in the National Academy of Sciences' (NAS) April 2010 report titled: *Gulf War and Health, Volume 8: Update on the Health Effects of Serving in the Gulf War* (NAS 2010 Report) and the Secretary's determination that there is a positive association between service in Southwest Asia during certain periods and the subsequent development of FGIDs.

In response to the proposed rule, VA received eight (8) public comments. Of these comments, 5 expressed general support for the rulemaking. The sixth commenter expressed belief that “presumptive service connection for gastrointestinal (GI) disorders and any gastroesophageal reflux disease (GERD) or “bowel inflammatory conditions” should be related to Gulf War service for the period 1990 through 1991 because of the “hazardous chemical exposures known as a toxic bowl of soup.” VA appreciates this comment; however, based on findings from the NAS 2010 report, the NAS Committee concluded that there is sufficient evidence for an association between deployment to the Southwest Asia theater of operations

during the Gulf War and GI symptoms consistent with FGIDs such as irritable bowel syndrome and functional dyspepsia which involve “recurrent or prolonged clusters of symptoms that occur together.” NAS 2010 Report, at 154. By contrast, Inflammatory Bowel Disease (IBD), such as ulcerative colitis or Crohn's disease, and GERD are considered to be “organic” or structural diseases characterized by abnormalities seen on x-ray, endoscopy, or through laboratory tests. The NAS Committee concluded that there is inadequate/insufficient evidence to determine whether an association exists between deployment to the Southwest Asia theater of operations during the Gulf War and the development of structural gastrointestinal diseases, and NAS defines both IBD and GERD as structural gastrointestinal diseases. This rulemaking is limited to clarifying the scope of the presumption for FGIDs as medically unexplained chronic multisymptom illnesses. Therefore, we make no change based on this comment.

The seventh commenter expressed belief that noise and vibration exposure caused symptoms of various disorders, including intestinal disorders, among the “Gulf War Seabees” and that some also have neural damage as a result of vibration exposure. VA appreciates this comment; however, we make no changes based on this comment. This rule is intended to clarify the scope of the existing presumption of service connection for medically unexplained chronic multisymptom illnesses, which applies to all veterans who served in the Southwest Asia theater of operations during the Persian Gulf War irrespective of whether their illnesses can be shown to be linked to a specific cause in service, such as noise and vibration exposure. To the extent the commenter believes that noise and vibration exposure may cause FGIDs, no change to this rule is necessary, because the rule already provides a presumption of service connection for FGIDs in all Gulf War Veterans. To the extent the commenter believes presumptive service connection based on noise and vibration exposure is warranted for conditions other than medically unexplained chronic multisymptom illnesses, that matter is beyond the scope of this clarifying rule. We note that a Veteran who believes his or her injury, disease, or illness may be related to noise or vibration exposure in service may submit evidence of such effects in support of his or her claim for benefits and VA will consider that evidence in deciding the claim.

The eighth and final commenter advocated that VA broaden the scope of

the rule by adopting the same effective date standards established in *Nehmer v. United States Veterans' Administration*, CV–86–6160 TEH (N.D. Cal.). For the reasons explained below, we make no change based on this comment.

In *Nehmer*, based on circumstances unique to that case, a district court issued a series of orders requiring VA to readjudicate certain previously and finally denied claims of Vietnam Veterans and their survivors and, in some circumstances, to pay such claimants benefits retroactive to the date of their previously denied claims. VA has issued regulations at 38 CFR 3.816 to codify the requirements of the *Nehmer* court orders.

Pursuant to statute, when VA issues a final decision denying disability compensation for a condition, VA is, with one exception described below, prohibited from later awarding benefits retroactive to the date of the finally denied claim. 38 U.S.C. 5110. Claimants may seek to reopen their claims with new evidence or may seek a new decision based on an intervening change in law, but the effective date of awards in those circumstances generally may be no earlier than the date of the new claim or the effective date of the intervening change in law. *Id.*; 38 CFR 3.114, 3.400. Congress has authorized payment retroactive to the date of a previously and finally denied claim only in the limited circumstance where the prior final decision is shown to have been based on “clear and unmistakable error” of fact or law. *See* 38 U.S.C. 5109A and 7111.

The *Nehmer* court orders require VA in certain cases to pay benefits retroactive to the date of a previously denied claim, even if VA's prior decision did not involve clear and unmistakable error. The *Nehmer* court orders apply only to claims by certain Vietnam Veterans and their survivors based on disability due to herbicide exposure. Although VA is required to comply with the *Nehmer* court orders, VA has no independent authority to expand the court's orders or otherwise to pay retroactive benefits not authorized by statute. Accordingly, VA cannot in this rule authorize retroactive payments without regard to the effect of prior final decisions and without regard to the requirement for a showing of clear and unmistakable error in order to support such a retroactive award. Because existing statutes and regulations provide clear guidance concerning the effective dates of awards under this rule, we make no change to the rule based on this comment.

In this final rule we are making a change to subparagraph (3) to improve

clarity and revising the note to subparagraph (3) to clarify concepts involving medically unexplained chronic multisymptom illnesses that comprise FGIDs and facilitate understanding of information relating to diagnosis of such disorders. Subparagraph (3) of the proposed rule stated that the disorders entitled to presumptive service connection are “Functional gastrointestinal disorders, including, but not limited to irritable bowel syndrome and functional dyspepsia (excluding structural gastrointestinal diseases).” 75 FR at 70165. We believe this language, in conjunction with information in the note to paragraph (a)(2)(i)(B)(3), which lists irritable bowel syndrome and functional dyspepsia as specific functional gastrointestinal disorders, is repetitive and unnecessary. We have therefore revised subparagraph (3) to remove the language regarding irritable bowel syndrome and functional dyspepsia. Secondly, the proposed rule included the following language in a note to paragraph (a)(2)(i)(B)(3): “Functional gastrointestinal disorders are a group of conditions characterized by chronic or recurrent symptoms that were present for at least 6 months prior to diagnosis and have been currently active for 3 months, that are unexplained by any structural, endoscopic, laboratory, or other objective signs of disease or injury and that may be related to any part of the gastrointestinal tract. \* \* \*” We believe this language might be unclear as to when the 3-month period starts and what the difference is between the 6-month and 3-month periods. Established medical principles regarding these disorders generally require symptom onset at least 6 months prior to diagnosis and the presence of symptoms sufficient to diagnose the specific disorder at least 3 months prior to diagnosis. We have therefore revised the note to explain how a diagnosis of FGID is made.

Therefore, based on the rationale set forth in the proposed rule and this document, we are adopting the provisions of the proposed rule as a final rule with the changes discussed above.

#### **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 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 would 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**

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 final rule have been examined and it has been determined not to be a significant regulatory action under Executive Order 12866.

#### **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 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 final rule are 64.109, Veterans

Compensation for Service-Connected Disability, and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

#### 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. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on July 6, 2011, for publication.

#### List of Subjects in 38 CFR Part 3

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

Dated: July 12, 2011.

**Robert C. McFetridge,**

*Director, Regulation 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. Amend § 3.317 by revising paragraph (a)(2)(i)(B)(3) and adding a note to paragraph (a)(2)(i)(B)(3) to read as follows:

#### § 3.317 Compensation for certain disabilities due to undiagnosed illnesses.

- (a) \* \* \*  
(2) \* \* \*  
(i) \* \* \*  
(B) \* \* \*

(3) Functional gastrointestinal disorders (excluding structural gastrointestinal diseases).

#### Note to paragraph (a)(2)(i)(B)(3):

Functional gastrointestinal disorders are a group of conditions characterized by chronic or recurrent symptoms that are unexplained by any structural, endoscopic, laboratory, or other objective signs of injury or disease and may be related to any part of the gastrointestinal tract. Specific functional gastrointestinal disorders include, but are not limited to, irritable bowel syndrome, functional dyspepsia, functional vomiting, functional constipation, functional bloating, functional abdominal pain syndrome, and

functional dysphagia. These disorders are commonly characterized by symptoms including abdominal pain, substernal burning or pain, nausea, vomiting, altered bowel habits (including diarrhea, constipation), indigestion, bloating, postprandial fullness, and painful or difficult swallowing. Diagnosis of specific functional gastrointestinal disorders is made in accordance with established medical principles, which generally require symptom onset at least 6 months prior to diagnosis and the presence of symptoms sufficient to diagnose the specific disorder at least 3 months prior to diagnosis.

\* \* \* \* \*

[FR Doc. 2011-17814 Filed 7-14-11; 8:45 am]

**BILLING CODE 8320-01-P**

### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 52

[EPA-R06-OAR-2009-0647; FRL-9438-7]

#### Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Section 110(a)(2) Infrastructure Requirements for 1997 8-Hour Ozone and Fine Particulate Matter National Ambient Air Quality Standards

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is approving submittals from the State of New Mexico pursuant to the Clean Air Act (CAA or Act) that address the infrastructure elements specified in the CAA section 110(a)(2), necessary to implement, maintain, and enforce the 1997 8-hour ozone and 1997 fine particulate matter (PM<sub>2.5</sub>) national ambient air quality standards (NAAQS or standards). We are determining that the current New Mexico State Implementation Plan (SIP) meets the following infrastructure elements which were subject to EPA's completeness findings pursuant to CAA section 110(k)(1) for the 1997 8-hour ozone NAAQS dated March 27, 2008, and the 1997 PM<sub>2.5</sub> NAAQS dated October 22, 2008: 110(a)(2)(A), (B), (C), (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M). EPA is also approving a November 2, 2006, SIP revision to regulation 20.2.3 of the New Mexico Administrative Code (NMAC) (*Ambient Air Quality Standards*), to remove the state ambient air quality standards from being an applicable requirement under the State's Title V permitting program, found at 20.2.70 NMAC (*Operating Permits*). EPA is also converting our February 27, 1987, conditional approval of New Mexico's PSD program (52 FR 5964) to

a full approval based on the November 2, 1988, approval of New Mexico's stack height regulations (53 FR 44191). Lastly, EPA is making a number of U.S. Code of Federal Regulations (CFR) codification technical corrections to amend the description of the approved New Mexico SIP. This action is being taken under section 110 and part C of the Act.

**DATES:** This rule is effective on August 15, 2011.

**ADDRESSES:** EPA established a docket for this action under Docket ID No. EPA-R06-OAR-2009-0647. All documents in the docket are listed at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically through <http://www.regulations.gov> or in hard copy at the Air Planning Section (6PD-L), Environmental Protection Agency, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202-2733. The file will be made available by appointment for public inspection in the Region 6 Freedom of Information Act (FOIA) Review Room between the hours of 8:30 a.m. and 4:30 p.m. weekdays except for legal holidays. Contact the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below or Mr. Bill Deese at 214-665-7253 to make an appointment. Please make the appointment at least two working days in advance of your visit. There is a fee of 15 cents per page for making photocopies of documents. On the day of the visit, please check in at the EPA Region 6 reception area at 1445 Ross Avenue, Suite 700, Dallas, Texas.

**FOR FURTHER INFORMATION CONTACT:** Ms. Dayana Medina, Air Planning Section (6PD-L), Environmental Protection Agency, Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas 75202-2733, telephone 214-665-7241; fax number 214-665-6762; e-mail address [medina.dayana@epa.gov](mailto:medina.dayana@epa.gov).

#### SUPPLEMENTARY INFORMATION:

Throughout this document, "we," "us," and "our" means EPA.

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