

**ADDRESSES:** You may submit comments, identified by RIN 0648–AY66, by any one of the following methods:

- Electronic Submissions: Submit all electronic public comments via the Federal eRulemaking Portal <http://www.regulations.gov>

- Fax: 301–427–2211, Attn: Frank M. Sptrel, Attorney-Advisor

- Mail: Office of General Counsel for Enforcement and Litigation (GCEL), 8484 Georgia Avenue, Suite 400, Silver Spring, MD 20910

Instructions: No comments will be posted for public viewing until after the comment period has closed. All comments received are a part of the public record and will generally be posted to <http://www.regulations.gov> without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information. NOAA will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous). You may submit attachments to electronic comments in Microsoft Word, Excel, WordPerfect, or Adobe PDF file formats only.

**FOR FURTHER INFORMATION CONTACT:** Frank M. Sptrel, GCEL, (301) 427–2202.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

NOAA is proposing to amend the civil procedure rules that apply to its administrative proceedings as described below. NOAA is proposing the changes described here: (1) to improve the efficiency and fairness of administrative proceedings; and (2) to correct a citation error.

**II. Proposed Revisions**

*Subpart C—Hearing and Appeal Procedures*

**Duties and Powers of Judge**

Section 904.204: This revision removes the requirement in 15 CFR 904.204(m) that an Administrative Law Judge state good reason(s) for departing from the civil penalty or permit sanction, condition, revocation, or denial of permit application (collectively, “civil penalty or permit sanction”) assessed by NOAA in its charging document. This revision eliminates any presumption in favor of the civil penalty or permit sanction assessed by NOAA in its charging document (see *In the Matter of: AGA Fishing Corp.*, 2001 WL 34683852 (NOAA Mar. 17, 2001)). It requires

instead that NOAA justify at a hearing provided for under this Part that its proposed penalty or permit sanction is appropriate, taking into account all the factors required by applicable law. Additionally, by explicitly removing this presumption, this change provides Respondents with a full and fair opportunity to challenge the proposed Agency action.

This revision also corrects a citation in the regulation pertaining to protective orders issued by an Administrative Law Judge that is codified at 15 CFR 904.204(f). The current regulation incorrectly cites § 904.240(d). The regulation is revised to correctly cite § 904.251(h).

**Classification**

This proposed rule has been determined to be not significant for purposes of Executive Order 12866.

There are no reporting, recordkeeping or other compliance requirements in the proposed rule. Nor does this rule contain an information-collection request that would implicate the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*

The Chief Counsel for Regulation of the Department of Commerce has certified to the Chief Counsel for Advocacy of the Small Business Administration that this proposed rule, if adopted, would not have a significant economic impact on a substantial number of small entities.

The small businesses, as defined in the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, that this rule may affect include, but are not limited to, vessel owners, vessel operators, fish dealers, individual fishermen, small corporations, and others engaged in commercial and recreational activities regulated by NOAA. However, this rule does not have any compliance costs or associated fees for businesses, large or small. This rule is purely procedural, and merely amends and refines NOAA’s existing rules of civil procedure.

Because this regulation will impose no significant costs on any small entities, but rather will only modify existing procedural rules, the overall economic impact on small entities, if any, is expected to be nominal. Accordingly, this rule will not substantially impact a significant number of small businesses.

As a result of this certification, an initial regulatory flexibility analysis is not required and none has been prepared.

**List of Subjects in 15 CFR Part 904**

Administrative practice and procedure, fisheries, fishing, fishing

vessels, penalties, seizures and forfeitures.

Dated: March 12, 2010.

**Lois J. Schiffer,**

*General Counsel, National Oceanic and Atmospheric Administration.*

For reasons set forth in the preamble, 15 CFR part 904 is proposed to be amended as follows:

**PART 904—CIVIL PROCEDURES**

1. The authority citation for part 904 continues to read as follows:

**Authority:** 16 U.S.C. 1801 *et seq.*, 16 U.S.C. 1531–1544, 16 U.S.C. 1361 *et seq.*, 16 U.S.C. 3371–3378, 16 U.S.C. 1431–1445c–1, 16 U.S.C. 773–773k, 16 U.S.C. 951–962, 16 U.S.C. 5001–5012, 16 U.S.C. 3631–3645, 42 U.S.C. 9101 *et seq.*, 30 U.S.C. 1401 *et seq.*, 16 U.S.C. 971–971k, 16 U.S.C. 781–785, 16 U.S.C. 2401–2413, 16 U.S.C. 2431–2444, 16 U.S.C. 972–972h, 16 U.S.C. 916–916l, 16 U.S.C. 1151–1175 *et seq.*, 16 U.S.C. 3601–3608, 16 U.S.C. 3631–3645, 16 U.S.C. 1851 note; 15 U.S.C. 5601 *et seq.*, Pub. L. 105–277, 16 U.S.C. 1822 note, Section 801(f), 16 U.S.C. 2465(a), 16 U.S.C. 5103(b), 16 U.S.C. 1385 *et seq.*, 16 U.S.C. 1822 note (Section 4006), 16 U.S.C. 4001–4017, 22 U.S.C. 1980(g), 16 U.S.C. 5506(a), 16 U.S.C. 5601–5612, 16 U.S.C. 1822, 16 U.S.C. 973–973R, 15 U.S.C. 330–330(e).

2. Section 904.204 to subpart C is amended by revising paragraphs (f) and (m) to read as follows:

**Subpart C—Hearing and Appeal Procedures**

**§ 904.204 Duties and powers of Judge.**

\* \* \* \* \*

(f) Rule on contested discovery requests, establish discovery schedules, and, whenever the ends of justice would thereby be served, take or cause depositions or interrogatories to be taken and issue protective orders under § 904.251(h);

\* \* \* \* \*

(m) Assess a civil penalty or impose a permit sanction, condition, revocation, or denial of permit application, taking into account all of the factors required by applicable law;

\* \* \* \* \*

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**BILLING CODE 3510–12–S**

**DEPARTMENT OF VETERANS AFFAIRS**

**38 CFR Part 3**

**RIN 2900–AN24**

**Presumptions of Service Connection for Persian Gulf Service**

**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 certain diseases. This proposed amendment is necessary to implement a decision of the Secretary of Veterans Affairs that there is a positive association between service in Southwest Asia during certain periods and the subsequent development of certain infectious diseases. The intended effect of this proposed amendment is to establish presumptive service connection for these diseases and to provide guidance regarding long-term health effects associated with these diseases.

**DATES:** Comments must be received by VA on or before May 17, 2010.

**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 Ave., 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-AN24—Presumptions of Service Connection for Persian Gulf Service." 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:** 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:**

**I. Statutory Requirements**

The Persian Gulf War Veterans Act of 1998, Public Law 105-277, title XVI, 112 Stat. 2681-742 through 2681-749 (codified at 38 U.S.C. 1118), and the Veterans Programs Enhancement Act of 1998, Public Law 105-368, 112 Stat. 3315, directed the Secretary of Veterans Affairs to seek to enter into an agreement with the National Academy of Sciences (NAS) to review and

evaluate the available scientific evidence regarding associations between illnesses and exposure to toxic agents, environmental or wartime hazards, or preventive medicines or vaccines to which service members may have been exposed during service in the Persian Gulf during the Persian Gulf War. Congress directed the NAS to identify agents, hazards, medicines, and vaccines to which service members may have been exposed during service in the Persian Gulf during the Persian Gulf War.

*Congress mandated that the NAS determine, to the extent possible:* (1) Whether there is a statistical association between exposure to the agent, hazard, medicine, or vaccine and the illness, taking into account the strength of the scientific evidence and the appropriateness of the scientific methodology used to detect the association; (2) the increased risk of illness among individuals exposed to the agent, hazard, medicine, or vaccine; and (3) whether a plausible biological mechanism or other evidence of a causal relationship exists between exposure to the agent, hazard, medicine, or vaccine and the illness.

Section 1118 of title 38 of the United States Code 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 or animals to a biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine or vaccine known or presumed to be associated with service in the Southwest Asia theater of operations during the Persian Gulf War and the occurrence of a diagnosed or undiagnosed illness in humans or animals, the Secretary will publish regulations establishing presumptive service connection for that illness. 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.

**II. Prior National Academy of Sciences Reports**

The NAS issued its initial report titled, *Gulf War and Health, Volume 1: "Depleted Uranium, Sarin, Pyridostigmine Bromide, Vaccines,"* on

January 1, 2000. In that report, NAS limited its analysis to the health effects of depleted uranium, the chemical warfare agent sarin, vaccinations against botulism toxin and anthrax, and pyridostigmine bromide, which was used in the Persian Gulf War as a pretreatment for possible exposure to nerve agents. On July 6, 2001, VA published a notice in the **Federal Register** announcing the Secretary's determination that the available evidence did not warrant a presumption of service connection for any disease discussed in that report. See 66 FR 35702 (2001).

The NAS issued its second report titled, *Gulf War and Health, Volume 2: Insecticides and Solvents,* on February 18, 2003. In that report, the NAS focused on the health effects of insecticides and solvents that were shipped to the Persian Gulf during the Persian Gulf War. The pesticides considered by the NAS were organophosphorous compounds (malathion, diazinon, chlorpyrifos, dichlorvos, and azamethiphos), carbamates (carbaryl, propoxur, and methomyl), pyrethrins and pyrethyroids (permethrin and d-phenothrin), lindane, and *N,N*-diethyl-3-methylbenzamide (DEET). The NAS considered 53 solvents in eight groups: Aromatic hydrocarbons (including benzene), halogenated hydrocarbons (including tetrachloroethylene and dry-cleaning solvents), alcohols, glycols, glycol esters, esters, ketones, and petroleum distillates. On August 24, 2007, VA published a notice in the **Federal Register** announcing the Secretary's determination that the available evidence did not warrant a presumption of service connection for any disease discussed in that report. 72 FR 48734 (2007).

The NAS issued an update on sarin in a report titled *Gulf War and Health: Updated Literature Review of Sarin,* on August 20, 2004. In that report, the NAS focused on the long-term health effects from exposure to the nerve agent, sarin. VA published a **Federal Register** notice announcing the Secretary's determination that it was not necessary to establish new presumptions of service connection for any diseases based on the updated findings on long-term health effects from sarin. 73 FR 42411 (2008).

The NAS issued its third report, titled *Gulf War and Health, Volume 3: Fuels, Combustion Products, and Propellants,* on December 20, 2004. In that report, the NAS focused on the health effects of hydrazines, red fuming nitric acid, hydrogen sulfide, oil-fire byproducts, diesel-heater fumes, and fuels (for

example, jet fuel and gasoline). On August 28, 2008, VA published a **Federal Register** notice announcing the Secretary's determination that the available evidence does not warrant a presumption of service connection for any disease discussed in that report. 73 FR 50856.

The NAS issued its fourth report, titled "Gulf War and Health Volume 4: Health Effects of Serving in the Gulf War," on September 12, 2006. In that report the NAS focused on the health status of veterans of the 1991 Gulf War. The report was intended to inform VA about illnesses and clinical issues including possible relevant treatments, which might have been overlooked among this population, regardless of the specific underlying cause. VA is drafting a **Federal Register** notice announcing the Secretary's determination that the available evidence does not warrant a presumption of service connection for any disease discussed in that report.

### III. Gulf War and Health, Volume 5: Infectious Diseases

The NAS issued its fifth report, titled "Gulf War and Health Volume 5: Infectious Diseases" on October 16, 2006. This report differs from prior NAS reports in that it implicates two tiers of possible association between a hazard and resulting health outcomes. Prior NAS reports generally addressed only one tier of possible association—*i.e.*, the association between exposure to a particular hazard and the development of latent or long-term health effects. The recent NAS report implicates (1) the possible association between exposure to disease-causing pathogens and the subsequent development of an infectious disease (the "primary infectious disease") and (2) the possible association between development of the infectious disease and the development of secondary latent or long-term health effects (the "secondary health effects"). The NAS report addresses only the second tier of association. Specifically, it focused on scientific and medical literature addressing the incidence of long-term health effects in individuals who had been diagnosed with the primary infectious disease and stated findings with respect to only the strength of the evidence for associations between the primary infectious diseases and the secondary health effects. The NAS evaluated the published, peer-reviewed scientific and medical literature on long-term health effects associated with infectious diseases pertinent to service in Southwest Asia and those known to have been of special concern to veterans deployed to that

area. The NAS identified over 20,000 potentially relevant scientific reports, and focused on 1,200 that had the necessary scientific quality.

The NAS initially identified approximately 100 diseases that are known to be endemic to Southwest Asia. Because those diseases would in most instances become manifest within a relatively short time after infection, NAS eliminated from consideration any disease that had never been reported in any U.S. troops within a reasonable period following Persian Gulf deployments. The NAS also eliminated from consideration any diseases not known to produce long-term health effects. On that basis, the NAS limited the list of diseases to the nine diseases discussed below.

*The committee selected nine infectious diseases that:*

- (1) Are prevalent in Southwest Asia,
- (2) Have been diagnosed among U.S. troops serving there, and
- (3) Are known to cause long-term adverse health effects.

*The nine diseases are:* Brucellosis, *Campylobacter jejuni*, *Coxiella burnetii* (Q fever), Malaria, *Mycobacterium tuberculosis*, Nontyphoid *Salmonella*, *Shigella*, Visceral leishmaniasis, and West Nile virus.

In its previous reports, the NAS focused primarily upon health effects of exposure to hazards associated with service in the Southwest Asia theater of operations, as that area was defined for purposes of the 1991 Gulf War. That area was defined to encompass Iraq, Kuwait, Saudi Arabia, the neutral zone between Iraq and Saudi Arabia, Bahrain, Qatar, the United Arab Emirates, Oman, the Gulf of Aden, the Gulf of Oman, the Persian Gulf, the Arabian Sea, the Red Sea, and the airspace above these locations. See Executive Order 12744 (Jan. 12, 1991); 60 FR 6665 (Feb. 3, 1995); 38 CFR 3.317(d)(2). In its 2006 report, at the Secretary's request, the NAS also reviewed infectious diseases that might have affected U.S. troops who served in Operation Enduring Freedom (OEF) and Operation Iraqi Freedom (OIF) in Southwest Asia, including service in Afghanistan, which was designated a combat zone effective September 19, 2001, by Executive Order 13239 (Dec. 12, 2001). The NAS indicated that the nine infectious diseases are endemic to the region including Afghanistan and the areas previously designated as the Southwest Asia theater of operations.

#### *Presumptively Service-Connected Illnesses*

Although the NAS report focused on the association between a primary

infectious disease and secondary health effects, we believe it is necessary to address the issue of the association between exposure to disease-causing pathogens in service and the development of the primary infectious diseases. We do this for two reasons. First, 38 U.S.C. 1118 contemplates that VA will establish presumptions of service connection when there is a positive association between exposure to certain pathogens in Gulf War service and the development of a disease or illness. Second, establishing presumptions of service connection for the primary infectious diseases would facilitate grants of service connection for the secondary health effects identified in the NAS report because, when VA grants service connection for a primary disease, all secondary conditions proximately caused by that disease are also service connected. See 38 CFR 3.310.

VA proposes to establish new presumptions of service connection for veterans who have served in the Southwest Asia theater of operations or Afghanistan during certain periods, and who subsequently develop one of the nine diseases known to have long-term adverse health effects.

The NAS did not state specific conclusions regarding the strength of the evidence linking the nine primary infectious diseases to Persian Gulf service. However, its report reflects the view that those diseases and the pathogens that cause them are associated with Persian Gulf service due to their prevalence in Southwest Asia and their incidence in deployed U.S. troops. As the NAS report reflects, the identified disease pathogens, which generally are specific types of bacteria, are known to cause the identified infectious diseases. Accordingly, exposure to those pathogens is necessarily associated with the incurrence of the infectious diseases.

The NAS noted that visceral leishmaniasis is endemic to Southwest Asia and is transmitted by sand fly bites, which are exceedingly common in that region. The NAS noted that malaria is endemic in portions of Southwest Asia, including many parts of Afghanistan, accounting for approximately 6 million cases and 59,000 deaths annually in Southwest and South Central Asia, and that Iraq experienced an epidemic in the wake of the 1991 Gulf War. The NAS noted that West Nile virus is endemic in Afghanistan and other countries in Southwest Asia. The NAS noted that diarrheal diseases were the most common illnesses manifest during the 1991 Gulf War and that studies had

identified shigella, campylobacter, and nontyphoid salmonella bacteria, all endemic in the region, as the pathogens involved in a number of cases (and the only ones known to cause long-term health effects). The NAS noted that the Middle East, including Iraq, Kuwait, and Saudi Arabia, is one of three major endemic zones for brucellosis. Finally, the NAS noted that Q fever is endemic in Southwest Asia, and that tuberculosis is highly endemic in that region. The NAS findings that those diseases are endemic to Southwest Asia reflect well-established and documented facts.

Veterans who were diagnosed with any of these nine infectious diseases while they were serving on active duty will be able to establish direct service connection for their illness and any related health complications. Most of the infectious diseases that were the focus of the NAS were comparatively rare during the 1991 Gulf War, OEF, and OIF. Because these acute infectious diseases are generally quite serious, most cases of these infectious diseases would be diagnosed during service. For example, during the 1991 Gulf War, 20 veterans were diagnosed with cutaneous leishmaniasis, which can cause significant morbidity if left untreated. However, no additional cases have been diagnosed since the end of that conflict. Although diarrheal diseases were one of the most common major infectious disease problems for troops during the 1991 Gulf War, diagnosis of these diseases is defined in large part by their acute and obvious symptomatology.

However, some of the nine infectious diseases reviewed by the NAS might be diagnosed only after the veteran separates from active duty. Furthermore, a service member's initial, in-theater infection may not be detected or reported in the service member's treatment records. That is, in some instances, cases might be overlooked or misdiagnosed while the service member is still on active duty in Southwest Asia. For example, the NAS report describes how tuberculosis infection may remain asymptomatic such that the initial infection might not be expected to be documented in the service member's treatment record. Similarly, visceral leishmaniasis can be initially asymptomatic. Tuberculosis and visceral leishmaniasis can each manifest as an acute infectious disease years or even decades (for tuberculosis) following an initial asymptomatic infection.

Therefore, to respond to concerns of overlooked or delayed diagnoses, we propose to establish new presumptions of service connection for veterans who are initially diagnosed with one of these

nine infectious diseases during the defined period discussed below following their military service in Southwest Asia. Such a presumption will benefit Southwest Asia veterans who experienced an initial asymptomatic infection that was not documented in their service treatment records, so long as the condition was later diagnosed within the presumptive period. This would be consistent with existing presumptions of service connection set forth at 38 CFR 3.307 and 3.309 and discussed in greater detail below.

We propose to make the presumptions applicable to veterans who served in the Southwest Asia theater of operations, as currently defined in 38 CFR 3.317(d) (which we propose to redesignate as 3.317(e)), and to veterans who served in Afghanistan on or after September 19, 2001, the date specified in Executive Order 13239 as the date combatant activities commenced in that country. This is based on the findings in the NAS report that the nine infectious diseases are endemic in those regions and were experienced by servicemembers in the 1991 Gulf War, OEF, and OIF.

Some of these nine infectious diseases associated with service in Southwest Asia are already recognized as presumptively service connected for veterans who served during a war period or after 1946. Although this would include veterans who served in the 1991 Gulf War, OEF, and OIF, VA believes there is value in developing new presumptions of service connection that recognize these veterans specifically.

Chronic and tropical diseases that are presumed to be service connected when they become manifest within a specified time period in certain veterans are listed at 38 CFR 3.307 and 3.309 in accordance with 38 U.S.C. 1112(a). Sections 3.307(a)(3) and 3.309(a) include active tuberculosis if manifested to a degree of 10 percent or more within 3 years from the date of separation from service, and §§ 3.307(a)(4) and 3.309(b) include leishmaniasis and malaria if manifested to a degree of 10 percent or more either within 1 year from date of separation from service "or at a time when standard accepted treatises indicate that the incubation period commenced during such service." 38 CFR 3.307(a)(4). Because the current presumptions for tuberculosis, leishmaniasis, and malaria are available to veterans who served in the 1991 Gulf War, OEF, and OIF, it may not seem to be necessary to establish new presumptions of service connection for these three diseases. However, we find that establishing new presumptions of service connection for such veterans

serves to acknowledge the specific health risks experienced by this group.

Except as provided below for three diseases, we propose that a covered infectious disease be manifest within 1 year following service in the Southwest Asia theater of operations or Afghanistan in order to qualify for presumptive service connection. This 1-year period would be consistent with the general 1-year presumptive period for tropical diseases currently in 38 U.S.C. 1112(a)(2) and § 3.307(a)(4) and would be consistent with medical principles, reflected in the NAS report, that those diseases ordinarily would be manifest within a short period following infection. We believe this 1-year period would be sufficient to encompass infectious diseases that are likely to have resulted from infection during service in the Southwest Asia theater of operations or Afghanistan.

With respect to malaria, we propose to adopt the same presumptive period as provided for malaria in 38 U.S.C. 1112(a)(2) and § 3.307(a)(4), which require malaria to become manifest within 1 year of service or at a time when standard or accepted treatises indicate that the incubation period commenced during service. This standard would promote consistency with existing law and is consistent with medical principles. The NAS noted that all known cases of malaria in veterans of OEF and OIF were diagnosed between 1 and 399 days after leaving the theater of operations, but that malaria may relapse up to 5 years after initial infection.

We propose no time limit on the presumption for visceral leishmaniasis. We note that the existing presumption of service connection for leishmaniasis in 38 U.S.C. 1112(a)(2) and § 3.307(a)(4) requires the disease to become manifest within 1 year of service or at a time when standard or accepted treatises indicate that the incubation period commenced during service. That flexible standard may encompass latency periods significantly greater than 1 year. However, because the NAS noted that the period of latent infection with visceral leishmaniasis organisms may be long, and that a period of 10 years is commonly cited, we believe that an open-ended presumption period is justified and will be clearer to claimants and adjudicators. To the extent that VA receives a claim under § 3.307(a)(4), the claimant may rely on "Gulf War and Health Volume 5: Infectious Diseases" as a standard treatise indicating the potentially lengthy latency period for leishmaniasis.

The proposed presumption for tuberculosis also would not be time-

limited as the current presumption for that disease is by statutory direction. However, we do not believe this would result in a significant inconsistency. The existing 3-year presumptive period for service connection for tuberculosis in 38 U.S.C. 1112(a) applies to all veterans regardless of period or location of service. That presumption reflects the apparent conclusion that when tuberculosis is manifest within a relatively short time after service, it is reasonable to assume that it had its onset in service, even if there is no identified precipitating factor in service. In contrast, the proposed presumption period is based on a specific risk factor in service (service in the Southwest Asia theater of operations or Afghanistan), rather than a purely temporal relationship. Because tuberculosis may manifest decades after an initial infection, we believe it is reasonable to presume that tuberculosis manifest at any time after such service is related to the known risk factor in service unless the evidence shows otherwise.

With respect to the presumptive periods for visceral leishmaniasis and tuberculosis discussed above, we solicit comments on the following matters. First, whether it would be clearer to claimants and adjudicators to have the same presumptive periods as prescribed in § 1112(a) apply to the presumptions proposed for these two diseases. Second, whether NAS's statement that the period of latent infection with visceral leishmaniasis organisms may be long, and that a period of 10 years is commonly cited, justifies an open-ended presumption period. Third, whether the risk factor of service in the Southwest Asia theater of operations or Afghanistan justifies an open-ended presumption period for tuberculosis.

#### *Secondary Health Effects*

In its report, the NAS identified 34 different long-term health effects that might appear weeks to years after initial infection, associated with the nine infectious diseases. Most, if not all, identified long-term health effects are well known to be associated with the initial acute infection. If service connection is granted for a primary infectious disease pursuant to this proposed rule, any secondary health effects proximately due to or caused by the primary infectious disease will also be service connected under existing regulations.

We do not propose to establish presumptions of service connection for the secondary health effects discussed in the NAS report. As explained above, the findings in the NAS report pertained to individuals who had actually

developed a primary infectious disease. Those findings thus do not support a presumption that the identified secondary health effects are independently associated with in-service exposure to the disease-causing pathogen in the absence of the primary disease.

Section 1118 of title 38, United States Code, does not direct VA to establish presumptions of service connection for conditions secondarily caused by a primary service-connected disease or illness. Rather, it requires presumptions for disease or illness associated with "exposure to a biological, chemical, or other toxic agent, environmental or wartime hazard, or preventive medicine known or presumed to be associated with service in the Armed Forces in the Southwest Asia theater of operations during the Persian Gulf War." With respect to infectious diseases endemic to the Southwest Asia theater of operations, the relevant "exposure" is exposure to the pathogens that cause the primary infectious disease. The incurrence of the primary infectious disease is not, separately, an "exposure" within the meaning of the statute.

Any long-term health effects among troops serving in Southwest Asia who suffered an initial serious acute infectious disease should in general be addressed via the conventional direct-service-connection route. For example, if an active duty service member were diagnosed with Q fever (*Coxiella burnetii*) while serving in Southwest Asia, and was diagnosed years later with endocarditis, which is known to be associated with Q fever infection, then that veteran would have a reasonable case for establishing a direct service connection for any related disability.

Chronic long-term health effects associated with these infectious diseases generally would be compensable under the diagnostic code assigned to the service-connected disease or would be considered proximately due to that disease under 38 CFR 3.310(a) (secondary service connection) and rated separately.

As noted above, the NAS's findings concerning the secondary health effects of the nine infectious diseases generally reflect well established medical knowledge. However, to ensure that claimants and VA raters are aware of the NAS findings regarding the potential long-term health effects of the nine infectious diseases associated with service in Southwest Asia, we propose to include information about the long-term health effects in the regulation. The table in proposed paragraph (d), entitled "Table to § 3.317—Long-Term Health Effects Potentially Associated

With Infectious Diseases," summarizes the long-term health effects that the NAS reported as associated with the nine infectious diseases. These health effects and diseases are listed alphabetically and are not categorized by the level of association stated in the NAS report. We propose to provide in the regulation that, if a veteran who has or had an infectious disease identified in column A also has a condition identified in column B as potentially related to that infectious disease, VA must determine, based on the evidence in each case, whether the column B condition was caused by the infectious disease for purposes of paying disability compensation.

#### **IV. Regulatory Amendment**

After considering all of the evidence as discussed above, the Secretary has determined that there is a positive association between the exposure to a biological, chemical or other toxic agent, environmental or wartime hazard, or preventative medicine or vaccine known or presumed to be associated with service in the Armed Forces in the Southwest Asia theater of operations during certain periods and the occurrence of Brucellosis, *Campylobacter jejuni*, *Coxiella burnetii* (Q fever), Malaria, *Mycobacterium tuberculosis*, Nontyphoid *Salmonella*, *Shigella*, Visceral leishmaniasis, and West Nile virus. Accordingly, the Secretary has determined that a presumption of service connection for these nine diseases is warranted pursuant to 38 U.S.C. 1118. Therefore, we propose to amend 38 CFR 3.317 to incorporate the new presumptions.

##### *The major changes we propose are:*

- To revise the title of the regulation to better reflect the content of the regulation and better reflect the authorizing statute (38 U.S.C. 1117).

- To remove current § 3.317(a)(2)(i)(C). This statement is a blanket statement regarding service connection for diagnosed illnesses determined to be presumptively service connected. Because we are establishing presumptive service connection for specified diseases, we propose to create separate sections to address these diseases. We propose to add the new sections at new § 3.317(c) and (d) and redesignate current § 3.317(c) and (d) as § 3.317 (a)(7) and (e) respectively.

- To establish presumptions of service connection for nine infectious diseases becoming manifest within a specified time after service in the Southwest Asia theater of operations or Afghanistan during certain time periods.

## V. Other Diseases

This proposed rule does not reflect determinations concerning any diseases other than those discussed in this proposal. The Secretary's determinations concerning other diseases discussed in the NAS report will be addressed in other 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 rule are 64.009, Veterans Medical Care Benefits; 64.100, Automobiles and Adaptive Equipment for Certain Disabled Veterans and Members of the Armed Forces; 64.101, Burial Expenses Allowance for Veterans; 64.106, Specially Adapted Housing for Disabled Veterans; 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, Radioactive materials, Veterans, Vietnam.

Approved: December 9, 2009.

**John R. Gingrich,**

*Chief of Staff, Department 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.

2. Revise § 3.317 to read as follows:

#### **§ 3.317 Compensation for certain disabilities occurring in Persian Gulf veterans.**

(a) *Compensation for disability due to undiagnosed illness and medically unexplained chronic multisymptom*

*illnesses.* (1) Except as provided in paragraph (a)(7) of this section, VA will pay compensation in accordance with chapter 11 of title 38, United States Code, to a Persian Gulf veteran who exhibits objective indications of a qualifying chronic disability, provided that such disability:

(i) Became manifest either during active military, naval, or air service in the Southwest Asia theater of operations, or to a degree of 10 percent or more not later than December 31, 2011; and

(ii) By history, physical examination, and laboratory tests cannot be attributed to any known clinical diagnosis.

(2)(i) For purposes of this section, a *qualifying chronic disability* means a chronic disability resulting from any of the following (or any combination of the following):

(A) An undiagnosed illness;

(B) The following medically unexplained chronic multisymptom illnesses that are defined by a cluster of signs or symptoms:

(1) Chronic fatigue syndrome;

(2) Fibromyalgia;

(3) Irritable bowel syndrome; or

(4) Any other illness that the

Secretary determines meets the criteria in paragraph (a)(2)(ii) of this section for a medically unexplained chronic multisymptom illness.

(ii) For purposes of this section, the term *medically unexplained chronic multisymptom illness* means a diagnosed illness without conclusive pathophysiology or etiology that is characterized by overlapping symptoms and signs and has features such as fatigue, pain, disability out of proportion to physical findings, and inconsistent demonstration of laboratory abnormalities. Chronic multisymptom illnesses of partially understood etiology and pathophysiology will not be considered medically unexplained.

(3) For purposes of this section, "objective indications of chronic disability" include both "signs," in the medical sense of objective evidence perceptible to an examining physician, and other, non-medical indicators that are capable of independent verification.

(4) For purposes of this section, disabilities that have existed for 6 months or more and disabilities that exhibit intermittent episodes of improvement and worsening over a 6-month period will be considered chronic. The 6-month period of chronicity will be measured from the earliest date on which the pertinent evidence establishes that the signs or symptoms of the disability first became manifest.

(5) A qualifying chronic disability referred to in this section shall be rated using evaluation criteria from part 4 of this chapter for a disease or injury in which the functions affected, anatomical localization, or symptomatology are similar.

(6) A qualifying chronic disability referred to in this section shall be considered service connected for purposes of all laws of the United States.

(7) Compensation shall not be paid under this section for a chronic disability:

(i) If there is affirmative evidence that the disability was not incurred during active military, naval, or air service in the Southwest Asia theater of operations; or

(ii) If there is affirmative evidence that the disability was caused by a supervening condition or event that occurred between the veteran's most recent departure from active duty in the Southwest Asia theater of operations and the onset of the disability; or

(iii) If there is affirmative evidence that the disability is the result of the veteran's own willful misconduct or the abuse of alcohol or drugs.

(b) *Signs or symptoms of undiagnosed illness and medically unexplained chronic multisymptom illnesses.* For the purposes of paragraph (a)(1) of this section, signs or symptoms which may be manifestations of undiagnosed illness or medically unexplained chronic multisymptom illness include, but are not limited to:

- (1) Fatigue.
- (2) Signs or symptoms involving skin.
- (3) Headache.
- (4) Muscle pain.
- (5) Joint pain.
- (6) Neurologic signs or symptoms.
- (7) Neuropsychological signs or symptoms.
- (8) Signs or symptoms involving the respiratory system (upper or lower).
- (9) Sleep disturbances.
- (10) Gastrointestinal signs or symptoms.
- (11) Cardiovascular signs or symptoms.
- (12) Abnormal weight loss.
- (13) Menstrual disorders.

(c) *Presumptive service connection for infectious diseases.* (1) A disease listed in paragraph (c)(2) of this section will be service connected if it becomes manifest in a Persian Gulf veteran, as defined in paragraph (e)(1) of this section or a veteran who served on active military, naval, or air service in Afghanistan on or after September 19, 2001, provided the provisions of paragraph (c)(3) of this section are also satisfied.

(2) The diseases referred to in paragraph (c)(1) of this section are the following:

- (i) Brucellosis.
- (ii) *Campylobacter jejuni*.
- (iii) *Coxiella burnetii* (Q fever).
- (iv) Malaria.
- (v) *Mycobacterium tuberculosis*.
- (vi) Nontyphoid *Salmonella*.
- (vii) *Shigella*.
- (viii) Visceral leishmaniasis.
- (ix) West Nile virus.

(3) The diseases listed in paragraph (c)(2) of this section will be considered to have been incurred in or aggravated by service under the circumstances outlined in paragraphs (c)(3)(i) and (ii) of this section even though there is no evidence of such disease during the period of service.

(i) With three exceptions, the disease must have become manifest to a degree of 10 percent or more within 1 year from the date of separation from a qualifying period of service as specified in paragraph (c)(3)(ii) of this section. Malaria must have become manifest to a degree of 10 percent or more within 1 year from the date of separation from a qualifying period of service or at a time when standard or accepted treatises indicate that the incubation period commenced during a qualifying period of service. There is no time limit for visceral leishmaniasis or tuberculosis to have become manifest to a degree of 10 percent or more.

(ii) For purposes of this paragraph (c), the term *qualifying period of service* means a period of service meeting the requirements of paragraph (e) of this section or a period of active military, naval, or air service on or after September 19, 2001, in Afghanistan.

(4) A disease listed in paragraph (c)(2) of this section shall not be presumed service connected:

(i) If there is affirmative evidence that the disease was not incurred during a qualifying period of service; or

(ii) If there is affirmative evidence that the disease was caused by a supervening condition or event that occurred between the veteran's most recent departure from a qualifying period of service and the onset of the disease; or

(iii) If there is affirmative evidence that the disease is the result of the veteran's own willful misconduct or the abuse of alcohol or drugs.

(5) If a veteran presumed service connected for one of the diseases listed in paragraph (c)(2) of this section is diagnosed with one of the diseases listed in column "B" in the table set forth in paragraph (d) of this section within the time period specified for the disease in that same table, if a time period is specified or, otherwise, at any time, VA will request a medical opinion as to whether it is at least as likely as not that the condition was caused by the veteran having had the associated disease in column "A" in that same table.

(d) *Long-term health effects potentially associated with infectious diseases*—A report of the Institute of Medicine of the National Academy of Sciences has identified the following long-term health effects that potentially are associated with the infectious diseases listed in paragraph (c)(2) of this section. These health effects and diseases are listed alphabetically and are not categorized by the level of association stated in the National Academy of Sciences report. If a veteran who has or had an infectious disease identified in column A also has a condition identified in column B as potentially related to that infectious disease, VA must determine, based on the evidence in each case, whether the column B condition was caused by the infectious disease for purposes of paying disability compensation. This does not preclude a finding that other manifestations of disability or secondary conditions were caused by an infectious disease.

TABLE TO § 3.317—LONG-TERM HEALTH EFFECTS POTENTIALLY ASSOCIATED WITH INFECTIOUS DISEASES

A	B Disease
Brucellosis .....	<ul style="list-style-type: none"> <li>• Arthritis.</li> <li>• Cardiovascular, nervous, and respiratory system infections.</li> <li>• Chronic meningitis and meningoencephalitis.</li> <li>• Deafness.</li> <li>• Demyelinating meningovascular syndromes.</li> <li>• Episcleritis.</li> </ul>

TABLE TO § 3.317—LONG-TERM HEALTH EFFECTS POTENTIALLY ASSOCIATED WITH INFECTIOUS DISEASES—Continued

A	B Disease
<i>Campylobacter jejuni</i> .....	<ul style="list-style-type: none"> <li>• Fatigue, inattention, amnesia, and depression.</li> <li>• Guillain-Barré syndrome.</li> <li>• Hepatic abnormalities, including granulomatous hepatitis.</li> <li>• Multifocal choroiditis.</li> <li>• Myelitis-radiculoneuritis.</li> <li>• Nummular keratitis.</li> <li>• Papilledema.</li> <li>• Optic neuritis.</li> <li>• Orchioepididymitis and infections of the genitourinary system.</li> <li>• Sensorineural hearing loss.</li> <li>• Spondylitis.</li> <li>• Uveitis.</li> </ul>
<i>Coxiella burnetii</i> (Q fever) .....	<ul style="list-style-type: none"> <li>• Guillain-Barré syndrome <i>if manifest within 2 months of the infection.</i></li> <li>• Reactive Arthritis <i>if manifest within 3 months of the infection.</i></li> <li>• Uveitis <i>if manifest within 1 month of the infection.</i></li> <li>• Chronic hepatitis.</li> <li>• Endocarditis.</li> <li>• Osteomyelitis.</li> <li>• post-Q-fever chronic fatigue syndrome.</li> <li>• Vascular infection.</li> </ul>
Malaria .....	<ul style="list-style-type: none"> <li>• Demyelinating polyneuropathy.</li> <li>• Guillain-Barré syndrome.</li> <li>• Hematologic manifestations (particularly anemia after falciparum malaria and splenic rupture after vivax malaria).</li> <li>• Immune-complex glomerulonephritis.</li> <li>• Neurologic disease, neuropsychiatric disease, or both.</li> <li>• Ophthalmologic manifestations, particularly retinal hemorrhage and scarring.</li> <li>• <i>Plasmodium falciparum.</i></li> <li>• <i>Plasmodium malariae.</i></li> <li>• <i>Plasmodium ovale.</i></li> <li>• <i>Plasmodium vivax.</i></li> <li>• Renal disease, especially nephrotic syndrome.</li> </ul>
<i>Mycobacterium tuberculosis</i> .....	<ul style="list-style-type: none"> <li>• Active tuberculosis.</li> <li>• Long-term adverse health outcomes due to irreversible tissue damage from severe forms of pulmonary and extrapulmonary tuberculosis and active tuberculosis.</li> </ul>
Nontyphoid <i>Salmonella</i> .....	<ul style="list-style-type: none"> <li>• Reactive Arthritis <i>if manifest within 3 months of the infection.</i></li> </ul>
<i>Shigella</i> .....	<ul style="list-style-type: none"> <li>• Hemolytic-uremic syndrome <i>if manifest within 1 month of the infection.</i></li> </ul>
Visceral leishmaniasis .....	<ul style="list-style-type: none"> <li>• Reactive Arthritis <i>if manifest within 3 months of the infection.</i></li> <li>• Delayed presentation of the acute clinical syndrome.</li> <li>• Post-kala-azar dermal leishmaniasis <i>if manifest within 2 years of the infection.</i></li> <li>• Reactivation of visceral leishmaniasis in the context of future immunosuppression.</li> </ul>
West Nile virus .....	<ul style="list-style-type: none"> <li>• Variable physical, functional, or cognitive disability.</li> </ul>

(e) *Service.* For purposes of this section:

(1) The term *Persian Gulf veteran* means a veteran who served on active military, naval, or air service in the Southwest Asia theater of operations.

(2) The *Southwest Asia theater of operations* refers to Iraq, Kuwait, Saudi Arabia, the neutral zone between Iraq and Saudi Arabia, Bahrain, Qatar, the United Arab Emirates, Oman, the Gulf of Aden, the Gulf of Oman, the Persian Gulf, the Arabian Sea, the Red Sea, and the airspace above these locations during the Persian Gulf War.

**Authority:** 38 U.S.C. 1117, 1118.

**Editorial Note:** This document was received in the Office of the Federal Register on March 15, 2010.

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**BILLING CODE P**

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA-R10-OAR-2008-0482; FRL-9128-3]

**Approval and Promulgation of Implementation Plans; Idaho**

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

**ACTION:** Proposed rule.

**SUMMARY:** EPA is proposing to approve numerous revisions to the Idaho State Implementation Plan (SIP) that were submitted to EPA by the State of Idaho