Regulations Branch, Office of Regulations and Rulings, U.S. Customs and Border Protection. However, personnel from other offices participated in its development.

List of Subjects in 19 CFR Part 191

Claims, Commerce, CBP duties and inspection, Drawback.

Amendments to the Regulations

■ For the reasons stated above, part 191 of the CBP Regulations (19 CFR part 191) is amended as follows:

PART 191 — DRAWBACK

■ 1. The general authority citation for part 191 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 23, Harmonized Tariff Schedule of the United States), 1313, 1624.

■ 2. Section 191.3(a)(4) and (b)(2) are revised as follows:

§ 191.3 Duties and fees subject or not subject to drawback.

(a) Duties and fees subject to drawback include:

* * * * *

(4) Merchandise processing fees (see § 24.23 of this chapter) for unused merchandise drawback pursuant to 19 U.S.C. 1313(j), and drawback for substitution of finished petroleum derivatives pursuant to 19 U.S.C. 1313(p)(2)(A)(iii) or (iv).

(b) * * *

(2) Merchandise processing fees (*see* § 24.23 of this chapter), except where unused merchandise drawback pursuant to 19 U.S.C. 1313(j) or drawback for substitution of finished petroleum derivatives pursuant to 19 U.S.C. 1313(p)(2)(A)(iii) or (iv) is claimed; and

* * * * *

■ 3. In § 191.51, paragraph (b)(2) introductory text is revised to read as follows:

§ 191.51 Completion of drawback claims.

* * * * *

(b) * * *

(2) *Merchandise processing fee apportionment calculation.* Where a drawback claimant seeks unused merchandise drawback pursuant to 19 U.S.C. 1313(j), or drawback for substitution of finished petroleum derivatives pursuant to 19 U.S.C. 1313(p)(2)(A)(iii) or (iv), for a merchandise processing fee paid pursuant to 19 U.S.C. 58c(a)(9)(A), the claimant is required to correctly apportion the fee to that merchandise that provides the basis for drawback when calculating the amount of drawback requested on the drawback entry. This is determined as follows:

* * * * *

■ 4. In § 191.171, a new paragraph (c) is added to read as follows:

§ 191.171 General; drawback allowance.

* * * * *

(c) *Merchandise processing fees.* In cases where the requirements of paragraph (b)(1) of this section have been met, merchandise processing fees will be eligible for drawback.

Approved: October 4, 2004.

Robert C. Bonner,

Commissioner, U.S. Customs and Border Protection.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 04–22599 Filed 10–6–04; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Parts 1 and 3

RIN 2900–AM09

Presumptions of Service Connection for Diseases Associated With Service Involving Detention or Internment as a Prisoner of War

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) is issuing this interim final rule to establish guidelines for establishing presumptions of service connection for diseases associated with service involving detention or internment as a prisoner of war. In accordance with those guidelines, this interim final rule also establishes presumptions of service connection for atherosclerotic and hypertensive heart disease and for stroke disease arising in former prisoners of war. These rules are necessary because claims based on service involving detention or internment as a prisoner of war present unique medical issues and because factors including the lack of contemporaneous medical records during periods of captivity and the relatively small body of available medical information present obstacles to substantiating claims for service-connected benefits based on prisoner-of-war service. By establishing guidelines for identifying diseases associated with service involving detention or internment as a prisoner of war, these rules will help VA to ensure that claims for service-connected benefits for disability or death of former prisoners of war are decided fairly, consistently, and based on all available medical information concerning the diseases associated with detention or internment as a prisoner of war.

DATES: This interim final rule is effective October 7, 2004. Comments must be received on or before November 8, 2004.

ADDRESSES: Written comments may be submitted by: mail or hand-delivery to Director, Regulations Management (00REG1), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1068, Washington, DC 20420; fax to (202) 273–9026; e-mail to *VAregulations@mail.va.gov*; or, through *http://www.Regulations.gov.* Comments should indicate that they are submitted in response to ''RIN 2900–AM09.'' All 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) 273–9515 for an appointment.

FOR FURTHER INFORMATION CONTACT: David Barrans, Deputy Assistant General Counsel (022D), Office of General Counsel, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 273–6332.

SUPPLEMENTARY INFORMATION: VA is revising its regulations to include a new provision, codified at 38 CFR 1.18, establishing guidelines for determining whether to establish new presumptions of service connection for any disease associated with service involving detention or internment as a prisoner of war. VA is also amending its adjudication regulations at 38 CFR 3.309(c) to add atherosclerotic heart disease or hypertensive vascular disease and stroke to the list of diseases VA will presume to be associated with service involving detention or internment as a prisoner of war (POW), and to reflect statutory changes. These new presumptions of service connection reflect VA's determination that presumptions for heart disease and stroke are warranted by application of the guidelines set forth in § 1.18.

Guidelines for Identifying POW Presumptive Conditions

Statutory and regulatory standards currently exist to guide VA in identifying diseases associated with exposure to herbicide agents, hazards of service in the Gulf War, and ionizing radiation. *See* 38 U.S.C. 1116 and 1118; 38 CFR 1.17. VA has determined that it would be helpful to establish standards to guide VA in identifying diseases

associated with service involving detention or internment as a POW and establishing new presumptions of service connection for such diseases. We are establishing a new provision at 38 CFR 1.18 setting forth guidelines for such determinations. The guidelines are substantially similar to the above-referenced existing guidelines, with minor differences necessary to reflect considerations unique to former POWs.

VA is authorized to provide compensation and other benefits for disability or death due to disease or injury incurred in or aggravated by service. To establish service connection for a disease or injury, a claimant ordinarily must provide evidence, with VA's assistance, establishing that the claimed disease or injury was incurred in or aggravated by service. Statutory and regulatory presumptions of service connection relieve claimants of this evidentiary burden in certain circumstances by directing VA adjudicators to presume that certain diseases were incurred in or aggravated by service unless evidence shows otherwise. These presumptions are generally based on scientific and medical data that provide a basis for inferring a connection between a particular disease and some circumstance regarding the veteran's service.

Evidentiary presumptions of service connection serve a number of purposes. By codifying medical findings and principles that otherwise may not be familiar to VA adjudicators, they promote the efficient resolution of issues of service connection without the need for case-by-case investigation and interpretation of the available medical literature. They promote fair and consistent decision making by establishing simple adjudicatory rules to govern the claims of similarly situated veterans. They also may assist claimants who would otherwise face substantial difficulties in obtaining direct proof of service connection due to the complexity of the factual issues, the lack of contemporaneous medical records during service, or other circumstances.

Currently, 38 U.S.C. 1112(b) establishes presumptions of service connection for sixteen categories of disease that are deemed to be associated with detention or internment as a POW. Eleven of those conditions are presumed to be service connected only if the veteran was detained or interned for a period of at least thirty days, and the remaining five are presumed to be service connected if the veteran was detained or interned for any period.

The Secretary of Veterans Affairs is authorized by 38 U.S.C. 501(a) to prescribe all rules and regulations that are necessary or appropriate to carry out the laws administered by VA, including regulations with respect to the nature and extent of proof necessary to establish entitlement to benefits under such laws. Pursuant to that authority, the Secretary may establish reasonable evidentiary presumptions of service connection for diseases. The Secretary has determined that presumptions of service connection are particularly appropriate for former POWs.

Veterans who were detained or interned as POWs generally were subjected to unique hardships including malnutrition, torture, physical and psychological abuse, and a lack of adequate medical care. Although POW experiences have varied with time, place, and other factors, certain hardships are so prevalent across the spectrum of POW experience as to support the presumption that POWs as a group have incurred similar health risks. The lack of contemporaneous personnel and health records to document events, injuries, or diseases during periods of captivity also provides a strong justification for relying on evidentiary presumptions rather than requiring direct proof of service connection. Further, presumptions may simplify and expedite the claims adjudication process, a particularly significant consideration for former POWs, more than ninety percent of whom served in World War II and are now, on average, over eighty years old.

Additionally, although several health effects associated with prisoner-of-war experiences are well known and reflected in existing presumptions of service connection, determining whether other health effects may be associated with prisoner-of-war experience is not a simple task. This is due in part to the discrete nature of the POW experience. The effects of certain other service-related risk factors such as exposure to ionizing radiation or herbicide agents have been extensively studied in relation to exposures occurring in occupational and other civilian settings in addition to studies of veteran populations. In contrast, the effects of the POW experience have been less extensively studied, because there generally are not comparable civilian populations and the number of former POWs available for study is comparatively small. Although studies of former POWs do exist, the limited amount of information available complicates the task of identifying diseases associated with the POW experience. In view of these circumstances, VA has determined that it is appropriate to establish guidelines for VA's review of the medical evidence concerning the association between the POW experience and particular diseases and to establish presumptions of service connection when the evidence reasonably establishes an association.

We are setting forth the guidelines VA will apply in a new regulation at 38 CFR 1.18. Paragraph (a) of § 1.18 states VA's policy to establish presumptions of service connection for former POWs when necessary to prevent denials of benefits in significant numbers of meritorious claims.

Paragraph (b) of § 1.18 states the standard VA will apply in determining whether a presumption of service connection is warranted. That paragraph states that the Secretary may establish a presumption of service connection for a disease when 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.'' We define the term ''limited/suggestive evidence'' in paragraph (b)(1) to refer to ''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.'' Paragraph (b)(2) states, for purposes of illustration, that ''limited/suggestive evidence'' may be found where one high-quality study detects a statistically significant association or where several smaller studies detect an association that is consistent in magnitude and direction.

The ''limited/suggestive evidence'' standard is essentially the same standard that the Institute of Medicine (IOM) of the National Academy of Sciences employs in reports it prepares for VA analyzing the health effects of exposure to herbicide agents. In those reports, which are mandated by statute, the IOM classifies the association between a particular disease and the hazard in question as belonging to one of the following four categories: ''Sufficient evidence of an association,'' ''limited/suggestive evidence of an association,'' ''inadequate or insufficient evidence to determine whether an association exists,'' and ''sufficient evidence of no association.'' VA has established presumptions of service connection for each of the diseases the IOM has classified as having at least

''limited/suggestive evidence'' of an association. The ''limited/suggestive evidence'' standard employed by the IOM is familiar to VA and has proven to be a useful analytical framework for assessing scientific evidence and determining whether a presumption of service connection may be warranted. Accordingly, we will use that standard for determining when a presumption may be warranted for former POWs.

The IOM defines the ''limited/suggestive evidence'' standard to refer to circumstances in which evidence is suggestive of an association but is limited because matters of chance, bias, and confounding cannot be ruled out with confidence. Our definition adds that the evidence may be limited because the relatively small size of the affected population may restrict the data available for study. We believe this additional consideration is significant with respect to former POWs. As noted above, the lack of a comparable civilian population for study may limit the amount of data available for discerning the health effects of the POW experience. The data available for study are also severely restricted by the fact that there is often little or no information about veterans' health status or adverse exposures during captivity. Moreover, opportunities for future studies are increasingly limited because the population of surviving former POWs, most of whom served in World War II, is declining rapidly. Although we intend that any presumptions VA establishes will be based on sound scientific and medical evidence, we believe that VA's analysis of the evidence should take account of the unique circumstances and evidentiary hurdles affecting this deserving group of veterans. It may be unrealistic to expect the same degree of data or the same number of corroborative studies that may exist with respect to the health effects of herbicide exposure or other areas of investigation. We believe that fairness to former POWs requires that VA fully evaluate the available data and not accord undue significance to the fact that such data are comparatively limited by the small size of the affected population.

The requirement that the association be biologically ''plausible'' does not require proof of a casual relationship. This is further clarified by § 1.18(d), discussed below. Rather, it requires only a determination that there is a possible biological mechanism, consistent with sound scientific evidence, by which the suspected precipitating event (POW experience) could lead to the health outcome. The IOM routinely applies the concept of biologic plausibility in its reviews of the literature concerning the health effects of herbicide exposure and hazards of Gulf War service and is required by statute to consider biologic plausibility. *See* Pub. L. 102–4, § 3(d)(1)(C), and Pub. L. 105–277, § 1603(e)(1)(C).

Paragraph (c) of § 1.18 states that, in establishing a presumption of service connection for a disease, the Secretary may specify a minimum period of detention or internment necessary to qualify for the presumption. As noted above, some of the current statutory presumptions apply only to former POWs who were detained or interned for a period of at least thirty days. That requirement apparently reflects the determination that certain conditions, such as certain diseases associated with vitamin deficiency, ordinarily may arise only after a prolonged period of food deprivation during confinement. Our rule is intended to allow the Secretary to establish a similar requirement concerning the length of detention or internment for new presumptions established in the future, if warranted by sound scientific or medical evidence.

Paragraph (d) of § 1.18 explains that the requirement in paragraph (b) that a disease be ''associated'' with the POW experience may be satisfied by evidence demonstrating either a statistical or a causal association. Paragraph (e) of the rule specifies the types of evidence the Secretary will consider in deciding whether a presumption is warranted. This paragraph makes clear that the Secretary need not rely exclusively on studies of former POWs, but may consider studies concerning the health effects of circumstances or hardships similar to those experienced by POWs, if available, as well as any other sound scientific or medical evidence the Secretary considers relevant.

Paragraph (f) of § 1.18 states several factors that VA will consider in evaluating any scientific study concerning diseases possibly associated with the POW experience. The specified factors are similar to the factors VA considers in assessing studies relating to herbicide exposure and other hazards. See 38 U.S.C. 1116(b)(2) and 1118(b)(2)(B); 38 CFR 1.17(b).

Paragraph (g) of § 1.18 states that the Secretary may contract with an appropriate expert body, such as the IOM, to review and summarize the scientific evidence or for any other purpose relevant to the Secretary's determinations under this rule.

Evidence of Association Between POW Experience and Stroke

There are very few studies investigating the possible relationship between POW experience and stroke. In September 2000, the VA Advisory Committee on Former Prisoners of War received the report of an Expert Panel on Stroke in Former Prisoners of War, which, based on review of the existing scientific literature, found only one relevant study. That 1996 study examined records of 475 former World War II POWs and a control group of 81 non-POW World War II veterans who had been followed as part of a long-term study by the Medical Follow-up Agency of the National Academy of Sciences' IOM. The study found a seven-fold increase in the incidence of stroke among the POWs as compared to the control group (relative risk = 7.03), and a statistically significant nearly ten-fold increase in stroke incidence among POWs who had suffered extreme malnutrition during captivity (relative risk = 9.76). (Brass LM, Page WF. Stroke in Former Prisoners of War. J Stroke and Cerebrovascular Diseases 1996; 6:72–78.) The study also found that the risk of stroke was higher among former POWs suffering from post-traumatic stress disorder (PTSD) than among former POWs without PTSD (relative risk = 1.67). The strength of those findings is limited by the small size of the study population.

Two more recent studies have also addressed the relationship between POW experience and stroke. A 2001 study used Federal death records to obtain death data through 1996 for a study population of 9,457 former POWs and 7,178 controls. The study found that former POWs aged 75 years and older had an increased risk of stroke mortality (hazard ratio = 1.13), although the risk was not statistically significant. (Page WF, Brass LM. Long-Term Heart Disease and Stroke Mortality Among Former American Prisoners of War of World War II and the Korean Conflict: Results of a 50-Year Follow-Up. Military Medicine 2001; 166:803–08.) A subsample of the overall study population had completed a questionnaire in 1967 indicating the presence or absence of certain symptoms during their captivity. The study authors found a statistically significant increase in death due to stroke among veterans who had experienced visual symptoms, such as night blindness, during their captivity (hazard ratio = 3.10). Because the presence of visual symptoms during captivity may be associated with vitamin A deficiency (Page WF. The

Health of Former Prisoners of War: Results from the Medical Examination Survey of Former Prisoners of World War II and the Korean Conflict, p. 75. Washington DC, National Academies Press, 1992.), this finding is consistent with the 1996 Brass and Page study in suggesting an association between malnutrition during POW captivity and subsequent stroke.

On the recommendation of the Expert Panel on Strokes in Former Prisoners of War, VA's Environmental Epidemiology Service in 2003 conducted a study using medical and death data from records of VA and the Health Care Financing Administration (HCFA) of the Department of Health and Human Services for the period from 1991 to 2002. This study, which has not yet been published, included 16,641 World War II POWs and 1,051 Korean War POWs, as well as 8,406 World War II controls and 3,816 Korean War controls. This study found that POWs had a significantly higher incidence of PTSD than the controls and that POWs with PTSD had a higher incidence of stroke than POWs without PTSD (odds ratio = 1.12 for World War II and 1.25 for Korean War). (Kang HK, Bullman TA. Ten Year Mortality and Morbidity Follow-up of Former World War II and Korean War Prisoners of War (unpublished VA Study 2003).) Although the study did not find a significantly increased risk of stroke among POWs as compared to non-POWs, the evidence for an association between PTSD and stroke among POWs is consistent with findings stated in the 1996 study by Brass and Page.

The 1996 Brass and Page study noted that several studies have provided evidence suggesting an association between stress and stroke, although the evidence overall is not conclusive. The authors also noted that the effects of stress on stroke may vary depending upon individual reactions to stress. As stated in paragraph (e)(2) of § 1.18, the Secretary will consider evidence concerning the effects of circumstances or hardships similar to those experienced by POWs, including stress, in assessing the evidence for establishing presumptions of service connection.

Based on the evidence discussed above, the Secretary has determined that a presumption of service connection is warranted for stroke among former prisoners of war. The 1996 and 2001 POW studies both found an increased risk of stroke among former POWs. Although there is an absence of other directly corroborating studies, the lack of additional data is due in part to the small size of the POW population available for study and the limited number of studies generally undertaken in this field. Accordingly, the lack of corroborating data does not imply the absence of an association under these circumstances.

The evidence that the risk of stroke is increased among POWs who suffered extreme malnutrition or visual symptoms during captivity or who have been diagnosed with PTSD also lends support to the finding of an association between POW experience and stroke. As indicated in § 1.18, VA considers stress and malnutrition to be among the hardships ordinarily associated with POW experience. Evidence suggesting that the risk of stroke increases with the severity of those hardships supports the conclusion that stroke is associated with POW experience.

Under the standards set forth in § 1.18, the Secretary finds that the available evidence is suggestive of an association between POW experience and stroke because sound scientific studies provide evidence of an association that is consistent in magnitude and direction, even though it is limited in some respects by the small size of the affected population and the correspondingly limited data available for study. The Secretary further finds that an association between stroke and POW experience is biologically plausible, as discussed below. Accordingly, the Secretary is establishing a presumption of service connection for stroke in former POWs.

The interim final rule establishing this presumption refers generally to ''stroke and its complications'' and thus will apply to any type of stroke. The associations detected in the 1996 and 2001 POW studies were based on diagnoses of all types of stroke, and the studies did not state separate findings for specific types of stroke. Although there are known differences in the three major categories of stroke (ischemic, hemorrhagic, and embolic) that may suggest etiological differences in some circumstances, the existing data do not provide a basis for excluding any category of stroke from the presumption, and we believe that any uncertainty regarding the strength of the association for these closely related diseases should be resolved in favor of the former POWs. Further, VA believes that the requirements of biologic plausibility are satisfied for each of the major categories of stroke. Presumptions of service connection for former POWs can be rebutted as provided in 38 U.S.C. 1113(a) and 38 CFR 3.307(d). Accordingly, if evidence in a case supports a finding that a particular presumptive condition was not actually caused by a veteran's POW experience, VA may consider the presumption to be rebutted.

Evidence of Association Between POW Experience and Heart Disease

As with stroke, there are relatively few studies addressing the association between POW experience and heart disease. A series of older studies did not find consistent evidence of an association, as summarized in Page WF, Ostfeld AM. Malnutrition and Subsequent Ischemic Heart Disease in Former Prisoners of War of World War II and the Korean Conflict. (J Clin Epidemiol 1994; 47:1437–41.) A 1954 study found an excess of cardiovascular deaths among World War II POWs (Cohen BM, Cooper MZ. A Follow-up Study of World War II Prisoners of War. Veterans Administration Medical Monograph, Washington DC: Government Printing Office; 1954.), although subsequent mortality studies in 1970 and 1980 found no excess deaths due to cardiovascular diseases (Nefzger, MD. Follow-up Studies of World War II and Korean War Prisoners. I. Study Plan and Mortality Findings. Am J Epidemiol 1970; 91:123–38; Keehn RJ. Follow-up Studies of World War II and Korean War Prisoners III. Mortality to January 1, 1976. Am J Epidemiol 1980; 111:194–211.) A 1975 morbidity study found a significantly higher rate of hospitalization for heart disease among World War II Pacific Theater POWs as compared to controls. (Beebe GW. Follow-up Studies of World War II and Korean War Prisoners: II. Morbidity, Disability, and Maladjustments. Am J Epidemiol 1975; 101:400–22.) Studies of POWs from other countries also yielded inconsistent results.

More recent studies have yielded intriguing findings concerning the association between heart disease and POW experience. The 1994 study by Page and Ostfeld found a statistically significant increase in deaths due to ischemic heart disease among former POWs who experienced edema (swelling) in their lower limbs during captivity (odds ratio = 2.83). Because localized edema is a symptom of thiamine deficiency, the authors theorized that the findings may suggest an association between malnutrition during captivity and subsequent ischemic heart disease. Current VA regulations provide for presumptive service connection of ischemic heart disease in former POWs who experienced localized edema during captivity. 38 CFR 3.309(c).

The 2001 study by Page and Brass analyzed the increased risk of heart disease among former POWs by age

group and found a trend of increased excess risk with advanced age, with a statistically significant increased risk for former POWs aged 75 years or over (hazard ratio = 1.25). The authors stated that the findings may indicate that the sequelae of serious, acute malnutrition may not appear until after many decades.

The 2003 VA study analyzed records of inpatient and outpatient treatment from VA and HCFA records to determine whether POWs had an increased incidence of certain diseases in comparison to the non-POW controls. The study detected small increases in the incidence of hypertension and myocardial infarction among some, but not all of the subpopulations examined, and not all of the findings were statistically significant. However, the study did find a statistically significant increased incidence of hypertension and chronic heart disease among World War II veterans with PTSD (odds ratio = 1.25 for hypertension and 1.19 for chronic heart disease).

The conclusion that PTSD may be associated with cardiovascular disorders is also supported by a 1997 study finding that Vietnam veterans diagnosed with PTSD had a significantly increased risk of circulatory disease many years after service. (Boscarino JA. Diseases Among Men 20 Years After Exposure to Severe Stress: Implications for Clinical Research and Medical Care. Psychosom Med 1997; 59:605–14.)

Based on the evidence discussed above, the Secretary has determined that a presumption of service connection is warranted for atherosclerotic heart disease and hypertensive vascular disease among former POWs. The 2001 study by Page and Brass found a statistically significant increased risk of mortality due to heart disease in former POWs aged 75 and older, based on a relatively large population of former POWs and controls, many of whom had been followed for as many as fifty years by the Medical Follow-up Agency of the National Academy of Sciences' IOM. The 1994 Page and Ostfeld study also found a statistically significant increased risk of heart disease in former POWs who experienced edema, a consequence of malnutrition, and the 2003 VA study found a statistically significant increased risk of heart disease among former POWs with PTSD. As noted above with respect to stroke, the Secretary concludes that the evidence suggesting an association between heart disease and specific hardships of POW experience—malnutrition and stress—is significant. Although the available data concerning the health effects of POW experience are limited, the link to specific aspects of POW experience strengthens the evidence for an association between heart disease and POW service. Accordingly, the Secretary concludes that sound scientific studies provide limited/suggestive evidence of an association between POW experience and heart disease. As discussed below, the Secretary has also determined that the association between POW experience and heart disease is biologically plausible. Accordingly, the Secretary is establishing a presumption of service connection for heart disease in former POWs.

The studies discussed above did not all investigate the same range of heart diseases and thus do not clearly resolve the question of which types of heart disease may be associated with POW experience. For purposes of this presumption, we will include all cardiovascular diseases that are consistent, in terms of biologic plausibility, with the findings in the relevant studies in that the diseases are potentially capable of being caused by the circumstances or hardships of POW service such as extreme stress or malnutrition. We describe these diseases as atherosclerotic heart disease or hypertensive vascular disease (to include hypertensive heart disease). Atherosclerotic heart disease is a term used to refer to a heart disease involving progressive narrowing and hardening of the arteries over time and encompasses ischemic heart disease, coronary artery disease, and other diseases that may be described by a more specific diagnosis. Hypertensive vascular disease refers to disease associated with elevated blood pressure. The presumption would not extend to diseases that arise from viral or bacterial causes, because we conclude that the relevant studies, and the evidence concerning biologic plausibility, do not support a finding at this time that such heart diseases are associated with POW experience.

With respect to certain types of atherosclerotic heart disease or hypertensive vascular disease that are to be covered by these presumptions, there is little available evidence upon which to rule in or rule out the possibility that the condition is capable of being caused by the hardships of POW service. In those cases, we have chosen to resolve the doubt in favor of veterans and include the condition within the scope of the presumption. Although the necessity of inclusion of some conditions may be uncertain from a purely scientific perspective, VA has decided as a policy matter to resolve this issue in favor of veterans because there is a reasonable basis for doing so. Presumptions of service connection for former POWs can be rebutted as provided in 38 U.S.C. 1113(a) and 38 CFR 3.307(d). Accordingly, if evidence in a case supports a finding that a particular presumptive condition was not actually caused by a veteran's POW experience, VA may consider the presumption to be rebutted.

The interim final rule also states that the presumption of service connection applies to the complications of atherosclerotic heart disease and hypertensive vascular disease, to make clear that congestive heart failure, myocardial infarction, arrhythmias, and similar complications may be service connected if they result from atherosclerotic heart disease or hypertensive vascular disease.

Biologic Plausibility

The Secretary has concluded that an association between POW experience and both heart disease and stroke is biologically plausible. The concept of biologic plausibility refers to knowledge of the biological mechanism by which a particular event can lead to a health outcome. It does not require conclusive proof of a causal relationship between the event and the health outcome, but requires a determination as to whether there is a possible biological mechanism that is consistent with sound scientific evidence by which the event could lead to the health outcome. Accordingly, to be biologically plausible, an association must be consistent with existing scientific and medical knowledge, even if current evidence does not conclusively identify a specific known mechanism by which the circumstances in question cause the diseases associated with such circumstances. Current medical literature suggests plausible, though not established, biological mechanisms by which stress and/or malnutrition during POW captivity could contribute to heart disease or stroke.

A number of authorities have postulated that stress may contribute to cardiovascular disease through a concept referred to as ''allostatic load,'' which is described as the long-term effect of the physiological response to stress. Through the process of allostasis, the autonomic nervous system, the hypothalamic-pituitary-adrenal (HPA) axis, and the cardiovascular, metabolic, and immune systems protect the body by responding to stress with adaptive changes. Those adaptations can cause wear and tear on the systems involved in this response and may produce a variety of cardiovascular changes associated with atherosclerosis, hypertension, cardiac arrhythmias,

compromised coronary function, and increased risk of myocardial infarction and stroke. (McEwen BS. Protective and Damaging Effects of Stress Mediators. N Engl J Med 1998; 338:171–79; Brunner E. Stress Mechanisms in Coronary Artery Disease. In: Stansfeld S, Marmot M (eds.). Stress and the Heart: Psychosocial Pathways to Coronary Heart Disease. London. BMJ Books 2002.)

Support for the biologic plausibility of an association between malnutrition and heart disease and stroke comes from evidence that vitamin deficiencies may cause elevated plasma levels of homocysteine, a naturally occurring amino acid. A number of studies suggest that elevated homocysteine levels may produce effects on the cardiovascular system that can lead to heart disease or stroke. (Stein, JH, McBride PE. Hyperhomocysteinemia and Atherosclerotic Vascular Disease: Pathophysiology, Screening, and Treatment. Arch Int Med 1998; 158:1301–06; Tsai J, Perrella MA, Yoshizumi M, Hseih C, Haber E, Schlegel R, Lee M. Promotion of Vascular Smooth Muscle Cell Growth by Homocysteine: A Link to Atherosclerosis. 91 Proc Natl Acad Sci 1994; 91:6369–73.) Although the available evidence is not conclusive, it satisfies the requirement of biologic plausibility for purposes of the Secretary's determination.

Presumptions of Service Connection

VA's regulation at 38 CFR 3.309(c) identifies the diseases VA presumes to be service connected for former POWs. We are amending this list of diseases by adding atherosclerotic heart disease, hypertensive vascular disease (including hypertensive heart disease), stroke, and their complications.

We are removing the note in current § 3.309(c) specifying that the term ''beriberi heart disease'' includes ischemic heart disease in a former POW who experienced localized edema during captivity. This note was added based on the 1994 Page and Ostfeld study finding an association between the presence of lower-limb edema during POW captivity and subsequent ischemic heart disease. This interim final rule establishes a presumption of service connection for heart disease, including ischemic heart disease, without regard to whether localized edema was present in service. Accordingly, we are removing the current note to make clear that the presence of edema is no longer required in order to establish service connection for ischemic heart disease.

Other Changes to § 3.309(c)

We are making one other change to § 3.309(c). Section 3.309(c) states that the presumptions of service connection apply only to veterans who were interned or detained for not less than 30 days. The 30-day requirement was formerly mandated by the governing statutory provisions at 38 U.S.C. 1112(b). Effective December 16, 2003, however, section 201 of the Veterans Benefits Act of 2003, Pub. L. No. 108–183, 117 Stat. 2651, amended 38 U.S.C. 1112(b) to eliminate the 30-day requirement for psychosis, any anxiety states, dysthymic disorders, organic residuals of frostbite and post-traumatic osteoarthritis. We are revising § 3.309(c) to conform to the current provisions of section 1112(b). We are including heart disease and stroke among the conditions that will be presumed to be service connected following any period of POW captivity. The diseases that remain subject to a 30-day detention or internment requirement generally are those that would be expected to be incurred only over a prolonged period of detention or internment, such as diseases associated with malnutrition. Because the evidence indicates that heart disease and stroke potentially may be associated either with malnutrition during prolonged captivity or with stress due to circumstances such as torture or abuse, which may occur during even brief periods of captivity, we do not believe a minimum period of detention or internment is warranted for these presumptions.

As part of a VA project to rewrite all of its adjudication regulations in part 3 of title 38, Code of Federal Regulations, we published a notice of proposed rule making in the **Federal Register** of July 27, 2004 (69 FR 44614), proposing a new regulation that would implement the provisions of section 201 of the Veterans Benefits Act of 2003 removing the 30-day detention or internment requirement for certain POW diseases. Because we are now issuing this interim final rule to amend the list of diseases in § 3.309(c) effective immediately, we believe it is desirable to make these additional changes at this time to bring the regulation into conformity with the current statute.

Administrative Procedure Act

VA has determined that it is appropriate to issue this rule as an interim final rule without providing an opportunity for prior public comment. The provisions of this rule to be codified at 38 CFR 1.18 specify the procedures VA intends to follow in exercising its discretionary authority under 38 U.S.C. 501(a) to establish new presumptions of service connection for former POWs. These portions of the rule constitute a general statement of VA policy or, alternatively, rules of VA procedure and practice. Accordingly, they are exempt under 5 U.S.C. 553(b)(3)(A) from the notice and comment requirements of the Administrative Procedure Act. The portions of this rule revising 38 CFR 3.309(c) to conform to the provisions of 38 U.S.C. 1112(b), as amended by the Veterans Benefits Act of 2003, do not involve any change in law, but merely restate the statutory provisions of 38 U.S.C. 1112(b). Accordingly, these portions of the rule are, at most, interpretative rules that are also exempt under 5 U.S.C. 553(b)(3)(A) from the notice and comment requirements of the Administrative Procedure Act. Alternatively, pursuant to 5 U.S.C. 553(b)(3)(B), the Secretary for good cause finds that notice and an opportunity for prior public comment is unnecessary with respect to this portion of the rule because it merely tracks a statutory provision that VA is required to follow.

In accordance with 5 U.S.C. 553(b)(3)(B), the Secretary finds that there is good cause for dispensing with the opportunity for prior comment with respect to the portions of this rule establishing new presumptions of service connection for atherosclerotic heart disease, hypertensive vascular disease, and stroke among former POWs. The Secretary concludes that providing an opportunity for prior comment is unnecessary because this portion of the rule is unlikely to generate any adverse public comment, inasmuch as it confers a benefit on a deserving class of veterans based on sound scientific evidence. The Secretary further finds that it is impracticable to delay this regulation for the purpose of soliciting prior public comment because the class of veterans affected by this rule is elderly and rapidly dwindling. More than 90% of all POWs served in World War II and are now, on average, over eighty years old. As of January 1, 2003, this population of World War II veterans had an annual mortality rate of nine percent. Delay in implementing these rules would have a significant adverse effect and frustrate the beneficial purpose of this rule in view of the high mortality rate among the POW population and the fact that the majority of former POWs are at an age where their medical and financial needs are likely to be at their greatest.

For the foregoing reasons, the Secretary is issuing this rule as an interim final rule. The Secretary will

consider and address comments that are received within 30 days of the date this interim final rule is published in the **Federal Register**.

Unfunded Mandates

The Unfunded Mandates Reform Act requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before developing any rule that may result in an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more in any given year. This rule will have no such effect on State, local, or tribal governments, or the private sector.

Executive Order 12866

The Office of Management and Budget has reviewed this document under Executive Order 12866.

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 regulatory amendment will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612. The reason for this certification is that these amendments will not directly affect any small entities. Only VA beneficiaries and their survivors will be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), these amendments are exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program numbers are 64.109, and 64.110.

List of Subjects

38 CFR Part 1

Administrative practice and procedure, Claims.

38 CFR Part 3

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

Approved: September 8, 2004.

Anthony J. Principi,

Secretary of Veterans Affairs.

■ For the reasons set forth in the preamble, the Department of Veterans Affairs amends 38 CFR parts 1 and 3 as follows:

PART 1—GENERAL PROVISIONS

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

Authority: 38 U.S.C. 501(a), unless otherwise noted.

■ 2. Section 1.18 is added to read as follows:

§ 1.18 Guidelines for establishing presumptions of service connection for former prisoners of war.

(a) *Purpose.* The Secretary of Veterans Affairs will establish presumptions of service connection for former prisoners of war when necessary to prevent denials of benefits in significant numbers of meritorious claims.

(b) *Standard.* The Secretary may establish a presumption of service connection for a disease when the Secretary finds that 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.

(1) *Definition.* The phrase ''limited/suggestive evidence'' refers to 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.

(2) *Examples.* ''Limited/suggestive evidence'' may be found where one high-quality study detects a statistically significant association between the prisoner-of-war experience and disease, even though other studies may be inconclusive. It also may be satisfied where several smaller studies detect an association that is consistent in magnitude and direction. These examples are not exhaustive.

(c) *Duration of detention or internment.* In establishing a presumption of service connection under paragraph (b) of this section, the Secretary may, based on sound scientific or medical evidence, specify a minimum duration of detention or internment necessary for application of the presumption.

(d) *Association.* 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.

(e) *Evidence.* In making determinations under paragraph (b) of this section, the Secretary will consider, to the extent feasible:

(1) Evidence regarding the increased incidence of disease in former prisoners of war;

(2) Evidence regarding the health effects of circumstances or hardships similar to those experienced by prisoners of war (such as malnutrition, torture, physical abuse, or psychological stress);

(3) Evidence regarding the duration of exposure to circumstances or hardships experienced by prisoners of war that is associated with particular health effects; and

(4) Any other sound scientific or medical evidence the Secretary considers relevant.

(f) *Evaluation of studies.* In evaluating any study for the purposes of this section, the Secretary will consider:

(1) The degree to which the study's findings are statistically significant;

(2) The degree to which any conclusions drawn from the study data have withstood peer review;

(3) Whether the methodology used to obtain the data can be replicated;

(4) The degree to which the data may be affected by chance, bias, or confounding factors; and

(5) The degree to which the data may be relevant to the experience of prisoners of war in view of similarities or differences in the circumstances of the study population.

(g) *Contracts for Scientific Review and Analysis.* To assist in making determinations under this section, the Secretary may contract with an appropriate expert body to review and summarize the scientific evidence, and assess the strength thereof, concerning the association between detention or internment as a prisoner of war and the occurrence of any disease, or for any other purpose relevant to the Secretary's determinations.

Authority: 38 U.S.C. 501(a), 1110.

PART 3—ADJUDICATION

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

■ 3. The authority citation for part 3, subpart A continues to read as follows:

Authority: 38 U.S.C. 501(a), unless otherwise noted.

■ 4. Section 3.309 (c) is amended by removing the ''Note'' immediately following the list of diseases and by revising the paragraph and its authority citation to read as follows:

§ 3.309 Disease subject to presumptive service connection.

* * * * *

(c) *Diseases specific as to former prisoners of war.* (1) If a veteran is a former prisoner of war, the following diseases shall be service connected if manifest to a degree of disability of 10 percent or more at any time after discharge or release from active military, naval, or air service even though there is no record of such disease during service, provided the rebuttable presumption provisions of § 3.307 are also satisfied.

Psychosis.

Any of the anxiety states.

Dysthymic disorder (or depressive neurosis).

Organic residuals of frostbite, if it is determined that the veteran was interned in climatic conditions consistent with the occurrence of frostbite.

Post-traumatic osteoarthritis.

Atherosclerotic heart disease or hypertensive vascular disease (including hypertensive heart disease) and their complications (including myocardial infarction, congestive heart failure, arrhythmia).

Stroke and its complications.

(2) If the veteran:

(i) Is a former prisoner of war and;

(ii) Was interned or detained for not less than 30 days, the following diseases shall be service connected if manifest to a degree of 10 percent or more at any time after discharge or release from active military, naval, or air service even though there is no record of such disease during service, provided the rebuttable presumption provisions of § 3.307 are also satisfied.

Avitaminosis.

Beriberi (including beriberi heart disease).

Chronic dysentery.

Helminthiasis.

Malnutrition (including optic atrophy associated with malnutrition).

Pellagra.

Any other nutritional deficiency.

Irritable bowel syndrome.

Peptic ulcer disease.

Peripheral neuropathy except where directly related to infectious causes.

Cirrhosis of the liver.

Authority: 38 U.S.C. 1112(b).

* * * * *

[FR Doc. 04–22543 Filed 10–6–04; 8:45 am]

BILLING CODE 8320–01–P

POSTAL SERVICE

39 CFR Part 501

Authorization to Manufacture and Distribute Postage Meters

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations that define a postage meter and its components and a manufacturer and/or distributor of postage meters. The rule also puts forth the responsibilities of any authorized person or entity to notify the Postal Service upon a change in ownership or control, or bankruptcy or insolvency, and identifies factors the Postal Service will consider in acting upon requests for changes of approval, ownership, or control of an approved manufacturer or distributor.

DATES: This rule is effective on October 7, 2004.

FOR FURTHER INFORMATION CONTACT: Wayne Wilkerson, manager of Postage Technology Management, by fax at 703–292–4050.

SUPPLEMENTARY INFORMATION: A proposed rule was published in the **Federal Register** on May 10, 2004, pages 25864–25865, with comments due on or before July 9, 2004. Written comments were received from the vendor community.

The Postal Service gave thorough consideration to these comments, and incorporated as appropriate with only minor, non-material exception. You may review comments received by submitting a request of the office of Postage Technology Management at 703–292–3691 or by fax at 703–292–4073.

The final plan follows.

List of Subjects in 39 CFR Part 501

Administrative practice and procedure, Postal Service.

The Amendment

■ For the reasons set out in this document, the Postal Service is amending 39 CFR Part 501 as follows:

PART 501—AUTHORIZATION TO MANUFACTURE AND DISTRIBUTE POSTAGE METERS

■ 1. The authority citation for Part 501 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 410, 2601, 2605; Inspector General Act of 1978, as amended (Pub. L. 95'452, as amended), 5 U.S.C. App. 3.

■ 2. Revise § 501.1 to read as follows:

§ 501.1 Postage evidencing system/infrastructure authorization.

(a) Postage evidencing systems produce evidence of prepayment of U.S. postage by any method other than postage stamps or permit imprint. They include but are not limited to postage meters and PC Postage'' systems. The Postal Service considers the infrastructure associated with such systems to be essential to the exercise of its specific powers to prescribe postage and provide evidence of payment of postage under 39 U.S.C. 404(a)(2) and (4).

(b) Due to the potential for adverse impact upon Postal Service revenue, the following activities may not be engaged in by any person or concern without prior, written approval of the Postal Service:

(1) Producing or distributing any postage evidencing system that generates U.S. postage.

(2) Repairing, distributing, refurbishing, remanufacturing, or destroying any component of a postage evidencing system that accounts for or authorizes the printing of U.S. postage.

(3) Owning or operating an infrastructure that maintains operating data for the production of U.S. postage, or accounts for U.S. postage purchased for distribution through a postage evidencing system.

(4) Owning or operating an infrastructure that maintains operating data that is used to facilitate licensing or registration with the Postal Service of users of a postage evidencing system.

(c) Any person or entity seeking authorization to perform any activity described in paragraph (b) of this section must submit a request to the Postal Service in person or in writing.

(d) Approval shall be based upon satisfactory evidence of the applicant's integrity and financial responsibility, and commitment to the security of the postage evidencing system, and a determination that disclosure to the applicant of the Postal Service customer, financial, or other data of a commercial nature necessary to perform the function for which approval is sought would be appropriate and consistent with good business practices within the meaning of 39 U.S.C. 410 (c)(2). The Postal Service may condition its approval on the agreement to undertakings by the applicant that would give the Postal Service appropriate assurance of the applicant's ability to meet its obligations under this section, including but not limited to the method and manner of performing certain financial, security, and servicing functions and the need to maintain sufficient financial reserves to guarantee