other than a program as described in paragraph (h) of this section, if the Secretary determines that such termination of collection is in the best interest of the United States. For purposes of this paragraph, an *individual* is any member of the Armed Forces or veteran who dies as a result of an injury incurred or aggravated in the line of duty while serving in a theater of combat operations in a war or in combat against a hostile force during a period of hostilities on or after September 11, 2001.

(c) For purposes of this section:

(1) *Theater of combat operations* means the geographic area of operations where the Secretary in consultation with the Secretary of Defense determines that combat occurred.

(2) *Period of hostilities* means an armed conflict in which members of the United States Armed Forces are subjected to danger comparable to danger to which members of the Armed Forces have been subjected in combat with enemy armed forces during a period of war, as determined by the Secretary in consultation with the Secretary of Defense.

(d) The Secretary may refund amounts collected after the death of a member of the Armed Forces or veteran in accordance with this paragraph and paragraph (e) of this section.

(1) In any case where all or any part of a debt of a member of the Armed Forces, as described under paragraph (a) of this section, was collected, the Secretary may refund the amount collected if, in the Secretary's determination, the indebtedness would have been suspended or terminated under authority of 31 U.S.C. 3711(f). The member of the Armed Services must have been serving on active duty on or after September 11, 2001. In any case where all or any part of a debt of a covered member of the Armed Forces was collected, the Secretary may refund the amount collected, but only if the Secretary determines that, under the circumstances applicable with respect to the deceased member of the Armed Forces, it is appropriate to do so.

(2) In any case where all or any part of a debt of a covered member of the Armed Forces or veteran, as described under paragraph (b) of this section, was collected on or after September 11, 2001, the Secretary may refund the amount collected if, in the Secretary's determination, the indebtedness would have been terminated under authority of 38 U.S.C. 5302A. In addition, the Secretary may refund the amount only if he or she determines that the deceased individual is equitably entitled to the refund.

(e) Refunds under paragraph (d) of this section will be made to the estate of the decedent or, in its absence, to the decedent's next-of-kin in the order listed below.

(1) The decedent's spouse.

(2) The decedent's children (in equal shares).

(3) The decedent's parents (in equal shares).

(f) The authority exercised by the Secretary to suspend or terminate collection action and/or refund amounts collected on certain indebtedness is reserved to the Secretary and will not be delegated.

(g) Requests for a determination to suspend or terminate collection action and/or refund amounts previously collected as described in this section will be submitted to the Office of the Secretary through the Office of the General Counsel. Such requests for suspension or termination and/or refund may be initiated by the head of the VA administration having responsibility for the program that gave rise to the indebtedness, or any concerned staff office, or by the Chairman of the Board of Veterans' Appeals. When a recommendation for refund under this section is initiated by the head of a staff office, or by the Chairman, Board of Veterans' Appeals, the views of the head of the administration that administers the program that gave rise to the indebtedness will be obtained and transmitted with the recommendation of the initiating office.

(h) The provisions of this section concerning suspension or termination of collection actions and the refunding of moneys previously collected do not apply to any amounts owed the United States under any program carried out under 38 U.S.C. chapter 37.

(Authority: 38 U.S.C. 501, 5302A; 31 U.S.C. 3711(f)).

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900–AN54

Diseases Associated With Exposure to Certain Herbicide Agents (Hairy Cell Leukemia and Other Chronic B-Cell Leukemias, Parkinson's Disease and Ischemic Heart Disease)

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) adjudication regulations concerning presumptive service connection for certain diseases based upon the most recent National Academy of Sciences (NAS) Institute of Medicine committee report, Veterans and Agent Orange: Update 2008 (Update 2008). This amendment is necessary to implement the decision of the Secretary of Veterans Affairs that there is a positive association between exposure to certain herbicides and the subsequent development of hairy cell leukemia and other chronic B-cell leukemias, Parkinson's disease, and ischemic heart disease. The effect of this amendment is to establish presumptive service connection for these diseases based on herbicide exposure.

DATES: *Effective Date:* This final rule is effective August 31, 2010. This final rule is a major rule and the implementation of this rule is subject to the provisions of the Congressional Review Act (CRA). The CRA provides for a 60-day waiting period before an agency may implement a major rule to allow Congress the opportunity to review the regulation. The impact of the CRA will require at least a 60-day delay between the issuance of the final regulation and when VA can begin paying benefits.

Applicability Date: This final rule shall apply to claims received by VA on or after the date of publication of the final rule in the **Federal Register** and to claims pending before VA on that date. Additionally, VA will apply this rule in readjudicating certain previously denied claims as required by court orders in *Nehmer* v. *Department of Veterans Affairs,* No. CV–86–6161 TEH (N.D. Cal.) (*Nehmer*).

FOR FURTHER INFORMATION CONTACT: Thomas J. Kniffen, Regulations Staff (211D), Compensation and Pension Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461–9725 (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On March 25, 2010, VA published in the **Federal Register** (75 FR 14391) a proposal to amend 38 CFR 3.309 to add hairy cell leukemia and other chronic B-cell leukemias, Parkinson's disease and ischemic heart disease to the list of diseases subject to presumptive service connection based on herbicide exposure. Interested persons were invited to submit written comments on or before April 26, 2010. VA received 670 comments on the proposed rule. Overall, the comments VA received are

in favor of the Secretary's decision to establish the new presumption of service connection for hairy cell leukemia and other chronic B-cell leukemias, Parkinson's disease and ischemic heart disease.

VA received comments from service organizations, including Vietnam Veterans of America, Inc. (VVA), The Blue Water Navy Vietnam Veterans Association (BWNVVA), and other organizations, which include The Parkinson's Action Network, National Parkinson's Foundation, U.S. Military Veterans with Parkinson's (USMVP), Team Parkinson, Parkinson's Focus Today, Middle Tennessee Chapter of the American Parkinson Disease Association, Froedtert & The Medical College of Wisconsin, and the National Organization of Veterans' Advocates, as well as from individuals. Those comments, which have been grouped by category, are addressed below.

VA also received numerous comments from veterans and surviving spouses regarding their individual claims for veterans' benefits. We do not respond to these comments in this notice as they are beyond the scope of this rulemaking.

A. Comments Concerning the Effective Date

VA received more than 20 comments concerning the effective date of the regulation. Comments included suggestions that this rule should be effective on the date the Secretary announced his decision to establish the new presumptives or on the date an eligible veteran incurred one of the presumptive diseases. Other commenters stated that the rule should be effective when an eligible veteran was diagnosed with a presumptive disease, rather than when the veteran submitted a claim for compensation.

VA Response: The proposed rule did not state when this regulation will be effective. The final rule makes clear that the effective date of this rule is the date of publication in the **Federal Register**. This is consistent with the terms of section 1116, title 38, United States Code (U.S.C.), which provides detailed instructions as to promulgation of regulations relating to presumptions of service connection for diseases associated with herbicide agents, including the effective date for such rules. The statute prescribes that when the Secretary determines that such a presumption is warranted, the Secretary "shall issue proposed regulations setting forth [the] determination." 38 U.S.C. 1116(c)(1)(A). The Secretary must then "issue final regulations" which "shall be effective on the date of issuance." 38 U.S.C. 1116(c)(2). Many of the comments received about the effective date of the regulation encouraged VA to establish an effective date earlier than the date of issuance of the final rule for equitable reasons. These comments include statements that it would be more appropriate to compensate veterans back to when the newly established presumptive disease was diagnosed or when they became disabled. Other commenters stated that veterans who filed claims years ago that had little chance of being granted will now receive large retroactive awards but those who did not file such claims will be penalized for not filing such claims. As the governing statute mandates that the effective date of the new regulation be the date of issuance of the final rule the Secretary of Veterans Affairs has no discretion to set an effective date for the new presumptions earlier than the date the final regulation is issued.

Significantly, however, VA may pay benefits for periods prior to the rule's effective date in certain circumstances which are set forth in detail in 38 CFR 3.816(c) and (d). These provisions, which implement a stipulation and various court orders in the *Nehmer* class action litigation, pertain to claims where VA previously denied benefits or VA received a claim for benefits for a newly added condition between September 25, 1985, and the date VA publishes the final regulation adding the new condition to the list of diseases presumptively associated with exposure to herbicides used in Vietnam.

As set forth in 38 CFR 3.816(c) and (d), the effective date for such claims is the *later* of the date VA received the above described claim or the date the disability arose. As a result, effective dates for benefits earlier than the date the final regulation is issued may be assigned in cases governed by the *Nehmer* litigation. This means that in many cases veterans and their dependents who filed claims prior to the issuance of the final rule will be awarded retroactive benefits to the date the claim was filed. However, even in *Nehmer* cases there is no basis for a retroactive award of benefits based solely upon the date a condition was incurred or diagnosed, or when the veterans became disabled. Under 38 U.S.C. 5110(a), VA generally may not pay benefits for any period prior to the date it receives an application for those benefits.

We recognize the concern stated by some commenters that the retroactive payments authorized under *Nehmer* do not extend to persons who refrained from filing prior claims that they reasonably believed would not have been granted at that time. As explained above, however, VA generally cannot pay benefits prior to the date of a claim for benefits. Ordinarily, when VA establishes a new presumption of service connection, it cannot pay retroactive benefits for any period before the new presumption takes effect, due to the operation of 38 U.S.C. 5110(g). The *Nehmer* court orders create a limited exception to that statutory rule for cases where a *Nehmer* class member filed a claim before the new rule took effect. VA does not have authority to further expand that judicial exception in a manner that would conflict with the governing statutes.

B. Comments Regarding the Addition of Parkinson's Disease to VA's List of Presumptive Diseases

VA received nearly 400 comments in favor of the proposed regulation from individuals and organizations that, for various reasons, support the addition of Parkinson's disease to VA's regulation listing diseases that are presumptively service connected based upon exposure to herbicides used in Vietnam. Many of these comments also suggest that VA clarify its definition of Parkinson's disease, to include diseases of Parkinsonism (primary, atypical, and secondary Parkinson's diseases) and secondary Parkinsonism syndromes, as well as other Parkinsonian disorders.

VA Response: Update 2008 only evaluated the correlation between certain herbicide exposure and Parkinson's disease. Parkinsonism, and other similar diseases, is not the same disease as Parkinson's disease. According to Update 2008,

> PD [Parkinson's Disease] must be distinguished from a variety of parkinsonian syndromes, including drug-induced parkinsonism and neurodegenerative diseases, such as multiple systems atrophy, which have parkinsonian features combined with other abnormalities * * * Pathologic findings in other causes of parkinsonism show different patterns of brain injury [than with PD].

Institute of Medicine of the National Academies, *Veterans and Agent Orange: Update 2008,* The National Academies Press (Washington, DC, 2009), pp. 515–16; available online at *http://www.nap.edu/openbook.php?record_id=12662&page=515* (accessed May 19, 2010).

VA greatly appreciates the outpouring of support of the proposed regulation by individuals affected by Parkinson's disease and organizations that advocate on behalf of the Parkinson's community. VA is not, however, able to revise the definition of Parkinson's disease to include Parkinsonism within this presumptive category. We understand that there are differing views in the

medical community concerning the clinical and pathological features of Parkinson's disease and other diseases that manifest similar symptoms. In VA's view, medical evidence, as described in Update 2008, simply does not support the expansion of the definition to include Parkinsonism and/or Parkinsonian syndromes and/or similar conditions at this time. If the Institute of Medicine (IOM) provides additional guidance regarding Parkinsonism, secondary Parkinsonian disorders, Parkinsonian syndromes or other similar conditions, and/or the synergistic effects of exposure to a combination of herbicides in future reports, VA will, of course, consider that guidance in assessing whether additional presumptive diseases should be added and/or whether its regulatory definitions should be revised. As acknowledged by the IOM in Update 2008, "the preponderance of epidemiologic evidence now supports an association between herbicide exposure and PD." The IOM, however, also expressed concerns about the "lack of data relating PD incidence to exposure in the Vietnam-Veteran population" and "recommend[ed] strongly that studies to produce such data be performed." To that end, the IOM stated "we are also concerned that a biologic mechanism by which the chemicals of interest may cause PD has not been demonstrated."

Institute of Medicine of the National Academies, *Veterans and Agent Orange: Update 2008,* The National Academies Press (Washington DC, 2009), pp. 526–27; available online at *http://www.nap.edu/openbook.php?record_id=12662&page=526* (accessed June 15, 2010).

Expansion of VA's definition beyond Parkinson's disease is not warranted under such circumstances, particularly in light of the IOM's findings quoted above that "PD must be distinguished from a variety of [P]arkinsonian syndromes." Accordingly, VA makes no change based on comments requesting a broader and/or more inclusive regulatory definition of Parkinson's disease.

Included in the comments received concerning the addition of Parkinson's disease to VA's list of presumptive conditions were comments suggesting that VA make various improvements regarding procedures and services provided to veterans with Parkinson's disease and their caregivers. These suggestions, which range from conducting additional research and studies regarding Parkinson's disease and other similar conditions to revising the VA Schedule for Rating Disabilities, are beyond the scope of this rulemaking and will not be addressed.

C. Comments Concerning VA's Definition of Ischemic Heart Disease (IHD)

(1) Lack of Reference to ICD–9–CM Medical Terminology and Codes

One commenter expressed concern that VA regulations do not include any references to The International Classification of Diseases, 9th Revision, Clinical Modification, Sixth Edition (ICD–9 CM) codes in addition to the cited definition of IHD from *Harrison's Principles of Internal Medicine* (Harrison's Online, Chapter 237, Ischemic Heart Disease, 2008). The commenter is concerned that a VA employee reviewing a claim for disability would be "limited to the narrow and probably not extensive enough scope of representative criteria provided by the VA's definition."

VA Response: VA believes that the definition of IHD in the proposed rule and the clarifying description in the preamble to the proposed rule are actually more accommodating to appropriate ratings determinations than ICD–9–CM because the description of IHD contained in the proposed rule is not restricted to a finite list of diagnoses as would be the case if ICD–9–CM codes were employed. To this end, for purposes of establishing service connection VA interprets IHD, as referred to in the regulation, as encompassing any atherosclerotic heart disease resulting in clinically significant ischemia or requiring coronary revascularization.

VA views ICD–9–CM as a reference tool "used to code and classify morbidity data from the inpatient and outpatient records, physician offices, and most National Center for Health Statistics (NCHS) surveys." Centers for Disease Control and Prevention, *ICD—Classification of Diseases, Functioning, and Disability,* available at *http://www.cdc.gov/nchs/icd.htm* (accessed May 13, 2010). It serves as a standardized listing of diseases designed to facilitate effective communication between medical personnel. It does not contain any descriptive definition of IHD; therefore, it does not provide any additional assistance to either VA employees or veterans in understanding what constitutes IHD or what criteria must be used in making a medical diagnosis of such.

Consequently, VA chose to base its definition of Ischemic Heart disease upon the definition contained in a leading medical treatise, *Harrison's Principles of Internal Medicine,* and does not believe it is necessary to revise that definition to include ICD–9–CM references. VA makes no change based on this comment.

(2) Exclusion of Diseases That Do Not Result in Oxygen Deficiency in the Heart

Three commenters expressed a desire for VA to expand the definition of IHD to include diseases (such as hypertension, peripheral arterial disease, and stroke) that are potentially secondarily connected to IHD.

VA Response: In the preamble to the proposed rule, VA, citing *Harrison's Principles of Internal Medicine*—a respected and universally recognized reference in the medical community, clarified and explained the definition of IHD as "an inadequate supply of blood and oxygen to a portion of the myocardium; it typically occurs when there is an imbalance between myocardial oxygen supply and demand." 75 FR 14393; *See Harrison's Principles of Internal Medicine* (Harrison's Online, Chapter 237, Ischemic Heart Disease, 2008). This definition is limited to conditions that directly affect the myocardium. "Myocardium" is defined as "the middle muscular layer of the heart wall." Merriam-Webster Dictionary Online, "Myocardium" available at *http://www.merriam-webster.com/dictionary/myocardium* (accessed May 13, 2010). Therefore, based on the definition found in *Harrison's,* IHD pertains only to conditions that directly affect the muscles of the heart. The accepted medical definition of IHD does not extend to other conditions, such as hypertension, peripheral artery disease, and stroke, that do not directly affect the muscles of the heart. As a result, VA will not include these conditions within the definition of IHD contained in this rulemaking.

Additionally, this definition and limitation are consistent with the definition of IHD used by the IOM in Update 2008. IOM limited its consideration of IHD studies to ICD–9–CM codes 410–414. These codes explicitly exclude such disease as hypertension, which has its own unique code (402) in ICD–9–CM. The selection of these particular ICD–9–CM codes shows that IOM chose to limit its consideration of IHD to only those diseases that affect the muscles of the heart. Hence, the definition of IHD used by IOM in Update 2008 confirms the medical soundness of VA's definition, and makes clear that the medical evidence on which VA based its decision relates only to those conditions directly affecting the oxygen supply in

the muscles of the heart and does not encompass such conditions as hypertension. Therefore, VA makes no change based on these comments.

Two of these commenters would also have VA allow excluded conditions to be rated as secondarily caused by IHD.

VA Response: The presumptive conditions addressed in this rulemaking only concern establishment of a primary service-connected condition. This rulemaking does not affect a claimant's ability to establish secondary conditions proximately caused by a service-connected condition, including those conditions for which service connection is established presumptively. Section 3.310, title 38, Code of Federal Regulations, states that any disability which is proximately due to or the result of a service-connected disease or injury shall be service connected. This principle has not changed and there is no need to reiterate it in this rule. Therefore, VA makes no change based on these comments.

(3) Perceived Uncertainty Concerning the Definition of IHD

One commenter queried "what is ischemic heart disease"?

VA Response: VA's definition of IHD in the proposed rule is based upon the accepted medical premise that, as stated in the preamble, IHD is "an inadequate supply of blood and oxygen to a portion of the myocardium; it typically occurs when there is an imbalance between myocardial oxygen supply and demand." 75 FR 14393; *See Harrison's Principles of Internal Medicine* (Harrison's Online, Chapter 237, Ischemic Heart Disease, 2008). As previously stated, VA interprets IHD, for purposes of service connection, to encompass any atherosclerotic heart disease resulting in clinically significant ischemia or requiring coronary revascularization. In the notice of proposed rulemaking, we explained that the term "ischemic heart disease" does not encompass hypertension or peripheral manifestations of arteriosclerotic heart disease, such as peripheral vascular disease or stroke. To ensure that lay readers are aware of the distinction between these diseases, we are adding a Note 3 following 38 CFR 3.309(e) to include the information stated in the notice of proposed rulemaking.

(4) Inclusion of Angina as a Compensable Disability

One commenter asked whether the rule will include Prinzmetal's Angina, and Stable and Unstable Angina in the list of compensable disabilities.

VA Response: Prinzmetal's Angina, and Stable and Unstable Angina are explicitly included as forms of IHD in the list of illnesses that may be presumptively service connected due to exposure to certain herbicides. 75 FR 14393.

D. Comments Concerning the Scope of Applicability of the Presumptions

(1) Expanding the Presumption of Herbicide Exposure Beyond Service in the Republic of Vietnam

Approximately ten commenters advocated expanding coverage geographically, to include veterans who did not deploy within the land borders of the Republic of Vietnam, but may have been exposed to tactical herbicides in the course of their military service. For example, one commenter, the Vietnam Veterans of America (VVA), cited Update 2008 in support of its recommendation that VA adopt a presumption that veterans who served in the South China Sea during the Vietnam era were exposed to herbicides. Another commenter encouraged amending 38 CFR 3.307(a)(6)(iii), to include "Blue Water Navy Veterans" as qualifying for the presumptions listed in 38 CFR 3.309(e).

VA Response: These comments are beyond the scope of this rulemaking. We proposed to revise 38 CFR 3.309(e) to implement the requirements of 38 U.S.C. 1116(b) and (c) directing the Secretary of Veterans Affairs to determine whether there is a positive association between exposure to the herbicides used in Vietnam and the occurrence of specific diseases. The issue of which diseases are associated with herbicide exposure is distinct from the issue of which individuals are presumed to have been exposed to herbicides in service. The latter issue is governed by a separate regulation in 38 CFR 3.307(a)(6)(iii), which we did not propose to revise in this rulemaking. Accordingly, we make no change based on these comments.

With respect to the issues raised by these comments, we note that, in a separate rulemaking (RIN 2900–AN27, Herbicide Exposure and Veterans With Covered Service in Korea), VA has proposed to provide a presumption of exposure to tactical herbicides for veterans who served with specific military units stationed at or near the Korean DMZ during the April 1968—July 1969 time frame. 74 FR 36640. We note further that, at VA's request, the NAS is undertaking a comprehensive study of the potential herbicide exposure among veterans who served in the offshore waters around Vietnam and VA will carefully evaluate the findings of the NAS resulting from that study. Finally, we wish to make clear that the presumptions of service connection provided by this rule will apply to any veteran who was exposed during service to the herbicides used in Vietnam, even if exposure occurred outside of Vietnam. A veteran who is not presumed to have been exposed to herbicides, but who is shown by evidence to have been exposed, is eligible for the presumption of service connection for the diseases listed in § 3.309(e), including the three diseases added by this rule.

(2) Expanding the Presumptions To Include Other Herbicides

Other commenters, including USMVP, seek to persuade VA to presume service connection for veterans exposed to trichloroethylene (TCE) (a substance found in organic solvents) and malathion (an insecticide). USMVP concedes that TCE and malathion are differently formulated chemical compounds used for pest control and equipment maintenance, respectively. Nevertheless, USMVP contends that VA's mandate is sufficiently broad to allow the Secretary to presume diseases to be service connected upon exposure to TCE and Malathion.

VA Response: These comments are beyond the scope of this rulemaking. We proposed to revise 38 CFR 3.309(e) to implement the requirements of 38 U.S.C. 1116(b) and (c) directing the Secretary of Veterans Affairs to determine whether there is a positive association between exposure to the herbicides used in Vietnam and the occurrence of specific diseases. The comments concerning the health effects of other types of exposures are distinct from the scope and purpose of the proposed rule.

USMVP notes that section 6 of the Agent Orange Act of 1991 directed VA to compile data that is likely to be scientifically useful in determining the association, if any, between disabilities and exposure to toxic substances including, but not limited to, dioxin. This rulemaking, however, is based on the distinct provisions in section 2 of the Agent Orange Act, codified in pertinent part at 38 U.S.C. 1116, requiring VA to determine whether diseases are associated with an "herbicide agent," which is defined to refer to "a chemical in an herbicide used in support of the United States and allied military operations in the Republic of Vietnam during the period beginning on January 9, 1962, and ending on May 7, 1975." 38 U.S.C. 1116(a)(3). Accordingly, VA's regulation

that implements 38 U.S.C. 1116(a)(3), 38 CFR 3.307(a)(6)(i), defines herbicide agents specifically: "2,4–D; 2,4,5–T and its contaminant TCDD; cacodylic acid; and picloram." Therefore, VA makes no changes based on these comments.

(3) Secondary Service Connection Explicitly Listed in Regulation

Some commenters suggest that the proposed regulation should include secondary conditions that result from disabilities presumptively service connected due to certain herbicide exposure. The commenters note that VA published a proposed rule establishing presumptive service connection for nine specific infectious diseases associated with military service in the Southwest Asia theater of operations and that the proposed rule listed secondary conditions potentially caused by those infectious diseases. 75 FR 13051–13058 (March 18, 2010). Furthermore, the commenters stated that when VA grants service connection for a primary disease, all secondary conditions proximately caused by that disease are also service connected. 38 CFR 3.310.

VA Response: VA's proposed rule to establish presumptive service connection for nine specific infectious diseases associated with military service in the Southwest Asia theater of operations was based, in part, on the report issued by the National Academy of Sciences (NAS) entitled "Gulf War and Health Volume 5: Infectious Diseases," which reported on the association between primary infectious disease and secondary health effects as a result of service in the Southwest Asia theater of operations. This report differed from previous NAS reports in that it implicated two tiers of possible association between a hazard and resulting health outcomes. In particular, NAS made comprehensive findings as to the conditions that may be secondarily caused by the primary infectious diseases, and VA determined that it would be helpful to include those findings in its rules. In contrast, the NAS reports on Agent Orange address only one tier of possible association between exposure to herbicides and the development of long-term health effects. In view of the divergent structure of the two studies and the absence of findings in Update 2008 regarding secondary health effects, VA did not propose to list secondary health effects in this rule. Although it may be feasible to identify and list known secondary effects of the three diseases covered in this rule, doing so is beyond the scope of this rule and, moreover, is not necessary to ensure that veterans are properly compensated for such secondary effects.

As the commenters correctly note, pursuant to 38 CFR 3.310, when VA grants service connection for a condition, all conditions proximately caused by that condition may also be service connected. This principle would apply to conditions where service connection is established by presumption or by other means, such as a direct link to incurrence during military service.

Consequently, VA makes no change based on these comments.

E. Negative Comment

Only one comment indicated clear opposition to the final rule. The commenter asserted that "[t]he proposed rule for presumptive conditions to Agent Orange exposure * * * is ridiculous. Just because gen[e]tic and life style illness are now affecting those of an age that served in Vietnam, does not mean that their service in Vietnam caused this." The commenter went on to ask "No medical expert links these diseases to Agent Orange exposure why should the VA?"

VA Response: First we note that the comment only pertains to the addition of ischemic heart disease to VA's presumptive list. It does not express any opposition to the addition of Parkinson's disease or B-cell Leukemias to VA's presumptive list.

VA's decision to add ischemic heart disease to the list of diseases that are presumptively service connected based upon exposure to herbicides used in Vietnam was issued after the Secretary considered the IOM's Update 2008, concerning the health effects in Vietnam Veterans of exposure to herbicides. That report states as follows:

> After consideration of the relative strengths and weaknesses of the evidence regarding the chemicals of interest and ischemic heart disease (ICD 410–414), which includes a number of studies that showed a strong dose-response relationship and that had good toxicologic data demonstrating biologic plausibility, the committee judged that the evidence was adequately informative to advance this health outcome from the "inadequate or insufficient" category into the "limited or suggestive" category, again acknowledging that bias and confounding could not be ruled out. (Page 631 of Update 2008) [1]

The IOM report's discussion demonstrates that there are medical studies that show a correlation between exposure to herbicides and ischemic heart disease. As we explained in the notice of proposed rulemaking, the IOM committee found that, of the nine most informative studies on this issue, five showed strong statistically significant associations between herbicide exposure and IHD. The IOM committee noted that the evidence for an association was further strengthened by findings of a dose-response relationship, meaning that the risk of IHD was found to be highest in populations with the highest levels of herbicide exposure. As stated in the notice of proposed rulemaking, the Secretary has determined that this evidence meets the standard in 38 U.S.C. 1116 for finding a "positive association" between herbicide exposure and IHD. The Secretary considers the analysis in the IOM report to provide sufficient scientific basis to conclude that ischemic heart disease merited inclusion on VA's list of presumptive diseases. It is important to note that 38 U.S.C. 1116 directs VA to establish a presumption if the credible evidence for an association between herbicide exposure and a disease is equal to or outweighs the credible evidence against the association. This evidentiary standard does not require the same level of proof that members of the scientific community might require before concluding that the disease is necessarily associated with herbicide exposure. The Secretary has determined that this decision is consistent with the standard of proof established by statute, and VA has no authority to change that statutory standard. Accordingly VA makes no changes based on this comment.

F. Comments Indicating General Support of the Rulemaking

In addition to the nearly 400 comments received from the Parkinson's community expressing support for the addition of Parkinson's disease to VA's presumptive list, VA received just over 100 additional comments that expressed support for the rulemaking in general. Many of these comments, which were received from individuals as well as public and private organizations, stated appreciation for VA's actions in adding one or more of the three diseases to its regulatory list of conditions that are presumptively service connected based upon herbicide exposure in Vietnam. VA appreciates the time and effort expended by these commenters in reviewing the proposed rule and in submitting comments, as well as their support for this rulemaking.

[1] Institute of Medicine of the National Academies, *Veterans and Agent Orange: Update 2008.* The National Academies Press (Washington DC, 2009); available online at *http://www.nap.edu/openbook.php?record_id=12662&page=515* (accessed May 25, 2010).

G. Additional Comments Outside the Scope of This Rulemaking

(1) Comments Related to VA's Cost Estimate and Assignment of Disability Ratings.

VA received 25 comments from organizations and members of the public concerning the assumptions stated in VA's budget estimates that: (1) The average disability rating for Parkinson's disease will be 100 percent; (2) the average disability rating for IHD will be 60 percent; and (3) the average disability rating for leukemia will be 100 percent. Many of these comments construed these cost estimates as an expression of VA policy concerning the assignment of particular disability thresholds for each of the new presumptive conditions. Some of the comments urged VA to assign 100 percent evaluations for each of the three diseases.

VA Response: The proposed rule contained cost estimate assumptions based on VA data which indicated that VA assumed the average disability evaluation for Parkinson's disease and leukemia to be 100 percent and for IHD to be 60 percent. VA would like to clarify that these assumptions are merely estimates and were made based on VA program experience. They are used for cost estimate purposes only, and they have no binding effect on any particular disability rating actually assigned. The fact that VA projects, for cost purposes, that particular disabilities will result in a particular average impairment, does not indicate the existence of a minimum level of disability compensation for any of the three new presumptive conditions. The disability rating assigned will be based on the individual factual situations and, in the case of Parkinson's disease and hairy cell leukemias, individual ratings may be less than 100 percent. Similarly, individual ratings for IHD may be greater, less, or equal to 60 percent. Indeed VA anticipates that some disabilities which are granted presumptive service connection will be assigned non-compensable ratings. This would occur, for example, if an individual was diagnosed with a disease, IHD for example, but manifested no current disabling symptoms.

The disability ratings to be assigned for any disease or injury are based upon application of VA's Schedule for Rating Disabilities in 38 CFR Part 4 to the facts of each case. VA did not propose in this rulemaking to revise any of the provisions in that schedule. As explained above, the assumptions stated for purposes of VA's cost estimate did not propose to adopt specific minimum ratings or to make any change to the rating schedule. To the extent these comments suggest adoption of minimum disability ratings they are outside the scope of this rulemaking. Accordingly, VA makes no changes based on these comments.

(2) Perceived Nehmer Contradiction

One commenter expressed concern that the statement in the preamble of the proposed rule at 75 FR at 14394 that retroactive benefit costs are paid in the first year only conflicts with the decision in the *Nehmer* case. The stated concern appears to be that paying retroactive benefits in the first year only may limit retroactive payments authorized by the *Nehmer* court orders.

VA Response: The commenter's reference pertains to the Preamble and cost estimate assumptions, which, as stated above, were used for cost estimating purposes only and will have no binding effect upon claims involving retroactive benefits under the proposed rule. Because this comment relates to a factual assumption in VA's cost analysis, which does not affect the scope of the final rule, the comment has no bearing on the final rule.

We want to make clear, however, that nothing in this rule would contravene or limit the *Nehmer* court orders. When retroactive benefits are paid as a result of a claim that qualifies under the *Nehmer* litigation, the award is paid from current year appropriations and that VA's cost estimates for this regulation include first year, five year, and ten year costs. The statement in VA's cost estimate that retroactive benefits are paid in the first year only is intended merely to reflect that VA expects to process all claims involving retroactive payments for the new presumptions under *Nehmer* within the first year after this rule is issued. Accordingly, VA makes no changes based on these comments.

(3) Statements About Personal Situations and Hypothetical Benefit Questions

Many commenters made general statements about their own personal difficulties battling one or more of the presumptive diseases. Another commenter inquired as to the possible implications of *Bradley* v. *Peake,* 22 Vet. App. 280 (2008). The commenters who inquired about *Bradley* asked whether, hypothetically, an IHD disability rating in addition to another disability that meet the statutory criteria under 38 U.S.C. 1114(s), could potentially establish eligibility for special monthly compensation.

VA Response: Comments regarding hypothetical situations involving the possible outcome of benefit claims or the medical or claims history presented by individual veterans are beyond the scope of this rulemaking. Claimants should contact their VA regional office for assistance with their individual claims.

(4) Comments Unrelated to the Subject of the Rulemaking

VA received approximately 40 comments dealing with issues not directly related to the addition of the three new presumptively service-connected diseases. Such comments covered a wide range of topics. Examples of such comments appear below.

One commenter opined that spouses of veterans should be compensated. One commenter stated that more should be done for caregivers of veterans. Another commenter suggested that VA should guide the military services on presumptives related to Agent Orange. Some commenters complained that the rulemaking process is too lengthy. Two commenters disapproved of the fact that herbicides were allowed to be used during conflict. Several commenters criticized the benefit claims system, including the VA's Schedule for Rating Disabilities. One commenter stated that 38 CFR 3.816 (*Nehmer* Awards) should be revised to list the three new presumptions. A commenter recommended that a working group be created to define needed research and studies on diseases and Vietnam veterans. One commenter questioned whether there is a relationship between PTSD or stress and cardiovascular disease. Another commenter wanted VA to give greater weight to finding of total disability by the Social Security Administration. A commenter requested special guidance for compensation and pension examinations to ensure comprehensive evaluation of cognitive and dementia issues related to Parkinson's disease; another commenter similarly requested an update in rating templates for Parkinson's disease. A commenter wanted VA to provide guidance to the Department of Defense concerning the new presumptive conditions. Another commenter indicated disagreement with the findings and conclusion included in Update 2008. Some commenters expressed dissatisfaction with the note in the current regulation regarding requirements for peripheral neuropathy.

VA Response: VA does not respond to these comments because they are either unrelated to this rulemaking or beyond its scope.

Paperwork Reduction Act

The collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521) that is contained in this document is authorized under OMB Control No. 2900–0001.

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.

VA has examined the economic, interagency, budgetary, legal, and policy implications of this rulemaking and determined that it is an economically significant rule under this Executive Order, because it will have an annual effect on the economy of $100 million or more.

Regulatory Impact Analysis

VA followed OMB Circular A–4 to the extent feasible in this Regulatory Impact Analysis. The circular first calls for a discussion of the Statement of Need for the regulation. The Agent Orange Act of 1991, as codified at 38 U.S.C. 1116 requires the Secretary of Veterans Affairs to publish regulations establishing a presumption of service connection for those diseases determined to have a positive association with herbicide exposure in humans.

Statement of Need: On October 13th, 2009, the Secretary of Veterans Affairs, Eric K. Shinseki, announced his intent to establish presumptions of service connection for PD, IHD, and hairy cell/B cell leukemia for veterans who were exposed to herbicides used in the Republic of Vietnam during the Vietnam era.

Summary of the Legal Basis: This rulemaking is necessary because the Agent Orange Act of 1991 requires the Secretary to promulgate regulations establishing a presumption of service connection once he finds a positive association between exposure to herbicides used in the Republic of Vietnam during the Vietnam era and the subsequent development of any particular disease. This final rulemaking is required by statute and the result of the Secretary's discharge of his statutory mandate pursuant to the statute.

Alternatives: There are no feasible alternatives to this rulemaking, since the Agent Orange Act of 1991 requires the Secretary to initiate rulemaking once the Secretary finds a positive association between a disease and herbicide exposure in Vietnam during the Vietnam era. The rule implements statutorily required provisions to expand veteran benefits.

Risks: The rule implements statutorily required provisions to expand veteran benefits. No risk to the public exists.

Anticipated Costs and Benefits: In the proposed rule, we estimated the total cost for this rulemaking to be $13.6 billion during the first year (FY2010), $25.3 billion for 5 years, and $42.2 billion over 10 years. These amounts included benefits costs and government operating expenses for both Veterans Benefits Administration (VBA) and Veterans Health Administration (VHA). A detailed cost analysis for each Administration is provided below.

The proposed rule indicated costs beginning in FY2010. At the time the proposed rule impact analysis was developed, VA anticipated the final rulemaking would be published more than 60 days before the end of FY2010, including allowing time for the 60 day requirement under the CRA, and therefore payments would commence in FY2010. VA now knows that the timing of the final rulemaking will not allow payments to begin prior to FY2011. As a result, VA expects FY2010 and FY2011 costs, as shown in some of the tables below from the proposed rule, will both now occur in FY2011. We have not recalculated the tables to reflect this change.

Veterans Benefits Administration (VBA) Costs

We estimated VBA's total cost to be $13.4 billion during the first year (FY2010), $24.3 billion for five years, and $39.7 billion over ten years.

Benefits costs ($000's)	1st year (FY10)	5-year	10-year
Retroactive benefits costs *	$12,286,048	** $12,286,048	** $12,286,048
Recurring costs from retroactive processing	0	4,388,773	10,300,132
Increased benefits costs for Veterans currently on the rolls	415,927	2,188,784	4,864,755
Accessions	675,214	4,645,609	11,330,294
Administrative Costs	.....	.....	.....
FTE costs	*** 4,554	797,473	894,614
New office space (minor construction)	.....	12,835	12,835
IT equipment	.....	30,232	32,805
Totals	13,381,743	24,349,746	39,721,476

* Retroactive benefits costs are paid in the first year only.
** Inserted for cumulative totals.
*** FTE costs in FY 2010 represented a level of effort of current FTE that would be used to work claims received in FY2010. New hiring would begin in 2011.

Of the total VBA benefits costs identified for FY 2010, $12.3 billion accounted for retroactive benefit payments. Ten-year total costs for ischemic heart disease is $31.9 billion, Parkinson's disease accounts for $3.5 billion, and hairy cell and B-cell leukemia is the remaining $3.4 billion.

TOTAL OBLIGATIONS BY PRESUMPTIVE CONDITION

($000's)	Retroactive payments	1st year	5-year	10-year
Ischemic heart disease	$9,877,787	$900,470	$9,307,716	$21,978,301
Parkinson's	692,20	166,300	1,189,143	2,796,852
Hairy cell/B-cell leukemia	1,716,057	24,372	726,306	1,720,028
Sub-total	12,286,048	1,091,142	11,223,165	26,495,181
Total	12,286,048	*13,377,190	*23,509,213	*38,781,229

*Includes retroactive payments.

Methodology

The cost estimate for the three presumptive conditions considers retroactive benefit payments for veterans and survivors, increases for veterans currently on the compensation rolls, and potential accessions for veterans and survivors. There are numerous assumptions made for the purposes of this cost estimate. At a minimum, four of those could vary considerably and the result could be dramatic increases or decreases to the mandatory benefit numbers provided. The estimate assumes:

- A prevalence rate of 5.6% for IHD based upon information extracted from the CDC's Web site. Even slight variations to this number will result in significant changes.
- An 80% application rate in most instances. We have prior experiences that have been as low as in the 70% range and as high as in the 90% range.
- New enrollees will, on average, be determined to have about a 60% degree of disability for IHD. This would mirror the degree of disability for the current Vietnam Veteran population on VA's rolls. However, most of the individuals have had the benefit of VHA health care. We cannot be certain that the new population of Vietnam Veterans coming into the system will mirror that average.
- Only the benefit costs of the presumptive conditions listed. Secondary conditions, particularly to IHD, may manifest themselves and result in even higher degrees of disability ultimately being granted.

Retroactive Veteran and Survivor Payments

Vietnam Veterans Previously Denied

In 2010, approximately, 86,069 Vietnam beneficiaries (as of August 2009 provided by PA&I) are eligible to receive retroactive payments for the new presumptive conditions under the provisions of 38 CFR 3.816 (Nehmer). Of this total, 69,957 are living Vietnam Veterans, of which 62,206 were denied for IHD, 5,441 were denied for hairy cell or B cell leukemia, and the remaining 2,310 for Parkinson's disease. Of those previously denied service connection for the three new presumptive conditions, 52,918, or nearly 76 percent, are currently on the rolls for other service-connected disabilities.

Compensation and Pension (C&P) Service assumes the average degree of disability for both Parkinson's disease and hairy cell/B cell leukemia will be 100 percent, and IHD will be 60 percent. Based on the Combined Rating Table, we assume veterans currently not on the rolls would access at the percentages identified above. For those veterans currently on the rolls for other service-connected disabilities, we assume they would receive a retroactive award based on the higher combined disability rating. For example, a veteran who is on the rolls and rated 10 percent disabled who establishes presumptive service connection for Parkinson's disease will result in a higher combined rating of 100 percent and receive a retroactive award for the difference. For purposes of this cost estimate, we assumed that veterans previously denied service connection for one of the three new conditions who are currently receiving benefits were awarded benefits for another disability concurrently.

Based on the Nehmer case review in conjunction with the August 2006 Haas Court of Appeals for Veterans Claims (CAVC) decision, C&P Service identified an average retroactive payment of 11.38 years for veterans whose claims were previously denied. Obligations for retroactive payments for veterans not currently on the rolls were calculated by applying the caseload to the benefit payments by degree of disability, multiplied by the average number of years for veterans' claims. For those who are on the rolls, based on a distribution by degree of disability, obligations were calculated by applying the increased combined degree of disability for those currently rated zero to ninety percent. Of the total 52,918 currently on the rolls, 8,348 are currently rated 100 percent disabled and, therefore, would not likely receive a retroactive award payment.

Of the total 86,069 Vietnam beneficiaries, a total of 69,957 are living Vietnam Veterans. Of this total, 52,918 are currently on the rolls for other service-connected disabilities and 17,039 are off the compensation rolls (52,918 + 17,039 = 69,957). Of the 52,918 Vietnam Veterans who are on the rolls, 8,348 are currently rated 100 percent disabled and would not likely receive a retroactive payment (17,039–8,348 = 8,691 + 52,918 = 61,609).

VETERAN CASELOAD AND OBLIGATIONS FOR RETROACTIVE BENEFITS

Presumptive conditions	Caseload	Retroactive payments ($000's)
Ischemic Heart Disease	54,926	$7,837,369
Parkinson's Disease	2,042	568,920
Hairy Cell/B Cell Leukemia	4,641	1,209,586
Total	61,609	9,615,875

Vietnam Veteran Survivors Previously Denied

Survivor caseload was determined based on veteran terminations. Based on data obtained from PA&I, of the 86,069 previous denials, 16,112 of the Vietnam veterans are deceased. Of the deceased population, 13,420 were veterans previously denied claims for IHD, 2,165 were denied for hairy cell or B cell leukemia, and 527 were denied for Parkinson's disease. We assumed that 90 percent of the survivor caseload will be new to the rolls and the remaining ten percent are currently in receipt of survivor benefits.

The 2001 National Survey of Veterans found that approximately 75 percent of veterans are married. With the marriage rate applied, we estimate there are 12,084 survivors in 2010. Based on the Nehmer case review in conjunction with the August 2006 Haas Court of Appeals for Veterans Claims (CAVC) decision, C&P Service identified an average retroactive payment of 9.62 years for veterans' survivors. Under Nehmer, in addition to survivor dependency and indemnity compensation (DIC) benefits, survivors are also entitled to the veteran's retroactive benefit payment to the date of the veteran's death. Obligations for survivors who were denied claims were determined by applying the survivor caseload for each presumptive condition to the average survivor compensation benefit payment from the 2010 President's Budget and the average number of years for the survivor's claim (9.62 years). Veteran benefit payments to which survivors are entitled were calculated similarly with the exception of applying the survivor caseload for each presumptive condition to the difference between the average veteran claim of 11.38 years and the average survivor claim of 9.62 years. The estimated remaining 4,028 deceased veterans who were not married would have their retroactive benefit payment applied to their estate.

Of the 86,069 Vietnam beneficiaries, a total of 16,112 are Vietnam Veterans that are deceased. Of this total, an estimated 12,084 were married and an estimated 4,028 were not married (12,084 + 4,028 = 16,112).

SURVIVOR CASELOAD AND OBLIGATIONS FOR RETROACTIVE BENEFITS

Presumptive conditions	Caseload	Retroactive payments ($000's)
Ischemic Heart Disease	13,420	$2,040,418
Parkinson's Disease	527	123,284
Hairy Cell/B Cell Leukemia	2,165	506,470
Total	16,112	2,670,173

Recurring Veteran and Survivor Payments

Retroactive caseload obligations for both veterans and survivors become a recurring cost and are reflected in out-year estimates. Mortality rates are applied in the out years to determine caseload.

RECURRING VETERAN AND SURVIVOR CASELOAD AND OBLIGATIONS FROM RETROACTIVE PROCESSING

FY	Veteran caseload	Survivor caseload	Obligations ($000's)
2010	N/A	N/A	N/A
2011	61,365	10,672	$1,079,310
2012	61,243	10,570	1,084,209
2013	61,121	10,458	1,102,800
2014	61,000	10,336	1,122,454
2015	60,879	10,201	1,142,251
2016	60,758	10,052	1,162,167
2017	60,637	9,891	1,182,189
2018	60,517	9,716	1,202,298
2019	60,397	9,526	1,222,453
Total	.....	.....	10,300,132

Vietnam Veterans (Reopened Claims)

We expected veterans who are currently on the compensation rolls and have any of the three presumptive conditions to file a claim and receive a higher combined disability rating beginning in 2010. We anticipate that veterans receiving compensation for other service-connected conditions will continue to file claims over ten years. Total costs are expected to be $415.9 million the first year and approximately $4.9 billion over ten years.

According to the Defense Manpower Data Center (DMDC), there are 2.6 million in-country Vietnam Veterans. With mortality applied, an estimated 2.1 million will be alive in 2010. C&P Service assumes that 34 percent of this population are service connected for other conditions and are already in receipt of compensation benefits. In 2010, we anticipated that 725,547 Vietnam Veterans would be receiving compensation benefits. This number is further reduced by the number of veterans identified in the previous estimate for retroactive claims (52,918). C&P Service assumes an average age of 63 for all Vietnam Veterans. With prevalence and mortality rates applied, and an estimated 80 percent application rate and 100 percent grant rate, we calculate that 32,606 veterans currently on the rolls would have a presumptive condition in 2010. Of this total, we anticipated 27,909 cases would result in increased obligations. Of the 27,909 veterans, 25,859 are associated with IHD, 1,693 are associated with Parkinson's disease, and the remaining 357 are associated with hairy cell/B cell leukemia. In future years, the estimated

number of veteran reopened claims decreases to almost one thousand cases and continues at a decreasing rate. The cumulative effect of additional cases with mortality rates applied is shown in the chart below.

The Vietnam Era caseload distribution by degree of disability provided by C&P Service was used to further distribute the total Vietnam Veterans who will have a presumptive condition in 2010 by degree of disability for each of the three new presumptive conditions. We assume 100 percent for the average degree of disability for both Parkinson's disease and hairy cell/B cell leukemia and 60 percent for IHD. Based on the Combined Rating Table, veterans that are on the rolls for other service-connected conditions (with the exception of those that are currently receiving compensation benefits for 100 percent disability), would receive a higher combined disability rating if they have any of the three new presumptive conditions.

September average payments from the 2010 President's Budget were used to calculate obligations. These average payments are higher than schedular rates due to adjustments for dependents, Special Monthly Compensation, and Individual Unemployability. The difference in average payments due to higher ratings was calculated, annualized, and applied to the on-rolls caseload to determine increased obligations. Because this particular veteran population is currently in receipt of compensation benefits, survivor caseload and obligations would not be impacted.

REOPENED CASELOAD AND OBLIGATIONS

FY	Veteran caseload	Obligations ($000's)
2010	27,909	$415,927
2011	28,340	418,928
2012	29,051	431,726
2013	29,746	451,042
2014	30,425	471,161
2015	31,086	491,648
2016	31,746	512,767
2017	32,404	534,529
2018	33,061	556,958
2019	33,716	580,070
Total	.....	4,864,755

Vietnam Veteran and Survivor Accessions

We anticipated accessions for both veterans and survivors beginning in 2010 and continuing over ten years. Total costs were expected to be $675.2 million in the first year and total just over $11.3 billion from the cumulative effect of cases accessing the rolls each year.

To identify the number of veteran accessions in 2010, we applied prevalence rates to the anticipated living Vietnam Veteran population of 2,133,962, and reduced the population by those identified in the previous estimates for retroactive and reopened claims. Based on an expected application rate of 80 percent and a 100 percent grant rate, 28,934 accessions are expected. Of the 28,934 veteran accessions, 25,505 are associated with IHD, 3,074 are associated with Parkinson's disease, and the remaining 355 are associated with hairy cell/B cell leukemia. In the out years, anticipated veteran accessions drop to approximately 3,400 cases in 2011, and continue at a decreasing rate. The cumulative effect of additional cases coupled with applying mortality rates is shown in the chart below.

To calculate obligations, the caseload was multiplied by the annualized average payment. We assumed those accessing the rolls due to IHD will be rated 60 percent disabled and those with either Parkinson's disease or hairy cell/B cell leukemia will be rated 100 percent disabled. Average payments were based on the 2010 President's Budget with the Cost of Living Adjustments factored into the out years.

The caseload for survivor compensation is associated with the number of service-connected veterans' deaths. There are two groups to consider for survivor accessions: Those survivors associated with veterans who never filed a claim and died prior to 2010; and survivors associated with the mortality rate applied to the veteran accessions noted above.

To calculate the survivor caseload associated with veterans who never filed a claim and died prior to 2010, general mortality rates were applied to the estimated total Vietnam Veteran population (2.6 million). We estimate that almost 500,000 Vietnam Veterans were deceased by 2010. Prevalence rates for each condition were applied to the total veteran deaths to estimate the number of deaths due to each condition. With the marriage rate and survivor mortality applied, we anticipated 20,961 eligible spouses at the end of 2010. We assumed that half of this population would apply in 2010 and the remaining in 2011. Obligations were calculated by applying average survivor compensation payments to the caseload each year.

The second group of survivors associated with veteran accessions was calculated by applying mortality rates for each of the presumptive conditions to the estimated eligible veteran population (28,934). In 2010, 57 veteran deaths were anticipated as a result of one of the new presumptive conditions. With the marriage rate applied and aging the spouse population (and assuming spouses were the same age as veterans), we calculated 42 spouses at the end of 2010. Average survivor compensation payments were applied to the spouse caseload to determine total obligations.

VETERAN AND SURVIVOR ACCESSIONS CUMULATIVE CASELOAD AND TOTAL OBLIGATIONS

FY	Veteran caseload	Survivor caseload	Total obligations
2010	28,934	10,416	$675,214
2011	32,270	20,265	882,974
2012	35,541	20,693	955,525
2013	38,744	20,487	1,028,467
2014	41,874	20,283	1,103,429
2015	44,928	20,081	1,179,725
2016	47,900	19,881	1,257,259
2017	50,787	19,682	1,335,922
2018	53,583	19,485	1,415,601
2019	56,285	19,290	1,496,178
Total			11,330,294

Estimated Claims From Veterans Not Eligible

Based on program history, we anticipate that we will also receive claims from veterans who will not be eligible for presumptive service connection for the three new conditions.

These claims will be received from two primary populations:

- Veterans with a presumptive disease who did not serve in the Republic of Vietnam.
- Claims from Vietnam Veterans with hypertension who claim "heart disease."

We applied the prevalence rate of IHD, Parkinson's disease and hairy cell/B cell leukemia to the estimated population of veterans who served in Southeast Asia during the Vietnam Era (45,304, 32, and 6 respectively), and assumed that 10 percent of that population will apply for presumptive service connection.

Review of data obtained from PA&I shows that 23 percent of Vietnam Veterans who have been denied entitlement to service connection for hypertension also have nonservice-connected heart disease. We applied the prevalence rate of hypertension to the living Vietnam Veteran population, and then subtracted 23 percent who are assumed to also have IHD. We assumed that 10 percent of the remaining population would apply for presumptive service connection to arrive at an estimated caseload of 111,256.

We then assumed that 25 percent of the ineligible population would apply in 2010, 25 percent would apply in 2011, and the remaining population would apply over the next 8 years. For purposes of claims processing, anticipated claims are as follows. The chart below reflects workload, which is not directly comparable to the preceding caseload charts.

TOTAL CLAIMS

FY	Retroactive claims	Reopened claims	Accessions	Claims not eligible	Total claims
2010	86,069	32,606	39,350	27,814	185,839
2011		1,069	13,806	27,814	42,689
2012		1,051	3,386	6,954	11,391
2013		1,032	3,329	6,954	11,314
2014		1,011	3,267	6,954	11,232
2015		989	3,201	6,954	11,143
2016		989	3,129	6,953	11,071
2017		989	3,053	6,953	10,995
2018		989	2,971	6,953	10,913
2019		989	2,885	6,953	10,827

VBA Administrative Costs

Administrative costs, including minor construction and information technology support were estimated to be $4.6 million during FY2010, $841 million for five years and $940 million over ten years.

C&P Service, along with the Office of Field Operations, estimated the FTE that would be required to process the anticipated claims resulting from the new presumptive conditions using the following assumptions:

1. 185,839 additional claims in addition to the projected 1,146,508 receipts during FY2010. This includes:

- 86,069 retroactive readjudications under Nehmer.
- 89,354 new and reopened claims from veterans.
- 10,416 new claims from survivors.

2. The average number of days to complete all claims in FY2010 would be 165.

3. Priority will be given to those Agent Orange claims that fall in the Nehmer class action.

In FY2010, we intended to leverage the existing C&P workforce to process as many of these new claims as possible, once the regulation was approved, but especially the Nehmer cases. However, to fully accommodate this additional claims volume with as little negative impact as possible on the processing of other claims, we plan to add 1,772 claims processors to be brought on in the FY2011 budget and timeframe. This approximate level of effort will be sustained through 2012 and into 2013 in order to process these claims without significantly degrading the processing of the non-presumptive workload.

- Net administrative costs for payroll, training, additional office space, supplies and equipment were estimated to be $4.6 million in FY2010, $165 million in FY2011, $798 million over five years, and $895 million over 10 years. Additional support costs for minor construction are expected to be $12.8 million over the five and ten year period. Information Technology (computers and support) are assumed to

require $30.2 million over five years and $32.8 million over ten years.

Veterans Health Administration (VHA) Costs

We estimated VHA's total cost to be $236 million during the first year (FY2010), $976 million for five years, and $2.5 billion over ten years.

FY2010 and FY2011 Summary

- FY2010 new enrollee patients are expected to number 8,680.
- FY2011 additional new enrollees are expected to number 1,018.
- FY2010 costs for C&P examinations are expected to be $114M.
- FY2011 costs for C&P examinations are expected to be $23M.
- FY2010 health care costs (inclusive of travel) are expected to be $236M (using cost per patient of 13,500).
- FY2011 health care costs (inclusive of travel) are expected to be $165M (using cost per patient of 14,100).
- Combined costs are as follows:
  - FY2010: $236M.
  - FY2011: $165M.

Assumptions

- 30% of veterans newly determined to be service-connected will enroll and will use VA health care.
- Newly enrolled veterans will be Priority Group 1 veterans.
- The cost per patient is arrived at using the average cost per Priority Group 1 patient aged between 45–64.
- Every VBA case will require a new exam.
- It is assumed that 100% of newly enrolled veterans will request mileage reimbursement. The average amount of mileage reimbursement claims per veteran is $511 (this amount reflects to the FY2009 actual average amount).

We note that many assumptions, which form the foundation for an agency's cost forecasts, seldom prove to be completely accurate due to variables over which VA has no control, such as application rates, veteran Priority Group designation, diagnostic examinations in the future, or changes in incidence rates. For example, we assumed that all newly enrolled veterans would be in Priority Group 1. If we were to assume that a substantial number of these new enrollees would be in Priority Group 2, the cost estimate could decrease significantly.

Distribution of Disability Claims

VBA has established estimates for claims workload for veterans. Figure 1 provides breakdown of disability claims.

Overall, VBA anticipates 69,957 claims. Of these, 17,039 will be for veterans whose previous claims for disability compensation were denied. Additionally, VBA anticipates reopened claim volume of 32,606 claims in FY2010 with subsequent decreases to 1,069 per year in FY2011. VBA anticipates 28,934 accessions in FY2010. These are new disability compensation awards—for veterans who did not previously have an award for service connected disability compensation. Additionally, in FY2010 VBA anticipates disability claim volume associated with the presumptive SC determination to be 159,311 and to exceed 270,000 through FY2019.

FIGURE 1

FY	Retroactive claims	Retroactive claims representing new SC disability award	Reopened claims	Accessions	Total disability claim volume
2010	69,957	17,039	32,606	28,934	159,311
2011	.....	.....	1,069	3,393	31,207
2012	.....	.....	1,051	3,335	10,289
2013	.....	.....	1,032	3,273	10,227
2014	.....	.....	1,011	3,207	10,161
Subtotals	.....	.....	36,769	42,142	221,195
2015	.....	.....	989	3,137	10,091
2016	.....	.....	989	3,062	10,016
2017	.....	.....	989	2,983	9,937
2018	.....	.....	989	2,898	9,852
2019	.....	.....	989	2,809	9,763
Totals	69,957	.....	41,714	57,031	270,854

New Enrollments and Changed Enrollments

The disability compensation workload, the resulting increases in service-connected patients, and the increased combined service connected percents will both add new patients to VA's health care system and will change the priority levels of veterans currently enrolled in VA's health care system.

For purposes of estimation, it is assumed that 30% of veterans "Accessions" will enroll in the system each year. For FY2010, this means that 8,680 of the 28,934 veteran "Accessions". Figure 2 provides the estimate of new enrollments per year for the ten year period. In all, it is estimated that 17,109 new veterans will enroll in VA's health care system.

FIGURE 2

FY	New enrollees per year	New enrollees cumulative
2010	8,680	8,680
2011	1,018	9,698
2012	1,001	10,699
2013	982	11,681

FIGURE 2—Continued

FY	New enrollees per year	New enrollees cumulative
2014	962	12,643
Subtotals	12,643	
2015	941	13,584
2016	919	14,502
2017	895	15,397
2018	869	16,267
2019	843	17,109
Totals	17,109	17,109

It is assumed that veterans enrolling will be Priority Group 1 veterans and that they will use VA health care services.

For purposes of estimation, it is assumed that 40% of the veterans whose claims are reopened will have been enrolled in VA's health care system and that their Priority Group will move from a copayment required status to a copayment exempt status. Additionally, it is assumed that their third party collections will be lost. It is assumed that 10% of the accessions will result in changes to veterans who are currently enrolled. These veterans would be enrolled in a copayment required status and would move to copayment exempt status. In FY2010 it is estimated that 43,919 veterans would have their enrollment status changed, and FY 2011 it is estimated that an additional 767 veterans would have their enrollment status changed. Figure 3 provides these estimated changes in enrollment status per year and cumulatively.

FIGURE 3

FY	Upgraded enrollees per year	Upgraded enrollees cumulative
2010	43,919	43,919
2011	767	44,686
2012	754	45,439
2013	740	46,180
2014	725	46,905
Subtotals	46,905	46,905
2015	709	47,614
2016	702	48,316
2017	694	49,010
2018	685	49,695
2019	677	50,372
Totals	50,372	50,372

Disability Exams Associated Costs

It is assumed that each VBA case will result in disability examinations for the veteran. In all, it is estimated that 270,854 disability examinations will need to be performed. An escalation factor of 4% is applied to cost of disability examinations.

FIGURE 4

FY	Total disability claim volume	Cost per disability exam *	Annual cost per disability exams
2010	159,311	$719	$114,544,609
2011	31,207	748	23,335,346
2012	10,289	778	8,001,451
2013	10,227	809	8,271,365
2014	10,161	841	8,546,705
Subtotals	221,195		162,699,475
2015	10,091	875	8,827,339
2016	10,016	910	9,112,200
2017	9,937	946	9,401,942
2018	9,852	984	9,694,379
2019	9,763	1,023	9,991,075
Totals	270,854		209,726,410

* *Source:* Allocation Resource Center.

Health Care and Total Costs

Figure 5 provides extended health care costs per year and includes costs for C&P disability examinations and travel associated with C&P examinations. The cost per patient is arrived at using the average cost per Priority Group 1 patient, ages 45–64. It is assumed that 100% of newly enrolled veterans will request mileage reimbursement. The average amount of mileage reimbursement claims per veteran is $511 (this amount reflects to the FY2009 actual average amount). Total costs over the 10-year period are estimated to be in excess of $2.4B.

FIGURE 5

FY	Annual cost per disability exams	Cost per BT mileage claim	Beneficiary travel costs (41.5 cents/mile)	Cost per patient	Health care costs per patient	Extended annual costs
2010	$114,544,609	$511	$4,435,582	$13,500	$117,182,700	$236,162,891
2011	23,335,346	511	4,955,729	14,100	136,743,210	165,034,285
2012	8,001,451	511	5,466,985	14,700	157,269,420	170,737,855
2013	8,271,365	511	5,968,736	15,100	176,375,550	190,615,650
2014	8,546,705	511	6,460,369	15,700	198,488,820	213,495,893
Subtotals	162,699,475		27,287,400		786,059,700	976,046,575
2015	8,827,339	511	6,941,271	16,300	221,414,310	237,182,919
2016	9,112,200	511	7,410,675	17,100	247,989,330	264,512,205
2017	9,401,942	511	7,867,969	17,900	275,609,880	292,879,791
2018	9,694,379	511	8,312,233	18,800	305,812,080	323,818,692
2019	9,991,075	511	8,742,852	19,800	338,764,140	357,498,068
Totals	209,726,410		66,562,400		2,175,649,440	2,451,938,251

Summary

Combined estimated increases in health care costs are presented in Figure 6.

FIGURE 6

FY	Extended annual costs
2010	$236,162,891
2011	165,034,285
2012	170,737,855
2013	190,615,650
2014	213,495,893
Subtotals	976,046,575
2015	237,182,919
2016	264,512,205
2017	292,879,791
2018	323,818,692
2019	357,498,068
Totals	2,451,938,251

Uncertainties: After the comment period had expired, VA received correspondence from the Chairman of the Senate Committee on Veterans Affairs which questioned VA's use of the prevalence rate of 5.6 percent for IHD in the proposed rule. The Chairman mentioned that the 5.6 percent prevalence rate was for the general U.S. population, instead of a rate more representative of the Vietnam Veteran population, which is older. He also asked why the prevalence rate for IHD among Vietnam Veterans was not assumed to increase on a yearly basis as they age over the next ten years, citing Centers for Disease Control (CDC) findings that the prevalence rate for IHD increases as an individual ages.

For purposes of costing the three new presumptive conditions in the proposed rule, VA's assumptions for the prevalence and mortality rates were identified based on information obtained from the CDC, the National Institutes of Health (NIH), and the Census Bureau. In FY2000, 15,800,000 people were identified with coronary heart disease. The total U.S. population according to the Census Population Survey in the same year was 281,421,906, reflecting the 5.6 percent prevalence rate. Since veteran-specific prevalence and mortality rates are not commonly reported, it is standard practice to use general population prevalence and mortality rates for cost estimating purposes.

After publishing a proposed rule, agencies often receive additional information, which in turn improves the analysis of agency action. It is not unusual for an agency to receive new data during or after the comment period, either submitted by the public with comments or collected by the agency in a continuing effort to give the agency's regulations a more complete foundation. An agency may use such data to address potential deficiencies in the proposed rule's data, so long as no prejudice is shown.

We have, therefore, conducted a separate analysis based on the CDC's age-adjusted prevalence rates for coronary heart disease. We found that CDC's data uses the age categories of 45–54, 55–64, 65–74, 75–84, and 85 and older, for both males and females. These age-adjusted prevalence rates were applied in a separate analysis, which resulted in much higher potential costs.

Using age-adjusted prevalence rates, shifting initial costs data from FY2010 to FY2011, adjusting the assumed degree of disability, and updating the assumed caseload, the estimated VBA costs in the first year would decrease by nearly $1.5 billion compared to VA's proposed rule estimate and the overall ten-year costs would increase by nearly $19.8 billion. Similarly, VHA developed a methodology based on the data provided by VBA to evaluate VBA projected claims data from a health care cost analysis perspective. Making adjustments for priority group distributions and shifting the FY2010 cost data to FY2011, the associated VHA costs in the first year would increase by nearly $100 million compared to VA's proposed rule estimate and the overall ten-year costs would increase by nearly $5.0 billion. The details of this analysis are available on VA's Web site at: *http://vaww1.va.gov/ORPM/FY_2010_Published_VA_Regulations.asp,* and also may be viewed online through the Federal Docket Management System at *http://www.regulations.gov.*

We note that many assumptions, which form the foundation for an agency's cost forecasts, seldom prove to be completely accurate due to variables over which VA has no control, such as application rates, better diagnostic techniques in the future, or changes in incidence rates. As documented in the Department's analysis, there are various

assumptions applied in the cost estimate that, if altered, could result in dramatic increases (*e.g.* age adjustment of prevalence rates) or decreases (*e.g.,* lower application rates) in the range of costs attributed to the rule. We further note that, in addition to being subject to various sources of uncertainty, the model applied by the Department for estimating the range of prospective impacts is further subject to the relative sensitivity of variation in the respective inputs to the model; for example, the model is highly sensitive to variation in the prevalence rates, such as that resulting from age adjustment.

While all three presumptive conditions covered by this rule are subject to these variations and the resulting impacts on projected obligations, VA considers the proposed rule's cost estimate to remain a reasonable baseline projection of the costs associated with this final rule. However, cost estimates provided and the assumptions used to develop them have no binding effect, and veterans who qualify for benefits on the basis of these presumptions will receive their benefits regardless of cost estimates used at this time. VA's discretionary and mandatory funding require explicit appropriations on an annual basis. Mandatory out-year estimates are evaluated for relevant current data as they become available and budget estimates are adjusted accordingly.

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 final rule would have no such effect on State, local, and Tribal governments, or on the private sector.

Regulatory Flexibility Act

The Secretary of Veterans Affairs hereby certifies that this final 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 final rule will not affect any small entities. Only individuals will be directly affected. Therefore, pursuant to 5 U.S.C. 605(b), this final rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance Numbers and Titles

The Catalog of Federal Domestic Assistance program numbers and titles for this rule are 64.109, Veterans Compensation for Service-Connected Disability and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. John R. Gingrich, Chief of Staff, Department of Veterans Affairs, approved this document on July 7, 2010, for publication.

List of Subjects in 38 CFR Part 3

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

Dated: August 25, 2010.

Robert C. McFetridge,

Director, Regulation Policy and Management, Office of the General Counsel, Department of Veterans Affairs.

■ For the reasons set out in the preamble, VA is amending 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. Section 3.309 is amended as follows:

■ a. In paragraph (e), by removing "Chronic lymphocytic leukemia" and adding, in its place, "All chronic B-cell leukemias (including, but not limited to, hairy-cell leukemia and chronic lymphocytic leukemia)."

■ b. In paragraph (e), by adding "Parkinson's disease" immediately preceding "Acute and subacute peripheral neuropathy".

■ c. In paragraph (e), by adding "Ischemic heart disease (including, but not limited to, acute, subacute, and old myocardial infarction; atherosclerotic cardiovascular disease including coronary artery disease (including coronary spasm) and coronary bypass surgery; and stable, unstable and Prinzmetal's angina)" immediately following "Hodgkin's disease".

■ d. At the end of § 3.309, immediately following Note 2, adding a new Note 3 to reads as follows:

§ 3.309 Disease subject to presumptive service connection.

* * * * *

Note 3: For purposes of this section, the term ischemic heart disease does not include hypertension or peripheral manifestations of arteriosclerosis such as peripheral vascular disease or stroke, or any other condition that does not qualify within the generally accepted medical definition of Ischemic heart disease.

[FR Doc. 2010–21556 Filed 8–30–10; 8:45 am]

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POSTAL REGULATORY COMMISSION

39 CFR Part 3020

[Docket Nos. MC2009–19, et al.]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Commission is updating the postal product lists. This action reflects the disposition of recent dockets, as reflected in Commission orders, and a publication policy adopted in a recent Commission order. The referenced policy assumes periodic updates. The updates are identified in the body of this document. The product lists, which are re-published in their entirety, include these updates.

DATES: *Effective Date:* August 31, 2010.

Applicability Dates: July 13, 2010 (Stamp Fulfillment Services); July 29, 2010 (GEPS 3); July 30, 2010 (Global Plus 1A and Global Plus 2A); and August 6, 2010 (Priority Mail Contract 25, Priority Mail Contract 26, and Priority Mail Contract 27).

FOR FURTHER INFORMATION CONTACT: Stephen L. Sharfman, General Counsel, at *stephen.sharfman@prc.gov* or 202–789–6820.

SUPPLEMENTARY INFORMATION: This document identifies recent updates to the product lists, which appear as 39 CFR Appendix A to Subpart A of Part 3020–Mail Classification Schedule.[1] Publication of updated product lists in the **Federal Register** is consistent with

[1] Docket Nos. MC2009-19; MC2010-28 and CP2010-71; MC2010-26, CP2010-67 and CP2010-68; MC2010-27, CP2010-69 and CP2010-70; MC2010-30 and CP2010-75; MC2010-31 and CP2010-76; and MC2010-32 and CP2010-77.