



G A O

Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

B-320584

September 14, 2010

The Honorable Daniel K. Akaka
Chairman
The Honorable Richard M. Burr
Ranking Member
Committee on Veterans' Affairs
United States Senate

The Honorable Bob Filner
Chairman
The Honorable Steve Buyer
Ranking Member
Committee on Veterans' Affairs
House of Representatives

Subject: *Department of Veterans Affairs: Diseases Associated With Exposure to Certain Herbicide Agents (Hairy Cell Leukemia and Other Chronic B-Cell Leukemias, Parkinson's Disease and Ischemic Heart Disease)*

Pursuant to section 801(a)(2)(A) of title 5, United States Code, this is our report on a major rule promulgated by the Department of Veterans Affairs (VA), entitled "Diseases Associated With Exposure to Certain Herbicide Agents (Hairy Cell Leukemia and Other Chronic B-Cell Leukemias, Parkinson's Disease and Ischemic Heart Disease)" (RIN: 2900-AN54). We received the rule on August 25, 2010. It was published in the *Federal Register* as a final rule on August 31, 2010. 75 Fed. Reg. 53,202.

The final rule amends VA's 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.

This final rule has a stated effective date of August 31, 2010. The Congressional Review Act (CRA) generally requires a 60-day delay in the effective date of a major rule from the date of publication in the *Federal Register* or receipt of the rule by Congress, whichever is later. 5 U.S.C. § 801(a)(3)(A). We received the rule on August 25, 2010, and the rule was published in the *Federal Register* on August 31, 2010. Therefore, the final rule does not have the required 60-day delay in its stated effective date. However, VA notes in the rule that 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.

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*).

Enclosed is our assessment of the VA's compliance with the procedural steps required by section 801(a)(1)(B)(i) through (iv) of title 5 with respect to the rule. Our review of the procedural steps taken indicates that VA complied with the applicable requirements.

If you have any questions about this report or wish to contact GAO officials responsible for the evaluation work relating to the subject matter of the rule, please contact Shirley A. Jones, Assistant General Counsel, at (202) 512-8156.

signed

Robert J. Cramer
Managing Associate General Counsel

Enclosure

cc: Robert C. McFetridge
Director, Regulations Policy and
Management, Office of the General Counsel
Department of Veterans Affairs

REPORT UNDER 5 U.S.C. § 801(a)(2)(A) ON A MAJOR RULE
ISSUED BY THE
DEPARTMENT OF VETERANS AFFAIRS
ENTITLED
"DISEASES ASSOCIATED WITH EXPOSURE TO
CERTAIN HERBICIDE AGENTS (HAIRY CELL LEUKEMIA
AND OTHER CHRONIC B-CELL LEUKEMIAS,
PARKINSON'S DISEASE AND ISCHEMIC HEART DISEASE)"
(RIN: 2900-AN54)

(i) Cost-benefit analysis

In the proposed rule, VA estimated the total cost for this rulemaking to be \$13.6 billion during FY 2010, \$25.3 billion for 5 years, and \$42.2 billion over 10 years. However, VA now knows that based on the publication date of the final rulemaking the timing will not allow payments to begin prior to FY 2011. As a result, VA expects FY 2010 and FY 2011 costs will both now occur in FY 2011. These costs include retroactive benefit costs in the first year and increased benefit costs for veterans currently on the rolls.

(ii) Agency actions relevant to the Regulatory Flexibility Act, 5 U.S.C. §§ 603-605, 607, and 609

VA 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.

(iii) Agency actions relevant to sections 202-205 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. §§ 1532-1535

VA states that the final rule will not 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.

(iv) Other relevant information or requirements under acts and executive orders

Administrative Procedure Act, 5 U.S.C. §§ 551 *et seq.*

The final regulations were issued using the notice and comment procedures found at 5 U.S.C. § 553. On March 25, 2010, VA published in the *Federal Register* a proposal to amend 38 C.F.R. § 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. 75 Fed. Reg. 14,391. VA received 670 timely comments from service organizations, other organizations, and individuals which are addressed in this final rule. VA did not address comments from veterans and surviving spouses regarding their individual claims for veterans' benefits as they were considered beyond the scope of this rulemaking.

Paperwork Reduction Act, 44 U.S.C. §§ 3501-3520

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

Statutory authorization for the rule

VA states that the Agent Orange Act of 1991 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. 38 U.S.C. § 1116.

Executive Order No. 12,866 (Regulatory Planning and Review)

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.

Executive Order No. 13,132 (Federalism)

In its submission to the Comptroller General, VA did not include an analysis of the final rule under the Order.