



DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 3

RIN 2900-AP43

Presumption of Herbicide Exposure and Presumption of Disability During Service for Reservists Presumed Exposed to Herbicides

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) is adopting as final an interim final rule published on June 19, 2015, to amend its adjudication regulation governing individuals presumed to have been exposed to certain herbicides. Specifically, VA expanded the regulation to include an additional group consisting of individuals who performed service in the Air Force or Air Force Reserve under circumstances in which they had regular and repeated contact with C-123 aircraft known to have been used to spray an herbicide agent (“Agent Orange”) during the Vietnam era. In addition, the regulation established a presumption that members of this group who later develop an Agent Orange presumptive condition were disabled during the relevant period of service, thus establishing that service as “active military, naval, or air service.” The effect of this action is to presume herbicide exposure for these individuals and to create a presumption that the individuals who are presumed exposed to herbicides during reserve service also meet the statutory definition of “veteran” (hereinafter, “veteran status”) for VA purposes and eligibility for some VA benefits.

DATES: Effective Date: This rule is effective [INSERT DATE OF PUBLICAITON IN THE FEDERAL REGISTER].

Applicability Date: This final rule is applicable to any claim for service connection for an Agent Orange presumptive condition filed by a covered individual that was pending on or after June 19, 2015.

FOR FURTHER INFORMATION CONTACT: Stephanie Li, Chief, Regulations Staff (211D), Compensation Service, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461-9700. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: In a document published in the Federal Register on June 19, 2015 (80 FR 35246), VA amended its regulation at 38 CFR 3.307 governing individuals presumed to have been exposed to certain herbicides. VA provided the public 60 days in which to comment on the amendment made by the interim final rule, with the comment period ending August 18, 2015. VA received 46 comments from various organizations and individuals. The issues raised by the commenters that concerned a similar topic have been grouped together and VA's discussion of the comments organized accordingly. For the reasons set forth in the interim final rule and for those reasons discussed below, we are adopting the interim final rule as final without changes.

The majority of public comments asserted a need for retroactive application of the effective date assigned for the interim final rule. Retroactivity is generally not

avored in the law and an agency will not generally be considered to have authority to provide retroactive effect unless an exception to this general rule is provided via an express statutory delegation of authority. See Bowen v. Georgetown Univ. Hosp., 488 U.S. 204, 208 (1988). Further, 38 U.S.C. 5110(g) stipulates that the effective date of an award or increase based on a liberalizing law or VA issue will either be the “effective date of the Act or administrative issue,” or the date entitlement arose, whichever is later. This statute is implemented through regulation (38 CFR 3.114), which generally does not contemplate VA providing benefits effective prior to the effective date of the liberalizing regulation itself.

Even to the extent VA’s rulemaking authority under 38 U.S.C. 501 includes authority to issue retroactive regulations, and assuming such an understanding can be reconciled with section 5110(g), VA declines to do so in this matter. Even if VA’s rulemaking authority extends to assigning a retroactive effective date in the abstract, doing so is nevertheless inconsistent with the intent of section 5110(g) and would certainly be inconsistent with VA’s usual and longstanding practice to make substantive rules effective prospectively. Maintaining a general policy of applying new regulations prospectively helps ensure that all new liberalizing regulations are applied in a fair and consistent manner. The United States Court of Appeals for the Federal Circuit has reviewed this authority and held that VA did not act unreasonably in using a prospective effective date for a liberalizing regulation rather than a retroactive effective date in circumstance similar to this. McKinney v. McDonald, 796 F.3d 1377, 1384-85 (Fed. Cir. 2015). Additionally, we note that avoiding retroactivity serves the interests of orderly administration and clarity in the law. If new regulations apply only prospectively, then

determining what law applied to a past claim as of a given point in time is a matter of looking up the regulation for the applicable year. When new regulations are given retroactive effect, agency personnel must navigate considerably more complexity (e.g., having to consult the law in 2018 in order to figure out what the law was in 1990). Retroactive application of a new regulation also entails significant complexity insofar as adjudicators may have to assess intervening changes to other relevant statutes and regulations and seek to develop evidence, years after the fact, regarding the existence and extent of disability during past periods. This would increase the potential for confusion, inconsistency, and delay in VA claim adjudications, in addition to the disparate treatment that would result from making some presumptions retroactive, but not others. Therefore, although it may be possible for VA to provide retroactive effect in some exceptional circumstance, this would be inappropriate as a routine matter. VA will make the provisions addressed herein effective prospectively from the date of enactment consistent with the approach both VA and Congress generally have followed in establishing liberalizing regulations and statutes benefitting other groups of veterans, and makes no change based on the comments suggesting a retroactive effective date for the amendments to 38 CFR 3.307.

Multiple sub-categories were present within the broad category of requests for a retroactive effective date. Numerous commenters argued that this regulation is unnecessary as current VA policies and procedures already allow for establishing service-connected disability status based on exposure to residual dioxin aboard C-123 aircraft and the subsequent development of disabilities related thereto. Multiple commenters theorized that the regulation is unnecessary to establish presumption of

exposure as an in-service injury during inactive duty training or active duty for training status. The comments referenced an opinion of VA's Office of General Counsel (OGC), VAOPGCPREC 4-2002, as a basis for establishing that the exposure to residual dioxin was an in-service "injury" sufficient to satisfy the criteria for service connection under 38 U.S.C. 101(24). Similarly, other comments received referenced another OGC opinion, VAOPGCPREC 08-2001, as a basis to establish occurrence of an "injury" for the purposes of establishing active service to satisfy section 101(24).

The two cited opinions and the argument that reservists can meet the statutory definition of "veteran" simply on the basis of injury are all inapposite to this rulemaking. Current law, specifically 38 U.S.C. 101(2), defines "veteran" as "a person who served in the active military, naval, or air service, and who was discharged or released therefrom under conditions other than dishonorable." Section 101(24) then clarifies that "active military, naval, or air service" includes active duty for training during which an injury or disease is incurred or aggravated in the line of duty, or inactive duty for training during which an injury was incurred or aggravated in the line or duty or during which an acute myocardial infarction, a cardiac arrest, or a cerebrovascular accident occurs. Further, in both scenarios, section 101(24) requires that, "during" the referenced duty period, the putative veteran "was disabled or died" from a covered injury or disease. Thus, two discrete elements are required before VA can conclude that active duty for training (ADT) or inactive duty training (IDT) are considered active service: injury (or in the case of ADT, disease as well, or in the case of IDT, the events specified in section 101(24)(C)(ii)) incurred or aggravated in the line of duty, and incurrence of disability during such duty period from that same covered injury or disease. Although the

commenters are correct in that VA stated in the interim final rule that exposure to Agent Orange constitutes injury for veteran status purposes, insofar as the commenters argue that injury alone is sufficient to establish veteran status they are incorrect. In both ADT and IDT cases, disability must be incurred during the period of service. See section 101(24) (B) and (C). In the absence of incurrence of disability or death during service, veteran status is still not established. The operation of the presumption at issue in this regulation is therefore necessary for the putative veterans in question to achieve service connection on a presumptive basis.

Both of the OGC opinions cited by commenters addressed whether specific incidents during service were legally sufficient to satisfy the definition of injury in section 101(24). The opinions did not address whether the injuries at issue could or did cause a disability or death during the same period of service, much less create a presumption that the injuries at issue would do so. See VAOPGCPREC 08-2001, 04-2002. Nor did the opinions create a presumption that an entire class of servicemembers was, in fact, exposed to herbicide. Claimants who present evidence of both injury during ADT or IDT service and disability first manifest or aggravated during that same service – the situation addressed in both VAPGCPREC 08-2001 and 04-2002 – could be entitled to service connection on a direct basis if the elements for service connection are otherwise established. This rule does not affect that basis of service connection for any individual. Rather, this rule creates presumptions for individuals who performed service in the Air Force or Air Force Reserve under circumstances in which they had regular and repeated contact with C-123 aircraft known to have been used to spray an herbicide agent regarding exposure to herbicides, injury, and onset of diseases specified in 38

CFR 3.309(e). Thus, we disagree that this rule is unnecessary and/or conflicts with VAPGCPREC 08-2001 and 04-2002. No changes are made in response to these comments.

Multiple comments referenced a March 2013 correspondence from the Joint Services Records Research Center (JSRRC) to VA. JSRRC had cited the findings of a study by the Agency for Toxic Substances and Disease Registry (ATSDR) as relevant documentation establishing exposure to residual dioxin. The commenters requested that this memorandum be utilized as a basis for a retroactive effective date. Similarly, multiple comments referenced the 2015 findings of the Institute of Medicine (IOM) and requested that the date of these findings be utilized as a basis for the effective date of this regulation.

VA finds no basis to utilize the JSRRC correspondence or the IOM findings to establish an earlier effective date for the regulation. For all regulations in which VA has established a presumption of exposure, there is a body of scientific evidence that must be considered and ultimately informs the decision to establish the presumption of exposure. This body of scientific evidence, by logical necessity, predates the effective date of the regulation. Exposure aboard contaminated C-123 aircraft is no different. As discussed above, to the extent VA has legal authority to establish a retroactive effective date, it is unquestionably the well-established practice of VA and Congress to establish liberalizing regulations and statutes benefitting other groups of veterans with prospective effective dates. Therefore, no change is warranted based on any of these multiple theories asserted in support of assigning a retroactive effective date for this regulation.

Some comments referenced prior VA decisions to grant service-connected disability benefits based on exposure during inactive or active duty for training status aboard contaminated C-123 aircraft and utilized this as a basis for the argument to assign an earlier effective date for this regulation. Prior decisions granting benefits as described were made on the basis of the facts found in the individual case and the law that existed at the time, and are not a means for assigning an effective date for a regulation. As previously noted, under 38 U.S.C. 5110(g), effective dates “shall be fixed in accordance with the facts found but shall not be earlier than the effective date of the Act or administrative issue.” The prior cases referenced in the comments were all granted on the basis of individual facts found, and as already discussed above, the current regulation establishes entitlement on a presumptive basis. Thus, no change is warranted based on these comments.

Some commenters objected to the regulation on the basis that the regulation imposes an additional challenge for cases already on appeal as veteran status must now be considered. Determining veteran status is always part of the claims process. Although veteran status may not be directly addressed and discussed in the adjudication of every claim or an appeal, it is one of many determinations that must be made along the path of considering entitlement to any VA benefit, and is frequently at issue in claims arising from periods of active duty for training or inactive duty training. See, e.g., Collaro v. West, 136 F.3d 1304, 1308 (Fed. Cir. 1998) (noting that “status as a veteran” is one of five elements to be resolved in an application for service-connected disability benefits). Thus, no change is made based upon these comments as veteran

status is and has been a consideration always inherent in deciding claims for VA benefits.

An additional category of comments objected to the effective date on the basis that failure to allow for retroactive benefits results in denial of due process for those individuals who had previously submitted claims. For a denial of due process to occur, there must be a property interest, such as entitlement to a benefit, and deprivation of the property interest flowing from the defective process. At the time any claim was received prior to the effective date of this regulation, presumptive entitlement to a benefit did not exist as a matter of law (38 U.S.C. 5110(g) and 38 CFR 3.114). Due process serves to protect property interests that are recognized or created by the law – it does not itself create property interests. Leis v. Flynt, 439 U.S. 438, 441 (1979); Town of Castle Rock v. Gonzalez, 545 U.S. 748, 771 (2005). The requirements of due process therefore cannot serve to create a presumption of entitlement to benefits prior to the time that presumption actually existed. Additionally, the creation of a presumption of exposure to dioxin effective June 19, 2015, does not prevent a claimant from introducing evidence in an earlier claim in order to establish service connection on a facts found basis. As noted earlier, VA granted entitlement to benefits on the basis of individual facts found before enactment of this rule. Consequently, there is no deprivation of due process, and no change is warranted based upon these comments.

Multiple comments referenced what was viewed as unfavorable treatment of reserve service as compared to individuals who established status as a veteran after other types of service. As described in the explanation of responses to effective date comments, the term “veteran” is defined in existing statutes. This rule serves as a

vehicle to help members of the Air Force Reserve establish that their herbicide-related disease was incurred during active service. VA is without authority to ignore the statutory definition of the term “veteran” regardless of whether that term treats reserve service differently than other types of service. Therefore, no change is warranted based on these comments.

VA received comments requesting action in accordance with the effective date rules governed by the class action case of Nehmer v. United States Department of Veterans Affairs, No. CV-86-6160 TEH (N.D. Cal.). The Nehmer case established herbicide exposure claim procedures for veterans who served in Vietnam. Thus, reservists who served aboard C-123 aircraft outside Vietnam are not Nehmer class members, unless the individual in question separately deployed to Vietnam, in which case they have long been presumed exposed to herbicides without regard to the impact of this regulation. The stipulations that the parties entered into in Nehmer therefore do not apply to this rulemaking. Consequently, no changes are warranted based on these comments.

VA received four comments in which the commenter objected to concession of exposure based on a lack of and/or faulty scientific evidence confirming actual exposure to residual dioxin. One of these comments also cited a 20-year Air Force Health Study that showed no correlation between exposure in crews participating in Operation Ranch Hand and those disabilities that VA presumes associated with herbicide exposure. VA has based its decision to add presumptions for C-123 veterans on the entire body of relevant evidence, including the findings of the February 24, 2015, IOM report “Post-Vietnam Dioxin Exposure in Agent Orange-Contaminated C-123 Aircraft.” The report

found evidence of potentially harmful exposure to residual dioxin for those Air Force Reservists who worked aboard contaminated, former Operation Ranch Hand C-123 aircraft. VA considered the comments and evidence cited by the commenters, but determined that they are not sufficient to outweigh the IOM's finding that "[Air Force] Reservists working in [Operation Ranch Hand] C-123s were exposed (in the technical sense of the word of having bodily contact with the chemicals) to the components of Agent Orange to some extent." Therefore, no change is warranted based on these comments.

Further, with regard to the comment questioning the validity of the presumptive correlation between exposure to residual dioxin and the subsequent development of diseases, the IOM report clearly states and provides sufficient analysis to confirm that it is plausible that Air Force Reservists "would have experienced some exposure to chemicals from herbicide residue when working inside [Operation Ranch Hand] C-123s." The IOM committee reported that "[n]o matter what" decontamination methods were used, "TCDD and phenoxy herbicide residues were still detected 30 years later in several of the C-123 aircraft at levels in excess of international guidelines." TCDD refers to the dioxin, an unintended contaminant in Agent Orange, which was later determined to be a human carcinogen. The IOM was able to find sufficient sampling data to demonstrate that the C-123s experienced long-term contamination with Agent Orange and TCDD. The report further explains that the available data was sufficient to suggest that "the C-123s did contribute to some adverse health consequences among the [Air Force] Reservists who worked in [Operation Ranch Hand] C-123s." It has been longstanding VA policy to presume service-connection for certain disabilities determined

to have been related to exposure to Agent Orange or related herbicides during military service. See 38 CFR 3.309(e), Disease associated with exposure to certain herbicide agents. Consequently, no changes are made with regard to that comment.

Two comments were received requesting Agent Orange Registry examinations. Entitlement to Agent Orange Registry examinations is not within the scope of this rule making. Agent Orange Registry examinations are made available to individuals who may have been exposed to herbicides during a military operation or as a result of testing, transporting, or spraying herbicides for military purposes. This rulemaking does not impact the availability of Agent Orange Registry examinations. Consequently, no change is made based upon these comments.

Several comments were received pertaining to exposure aboard C-123 aircraft at specific locations. This regulation does not establish criteria based on specific locations, but rather based on the type of service (Air Force or Air Force Reserve) and circumstances of that service (regular and repeated contact with C-123 aircraft known to have been used to spray Agent Orange during the Vietnam era). Specifically, the amended regulation establishes that VA will presume exposure to herbicides and in-service injury and incurrence of disability for individuals who suffer from specified herbicide-related diseases and “regularly and repeatedly operated, maintained, or served onboard C-123 aircraft known to have been used to spray an herbicide agent during the Vietnam era.” It further clarifies that the individual had to have been assigned to an Air Force or Air Force Reserve squadron that was permanently assigned one of the affected aircraft, and that he/she had an Air Force specialty code indicating duties as a flight, ground maintenance, or medical crew member. VA procedures have been

established based upon the interim final rule to set forth this criteria in order to determine whether an individual was exposed based on the circumstances of service. Therefore, no change is warranted in response to these comments.

One commenter requested that breast cancer be designated as a disability presumptively related to exposure to residual dioxin on C-123 aircraft. This comment is outside the scope of this rulemaking. This rulemaking establishes means for presuming exposure to herbicides and establishing veteran status. The designation of a presumptive relationship between herbicide exposure and the subsequent development of any type of disease, such as breast cancer, is not within the scope of this rulemaking. Consequently, no change is warranted based upon this comment. However, VA will continue to monitor relevant scientific and medical reports for conditions associated with exposure to certain herbicide agents. If, at a later date, there is sufficient evidence to suggest a relationship between exposure and additional disabilities, VA will initiate additional rulemaking as appropriate.

One comment was received requesting clarification of entitlement to survivor benefits within the rulemaking. Although clarification of entitlement to survivor benefits is not within the scope of this rulemaking in particular, we note that status to claim entitlement to survivor benefits is generally predicated on the basis of the survivor's relationship to a veteran, while the benefits that a survivor may claim can be dependent on the benefits to which that veteran was entitled. Whether a veteran's entitlement to benefits is established based in part on this liberalizing rule would not itself impact a survivor's ability to claim benefits or the benefits to which the survivor would be entitled. No change is warranted based upon this comment.

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess the 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 effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a “significant regulatory action,” which requires 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 this Executive Order.”

The economic, interagency, budgetary, legal, and policy implications of this regulatory action have been examined and it has been determined to be a significant regulatory action under Executive Order 12866, because it raises novel legal or policy

issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order. VA's impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's website at <http://www.va.gov/orpm> by following the link for VA Regulations Published from FY 2004 through FYTD. This rule is not subject to the requirements of EO 13771 because this rule results in no more than *de minimis* costs.

Regulatory Flexibility Act

The Secretary 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 directly affect only individuals and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

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 one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This regulatory action contains provisions constituting a collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Specifically, this rule is associated with information collections related to the filing of disability benefits claims, VA Forms 21-526EZ and 21P-534EZ. The information collections are currently approved by the Office of Management and Budget (OMB) and have been assigned OMB control numbers 2900-0747 and 2900-0004. There are no changes to any of these collections and, thus, no incremental costs associated with this rulemaking.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.100, Automobiles and Adaptive Equipment for Certain Disabled Veterans and Members of the Armed Forces; 64.101, Burial Expenses Allowance for Veterans; 64.102, Compensation for Service-Connected Deaths for Veterans' Dependents; 64.104, Pension for Non-Service-Connected Disability for Veterans; 64.105, Pension to Veterans Surviving Spouses and Children; 64.106, Specially Adapted Housing for Disabled Veterans; 64.109, Veterans Compensation for Service-Connected Disability; and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

List of Subjects in 38 CFR Part 3

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

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Jacquelyn Hayes-Byrd, Acting Chief of Staff, Department of Veterans Affairs, approved this document on June 12, 2018, for publication.

Dated: October 11, 2018.

Jeffrey M. Martin,
Assistant Director,
Office of Regulation Policy & Management,
Office of the Secretary,
Department of Veterans Affairs.

PART 3—ADJUDICATION

Based on the rationale set forth in the interim final rule published in the Federal Register at 80 FR 35246 on June 19, 2015, and in this document, VA is adopting the provisions of the interim final rule amending 38 CFR part 3 as a final rule without change.

[FR Doc. 2018-22892 Filed: 10/19/2018 8:45 am; Publication Date: 10/22/2018]