

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 3

RIN 2900-AP66

Diseases Associated With Exposure to Contaminants in the Water Supply at Camp Lejeune

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its adjudication regulations relating to presumptive service connection to add certain diseases associated with contaminants present in the base water supply at U.S. Marine Corps Base Camp Lejeune (Camp Lejeune), North Carolina, from August 1, 1953 to December 31, 1987. The chemical compounds involved have been associated by various scientific organizations with the development of certain diseases. This proposed rule would establish that veterans, former reservists, and former National Guard members, who served at Camp Lejeune for no less than 30 days (consecutive or nonconsecutive) during this period, and who have been diagnosed with any of eight associated diseases, are presumed to have a service-connected disability for purposes of entitlement to VA benefits. In addition, VA proposes to establish a presumption that these individuals were disabled during the relevant period of service, thus establishing active military service for benefit purposes. Under this proposed presumption, affected former reservists and National Guard members would have veteran status for purposes of entitlement to some VA benefits. This proposed amendment would implement a decision by the Secretary of Veterans Affairs that service connection on a presumptive basis is warranted for claimants who served at Camp Lejeune during the relevant period and for the requisite amount of time and later develop certain diseases. The

Secretary's decision is supported by the conclusions of internationally recognized scientific authorities that strong evidence exists establishing a relationship between exposure to certain volatile organic compounds (VOCs) that were in the water at Camp Lejeune and later development of certain disabilities.

DATES: *Comment Date:* Comments must be received on or before October 11, 2016.

ADDRESSES: Written comments may be submitted through www.Regulations.gov; by mail or hand-delivery to Director, Regulation Policy and Management (00REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to "RIN 2900-AP66—Diseases Associated with Exposure to Contaminants in the Water Supply at Camp Lejeune." Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at www.Regulations.gov.

FOR FURTHER INFORMATION CONTACT: Eric Mandle, Policy Analyst, 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:

I. Background

In the early 1980s, in response to new Environmental Protection Agency standards, the Marine Corps monitored its water quality for volatile organic compounds (VOCs). In 1982, the Marine Corps discovered elevated levels of the VOCs trichloroethylene (TCE), a metal degreaser, and perchloroethylene (PCE), a dry cleaning agent, in two of the eight on-base water supply systems at Camp Lejeune. U.S. General Accounting Office, Defense Health Care: Activities Related to Past Drinking Water Contamination at Marine Corps Base Camp Lejeune (2007) (GAO 2007).

Subsequent investigations found that the main source of TCE contamination was on-base industrial activities, while the main source of PCE was an off-base dry cleaning facility. *Id.* Benzene and vinyl chloride were also found in the water supply systems. Committee on Contaminated Drinking Water at Camp Lejeune; National Research Council, *Contaminated Water Supplies at Camp Lejeune, Assessing Potential Health Effects 4* (National Academies Press, 2009) (NRC 2009). These water systems served housing, administrative, and recreational facilities, as well as the base hospital. GAO 2007. The contaminated wells supplying the water systems were shut down by February 1985. *Id.*

Although the Agency for Toxic Substances and Disease Registry (ATSDR), an agency of the Department of Health and Human Services, conducted an initial Public Health Assessment of Camp Lejeune in 1997, additional information led ATSDR to conduct a number of follow-up studies focused on a variety of specific aspects of potential exposure and their implications for specific health endpoints (see: <http://www.atsdr.cdc.gov/sites/lejeune/activities.html>). Potentially exposed individuals who served at Camp Lejeune are encouraged to participate in a registry to receive information from new health-related scientific studies initiated by the Navy. *See Camp Lejeune Historic Drinking Water*, U.S. Marine Corps, <https://clnr.hqi.usmc.mil/clwater/Home.aspx> (last visited Aug. 12, 2016).

II. Scientific Evidence and VA's Presumptive Analysis

A. The National Research Council Review of 2009

Based on a congressional mandate in section 318 of Public Law 109-364, the Navy requested that the National Research Council (NRC) undertake a study to assess the potential long-term health effects for individuals who served at Camp Lejeune during the period of water contamination. In generating its 2009 report, "*Contaminated Water Supplies at Camp Lejeune, Assessing Potential Health Effects*", the NRC evaluated scientific studies regarding the potential health conditions associated with TCE, PCE, and other VOCs. NRC 2009 at 5. NRC also examined information relating to

exposures at Camp Lejeune, including research conducted by ATSDR. *Id.* at 195.

The NRC categorized fourteen health conditions that have limited/suggestive evidence of an association with TCE, PCE, or a solvent mixture. *Id.* at 8. Limited/suggestive evidence of an association was defined as: “[e]vidence from available studies suggests an association between exposure to a specific agent and a specific health outcome in human studies, *but the body of evidence is limited by the inability to rule out chance and bias, including confounding, with confidence*” (emphasis added). *Id.* at 6. The fourteen diseases categorized by the NRC report as having limited/suggestive evidence of an association with the VOCs at issue at Camp Lejeune are:

- Esophageal cancer (PCE)
- lung cancer (PCE)
- breast cancer (PCE)
- bladder cancer (PCE)
- kidney cancer (PCE and TCE)
- adult leukemia (solvent mixtures)
- multiple myeloma (solvent mixtures)
- myelodysplastic syndromes (solvent mixtures)
- renal toxicity (solvent mixtures)
- hepatic steatosis (solvent mixtures)
- female infertility (with concurrent exposure to solvent mixtures)
- miscarriage, with exposure during pregnancy (PCE)
- scleroderma (solvent mixtures)
- neurobehavioral effects (solvent mixtures). *Id.* at 8.

The NRC based this categorization on its conclusion that “the epidemiologic studies give some reason to be concerned that sufficiently high levels of the chemical may cause the disease, but the studies do not provide strong evidence that they actually do so”. *Id.* at 7. Specific to the research studies conducted by the ATSDR, the NRC stated that they may not have produced definitive results because of the difficulties inherent in attempting to reconstruct past events and determine the amount of exposure experienced by any given individual. *Id.* at 195.

B. Honoring America’s Veterans and Caring for Camp Lejeune Families Act of 2012

On August 6, 2012, Congress enacted the Honoring America’s Veterans and Caring for Camp Lejeune Families Act of 2012, Public Law 112–154 (hereinafter “Camp Lejeune Act”). Section 102 of the Camp Lejeune Act established health care entitlement for veterans who served on active duty at Camp Lejeune for at least thirty days during the period between January 1, 1957, through

December 31, 1987, for treatment of the fourteen conditions identified by the NRC as well as non-Hodgkin’s lymphoma. Honoring America’s Veterans and Caring for Camp Lejeune Families Act of 2012, Public Law 112–154, section 102(a), 126 Stat. 1165, 1167 (2012) (codified at 38 U.S.C.

1710(e)(1)(F)). Congress later amended this time period to expand health care eligibility to those serving at Camp Lejeune from August 1, 1953 through December 31, 1987. Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113–235, Div. I, Title II, section 243. The Camp Lejeune Act also extended healthcare benefits in the form of reimbursements to certain family members of veterans who also resided at Camp Lejeune during the qualifying period. Camp Lejeune Act, section 102(b) (codified at 38 U.S.C. 1787).

The Camp Lejeune Act noted that medical care is being afforded “notwithstanding that there is insufficient medical evidence to conclude that such illnesses or conditions are attributable to such service” or “residence.” *Id.* Section 102(a) and (b) (codified at 38 U.S.C. 1710(e)(1)(F) and 1787(a)). Despite the NRC’s report noting the difficulty of establishing direct scientific evidence of causation between the contaminated drinking water and the development of disease over time, Congress sought a policy that “gives sick veterans and their families the benefit of the doubt their illness or condition was caused by the water at Camp Lejeune so they can finally get the healthcare they need.” *Honoring America’s Veterans and Caring for Camp Lejeune Families Act of 2012, Proceedings and Debates of the 112 Congress, Second Session, 158 Cong. Rec. S5154–04, 2012 WL 2923422 (2012) (statement of Sen. Murray).* This law, however, is limited to the provision of healthcare for the named disabilities. It does not establish a presumption of service connection for purposes of entitlement to VA disability compensation and other benefits.

C. VA’s Method of Analysis

On August 3, 2015, the Secretary of Veterans Affairs announced that he had met with members of Congress, as well as the Director of ATSDR, to discuss the possibility of creating presumptions of service connection for those who served at Camp Lejeune and may have been exposed to the contaminated water supply. News Release, U.S. Department of Veterans Affairs, VA Expands Review of Chemical Exposure in Drinking Water at Marine Corps Base Camp Lejeune (August 3, 2015). Following that

announcement, VA began a deliberative process to determine whether available scientific evidence was sufficient to support a presumption of service connection for any health conditions as a result of exposure to the chemicals found in the contaminated drinking water at Camp Lejeune.

At VA’s request, ATSDR collaborated with VA’s Camp Lejeune Science Liaison Team (CLSLT). The CLSLT was chaired by the Chief Medical Officer of the Veterans Health Administration (VHA) and consisted of representatives from VHA’s Post-Deployment Health Services (Office of Patient Care Services) and the Veterans Benefits Administration’s Compensation Service. The purpose of ATSDR’s collaboration with the CLSLT was to provide VA with its evaluation of the scientific literature regarding the potential hazards generally associated with the contaminants found in the water at Camp Lejeune during the contamination period (but not specifically associated with exposures at Camp Lejeune). The CLSLT presented its hazard evaluation to a newly formed VA Technical Workgroup (TWG), represented by subject matter experts in disability compensation, health care, environmental medicine, toxicology, epidemiology, Federal rulemaking, communications, and veterans benefits law. The CLSLT presented the VA TWG with its findings based on the CLSLT’s independent review of the scientific literature and discussions with ATSDR staff. In this review, the CLSLT summarized the weight of evidence for all health conditions for which an association with the chemicals of interest has been suggested. The environmental health experts on the TWG then conducted their own assessment of the scientific evidence.

The TWG’s assessment focused on the strength of the evidence that a chemical is capable of causing a given health condition (commonly referred to as a hazard evaluation); the TWG’s assessment did not take into account the estimated levels of contamination in the water during the period of contamination at Camp Lejeune. As such, the TWG did not attempt to characterize the risk associated with the estimated exposures of those who resided at Camp Lejeune during the period of contamination.

The TWG evaluation relied upon comprehensive hazard evaluations conducted by the following internationally respected expert bodies: The Environmental Protection Agency’s Integrated Risk Information System (EPA/IRIS), the National Institute of Health’s National Toxicology Program

(NIH/NTP), the World Health Organization's International Agency for Research on Cancer (WHO/IARC), and the National Academies of Sciences' National Research Council and Institute of Medicine (NAS/NRC/IOM). These organizations were chosen for their rigorous expert selection and peer review processes to ensure objective and nuanced conclusions.

As previously discussed, the findings of a report on the contaminated water at Camp Lejeune published by the NRC in 2009 reviewed the health effects associated with TCE, PCE, and solvent mixtures and were the basis of the 2012 Camp Lejeune Act. Starting with the findings of the 2009 NRC study, the TWG analyzed additional scientific data to determine if additional evidence existed to support a causal relationship between various conditions and the contaminants found in the water supply at Camp Lejeune. The TWG review evaluated the hazards associated with not only these chemicals, but benzene and vinyl chloride as well, thus broadening the scope beyond that of the 2009 NRC assessment. The TWG was particularly interested in weight of evidence evaluations conducted since the 2009 study, as they incorporate scientific information that was not available when the NRC's 2009 report was being developed. Furthermore, because each of these expert bodies reviewed the literature through different scientific perspectives, this approach provided the TWG with increased confidence in its conclusions.

The TWG examined the results of EPA's Toxicological Reviews for the IRIS program (TCE, 2011; PCE, 2012; benzene, 2002; and vinyl chloride, 2000), the WHO's IARC Monographs on the Evaluation of Carcinogenic Risks to Humans (TCE, 2014; PCE, 2014; benzene, 2012; and vinyl chloride, 2013), and the NIH's NTP Report on Carcinogens (TCE, 2015; PCE, 2014; benzene, 2014; and vinyl chloride, 2014). In addition to the 2009 NRC report, the TWG drew on two other NAS reports, both published by the IOM: Gulf War and Health, vol. 2: Insecticides and Solvents (2003) and Review of the VA Clinical Guidance for Health Conditions Identified by the Camp Lejeune Legislation (2015). Section E below contains full references for all scientific literature reviewed by the TWG.

D. Results of the TWG Analysis

The TWG found that at least one of the internationally recognized scientific authorities cited above recently concluded that there is strong evidence supporting a causal relationship

between kidney cancer and TCE (EPA 2011, IARC 2014, NTP 2015), adult leukemia and benzene (EPA 2002, IARC 2012, IOM 2003, NTP 2014), non-Hodgkin's lymphoma and TCE (NTP 2015), and liver cancer and vinyl chloride (EPA 2000, IARC 2012, NTP 2014). Note that this list includes liver cancer, which was not named in the Camp Lejeune Act. Liver cancer was included in the list of health conditions as studies have established a causal relationship exists between liver cancer and vinyl chloride, and because the effects of vinyl chloride were not included in the 2009 NRC report's review of adverse health effects resulting from exposure, although it was identified in the water at Camp Lejeune.

The TWG also noted that both the EPA (2002) and the IOM (2003) concluded that there is evidence supporting a causal relationship between aplastic anemia and other myelodysplastic syndromes and benzene, which appears to be supported by NTP (2012). The TWG also found that at least one of the internationally recognized scientific authorities cited above recently concluded that there is a positive association between bladder cancer and PCE (EPA 2012, IARC 2014, IOM 2003) and between multiple myeloma and PCE (EPA 2012) and benzene (IARC 2012).

In the context of providing VA with clinical guidance for implementing the 2012 Camp Lejeune Act, the IOM (2015) identified four published scientific analyses that address solvent exposure that had not been available during the NAS 2009 study. The IOM committee concluded that "Parkinson's disease is a neurobehavioral effect that may have resulted from consumption of contaminated drinking water at Camp Lejeune." IOM (2015) at 39.

Although the CLSLT recommended to VA that they propose the creation of a presumption for scleroderma, additional reviews by the TWG concluded that the evidence is currently not strong enough to establish a positive association between any of the VOCs of interest and the development of scleroderma. Evaluations conducted by EPA (2011), IARC (2014), and NRC/IOM (2009) discuss a probable link between exposure to TCE and autoimmune diseases in general; however, none of the internationally recognized scientific authorities cited above concluded that there is positive association between scleroderma and the VOCs of interest, due in part to insufficient sample sizes and uncertainties about the cause of gender-specific differences. Therefore, the TWG did not recommend the creation of a presumption for

scleroderma at this time, even though it was included in the Camp Lejeune Act.

Likewise, none of the internationally recognized scientific authorities cited above concluded that there is a positive association between breast cancer, lung cancer, or esophageal cancer and the VOCs of interest. As such, the TWG concluded that the evidence was not strong enough to support recommending the creation of presumptions for these conditions at this time, even though they were included in the Camp Lejeune Act.

Because the TWG analysis was conducted in the context of a rulemaking to establish presumptions of service connection for diseases associated with exposure to the VOCs of interest, the TWG did not recommend establishing presumptions for health effects that are not themselves diagnosed diseases or clearly associated with a specific diagnosis and therefore do not represent a disability for the purposes of VA compensation benefits. See 38 U.S.C. 1110. This is consistent with VA's practice in establishing presumptions of service connection for diseases arising potentially years after exposures of interest. For the purposes of entitlement to disability compensation and related benefits, the health endpoint must be associated with a diagnosis of a chronic disability. The TWG concluded that, at this time, there is not a specific or generalizable diagnosis of a disability related to renal toxicity or hepatic steatosis that may have been caused by exposure to the contaminants. Similarly, neither female infertility nor miscarriage, in and of themselves, are disabilities for which VA can provide disability compensation. Further, the NRC findings regarding female infertility and miscarriage were limited to exposure concurrent with those health effects and therefore would not provide a basis for presuming current health effects of this type to be associated with past exposure.

E. Weight-of-Evidence Analyses Considered by the TWG

- EPA. IRIS Toxicological Review of Benzene. U.S. Environmental Protection Agency, Washington, DC, EPA/635/R-02/001F, 2002. (EPA 2002)
- EPA. IRIS Toxicological Review of Tetrachloroethylene. U.S. Environmental Protection Agency, Washington, DC, EPA/635/R-08/011F, 2012. (EPA 2012)
- EPA. IRIS Toxicological Review of Trichloroethylene. U.S. Environmental Protection Agency,

- Washington, DC, EPA/635/R-09/011F, 2011. (EPA 2011)
- EPA. IRIS Toxicological Review of Vinyl Chloride. U.S. Environmental Protection Agency, Washington, DC, EPA/635R-00/004, 2000. (EPA 2000)
 - IARC Working Group on the Evaluation of Carcinogenic Risk to Humans. Chemical Agents and Related Occupations. Lyon (FR): International Agency for Research on Cancer; 2012. (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, No. 100F.) (IARC 2012)
 - IARC Working Group on the Evaluation of Carcinogenic Risk to Humans. Trichloroethylene, Tetrachloroethylene, and Some Other Chlorinated Agents. Lyon (FR): International Agency for Research on Cancer; 2014. (IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, No. 106.) (IARC 2014)
 - Institute of Medicine. Gulf War and Health: Volume 2. Insecticides and Solvents. Washington, DC: The National Academies Press, 2003. (IOM 2003)
 - Institute of Medicine. Review of VA Clinical Guidance for the Health Conditions Identified by the Camp Lejeune Legislation. Washington, DC: The National Academies Press, 2015. (IOM 2015)
 - National Research Council. Contaminated Water Supplies at Camp Lejeune: Assessing Potential Health Effects. Washington, DC: The National Academies Press, 2009.
 - National Toxicology Program. 2014. *Report on Carcinogens, Thirteenth Edition*. Research Triangle Park, NC: U.S. Department of Health and Human Services, Public Health Service. <http://ntp.niehs.nih.gov/pubhealth/roc/roc13/>
 - National Toxicology Program. 2015. Report on Carcinogens, Monograph on Trichloroethylene. http://ntp.niehs.nih.gov/ntp/roc/monographs/finaltce_508.pdf

III. Secretary's Proposal

A. Secretary's Authority

Section 501(a)(1) of title 38, United States Code, provides that "[t]he Secretary has authority to prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by [VA] and are consistent with those laws, including . . . regulations with respect to the nature and extent of proof and evidence and the method of taking and furnishing them in order to establish the right to benefits under such laws." This broad authority encompasses the establishment of an evidentiary

presumption of service connection and exposure under specified circumstances, provided there is a rational basis for the presumptions. In this case, the Secretary has determined that proof of qualifying service at Camp Lejeune, consistent with the statute providing health care coverage for Camp Lejeune veterans, and the subsequent development of one or more of the eight disabilities identified by the TWG is sufficient to support proposing a presumption that the resulting disability was incurred in the line of duty during active military, naval, or air service, to include qualifying reserve or National Guard service, to establish entitlement to service connection. See 38 U.S.C. 1110.

VA notes it is well-established that the Secretary's authority under 38 U.S.C. 501(a)(1) includes issuing discretionary regulations for presumptive service connection, as evidenced by past rulemakings (issued in response to National Academy of Sciences' studies of exposures) to establish presumptive service connection for Amyotrophic Lateral Sclerosis (see 73 FR 54691), presumptive service connection for exposure to herbicides for certain qualifying individuals aboard C-123 aircraft (see 80 FR 35246), and presumptive service connection for various diseases in veterans with exposure to specified vesicant agents (see 59 FR 42497).

B. Presumptive Conditions

Based upon the results of the TWG analysis, the Secretary proposes that VA acknowledge the relationship between exposure to contaminants in the water supply at Camp Lejeune (in unknown quantities) and the subsequent development of the following health conditions: Kidney cancer, non-Hodgkin's lymphoma, adult leukemia, liver cancer, bladder cancer, multiple myeloma, Parkinson's disease, and aplastic anemia and other myelodysplastic syndromes.

Because these health conditions represent a disability, VA proposes to amend 38 CFR 3.307 to establish presumptions of service connection associated with exposure to contaminants in the water supply at Camp Lejeune. VA also proposes to amend 38 CFR 3.309 to prescribe the conditions that are subject to presumptive service connection in relation to exposure to the contaminants in the Camp Lejeune water supply. At this time, VA does not propose to establish presumptions of service connection for any other conditions. VA may consider additional rulemaking in

the future, consistent with the available science at that time.

C. Exposure Requirements

VA proposes to presume exposure to contaminants in the water supply at Camp Lejeune for all active duty, reserve, and National Guard personnel who served for no less than 30 days (consecutive or nonconsecutive) at Camp Lejeune during the period beginning August 1, 1953, and ending on December 31, 1987. VA proposes to include both consecutive and nonconsecutive days in the calculation of the 30-day requirement to clarify that VA will presume exposure to contaminants in the water supply at Camp Lejeune for veterans who may have served at Camp Lejeune on multiple occasions that total no less than 30 days.

VA based its determination to require no less than 30 days of service at Camp Lejeune to establish a presumption of exposure to contaminants in the water supply based on both the available scientific evidence and prior implementation of the provisions of section 102 of the Camp Lejeune Act. As previously discussed, the TWG's assessment relied on a hazard evaluation model, focusing on the conclusions of internationally respected expert scientific bodies. The TWG did not take into account the estimated levels of contamination in the water at Camp Lejeune and therefore could not characterize any risk associated with a specific level of exposure to contaminated water. As the available scientific evidence does not provide specific data on exposure levels, VA proposes to use its prior implementation of the health care provisions of Public Law 112-154 as a guide.

While section 102 of Public Law 112-154 requires that the veteran served at Camp Lejeune for at least 30 days, it does not specify whether these days must be consecutive. VA's implementation of the provisions of section 102, contained in 38 CFR 17.400, requires that a veteran served at least 30 days at Camp Lejeune to establish entitlement to health care. 78 FR 55671. Section 17.400 specifically notes that the 30 days may be consecutive or non-consecutive. While VA is not bound by Public Law 112-154 or 38 CFR 17.400 in proposing the current presumptions of exposure and service connection, VA has determined that inclusion of the 30-day requirement would ensure consistency and parity with both its healthcare regulations and the statute.

However, the enactment of Public Law 112-154, by itself, does not provide

a legal requirement for prescribing a 30-day service requirement for the purposes of disability compensation. Further, Congress did not provide any scientific references for prescribing a 30-day service requirement when it enacted Public Law 112–154. VA acknowledges that current science establishes a link between exposure to certain chemicals found in the water supply at Camp Lejeune and later development of one of the proposed presumptive conditions. However, VA experts agree that there is no science to support a specific minimum exposure level for any of the conditions. Therefore, VA welcomes comments on this requirement and will consider other practical alternatives when drafting the final rule.

VA also notes that the proposed 30-day requirement serves to establish eligibility for service connection on a presumptive basis; nothing in this proposed regulation prohibits consideration of service connection on a non-presumptive basis. Veterans without the requisite 30 days of service at Camp Lejeune may still establish service connection for any disease or disability on a direct basis. Direct service connection for any disease alleged to have been caused by contaminants in the water supply at Camp Lejeune requires evidence of a current disease or disability, evidence of exposure to the contaminated water at Camp Lejeune, and a medical nexus between the two, supported by a sufficient scientific explanation.

D. Application to Reservists and National Guard

Basic eligibility for VA benefits requires that an individual be a “veteran” as that term is defined in 38 U.S.C. 101(2): “The term ‘veteran’ means a person who served in the active military, naval, or air service, and who was discharged or released therefrom under conditions other than dishonorable.” Reserve or National Guard service during a period of active duty for training or inactive duty training generally does not qualify an individual as a “veteran” because it does not constitute “active military, naval or air service,” unless the individual is disabled or dies during that period of service as prescribed by 38 U.S.C. 101(24)(B) and (C).

This proposed rule would establish presumptions that former reservists and National Guard members were exposed to contaminants in the water supply between August 1, 1953 and December 31, 1987, if their military personnel record includes orders or other records of no less than 30 days service (consecutive or nonconsecutive) at

Camp Lejeune during the contamination period, and would allow them to establish veteran status by presuming that a covered disability was incurred in the line of duty and arose during the qualifying period of service.

Although 38 U.S.C. 101(24) requires a period of active duty for training or inactive duty training “during which the individual concerned was disabled or died” for a period of active duty for training or inactive duty training to constitute “active military, naval, or air service,” the latent effects of exposures to certain harmful chemicals were unrecognized when section 101(24) was enacted in 1958. The legislative history regarding the enactment of section 101(24) does not specifically explain Congress’ intent in requiring that the individual “was disabled or died” during the period of service. It is probable that Congress required a reserve component member to have been disabled “during” training because the medical science of the time understood that, if an in-service injury were to result in disability, at least some aspect of that disability generally would be manifest contemporaneous with the injury. However, subsequent developments with regard to medical understanding of the health effects of harmful chemical exposures, such as the VOCs that contaminated the Camp Lejeune water supply, raise a question regarding the application of section 101(24) to disability associated with such exposure.

Viewing the generally beneficial purpose of section 101(24) in light of an evolved medical understanding, the Secretary believes it is reasonable to propose a factual presumption that disability occurred during the period of service as required under section 101(24) when an individual has a present disability from: Kidney cancer, liver cancer, adult leukemia, non-Hodgkin’s lymphoma, bladder cancer, multiple myeloma, aplastic anemia and other myelodysplastic syndromes, and Parkinson’s disease. Specifically, the proposed disease presumptions enumerated in 38 CFR 3.309, coupled with the potential for clinical uncertainty regarding when such diseases first manifested, provide a reasonable basis for presuming that disability occurred during a period of reserve or National Guard service for purposes of satisfying the requirements under section 101(24)(B) or (C) in order to ensure compensation and health care for reservists and National Guard personnel disabled as a result of exposure to the contaminants in the water supply at Camp Lejeune on

qualifying reserve and National Guard duty.

IV. Application of Rulemaking to Previously Adjudicated Claims

This proposed rule would 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. This proposed rule would not apply retroactively to claims previously adjudicated. VA would adhere to the provisions of its change of law regulation, 38 CFR 3.114, which states, “[w]here pension, compensation, dependency and indemnity compensation, . . . is awarded or increased pursuant to a liberalizing law, or a liberalizing VA issue approved by the Secretary or by the Secretary’s direction, the effective date of such award or increase shall be fixed in accordance with the facts found, but shall not be earlier than the effective date of the act or administrative issue.” See also 38 U.S.C. 5110(g).

This proposed regulation is based on the Secretary’s broad authority under 38 U.S.C. 501(a) to “prescribe all rules and regulations which are necessary or appropriate to carry out the laws administered by the Department and are consistent with those laws, including— . . . regulations with respect to the nature and extent of proof and evidence . . . in order to establish the right to benefits under such laws.” This rulemaking authority does not explicitly afford the Secretary authority to assign retroactive effect to the regulations created thereunder. It is well-settled that “[r]etroactivity is not favored in the law. . . . [A] statutory grant of legislative rulemaking authority will not, as a general matter, be understood to encompass the power to promulgate retroactive rules unless that power is conveyed by Congress in express terms.” *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). As there is no explicit statutory authority to apply this proposed regulation retroactively, the Secretary, based on the current state of the scientific evidence, will take into consideration the evidentiary burden on claimants for certain Camp Lejeune contaminated water related claims pending (for the diseases specified in the proposed regulation) at the time of publication of the final rule and for all future claims.

Although this proposed regulation would not apply retroactively, a claimant whose claim was previously and finally denied may file a new claim to obtain a new determination of entitlement under the final regulation. See *Spencer v. Brown*, 17 F.3d 368, 372

(Fed. Cir. 1994) (“When a provision of law or regulation creates a new basis of entitlement to benefits, as through liberalization of the requirements for entitlement to a benefit, an applicant’s claim of entitlement under such law or regulation is a claim separate and distinct from a claim previously and finally denied prior to the liberalizing law or regulation.”) (quoting *Spencer v. Brown*, 4 Vet. App. 283, 288–89 (1993)).

V. Regulation Amendments

VA proposes to amend the § 3.307 heading to read “Presumptive service connection for chronic, tropical or prisoner-of-war related disease, disease associated with exposure to certain herbicide agents, or disease associated with the contaminants in the water supply at Camp Lejeune; wartime and service on or after January 1, 1947.” Likewise, VA proposes to revise paragraph (a) of § 3.307 to add the phrase “, or disease associated with the contaminants in the water supply at Camp Lejeune” after the words “herbicide agents.” Both of these proposed amendments are necessary to inform the public that certain diseases associated with contaminants in the water supply at Camp Lejeune are now included among those covered by VA’s proposed presumptive service connection regulations. Paragraph (a)(1) of § 3.307 establishes service criteria necessary to establish entitlement to presumptive treatment of a disease related to particular types of exposure. VA proposes to amend this paragraph to specify that any period of service is sufficient for purposes of presumptive service connection of conditions associated with service at Camp Lejeune, as long as the service also satisfies the requirements to establish a presumption of exposure to contaminants in the water supply at that facility under § 3.307(a)(7)(iii).

As noted above, VA previously implemented health care benefits for veterans who served on active duty at Camp Lejeune for at least thirty days (consecutive or nonconsecutive) during the contamination period through 38 CFR 17.400. To maintain consistency and parity with VA’s interpretation of Public Law 112–154 in implementing its healthcare regulations, VA proposes that a veteran, or former reservist or National Guard member, must have a record of no less than 30 days of service (consecutive or nonconsecutive) at Camp Lejeune for any period between the prescribed dates to establish service connection on a presumptive basis for the eight conditions addressed in this proposed rule. Service at Camp Lejeune, for the purpose of establishing service

connection on a presumptive basis, means that the veteran, or former reservist or National Guard member, as established by military orders or other official service department records, lived or worked within the confines of the Camp Lejeune border. Any such veteran, or former reservist or National Guard member, could have been exposed to contaminants in the water supply through drinking, bathing or other activities. We believe that military orders or other official service department records documenting no less than 30 days of service at Camp Lejeune provide a rational basis for presuming that the individual likely had more than isolated and minimal opportunity for contact with the relevant VOCs.

VA also proposes adding paragraph (a)(7) to § 3.307 to describe entitlement criteria for diseases associated with exposure to contaminants in the water supply at Camp Lejeune. Paragraph (a)(7)(i) defines “contaminants in the water supply” to mean the on-base water-supply systems located at Camp Lejeune that were contaminated with TCE, PCE, benzene, and vinyl chloride during the period beginning August 1, 1953, and ending December 31, 1987. Proposed paragraph (a)(7)(ii) cross-references proposed § 3.309(f), which lists the diseases that are presumptively service connected based on exposure to contaminants in the water supply at Camp Lejeune, and requires that they manifest to a compensable degree at any time after service for VA to award presumptive service connection. Proposed paragraph (a)(7)(iii) describes the population covered by the presumption of exposure.

Proposed paragraph (a)(7)(iii) applies the presumption of exposure to a veteran, reservist, or National Guard member who had no less than 30 days of service (consecutive or nonconsecutive) at Camp Lejeune at any time during the period beginning August 1, 1953, and ending December 31, 1987. Such individuals are presumed to have been exposed to the contaminants in the water supply at Camp Lejeune, unless there is affirmative evidence to establish that there was no such exposure. Affirmative evidence showing that there was no exposure is likely to be rare, but if there is evidence showing that the veteran was not actually exposed to contaminants in the water supply, the veteran must establish that the disability is related to military service in some other way (e.g., had its onset during service). The disability will not be presumed to have been caused by

contaminants in the water supply at Camp Lejeune.

VA proposes to prescribe the same contamination period as 38 U.S.C. 1710(e)(1)(F). As noted above, section 1710(e)(1)(F) was amended by Public Law 113–235 to change the Camp Lejeune contamination period to August 1, 1953, through December 31, 1987. The legislative history does not explain why Congress selected this contamination period, but it is likely based on some of the earliest assessments of the Camp Lejeune water supply noted in the NRC report. *Contaminated Water Supplies*, at 60. This period represents the ATSDR’s best estimate of the period of contamination at Camp Lejeune and likely captures all potentially affected veterans.

Paragraph (a)(7)(iii) also defines “service at Camp Lejeune” as any service within the borders of the entirety of the United States Marine Corps Base Camp Lejeune and Marine Corps Air Station New River, North Carolina, during the relevant period, as established by military orders or other service department records. Neither the statute nor the legislative history of Public Law 112–154 indicates Congress’ intent as to the geographic area covered by reference to “Camp Lejeune, North Carolina” in 38 U.S.C. 1710(e)(1)(F). VA acknowledges that it would be too difficult to determine with specificity which residential or workplace facilities were serviced with the contaminated water, or whether and to what degree the veteran would have come into contact with that facility during active service. Therefore, this proposed rule covers any veteran, reservist, or member of the National Guard, whose military orders or records establish their presence within the borders of the entirety of the United States Marine Corps Base Camp Lejeune border, which includes Marine Corps Air Station New River, for no less than 30 days (consecutive or nonconsecutive) and therefore could potentially have come into physical contact (e.g., by drinking or bathing) with contaminants in the water supply on more than an isolated and minimal basis. VA specifically included Marine Corps Air Station New River in the definition of service Camp Lejeune to clarify that official military records indicating service at Marine Corps Air Station New River are sufficient to establish service at Camp Lejeune for the purposes of this rulemaking. This would ensure consistency with the definition of Camp Lejeune in 38 CFR 17.400(b) for purposes of health care.

Proposed paragraph (a)(7)(iv) prescribes that the presumed exposure

to contaminants in the water supply is an “injury” under section 101(24)(B) and (C). In turn, if an individual develops a presumptive disease listed in 38 CFR 3.309(f), “VA will presume that the individual concerned became disabled during that service for purposes of establishing that the individual served in the active military, naval, or air service.” As explained previously, this is consistent with section 101(24) because exposure to contaminants in the water supply at Camp Lejeune is associated with latent adverse health effects that were largely unrecognized in 1958. Covered individuals may therefore establish veteran status for purposes of VA’s disability compensation, dependency and indemnity compensation, medical care, and burial benefits related to any Camp Lejeune-related presumptive condition.

VA also proposes to amend 38 CFR 3.309 by adding paragraph (f). This proposed paragraph is titled “Disease associated with exposure to contaminants in the water supply at Camp Lejeune.” The primary purpose of this proposed amendment is to list the diseases that are presumptively service connected based on exposure to contaminants in the water supplies at Camp Lejeune during the exposure period. For the reasons described above, the diseases are as follows: Kidney cancer, liver cancer, non-Hodgkin’s lymphoma, adult leukemia, multiple myeloma, Parkinson’s disease, aplastic anemia and other myelodysplastic syndromes, and bladder cancer. Proposed paragraph (f) notes that the provisions of 38 CFR 3.307(d), regarding circumstances in which presumptions of service connection may be rebutted, apply to these presumptions.

Administrative Procedure Act

The Secretary of Veterans Affairs is providing a 30 day period for public comment. Kidney cancer, liver cancer, non-Hodgkin’s lymphoma, adult leukemia, multiple myeloma, Parkinson’s disease, bladder cancer, and aplastic anemia and other myelodysplastic syndromes are debilitating and life-threatening illnesses, and any delay in implementing a final rule could have severe detrimental impact on Veterans exposed to contaminants in the water supply at Camp Lejeune now suffering from these diseases. Based on the age of the individuals affected by this proposed rule and the severity of the disabilities associated with their exposure, it is likely that affected individuals would have significant and urgent financial and medical needs. In

the absence of a shortened public comment period and publication of a final rule, these Veterans may not receive proper health care or assistance with daily functions due to financial hardship or the absence of service-connected status for their disability.

While VA believes the severity of the conditions and the age of the individuals affected themselves justify a 30 day period for public comment, there is an even more acute basis for the Secretary’s decision. VA is aware of roughly thirty individuals who are terminally ill, and would be covered by the presumptions in the event they become effective. Provision of a 60-day comment period would increase the likelihood that some affected veterans who have incurred or will incur one or more of the covered illnesses will die from the disease before a final rule could be issued. In order for these individuals to have access to VA health care, some for the first time, and disability compensation benefits, it is critical that VA establish these presumptions as soon as possible. Therefore, the Secretary is providing a public comment period of 30 days. VA invites public comments on this proposed rule and notes that it will fully consider and address any comments received.

Executive Orders 12866 and 13563

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,” requiring review by the Office of Management and Budget (OMB), unless OMB waives such review, 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 is likely to result in a rule that may have an annual effect on the economy of \$100 million or more and may raise 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 this rulemaking and its impact analysis are available on VA’s Web site at <http://www.va.gov/orpm/>, by following the link for “VA Regulations Published from FY 2004 Through Fiscal Year to Date.”

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612). This proposed rule would directly affect only individuals and would not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the 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 proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This proposed rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.109, Veterans Compensation for Service-Connected Disability; 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. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on August 30, 2016, for publication.

Dated: September 1, 2016.

Michael Shores,

Acting Director, Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

List of Subjects in 38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits, Veterans.

For the reasons stated in the preamble, the Department of Veterans Affairs proposes to amend 38 CFR part 3 as follows:

PART 3—ADJUDICATION

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

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

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

■ 2. Amend § 3.307 by revising the section heading and paragraphs (a) introductory text and (a)(1), and adding paragraph (a)(7) to read as follows:

§ 3.307 Presumptive service connection for chronic, tropical or prisoner-of-war related disease, disease associated with exposure to certain herbicide agents, or disease associated with contaminants in the water supply at Camp Lejeune; wartime and service on or after January 1, 1947.

(a) *General.* A chronic, tropical, prisoner of war related disease, a disease associated with exposure to certain herbicide agents, or a disease associated with contaminants in the water supply at Camp Lejeune listed in § 3.309 will be considered to have been incurred in or aggravated by service under the circumstances outlined in this section even though there is no

evidence of such disease during the period of service. No condition other than one listed in § 3.309(a) will be considered chronic.

(1) *Service.* The veteran must have served 90 days or more during a war period or after December 31, 1946. The requirement of 90 days' service means active, continuous service within or extending into or beyond a war period, or which began before and extended beyond December 31, 1946, or began after that date. Any period of service is sufficient for the purpose of establishing the presumptive service connection of a specified disease under the conditions listed in § 3.309(c) and (e). Any period of service is sufficient for the purpose of establishing the presumptive service connection of a specified disease under the conditions listed in § 3.309(f), as long as the period of service also satisfies the requirements to establish a presumption of exposure to contaminants in the water supply at Camp Lejeune under paragraph (a)(7)(iii) of this section.

(7) *Diseases associated with exposure to contaminants in the water supply at Camp Lejeune.* (i) For the purposes of this section, *contaminants in the water supply* means the volatile organic compounds trichloroethylene (TCE), perchloroethylene (PCE), benzene and vinyl chloride, that were in the on-base water-supply systems located at United States Marine Corps Base Camp Lejeune, during the period beginning on August 1, 1953, and ending on December 31, 1987.

(ii) The diseases listed in § 3.309(f) shall have become manifest to a degree of 10 percent or more at any time after service.

(iii) A veteran, or former reservist or member of the National Guard, who had no less than 30 days (consecutive or nonconsecutive) of service at Camp Lejeune during the period beginning on August 1, 1953, and ending on December 31, 1987, shall be presumed to have been exposed during such service to the contaminants in the water supply, unless there is affirmative evidence to establish that the individual was not exposed to contaminants in the water supply during that service. The last date on which such a veteran, or former reservist or member of the National Guard, shall be presumed to have been exposed to contaminants in the water supply shall be the last date on which he or she served at Camp Lejeune during the period beginning on August 1, 1953, and ending on December 31, 1987. For purposes of this section, *service at Camp Lejeune* means

any service within the borders of the entirety of the United States Marine Corps Base Camp Lejeune and Marine Corps Air Station New River, North Carolina, during the period beginning on August 1, 1953, and ending on December 31, 1987, as established by military orders or other official service department records.

(iv) Exposure described in paragraph (a)(7)(iii) of this section is an injury under 38 U.S.C. 101(24)(B) and (C). If an individual described in paragraph (a)(7)(iii) of this section develops a disease listed in 38 CFR 3.309(f), VA will presume that the individual concerned became disabled during that service for purposes of establishing that the individual served in the active military, naval, or air service.

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

■ 3. Add § 3.309(f) to read as follows:

§ 3.309 Disease subject to presumptive service connection.

* * * * *

(f) *Disease associated with exposure to contaminants in the water supply at Camp Lejeune.* If a veteran, or former reservist or member of the National Guard, was exposed to contaminants in the water supply at Camp Lejeune during military service and the exposure meets the requirements of § 3.307(a)(7), the following diseases shall be service-connected even though there is no record of such disease during service, subject to the rebuttable presumption provisions of § 3.307(d).

- (1) Kidney cancer.
- (2) Liver cancer.
- (3) Non-Hodgkin's lymphoma.
- (4) Adult leukemia.
- (5) Multiple myeloma.
- (6) Parkinson's disease.
- (7) Aplastic anemia and other myelodysplastic syndromes.
- (8) Bladder cancer.

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

[FR Doc. 2016-21455 Filed 9-8-16; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 70

[EPA-R07-OAR-2016-0453; FRL-9951-85-Region 7]

State of Iowa; Approval and Promulgation of the Title V Operating Permits Program, the State Implementation Plan, and 112(I) Plan

AGENCY: Environmental Protection Agency (EPA).