

Thus, increasing the current civil penalty amount would not result in an annual effect on the economy of \$100 million or more.

Regulatory Flexibility Act

We have also considered the impacts of this notice under the Regulatory Flexibility Act. I certify that this rule will not have a significant economic impact on a substantial number of small entities. The following provides the factual basis for this certification under 5 U.S.C. 605(b). The St. Lawrence Seaway Regulations and Rules primarily relate to the activities of commercial users of the Seaway, the vast majority of whom are foreign vessel operators. Therefore, any resulting costs will be borne mostly by foreign vessels.

Executive Order 13132 (Federalism)

Executive Order 13132 requires SLSDC to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” Under Executive Order 13132, the agency may not issue a regulation with Federalism implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by State and local governments, the agency consults with State and local governments, or the agency consults with State and local officials early in the process of developing the proposed regulation.

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132.

The reason is that this rule will generally apply to commercial users of the Seaway, the vast majority of whom are foreign vessel operators. Therefore, any resulting costs will be borne mostly by foreign vessels. Thus, the requirements of Section 6 of the Executive Order do not apply.

Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995, Public Law 104–4, requires agencies to prepare a written assessment of the cost, benefits and other effects of proposed or final rules that include a Federal mandate likely to result in the expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of more than \$100 million annually. Because this rule will not have a \$100 million effect, no Unfunded Mandates assessment will be prepared.

Executive Order 12778 (Civil Justice Reform)

This rule does not have a retroactive or preemptive effect. Judicial review of a rule based on this proposal may be obtained pursuant to 5 U.S.C. 702. That section does not require that a petition for reconsideration be filed prior to seeking judicial review.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980, we state that there are no requirements for information collection associated with this rulemaking action.

Privacy Act

Please note that anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT’s complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78), or you may visit <http://dms.dot.gov>.

List of Subjects in 33 CFR Part 401

Hazardous materials transportation, Navigation (water), Penalties, Radio, Reporting and recordkeeping requirements, Vessels, Waterways.

Accordingly, the Saint Lawrence Seaway Development Corporation is amending 33 CFR part 401 as follows:

PART 401—SEAWAY REGULATIONS AND RULES

Subpart A—Regulations

- 1. The authority citation for subpart A of part 401 is amended to read as follows:

Authority: 33 U.S.C. 981–990, 1231 and 1232, 49 CFR 1.52, unless otherwise noted.

- 2. In § 401.102, paragraph (a) is revised to read as follows:

§ 401.101 Criminal penalty.

(a) A person, as described in § 401.101(b) who violates a regulation is liable to a civil penalty of not more than \$90,063.

* * * * *

Issued on December 30, 2016.

Carrie Lavigne,

Chief Counsel.

[FR Doc. 2016–32050 Filed 1–12–17; 8:45 am]

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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: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) amends its adjudication regulations regarding presumptive service connection, adding 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. This final rule establishes 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 incurred or aggravated the disease in service for purposes of entitlement to VA benefits. In addition, this final rule establishes a presumption that these individuals were disabled during the relevant period of service for purposes of establishing active military service for benefits purposes. Under this presumption, affected former reservists and National Guard members have veteran status for purposes of entitlement to some VA benefits. This amendment implements 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.

DATES: *Effective Date:* This final rule is effective March 14, 2017.

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. Purpose of the Final Rule

VA amends its adjudication regulations to add certain diseases associated with contaminants present in the base water supply at U.S. Marine Corps Base Camp Lejeune, North Carolina, from August 1, 1953, to December 31, 1987. This final rule establishes 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 incurred or aggravated the disease in service for purposes of entitlement to VA benefits. In addition, this final rule establishes a presumption that these individuals were disabled during the relevant period of service for purposes of establishing active military service for benefits purposes. Under this presumption, affected former reservists and National Guard members have veteran status for purposes of entitlement to some VA benefits.

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 Public Law 112-154, the Honoring America’s Veterans and Caring for Camp Lejeune Families Act of 2012 (Camp Lejeune Act), and the subsequent development of one of the eight listed diseases is sufficient to support the presumption that the resulting disease 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 and 1131.

II. Summary of Major Provisions

The major provisions of this final rule include the following: VA will amend 38 CFR 3.307 to establish presumptions of service connection associated with exposure to contaminants in the water supply at Camp Lejeune. This amendment presumes 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. This presumption specifically allows former reservists and National Guard members to establish veteran status by presuming that a covered disease was incurred in the line of duty and was disabling during a period of qualifying service.

VA will also amend 38 CFR 3.309 to prescribe the eight conditions that are subject to presumptive service connection in relation to exposure to contaminants in the water supply at Camp Lejeune.

III. Technical Correction

In the proposed rule, VA proposed amending the heading of 38 CFR 3.307 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.” Additionally, VA proposed amending paragraph (a) of § 3.307 to mirror the title. In reviewing this amendment for the final rule, however, VA realized that the current and proposed text of paragraph (a) contain errors. Namely, they refer to a “chronic, tropical, prisoner of war related disease” rather than a “chronic, tropical or prisoner of war related disease,” as referenced in the heading of § 3.307. Additionally, the heading and proposed text omitted the words “exposure to” before “contaminants in the water supply.” This document corrects these errors by inserting “or” in place of the comma between “tropical” and “prisoner of war” in paragraph (a) to clarify that the terms “chronic,” “tropical,” and “prisoner of war related” refer to three separate categories of disease rather than characteristics of a single disease; and inserting “exposure to” in the heading and paragraph (a) in the phrase pertaining to contaminants in the water supply at Camp Lejeune.

IV. Public Comments

On September 9, 2016, VA published in the **Federal Register** (81 FR 62419) a notice of a proposed rulemaking to amend 38 CFR 3.307 and 3.309 to establish presumptive service connection for certain diseases associated with contaminants present in the base water supply at U.S. Marine Corps Base Camp Lejeune, North Carolina, from August 1, 1953 to December 31, 1987. VA provided a 30-day public comment period, which ended on October 11, 2016, and received 290 comments on the proposed rule, one of which was received after the comment period. Although VA is not legally required to consider late-filed comments, it has reviewed, considered, and addressed all comments received in the interest of maximizing public dialogue to further serve veterans, claimants, and authorized representatives. VA received comments from various organizations and individuals, including Disabled American Veterans (DAV), Veterans of Foreign Wars (VFW), Vietnam Veterans of America (VVA), National Organization of Veterans’ Advocates (NOVA), C-123 Veterans Association, Fort McClellan Veterans Stakeholders Group, Reserve Officers Association, Marine Corps Reserve Association, United Parkinson’s Advocacy Council, Legal Counsel for the Elderly, Project on Government Oversight, a member of Congress, and other interested persons. VA responds to all commenters as follows.

All of the issues raised by the commenters that concerned at least one portion of the rule can be grouped together by similar topic, and VA has organized the discussion of the comments accordingly. VA also received 85 comments from veterans and surviving spouses regarding individual claims for veterans’ benefits. VA does not respond to these comments in this document as they are beyond the scope of this rulemaking.

For the reasons set forth in the proposed rule and below, VA adopts the proposed rule as final, with changes, as explained below.

A. 30-Day Exposure Requirement

VA received 18 comments, including organizational comments from DAV, VVA, NOVA, Project on Government Oversight, and Legal Counsel for the Elderly, regarding its proposal that a veteran, or former reservist or National Guard member must serve no less than 30 days (consecutive or nonconsecutive) at Camp Lejeune during the period beginning August 1, 1953, and ending

on December 31, 1987, to receive a presumption of service connection for the eight listed diseases based on exposure to contaminants in the water supply. Two commenters suggested changing the exposure requirement to one week and two weeks, respectively; neither commenter offered a rationale for these time limits. Several commenters suggested eliminating the exposure requirement completely, noting that the 30-day requirement was inconsistent with other toxic exposure presumptions and that it was not supported with scientific evidence. One commenter stated that the 30-day requirement would essentially exclude National Guard members from eligibility. One commenter stated that a 30-day exposure requirement would exclude veterans serving in the Naval Amphibious Force who docked at Camp Lejeune.

1. Comparison to Prior Exposure Regulations

VA received several comments, including from DAV, NOVA, VVA, Legal Counsel for the Elderly, and Project on Government Oversight, stating that a 30-day exposure period is inconsistent with VA's requirements for presumptive service connection based on toxic and other exposures. For example, VA has previously established regulations governing presumptive service connection for diseases associated with exposure to certain herbicide agents and certain disabilities occurring in Persian Gulf veterans. See 38 CFR 3.307, 3.309, and 3.317. These regulations do not include a minimum exposure requirement; a veteran must show that he or she served in an identified location or under enumerated circumstances to receive a presumption of service connection.

While the commenters are correct in that VA does not require a minimum level or duration of exposure for some previously-established presumptions, VA notes that these regulations serve to provide presumptive service connection based on the specified and particular exposures, conditions, and nature of military service in accordance with the scientific and other evidence supporting them. They do not set a binding precedent for future rulemakings that address unrelated circumstances. For example, while presumptive service connection for certain disabilities occurring in Persian Gulf veterans does not require a minimum exposure during military service, 38 CFR 3.317 requires that the qualifying chronic disability must manifest to a degree of 10 percent or more no later than December 31, 2021. This regulation, though, does not

require conditions associated with exposure to contaminants in the water supply at Camp Lejeune to manifest by a certain date. Similarly, 38 CFR 3.311 specifies that disabilities presumed to be associated with exposure to ionizing radiation must manifest within certain time periods after exposure to radiation (the time period varies depending on the condition in question). Nothing in this regulation requires a condition associated with exposure to contaminants in the water supply at Camp Lejeune to manifest within a certain period of time following service.

In addition to being based on different scientific, medical, and military evidence, the prior toxic exposure regulations often stem from a specific, separate statutory authority or requirement. These statutes prescribe the method by which the Secretary may create a regulatory presumption, to include the evidentiary basis for establishing a presumption, periods in which a disability must manifest, covered disabilities, how the Secretary shall determine that a condition is associated with a given toxic exposure, and other requirements specific to the toxic exposure under review. For example, the statutory authority to award presumptive service connection for certain disabilities associated with herbicide exposure in the Republic of Vietnam prescribes the dates during which the veteran must have served within the Republic of Vietnam. See 38 U.S.C. 1116. Similarly, 38 U.S.C. 1117 prescribes the requirements for eligibility for benefits associated with service in the Persian Gulf War. Notably, this statute also grants the Secretary the authority to determine the period of time following service during which a qualifying disability must manifest. See 38 U.S.C. 1117(b).

In the case of this regulation, Congress did not enact a specific statute authorizing the Secretary to establish compensation for disabilities presumptively related to exposure to contaminants in the water supply at Camp Lejeune. While creating this presumption via regulation fits within the authority conferred by section 501, the Secretary's rulemaking actions must have a rational basis. The Secretary has determined that, in the absence of evidence establishing an appropriate period of time for an exposure requirement, the soundest course is to maintain consistency with the Camp Lejeune Act, which establishes eligibility for VA health care for Camp Lejeune veterans who meet applicable criteria, including a 30-day service requirement. See 38 U.S.C. 1710(e)(1)(F), 38 CFR 17.400. This will

help to avoid public confusion and inconsistent results, for example where some Camp Lejeune veterans would be eligible for a presumption for purposes of disability compensation, but not the statutory presumption for health care benefits.

2. Modality of Exposure to Contaminants

Comments from DAV and Legal Counsel for the Elderly stated that failure to consider periods of service shorter than 30 days ignores the likelihood of regular and repeated exposure to contaminants through multiple modalities. The commenters noted that the National Research Council (NRC) explored three major routes of exposure to contaminants: Inhalation, skin contact, and ingestion. The NRC's 2009 study noted that doses of contaminants from showering could provide inhalation and dermal exposures that are equivalent to ingesting two liters of water, as water temperature impacted the volatility of the contaminants. Accordingly, commenters argued that when taking into account multiple modalities of exposure, the exposure to contaminants could be much greater in a shorter time period than compared to 30 days of drinking the water. This comment was echoed by several individual commenters.

As noted in the proposed rule, the Technical Working Group's (TWG) assessment relied on a hazard evaluation model, focusing on the strength of the evidence that a chemical is capable of causing a given health condition. The TWG did not take into account estimated levels of contamination in the water during the period of contamination at Camp Lejeune or the estimated length or intensity of exposure. This is in part because contamination levels and exposures were not well documented. For example, the 2009 NRC committee was "not aware of any historical information that documents individual water-use patterns and behaviors of residents of base housing." Committee on Contaminated Drinking Water at Camp Lejeune; National Research Council, *Contaminated Water Supplies at Camp Lejeune, Assessing Potential Health Effects* 61 (National Academies Press, 2009). Accordingly, the TWG did not characterize the risk associated with potential alternative levels of exposure (to include various modalities of exposure) of those who served or resided at Camp Lejeune during the period of contamination.

It is also relevant to note that the scientific evidence was not analyzed by

VA for sufficiency to support an expert opinion in a legal proceeding regarding causation in any individual case. Therefore, VA intimates no conclusion regarding any individual veteran's development of a disease and its relationship to exposure to contaminated water at Camp Lejeune for any purpose beyond entitlement to disability benefits administered by VA.

In the notice of proposed rulemaking, VA acknowledged that the available scientific evidence does not provide data on levels of exposure associated with each condition and proposed to rely upon the 30-day service requirement contained in the provisions of the Camp Lejeune Act. In the absence of scientific evidence which supports establishment of an alternative service or exposure requirement, VA's determination favors consistency and parity with its own health care regulation and the statute stands. Congress understood the Camp Lejeune Act to mean that "veterans deserve the presumptions of the service connection in the bill to ensure that they receive the benefits to which they are due," and did not specify that a different service requirement should exist for purposes of disability compensation. 158 Cong. Rec. H5430 (July 31, 2012) (statement by Rep. Dingell). Creation of a separate standard for the purposes of disability compensation would create inconsistency in the administration of benefits for Camp Lejeune veterans where the statute includes a clear service requirement for health care eligibility; inclusion of the 30-day requirement ensures consistency and parity in this regard with both the Camp Lejeune Act and VA's own regulations implementing the health care provisions of the act. For example, including a service requirement less than that in the Camp Lejeune Act could lead to the situation wherein a veteran is determined to be ineligible for VA health care on the grounds that he or she did not have the necessary 30 days of service at Camp Lejeune, but is then granted service connection on a presumptive basis based on the same service at Camp Lejeune upon filing a claim for compensation. A veteran in this situation could, via operation of this presumption, become eligible for VA health care based on their service connection rating, even though he or she would not have been eligible under the 30-day service requirement of the Camp Lejeune Act. This confusing result could raise a question as to whether VA had indirectly contravened a portion of the Camp Lejeune Act by virtue of a liberalizing evidentiary

presumption meant for compensation claims.

One commenter expressed concern with the 30-day requirement because the individual had documentation stating that his or her length of stay at Camp Lejeune was four weeks (which would be 28 days if read strictly). The individual noted that Department of Defense documentation sometimes references weeks of training, rather than days of training and expressed concern with personal and administrative burden associated with documenting presence on base for a day or two before and/or after training. As stated above, VA is adopting a 30-day requirement to ensure consistency with the Camp Lejeune Act. In adjudicating individual claims, VA is required to assist claimants in obtaining evidence and to resolve reasonable doubt in claimants' favor.

Thus, while VA acknowledges and thanks the commenters for their input, VA is unable to make any changes based upon these comments at this time. However, VA will continue to review relevant information as it becomes available and will consider future amendments to the 30-day requirement as appropriate.

3. Decide Claims Through Tort Law

Another commenter felt that the statutory 30-day requirement lacked a medical basis and felt that veterans' claims should be handled through tort law rather than the disability claim process. VA notes that the 30-day requirement for health care benefits was established by Congress. Furthermore, the presumptions set forth in this rulemaking are for the purposes of administering VA disability compensation benefits only; VA expresses no view regarding the potential correlation between any given level or duration of exposure and the increased risk of disease and/or disability for any purpose beyond this rulemaking. Accordingly, VA takes no action based on this comment.

4. Eliminate 30-Day Requirement for Health Care

Another commenter stated that VA should not require 30 days of service at Camp Lejeune to establish entitlement to health care benefits. The service requirement to establish entitlement to health care is mandated by the Camp Lejeune Act. The Camp Lejeune Act is a statute, the provisions of which were enacted by Congress. VA lacks the legal authority to alter, amend, or otherwise change the provisions of a statute and therefore takes no action based on this comment. We discuss the difference in

scope between the Camp Lejeune Act and this final rule in greater detail in section D.1, below.

5. Conduct Additional Studies on Exposure Requirements

A comment from VFW stated that VA should conduct additional studies to cover the impact of exposure on individuals who served less than 30 days, with the ultimate goal of reducing the 30-day exposure requirement. VA thanks VFW for its suggestion regarding conducting additional studies. However, this rulemaking pertains solely to establishing presumptions of service connection associated with exposure to contaminants in the water supply at Camp Lejeune; conducting scientific and/or medical studies is beyond the scope of this rulemaking. As such, VA makes no change to the final rule based on this comment.

6. Miscellaneous Alternative Exposure Requirement Comments

VA received several comments offering additional alternative minimum exposure requirements, with suggestions including a single day at Camp Lejeune and an increase to 90 days. While these comments offered alternative exposure criteria, they did not provide a rationale for the suggested alternative that was rooted in scientific, medical, or other rational basis.

As discussed above, the notice of proposed rulemaking acknowledged that the current science does not support a specific minimum exposure level for any of the conditions, as the available scientific and medical evidence focused on hazard models when studying the long-term health effects of the contaminants. Lacking such a scientific basis, VA relied upon the only source available in deciding to establish a 30-day exposure requirement: The Camp Lejeune Act. As VA acknowledged in the notice of proposed rulemaking, the Camp Lejeune Act does not provide a legal requirement for prescribing a 30-day service requirement for the purposes of disability compensation. However, the Camp Lejeune Act and VA's prior implementation of its provisions require 30 days of service at Camp Lejeune for a veteran to establish entitlement to health care. See 38 CFR 17.400. In light of the Camp Lejeune Act, VA's implementation of its provisions through 38 CFR 17.400, and the lack of an alternative exposure requirement supported by scientific, medical, or other rational evidence, VA determined that inclusion of the 30-day requirement in this rulemaking ensures consistency

and parity with both its health care regulations and the statute.

Without a rational basis to explain and support an alternative exposure requirement, VA's rulemaking would not comply with the statutory requirements of 38 U.S.C. 501 and therefore takes no action based on these comments. VA will continue to review relevant information as it becomes available and will consider future changes to the regulation as appropriate.

VA notes that nothing in the provisions of this rule prevents veterans without the requisite 30 days (consecutive or nonconsecutive) of service at Camp Lejeune from establishing service connection for any disease or disability on a direct basis. Direct service connection for any disease alleged to have been caused by the contaminants in the water supply at Camp Lejeune requires evidence of a current disease or disability, evidence of exposure to contaminated water at Camp Lejeune, and a medical nexus between the two, supported by a sufficient medical explanation.

B. Definition of Service at Camp Lejeune

VA received seven comments concerning the definition of *service at Camp Lejeune* for the purposes of establishing entitlement to disability benefits on a presumptive basis, as contained in proposed § 3.307(f)(7)(iii). These comments suggested that the rule make reference to specific locations within the borders of Camp Lejeune, some of which may be considered satellite camps/locations. One commenter noted that veterans may have lived in one of the specified satellite camps/locations while assigned to Camp Lejeune, or vice versa. Another commenter stated that listing specific satellite locations included within the definition of Camp Lejeune would avoid confusion for eligible veterans and minimize the risk of improper denials by claims processors who may not be aware of the satellite camps/locations. One commenter stated that the proposed rule did not include Marine Corps Air Station New River. Legal Counsel for the Elderly stated the presumption should extend to those who served in circumstances "likely" to have resulted in exposure to contaminants in the water supply at Camp Lejeune. This comment gave examples of those who served in training exercises or ships outside of Camp Lejeune but "likely" used water drawn from Camp Lejeune. An additional comment referenced Navy Amphibious Forces that docked at Camp Lejeune and most likely took on board fresh water from the Camp.

VA makes no change based on these comments. As stated in the proposed rule, VA broadly defined *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 period beginning on August 1, 1953, and ending on December 31, 1987, as established by military orders or other official service department records. This definition is consistent with the Camp Lejeune Act and VA's prior implementation of the act, promulgated at 38 CFR 17.400. To ensure accurate and consistent application of the definition of *service at Camp Lejeune*, VA will administratively provide claims processors with all necessary factual and background information to process claims in accordance with this regulation.

Marine Corps Air Station (MCAS) New River, while located within the borders of the entirety of Camp Lejeune, falls under a separate command from Camp Lejeune itself. VA identified MCAS New River as a separate location as military orders or other official service department records may specifically denote service at or assignment to MCAS New River; failure to specify this location may result in improper denials of claims or create confusion for otherwise eligible veterans. VA notes that service at MCAS Cherry Point, which is geographically separate from Camp Lejeune (approximately 55 miles away), has a separate water source, and is under a separate command structure, does not meet the definition of *service at Camp Lejeune* for purposes of this rulemaking.

VA notes that the definition of *service at Camp Lejeune* relies on military orders or other official service department records to establish that an individual *had service at Camp Lejeune* for the purposes of entitlement to presumptive service connection based on exposure to contaminants in the water supply. As discussed in the proposed rule, the 2007 United States General Accounting Office (GAO) study found that the contaminated water supply systems served housing, administrative, and recreational facilities, as well as the base hospital at Camp Lejeune. See U.S. General Accounting Office, *Defense Health Care: Activities Related to Past Drinking Water Contamination at Marine Corps Base Camp Lejeune* (2007). Neither the GAO nor any other available study indicated that individuals who served aboard amphibious vessels were exposed to contaminants found in the water supply at Camp Lejeune. Without

evidence in official service department records documenting official orders or assignment to serve, either in an individual capacity or as part of a larger unit, at Camp Lejeune, a claimant does not meet the evidentiary standard for presumptive service connection. As such, without military orders or other official service department records reflecting service at Camp Lejeune, veterans, former reservists or National Guard members who served aboard vessels that docked at Camp Lejeune during the period of contamination are not eligible for presumptive service connection under the provisions of this rule.

As stated in the proposed rule, veterans without the requisite 30 days (consecutive or nonconsecutive) of service at Camp Lejeune, including those who allege exposure aboard amphibious vessels without military orders or other official service department records reflecting assignment to serve 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 the contaminants in the water supply at Camp Lejeune requires evidence of a current disease or disability, evidence of exposure to contaminated water at Camp Lejeune, and a medical nexus between the two, supported by a sufficient medical explanation.

C. Benefits for Former Reservists and National Guard Members

VA received five comments regarding benefits for former reservists and National Guard members. One commenter stated that VA should define what benefits are available to reservists under the rule, noting that the rule states reservists would be entitled to "some" benefits under the rulemaking. Similarly, another commenter stated that VA does not consider reservists and former National Guard members "veterans" unless they have a service-connected disability. Another commenter noted that reserve and National Guard status does not meet the requirements of 38 CFR 3.6, and urged VA to amend other regulations to eliminate any conflict for applying presumptions of disability to reserve and National Guard members. Finally, one commenter stated that the rule does not include reservists and asked for VA to amend the rulemaking to include reservists.

As stated in the proposed rule, basic eligibility for VA benefits requires that an individual be a "veteran" as that term is defined in 38 U.S.C. 101(2). Reserve duty during a period of active

duty for training or inactive duty for training generally does not qualify an individual as a “veteran,” because it does not constitute “active military, naval, or air service,” unless the person is disabled or dies during that period of service as prescribed by 38 U.S.C. 101(24)(B) and (C). However, under this rule, former reservists and National Guard members meeting the service criteria for presumptive service connection based on exposure to contaminants at Camp Lejeune have veteran status for the purpose of entitlement to service connection for the enumerated disabilities; there is no limitation of benefits to former reservists and National Guard members under this rule. VA makes no change based upon these comments.

Another commenter stated that VA’s inclusion of former reservists and National Guard members in the rulemaking stretches Congressional intent with regards to the definition of “veteran.” The commenter also suggested that Congress should provide guidance on the definition of a veteran, and that VA is underestimating the financial impact of this rule. As explained in the proposed rule, although 38 U.S.C. 101(24) requires a period of active duty for training or inactive duty training “during which the individual was disabled or died” for this period to constitute active military, naval, or air service, this statute was enacted at a time when the latent effects of exposures to certain harmful chemicals were unrecognized. Further, the legislative history behind this statute does not specifically explain Congress’ intent in requiring that the individual “was disabled or died” during the period of service in question. As section 101(24) serves a generally beneficial purpose to recognize certain reserve and National Guard service which results in disability or death as affording veteran status for the purposes of VA disability benefits, and in light of increased medical understanding of the possible latent effects of toxic exposure, VA feels it is reasonable to include former reservists and National Guard members with qualifying service under this rule. Accordingly, VA makes no change based upon this comment.

D. Comments Pertaining to Presumptive Disabilities

VA received several comments regarding the disabilities included in the proposed rulemaking. These comments fell into two basic categories: One group related to the general differences between the disabilities in the proposed rule and the health care provisions in the Camp Lejeune Act,

while the other comments focused on individual disabilities.

1. Presumptive Disabilities Differ From the Camp Lejeune Act

VA received 42 comments, including from VVA, NOVA, and Legal Counsel for the Elderly, regarding the disabilities in our proposed rulemaking and the disabilities listed in the Camp Lejeune Act. The commenters noted that VA’s proposed rulemaking contained fewer and different conditions than the Camp Lejeune Act, with several commenters urging VA to adopt the list of disabilities in the Camp Lejeune Act in its entirety, without change. One commenter stated that veterans who develop a condition listed in the health care provisions of the Camp Lejeune Act but not listed as a presumptive disability would be denied compensation benefits for conditions for which health care is being provided. For the reasons enumerated below, VA makes no change based on these comments.

As explained in the proposed rule, the Camp Lejeune Act provides medical care, but not compensation benefits, to veterans who served on active duty at Camp Lejeune for the 15 identified conditions “notwithstanding that there is insufficient medical evidence to conclude that such illnesses or conditions are attributable to such service.” VA’s more recent review of scientific evidence was undertaken to determine the appropriateness of establishing presumptions of service connection for claimants who served at Camp Lejeune. As noted in the proposed rulemaking, this review included the analysis of several hazard evaluations on the chemicals of interest conducted by multiple bodies of scientific experts and was not an evaluation of the specific risks of exposure to contaminated water at Camp Lejeune. VA’s review resulted in the recognition that liver cancer and Parkinson’s disease, two diseases that were not included in the Camp Lejeune Act, are conditions for which there is strong evidence of a causal relationship and evidence that the condition may be caused by exposure to the contaminants. However, at this time, VA concludes that there is insufficient evidence to establish presumptions of service connection for the following diagnosed chronic disabilities in the Camp Lejeune Act: Esophageal cancer, lung cancer, breast cancer, neurobehavioral effects, and scleroderma. As noted in the notice of proposed rulemaking, none of the evidence reviewed concluded that there is a positive association between these conditions and the volatile organic

compounds of interest. The exclusion of scleroderma is addressed separately in the next section.

Additionally, the health care provisions of the Camp Lejeune Act provide medical coverage for health effects that are not themselves diagnosed diseases or clearly associated with a specific diagnosed disease. To establish that disability arising years after service is associated with harmful exposure in service, the evidence generally must show that the disability results from a disease associated with the in-service exposure. Accordingly, in § 3.307, VA has established presumptions of service connection for specific diseases, as distinguished from general health effects that may result from specific diseases but are not themselves diseases. The available scientific evidence did not identify a specific or general diagnosis of disease associated with renal toxicity or hepatic steatosis, conditions which are included in the provisions of the Camp Lejeune Act.

Finally, the Camp Lejeune Act included health care for female infertility and miscarriage. However, as noted in the proposed rule, the NRC’s 2009 report indicated that the occurrence of female infertility and miscarriage were limited to exposure concurrent with those health effects. As such, the inclusion of these conditions in the Camp Lejeune Act does not provide a basis at this time for presuming current health effects of this type to be associated with past exposure. Additionally, as stated in the proposed rule, these two conditions are not in and of themselves disabilities for which VA can provide disability compensation.

Accordingly, as noted by one commenter, an outcome of VA’s review of the available scientific evidence, to include additional evidence that did not exist at the time the Camp Lejeune Act was passed, may result in situations where an individual receives VHA health care for a covered condition without an associated copayment under the Camp Lejeune Act, but is not eligible for presumptive service connection for disability compensation for that condition under this rulemaking. While these individuals may not be eligible for presumptive service connection under this rulemaking, they may be eligible for direct service connection for any disease alleged to have been caused by the contaminants in the water supply at Camp Lejeune, including a disease or disability covered under the Camp Lejeune Act. As noted earlier in section B, direct service connection requires

evidence of a current disease or disability, evidence of exposure to contaminated water at Camp Lejeune, and a medical nexus between the two, supported by a sufficient medical explanation. Conversely, it is similarly possible that a condition not exempted from copayment under the Camp Lejeune Act, such as liver cancer or Parkinson's disease, could be granted presumptive service connection pursuant to this final rule. We note that a grant of service connection for such a condition would exempt treatment associated with that condition from copayment requirements, as VA copayments do not apply to treatment of service connected disabilities. A grant of presumptive service connection could also create an alternative basis for enrollment in the VA health care system. See 38 CFR 17.36.

VA will continue to review relevant information as it becomes available and will consider future additions to the list of covered conditions as appropriate.

In addition to suggesting that VA should provide disability compensation for the conditions in the Camp Lejeune Act, one commenter suggested that, alternatively, VA should change the provisions of the Camp Lejeune Act to match the eight disabilities covered in the proposed rule. The Camp Lejeune Act is a statute, the provisions of which were enacted by Congress. VA lacks the legal authority to alter, amend, or otherwise change the provisions of a statute and therefore takes no action based on this comment.

2. Exclusion of Scleroderma as a Presumptive Disability

Eight commenters, including the Project on Government Oversight, Legal Counsel for the Elderly, and a member of Congress, specifically questioned VA's exclusion of scleroderma as a presumptive disability. These commenters noted that scleroderma was included in the health care provisions of the Camp Lejeune Act and suggested that VA specifically include this condition as a presumptive disability. Additionally, the comment from a member of Congress stated that there was modest causal evidence from the Agency for Toxic Substances and Disease Registry (ATSDR) and the economic impact of including scleroderma would be minimal, as the number of Camp Lejeune veterans suffering from this condition is small.

As explained in the proposed rule, due to the lack of new scientific/medical evidence (outside of the available evidence considered by the TWG) linking any of the contaminants found in the water supply with the

development of scleroderma specifically, VA cannot create a presumption of service connection for Camp Lejeune veterans at this time. Though the available evidence has established a role for trichloroethylene (TCE) in the development of autoimmune diseases, the studies that specifically report on scleroderma include factors that introduce significant uncertainty into their results, to include small sample sizes and an unexplained gender effect. Although the science does not at this time support the addition of scleroderma to the list of covered diseases, VA will continue to monitor and review future studies as they become available and will consider future additions to the list of covered diseases as appropriate.

3. Inclusion of Neurobehavioral Effects and Parkinsonism

VA received eight comments regarding the issue of neurobehavioral effects and parkinsonism, including an organizational comment from the United Parkinson's Advocacy Council. Three commenters stated the presumptive disabilities should include neurobehavioral effects, with one commenter specifying inclusion of specific types of neurobehavioral effects. Another commenter suggested that VA include "Parkinson-like" symptoms as a presumptive disability under the general diagnosis of neurobehavioral effects. The third commenter asked if parkinsonism was included under the definition of Parkinson's disease. Another commenter stated that there is no way to definitively diagnose Parkinson's disease. The United Parkinson's Advocacy Council stated VA should include "atypical parkinsonism" in the rulemaking.

Parkinson's disease was included in the list of presumptive disabilities due to a recommendation made by the Institute of Medicine (IOM) in their 2015 report "Review of VA Clinical Guidance for the Health Conditions Identified by the Camp Lejeune Legislation." The IOM noted that Parkinson's disease is a specific neurobehavioral effect that may be experienced by individuals exposed to the contaminants in the water supply at Camp Lejeune.

Parkinson's disease is medically distinguishable and separately diagnosable from a variety of parkinsonian syndromes, including drug-induced parkinsonism and neurodegenerative diseases, such as multiple systems atrophy, which have parkinsonian features combined with other abnormalities. Most notably, the

pathologic findings in cases of parkinsonism show different patterns of brain injury than those noted in patients with Parkinson's disease. See Institute of Medicine of the National Academies, *Veterans and Agent Orange: Update 2012*, The National Academies Press (Washington, DC, 2014). The studies that have established a relationship between the contaminants in the water supply at Camp Lejeune and Parkinson's disease reported specifically on Parkinson's disease, not parkinsonism or other parkinsonian syndromes. At this time, the available evidence does not establish that parkinsonism and other manifestations of small fiber nerve damage are associated with exposure to the contaminants in the water supply at Camp Lejeune. Therefore, VA makes no change based on these comments.

4. Adult Leukemia

VA received 12 comments, including from the Project on Government Oversight and VFW, and one from a member of Congress, addressing the condition of adult leukemia. The commenters stated that VA should clarify the disabilities included in adult leukemia by changing the term to "leukemia," "adult leukemias," or by listing all sub-types of leukemia included in the definition of adult leukemia. A comment from a member of Congress specifically cited an ATSDR report, which noted all leukemia subtypes are associated with exposure to contaminants in the water supply at Camp Lejeune. The same member of Congress also stated the use of "adult leukemia" was unnecessary because all who qualify for this benefit are adults, as the rulemaking does not apply to dependents. Another commenter stated that VA should replace the term "adult leukemia" with "chronic or acute forms of lymphocytic and myeloid leukemia" to clarify what conditions are covered. VA disagrees and makes no change based on these comments.

The term "adult leukemia" clarifies that the types of leukemia covered under this rulemaking must have their onset in adulthood. This distinction between adult and non-adult leukemias is necessary, as the disability compensation provided by this rulemaking applies only to disabilities arising in veterans, reservists, or National Guard members as a result of their exposure to contaminants in the water supply at Camp Lejeune while serving under official military orders or other official assignment. As such, the presumptions of this rulemaking do not apply to veterans, reservists or National Guard members who develop leukemia

prior to qualifying service at Camp Lejeune.

The use of the term “adult leukemia” was not intended to restrict the types of leukemia covered by this rulemaking. No sub-type of leukemia was identified in the rulemaking in order to be inclusive to all types of leukemia, including the sub-types identified by commenters. VA notes that inclusion of specific sub-types included within this definition will lead to an incomplete list, potentially confusing veterans, reservists and National Guard members who have a qualifying disability, as well as claims processors.

5. Miscellaneous Disabilities

VA received 53 comments, including organizational comments from the Fort McClellan Veterans Stakeholders Group, which requested inclusion of miscellaneous conditions and disabilities, both specified and unspecified, that were not the subject of the proposed rulemaking, nor were they included in the provisions of the Camp Lejeune Act. These conditions include: Hodgkin’s disease, diabetes mellitus, depression, sleep apnea, throat cancer, fibroid sarcoma, prostate cancer, colon cancer, brain cancer, mesothelioma, soft tissue sarcoma, gynecomastia, prolactemia, Crohn’s disease, amyloidosis, hidradenitis suppurativa, immune system toxicity, gastrointestinal cancers, other unspecified immune system effects, unspecified neurologic disorders, unspecified skin conditions, unspecified endocrine disorders, unspecified cellular mutation, cancerous and non-cancerous urinary tract conditions, unspecified kidney effects, unspecified liver effects, unspecified endocrine effects, unspecified cardiovascular disorders, and unspecified cancers. Additionally some commenters stated that VA should include additional disabilities without specifying those additions. Two commenters stated that VA should consider all diseases and disabilities as associated with exposure to contaminants in the water supply at Camp Lejeune, noting that VA should bear the burden of proof as to why any disability is unrelated to exposure to contaminants at Camp Lejeune. Another commenter suggested inclusion of conditions not identified by scientific evidence. Finally, one commenter cited a decision by the Board of Veterans’ Appeals (BVA) as sufficient evidence to support adding prostate cancer to the list of presumptive disabilities. The same commenter also stated VA should consider adding hepatitis C, noting a correlation between it and prostate cancer.

As stated in the proposed rule, VA undertook a deliberative scientific process to determine whether available scientific evidence was sufficient to support a presumption of service connection for any health condition as a result of exposure to the chemicals found in the drinking water at Camp Lejeune. This process involved an evaluation of comprehensive hazard studies conducted by several internationally respected expert bodies. VA also notes that BVA decisions are made on the facts, circumstances, and evidence of individual claims on a case-by-case basis; these cases do not set precedent. At this time, there is insufficient medical and scientific evidence to establish a presumption of service connection for any disability beyond the eight conditions included in the rulemaking; therefore, VA makes no change in response to these comments at this time.

VA relies heavily on studies of exposed populations in order to establish such an association, and will continue to monitor future studies, especially those conducted on the Camp Lejeune population, as they become available. VA will consider additions to the list of presumptive disabilities as appropriate, should future studies provide sufficient evidence for such a change.

As previously discussed, it is also relevant to note that the scientific evidence was not analyzed by VA for sufficiency to support an expert opinion in a legal proceeding regarding causation in any individual case. Therefore, VA intimates no conclusion regarding any individual veteran’s development of a disease and its relationship to exposure to contaminated water at Camp Lejeune.

6. Kidney Cancer

One commenter asked why VA is not recognizing kidney cancer as a presumptive disability. As noted in the proposed rule under amended § 3.309(f), kidney cancer is one of the listed conditions VA recognizes as presumptively associated with exposure to contaminants in the water at Camp Lejeune. VA makes no change based upon this comment.

E. Effective Date

VA received 27 comments, including from the C-123 Veterans Association, VFW, and NOVA, concerning the effective date of the regulation. Comments included suggestions that this rule should be effective the date a claim was initially filed, even if prior to the effective date of the final rule, or on the date of onset or diagnosis of a

covered illness. Other commenters stated the rule should be effective retroactively to the date an eligible veteran first served at Camp Lejeune. Some commenters stated that the rule excludes previously denied claims, and therefore VA should apply the provisions of the *Nehmer v. U.S. Department of Veterans Affairs (Nehmer)* court order to determine a retroactive effective date for awards. See *Nehmer v. U.S. Department of Veterans Affairs*, No. CV-86-6161 TEH (N.D. Cal.). One commenter suggested that the rule should be effective the date the proposed rule was published, as it should have been published as an interim final rule. Finally, one commenter asked if a “pending” claim includes the one-year period following notice of a denial as well as appeals before the BVA.

As stated in the proposed rule, this rule will apply to claims received by VA on or after the effective date of the final rule and to claims pending before VA on that date. Under 38 CFR 3.160(c), a claim that has not been finally adjudicated (which includes claims where a final and binding decision has been issued but the appeal period has not expired) is still considered a pending claim. The rule does not apply retroactively to claims that are finally adjudicated. VA must adhere to the provisions of its change of law regulation, 38 CFR 3.114, which states that where 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 final 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, and retroactivity is heavily disfavored in the law. As explained in the proposed rule, 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. Finally, VA notes that the effective date provisions of the *Nehmer* court order apply only to claims based on exposure to herbicides in the Republic of Vietnam during the Vietnam era and are therefore inapplicable to this final rule.

The Administrative Procedures Act (APA) provides guidance as to when a rulemaking may be published as an interim final rule. Under the APA, a rulemaking may be published as an interim final rule if it is determined that notice and public comment "are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. 553(b)(3)(B). As this rulemaking involves significant economic costs, the opportunity for prior review and comment was necessary and in accordance with the public interest. VA has acted expeditiously to consider these public comments and prepare a final rulemaking. Therefore, VA makes no changes based on these comments.

F. Date Range for Contamination

One commenter stated the date range for exposure should be extended without specifying exact dates. The commenter stated that contamination likely still existed even after the water supply met unspecified Environmental Protection Agency (EPA) standards. Similarly, VVA stated the contamination period should be extended until December 31, 2000, the last day of the year that the Navy removed contaminated soil and other items from the sites surrounding Camp Lejeune. Another commenter stated the background information in the proposed rule regarding contamination was incorrect; this commenter stated that contamination ended in 1987 and the initial contamination warnings were in 1980. Another commenter stated VA should expand the date range to include those who served from January 1, 1947, through July 31, 1953, without further elaboration.

As stated in the proposed rule, the Camp Lejeune Act specified a period of contamination from August 1, 1953, through December 31, 1987. This date range is likely based on some of the earliest assessments of the Camp Lejeune water supply noted in the NRC report. This period also represents the ATSDR's best estimate of the period of contamination at Camp Lejeune. In the absence of additional scientific evidence to support an expansion of the contamination period, VA makes no change based upon these comments at this time.

G. Additional Contaminants

VA received two comments regarding consideration of additional contaminants. One commenter stated that VA should include information about unspecified lead contamination during the 1990s. The commenter also requested inclusion of information contained in an unspecified 1997 study. Another commenter stated that VA's assessment of contaminants is incomplete, as it does not consider toxic compounds outside those noted in the rulemaking.

As stated in the proposed rule, VA is only addressing the contamination of the water supplies by the four chemicals of interest (*i.e.*, TCE, perchloroethylene (PCE), benzene, and vinyl chloride) that occurred between August 1, 1953, and December 31, 1987, as a result of on-base industrial activities and an off-base dry cleaning facility. Exposure events unrelated to the specified date range and sources of contamination are unrelated to the subject and scope of this rulemaking; therefore VA makes no change in response to this comment.

H. Additional Scientific or Medical Evidence

Two commenters stated that VA should reference additional, uncited studies, stating the rulemaking should consider the effects of exposure to solvent mixtures. One commenter stated VA should reference an unspecified study of the individuals who were actually exposed to contaminants in the water supply at Camp Lejeune. Another commenter, the Fort McClellan Veterans Stakeholders Group, without further elaboration, stated that VA uses the wrong method to evaluate toxic exposures. VA also received a comment stating that unspecified evidence exists to possibly support the addition of more disabilities. One commenter stated that the NRC did not perform a study, it merely reviewed available literature, and the 2009 NRC is flawed and outdated. This same commenter also stated that the description of the collaboration between ATSDR, VA's Camp Lejeune Science Liaison Team, and VA's Technical Workgroup (TWG) was incorrect. The commenter stated that the community was not directly involved in this collaboration. Another commenter stated it was unclear which ATSDR studies were considered in the rulemaking. Other commenters stated generally that inclusion or performance of additional studies could result in a larger list of presumptive disabilities. Finally, one commenter stated that a source with the Center for Disease Control stated it is impossible to

determine the minimum level of exposure to a contaminant needed to result in negative health effects.

VA currently has no information as to its disposal to define the specific hazardous exposure levels or combinations of exposure that any one individual received, which would determine exactly who in the veteran population might be at an increased risk of experiencing adverse health effects related to their service at Camp Lejeune. As explained in the proposed rule, the VA review consisted of a hazard evaluation for the four chemicals of interest: TCE, PCE, benzene and vinyl chloride, and focused on the effects of these individual contaminants without regard to specific exposure levels. Additionally, as explained in the rulemaking, VA reviewed evidence from several internationally recognized scientific authorities, including groups other than the NRC. Regarding the description of the process employed by ATSDR, VA notes that ATSDR is an external entity and, as such, is not subject to VA's control. VA also notes that the notice of proposed rulemaking contains a full list of scientific studies and reviews cited in the rulemaking in section E, "Weight-of-Evidence Analyses Considered by the TWG."

VA's rule is as inclusive as possible in covering the illnesses of veterans, former reservists and National Guard members exposed to contaminants in the water supply at Camp Lejeune based on the available scientific evidence, in the absence of specific exposure information. VA makes no change based on these comments.

I. Expedite Rulemaking

VA received 17 comments, including an organizational comment from VFW, urging VA to expedite the rulemaking, to include publication of a final rule under which benefits may be granted. VA must adhere to the requirements of the APA, which includes a period for public comment and review of the rulemaking. VA appreciates these comments and has taken the necessary steps to ensure this rule is finalized while conforming to the legal requirements of notice and comment rulemaking.

J. Benefits for Veterans Born at Camp Lejeune Without Service at Camp Lejeune

One commenter asked if the rule provides compensation for veterans who were born at Camp Lejeune but do not have qualifying active duty, reserve, or National Guard service at Camp Lejeune. VA is only authorized to pay disability compensation for disability

resulting from injury suffered or disease contracted in line of duty “in the active military, naval, or air service”. 38 U.S.C. 1110, 1131. Thus, VA has no authority to pay compensation for disability arising from events prior to service entry. VA makes no change based upon this comment.

K. Standard of Evidence for Claims

One commenter stated that the proposed rulemaking would still require eligible veterans, former reservists and National Guard members to present a medical opinion in support of their claim for a presumptive disability. As stated in the proposed rulemaking, if a veteran, former reservist or National Guard member meets the stated requirements for service at Camp Lejeune, then the subsequent development of any of the eight listed disabilities is presumed to be related to the exposure to contaminants, in the absence of clear and convincing evidence to the contrary. These presumptions do not require any further evidence to support a claim, including a medical opinion. Therefore, VA makes no change based on this comment.

Another commenter stated that the proposed rule makes no reference for individual genetic predisposition to increased vulnerability to a specific toxin. The commenter stated this places an unrealistic burden of proof on an individual to prove that he or she suffers a disability due to exposure to toxins. VA has no information at its disposal to define the specific hazardous exposure any individual received, which could assist in determining who in the veteran population was or would be at an increased risk of suffering adverse health effects related to their service at Camp Lejeune. Furthermore, once the basic eligibility requirements of this rule are met (qualifying service and diagnosis of a listed disability), no further information, to include evidence of a genetic vulnerability to a specific toxin, is necessary. Therefore, VA makes no change based on this comment.

Two commenters asked if a medical opinion that served as the basis of a previous denial could serve as affirmative evidence to rebut the presumption created by this rule. The circumstances of individual claims are beyond the scope of this rulemaking and VA makes no change based upon this comment. However, VA notes that 38 CFR 3.307(d), which pertains to rebuttal of presumptive service connection, specifically requires consideration of all evidence of record when determining the issue of presumptive service connection. As noted above, 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. All claims are adjudicated individually based upon the entire evidentiary record and in accordance with all applicable regulations.

Legal Counsel for the Elderly stated that VA should allow for a veteran’s lay testimony to establish the occurrence of exposure to contaminants in the water supply at Camp Lejeune. VA will consider all evidence of record when deciding claims, including lay testimony. However, VA notes that current regulations provide very specific circumstances as to when a veteran’s lay testimony is sufficient to establish an occurrence for the purposes of entitlement to disability benefits. For example, a veteran’s lay testimony may be sufficient to establish the occurrence of an injury or event that occurred during combat, if that testimony is consistent with the circumstances, conditions, or hardships of that veteran’s service, even where no official record of such incurrence exists. The purpose of this lay statement exception is to acknowledge certain circumstances where official records likely will not exist to establish a fact; in this example, it is highly unlikely that medical records will exist to document the occurrence of an injury at the time it occurred during combat. In the present rulemaking, establishing service at Camp Lejeune requires documentation of 30 days of service at Camp Lejeune by military orders or other official service department records. These documents are regularly and routinely issued by the military as a part of its normal duties in documenting personnel assignments and location and are a part of every servicemember’s personnel file. As the evidence required to establish service at Camp Lejeune, and therefore satisfy the condition necessary to presume exposure to contaminants in the water supply, is readily available, VA makes no change based upon this comment.

Similarly, one commenter stated VA should provide a “benefit of the doubt” to anyone who served at Camp Lejeune in the 1980s. As stated in the rule, this presumption of service connection applies to any veteran, to include former reserve and National Guard members, who served at Camp Lejeune during the relevant time period. This presumption reduces the evidentiary burden required to establish entitlement to disability compensation for certain claims, as further explained in the notice of proposed rulemaking. VA makes no change based upon this comment.

L. Benefits for Family Members or Civilians

VA received 11 comments, including an organizational comment from the United Parkinson’s Advocacy Council, stating that family members or civilians who were exposed to contaminants in the water supply at Camp Lejeune should receive disability compensation. VA notes that this rulemaking provides disability compensation for qualifying veterans, former reservists or National Guard members; benefits for family members or civilians are beyond the scope of the rulemaking and therefore VA will not respond to this comment. Additionally, VA notes that there is currently no statutory authority to provide benefits to the classes of people identified by the commenters.

M. General Support for the Rulemaking

VA received 56 comments, including from the C-123 Veterans Association, DAV, VFW, VVA, Project on Government Oversight, Reserve Officers Association, Marine Corps Reserve Association, United Parkinson’s Advocacy Council, and Legal Counsel for the Elderly, expressing support for the rulemaking in general. Many of these comments, which were received from individuals as well as organizations in the veteran community, stated appreciation for VA’s actions in establishing a presumption of exposure and service connection for veterans, reservists, and National Guard members exposed to contaminants in the water supply at Camp Lejeune. VA appreciates the time and effort expended by these commenters in reviewing the proposed rule and in submitting comments, as well as their support for this rulemaking.

N. Negative Comments

VA received five comments indicating opposition to the rulemaking. These comments expressed disagreement with the rulemaking process in general, and presumptive service connection in particular. VA’s decision to create a presumption of exposure to contaminants in the water supply at Camp Lejeune and presumptive service connection for the listed disabilities was issued after the Secretary considered the available scientific evidence and recommendations, as explained in the notice of proposed rulemaking. This evidence demonstrated at least an association between the contaminants in the water supply at Camp Lejeune and the eight listed disabilities. This evidence is supported by published reports from multiple internationally-recognized authorities, and the

Secretary has determined this evidence provides a rational basis to issue regulations for presumptions of exposure and service connection. Accordingly, VA makes no change based on these comments.

O. Character of Discharge and Eligibility for Benefits

One commenter stated that individuals with an other than honorable discharge are excluded from eligibility under this rulemaking. This rulemaking amends 38 CFR 3.307 and 3.309; it does not affect the provisions of 38 CFR 3.12, which pertains to the character of discharge requirements for benefits eligibility. Therefore, this comment is outside the scope of the rulemaking and VA makes no change based on it.

P. Statements About Personal Claims

As stated previously, many commenters made general statements about their own experiences with one or more of the presumptive disabilities, non-presumptive disabilities, their personal disability claims, or their personal health care claims. Comments regarding situations involving the possible outcome of individual claims, or the medical or claims history presented by individual veterans are beyond the scope of this rulemaking. Claimants should contact their VA regional office for assistance with their individual claims.

Q. Other Comments Unrelated to or Outside the Scope of This Rulemaking

VA received 30 comments dealing with issues not directly related to the new presumption of exposure or the new presumptively service-connected diseases. Such comments covered a wide range of topics; examples of such comments appear below.

One commenter stated that VA needs to update the VA Schedule for Rating Disabilities, noting that the criteria used to evaluate the diseases covered under this rulemaking are subjective. Another commenter stated that VA should evaluate individuals who were previously denied as 100 percent disabled. One commenter stated that VA should provide a zero-percent evaluation for any veteran, reservist, or former National Guard member who served at Camp Lejeune during the qualifying period. Two commenters stated that VA should provide health care in addition to disability compensation for veterans, reservists, and former National Guard members contemplated under this rulemaking. Two commenters stated that the rule does not include a mechanism for

notifying eligible veterans who may be unaware of their exposure to contaminants in the water supply at Camp Lejeune. Similarly, VFW stated VA should provide notification to claimants who were previously denied benefits. VFW also stated that VA should update the Catalog of Federal Domestic Assistance titles in the rulemaking to indicate the eligibility to additional benefits available to reservists and National Guard members as a result of the rulemaking. Another commenter urged VA to change the health care priority group level for reservists and National Guard members. Another comment stated that the same standards of evidence used to prosecute a corporation that harms an individual with toxic chemicals should be re-introduced in this rulemaking. Two commenters, including the Fort McClellan Veterans Stakeholders Group and the Project on Government Oversight, stated VA should pay benefits to veterans who served at Fort McClellan. Another commenter asked what effect this rulemaking has on the Camp Lejeune Act or House Resolution 3954—The Camp Lejeune Reservist Parity Act of 2015. One commenter stated the government uses members of the armed forces as guinea pigs for vaccines that have not been approved by the Food and Drug Administration. VA received one comment that stated this policy change does not protect the rights of veterans. Another commenter stated that the contamination is a violation of the 5th Amendment rights of those who were exposed and stated the base should be evacuated. Six commenters, including the Reserve Officers Association, requested that VA create or add their information to unspecified lists/registries. Another commenter stated that Parkinson's disease should have been specifically listed as a neurobehavioral effect. One commenter stated that VA should use available scientific evidence to “dismantle” the provisions of other exposure presumptions, such as benefits related to radiation exposure. The same commenter stated that the presumption of soundness does not apply to National Guard or reserve members who did not undergo physical examination during active duty. Finally, this commenter stated that VA should consider National Guard and reserve members as exposed to herbicides while serving in Canada. Another commenter asked if VA would provide compensation to private insurers for treatment of a covered disability. Without elaborating further, one commenter stated the proposal is too limited in scope and took too long

to enact; a similar comment was received stating that the rule does not provide “sufficient redress.” Another commenter stated VA should cover the cost of in-vitro fertilization or adoption for veterans experiencing female infertility. One commenter, the Reserve Officers Association, urged Congress to enact additional legislation. A comment from VFW suggested VA study the combined effects of exposure to herbicides and contaminants in the water supply at Camp Lejeune. Another commenter stated that there is nothing in writing that pertains to the individuals who were stationed at Camp Lejeune. VA received a comment stating that VA should provide former Marines with the Purple Heart. One individual stated that qualifying individuals should receive a blanket settlement from the government.

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

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 these regulatory amendments 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). These amendments will directly affect only individuals and will not directly affect small entities. Therefore, pursuant to 5 U.S.C. 605(b), these amendments are 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 final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

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

Congressional Review Act

Generally, under the Administrative Procedure Act, the required publication of a substantive rule shall be made not less than 30 days before its effective date. 5 U.S.C. 553(d). However, this regulatory action is a major rule under the Congressional Review Act, 5 U.S.C. 801–808, because it may result in an

annual effect on the economy of \$100 million or more. Therefore, in accordance with 5 U.S.C. 801(a)(1), VA will submit to the Comptroller General and to Congress a copy of this regulatory action and VA's Regulatory Impact Analysis. Provided Congress does not adopt a joint resolution of disapproval, this rule will become effective the later of the date occurring 60 days after the date on which Congress receives the report, or the date the rule is published in the **Federal Register**. 5 U.S.C. 801(a)(3)(A).

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. Farrissee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on November 16, 2016, for publication.

Dated: January 9, 2017.

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 amends 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 exposure to contaminants in the water supply at Camp Lejeune; wartime and service on or after January 1, 1947.

(a) *General.* A chronic, tropical, or prisoner of war related disease, a disease associated with exposure to certain herbicide agents, or a disease associated with exposure to 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 § 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.

* * * * *

■ 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.

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 0 and 1

[FCC 16-171]

Freedom of Information Act Improvement Act Implementation Order

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission amends its rules to update various sections implementing the Freedom of Information Act (FOIA) to reflect changes in the law made by the FOIA Improvement Act of 2016, to making conforming edits to reflect existing Commission FOIA practice, to streamline the Commission's FOIA procedures, and to provide for clerical corrections.

DATES: Effective February 13, 2017.

FOR FURTHER INFORMATION CONTACT: Ryan Yates, 202-418-0886 or TTY: 202-418-0484; Ryan.Yates@fcc.gov.

SUPPLEMENTARY INFORMATION:

1. This is a synopsis of the Federal Communication Commission's Order, FCC 16-171, released on December 15, 2016, amending Parts 0 and 1 of the Commission's rules to update sections implementing the FOIA. The complete text of the document is available on the Commission's Web site at <http://www.fcc.gov> or at https://apps.fcc.gov/edocs_public/attachmatch/FCC-16-171A1.pdf. It is also available for inspection and copying during normal business hours in the FCC Reference Information Center, Portals II, 445 12th Street SW., Room CY-A257, Washington, DC 20554.

2. By this Order, we amend Part 0 of the Commission's rules to update various sections implementing the Freedom of Information Act (FOIA). On June 30, 2016, the President signed into law the FOIA Improvement Act of 2016 (FOIA Improvement Act). The law went into effect July 1, 2016, and requires, inter alia, that agencies review their FOIA regulations and promulgate new rules in accordance with the substantive provisions of the law. These provisions included providing 90 days for requesters to file appeals of FOIA requests, ensuring that requesters are informed of avenues for FOIA dispute resolution, and providing for public posting of materials that are requested multiple times. The Commission has completed review of its FOIA regulations and in this Order adopts

amendments to the rules, thus fulfilling the requirements of section 3(a) of the FOIA Improvement Act.

3. The amendments made by this Order can generally be grouped into two categories. First are rule amendments that are required by or flow directly from changes made by the FOIA Improvement Act. These include regulatory changes specifically mandated by the FOIA Improvement Act, as well as changes that are informed by the FOIA Improvement Act. Second are rule amendments designed to conform the rules to existing Commission FOIA practice, streamline FOIA procedures, and provide for clerical corrections. A number of years have passed since the Commission's FOIA regulations were last updated, and new technology, practices, and procedures have arisen since that time. We update the regulations to reflect the current state of the Commission's FOIA process.

4. The Commission's FOIA implementing rules are presently found at 47 CFR 0.441-0.470. The amended rules are set forth in the Appendix to this Order and are described in more detail below.

5. The following rule changes are either required by the text of the FOIA Improvement Act or are made in response to issues raised in the FOIA Improvement Act.

6. *Section 0.251—Authority Delegated.* Section 0.251 describes the authorities delegated to the General Counsel by the Commission. We add to the rule by delegating to the General Counsel the authority to act as the Chief FOIA Officer. The position of Chief FOIA Officer was created by the Open Government Act of 2007 and expanded upon by the FOIA Improvement Act.

7. *Section 0.441—General.* Section 0.441 sets forth general information related to the Commission's FOIA practice. We make two changes to this section that are required by the FOIA Improvement Act. First, we include a notice that FOIA requesters may seek the assistance of the FOIA Public Liaison or the Office of Government Information Services to assist in resolving disputes, along with the procedure for engaging such assistance. These changes are specifically required by the FOIA Improvement Act. Second, in light of the FOIA Improvement Act's emphasis on the duties of the Chief FOIA Officer, including new responsibilities to offer training to agency staff and to serve as the liaison with the National Archives and Records Administration's Office of Government Information Services and the Department of Justice's Office of