DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900-AO78

Hospital Care and Medical Services for Camp Lejeune Veterans

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend its regulations to implement a statutory mandate that VA provide health care to certain veterans who served at Camp Lejeune, North Carolina, for at least 30 days during the period beginning on January 1, 1957, and ending on December 31, 1987. The law requires VA to furnish hospital care and medical services for these veterans for certain illnesses and conditions that may be attributed to exposure to toxins in the water system at Camp Lejeune. This proposed rule does not implement the statutory provision requiring VA to provide health care to these veterans’ family members; regulations applicable to such family members are currently in development and will be promulgated through a separate notice.

DATES: Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Written comments may be submitted through
http://www.regulations.gov; by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue, NW,
Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to “RIN 2900-AO78, Hospital Care and Medical Services for Camp Lejeune Veterans.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1068, between the hours of 8:00 a.m. and 4:30 p.m. Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System at http://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Terry Walters, Deputy Chief Consultant, Post-Deployment Health, Office of Public Health (10P3A), Veterans Health Administration, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461-1017 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: On August 6, 2012, the President signed into law the Honoring America’s Veterans and Caring for Camp Lejeune Families Act of 2012, Public Law 112-154 (the Act). Among other things, section 102 of the Act amended section 1710 of title 38, United States Code (U.S.C.), to require VA to provide hospital care and medical services, for certain specified illnesses and conditions, to veterans who served at the Marine Corps base at Camp Lejeune, North Carolina (hereinafter referred to as Camp Lejeune), while on active duty in the Armed Forces for at least 30 days during the period beginning on January 1, 1957, and ending on December 31, 1987. This proposed rule would implement this statutory requirement by amending existing VA regulations and creating a new § 17.400 in title 38, Code of Federal Regulations (CFR).
The purpose of the Act is to ensure that these veterans receive care for illnesses and conditions that may have been the result of drinking contaminated water while they were stationed at Camp Lejeune. From at least 1957 to 1987, drinking-water systems that supplied Camp Lejeune were contaminated with industrial chemicals. The contaminated wells were shut down in February 1985. The primary chemicals found in the drinking water included perchloroethylene, trichloroethylene, benzene, and vinyl chloride. The duration and intensity of individuals’ exposure to contaminated water at Camp Lejeune are unknown and cannot be positively determined. The geographic extent of contamination is unclear but can be limited based on certain factors that we discuss in greater detail below. In a 2009 report created at the request of the U.S. Navy, the National Academy of Sciences’ National Research Council (hereinafter referred to as NAS) issued a study titled, “Contaminated Water Supplies at Camp Lejeune: Assessing Potential Health Effects,” which found that it cannot be determined reliably whether diseases and disorders experienced by former residents and workers at Camp Lejeune are associated with their exposure to contaminants in the water supply because of data shortcomings and methodological limitations, and these limitations cannot be overcome with additional study. Therefore, the NAS report recommended that policy changes or administrative actions should not wait for further studies. NAS, “Contaminated Water Supplies at Camp Lejeune: Assessing Potential Health Effects,” p. 22, National Academies Press (2009) (the NAS report).

In response to information, including the NAS report, and informed by studies conducted by the Centers for Disease Control’s Agency for Toxic Substance and Disease Registry, Congress established in 38 U.S.C. 1710(e)(1)(F) that veterans who
“served on active duty in the Armed Forces at Camp Lejeune, North Carolina, for not fewer than 30 days during the period beginning on January 1, 1957, and ending on December 31, 1987, [are] eligible for hospital care and medical services” under 38 U.S.C. 1710(a)(2)(F) for illnesses and conditions listed in 38 U.S.C. 1710(e)(1)(F)(i) through (xv). Although this rulemaking proposes regulations to implement this statutory requirement, we note that VA is currently providing veterans with health care under the statutory mandate.

We also note that a related statutory provision in section 102 of the Act codified 38 U.S.C. 1787, which requires VA to furnish health care to certain family members of veterans who resided at Camp Lejeune during the same time period to the extent and in the amount provided in advance in appropriations Acts for this purpose. This proposed rule does not implement section 1787, nor does it otherwise address family members. The implementation of section 1787 will be the subject of a future rulemaking.

We now discuss each paragraph of the proposed regulation, 38 CFR 17.400, implementing and interpreting our new authority under 38 U.S.C. 1710(e)(1)(F).

In § 17.400(a), we would set forth the general principle, discussed above, that VA will provide hospital care and medical services to Camp Lejeune veterans. We also would state that VA will enroll these veterans in the VA health care system in accordance with § 17.36(b)(6). The basis for enrollment under § 17.36(b)(6), referred to as “priority category 6,” is established as follows. Under 38 U.S.C. 1710(a)(2)(F), VA is required to furnish hospital care and medical services to a veteran exposed to toxic substances and identified in section 1710(e). Section 1710(e)(1)(F) applies to Camp Lejeune veterans. 38 U.S.C. 1705 directs VA to establish a patient enrollment system,
and 38 CFR 17.36(b) implements this authority through an enrollment system that establishes eight priority categories and directs VA to enroll veterans in accordance with the priorities. Priority category 6 applies to veterans who are not covered under priority categories 1 through 5 and are "eligible for hospital care, medical services, and nursing home care under [38 U.S.C.] 1710(a)(2)." 38 U.S.C. 1705(a)(6). As noted above, section 1710(a)(2)(F) requires the provision of hospital care and medical services to veterans who are identified in section 1710(e), i.e., Camp Lejeune veterans. Under current 38 CFR 17.36(b)(6), these exposed veterans are enrolled in priority category 6. Therefore, we would amend § 17.36(b)(6) to include Camp Lejeune veterans.

Under 38 U.S.C. 1710(f) and (g) and 1722A, VA must collect copayments from certain veterans for VA-furnished hospital care and medical services. VA implements the requirements to assess such copayments in 38 CFR 17.108, 17.110, and 17.111. However, veterans eligible for hospital care and medical services based on specified toxic exposures under section 1710(a)(2)(F) and (e) are not required to pay copayments for such health care. VA exempts these veterans from copayments in §§ 17.108(e), 17.110(c), and 17.111(f). However, pursuant to 38 CFR 17.36(d)(3)(iii), for care not related to such exposure, these priority category 6 veterans are placed in priority category 7 or 8, as applicable, for all other VA hospital care and medical services (if the veteran agrees to pay the applicable copayment for matters not covered by priority category 6, i.e., treatment for illnesses or conditions not related to the exposure that served as the veteran’s basis for enrollment in priority category 6).

We would amend current §§ 17.108(e)(2), 17.110(c)(4), and 17.111(f)(5) to reflect that copayment requirements do not apply to Camp Lejeune veterans, subject to
§ 17.400. We note that veterans who will be eligible for health care as Camp Lejeune veterans, but are already enrolled in priority categories 1-5, would not be moved to priority category 6 as a result of this rulemaking because under 38 U.S.C. 1705(a), VA is required to enroll veterans in the order of the priority categories listed in that section. VA implements this requirement in 38 CFR 17.36(d)(3)(ii). In this manner, Camp Lejeune veterans enrolled in a higher priority category would not lose their enrollment status as a result of this rulemaking.

In proposed paragraph (b) of § 17.400, we would define Camp Lejeune as “any area within the borders of the U.S. Marine Corps Base Camp Lejeune.” Neither the statute nor the legislative history of Public Law 112-154 indicates Congress’ intent as to the geographic area covered by the reference to “Camp Lejeune, North Carolina” in 38 U.S.C. 1710(e)(1)(F). The NAS report identifies contaminated drinking water as the method of exposure most likely to have the potential to cause the negative health effects noted in the study as being related to the chemical exposure. Because the water systems that supplied water to most of the residences and workplaces, in addition to other water systems on Camp Lejeune, have tested positive for contamination as noted in pages 29 and 67 of the NAS report, the geographic extent of Camp Lejeune for the purposes of this rule would include the entirety of the U.S. Marine Corps Base. We believe that this would allow VA to provide health care to all veterans who may have been exposed to toxic substances while at Camp Lejeune. U.S. Marine Corps Base Camp Lejeune includes base housing, training sites, and other facilities that would likely have exposed veterans who frequented these grounds to any toxic water.

We propose to define a Camp Lejeune veteran in § 17.400(b) as “any veteran
who served at Camp Lejeune on active duty, as defined in 38 U.S.C. 101(21), in the Armed Forces for at least 30 (consecutive or nonconsecutive) days during the period beginning on January 1, 1957, and ending on December 31, 1987.” This definition aligns with the language in section 102 of the Act. We would include both consecutive and nonconsecutive days in the calculation of the 30-day requirement to clarify that VA will provide treatment to veterans who may have served at Camp Lejeune on multiple occasions that total at least 30 days. Although section 102 of the Act requires that the veteran served at Camp Lejeune for at least 30 days, the Act does not specify whether these days must be consecutive. For the purposes of exposure to toxins, we are not aware of a scientific or medical justification to interpret the law to require that the days be consecutive.

Veterans would apply for hospital care and medical services as a Camp Lejeune veteran in the same manner as any other veteran applies for VA health care: They would complete VA Form 10-10EZ, “Application for Health Benefits.” This is the form used by all veterans to apply for hospital care and medical services. See 38 CFR 17.36(d). We would amend this form to include a specific box for individuals to identify themselves as meeting the requirements of being a Camp Lejeune veteran.

As explained above, Camp Lejeune veterans, like all other veterans in priority category 6, would not be required to pay copayments for VA health care provided in connection with one of the 15 illnesses or conditions listed in 38 U.S.C. 1710(e)(1)(F)(i) through (xv). In § 17.400(d)(1), we would clearly state that the veteran would not be subject to copayments for care that is clinically associated with a condition or illness attributable to the veteran’s service at Camp Lejeune. In § 17.400(d)(1)(A) through (O),
we would restate the 15 conditions listed in 38 U.S.C. 1710(e)(1)(F)(i) through (xv). Although the copayment exemptions are addressed in the copayment regulations discussed above, (i.e., 38 CFR 17.108, 17.110, and 17.111) and the requirement that such care be for an illness or condition listed in the statute is established by section 1710(e)(1)(F), we believe it would be helpful and clear to restate these provisions in the regulation applicable to Camp Lejeune veterans.

We note that, under 38 U.S.C. 1710(e)(2)(B), VA may not provide hospital care or medical services under 38 U.S.C. 1710(a)(2)(F) to veterans who would otherwise be eligible for health care under section 1710(e) for “a disability that is found, in accordance with guidelines issued by the Under Secretary for Health, to have resulted from a cause other than” service at Camp Lejeune. A diagnosis of whether an individual has a specific illness or condition and identification of the cause of an illness or condition are clinical determinations. VA proposes to satisfy the requirements of the 38 U.S.C. 1710(e)(2)(B) limitation by implementing clinical practice guidelines developed by VA, as specifically authorized by the statute and referenced in 38 CFR 17.400(c). In § 17.400(c), we would explain that VA would assume that a veteran who has been diagnosed with one of the 15 illnesses or conditions listed in § 17.400(d)(1)(A)-(O) has that specific condition or illness due to his or her exposure to contaminated water during service at Camp Lejeune. However, if VA is able to determine clinically, through guidance set forth in clinical practice guidelines developed for the conditions and illnesses listed in this rule, that the illness or condition resulted from a cause other than exposure to contaminants at Camp Lejeune, then any treatment for that condition would remain subject to the copayments. We would
develop these clinical practice guidelines over time, as VA subject matter experts build expertise in treating Camp Lejeune veterans. VA has been providing health care to Camp Lejeune veterans since the signing of the Act and has been developing clinical best practices for the provision of health care to Camp Lejeune veterans. VA would use this expertise, scientific evidence, and recognized standards of clinical practice in developing the clinical practice guidelines, and we expect that these guidelines will continue to develop as we gain further insight and knowledge about the connection between the exposures at Camp Lejeune and the 15 illnesses and conditions set forth in the law.

Section 17.400(d)(2) establishes that VA would retroactively reimburse certain copayments made by Camp Lejeune veterans for VA-provided health care. VA generally provides copayment exemptions to priority category 6 veterans for copayments as of the date they are assigned to that priority category, even if the veteran was previously enrolled in a lower priority category. However, because Camp Lejeune veteran status came into existence on August 6, 2012, we would consider them to be exempt from copayments as of that date only if they seek status as a Camp Lejeune veteran no later than [insert date 2 years after date of publication in the FEDERAL REGISTER]. We believe that 2 years would provide veterans sufficient time to learn about the new status and notify VA that they meet the requirements to be a Camp Lejeune veteran.

Since the Act was signed into law on August 6, 2012, this is the earliest date for which VA is authorized to reimburse any copayments previously charged to Camp Lejeune veterans pursuant to this regulation.
Effect of Rulemaking

The Code of Federal Regulations, as proposed to be revised by this proposed rulemaking, would represent the exclusive legal authority on this subject. No contrary rules or procedures would be authorized. All VA guidance would be read to conform with this proposed rulemaking if possible or, if not possible, such guidance would be superseded by this rulemaking.

Administrative Procedure Act

In accordance with 5 U.S.C. 553(b)(B), the Secretary of Veterans Affairs finds good cause to issue this proposed rule with prior notice and an abbreviated opportunity for public comment. This proposed rule is necessary to provide clarity regarding VA’s duty to provide health care to veterans who may have been exposed to toxic substances due to their service at Camp Lejeune. Section 102 of Public Law 112-154 requires VA to provide hospital care and medical services to Camp Lejeune veterans for the listed conditions and illnesses as of August 6, 2012. Many of the 15 listed conditions or illnesses are life-threatening and require immediate medical care. VA is capable of treating Camp Lejeune veterans for such illnesses or conditions immediately, which may lead to improved health outcomes for many veterans. However, this proposed rule is necessary to provide VA with the necessary framework to immediately implement this statutory requirement.

This proposed rule clearly defines how VA proposes to identify and integrate Camp Lejeune veterans into its enrollment system so VA can provide necessary health
care to these veterans. For example, Public Law 112-154 requires VA to provide hospital care and medical services to “a veteran who served on active duty in the Armed Forces at Camp Lejeune, North Carolina, for not fewer than 30 days during the period beginning on January 1, 1957, and ending on December 31, 1987.” The legislation, however, does not define the scope of who should be considered a Camp Lejeune veteran. This rule at § 17.400(b) in the definition for “Camp Lejeune veteran” would explain that “[a] veteran served at Camp Lejeune if he or she was stationed at Camp Lejeune, or if his or her professional duties required travel to Camp Lejeune.” The proposed rule also explains that the 30-day minimum service requirement may be “consecutive or nonconsecutive” days. Without this provision, VA would not be able to clearly identify all the veterans who should be provided the necessary health care as a result of their service at Camp Lejeune. With these provisions VA will be able to identify those individuals who should be considered Camp Lejeune veterans and conduct outreach to the identified class of veterans. Although we expect most Camp Lejeune veterans to seek VA medical care for treatment of their illness or condition regardless of this rulemaking, there may be some veterans who may go without treatment if they are not identified as a Camp Lejeune veteran, and their illness or condition does not result in eligibility for enrollment. Because many of the 15 listed conditions or illnesses are life-threatening and require immediate medical care, an abbreviated comment period is necessary and appropriate to allow VA to provide medical care to all individuals identified as Camp Lejeune veterans as soon as possible.

Furthermore, under the provisions of the proposed rule, VA would be able to reimburse veterans for copayments that certain veterans may already have paid for
illnesses or conditions identified in this rule. The shorter comment period will allow VA to proceed more quickly to a final rule stage and provide VA with the ability to reimburse unnecessary copayments to alleviate this financial hardship for some of these veterans.

For these reasons, the Secretary has concluded that a longer public comment period is unnecessary and contrary to the public interest. Accordingly, VA is issuing this proposed rule with an abbreviated comment period. VA will consider and address all comments that are received within 30 days of the date this proposed rule is published in the Federal Register.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any one year. This proposed rule would have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

This proposed rule contains no new provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). However, we note that veterans would apply for hospital care and medical services as a Camp Lejeune veteran under § 17.400 by completing VA Form 10-10EZ, “Application for Health Benefits,” which is required under 38 CFR 17.36(d) for all hospital care and medical services. As discussed in a separate notice (78 FR 39832,
July 2, 2013), we are amending this form, which will include a specific box for individuals to check to identify themselves as meeting the requirements of being a Camp Lejeune veteran. This particular amendment to the form will have no appreciable effect on the reporting burden for the revised VA Form 10-10EZ. We also do not anticipate a significant increase in the total number of applications filed because most Camp Lejeune veterans likely would have applied for VA medical care for treatment of their illness or condition regardless of this rulemaking.

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-12. This proposed rule would directly affect only individuals and would not affect any small entities. Therefore, pursuant to 5 U.S.C. 605(b), this proposed rulemaking is exempt from the initial and final flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Order 12866 and Executive Order 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) 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.”

VA has examined the economic, interagency, budgetary, legal, and policy implications of this regulatory action, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA’s impact analysis can be found as a supporting document at http://www.regulations.gov, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA’s website at http://www1.va.gov/orpm/, by following the link for “VA Regulations Published.”

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this rule are 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic
Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; and 64.022, Veterans Home Based Primary Care.

**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. Jose D. Riojas, Chief of Staff, Department of Veterans Affairs, approved this document on July 31, 2013, for publication.
List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Health care, Health facilities, Health professions, Health records, Homeless, Medical devices, Medical research, Mental health programs, Nursing homes, and Veterans.

Dated: September 5, 2013

Robert C. McFetridge,
Director, Regulation Policy and Management,
Office of the General Counsel,
Department of Veterans Affairs.
For the reasons set forth in the preamble, we propose to amend 38 CFR part 17 as follows:

PART 17 -- MEDICAL

1. The authority citation for part 17 continues to read as follows:

   AUTHORITY: 38 U.S.C. 501, and as noted in specific sections.

2. Amend § 17.36(b)(6) by removing “38 U.S.C. 1710(e);” and adding, in its place, “38 U.S.C. 1710(e); Camp Lejeune veterans pursuant to § 17.400;”.

3. Amend § 17.108(e)(2) by removing “or post-Gulf War combat-exposed veterans” and adding, in its place, “post-Gulf War combat-exposed veterans, or Camp Lejeune veterans pursuant to § 17.400;”.

4. Amend § 17.110(c)(4) by removing “or post-Persian Gulf War combat-exposed veterans” and adding, in its place, “post-Persian Gulf War combat-exposed veterans, or Camp Lejeune veterans pursuant to § 17.400;”.

5. Amend § 17.111(f)(5) by removing “or post-Persian Gulf War combat-exposed veterans” and adding, in its place, “post-Persian Gulf War combat-exposed veterans, or Camp Lejeune veterans pursuant to § 17.400;”.

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6. Add § 17.400 to read as follows:

§ 17.400 Hospital care and medical services for Camp Lejeune veterans.

(a) General. In accordance with this section, VA will provide hospital care and medical services to Camp Lejeune veterans. Camp Lejeune veterans will be enrolled pursuant to § 17.36(b)(6).

(b) Definitions. For the purposes of this section:

Camp Lejeune means any area within the borders of the U.S. Marine Corps Base Camp Lejeune or Marine Corps Air Station New River, North Carolina.

Camp Lejeune veteran means any veteran who served at Camp Lejeune on active duty, as defined in 38 U.S.C. 101(21), in the Armed Forces for at least 30 (consecutive or nonconsecutive) days during the period beginning on January 1, 1957, and ending on December 31, 1987. A veteran served at Camp Lejeune if he or she was stationed at Camp Lejeune, or traveled to Camp Lejeune as part of his or her professional duties.

(c) Limitations. For a Camp Lejeune veteran, VA will assume that illnesses or conditions listed in paragraph (d)(1)(A) through (O) of this section are attributable to the veteran’s active duty in the Armed Forces unless it is clinically determined, under VA clinical practice guidelines, that such an illness or condition is not attributable to the veteran’s service.

(d) Copayments. (1) Exemption. Camp Lejeune veterans are not subject to copayment requirements for hospital care and medical services provided on or after August 6, 2012, for the following illnesses and conditions:

(A) Esophageal cancer;
(B) Lung cancer;
(C) Breast cancer;
(D) Bladder cancer;
(E) Kidney cancer;
(F) Leukemia;
(G) Multiple myeloma;
(H) Myleodysplasic syndromes;
(I) Renal toxicity;
(J) Hepatic steatosis;
(K) Female infertility;
(L) Miscarriage;
(M) Scleroderma;
(N) Neurobehavioral effects; and
(O) Non-Hodgkin’s Lymphoma.

(2) **Retroactive Exemption.** VA will reimburse Camp Lejeune veterans for any copayments paid to VA for hospital care and medical services provided for one of the illnesses or conditions listed in paragraph (d)(1) of this section, if the following are true:

(A) The veteran requested Camp Lejeune veteran status no later than [insert date 2 years after date of publication in the FEDERAL REGISTER]; and

(B) VA provided the hospital care or medical services to the Camp Lejeune veteran on or after August 6, 2012.

(Authority: 38 U.S.C. 1710)