

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)(i) through (xv) 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:

- (i) Esophageal cancer;
- (ii) Lung cancer;
- (iii) Breast cancer;
- (iv) Bladder cancer;
- (v) Kidney cancer;
- (vi) Leukemia;
- (vii) Multiple myeloma;
- (viii) Myelodysplastic syndromes;
- (ix) Renal toxicity;
- (x) Hepatic steatosis;
- (xi) Female infertility;
- (xii) Miscarriage;
- (xiii) Scleroderma;
- (xiv) Neurobehavioral effects; and
- (xv) 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:

- (i) The veteran requested Camp Lejeune veteran status no later than September 24, 2016; and
- (ii) 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.

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900-AO79

Payment or Reimbursement for Certain Medical Expenses for Camp Lejeune Family Members

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) is promulgating regulations to implement statutory authority to provide payment or reimbursement for hospital care and medical services provided to certain veterans' family members who resided at Camp Lejeune, North Carolina, for at least 30 days during the period beginning on January 1, 1957, and ending on December 31, 1987. Under this rule, VA will reimburse family members, or pay providers, for medical expenses incurred as a result of certain illnesses and conditions that may be attributed to exposure to contaminated drinking water at Camp Lejeune during this time period. Payment or reimbursement will be made within the limitations set forth in statute and Camp Lejeune family members will receive hospital care and medical services that are consistent with the manner in which we provide hospital care and medical services to Camp Lejeune veterans.

DATES: *Effective Date:* This interim final rule is effective October 24, 2014.

Comment Date: Comments must be received on or before November 24, 2014.

ADDRESSES: Written comments may be submitted by email through <http://www.regulations.gov>; by mail or hand-delivery to Director, Regulation Policy and 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-AO79, Payment or Reimbursement for Certain Medical Expenses for Camp Lejeune Family Members." 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, comments may be viewed online through the Federal Docket Management System (FDMS) 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 created 38 U.S.C. 1787, requiring VA to furnish hospital care and medical services to certain family members of Camp Lejeune veterans for certain specified illnesses and conditions. The law requires the family members to have resided for at least 30 days at Camp Lejeune, North Carolina (hereinafter referred to as Camp Lejeune), while their veteran family member served on active duty in the Armed Forces at Camp Lejeune for at least 30 days during the period beginning on January 1, 1957, and ending on December 31, 1987. This interim final rule implements this statutory requirement by amending existing VA regulations and creating a new regulation, 38 CFR 17.410.

On September 11, 2013, VA published a notice of proposed rulemaking concerning hospital care and medical services provided to Camp Lejeune veterans. 78 FR 55671. In the supplementary information to that rulemaking, we provided our interpretation of the purposes of the Act, set forth criteria to identify a "Camp Lejeune veteran," defined the types of exposures experienced by veterans who served at Camp Lejeune during the statutorily defined period, and defined several terms relevant to this rulemaking. The final rule would apply equally and to the same extent to family members who resided at Camp Lejeune during the statutorily defined period. Under the law, family members, like veterans, experienced the same risks of exposure if they resided at Camp Lejeune during the statutorily prescribed period, and therefore should be considered as needing identical hospital care and medical services as those provided to Camp Lejeune veterans. This rulemaking addresses only those regulatory provisions specific to family members, which must be unique because VA has neither the authority nor the resources to provide comprehensive medical care to veterans' family members. In recognition of these limitations, we interpret the statutory authority to "furnish" "hospital care and medical services" as authorizing

VA to reimburse these family members, or pay providers, when they have exhausted all claims and remedies against a third party for payment of medical care for an illness or condition caused by Camp Lejeune exposure. VA will not directly provide care to family members under any circumstances outside VA's separate authorities to provide limited emergency care to non-veterans. In paragraph (a) of 38 CFR 17.410 VA states that it will pay providers or reimburse Camp Lejeune family members for certain hospital care and medical services associated with the specified conditions and furnished by non-VA health care providers. We clarify the terms of the payment or reimbursement in paragraph (d), which is discussed in detail below.

Paragraph (b) of § 17.410 sets forth the definitions applicable to 38 CFR 17.410. For the reasons explained above, we define Camp Lejeune in this section by using the same definition established in 38 CFR 17.400(b). Under § 17.400(b), "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. This area includes the areas in which non-military personnel would have resided while their active duty family member served at Camp Lejeune.

We define "Camp Lejeune family member" as an individual who meets two requirements. First, the individual resided (or was in utero while his or her mother either resided at Camp Lejeune or served at Camp Lejeune under § 17.400(b)) for at least 30 (consecutive or nonconsecutive) days during the period beginning on January 1, 1957, and ending on December 31, 1987. Second, the individual is either related to a Camp Lejeune veteran by birth, was married to such a veteran, or was a legal dependent of the veteran. Department of Defense rules determined whether servicemembers and their families were authorized to reside at Camp Lejeune during the relevant period; our definition here aligns with those rules. Eligible individuals must meet both the residency and relational requirements as set forth in 38 U.S.C. 1787(a). We note that the requirement that a family member be related to the veteran by birth includes individuals who were in utero while the mother of the individual resided at Camp Lejeune, as identified under 38 U.S.C. 1787(a). The requirement of relation by birth or marriage encompasses any relative of the Camp Lejeune veteran who could have been authorized by a service department to reside on Camp Lejeune and therefore may have been exposed to contaminated water. We also clarify that

family members include individuals who were legal dependents of the Camp Lejeune veteran during their residency at Camp Lejeune, such as adopted children, stepchildren, or individuals for whom the veteran had custody as determined by a U.S. court.

When referring to Camp Lejeune veterans, we use the same definition provided in 38 CFR 17.400(b). Under this definition, a "Camp Lejeune veteran" is 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.

We define a "health-plan contract" to carry the same definition under this section as we define the term in § 17.1001(a). The § 17.1001(a) definition of health-plan contract implements the definition set forth in 38 U.S.C. 1725(f). Under 38 U.S.C. 1787(b)(3), VA must use that same definition for the purposes of this rulemaking. Under that definition, health-plan contracts include insurance policies or contracts, medical or hospital service agreements, membership or subscription contracts, or similar arrangements under which health services for individuals are provided or the expenses of such services are paid, public insurance programs such as TRICARE, CHAMPVA, Medicare or Medicaid, and worker's compensation law or plans. Similarly, as directed by 38 U.S.C. 1787(b)(3), we define "third party" in accordance with the definition set forth by Congress in section 1725(f), and as defined in 38 CFR 17.1001(b). Under § 17.1001(b), third parties include: A Federal entity, a State or political subdivision of a State, an employer or an employer's insurance carrier, an automobile accident reparations insurance carrier, and a person or entity obligated to provide, or to pay the expenses of, health services under a health-plan contract. VA has not changed those definitions in this rulemaking because Congress specified in section 1787(b)(3) that VA must define these terms to have the same meaning given to them under section 1725(f).

In § 17.410(c), we explain that individuals who seek to apply for status as a Camp Lejeune family member must complete VA Form 10-068, "Camp Lejeune Family Member Health Care Program Application." Once an individual submits a form, VA will

confirm that the information is accurate in order to confirm Camp Lejeune family member status. VA has systems in place to verify that individuals meet the residence requirements and that they have the appropriate relationship to the Camp Lejeune veteran. VA will consider all supporting evidence submitted to confirm that an individual resided at Camp Lejeune for at least 30 days, including utility bills, pay stubs, tax forms, and similar documentation. Additionally, VA will consider as evidence any available internal housing records that show that the related Camp Lejeune veteran resided in family housing on Camp Lejeune along with all other residency-related evidence when confirming the accuracy of the family member's application.

Under § 17.410(d), we set out the process that providers of care or family members must follow in order to receive payment or reimbursement for hospital care and medical services provided by a non-VA health care provider that occurred after March 26, 2013 in connection with the 15 illnesses or conditions listed in 38 U.S.C. 1710(e)(1)(F) and 38 CFR 17.400(d)(1). These conditions are esophageal cancer, lung cancer, breast cancer, bladder cancer, kidney cancer, leukemia, multiple myeloma, myelodysplastic syndrome, renal toxicity, hepatic steatosis, female infertility, miscarriage, scleroderma, neurobehavioral effects, and non-Hodgkin's lymphoma. Pursuant to 38 U.S.C. 1787(b)(2), VA may not pay or reimburse for hospital care and medical services "for an illness or condition of a [Camp Lejeune] family member that is found, in accordance with guidelines issued by the Under Secretary for Health, to have resulted from a cause other than the residence of the family member [at Camp Lejeune]." We address this clinical determination made with the support of VA clinical practice guidelines in § 17.410(d), and discuss in detail below.

First, pursuant to § 17.410(d)(1), Camp Lejeune family members, or providers of hospital care or medical services, must file a timely claim for payment or reimbursement. The earliest that a Camp Lejeune family member can submit a claim for reimbursement will be the date that VA approves the application for Camp Lejeune family member status. VA will begin to accept applications immediately upon publication of this interim final rulemaking. We will apply a 2-year limit from the time of approved Camp Lejeune family member status for a timely claim filing. This 2-year limit is consistent with VA's review of applications for retroactive copayment

waivers made by Camp Lejeune veterans. Given that a number of claims may be for care received prior to the date of application, we set forth separate standards for timely claims. We will also pay for or reimburse certain claims for hospital care and medical services that took place before VA receives the Camp Lejeune family member's application. If the hospital care or medical services were provided prior to the date that the family member application was received by VA, we explain in § 17.410(d)(1)(i) that VA will accept claims for care dating as far back as two years prior to the date that the Camp Lejeune family member's application was received, but not earlier than March 26, 2013, the date on which appropriations to pay such claims were received, provided that claims for such care are received by VA no more than 60 days after VA approves the application. We note that the 2-year limit may be shortened if VA does not have the appropriation to provide payment or reimbursement due to the limitation set forth in § 17.410(d)(5). We note further that the 2-year limit is contingent upon claims being submitted within 60 days of the family member's application.

In § 17.410(d)(1)(ii), we explain the claim deadline for payment or reimbursement of hospital care and medical services that the Camp Lejeune family member received after VA has already received the Camp Lejeune family member's application. In that instance, the Camp Lejeune family member must file such a claim within two years after the date of discharge from hospital care or the date that the medical services were rendered. We believe that two years strikes an appropriate balance between allowing Camp Lejeune family members or providers adequate time to acquire the appropriate information to submit claims, and allowing VA to manage the claims process in an efficient and expedient manner. Further, this two-year requirement provides the family members and providers sufficient time to submit the medical claims to other health insurers for payment and receipt of their explanation of benefits.

We believe that VA can only effectively carry out its duty to reimburse for care provided to family members in 38 U.S.C. 1787(a) if both family members and providers can submit claims directly to VA. In order to satisfy the exhaustion requirement set forth in § 17.410(d)(4) (discussed in detail below), VA will ensure that third party payers with liability for a claim, such as private health insurers, have satisfied their respective liability before

VA will cover the remaining liability to the provider. VA will primarily rely on the Camp Lejeune family member to self-report his or her insurance information, and any future changes that might occur. VA will examine claims for falsified information, and VA will follow up to verify whether the individual is insured and filing accurate claims.

In § 17.410(d)(2), we require that the Camp Lejeune family member's treating physician certify that the claimed hospital care or medical services were provided for an illness or condition listed in § 17.400(d)(1). We also require under § 17.400(d)(2) that the treating physician provide information about any co-morbidities, risk factors, or other exposures that may have contributed to the illness or condition. Because VA is not going to be conducting clinical examinations, we must rely on the clinical determinations made by the individual's treating physician who did conduct such clinical examinations of the Camp Lejeune family member. VA will use this information to reach the clinical determinations described in § 17.410(d)(3). Because VA is not providing hospital care and medical services to the Camp Lejeune family member directly, we require this information from the treating physician in order to satisfy the requirements that the treatment be for one of the 15 illnesses or conditions set forth in 38 U.S.C. 1710(e)(1)(F). Pursuant to 38 U.S.C. 1787(b)(2), VA may not furnish hospital care and medical services to a Camp Lejeune family member for illnesses or conditions that VA finds to have resulted from a cause other than the individual's residence at Camp Lejeune. VA will use clinical practice guidelines to make this determination, which we discuss in greater detail in relation to § 17.410(d)(3). VA will evaluate the clinical information provided by the Camp Lejeune family member's treating physician in conjunction with these clinical practice guidelines, and any other medical and scientific evidence and research, to reach the clinical findings described and discussed in § 17.410(d)(3).

In § 17.410(d)(3), we incorporate a limitation similar to the one in § 17.400(c) by establishing that if a Camp Lejeune family member is diagnosed with one of the 15 illnesses or conditions listed in the Act, then the illness or condition is attributable to the individual's residence at Camp Lejeune. However, if VA clinically finds, after consideration of clinical practice guidelines and other accepted forms of medical documentation, evidence, or research with respect to the listed

illness or condition, that the illness or condition is not attributable to the individual's residence at Camp Lejeune, then VA will not provide payment or reimbursement for care under this rule. For many of the 15 conditions or illnesses specified in the Act, scientific knowledge limits VA's ability to make a determination regarding a specific cause. When the best scientific evidence available at the time limits VA's ability to attribute the family member's condition to a specific cause, VA will assume the condition or illness was caused by exposures while at Camp Lejeune, and thus will provide payment to providers or reimbursement to Camp Lejeune family members provided they meet all other requirements under this rule. For other conditions or illnesses, current medical knowledge offers more guidance. As such, the clinical practice guidelines represent best practices, providing factors for clinicians to consider when making determination about whether an illness or condition is attributable to a cause other than the individual's residence at Camp Lejeune. The guidelines encourage clinicians to consider each patient's full history in order to make the best possible clinical determination. Best practices cannot be static. Consistent with standard VA practice, the clinical guidelines used to make the determinations necessary to implement this regulation will be subject to continuous improvement. Specifically, over time we will update the clinical practice guidelines to reflect evolution in the science underlying these conditions, experience in implementing the guidelines, and other factors that reflect our understanding of clinical indications and the potential for more specific determinations. Camp Lejeune family members will have the option to request reconsideration of clinical determinations, and at that time will be able to submit additional evidence supporting the claim as well. Appeals will be reviewed by VA clinicians with expertise on Camp Lejeune matters, or experts on the specific illness or condition in question. To the extent that there are issues about the adequacy and sufficiency of VA's review of evidence presented by the Camp Lejeune family member, the individual can appeal to the Board of Veterans Appeals.

Under 38 CFR 17.410(d)(3), the claim must be for hospital care or medical services provided in connection with one of the 15 illnesses or conditions listed in § 17.400(d)(1). As explained in the proposed rule for "Hospital Care and Medical Services for Camp Lejeune Veterans," VA is in the process of

developing clinical practice guidelines in order to determine whether an individual has been diagnosed with one of the illnesses or conditions listed in the Act and to determine the clinical relationship of a specific illness or condition to possible exposure to contaminated drinking water at Camp Lejeune. 78 FR 55673, Sept. 11, 2013. We will utilize those same non-determinative clinical practice guidelines in concluding whether the similar requirement under 38 U.S.C. 1787(b)(2), that VA may not furnish hospital care and medical services for Camp Lejeune family members if the illness or condition is determined “to have resulted from a cause other than the residence of the family member [at Camp Lejeune],” is satisfied.

The VA health care system is designed to provide comprehensive health care to veterans. Section 1787(a) authorizes VA to furnish hospital care and medical services to veterans’ family members only for the 15 listed illnesses and conditions listed in 38 U.S.C. 1710(e)(1)(F). We believe that family members will receive continuity of health care for these 15 illnesses or conditions and any other health needs by receiving hospital care and medical services from their private providers. More importantly, because our authority to provide care to family members is limited to care specifically for one of the listed illnesses or conditions, there could be significant medical and ethical issues presented if VA were to attempt to provide direct care to family members. Our medical providers treat the “whole patient,” and it could be unethical (and bad for the patient) in many cases to treat a specific illness or condition while disregarding other medical issues. Therefore, as a matter of policy, VA has determined that it is in the best interests of Camp Lejeune family members to receive hospital care and medical services from private providers chosen by the family. In contrast, VA provides direct care to Camp Lejeune veterans by enrolling them in the VHA health care system because VA has separate authority to provide hospital care and medical services to eligible veterans. This is explained further in “Hospital Care and Medical Services for Camp Lejeune Veterans,” 78 FR 55671, September 11, 2013.

In 38 CFR 17.410(d)(4), we explain that any hospital care and medical services must be authorized under VA’s medical benefits package in § 17.38. In 38 CFR 17.38, VA sets forth the broad scope of the medical benefits package that it furnishes to veterans, based on our authority to provide “hospital care”

and “medical services” under 38 U.S.C. 1710. Because the authorizing statutes for both family members under 38 U.S.C. 1787 and veterans under 38 U.S.C. 1710 use the terms “hospital care” and “medical services,” we will pay only for care and services that meet the statutory definitions under section 1701, i.e., those that we would otherwise be authorized to provide to veterans. In short, through the payment and reimbursement system described in this rulemaking, we will “furnish” the same hospital care and medical services to family members that we would furnish to veterans for the 15 illnesses and conditions specified in Act.

Under § 17.410(d)(5), Camp Lejeune family members or hospital care or medical service providers must exhaust all claims and remedies reasonably available to the family member or provider against a third party, including health-plan contracts. We have repeated in § 17.410(d)(5) a statutory requirement under 38 U.S.C. 1787(b)(3). Section 1787(b)(3) specifically cites health-plan contracts, which we defined in § 17.1001(a) to include private health insurance. Generally, this requirement will be interpreted to be satisfied when the Camp Lejeune family member submits claims for all hospital care and medical services to the all relevant third party insurers, including Medicare and Medicaid, before submitting the claim to VA. We recognize that in some cases the only option available to the family member may have been to obtain out-of-network care, and in such cases we will find that the exhaustion requirement has been met and will cover the claimed amount so long as it is otherwise in compliance with all relevant third-party coverage.

Under paragraph § 17.410(d)(6), we note that payment or reimbursement will only be made if adequate funds have been appropriated to implement 38 U.S.C. 1787. Medical Services account funds will be available each fiscal year for Camp Lejeune care received by qualifying family members on or after the date that an appropriations act is signed into law. Under 38 U.S.C. 1787(b)(1), VA is authorized to furnish hospital care and medical services to Camp Lejeune family members “to the extent and in the amount provided in advance in appropriations Acts for such purpose.” VA is not authorized to provide payments or reimbursements before the date that an appropriation Act provides funds for the purpose of furnishing hospital care and medical service to Camp Lejeune family members. The Consolidated and Further Continuing Appropriations Act, 2013, Public Law 113–6, 127 Stat. 396,

appropriated funds to the Medical Services account for fiscal year 2014 for, among other things, “hospital care and medical services authorized by section 1787 of title 38, United States Code.” These funds became available on October 1, 2013, and will expire on September 30, 2014.

In 38 CFR 17.410(e), we establish the amounts that VA will pay or reimburse for hospital care and medical services furnished to family members. Under paragraph (e)(1), if a third party is liable for partial payment for hospital care or medical services provided to a Camp Lejeune family member consistent with the other requirements of § 17.410, then VA will pay or reimburse the lesser of two rates. The first possible rate is the amount for which the Camp Lejeune family member remains personally liable. For example, if a Camp Lejeune family member receives medical services consistent with paragraph (d) and is insured under a health-plan contract, then VA will pay or reimburse any cost share or copayment amounts for which the Camp Lejeune family member is personally liable under that health-plan contract.

The second rate calculation is based on VA’s existing mechanisms for paying for hospital care and medical services provided by non-VA providers to veterans under 38 CFR 17.55 and 17.56. Section 17.55 sets VA’s payment methodology for authorized public or private hospital care to veterans. Section 17.56 sets VA’s payment methodology for authorized medical services provided to veterans. Both 38 U.S.C. 1710(e)(1)(F) and 1787 require VA to “furnish hospital care and medical services” for the same set of 15 illnesses or conditions. Given the identical language, VA intends, to the extent possible, to furnish hospital care and medical services to Camp Lejeune family members in the same manner that it does for veterans receiving non-VA care, including calculating payments at the same rate. Under §§ 17.55(g) and 17.56(c), payments made by VA under those authorities “shall be considered payment in full.” Likewise, by cross-referencing §§ 17.55 and 17.56 in § 17.410(e)(1) and (2), any payments or reimbursements made will be payment in full, which in turn extinguishes all personal liability for the Camp Lejeune family member for the hospital care and medical services related to one of the 15 illnesses or conditions listed in the Act.

VA will pay the lesser of those two calculations because by extinguishing the Camp Lejeune family member’s individual liability, VA will satisfy the requirement under 38 U.S.C. 1787 to

furnish hospital care and medical services. By paying the lesser of the two rates listed in § 17.410(e)(1), VA will ensure that its resources are being managed in the most efficient way possible. Under paragraph (e)(2), if VA is the sole payer, meaning that no other party is liable for the provided hospital care and medical services, then VA will calculate payment amounts by using the methodologies in §§ 17.55 and 17.56.

Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this interim final rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Administrative Procedure Act

Under 5 U.S.C. 553(b)(B), the general requirements for notice of proposed rulemaking do not apply when the agency finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest. In accordance with that section, the Secretary of Veterans Affairs finds good cause to issue this interim final rule without prior notice and comment. Accordingly, it is not necessary to obtain public comment prior to implementation. Moreover, although public comments prior to implementation are not necessary to fulfill the mandate of the law in a timely manner, comments received after publication and a brief period of implementation may assist in understanding whether this interim final rule requires minor adjustments or refinement of attendant procedures.

First, VA believes that prior notice and comment would be contrary to the public interest. This interim final rule implements VA's duty to furnish hospital care and medical services to family members of veterans, pursuant to 38 U.S.C. 1787, who may have been exposed to toxic substances due to their residence at Camp Lejeune. Many of the 15 listed conditions or illnesses are life-threatening and require immediate medical care that is often quite costly to patients, regardless of whether they have health-plan contracts. For example, several of the 15 illnesses or conditions are serious cancers, and medical research indicates that the probability of survival increases with early diagnosis and treatment. The cost

of care for one of the 15 illnesses or conditions is frequently prohibitive, leading individuals to delay or forego obtaining vital hospital care and medical services. In addition to increased mortality, delays in pursuing care can unnecessarily complicate treatment when the individual eventually does seek care because, by that time, the illness or condition can progress and may directly lead to secondary conditions. VA is capable of reimbursing Camp Lejeune family members for such illnesses or conditions, and there are critical health care reasons to ensure that these family members can obtain care as soon as possible.

In addition, we believe that prior notice and comment are unnecessary. This interim final rule enforces the Congressional mandate of 38 U.S.C. 1787 very broadly. We do not believe that we would receive any comments suggesting that the proposed coverage is too broad and should be more restrictive than is provided in this rule. For these reasons, the Secretary has concluded that ordinary notice and comment procedures would be unnecessary, and contrary to the public interest and is accordingly issuing this rule as an interim final rule.

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 1 year. This interim final rule has no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3507) requires that VA consider the impact of paperwork and other information collection burdens imposed on the public. Under 44 U.S.C. 3507(a), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number. See also 5 CFR 1320.8(b)(3)(vi).

This interim final rule will impose the following new information collections requirements. Section 17.410(c) of title 38, CFR, requires an individual applying for benefits associated with hospital care and medical services for Camp Lejeune family members to submit an application to VA on VA

Form 10068, "Camp Lejeune Family Member Program Application." Section 17.410(d)(1) requires a Camp Lejeune family member or provider of care or services to submit a timely claim for payment or reimbursement. Section 17.410(d)(2) requires the provider of a Camp Lejeune family member to certify that a Camp Lejeune family member has been diagnosed with one of the 15 required illnesses or conditions. Section 17.410 requires VA to maintain timely information about the Camp Lejeune family member in order to correctly identify the individual in VA's system, and to submit any information or reimbursements. As required by the Paperwork Reduction Act of 1995 (at 44 U.S.C. 3507(d)), VA has submitted these information collections to OMB for its review. OMB assigns a control number for each collection of information it approves. Except for emergency approvals under 44 U.S.C. 3507(j), VA may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. We have requested that OMB approve the collections of information on an emergency basis. If OMB does not approve the collections of information as requested, we will immediately remove §§ 17.410(c), 17.410(d)(1), 17.410(d)(2), or take such other action as is directed by OMB.

Comments on the collection of information should be submitted to the Office of Management and Budget, Attention: Desk Officer for the Department of Veterans Affairs, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies mailed or hand-delivered to: Director, Office of Regulation Policy and Management (02REG), Department of Veterans Affairs, 810 Vermont Ave. NW., Room 1068, Washington, DC 20420; fax to (202) 273-9026; or through www.regulations.gov. Comments should indicate that they are submitted in response to "RIN 2900-AO79, Payment or Reimbursement for Certain Medical Expenses for Camp Lejeune Family Members."

Title: Camp Lejeune Family Member Program Application.

Summary of collection of information: Section 17.410(c) requires individuals to complete an application in order to be considered for designation by VA as Camp Lejeune Family Members.

Description of the need for information and proposed use of information: This information is needed to determine eligibility for benefits as a Camp Lejeune family member.

Description of likely respondents: Veterans' family members.
Estimated number of respondents per year: 3,000.

Estimated frequency of responses per year: 1.

Estimated total annual reporting and recordkeeping burden: 1,500 hours.

Estimated average burden per collection: 30 minutes.

Title: Camp Lejeune Family Members Claim Form.

Summary of collection of information: Claims for payment or reimbursement of hospital care or medical services will be submitted to VA by the Camp Lejeune family member.

Description of the need for information and proposed use of information: This information is needed to determine the amount that VA will pay or reimburse the Camp Lejeune family member.

Description of likely respondents: Veterans' family members.

Estimated number of respondents per year: 3,000.

Estimated frequency of responses per year: 11.

Estimated total annual reporting and recordkeeping burden: 16,500 hours.

Estimated average burden per collection: 30 minutes. VA estimates that there will be some claims that will be completed by filling out the information and attaching a recently-received bill, which may take as little as 15 minutes. Other complicated instances may require an hour or more of time. VA has decided to use an estimate of 30 minutes to represent the average time required to complete the form and submit the supporting documentation.

Title: Camp Lejeune Family Members Treating Physician Report.

Summary of collection of information: The physician providing hospital care or medical services will certify whether the Camp Lejeune family member has been diagnosed with one or more of the illnesses or conditions listed in 38 CFR 17.400(d)(1). The physician must also list any other co-morbidities, risk factors, or other exposures that may have contributed to the patient's development of the diagnosed illness or condition.

Description of the need for information and proposed use of information: VA will utilize the diagnosis information to determine whether the Camp Lejeune family member has been diagnosed with one of the illnesses or conditions identified in 38 CFR 17.400(d)(1). VA will also use this information to determine whether the condition or illness resulted from a

cause other than the Camp Lejeune family member's residence at Camp Lejeune.

Description of likely respondents: Camp Lejeune family members' treating physicians.

Estimated number of respondents per year: 3,000.

Estimated frequency of responses per year: 1.

Estimated total annual reporting and recordkeeping burden: 750 hours.

Estimated average burden per collection: 15 minutes.

Title: Camp Lejeune Family Members Information Update Form.

Summary of collection of information: The Camp Lejeune family member will complete this form if he or she changes his or her address or health plan contract.

Description of the need for information and proposed use of information: VA will use the information provided to update the Camp Lejeune family member's information as initially provided on the Camp Lejeune Family Member Program Application.

Description of likely respondents: Veterans' family members.

Estimated number of respondents per year: 1,000.

Estimated frequency of responses per year: 1.

Estimated total annual reporting and recordkeeping burden: 250 hours.

Estimated average burden per collection: 15 minutes.

A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment on the interim final rule. VA considers comments by the public on collections of information in:

- Evaluating whether the collections of information are necessary for the proper performance of the functions of the Department, including whether the information will have practical utility;
- Evaluating the accuracy of the Department's estimate of the burden of the collections of information, including the validity of the methodology and assumptions used;
- Enhancing the quality, usefulness, and clarity of the information to be collected; and
- Minimizing the burden of the collections of information on those who are to respond, including responses through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Regulatory Flexibility Act

The Secretary hereby certifies that this interim final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–12. This rule will not require any medical providers to provide care, does not specify that care be provided by any particular medical providers, and does not supersede any existing insurance or other payment mechanism. Rather, this rule simply authorizes VA to serve as a payer of last resort for care obtained privately by Camp Lejeune family members. Therefore, pursuant to 5 U.S.C. 605(b), this 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.

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. 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 Web site 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; 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 March 5, 2014, 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, Veterans.

Dated: September 18, 2014.

William F. Russo,

Acting Director, Office of Regulation Policy & Management, Office of the General Counsel, U.S. Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 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. Add § 17.410 under undesignated center heading "Hospital Care and

Medical Services for Camp Lejeune Veterans and Families" to read as follows:

§ 17.410 Hospital care and medical services for Camp Lejeune family members.

(a) *General.* In accordance with this section and subject to the availability of funds appropriated for such purpose, VA will provide payment or reimbursement for certain hospital care and medical services furnished to Camp Lejeune family members by non-VA health care providers.

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

Camp Lejeune has the meaning set forth in § 17.400(b).

Camp Lejeune family member means an individual who:

(i) Resided at Camp Lejeune (or was in utero while his or her mother either resided at Camp Lejeune or served at Camp Lejeune under § 17.400(b)) for at least 30 (consecutive or nonconsecutive) days during the period beginning on January 1, 1957, and ending on December 31, 1987; and

(ii) Meets one of the following criteria:

(A) Is related to a Camp Lejeune veteran by birth;

(B) Was married to a Camp Lejeune veteran; or

(C) Was a legal dependent of a Camp Lejeune veteran.

Camp Lejeune veteran has the meaning set forth in § 17.400(b).

Health-plan contract has the meaning set forth in § 17.1001(a).

Third party has the meaning set forth in § 17.1001(b).

(c) *Application.* An individual may apply for benefits under this section by completing and submitting an application form.

(d) *Payment or reimbursement of certain medical care and hospital services.* VA will provide payment or reimbursement for hospital care and medical services provided to a Camp Lejeune family member by a non-VA provider if all of the following are true:

(1) The Camp Lejeune family member or provider of care or services has submitted a timely claim for payment or reimbursement, which means:

(i) For hospital care and medical services provided before the date that the application discussed in paragraph (c) of this section was received by VA, the hospital care and medical services must have been provided no more than 2 years prior to the date that VA receives the application but not prior to March 26, 2013, and the claim for payment or reimbursement must be received by VA no more than 60 days after VA approves the application;

(ii) For hospital care and medical services provided on or after the date that the application discussed in paragraph (c) of this section was received by VA, the claim for payment or reimbursement must be received by VA no more than 2 years after the later of either the date of discharge from a hospital or the date that medical services were rendered;

(2) The Camp Lejeune family member's treating physician certifies that the claimed hospital care or medical services were provided for an illness or condition listed in § 17.400(d)(1), and provides information about any co-morbidities, risk factors, or other exposures that may have contributed to the illness or condition;

(3) VA makes the clinical finding, under VA clinical practice guidelines, that the illness or condition did not result from a cause other than the residence of the family member at Camp Lejeune;

(4) VA would be authorized to provide the claimed hospital care or medical services to a veteran under VA's medical benefits package in § 17.38;

(5) The Camp Lejeune family member or hospital care or medical service provider has exhausted without success all claims and remedies reasonably available to the family member or provider against a third party, including health-plan contracts; and

(6) Funds were appropriated to implement 38 U.S.C. 1787 in a sufficient amount to permit payment or reimbursement.

(e) *Payment or reimbursement amounts.* Payments or reimbursements under this section will be in amounts determined in accordance with this paragraph (e).

(1) If a third party is partially liable for the claimed hospital care or medical services, then VA will pay or reimburse the lesser of the amount for which the Camp Lejeune family member remains personally liable or the amount for which VA would pay for such care under §§ 17.55 and 17.56.

(2) If VA is the sole payer for hospital care and medical services, then VA will pay or reimburse in accordance with §§ 17.55 and 17.56, as applicable.

(Authority: 38 U.S.C. 1787)

(The information collection requirements have been submitted to OMB and are pending OMB approval.)

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