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## **Medical**

Book I

Title 38, Parts 17, 46, 47, 51–53,  
58–64, 70, 71, and 200

Supplement No. 129

Covering period of *Federal Register* issues  
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**GENERAL INSTRUCTIONS**

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**Supplemental Materials for *Book I***

**Code of Federal Regulations**

**Title 38, Parts 17, 46, 47, 51–53, 58–64, 70, 71, and 200**

***Medical***

**Supplement No. 129**

5 June 2020

Covering the period of Federal Register issues  
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**FILING INSTRUCTIONS**

**Book I, Supplement No. 129  
June 5, 2020**

<i>Remove these old pages</i>	<i>Add these new pages</i>	<i>Section(s) Affected</i>
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I-9 to I-10	I-9 to I-10	Book I Lead Material
17.INDEX-1 to 17.INDEX-2	17.INDEX-1 to 17.INDEX-2	Part 17 Index
17.INDEX-7 to 17.INDEX-8	17.INDEX-7 to 17.INDEX-8	Part 17 Index
17.32-1 to 17.32- <u>6</u>	17.32-1 to 17.32- <u>8</u>	§17.32
17.390-4 to 17.400-1	17.390-4 to 17.400-1	§17.390

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## HIGHLIGHTS

### Book I, Supplement No. 129 June 5, 2020

**Supplement Highlights references:** Where substantive changes are made in the text of regulations, the paragraphs of *Highlights* sections are cited at the end of the relevant section of text. Thus, if you are reading §17.100, you will see a note at the end of that section which reads: “Supplement *Highlights* references—37(1).” This means that paragraph 1 of the *Highlights* section in Supplement No. 37 contains information about the changes made in §17.100. By keeping and filing the *Highlights* sections, you will have a reference source explaining all substantive changes in the text of the regulations.

**Supplement frequency:** Beginning 1 January 2000, supplements for this Book I will be issued *every month* during which a final rule addition or modification is made to the parts of Title 38 covered by this book. Supplements will be numbered consecutively as issued.

#### **Modifications in this supplement include the following:**

1. On 27 May 2020, the VA published an interim final rule effective that same day, to amend its regulation regarding informed consent and advance directives. We amend the regulation by reorganizing it and amending language where necessary to enhance clarity. In addition, we amend the regulation to facilitate the informed consent process, the ability to communicate with patients or surrogates through available modalities of communication, and the execution and witness requirements for a VA Advance Directive. Changes:

- Revised §17.32.

2. On 28 May 2020, the VA published a correcting amendment to add the Office of Management and Budget approval number for the new collection of information in the Department of Veterans Affairs (VA) regulation that governs the reimbursement of qualifying adoption expenses incurred by a veteran with a service-connected disability that results in the inability of the veteran to procreate without the use of fertility treatment. Changes:

- In §17.390, revised parenthetical sentence at the end of the section.

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63	_____	_____	_____
64	_____	_____	_____
65	_____	_____	_____
66	_____	_____	_____
67	_____	_____	_____

**Index**

**Part 17 — Medical**

**Updating Fire Safety Standards**

17.1 Incorporation by reference ..... 17.1-1

**Definitions and Active Duty**

17.30 Definitions..... 17.30-1  
17.31 Duty periods defined..... 17.31-1

**Protection of Patient Rights**

17.32 Informed consent and advance directives ..... 17.32-1  
17.33 Patients’ rights ..... 17.33-1

**Tentative Eligibility Requirements**

17.34 Tentative eligibility determinations ..... 17.34-1

**Hospital or Nursing Home Care and Medical Services in Foreign Countries**

17.35 Hospital care and medical services in foreign countries ..... 17.35-1

**Enrollment Provisions and Medical Benefits Package**

17.36 Enrollment–provision of hospital and outpatient care to veterans..... 17.36-1  
17.37 Enrollment not required–provision of hospital and  
outpatient care to veterans..... 17.37-1  
17.38 Medical benefits package..... 17.38-1  
17.39 Certain Filipino veterans..... 17.39-1  
17.40 Additional services for indigents ..... 17.40-1

**Examination and Observation and Examination**

17.41 Persons eligible for hospital observation and physical examination. .... 17.41-1  
17.42 Examinations on an outpatient basis..... 17.42-1

**Hospital, Domiciliary and Nursing Home Care**

**Part 17 — Medical**

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Section 17.55 is also issued under 38 U.S.C. 513, 1703, and 1728.

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**— Section Title Index —**

**Aid to States for care of Veterans in State Homes**

Aid for domiciliary care.....	17.194-1
Aid for hospital care.....	17.196-1
Amount of aid payable.....	17.197-1
Approval of annexes and new facilities .....	17.192-1
Audit of State homes.....	17.200-1
Department of Veterans Affairs approval of eligibility required.....	17.198-1
Filing applications.....	17.191-1
Inspection of recognized State homes.....	17.199-1
Prerequisites for payments to State homes .....	17.193-1
Recognition of a State home .....	17.190-1

**Authority of Health Care Providers to Practice in VA**

Full practice authority for advanced practice registered nurses.....	17.415-1
Health care providers practicing via telehealth.....	17.417-1

**Automotive Equipment and Driver Training**

Definition-adaptive equipment .....	17.157-1
-------------------------------------	----------

Eligibility for automobile adaptive equipment ..... 17.156-1  
 Limitations on assistance ..... 17.158-1  
 Minimum standards of safety and quality for automotive adaptive equipment..... 17.155-1  
 Obtaining vehicles for special driver training courses ..... 17.159-1

**Autopsies**

Autopsies ..... 17.170-1

**Breaking Appointments**

Refusal of treatment by unnecessarily breaking appointments ..... 17.100-1

**Care During Certain Disasters and Emergencies**

Provision of hospital care and medical services during certain disasters and emergencies under 38 U.S.C. 1785 ..... 17.86-1

**Center for Innovation for Care and Payment**

Center for Innovation for Care and Payment ..... 17.450-1

**Ceremonies**

Services or ceremonies on Department of Veterans Affairs hospital or center reservations..... 17.112-1

**Chaplain Services**

Ecclesiastical endorsing organizations..... 17.655-1

**Charges, Waivers, And Collections**

Collection or recovery by VA for medical care or services provided or furnished to a veteran for a non-service connected disability ..... 17.101-1  
 Charges for care or services ..... 17.102-1  
 Referrals of compromise settlement offers ..... 17.103-1  
 Terminations and suspensions ..... 17.104-1  
 Waivers ..... 17.105-1

**Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA)—Medical Care for Survivors and Dependents of Certain Veterans**

Appeal/review process ..... 17.276-1  
 Benefit limitations/exclusions..... 17.272-1  
 Claim filing deadline..... 17.275-1  
 Confidentiality of records ..... 17.278-1  
 Cost sharing ..... 17.274-1  
 Eligibility ..... 17.271-1  
 General provisions ..... 17.270-1  
 Preauthorization ..... 17.273-1  
 Third party liability/medical care cost recovery..... 17.277-1

Outpatient medical services for military retirees and other beneficiaries ..... 17.94-1  
 Medication prescribed by non-VA physicians ..... 17.96-1  
 Priorities for medical services..... 17.99-1

**Payment and Reimbursement of the Expenses of Medical Services not Previously Authorized**

Allowable rates and fees ..... 17.128-1  
 Appeals ..... 17.132-1  
 Claimants ..... 17.123-1  
 Date of filing claims..... 17.127-1  
 Limitations on payment or reimbursement of the costs of emergency treatment not previously authorized..... 17.121-1  
 Payment for treatment dependent upon preference prohibited ..... 17.130-1  
 Payment of abandoned claims prohibited ..... 17.131-1  
 Payment or reimbursement for emergency treatment furnished by Non-VA providers to certain veterans with service-connected disabilities ..... 17.120-1  
 Payment or reimbursement of the expenses of repairs to prosthetic appliances and similar devices furnished without prior authorization ..... 17.122-1  
 Preparation of claims ..... 17.124-1  
 Retroactive payments prohibited ..... 17.129-1  
 Timely filing ..... 17.126-1  
 Where to file claims ..... 17.125-1

**Payment or Reimbursement for Emergency Services for Nonservice-Connected Conditions in Non-VA Facilities**

Balance billing prohibited..... 17.1008-1  
 Decisionmakers..... 17.1006-1  
 Definitions..... 17.1001-1  
 Emergency transportation ..... 17.1003-1  
 Filing claims..... 17.1004-1  
 Independent right of recovery ..... 17.1007-1  
 Payment limitations ..... 17.1005-1  
 Payment or reimbursement for emergency services for nonservice-connected conditions in non-VA facilities ..... 17.1000-1  
 Substantive conditions for payment or reimbursement..... 17.1002-1

**Program for Repayment of Educational Loans for Certain VA Psychiatrists**

Purpose ..... 17.640-1  
 Definitions..... 17.641-1  
 Eligibility ..... 17.642-1  
 Application for the program for the repayment of educational loans ..... 17.643-1  
 Selection of participants..... 17.644-1  
 Award procedures ..... 17.645-1  
 Obligated service..... 17.646-1  
 Failure to comply with terms and conditions of participation ..... 17.647-1

**Prosthetic, Sensory, and Rehabilitative Aids**

Devices to assist in overcoming the handicap of deafness ..... 17.152-1  
 Equipment for blind veterans..... 17.154-1  
 Invalid lifts for recipients of aid and attendance allowance or special  
     monthly compensation ..... 17.151-1  
 Prosthetic and similar appliances..... 17.150-1  
 Sensori-neural Aids..... 17.149-1  
 Service dogs ..... 17.148-1  
 Training in the use of appliances ..... 17.153-1

**Protection of Patient Rights**

Informed consent and advance directives ..... 17.32-1  
 Patients’ rights ..... 17.33-1

**Reconsideration of Denied Claims**

Procedures..... 17.133-1

**Reimbursement for Loss by Natural Disaster of Personal Effects of Hospitalized or Nursing Home Patients**

Claims in cases of incompetent patients ..... 17.115-1  
 Conditions of custody ..... 17.113-1  
 Submittal of claim for reimbursement ..... 17.114-1

**Reimbursement to Employees for the Cost of Repairing or Replacing Certain Personal Property Damaged or Destroyed By Patients or Members**

Adjudication of claims..... 17.116-1

**Research-related Injuries**

Treatment of research-related injuries to human subjects..... 17.85-1

**Sharing of Medical Facilities, Equipment, and Information**

Contingency backup to the Department of Defense..... 17.230-1  
 Coordination of programs with Department of Health and  
     Human Services ..... 17.242-1  
 Sharing medical information services..... 17.241-1  
 Sharing health-care resources ..... 17.240-1

**Tentative Eligibility Determinations**

Tentative eligibility determinations ..... 17.34-1

**Transitional Housing Loan Program**

## Protection of Patient Rights

### §17.32 Informed consent and advance directives.

(a) *Definitions.* The following definitions are applicable for purposes of this section:

*Advance directive.* A written statement by a person who has decision-making capacity regarding preferences about future health care decisions if that person becomes unable to make those decisions, in any of the following:

(i) *Durable power of attorney for health care.* A durable power of attorney for health care (DPAHC) is a type of advance directive in which an individual designates another person as an agent to make health care decisions on the individual's behalf.

(ii) *Living will.* A living will is a type of advance directive in which an individual documents personal preferences regarding future treatment options. A living will typically includes preferences about life-sustaining treatment, but it may also include preferences about other types of health care.

(iii) *Mental health (or psychiatric) advance directive.* A mental health or psychiatric advance directive is executed by patients whose future decision-making capacity is at risk due to mental illness. In this type of directive, the individual indicates future mental health treatment preferences.

(iv) *State-authorized advance directive.* A state-authorized advance directive is a non-VA DPAHC, living will, mental health directive, or other advance directive document that is legally recognized by a state. The validity of state-authorized advance directives is determined pursuant to applicable state law. For the purposes of this section, “applicable state law” means the law of the state where the advance directive was signed, the state where the patient resided when the advance directive was signed, the state where the patient now resides, or the state where the patient is receiving treatment. VA will resolve any conflict between those state laws regarding the validity of the advance directive by following the law of the state that gives effect to the wishes expressed by the patient in the advance directive.

(v) *Department of Defense (DoD) advance medical directive.* A DoD advance medical directive is executed for members of the armed services or military dependents pursuant to 10 U.S.C. 1044C. It may include a durable power of attorney for health care or a living will. Federal law exempts such advance directives from any requirement of form, substance, formality, or recording that is provided for under the laws of an individual state. Federal law requires that this type of advance directive be given the same legal effect as an advance directive prepared and executed in accordance with the laws of the state concerned.

(vi) *VA Advance Directive.* A VA Advance Directive is completed on a form specified by VA. In VA, this form can be used by patients to designate a health care agent and to document treatment preferences, including medical care, surgical care, and mental health care.

*Close friend.* Any person eighteen years or older who has shown care and concern for the welfare of the patient, who is familiar with the patient's activities, health, religious beliefs and values, and who has presented a signed written statement for the record that describes that person's relationship to and familiarity with the patient.

*Decision-making capacity.* The ability to understand and appreciate the nature and consequences of health care treatment decisions, and the ability to formulate a judgment and communicate a clear decision concerning health care treatments

*Health care agent.* An individual named by the patient in a durable power of attorney for health care (DPAHC) to make health care decisions on the patient's behalf, including decisions regarding the use of life-sustaining treatments, when the patient can no longer do so.

*Legal guardian.* A person appointed by a court of appropriate jurisdiction to make decisions, including medical decisions, for an individual who has been judicially determined to be incompetent.

*Practitioner.* A practitioner is any physician, dentist, or health care professional granted specific clinical privileges to perform the treatment or procedure. The term practitioner also includes:

(i) Medical and dental residents, regardless of whether they have been granted specific clinical privileges; and

(ii) Other health care professionals whose scope of practice agreement or other formal delineation of job responsibility specifically permits them to obtain informed consent, and who are appropriately trained and authorized to perform the procedure or to provide the treatment for which consent is being obtained.

*Signature consent.* The documentation of informed consent with the signature of the patient or surrogate and practitioner on a form prescribed by VA for that purpose.

*State-authorized portable orders.* Specialized forms or identifiers (e.g., Do Not Attempt Resuscitation (DNAR) bracelets or necklaces) authorized by state law or a state medical board or association, that translate a patient's preferences with respect to life-sustaining treatment decisions into standing portable medical orders.

*Surrogate.* An individual authorized under this section to make health care decisions on behalf of a patient who lacks decision-making capacity. The term includes a health care agent, legal guardian, next-of-kin, or close friend.

(b) *Informed consent.* Patients receiving health care from VA have the right to accept or refuse any medical treatment or procedure recommended to them. Except as otherwise provided in this section, no medical treatment or procedure may be performed without the prior, voluntary informed consent of the patient.

(1) In order to give informed consent, the patient must have decision-making capacity.

(2) In the event that the patient lacks decision-making capacity, the requirements of this section are applicable to consent for treatments or procedures obtained from a surrogate acting on behalf of the patient.

(c) *General requirements for informed consent.* Informed consent is the process by which the practitioner discloses to and discusses appropriate information with a patient so that the patient may make a voluntary choice about whether to accept the proposed diagnostic or

therapeutic procedure or course of treatment. Appropriate information is information that a reasonable person in the patient's situation would expect to receive in order to make an informed choice about whether or not to undergo the treatment or procedure. (Appropriate information includes tests that yield information that is extremely sensitive or that may have a high risk of significant consequence (e.g., physical, social, psychological, legal, or economic) that a reasonable person would want to know and consider as part of his or her consent decision.) The specific information and level of detail required will vary depending on the nature of the treatment or procedure.

(1) The informed consent discussion should be conducted in person with the patient whenever practical. If it is impractical to conduct the discussion in person, or the patient expresses a preference for communication through another modality, the discussion may be conducted by telephone, through video conference, or by other VA-approved electronic communication methods.

(2) The practitioner must explain in language understandable to the patient each of the following, as appropriate to the treatment or procedure in question: The nature of the proposed procedure or treatment; expected benefits; reasonably foreseeable associated risks, complications or side effects; reasonable and available alternatives; and anticipated results if nothing is done.

(3) The patient must be given the opportunity to ask questions, to indicate comprehension of the information provided, and to grant or withhold consent freely without coercion.

(4) The practitioner must advise the patient if the proposed treatment is novel or unorthodox.

(5) The patient may withhold or revoke consent at any time.

(6) The practitioner may delegate to other trained personnel responsibility for providing the patient with clinical information needed for the patient to make a fully informed consent decision but must personally verify with the patient that the patient has been appropriately informed and voluntarily consents to the treatment or procedure.

(7) Practitioners may provide necessary medical care in emergency situations without the express consent of the patient when all of the following apply:

(i) Immediate medical care is necessary to preserve life or prevent serious impairment of the health of the patient.

(ii) The patient is unable to consent.

(iii) The practitioner determines that the patient has no surrogate or that waiting to obtain consent from the surrogate would increase the hazard to the life or health of the patient.

(d) *Documentation of informed consent.*

(1) The informed consent process must be appropriately documented in the health record. For treatments and procedures that are low risk and within broadly accepted standards of

medical practice, a progress note describing the clinical encounter and the treatment plan are sufficient to document that informed consent was obtained for such treatments or procedures. For tests that provide information that is extremely sensitive or that may have a high risk of significant consequences (e.g., physical, social, psychological, legal, or economic) that a patient might reasonably want to consider as part of the consent decision, the health record must specifically document that the patient or surrogate consented to the specific test.

(2) The patient's and practitioner's signature on a form prescribed by VA for that purpose is required for all diagnostic and therapeutic treatments or procedures that meet any of the following criteria:

- (i) Require the use of sedation;
- (ii) Require anesthesia or narcotic analgesia;
- (iii) Are considered to produce significant discomfort to the patient;
- (iv) Have a significant risk of complication or morbidity; or
- (v) Require injections of any substance into a joint space or body cavity.

(3) Consent for treatments and procedures that require signature consent must be documented in the health record on a form prescribed by VA for that purpose, or as otherwise specified in this paragraph (d).

(i) If the patient or surrogate is unable to execute a signature on the form due to a physical impairment, the patient or surrogate may, in lieu of a signature, sign the consent form with an "X", thumbprint, or stamp. Two adult witnesses must witness the act of signing and sign the consent form. By signing, the witnesses are attesting only to the fact that they saw the patient or surrogate sign the form. As an alternative to such a patient or surrogate using a duly witnessed "X", thumbprint, or stamp to sign the form, a designated third party may sign the form if acting at the direction of the patient or surrogate and in the presence of the patient or surrogate. The signed form must be filed in the patient's health record.

(ii) A properly executed VA-authorized consent form is valid for a period of 60 calendar days. If, however, the treatment plan involves multiple treatments or procedures, it will not be necessary to repeat the informed consent discussion and documentation so long as the course of treatment proceeds as planned, even if treatment extends beyond the 60-day period. If there is a change in the patient's condition that might alter the diagnostic or therapeutic decision about upcoming or continuing treatment, the practitioner must initiate a new informed consent process and, if needed, complete a new signature consent form with the patient.

(iii) When signature consent is required, but it is not practicable to obtain the signature in person following the informed consent discussion, a signed VA consent form transmitted by mail, facsimile, in by secure electronic mail, or other VA-approved modalities and scanned into the record, is adequate to proceed with treatment or procedure.

(iv) When signature consent is required, but it is not practicable to obtain the signed consent form, the informed consent conversation conducted by telephone or video conference must be audiotaped, videotaped, or witnessed by a second VA employee in lieu of the signed consent form. The practitioner must document the details of the conversation in the

medical record. If someone other than the patient is giving consent, the name of the person giving consent and the authority of that person to act as surrogate must be adequately identified in the medical record.

(e) *Patients who lack decision-making capacity—*

(1) *Identifying a surrogate decision maker.* If the practitioner who has primary responsibility for the patient determines that the patient lacks decision-making capacity and is unlikely to regain it within a reasonable period of time, informed consent must be obtained from the surrogate. Patients who are incapable of giving consent as a matter of law will be deemed to lack decision-making capacity for the purposes of this section.

(i) The following persons are authorized to act as a surrogate to consent on behalf of a patient who lacks decision-making capacity in the following order of priority:

(A) Health care agent;

(B) Legal guardian;

(C) Next-of-kin: a close relative of the patient eighteen years of age or older in the following priority: Spouse, child, parent, sibling, grandparent, or grandchild; or

(D) Close friend.

(ii) A surrogate generally assumes the same rights and responsibilities as the patient in the informed consent process. The surrogate's decision must be based on his or her knowledge of what the patient would have wanted; that is, substituted judgment, or, if the patient's specific values and wishes are unknown, the surrogate's decision must be based on the patient's best interest.

(2) *Consent for a patient without a surrogate.*

(i) If none of the surrogates listed in paragraph (e)(1) of this section is available, a practitioner may either request the assistance of District Chief Counsel to obtain a legal guardian for health care or follow the procedures outlined in paragraph (e)(2)(ii) of this section.

(ii) Facilities may use the following process to make treatment decisions for patients who lack decision-making capacity and have no surrogate.

(A) For treatments and procedures that involve minimal risk, the practitioner must verify that no authorized surrogate can be located, or that the surrogate is not available. The practitioner must attempt to explain the nature and purpose of the proposed treatment to the patient and enter this information in the health record.

(B) For procedures that require signature consent, the practitioner must certify that the patient has no surrogate to the best of their knowledge. The attending physician and the Chief of Service (or designee) must indicate their approval of the treatment decision in writing. Any decision to withhold or withdraw life-sustaining treatment for such patients must be reviewed by a multi-disciplinary committee appointed by the facility Director, unless the patient has valid standing orders regarding life-sustaining treatment, such as state-

authorized portable orders. The committee functions as the patient's advocate and may not include members of the treatment team. The committee must submit its findings and recommendations in a written report to the Chief of Staff who must note his or her approval of the report in writing. The facility Director must be informed about the case and results of the review and may concur with the decision to withhold or withdraw life-sustaining treatment, delegate final decision-making authority to the facility Chief of Staff, or request further review by District Chief Counsel.

(f) *Special consent situations.*

(1) In the case of involuntarily committed patients where the forced administration of psychotropic medication is against the will of a patient (or the surrogate does not consent), the following procedural protections must be provided:

(i) The patient or surrogate must be allowed to consult with independent specialists, legal counsel or other interested parties concerning the treatment with psychotropic medication. Any recommendation to administer or continue medication must be reviewed by a multi-disciplinary committee appointed by the facility Director for this purpose.

(ii) The multi-disciplinary committee must include a psychiatrist or a physician who has psychopharmacology privileges. The facility Director must concur with the committee's recommendation to administer psychotropic medications contrary to the patient's or surrogate's wishes.

(iii) Continued administration of psychotropic medication must be reviewed every 30 days. The patient (or a representative on the patient's behalf) may appeal the treatment decision to a court of appropriate jurisdiction.

(2) The patient must be informed if a proposed course of treatment or procedure involves approved medical research in whole or in part. If so, the patient's separate informed consent must be obtained for the components that constitute research pursuant to the informed consent requirements for human-subjects research set forth in part 16 of this title.

(g) *Advance directives—*

(1) *General.* To the extent consistent with applicable Federal law, VA policy, and generally accepted standards of medical practice, VA will follow the wishes of a patient expressed in a valid advance directive when the practitioner determines and documents in the patient's health record that the patient lacks decision-making capacity and is unlikely to regain it within a reasonable period of time. An advance directive that is valid in one or more states under applicable law, including a mental health (or psychiatric) advance directive, a valid Department of Defense advance medical directive, or a valid VA Advance Directive will be recognized throughout the VA health care system, except for components therein that are inconsistent with applicable Federal law, VA policy, or generally accepted standards of medical practice.

(2) *Signing and witness requirements.*

(i) A VA Advance Directive must be signed by the patient. If the patient is unable to sign a VA Advance Directive due to a physical impairment, the patient may sign the advance directive form with an "X", thumbprint, or stamp. In the alternative, the patient may

designate a third party to sign the directive at the direction of the patient and in the presence of the patient.

(ii) In all cases, a VA Advance Directive must be signed by the patient in the presence of both witnesses. Witnesses to the patient's signing of an advance directive are attesting by their signatures only to the fact that they saw the patient or designated third party sign the VA Advance Directive form. Neither witness may, to the witness' knowledge, be named as a beneficiary in the patient's estate, appointed as health care agent in the advance directive, or financially responsible for the patient's care. Nor may a witness be the designated third party who has signed the VA Advance Directive form at the direction of the patient and in the patient's presence.

(3) *Instructions in critical situations.* In certain situations, a patient with decision-making capacity may present for care when critically ill and loss of decision-making capacity is imminent. In such situations, VA will document the patient's unambiguous verbal or non-verbal instructions regarding preferences for future health care decisions. These instructions will be honored and given effect should the patient lose decision-making capacity before being able to complete a new advance directive. The patient's instructions must have been expressed to at least two members of the health care team. To confirm that the verbal or non-verbal instructions of the patient are, in fact, unambiguous, the substance of the patient's instructions and the names of at least two members of the health care team to whom they were expressed must be entered in the patient's electronic health record.

(4) *Revocation.* A patient who has decision-making capacity may revoke an advance directive or instructions in a critical situation at any time by using any means expressing the intent to revoke.

(5) *VA policy and disputes.* Neither the treatment team nor surrogate may override a patient's clear instructions in an advance directive or in instructions given in a critical situation, except that those portions of an advance directive or instructions given in a critical situation that are not consistent with applicable Federal law, VA policy, or generally accepted standards of medical practice will not be given effect. (The information collection requirements in this section have been approved by the Office of Management and Budget under control number 2900-0556)

[49 FR 9173, Mar. 12, 1984. Redesignated and amended at 61 FR 21965, 21966, May 13, 1996; 62 FR 53961, Oct. 17, 1997; 70 FR 71774, Nov. 30, 2005; 71 FR 68740, Nov. 28, 2006; 72 FR 10366, Mar. 8, 2007; 74 FR 34503, July 16, 2009; 85 FR 31701, May 27, 2020]

**Supplement *Highlights* references:** 30(1), 34(2), 36(1), 49(1), 129(1).

Reserved

(e) *Failure to establish eligibility.* If documents submitted by a covered veteran in support of an application for reimbursement do not establish eligibility for reimbursement or justify claimed expenses, VA will retain the application and advise the covered veteran of additional documentation needed. All requested documentation must be submitted to VA within 90 calendar days of VA request.

(f) *Authority.* Authority to provide reimbursement for qualifying adoption expenses incurred by a covered veteran in the adoption of a child under 18 years of age expires September 30, 2018.

(The Office of Management and Budget has approved the information collection requirement in this section under control number 2900-0860)

[83 FR 9212, March 5, 2018; as amended at 85 FR 31983, May 28, 2020]

**Supplement *Highlights* references:** 114(1),129(2).

**§ 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 August 1, 1953, 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.

*Covered illness or condition* means any of 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.