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## Title 38, Parts 17, 46, 47, 51–53, 58–61, and 70

## *Medical*

# Veterans Benefits Administration

Supplement No. 49

Covering period of *Federal Register* issues through July 28,2009

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# Supplemental Materials for *Book* I

**Code of Federal Regulations**
**Title 38, Parts 17, 46, 47, 51–53, 58–61, and 70**

***Medical***

# Veterans Benefits Administration

**Supplement No. 49**

*5* August 2009

Covering the period of Federal Register issues
through July 28,2009

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**To ensure accuracy and timeliness of your materials, it is important that you follow these simple procedures:**

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# FILING INSTRUCTIONS

**Book I, Supplement No. 49**
**August 5,2009**

| *Remove these old pages* | *Add these new pages* | *Section(s) Affected* |
|---|---|---|
| **Do not file this supplement until you confirm that all prior supplements have been filed** | | |
| 17.32-1 to 17.32-6 | 17.32-1 to 17.32-6 | §17.32 |

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# HIGHLIGHTS

**Book I, Supplement No. 49**
**August 5,2009**

***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 Hook 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 16 July 2009. the VA published a final rule, effective 17 August 2009, to update informed consent requirements related to testing for the Human Immunodeficiency Virus for Veterans receiving health care from the VA by eliminating the regulatory requirement for written informed consent for HIV testing and specific pre- and post-test counseling of Veteran patients. Changes:

- In §17.32, revised paragraph (d)(1), and removed paragraph (g)(4).

**Protection of Patient Rights**

## §17.32 Informed consent and advance care planning.

(a) *Definitions:*

*Advance Directive.* Specific written statements made by a patient who has decision-making capacity regarding future health care decisions in any of the following:

(i) *VA Living Will.* A written statement made by a patient on an authorized VA form which sets forth the patient's wishes regarding the patient's health care treatment preferences including the withholding and withdrawal of life-sustaining treatment.

(ii) *VA Durable Power of Attorney for Health Care.* A written instruction on a VA form which designates the patient's choice of health care agent.

(iii) *State-Authorized Advance Directive. A* non-VA living will, durable power of attorney for health care, or other advance health care planning document, the validity of which is determined pursuant to applicable State law. For the purposes of this paragraph and paragraph (h) 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 expressed wishes in the advance directive.

*Close Friend.* Any person eighteen years or older who has shown care and concern for the patient's welfare, 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.

*Health care Agent.* An individual named by the patient in a Durable Power of Attorney for Health Care.

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

*Practitioner.* Any physician, dentist, or health care professional who has been granted specific clinical privileges to perform the treatment or procedure. For the purpose of obtaining informed consent for medical treatment, the term practitioner includes medical and dental residents and other appropriately trained health care professionals designated by VA regardless of whether they have been granted clinical privileges.

*Signature consent.* The patient's or surrogate's signature on a VA-authorized consent form.

*Special Guardian. A* person appointed by a court of appropriate jurisdiction for the specific purpose of malting health care decisions.

*Surrogate.* An individual, organization or other body authorized under this section to give informed consent on behalf of a patient who lacks decision-making capacity.

(b) *Policy.* Except as otherwise provided in this section, all patient care furnished under title 38 U.S.C. shall be carried out only with the full and informed consent of the patient or, in appropriate cases, a representative thereof. In order to give informed consent, the patient must have decision-making capacity and be able to communicate decisions concerning health care. If the patient lacks decision-making capacity or has been declared incompetent, consent must be obtained from the patient's surrogate. Practitioners may provide necessary medical care in emergency situations without the patient's or surrogate's express consent when immediate medical case is necessary to preserve life or prevent serious impairment of the health of the patient or others and the patient is unable to consent and the practitioner determines that the patient has no surrogate or that waiting to obtain consent from the patient's surrogate would increase the hazard to the life or health of the patient or others. In such circuinstances consent is implied.

(c) *General requirements for informed consent.* Informed consent is the freely given consent that follows a careful explanation by the practitioner to the patient or the patient's surrogate of the proposed diagnostic or therapeutic procedure or course of treatment. The practitioner, who has primary responsibility for the patient or who will perform the particular procedure or provide the treatment, must explain in language understandable to the patient or surrogate the nature of a proposed procedure or treatment; the expected benefits; reasonably foreseeable associated risks, complications or side effects; reasonable and available alternatives; and anticipated results if nothing is done. The patient or surrogate must be given the opportunity to ask questions, to indicate comprehension of the information provided, and to grant permission freely without coercion. The practitioner must advise the patient or surrogate if the proposed treatment is novel or unorthodox. The patient or surrogate may withhold or revoke his or her consent at any time.

(d) *Documentation of informed consent.*

(1) The informed consent process must be appropriately documented in the health record. In addition, signature consent is required for all diagnostic and therapeutic treatments or procedures that:

(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.

(2) A patient or surrogate will sign with an "X" when the patient or surrogate has a debilitating illness or disability, i.e., significant physical impairment and/or difficulty in executing a signature due to an underlying health condition(s), or is unable to read and write. When the patient's or surrogate's signature is indicated by an "X," two adults must witness the act of signing. By signing, the witnesses are attesting only to the fact that they saw the patient or surrogate and the practitioner sign the form. The signed form must be filed in the patient's health record. 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, the consent is automatically rescinded.

(3) If it is impractical to consult with the surrogate in person, informed consent may be obtained by mail, facsimile, or telephone. A facsimile copy of a signed consent form is adequate to proceed with treatment. However, the surrogate must agree to submit a signed consent form to the practitioner. If consent is obtained by telephone, the conversation must be audiotaped or witnessed by a second VA employee. The name of the person giving consent and his or her authority to act as surrogate must be adequately identified for the record.

(e) *Surrogate consent.* 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 patient's surrogate. Patients who are incapable of giving consent as a matter of law, i.e., persons judicially determined to be incompetent and minors not otherwise able to provide informed consent, will be deemed to lack decision-making capacity for the purposes of this section. If the patient is considered a minor in the state where the VA facility is located and cannot consent to medical treatment, consent must be obtained from the patient's parent or legal guardian. The 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, i.e., substituted judgment. If the patient's wishes are unknown, the decision must be based on the patient's best interest. The following persons are authorized to consent on behalf of patients who lack decision-making capacity in the following order of priority:

(1) Health care agent;

(2) Legal guardian or special guardian;

(3) 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

(4) Close friend.

(f) *Consent for patients without surrogates.*

(1) If none of the surrogates listed in paragraph (e) of this section are available, the practitioner may request Regional Counsel assistance to obtain a special guardian for health care or follow the procedures outlined in this paragraph (f).

(2) Facilities may use the following process to make treatment decisions for patients who lack decision-making capacity and have no surrogate. For treatments or procedures that involve minimal risk, the practitioner must verify that no authorized surrogate can be located. 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. For procedures that require signature consent, the practitioner must certify that the patient has no surrogate. The attending physician and the Chief of Service (or his or her 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. The committee functions as the patient's advocate and may not include members of the treatment team. The coininittee 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.

After reviewing the record, the facility Director may concur with the decision to withhold or withdraw life support or request further review by Regional Counsel.

(g) *Special consent situations.* In addition to the other requirements of this section, additional protections are required in the following situations.

(1) No patient will undergo any unusual or extremely hazardous treatment or procedure, e.g., that which might result in irreversible brain damage or sterilization, except as provided in this paragraph (g). Before treatment is initiated, the patient or surrogate must be given adequate opportunity to consult with independent specialists, legal counsel or other interested parties of his or her choosing. The patient's or surrogate's signature on a VA authorized consent form must be witnessed by someone who is not affiliated with the VA health care facility, e.g., spouse, legal guardian, or patient advocate. If a surrogate makes the treatment decision, a multi-disciplinary committee, appointed by the facility Director, must review that decision to ensure it is consistent with the patient's wishes or in his or her best interest. 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 facility Director. The Director may authorize treatment consistent with the surrogate's decision or request that a special guardian for health care be appointed to make the treatment decision.

(2) Administration of psychotropic medication to an involuntarily committed patient against his or her will must meet the following requirements. 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 against the patient's or surrogate's will must be reviewed by a multi-disciplinary committee appointed by the facility Director for this purpose. This 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. Continued therapy with 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.

(3) If a proposed course of treatment or procedure involves approved medical research in whole or in part, the patient or representative shall be advised of this. Informed consent shall be obtained specifically for the administration or performance of that aspect of the treatment or procedure that involves research. Such consent shall be in addition to that obtained for the administration or performance of the nonresearch aspect of the treatment or procedure and must meet the requirements for informed consent set forth in 38 CFR Part 16, Protection of I-Iuman Subjects.

(h) *Advance health care planning.* Subject to the provisions of paragraphs (h)(1) through (h)(4) of this section, VA will follow the wishes of a patient expressed in an Advance Directive when the attending physician determines and documents in the patient's health record that the patient lacks decision-making capacity and is not expected to regain it. An advance directive that is valid in one or more States under applicable State law, as defined in paragraph (a) of this section, will be recognized throughout the VA health care system.

*(1) Witnesses. A* VA Advance Directive: Living Will and Durable Power of Attorney for Health Care must be signed by the patient in the presence of two witnesses. Neither witness may to the witness' knowledge be named in the patient's will, appointed as health care

agent in the advance directive, or financially responsible for the patient's care. VA employees of the Chaplain Service, Psychology Service, Social Work Service, or nonclinical employees (e.g., Medical Administration Service, Voluntary Service, or Environmental Management Service) may serve as witnesses. Other individuals employed by the VA facility in which the patient is being treated may not sign as witnesses to the advance directive. Witnesses are attesting only to the fact that they saw the patient sign the form.

(2) *Instructions in critical situations.* VA will follow the unambiguous verbal or non-verbal instructions regarding future health care decisions of a patient who has decision-making capacity when the patient is admitted to care when critically ill and loss of capacity may be imminent and the patient is not physically able to sign a11 advance directive form, or the appropriate form is not readily available. The patient's instructions must have been expressed to at least two members of the health care team. The substance of the patient's instructions must be recorded in a progress note in the patient's health record and must be co-signed by at least two members of the health care team who were present and can attest to the wishes expressed by the patient. These instructions will be given effect only if the patient loses decision-making capacity during the presenting situation.

(3) *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.

(4) *VA policy and disputes.* Neither the treatment team nor surrogate may override a patient's clear instructions in an Advance Directive or in instructions in critical situations, except that those portions of an Advance Directive or instructions given in a critical situation that are not consistent with VA policy 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 2900-0583)

(Authority: 38 U.S.C. 7331-7334)

[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 16,20091

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

Reserved