

INFORMED CONSENT FOR CLINICAL TREATMENTS AND PROCEDURES

1. SUMMARY OF MAJOR CHANGES:

Amendment dated May 1, 2024: clarifies that VA practitioners must explain additional examination(s) that will be performed by a student(s) during the informed consent discussion and emphasize that patients have the right to accept a proposed treatment or procedure and still decline the additional examination(s) (see paragraph 4.b.(10)).

Amendment dated February 22, 2024:

a. Updates the policy statement to clarify that State law governs whether minors are authorized to provide consent to treatments and procedures. See paragraph 1.

b. Clarifies documentation requirements when it is known prior to initiating a procedure that a different VA practitioner will perform the procedure. See paragraph 4.b.(9).

c. Updates the policy owner from 10ETH to 12ETH. **NOTE:** *The policy is now realigned under the Assistant Under Secretary for Patient Care Services.*

d. Updates responsibilities to reflect this directive's realignment under the Assistant Under Secretary for Patient Care Services. See paragraph 2. **NOTE:** *Responsibilities for the Associate Deputy Under Secretary for Health for Oversight, Risk and Ethics have been relocated under the Assistant Under Secretary for Patient Care Services.*

Amendment dated January 12, 2024 removed language referring to pre-procedure preparations to eliminate barriers to accessing procedures that require pre-procedural preparations (language has been removed from paragraphs 4.b and 4.d.(1)(b)).

As published December 12, 2023, this directive:

a. Prohibited the use of patient contracts in addition to or in lieu of informed consent for treatments and procedures. See paragraph 2.i.

b. Combined Veterans Health Administration (VHA) policies on informed consent for treatments and procedures and the Electronic Signature Informed Consent (eSIC) software used to document those processes. See paragraph 4.

c. Incorporated VHA policy on informed consent for long-term opioid therapy (LTOT) for pain (previously located in VHA Directive 1005, Informed Consent for Long-Term Opioid Therapy for Pain, dated May 13, 2020), with VHA policy on informed consent for

all other treatments and procedures to ensure that consent for LTOT meets the ethical standards of informed consent outlined in this directive. See paragraph 4.

d. Incorporated VHA policy on honoring valid advance directives in accordance with VHA Directive 1004.03, Advance Care Planning, dated December 12, 2023, and establishes a process for identifying the authorized surrogate when there are multiple individuals at the same surrogate priority level. See paragraph 4.c.

e. Clarified processes that promote voluntary decision-making by ensuring that the informed consent process occurs prior to a patient being sedated in preparation for a procedure and when patients have access to resources and tools necessary to engage in communication. See paragraph 4.

f. Emphasized the importance of the discussion in the informed consent process by clarifying the required components of the discussion, regardless of the required documentation. See paragraph 4.b.

g. Established a process for addressing concerns about a surrogate acting contrary to a patient's values and wishes or a patient's best interests. See paragraph 4.c.(8)(f).

h. Updated the informed consent process for patients who lack decision-making capacity and do not have a surrogate by ensuring due diligence in identifying patients' values and preferences and making decisions that respect patients as individuals. See paragraph 4.c.(9).

i. Simplified the categories of informed consent documentation, treatments and procedures that require signature consent, and treatments and procedures that do not require signature consent; clarifies that signature consent may be required each time consent is obtained for a particular treatment or procedure or on a case-by-case basis. See paragraph 4.d.(1).

j. Stated informed consent requirements for treatments and procedures authorized for use under U.S. Food & Drug Administration's Emergency Use Authorization. See paragraph 5.d.

k. Removed the paragraph on consent for treatments and procedures delivered using telehealth as informed consent requirements are the same regardless of whether the treatment or procedure is delivered in-person or using telehealth.

l. Clarified requirements related to the forced administration of psychotropic medications, including updating the name of the associated multidisciplinary committee to the Forced Psychotropic Medication Review Committee. See paragraphs 2.n. and 5.b.

m. Removed the paragraph on consent for collection and release of evidentiary information and material(s) as this directive relates only to consent for clinical treatments and procedure.

n. Reflected revisions to 38 C.F.R. § 17.32 which aligns with VHA's team-based approach to health care and increased use of telehealth services.

2. RELATED ISSUES: VHA Directive 1004.03, Advance Care Planning, dated December 12, 2023.

3. POLICY OWNER: The National Center for Ethics in Health Care (NCEHC) (12ETH) is responsible for the content of this directive. Questions may be referred to NCEHC at vhaethics@va.gov.

4. RECISSIONS: VHA Directive 1005, Informed Consent for Long-Term Opioid Therapy for Pain, dated May 13, 2020; VHA Handbook 1004.01(5), Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009; and VHA Handbook 1004.05, iMedConsent™, dated December 10, 2014, are rescinded.

5. RECERTIFICATION: This VHA directive is scheduled for recertification on or before the last working day of December 2028. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

6. IMPLEMENTATION SCHEDULE: This directive is effective upon publication.

**BY DIRECTION OF THE OFFICE OF THE
UNDER SECRETARY OF HEALTH:**

/s/ Alan Hirshberg, MD, MPH, FACEP
Acting Associate Deputy Under Secretary
for Health for Oversight, Risk and Ethics

NOTE: All references herein to Department of Veterans Affairs (VA) and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

DISTRIBUTION: Emailed to the VHA Publications Distribution List on December 15, 2023.

CONTENTS

INFORMED CONSENT FOR CLINICAL TREATMENTS AND PROCEDURES

1. POLICY 1

2. RESPONSIBILITIES 1

3. DETERMINATION OF DECISION-MAKING CAPACITY 6

4. INFORMED CONSENT PROCESS 6

5. CONSENT IN SPECIAL SITUATIONS..... 17

6. INFORMED CONSENT FOR RESEARCH 19

7. TRAINING 19

8. RECORDS MANAGEMENT..... 20

9. BACKGROUND..... 20

10. DEFINITIONS..... 20

11. REFERENCES..... 22

INFORMED CONSENT FOR CLINICAL TREATMENTS AND PROCEDURES

1. POLICY

It is Veterans Health Administration (VHA) policy that patients have the right to accept or refuse medical treatments or procedures recommended to them. Prior to initiating a treatment or procedure, Department of Veterans Affairs (VA) practitioners must engage patients, or if the patient lacks decision-making capacity, the patient's authorized surrogate, in an informed consent process to ensure that the patient (or surrogate) understands the risks, benefits and alternatives, and voluntarily consents to the treatment or procedure. The use or enforcement of a patient contract, in addition to or in lieu of informed consent for a treatment or procedure, is prohibited. **AUTHORITY:** 38 U.S.C. §§ 7301(b), 7331; 38 C.F.R. § 17.32. **NOTE:** *Patients who are considered minors under the State law in the jurisdiction where the VA medical facility is located are not authorized to provide consent for treatments and procedures except as otherwise provided by that State law.*

2. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Product Manager, VHA Front Office, VA Office of Information Technology.** The Product Manager, VHA Front Office, VA Office of Information Technology (OIT) has agreed to be responsible for:

(1) Managing the Electronic Signature Informed Consent (eSIC) software vendor contract (or subsequent VA-developed solution).

(2) Facilitating the development of functional requirements to meet established business requirements related to eSIC software functionalities and enhancements, including directing and monitoring the eSIC vendor (or subsequent VA-developed solution developer).

(3) Conducting security impact analyses of proposed eSIC solution changes or enhancements as needed.

(4) Monitoring and coordinating the routing and resolution of OIT work orders (e.g., Service Now (SNOW) tickets) related to the eSIC software.

(5) Ensuring security of all electronic protected health information in the eSIC software in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule and VHA Directive 1907.08, Health Care Information Security Policy and Requirements, dated April 30, 2019.

c. **Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer.** The Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer (CNO) is responsible for:

(1) Supporting the National Center for Ethics in Health Care (NCEHC) with implementation and oversight of this directive.

(2) Collaborating and coordinating with the Assistant Under Secretary for Health for Clinical Services for updates to existing and new consent forms.

d. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

e. **Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer.** The Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer is responsible for coordinating content updates for existing and new consent forms maintained in the eSIC software in collaboration with the Assistant Under Secretary for Patient Care services.

f. **Executive Director, National Center for Ethics in Health Care.** The Executive Director, NCEHC is responsible for:

(1) Providing oversight for VISN and VA medical facility compliance with this directive by identifying and tracking performance measures to monitor implementation.

NOTE: Information on performance measures is available at https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Policy_Performance_Measures.aspx. This is an internal VA website that is not available to the public.

(2) Providing health care ethics consultation services, education and interpretation to VA medical facilities regarding the policy and procedures outlined in this directive.

(3) Meeting with the Assistant Under Secretary for Patient Care Services/CNO as needed to ensure there are sufficient resources to support VA medical facilities in implementing the requirements of the directive.

(4) Establishing ethical standards for the eSIC software program.

(5) Establishing a standardized process for reviewing and submitting requests to modify the list of treatments and procedures that require signature consent.

(6) Establishing a standardized process for reviewing and submitting requests to update the content of a consent form in the eSIC software.

g. **Veterans Integrated Services Network Director.** The VISN Director is responsible for:

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

(2) Communicating the contents of this directive to all VA medical facilities within the VISN.

(3) Ensuring that all VA medical facilities within the VISN have the resources to implement this directive.

h. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring overall VA medical facility compliance with this directive and appropriate corrective action is taken if non-compliance is identified.

(2) Providing information and data to NCEHC as requested regarding policy performance measures available at https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Policy_Performance_Measures.aspx. **NOTE:** *This is an internal VA website that is not available to the public.*

(3) Ensuring that patient contracts are not used at the VA medical facility in addition to or in lieu of informed consent for treatments and procedures. **NOTE:** *Performance measures to monitor implementation of this requirement are available at https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Policy_Performance_Measures.aspx. This is an internal VA website that is not available to the public.*

(4) Designating a VA medical facility staff member(s) to develop a standardized process to identify surrogates for patients who lack decision-making capacity.

(5) Designating a VA medical facility staff member(s) to develop a standardized process to identify the values, goals and preferences for care for patients who lack decision-making capacity and do not have a surrogate.

(6) Appointing a VA medical facility Forced Psychotropic Medication Review (FPMR) Committee and Chair to review the VA practitioner's recommendations of administering or continuing psychotropic medications against the will of a patient who is involuntarily committed (or when the surrogate does not consent).

(7) Reviewing the FPMR Committee's recommendation and approving the administration or continuation of psychotropic medications against the will of a patient who is involuntarily committed (or when the surrogate does not consent). **NOTE:** *For more information, see paragraph 5.b.*

(8) Ensuring that the VA medical facility has an established process for requesting support from the VA medical facility Health Care Ethics Consultants (ECs) and ensuring

that the VA medical facility Health Care ECs have the time and resources needed to address ethics consultations regarding informed consent.

(9) Ensuring that VA health care teams and VA practitioners follow eSIC software guidance to appropriately use the eSIC software. **NOTE:** *Guidance is available at <https://dvagov.sharepoint.com/sites/VHAethics/SitePages/iMedConsent.aspx>. This is an internal VA website that is not available to the public.*

i. **VA Medical Facility Chief of Staff.** The VA medical facility Chief of Staff (CoS) is responsible for:

(1) Collaborating with the VA medical facility Associate Director for Patient Care Services (ADPCS) to ensure that all relevant personnel under the VA medical facility CoS are supported to implement and follow this directive.

(2) Reviewing surrogate decisions that the VA practitioner believes are contrary to the patient's values, wishes or best interests and making a decision about whether to provide the treatment or procedure as outlined in paragraph 4.c.(8).

j. **VA Medical Facility Associate Director for Patient Care Services.** The VA medical facility ADPCS is responsible for collaborating with the VA medical facility CoS to ensure that all relevant personnel under the VA medical facility ADPCS are supported to implement and follow this directive.

k. **VA Medical Facility Service Chief.** The VA medical facility Service Chief for each service line is responsible for:

(1) Ensuring that non-practitioner VA health care team members are supported to implement and follow this directive and informed consent processes.

(2) Reviewing treatment decisions for patients who lack decision-making capacity and do not have a surrogate as outlined in paragraph 4.c.(9)(f). **NOTE:** *The VA medical facility Service Chief may designate this responsibility to an alternate staff member.*

(3) Reviewing to determine appropriate instances of using the emergency exception of obtaining signature consent, and subsequently documenting their review in the patient's electronic health record (EHR). **NOTE:** *See paragraph 5.a.(5) for additional information.*

l. **VA Medical Facility Chief, Health Information Management.** The VA medical facility Chief, Health Information Management is responsible for establishing a process to ensure that the note titles of revoked consent forms are updated in the EHR to reflect the revoked status as outlined at (see FAQs): <https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Policy.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

m. **Chair, VA Medical Facility Forced Psychotropic Medication Review Committee.** The Chair, VA medical facility FPMR Committee is responsible for:

(1) Reviewing recommendations from VA practitioners for administering or continuing psychotropic medications against the will of a patient who is involuntarily committed (or the surrogate does not consent as outlined in paragraph 5.b.) and functioning as the patient's advocate by determining that the least restrictive alternatives have been exhausted and that the proposed recommendation to administer or continue psychotropic medication is in the patient's best interests. **NOTE:** *The VA medical facility FPMR Committee must be multi-disciplinary and include a psychiatrist or a physician who has psychopharmacology privileges.*

(2) Developing a charter to outline the purpose, scope and responsibilities of the FPMR Committee. A FPMR Committee charter template is available at https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Informed_Consent.aspx. **NOTE:** *This is an internal VA website not available to the public.*

n. **VA Medical Facility Health Care Ethics Consultants.** VA medical facility Health Care ECs are responsible for providing health care ethics consultation services regarding informed consent for treatments and procedures. **NOTE:** *More information on health care ethics consultation services is available at <https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Guidebook.aspx>. This is an internal VA website that is not available to the public.*

o. **VA Practitioners.** **NOTE:** *Health professions trainees (HPT) who meet the definition of practitioner outlined in this directive must perform the responsibilities outlined in this paragraph under the supervision of their supervising practitioner. The supervising practitioner is ultimately responsible for the patient's care. For additional information, see VHA Directive 1400.01, Supervision of Physician, Dental, Optometry, Chiropractic, and Podiatry Residents, dated November 7, 2019; and VHA Handbook 1400.04, Supervision of Associated Health Trainees, dated March 19, 2015. VA practitioners are responsible for:*

(1) Performing and documenting clinical assessments of decision-making capacity as outlined in paragraph 3.

(2) Engaging patients (or surrogates, if applicable) in informed consent processes as outlined in this directive, including conducting informed consent discussions.

(3) Notifying the VA medical facility CoS and consulting with the VA medical facility Health Care ECs if the treatment or procedure chosen by the patient (or surrogate) poses potential hazards to others. **NOTE:** *For more information, see paragraph 4.b.(12).*

(4) Documenting consent as outlined in paragraph 4.

(5) Delegating elements of the informed consent process to VA health care team members as outlined in paragraph 4.

(6) Promoting the patient's (or surrogate's) voluntary decision-making during the informed consent process as outlined in paragraph 4.a.

(7) Consulting with the VA medical facility Health Care ECs as needed and as outlined in paragraph 4.

p. **VA Health Care Team Members.** VA health care team members (i.e., non-practitioner clinicians) are responsible for conducting elements of the informed consent process as appropriate to the competency of the VA health care team member and when delegated by the VA practitioner. **NOTE:** *Delegation of responsibilities to VA health care team members is dependent on the treatment or procedure, VA health care team member and VA practitioner. The VA practitioner is ultimately responsible for the informed consent process and must personally verify with the patient that the patient has been fully informed and voluntarily consents to the treatment or procedure.*

3. DETERMINATION OF DECISION-MAKING CAPACITY

a. Prior to initiating the informed consent discussion, the VA practitioner must determine whether the patient has capacity to make a decision about the specific treatment or procedure. **NOTE:** *A patient may lack capacity to make a decision about a specific treatment or procedure at a certain point in time but have capacity to make a decision about that specific treatment or procedure at a different point in time. In addition, a patient may lack capacity to make a decision about a specific treatment or procedure but have capacity to make a decision about a different treatment or procedure.*

b. Patients are presumed to have decision-making capacity unless:

(1) A VA practitioner's clinical assessment determines that the patient lacks capacity to make a decision about the specific treatment or procedure for which consent is being sought.

(2) The patient has been ruled incompetent by a court of law.

c. The VA practitioner must document the assessment in the patient's EHR.

d. In a medical emergency, the VA practitioner and VA health care team must follow the process outlined in paragraph 5.a. of this directive. Otherwise, if the VA practitioner determines that the patient is likely to regain capacity to make a decision about a specific treatment or procedure, the VA practitioner must wait until the patient's decision-making capacity returns and then undertake the informed consent process with the patient, provided that delaying the recommended treatment or procedure would not adversely affect the patient's condition. If the VA practitioner determines that the patient is unlikely to regain decision-making capacity within a reasonable period of time, an authorized surrogate must be sought per paragraph 4.c.

4. INFORMED CONSENT PROCESS

VHA does not recognize general or blanket consent for medical treatments and procedures (e.g., consent for all treatments and procedures during an inpatient admission) but requires that VA practitioners obtain a patient's consent prior to initiating

each diagnostic or therapeutic procedure or course of treatment. The VA practitioner is responsible for conducting the informed consent discussion and documenting consent. VA health care team members may assist with elements of the informed consent process (e.g., patient education, identifying the authorized surrogate for patients who lack decision-making capacity, assisting with obtaining the patient's (or surrogate's) signature for treatments and procedures that require signature consent) as appropriate to the competency of the VA health care team member and when delegated by the VA practitioner. The VA practitioner must still personally verify with the patient (or surrogate) that the patient (or surrogate) has been appropriately informed and voluntarily consents to the treatment or procedure. **NOTE:** See *VHA Directive 1004.03, Advance Care Planning, dated December 12, 2023, for additional information on informed consent for Life-Sustaining Treatment (LST) plans.*

a. **Promoting Voluntary Decision-Making.** The VA practitioner and VA health care team must promote the patient's (or surrogate's) voluntary decision-making during the informed consent process. The VA practitioner and VA health care team:

(1) Must convey that the patient (or surrogate) is free to make choices about the patient's health care, including the choice not to receive a treatment or procedure or to revoke a prior consent and those choices will not affect the patient's access to future health care or other benefits.

(2) Must not unduly pressure or coerce the patient (or surrogate) into consenting to a particular treatment or procedure, including by denying, or threatening to deny, the patient access to another procedure or treatment. **NOTE:** *When a particular treatment or procedure cannot be safely provided or performed without another treatment or procedure also being provided or performed, access to the particular treatment or procedure may be made contingent on the patient's consent to the other treatment or procedure.*

(3) Must ensure that the informed consent process, including decision-making capacity assessments, occurs when the patient (or surrogate) has the resources and tools necessary to engage in communication (e.g., personal assistance devices such as hearing aids or glasses and language interpreters or assistance).

(4) Must ensure that the informed consent process occurs prior to the patient being sedated in preparation for a procedure.

(5) When the patient (or surrogate) requests an alternate VA practitioner or VA health care team member, the VA practitioner or VA health care team member must convey that VA will honor a patient's (or surrogate's) request to the extent that the request supports a culture that values diversity and respect for patients, surrogates and VA employees.

b. **Informed Consent Discussion.** Prior to initiating a treatment or procedure, the VA practitioner must engage the patient (or surrogate) in a discussion about the treatment or procedure. The informed consent discussion should be conducted in

person whenever practical. If it is impractical to conduct the discussion in person, or the patient (or surrogate) 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. As part of the informed consent discussion, the VA practitioner must disclose and discuss appropriate 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 their consent decision. The specific information and level of detail required will vary depending on the nature of the treatment or procedure. In addition, the VA practitioner must explain in understandable language to the patient (or surrogate) each of the following, as appropriate to the proposed treatment or procedure: **NOTE:** *The proposed treatment or procedure must be consistent with prevailing medical standards, Federal law, VA policy and VA guidelines, and be expected to produce the intended physiologic effect.*

- (1) The patient's condition(s) or diagnosis(es) as they relate to the proposed treatment or procedure.
- (2) The nature of the proposed treatment or procedure, and the indications for that course of action, including alignment with the patient's goals of care.
- (3) The expected benefits, reasonably foreseeable associated risks, complications or side effects associated with the proposed treatment or procedure, including problems that might occur during recuperation.
- (4) If the proposed course of treatment involves multiple or recurrent treatments or procedures.
- (5) The patient's responsibilities when undertaking the treatment or procedure (e.g., taking medications at home, changing own bandages), when relevant.
- (6) If applicable, preconception and pregnancy counseling.
- (7) Reasonable and available alternatives, and why a particular proposed treatment is thought to be more beneficial to the patient than the alternatives.
- (8) The option of no treatment or procedure and the anticipated results if the patient does not receive the treatment or procedure.
- (9) The name and profession of the VA practitioner who has primary responsibility for the relevant aspect of the patient's care and the name and profession of any other individuals who will be performing any part of the treatment or procedure under consideration. **NOTE:** *If it is known prior to initiating a treatment or procedure that another VA practitioner will need to be substituted for any of those named, the patient (or surrogate) must be informed of the change and this discussion and the patient's (or*

surrogate's) assent must be documented in the patient's EHR, either in a progress note (or equivalent) or new consent form.

(10) Any additional examination(s) performed by a student(s) during the proposed treatment or procedure for educational purposes. **NOTE:** *The patient has the right to decline the additional examination(s). When the proposed treatment or procedure requires signature consent (e.g., hysterectomy) and the additional examination is sensitive (e.g., pelvic, prostate, breast, rectal examination), the VA practitioner must document the name(s) and role(s) of the student(s) performing the additional examination(s) in the consent form for the procedure. When the proposed procedure does not require signature consent (e.g., routine pelvic exam) and the additional exam is sensitive, the VA practitioner must document the patient's agreement for the additional examination in the patient's EHR.*

(11) If the proposed treatment or procedure is novel or unorthodox.

(12) If the proposed treatment is long-term opioid therapy (LTOT) for pain, the VA practitioner must review and discuss the contents of the patient information guide with the patient (or surrogate) and ensure that the patient (or surrogate) is offered a copy of it. **NOTE:** *The Patient Information Guide for Safe and Responsible Use of Opioids for Chronic Pain is available at: https://www.ethics.va.gov/for_veterans.asp.*

(13) The VA practitioner must give the patient (or surrogate) the opportunity to ask questions and ensure that the patient (or surrogate) indicates comprehension of the information provided. **NOTE:** *If the patient's (or surrogate's) choice of treatment or procedure poses a potential hazard to others (e.g., declining treatment for active tuberculosis disease), the VA practitioner must notify the patient (or surrogate) about potential consequences (e.g., requirement to report to local public health authorities) and notify the VA medical facility CoS for awareness.*

c. Patients Who Lack Decision-Making Capacity.

(1) If the VA practitioner determines that the patient lacks decision-making capacity and is unlikely to regain it within a reasonable period of time, the VA practitioner, with the assistance of the VA health care team, must immediately attempt to identify and contact the surrogate, in accordance with the VA medical facility's established process for identifying surrogates. The process must include examining personal effects, health records and other VA records such as benefits and pension records. The VA practitioner must initiate the informed consent process with the surrogate. Prior to initiating a treatment or procedure, the surrogate must provide consent even if that treatment or procedure does not require signature consent.

(2) The following persons are authorized to act as a surrogate to consent on behalf of a patient in the following order of priority. **NOTE:** *See paragraph 10 for the definitions of these terms:*

(a) Health care agent (HCA).

(b) Legal guardian.

(c) Next-of-kin (i.e., a close relative, 18 years of age or older, in the following order of priority: spouse; child; parent; sibling; grandparent; grandchild).

(d) Close friend, 18 years of age or older.

(3) If the patient has named an HCA in an advance directive and the HCA is available and willing to serve as surrogate, the VA practitioner must initiate the informed consent process with the HCA. If the patient has not named an HCA in an advance directive, but has a legal guardian, the VA practitioner must initiate the informed consent process with the legal guardian. If the patient has not named an HCA in an advance directive and does not have a legal guardian, the VA practitioner must follow the order of priority to identify the next-of-kin who is available and willing to serve as surrogate and the VA practitioner must initiate the informed consent process with that person.

NOTE: *For patients who do not have an HCA or legal guardian, the VA practitioner must start with the spouse and work down the list of next-of-kin; the VA practitioner cannot move on to the next person in the list until it has been determined that the previous person is unavailable or unwilling to serve as surrogate. For example, the VA practitioner cannot identify a sibling as the next-of-kin surrogate without first determining whether the patient has a spouse, adult child or parent to serve as surrogate.*

(4) A close friend may serve as surrogate if no next-of-kin is available and willing to serve as surrogate. The close friend must present a signed, written statement (to be placed in the patient's EHR) describing (with specific examples) that person's relationship to and familiarity with the patient.

(5) If there are multiple individuals at the same surrogate priority level (e.g., multiple children 18 years of age or older), the authorized surrogate is the individual who is willing and available to serve as surrogate and who is able to represent the patient's values, wishes and interests pertaining to the health care decision(s). VA practitioners and VA health care team members are not required to contact all individuals at the same surrogate priority level once an individual has been identified who can serve in the role as surrogate.

(6) If multiple individuals at the same surrogate priority level are identified and more than one of them can represent the patient's values, wishes and interests and those individuals are in agreement, they must work together to select one individual to serve as the surrogate and communicate decisions to the VA health care team. In circumstances when those individuals are not in agreement about the patient's values, wishes and interests, the VA practitioner must make reasonable efforts to reach a consensus (as explained in this paragraph). If consensus is reached, the individuals must work together to select one individual to serve as the surrogate and communicate decisions to the VA health care team. If consensus cannot be reached, the VA practitioner must choose the individual who is deemed best able to represent the patient's values, wishes and interests pertaining to the health care decision and document the reasons for choosing that individual in the EHR. In cases where the

choice is unclear, controversial or if a potential surrogate contests the VA practitioner's choice of surrogate, the VA practitioner must consult with the VA medical facility Health Care ECs and may consult with the Office of Chief Counsel in the District as needed.

(7) The VA practitioner must document, in the patient's EHR, the process and outcome of efforts to identify a surrogate.

(8) **Patients Who Have a Surrogate.** If it is determined that the patient lacks decision-making capacity and has a surrogate, the VA practitioner must initiate the informed consent process with the surrogate, including conducting the informed consent discussion as outlined in paragraph 4.b. Prior to initiating a treatment or procedure, even though the VA practitioner must obtain consent from the surrogate, the VA practitioner must attempt to explain the nature and purpose of the proposed treatment or procedure to the patient.

(a) The VA practitioner may disclose to the surrogate 38 U.S.C. § 7332-protected health information that is necessary for the surrogate to make an informed consent decision as outlined in VHA Directive 1605.01, Privacy and Release of Information, dated July 24, 2023.

(b) The surrogate must be informed that the treatment plan and decisions about the proposed treatment or procedure must be based on substituted judgment, that is, the surrogate's knowledge of what the patient would have wanted, including knowledge of the patient's specific values, goals, preferences and treatment decisions (including those documented in a LST plan or advance directive). If the patient's specific values and wishes are unknown, the treatment plan and decisions must be based on the patient's best interests and the surrogate, together with the VA health care team, must determine the optimal outcomes for the patient and the interventions most likely to produce them (taking into account the patient's cultural, ethnic and religious perspectives, if known).

(c) If the patient has a valid State-authorized advance directive (including a mental health or psychiatric State-authorized advance directive), a valid Department of Defense (DoD) advance directive, a valid VA Advance Directive (VA Form 10-0137, VA Advance Directive: Durable Power of Attorney for Health Care and Living Will) or instructions in critical situations (see paragraph 10.g.) documented in the EHR, the VA practitioner must review the valid advance directive or Instructions in Critical Situations with the surrogate. 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. **NOTE:** *The VA practitioner may collaborate with other VA health care team members who have knowledge of VA and State requirements regarding the validity of advance directives (e.g., social worker), and with the Office of Chief Counsel in the District if needed, to ensure that the advance directive(s) is valid to allow its use within the VA health care system. See VHA Directive 1004.03 for additional information on advance directives.*

(d) If a patient has more than one advance directive, including State-authorized advance directives and a DoD advance directive in addition to a VA Advance Directive, all apply and must be reviewed with the surrogate. For any inconsistent information across multiple advance directives, the conflicting information in the advance directive with the most recent date supersedes the inconsistent information in the other advance directives. **NOTE:** *The VA practitioner may consult with the VA medical facility Health Care ECs and the Office of Chief Counsel in the District when the patient has multiple valid advance directives that are inconsistent. See FAQs for more information: <https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Policy.aspx>. This is an internal VA website that is not available to the public.*

(e) If the patient has an active LST plan, the VA practitioner must review the LST plan with the surrogate as required by VHA Directive 1004.03. If the patient does not have an LST plan and decisions need to be made about LSTs or the surrogate has evidence that the patient's existing LST plan no longer reflects the patient's values, goals and preferences, the VA practitioner must conduct a goals of care conversation (GoCC) and establish an LST plan with the surrogate as required by VHA Directive 1004.03. **NOTE:** *See VHA Directive 1004.03 regarding inconsistencies between a patient's advance directive and LST plan, as well as for more information about GoCC.*

(f) The VA practitioner must consult with the VA medical facility Health Care ECs if the VA practitioner believes that the surrogate is making a decision about the proposed treatment or procedure that is contrary to the patient's values and wishes, or best interests.

(g) The VA medical facility Health Care ECs must collaborate with the VA health care team and other staff to review the surrogate's decision.

(h) If the VA medical facility Health Care ECs conclude that the surrogate's decision does align with the patient's values and wishes or best interests, the VA practitioner must obtain consent for the treatment, procedure or LST plan from the surrogate, document consent per paragraph 4 and initiate the treatment or procedure.

(i) If the VA medical facility Health Care ECs conclude that the surrogate's decision does not align with the patient's values and wishes or best interests, the VA medical facility CoS must review the VA medical facility Health Care ECs' assessment.

1. If the VA medical facility CoS concurs with the VA medical facility Health Care ECs' assessment, the VA medical facility CoS must document the basis for their concurrence in the EHR and the VA practitioner must identify an alternate surrogate per paragraph 4.c.(1)-(7) of this directive. If, following completion of the VA medical facility's established process for identifying surrogates, it is determined that the patient does not have an alternate surrogate, the VA practitioner must follow the processes outlined in paragraph 4.c.(9) for patients who lack decision-making capacity and do not have a surrogate. In addition, the VA medical facility CoS must communicate the decision and rationale to the original surrogate and inform the original surrogate about the clinical

appeals process as outlined in VHA Directive 1041, Appeal of Veterans Health Administration Clinical Decisions, dated September 28, 2020.

2. If the VA medical facility CoS does not concur with the VA medical facility Health Care ECs' assessment, the VA medical facility CoS must consult with NCEHC and make a decision about whether to provide the treatment or procedure. **NOTE:** *The VA medical facility Health Care ECs or VA medical facility CoS may consult with NCEHC at any time during this process when questions arise or support is needed to review the patient's (or surrogate's) decision.*

(9) **Patients Who Do Not Have a Surrogate.** If, after completing the VA medical facility's process for identifying surrogates, it is determined that none of the surrogates listed in paragraph 4.c.(2) are available, the VA practitioner may either contact the Office of Chief Counsel in the District for assistance in obtaining a guardian for health care decisions or implement the following procedures:

(a) Even if the patient lacks decision-making capacity, the VA practitioner must attempt to explain the nature and purpose of the proposed treatment or procedure to the patient and enter this information in the EHR.

(b) The VA practitioner and VA health care team must follow an established VA medical facility process to identify the patient's values, goals and preferences for care (including those documented in a LST plan or Living Will). If the patient's values, goals and preferences are known and applicable to the current clinical situation, the VA practitioner's decision to provide a treatment or procedure must be based on that information (substituted judgment).

(c) If the patient's values, goals and preferences are unknown, and decisions need to be made about LSTs, the VA practitioner must follow the process outlined in VHA Directive 1004.03. If the patient's values, goals and preferences are unknown, and decisions need to be made about treatment and procedures that are non-LSTs, the VA practitioner must engage the VA health care team in discussion and make a decision about the treatment or procedure that respects the patient as an individual by determining the optimal outcome for the patient and the intervention most likely to produce it, taking into account the patient's cultural, ethnic and religious perspectives, if known (best interests).

(d) If the VA practitioner needs assistance in determining whether a treatment or procedure is consistent with the patient's values, wishes or best interests, the VA practitioner must consult with the VA medical facility Health Care ECs.

(e) The VA practitioner must document the decision about the treatment or procedure and the basis for that decision (e.g., the patient's values) in the EHR.

(f) For treatments and procedures that require signature consent but do not involve the withholding or withdrawal of LST, the attending physician and VA medical facility Service Chief must review the VA practitioner's decision and basis for that decision and document their approval of the treatment decision in the EHR. If the attending physician

and VA medical facility Service Chief do not approve of the treatment decision, the attending physician and VA medical facility Service Chief must consult with the VA medical facility Health Care ECs, if not previously consulted, and recommend an alternate treatment or procedure that is consistent with the patient's values, wishes or best interests and document that decision and the basis for that decision in the EHR.

(g) For treatments and procedures that require signature consent, the informed consent process must be revisited if there is a significant change in the patient's condition that might alter the diagnostic or therapeutic decision about the upcoming or continuing treatments.

d. **Documenting Informed Consent.** After the informed consent discussion, the VA practitioner who is obtaining consent must ensure that the consent is appropriately documented. If consent is obtained from the surrogate for a patient who lacks decision-making capacity, documentation of consent must include the surrogate's name, relationship to the patient, authority to act as surrogate (whether they are an HCA, legal guardian, next-of-kin or close friend) and how the consent was obtained (e.g., in person, by telephone, by mail or by fax).

(1) Types of Informed Consent Documentation.

(a) Signature consent must be obtained for treatments and procedures that meet at least one of the following criteria:

1. Require the use of sedation.
2. Require anesthesia or narcotic analgesia.
3. Are considered to produce significant discomfort to the patient.
4. Are considered to produce significant risk of complication or morbidity.
5. Require injections of any substance into a joint space or body cavity.

(b) A list of treatments and procedures that require signature consent each time consent is obtained is available at

https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Informed_Consent.aspx.

NOTE: *This is an internal VA website that is not available to the public. This website also includes instructions for requesting updates to the list of treatments and procedures that require signature informed consent. It is not necessary to obtain a separate consent form for sedation, anesthesia or blood product transfusion if it was discussed during the informed consent discussion for the procedure and if the consent form for the procedure already contains consent for sedation, anesthesia or blood product transfusion, as in the eSIC software.*

(c) VA practitioners must also obtain signature consent for treatments and procedures not included in the above list of treatments and procedures that require signature consent when the treatment or procedure meets the criteria outlined in

paragraph 4.d.(1) for a specific patient (even if the criteria do not apply to all patients).

NOTE: A decision tool for determining whether signature consent is required is available at

https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Informed_Consent.aspx. This is an internal VA website that is not available to the public.

(d) For treatments and procedures that do not meet any of the criteria for signature consent, a progress note (or equivalent) written by the VA practitioner that describes the clinical encounter, treatment plan and a brief statement such as “patient consented to the treatment plan” is sufficient to document informed consent. Signature consent is not permitted for treatments and procedures that do not meet the criteria outlined in paragraph 4.d.(1)(a) as the extra documentation burden on the patient is ethically unjustifiable. 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 VA practitioner must document in the progress note (or equivalent) that the patient (or surrogate) consented to the specific test.

(2) How to Document Signature Consent.

(a) The eSIC software must be used to document signature consent on a nationally standardized consent form that is built into the eSIC software, unless one of the following circumstances exists:

1. The patient (or surrogate) declines to sign using the eSIC software.
2. There is a temporary system failure that prohibits proper use of the eSIC software. **NOTE:** Instructions for reporting technical issues related to the eSIC software are at <https://dvagov.sharepoint.com/sites/VHAethics/SitePages/iMedConsent.aspx>. This is an internal website and is not available to the public.
3. It is not possible to obtain a signed consent form in person (e.g., the patient (or surrogate) will not present to a VA medical facility prior to receiving a treatment or procedure).
4. Use of the equipment that supports the eSIC software program would introduce significant infection prevention and control issues. **NOTE:** Information on VA’s current eSIC software program and process to request updates to the content of national consent forms is available at <https://dvagov.sharepoint.com/sites/VHAethics/SitePages/iMedConsent.aspx>. This is an internal VA website that is not available to the public. To ensure standardization and consistency in practice, VA medical facilities are prohibited from creating and using locally-developed consent forms (except when a national consent form does not exist, but is under development, as outlined on the website) and must follow the process outlined on this website to request modifications to existing national consent forms and other documents maintained in the eSIC program or to request a new national consent

form or other document to be added to the eSIC program. The eSIC software must not be used to document informed consent for services provided by Occupational Health.

(b) When the eSIC software is not used due to one of these exceptions, signature consent must be documented as outlined in the Signature Informed Consent Workflow on the following website

https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Informed_Consent.aspx.

NOTE: *This is an internal VA website that is not available to the public.*

(c) In circumstances where the patient (or surrogate) is unable to sign the consent form due to a physical impairment, the patient (or surrogate) may place an “X”, thumbprint or stamp in the “Signature” block on the consent form in lieu of a signature. Two adult witnesses must witness when the patient (or surrogate) place an “X”, thumbprint or stamp on the consent form 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 a patient (or surrogate) using a duly witnessed “X”, thumbprint or stamp, 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).

(d) When delegated the responsibility by the VA practitioner, VA health care team members may facilitate obtaining the patient’s (or surrogate’s) signature on the consent form after the VA practitioner has conducted the informed consent discussion and signed the consent form.

(e) The patient (or surrogate) must be offered a copy of the completed and signed consent form.

(f) The signed consent form must be filed or scanned into the patient's EHR and saved under the appropriate EHR note title as outlined at (see FAQs): <https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Policy.aspx>. **NOTE:** *This is an internal VA website that is not available to the public. This link also includes EHR note titles for non-consent documents that can be completed using the eSIC software.*

(g) A properly executed VA-authorized consent form is valid for a period of 60 calendar days from the date the patient signed the form. If the treatment plan involves a course of treatment, it is not necessary to repeat the informed consent discussion and documentation if the course of treatment extends beyond the 60-day period. The VA practitioner is only required to initiate a new informed consent process and, if needed, complete a new signature consent form, with the patient (or surrogate) when:

1. There is a significant deviation from the treatment plan to which the patient or surrogate originally consented; or

2. There is a change in the patient’s condition or diagnosis that would be reasonably expected to alter the original informed consent **NOTE:** *Informed consent may also be revisited on as-needed basis, as determined by the VA practitioner, patient or surrogate.*

(3) If a patient (or surrogate) revokes consent for any treatment or procedure or a VA-authorized consent form is no longer valid, documentation of consent in the EHR must be modified to reflect the status of the consent as outlined on the following website at (see FAQs): <https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Policy.aspx>.

NOTE: *This is an internal VA website that is not available to the public.*

5. CONSENT IN SPECIAL SITUATIONS

a. Medical Emergencies.

(1) The VA practitioner may provide necessary medical care in emergency situations without the patient's express consent when all of the following apply:

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

(b) The patient is unable to consent.

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

(2) The patient's previously stated wishes (e.g., LST plans and orders, advance directive) must be followed to the extent that they are known and are applicable to the current situation.

(3) The VA practitioner and VA health care team must continue to attempt to identify a surrogate after the treatment has begun per the VA medical facility process for identifying surrogates.

(4) When the patient's consent is not obtained due to the emergency exception, the VA practitioner must date and sign a progress note (or equivalent) in the patient's EHR documenting the patient's inability to provide consent, the decision and its rationale and attempts that were made to identify and contact a surrogate.

(5) Whenever, due to the emergency exception, a treatment or procedure that requires signature consent has been provided without obtaining the patient's (or surrogate's) signature consent, the VA medical facility Service Chief must be notified and must review the patient's EHR to verify that the emergency exception to obtaining signature consent has been appropriately applied. The VA medical facility Service Chief must document their review in the patient's EHR by either co-signing or writing an addendum to the progress note (or equivalent depending on the EHR platform).

b. **Forced Administration of Psychotropic Medication.** The following represents the minimum in procedural constitutional due process protections afforded to patients by Federal courts. Because some States mandate more extensive procedural due process, VA personnel need to contact the Office of Chief Counsel in the District to determine if further protections are mandatory in their State. In addition, VA must follow State law

regarding the forced administration of psychotropic medications in the context of involuntary commitments. **NOTE:** See paragraph 5.a. for requirements regarding consent in medical emergencies. In the case of involuntarily committed patients where the forced administration of psychotropic medications is against the will of a patient (or the surrogate does not consent), the following procedural protections must be provided:

(1) The patient (or surrogate) must be allowed to consult with independent specialists, legal counsel or other interested parties concerning the treatment with psychotropic medication.

(2) Any recommendation by a VA practitioner to administer or continue psychotropic medication against the patient's wishes (or surrogate's consent) must be reviewed by the VA medical facility Forced Psychotropic Medication Review (FPMR) Committee appointed by the VA medical facility Director for this purpose. The VA medical facility FPMR Committee must be multi-disciplinary and must include a psychiatrist or a physician who has psychopharmacology privileges and may not include members of the primary treatment team. The VA medical facility FPMR Committee functions as the patient's advocate by determining if the least restrictive alternatives have been exhausted and that the proposed recommendation to administer or continue psychotropic medication is in the patient's best interests. The VA medical facility FPMR Committee must submit its findings and recommendations in a written report to the VA medical facility Director. The VA medical facility Director must review the VA medical facility FPMR Committee's recommendations and may concur, non-concur or consult the Office of Chief Counsel in the District. The VA medical facility Director's decision must be documented in the patient's EHR. Administration of psychotropic medications contrary to the patient's (or surrogate's) wishes may only be undertaken with the concurrence of the VA medical facility Director.

(3) The VA medical facility FPMR Committee and VA medical facility Director review process outlined in paragraph 5.b.(2) must be repeated every 30 days when a VA practitioner recommends continued therapy with psychotropic medication against the will of the patient or when the surrogate does not consent.

(4) The patient, surrogate or a representative on the patient's behalf may appeal the treatment decision to a court of appropriate jurisdiction. The VA practitioner must inform the patient and any surrogate or other representative about the right to appeal the decision.

(5) The VA practitioner must document compliance with these procedures in the patient's EHR.

c. Consent for Testing of a Source Patient after an Occupational Exposure.

(1) When a VA employee is inadvertently exposed to a patient's bodily fluids, tissues or excretions, medical follow-up for the VA employee depends upon the employee and the source patient's medical condition(s). Testing to determine the source patient's medical condition(s) must only be performed with the source patient's (or surrogate's)

informed consent, and that consent must be documented as outlined in paragraph 4.d. of this directive. Source patients have the right to refuse testing or procedures requested for the purposes of diagnosis or treatment of VA employees who have experienced an occupational exposure.

(2) To promote voluntary decision-making and prevent coercion or undue influence on the source patient (or surrogate):

(a) Informed consent for source patient testing must only be obtained after the occupational exposure has occurred. Consent must not be obtained prospectively (i.e., in case of a hypothetical or potential occupational exposure).

(b) Informed consent for testing of a source patient after an occupational exposure must be performed by a VA practitioner who does not have a personal relationship with the exposed VA employee (e.g., friend, family member, former spouse). The exposed employee must never seek consent from the source patient (or surrogate).

(3) If the VA practitioner determines that the source patient lacks decision-making capacity but is likely to regain capacity within a reasonable period of time, the VA practitioner must wait until the source patient's decision-making capacity returns, and then undertake the informed consent process with the source patient. If the VA practitioner determines that the source patient is unlikely to regain decision-making capacity within a reasonable period of time, the VA practitioner must undertake the informed consent process with the source patient's surrogate.

d. Consent for Treatments and Procedures Authorized for Use Under U.S. Food and Drug Administration's Emergency Use Authorization. Informed consent for treatments and procedures authorized for use under U.S. Food and Drug Administration's Emergency Use Authorization (EUA) must be obtained and documented as outlined in paragraph 4 (including whether or not signature consent is required). In addition, VA practitioners must also follow informed consent requirements outlined in the EUA (e.g., providing required patient education material).

6. INFORMED CONSENT FOR RESEARCH

a. VHA policy on informed consent for research is outlined in VHA Directive 1200.05(3), Requirements for the Protection of Human Subjects in Research, dated January 7, 2019.

b. The eSIC software may be used to document consent for research pursuant to the documentation requirements outlined in VHA Directive 1200.05(3).

7. TRAINING

There are no formal training requirements associated with this directive.

8. RECORDS MANAGEMENT

All records regardless of format (e.g., paper, electronic, electronic systems) created by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1. Questions regarding any aspect of records management should be addressed to the appropriate Records Officer.

9. BACKGROUND

a. VHA is committed to providing a health care environment that supports respect for patients and protects their right to autonomous, informed participation in health care decisions. This includes honoring patients' fundamental rights to decide what happens to their bodies, including the right to accept or refuse any medical treatment or procedure recommended to them and honoring their right to self-determination by engaging patients in shared decision-making.

b. This directive implements the requirements set forth in 38 C.F.R. § 17.32 which was established to ensure that VA practitioners and VA health care teams empower patients to be participants in decisions about their health care by seeking patients' (or surrogates', for patients who lack decision-making capacity) informed consent for treatments and procedures. The informed consent process ensures that patients (or surrogates) understand the risks, benefits and alternatives to a treatment and procedure and voluntarily consent.

c. This directive reflects revisions to 38 C.F.R. § 17.32 which aligns with VHA's team-based approach to health care and increased use of telehealth services.

10. DEFINITIONS

a. **Advance Directive.** An advance directive is 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. **NOTE:** See *VHA Directive 1004.03* for additional information.

b. **Close Friend.** A close friend is any person 18 years or older who has shown care and concern for the patient's welfare and is familiar with the patient's activities, health, religious beliefs and values, and who has presented a signed, written statement for EHR that describes that person's relationship to and familiarity with the patient.

c. **Course of Treatment.** A course of treatment consists of multiple or recurrent instances of the same treatment or procedure for a particular condition (e.g., chemotherapy, dialysis).

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

e. **Electronic Health Record.** EHR is the digital collection of patient health information resulting from clinical patient care, medical testing and other care-related activities. Authorized VA health care providers may access EHR to facilitate and document medical care. EHR comprises existing and forthcoming VA software including the Computerized Patient Record System (CPRS), Veterans Information Systems and Technology Architecture (VistA) and Cerner platforms. **NOTE:** *The purpose of this definition is to adopt a short, general term (EHR) to use in VHA national policy in place of software specific terms while VA transitions platforms.*

f. **Health Care Agent.** An HCA is an individual named in a Durable Power of Attorney for Health Care to make health care decisions on the patient's behalf, including decisions regarding LSTs, when the person can no longer do so. **NOTE:** *See paragraph 10.n. as a surrogate includes an HCA.*

g. **Instructions in Critical Situations.** Pursuant to 38 C.F.R. § 17.32, instructions in critical situations means that 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 VA health care team. **NOTE:** *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 VA health care team to whom they were expressed must be entered in the patient's EHR.*

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

i. **Life-Sustaining Treatment.** LST is a medical treatment that is intended to prolong the life of a patient who would be expected to die soon without the treatment (e.g., artificial nutrition and hydration, mechanical ventilation).

j. **Life-Sustaining Treatment Plan.** An LST plan is a treatment plan that directs care within VA medical facilities regarding the initiation, discontinuation and *limitation of LST.* **NOTE:** *For more information see VHA Directive 1004.03 and https://dva.gov.sharepoint.com/sites/VHAethics/SitePages/Advance_Care_Planning.aspx. This is an internal VA website that is not available to the public.*

k. **Long-Term Opioid Therapy for Pain.** LTOT for pain is the medically indicated use of opioids on a daily or intermittent basis for 90 or more calendar days out of the past 180 calendar days to treat non-cancer pain. **NOTE:** *For the purposes of this directive, opioids are opiates, opiate derivatives and chemically equivalent narcotic compounds listed in 21 U.S.C. § 812 as Schedule II or Schedule III controlled substances.*

l. **Patient Contract.** A patient contract is a document describing the expectations, responsibilities and obligations of the patient to receive a particular treatment or procedure. **NOTE:** *The term “patient contract” encompasses other documents with similar purposes including “treatment agreements” (e.g., Opioid Pain Care Agreement (OPCA)). Patient contracts are based on an adversarial rather than therapeutic model and often violate the patient’s right to self-determination. Their use of threatening language has the potential to be coercive and to undermine patient-provider trust. Use of patient contracts in addition to or in lieu of informed consent for clinical treatments and procedures is prohibited in VA.*

m. **Signature Consent.** Signature consent is documentation of informed consent with the signature of the patient or surrogate and VA practitioner. **NOTE:** *See paragraph 4 for information on signature consent requirements.*

n. **Surrogate.** For the purposes of this directive, a surrogate refers to an individual authorized under 38 C.F.R. § 17.32 and VHA policy to make health care decisions on behalf of a patient who lacks decision-making capacity. A surrogate includes an HCA, legal guardian, next-of-kin or close friend.

o. **VA Practitioner.** For purposes of this directive, a VA practitioner is any physician, dentist or health care provider granted specific clinical privileges to perform the treatment or procedure. A VA practitioner also includes medical and dental residents, regardless of whether they have been granted specific clinical privileges, and other health care professionals (e.g., physician assistants, nurse practitioners, health professions trainees) 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.

11. REFERENCES

- a. 38 U.S.C. § 7331, 7332.
- b. 29 C.F.R. § 1910.1030.
- c. 38 C.F.R. § 17.32.
- d. VHA Directive 1004.03, Advance Care Planning, dated December 12, 2023.
- e. VHA Directive 1041, Appeal of Veterans Health Administration Clinical Decisions, dated September 28, 2020.
- f. VHA Directive 1200.05(3), Requirements for the Protection of Human Subjects in Research, dated January 7, 2019.
- g. VHA Directive 1605.01, Privacy and Release of Information, dated July 24, 2023.

h. VHA Directive 1400.01, Supervision of Physician, Dental, Optometry, Chiropractic, and Podiatry Residents, dated November 7, 2019.

i. VHA Directive 1907.08, Health Care Information Security Policy and Requirements. dated April 30, 2019.

j. VHA Handbook 1400.04, Supervisions of Associated Health Trainees, dated March 19, 2015.

k. VA Form 10-0137, VA Advance Directive: Durable Power of Attorney for Health Care and Living Will, dated June 5, 2003.

l. Advance Care Planning Policy.

https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Advance_Care_Planning.aspx. **NOTE:** This is an internal VA website that is not available to the public.

m. Informed Consent Policy.

https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Informed_Consent.aspx. **NOTE:** This is an internal VA website that is not available to the public.

n. National Center for Ethics in Health Care. Health Care Ethics Policy FAQs.

<https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Policy.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

o. National Center for Ethics in Health Care. iMedConsent Web.

<https://dvagov.sharepoint.com/sites/VHAethics/SitePages/iMedConsent.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

p. National Center for Ethics in Health Care. Policy Performance Measures:

https://dvagov.sharepoint.com/sites/VHAethics/SitePages/Policy_Performance_Measures.aspx. **NOTE:** This is an internal VA website that is not available to the public.

q. Patient Information Guide for Safe and Responsible Use of Opioids for Chronic Pain: https://www.ethics.va.gov/for_veterans.asp.