

on locating the docket, see the **ADDRESSES** section of this preamble. This rule is categorically excluded under paragraph L56 of Appendix A, Table 1 of DHS Instruction Manual 023-01-001-01, Rev. 01. Paragraph L56 pertains to the training, qualifying, licensing, and disciplining of maritime personnel. This rule involves letters of designation to assign PICs of fuel oil transfers on inspected vessels.

List of Subjects in 33 CFR Part 155

Alaska, Hazardous substances, Oil pollution, Reporting, and recordkeeping requirements.

For the reasons discussed in the preamble, the Coast Guard amends part 155 as follows:

PART 155—OIL OR HAZARDOUS MATERIAL POLLUTION PREVENTION REGULATIONS FOR VESSELS

■ 1. The authority citation for part 155 is revised to read as follows:

Authority: 3 U.S.C. 301 through 303; 33 U.S.C. 1321(j), 1903(b), 2735; 46 U.S.C 3306, 3703, 70011, 70034; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; Department of Homeland Security Delegation No. 0170.1. Section 155.1020 also issued under section 316 of Pub. L. 114-120. Section 155.480 also issued under section 4110(b) of Pub. L. 101-380.

Note: Additional requirements for vessels carrying oil or hazardous materials are contained in 46 CFR parts 30 through 40, 150, 151, and 153

- 2. Amend § 155.710 as follows:
- a. In paragraph (e) introductory text, remove the word “shall” and add in its place the word “must”;
 - b. Revise paragraph (e)(1);
 - c. Remove paragraph (e)(2);
 - d. Redesignate paragraphs (e)(3) and (4) as paragraphs (e)(2) and (3), respectively; and
 - e. In newly redesignated paragraph (e)(2), remove the text “or (2)”.

The revision reads as follows:

§ 155.710 Qualifications of person in charge.

* * * * *

(e) * * *

(1) On each inspected vessel required by 46 CFR chapter I to have an officer aboard, and on each uninspected vessel, either:

- (i) Holds a valid merchant mariner credential issued under 46 CFR chapter I, subchapter B, with an endorsement as master, mate, pilot, engineer, or operator aboard that vessel, or holds a valid merchant mariner credential endorsed as Tankerman-PIC; or
- (ii) Carries a letter satisfying the requirements of § 155.715 and

designating him or her as a PIC, unless equivalent evidence is immediately available aboard the vessel or at his or her place of employment.

* * * * *

§ 155.715 [Amended]

■ 3. In § 155.715, remove the text “letter of instruction required in § 155.710(e)(2)” and add in its place the text “letter referenced in § 155.710(e)(1)”.

Dated: May 21, 2020.

R.V. Timme,

Rear Admiral, U.S. Coast Guard, Assistant Commandant for Prevention Policy.

[FR Doc. 2020-11366 Filed 5-26-20; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900-AQ97

Informed Consent and Advance Directives

AGENCY: Department of Veterans Affairs.

ACTION: Interim final rule.

SUMMARY: The Department of Veterans Affairs (VA) amends 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.

DATES:

Effective date: This final rule is effective May 27, 2020.

Comment date: Comments must be received by VA on or before July 27, 2020.

ADDRESSES: Written comments may be submitted through www.regulations.gov; by mail or hand-delivery to the Director, Office of Regulation Policy and Management (OOREG), Department of Veterans Affairs, 810 Vermont Ave. NW, Room 1064, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to “RIN 2900-AQ97—Informed Consent and Advance Directives.” Copies of comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1064,

between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461-4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Lucinda Potter, MSW, LSW, Ethics Policy Consultant, National Center for Ethics in Health Care (10E1E), Veterans Health Administration, 810 Vermont Ave. NW, Washington, DC 20420; 484-678-5150, lucinda.potter@va.gov. (This is not a toll-free number).

SUPPLEMENTARY INFORMATION: Section 7331 of title 38, United States Code (U.S.C.), requires, in relevant part, that the Secretary of Veterans Affairs, upon the recommendation of the Under Secretary for Health, prescribe regulations to ensure, to the maximum extent practicable, that all VA patient care be carried out only with the full and informed consent of the patient, or in appropriate cases, a representative thereof. Based on VA’s interpretation of this statute and our mandate in 38 U.S.C. 7301(b) to provide a complete medical and hospital service, we recognize that patients with decision-making capacity have the right to state their treatment preferences in a VA or other valid advance directive. VA’s use and recognition of advance directives is also consistent with practice in the health care industry at large; for instance, a condition of participation in the Medicare program requires providers to agree to abide by the requirements of the Patient Self-Determination Act of 1990 (codified at 42 U.S.C. 1395cc(f)), which, among other things, requires participating providers to inform patients of their rights under state law to indicate treatment preferences, including the right to accept or refuse medical or surgical treatment, in an advance directive.

VA regulations at 38 CFR 17.32 establish standards for obtaining informed consent from a patient for a medical treatment or a diagnostic or therapeutic procedure and standards for advance care planning; that is, the process by which a patient documents in an advance directive his or her future treatment preferences (encompassing medical, surgical, and mental health care) to be relied on in the event the patient loses the capacity to make health care decisions. We revise this section and publish it as an interim final rule to ensure that informed consent procedural and process changes are in

place immediately to address the urgent and emergent clinical care needs of patients related to delivery of health care services and for future health care decisions during the SARS-CoV-2 virus outbreak and the disease it causes named the “Coronavirus Disease 2019” (COVID-19) which has been declared a national emergency. The changes to current informed consent procedures and requirements, as described herein, are needed for the reasons explained, but the current national emergency has made it particularly vital that they be implemented immediately to deal with COVID-related treatment setting challenges (to include those arising from VA’s announced contingent (formerly “crisis”) standards of care during the COVID national emergency, VA’s recognition of scarce resources during this emergency requiring changes to resources allocations, to include staffing decisions, changes in treatment locations, etc.), greater use of telehealth services, and CDC guidance (to include social distancing requirements and separation of infected patients from other patients) issued for this highly infectious disease crisis. This is addressed in greater detail under the Administrative Procedures Act section, where we set forth the good cause reasons supporting this approach.

As discussed in detail below, we amend that rule by reorganizing it and amending language where necessary to enhance clarity. We amend the definition of practitioner to expand the types of health care professionals authorized to obtain informed consent from a patient and define the scope of information that must be provided as part of the informed consent discussion. We establish the type of documentation required both when a patient consents to treatments and procedures that are low risk and within broadly-accepted standards of medical practice and to those necessitating signature consent. We expand the approved communication modalities that may be used by VA when an in-person discussion with a patient or surrogate regarding a proposed treatment or procedure is impracticable. We remove the special process related to consent for unusual or extremely hazardous treatments or procedures (long interpreted in regulation as including those that may result in irreversible brain damage or sterilization) as VA no longer performs such treatments or procedures. We amend the definition of advance directive to include two other types that VA recognizes: The Department of Defense Advance Medical Directive and a Mental Health

(or Psychiatric) Advance Directive. We amend the witness requirement for advance directives to allow family members who are VA employees to serve as witness to the signing of a VA Advance Directive (if not otherwise precluded from serving as witness under the regulation), and remove restrictions on certain other VA employees serving as witness to the signing of a VA Advance Directive. Finally, we add a mechanism to allow a patient who, due to a physical impairment, is unable to execute a signature on a signature consent form to sign with an “X”, a thumbprint, or a stamp on the form. Signature by use of an “X”, thumbprint, or stamp is also available to a patient who, because of a physical impairment, cannot sign a VA Advance Directive and to a third party who is signing the directive at the direction and in the presence of the patient.

The title to prior § 17.32 is “Informed consent and advance care planning.” We change “advance care planning” to “advance directives” as we believe this term is more commonly used and understood by the public. These and other changes are discussed below in greater detail.

Definitions

We begin by amending the definitions found in paragraph (a). Former paragraph (a) defined three types of advance directive recognized by VA: a VA Living Will; a VA Durable Power of Attorney for Health Care; and State-Authorized Advance Directives. We amend the definition of VA Living Will to clarify the purpose of a living will, which is to document the personal preferences of an individual regarding future treatment options. We change the term from “VA Living Will” to “Living Will” to clarify that the definition is applicable to an instrument serving that purpose, regardless of whether the document is a VA form or not. For a similar reason we change the term “VA Durable Power of Attorney for Health Care” to “Durable Power of Attorney for Health Care.” Durable Power of Attorney for Health Care is defined as a type of advance directive in which an individual designates another person as a health care agent to make health care decisions on behalf of the individual.

VA believes that the best interests of veterans who have either a Mental Health Advance Directive or a DoD Advance Medical Directive are served by VA formally recognizing these types of advance care planning instruments. We therefore add a Mental Health (or Psychiatric) Advance Directive to the list of advance directives recognized by

VA. It is executed by patients whose future decision-making capacity is at risk due to mental illness, and it allows them to indicate preferences about their future mental health care. We likewise add the Department of Defense (DoD) Advance Medical Directive to the list of advance directives recognized by VA. This addition gives equal legal recognition to DoD-authorized advance directives executed for members of the armed services or military dependents under 10 U.S.C. 1044C.

We revise material in former paragraph (h)(1) to formulate a definition for a VA advance directive, which is one example within the broader category of advance directives. We specify that a VA advance directive is completed on a form that is specified by VA and can be used to designate a health care agent and to document treatment preferences for medical care, including mental health care. This language combines and condenses language found in former paragraph (a). VA believes that the amendment improves consistency by incorporating all of the relevant definitions in the definitions section rather than interspersing them throughout the section.

We make minor non-substantive changes to the definitions of a State-authorized advance directive, close friend, legal guardian, and signature consent, to clarify the meaning of these terms.

Decision-making capacity is a key concept in both informed consents for clinical treatments and procedures and advance directives. We previously defined decision-making capacity to mean the ability to understand and appreciate the nature and consequence of health care decisions. We amend the definition of decision-making capacity to also state that it includes the ability to formulate a judgment and communicate a clear decision concerning clinical treatments and procedures. We believe it is appropriate to include this clarification in the definition of decision-making capacity, because each of these elements is evaluated by a practitioner when determining whether a patient has decision-making capacity.

The definition of health care agent in former paragraph (a) is amended to clarify the powers and duties of a health care agent. The amended language states that a health care agent is the individual named by the patient in a durable power of attorney for health care 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 make such decisions.

For purposes of obtaining informed consent for medical treatment, we previously defined “practitioner” to include any physician, dentist, or health care professional who has been granted specific clinical privileges to perform the treatment or procedure, including medical and dental residents and other appropriately trained health care professionals designated by VA regardless of whether they have been granted clinical privileges. The responsibility to obtain informed consent for medical treatment from the patient was formerly assigned to the practitioner who has primary responsibility for the patient or who will perform the particular procedure or provide the treatment in paragraph (c).

We amend the definition of “practitioner” to include 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. This change is consistent with the team concept for delivery of health care currently adopted by VA. The rationale for this change is discussed in greater detail below, where we make changes to the general requirements for informed consent in former paragraph (c).

We add a definition of “State-authorized portable orders.” State-authorized portable orders (SAPO) are a specialized form or identifier (e.g., Do Not Attempt Resuscitation (DNAR) bracelets or necklaces) authorized by state law or a state medical board or association, that translates a patient’s preferences concerning specific life-sustaining treatment decisions into portable medical orders. While SAPO and advance directives each reflect patient goals and preferences for treatment, the two instruments differ. An advance directive is a legal instrument completed by a patient with decision-making capacity in which the patient expresses his or her preferences about future health care decisions in the event that the patient becomes unable to make these decisions. In some types of advance directives, the patient may appoint an individual to serve as the patient’s health care agent charged with making health care decisions on the patient’s behalf, when the patient can no longer make such decisions. SAPO, on the other hand, translate a patient’s preferences with regard to specific life-sustaining treatment decisions into

standing, actionable, and portable medical orders. Critically ill incoming patients with SAPOs need to have their SAPOs translated into and followed within the VA health care system, no matter where they are being treated by VA. This definition codifies in regulation what these are, helping the field to also understand the distinction between SAPOs and advance directives. While an advance directive is normally retained by the patient in a safe and secure place, SAPO are designed to be retained on or near the patient so that the orders are easily accessible to emergency medical personnel or other health care personnel and also travel with the patient whenever the patient is transported to or from a health care facility. SAPO have been authorized in the majority of states over the last decade to ensure that a patient’s portable orders are easily recognizable, understood, and respected by emergency medical service providers and receiving health care facilities. Examples of SAPO forms include: Oregon’s Physician Orders for Life-Sustaining Treatment (POLST); West Virginia’s Physician Orders for Scope of Treatment (POST); New York’s Medical Orders for Life Sustaining Treatment (MOLST); and out-of-hospital DNAR orders (e.g., New York State’s Out-of-Hospital Do Not Resuscitate (DNR) order form).

The term “surrogate” was previously defined to mean an individual, organization or other body authorized under § 17.32 to give informed consent on behalf of a patient who lacks decision-making capacity. We amend this definition to state that the term “surrogate” is an individual authorized under this section to make health care decisions on behalf of a patient who lacks decision-making capacity and includes a health care agent, legal guardian, next-of-kin, or close friend. This change is consistent with the categories of individuals identified in earlier VA regulation (§ 17.32(e)(1)-(4)) and hence with longstanding practice regarding whom VA recognizes as being authorized to make health care decisions on behalf of a patient who lacks decision-making capacity.

Informed Consent

Former paragraph (b) addressed the concept of informed consent for treatments and procedures as interpreted in VA, while paragraph (c) addressed the requirements for obtaining informed consent. Laypersons generally think of informed consent in the context of a patient agreeing to a medical procedure or course of treatment. However, the concept of

informed consent also encompasses a patient’s right to refuse, or withhold consent, for a medical procedure or course of treatment recommended by a health care provider. We therefore update language in paragraph (b) to reflect the established legal and ethical principle that patients receiving treatments and procedures within the VA health care system have the right to accept or refuse any medical treatment or procedure recommended to them. We also amend the former first sentence in paragraph (b) to state that except as otherwise provided in § 17.32, no medical treatment or procedure may be performed without the prior, voluntary informed consent of the patient.

Prior to this interim final rule, then-current paragraph (b) contained a long compound sentence discussing the requirement that a patient must have decision-making capacity to give informed consent and that informed consent is to be obtained from a surrogate if the patient lacks decision-making capacity. We separate these into paragraphs (b)(1) and (2) for ease of understanding. Paragraph (b) formerly referred to actions that can be taken by either the patient or surrogate. For purposes of clarity and to enhance readability, we amend these references to refer to only the patient. Paragraph (b)(2) specifically states that in the event the patient lacks decision-making capacity, the requirements of § 17.32 are applicable to consent for treatments or procedures obtained from the surrogate.

Paragraph (b) also stated that a practitioner may provide necessary medical care in emergency situations without the express consent of the patient or surrogate when immediate medical care is necessary to preserve life or prevent serious impairment of the health of the patient, the patient is unable to consent, and the practitioner determines that the patient has no surrogate or waiting to obtain consent of the surrogate would increase the hazard to life or health of the patient. We move this to new paragraph (c)(7).

General Requirements for Informed Consent

Former paragraph (c) delineated the general requirements for informed consent. The first sentence of this paragraph provided a definition of informed consent that we believe is both unclear and not entirely consistent with current VA practice. We amend this sentence to state that informed consent is the process by which a practitioner discloses to and discusses appropriate information with a patient so that the patient may make an informed, voluntary choice about whether to

accept the proposed diagnostic or therapeutic procedure or course of treatment. While the earlier iteration of the opening sentence of paragraph (c) focused on the act of providing consent, the revised language focuses on the process and the required actions of the practitioner in providing appropriate information so that the patient can make an informed, voluntary choice.

Medical practice evolves over time. VA believes that former § 17.32 is now inconsistent with contemporary standards for health care delivery and current VA practice. Paragraph (c) previously stated, in relevant part: “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.” We believe that the language “who has primary responsibility for the patient or who will perform the particular procedure or provide the treatment” is outdated and does not reflect the requirements of modern clinical practice. For example, medical residents (post-graduate trainees) frequently order blood testing for human immunodeficiency virus (HIV), which requires the patient’s informed consent. It would therefore be appropriate for consent to HIV testing to be obtained by residents. However, the old regulatory language does not clearly support this practice because residents do not ever have “primary responsibility for the patient” in that they function under the supervision of a more senior physician, nor would they typically “perform the particular procedure,” since blood tests are typically performed by phlebotomists who draw the blood, along with lab technicians who perform the test. As another example, a patient’s primary care physician might send a patient to a consulting physician who, in turn, might send the patient for a specialized treatment or procedure (e.g., a cardiac stress test). A different health care professional, such as a registered nurse or a trained technician, might administer the treatment or procedure. Under these circumstances it is appropriate for informed consent to be obtained by the consulting physician who referred the patient for the specialized treatment or procedure, because this individual would be most knowledgeable about it. However, the

former regulatory language requires that informed consent be obtained by either the primary care physician or the registered nurse or technician, neither of whom would be in the best position to communicate with the patient about the risks and benefits of, and alternatives to, the recommended procedure or treatment.

Further, former paragraph (c) is based on an outdated model of health care in which a single practitioner works in isolation from others. Health care is now typically delivered by teams in which professionals from a variety of clinical disciplines work together to achieve the patient’s health care goals. These interdisciplinary, inter-professional teams may include a range of medical specialists, such as physicians, nurses, pharmacists, nutritionists, dietitians, social workers, behavioral and mental health providers, and physician assistants.

Within VA, care delivery has transitioned to the team-based care model. Under this model, VA uses a Patient-Aligned Care Team (PACT) approach in which the primary care practitioner is responsible for overseeing but not necessarily directly providing all of the patient’s primary health care. Thus, the components of the patient visit that do not require the primary care practitioner’s expertise are assigned to other qualified clinical or support staff so that every member can “work to the top of his or her competence.” Department of Veterans Affairs, Report of the Universal Services Task Force, April 2009, p. 28. VA believes the changes to the definition of practitioner will provide sufficient flexibility to allow VA to respond in a timely manner to current and future changes in the scope of practice for appropriately trained team-based health care professionals.

To make the language in § 17.32 consistent with contemporary standards of team-based health care delivery, including those set by external organizations such as The Joint Commission and the Centers for Medicare & Medicaid Services, VA deletes the portion of paragraph (c) that reads “. . . who has primary responsibility for the patient or who will perform the particular procedure or provide the treatment . . .” and makes minor edits throughout § 17.32 to allow for the fact that components of the patient’s care are appropriately shared by multiple members of a team.

Former § 17.32 did not specify a standard for the adequacy of information disclosure and could therefore be interpreted to obligate VA to disclose all known information about

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. Accordingly, VA amends the rule to more clearly describe VA’s standard for adequate information disclosure by defining the term “appropriate information” in paragraph (c) as 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. The term “appropriate information” also 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. In these cases, the health record must specifically document that the patient or surrogate consented to the specific test.

Paragraph (c)(1) addresses the setting in which the informed consent discussion should take place. We state that the informed consent discussion should be conducted in person with the patient whenever practical. However, other forms of communication may also be appropriate depending on the circumstances. Former paragraph (c) did not reflect new modalities that facilitate communication between practitioners and patients or their surrogates. The widespread adoption of technology that allows for video conferencing and web-based communications now makes it possible for the informed consent process to be conducted in a way that is more convenient and flexible for patients. The informed consent process may reasonably take place over a period of time and involve educational activities and a number of discussions about the risks and benefits, as well as alternatives to a proposed treatment or procedure. To ensure that the regulation allows the flexibility enabled by these communication modalities, we amend paragraph (c)(1) to permit the informed consent discussion to be conducted either in person, by telephone, through video conference, or by other VA-approved electronic communication methods when it is impractical to conduct the discussion in person, or if preferred by the patient or surrogate.

Paragraphs (c)(2) through (4) address steps that must be taken by the practitioner during the informed consent discussion. Paragraph (c)(2) states that 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 treatment or procedure; expected benefits; reasonably foreseeable associated risks; complications or side effects; reasonable and available alternatives; and anticipated results if nothing is done. The language in paragraph (c) is substantively the same as in former paragraph (c), and in fact, the language in paragraphs (c)(2), (3) and (4) is essentially the same as in former paragraph (c). The only difference is that we remove references here to the surrogate, as obtaining informed consent from the surrogate is addressed in paragraph (e).

Paragraph (c)(5) states that the patient may withhold or revoke consent at any time, which is consistent with legal and ethical standards, and with paragraph (b), described above, which says VA patients have the right to refuse medical treatment. Consistent with the team-based care model, paragraph (c)(6) provides that the practitioner may delegate to other trained personnel responsibility for providing the clinical information needed for the patient to make a fully informed consent decision. However, the practitioner must personally verify with the patient that the patient has been appropriately informed and voluntarily consents to the treatment or procedure. We believe this requirement benefits both the patient and practitioner, providing the patient an opportunity to freely communicate with the practitioner and other team members regarding the proposed treatment or procedure, and allowing the practitioner to confirm that appropriate information was provided to the patient and that consent is voluntary.

As described above, paragraph (c)(7) states that express consent is not required when immediate medical care is necessary to preserve life or prevent serious impairment of the health of the patient, the patient is unable to consent, and the patient has no surrogate or waiting to obtain consent of the surrogate would increase the hazard to life or health of the patient.

Documentation of Informed Consent

Paragraph (d) focuses on documentation of informed consent. As noted in paragraph (d), the informed consent process must be appropriately documented in the health record. Content in former paragraph (d) could be interpreted to mean that VA practitioners must specifically document informed consent for every treatment or procedure a patient

receives. However, this is impractical and inconsistent with modern standards for health care delivery. The type of documentation required should depend on the level of risk for the particular treatment or procedure. For instance, while most, if not all, health care organizations require specific documentation of informed consent for major procedures such as surgery or radiation therapy, we are aware of no organization in the country that requires specific documentation of informed consent for oxygen administration, blood pressure measurement, electrocardiograms, and other treatments and procedures that are low risk and within broadly-accepted standards of medical practice. The new language in this interim final rule therefore differentiates between documentation requirements for patient consent to treatments and procedures that are low risk and within broadly-accepted standards of medical practice and those that require signature consent because they pertain to treatments and procedures that require anesthesia or narcotic analgesia, are considered to produce significant discomfort to the patient, have a significant risk of complication or morbidity, or require injections of any substance into a joint space or body cavity. Paragraph (d)(1) provides that, for purposes of 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 suffices to document that informed consent was obtained. 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 the patient might reasonably want to consider as part of their consent decision, the health record must specifically document that the patient or surrogate consented to the specific test.

The type of informed consent documentation required for a treatment or procedure is dependent on the level of risk for such procedure. Patient consent to treatments or procedures requiring signature consent, as discussed above, must be documented on a form prescribed by VA for that purpose that is signed by both the patient and practitioner, except as described in paragraph (d)(3). Paragraph (d)(2) lists the types of diagnostic and therapeutic treatments that continue to require signature consent. The content of paragraph (d)(2) is the same as that found in former paragraph (d)(1), with minor non-substantive edits. These

changes (related to documentation) are consistent with longstanding VA policy and practice. The documentation requirement for consent to a treatment or procedure requiring signature consent is addressed in paragraph (d)(3).

Due to a drafting error, former paragraph (d)(2) combines a discussion of how to document signature consent when the patient or surrogate has a significant physical impairment and/or difficulty in executing a signature due to an underlying health condition or is unable to read and write, and the 60-day validity period for signature consent. Due to a missing line break, the numbering in the paragraph could be misinterpreted to mean that the requirement of “valid for a period of 60 calendar-days” applies only if a patient signs the consent for with an “X.” We move the former to paragraph (d)(3)(i) with revisions as noted below. We move the latter to paragraph (d)(3)(ii), with amendments. Former paragraph (d)(3) is redesignated paragraph (d)(3)(iii), with changes as discussed below.

Paragraph (d)(3)(i) focuses on how signature consent is to be documented when physical impairment prevents the execution of a signature on a VA-authorized consent form. As noted above, we move this content from former paragraph (d)(2). Paragraph (d)(2) stated that a patient or surrogate will sign with an “X” when the patient or surrogate has a debilitating illness or disability; that is, a significant physical impairment and/or difficulty in executing a signature due to an underlying health condition(s) or is unable to read and write. The placing of the “X” on the form must be witnessed by two adults. That earlier version of the regulation referred to actions that can be taken by either the patient or surrogate. We remove the clause “and/or difficulty in executing a signature due to an underlying health condition(s)” because we believe this is redundant, and the concept is adequately covered by the phrase “physical impairment.” Likewise, we remove the clause “or is unable to read and write” because an individual unable to read or write, but otherwise not physically impaired, may still be able to place some type of mark on the document that would serve the purpose of a signature, and VA believes it is burdensome to require the signature of two witnesses to the “X” mark. Former paragraph (d)(2) further stated that 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 is then filed in the patient’s medical record. We remove the requirement that the witnesses attest

that they also saw the practitioner sign the form, as this is inconsistent with current VA practice and unnecessary. The overall purpose of the witness requirement is to confirm the validity of the patient's or surrogate's "X" mark on the form. This is accomplished by the witnesses documenting they witnessed the act of signing by the patient or surrogate.

Further, to allow greater flexibility to meet the needs of those with physical impairments, we allow either the placement of the "X" or the use of a thumbprint or stamp to meet the signature requirement in these cases. Finally, we state that a third party may also be designated to assist either the patient or the surrogate if physical impairment prevents signature by either. VA believes that obtaining signature consent is better facilitated if any third party, acting at the direction and in the presence of the patient or surrogate, performs this task.

Paragraph (d)(3)(ii) consists of that portion of former paragraph (d)(2) relating to the 60-day validity period of a properly executed VA-authorized consent form. Former paragraph (d)(2) stated that if there is a change in the patient's condition that might alter the diagnostic or therapeutic decision, the consent is automatically rescinded. We amend that sentence by removing the phrase "consent is automatically rescinded" and instead state that the practitioner must initiate a new informed consent process, and, if needed, complete a new signature consent form with the patient. We believe this will, consistent with current VA practice, ensure that the practitioner will further engage the patient in a discussion of treatment options whenever there is a change in clinical circumstances that might alter the diagnostic or therapeutic decision about upcoming or continuing treatment.

Paragraphs (d)(3)(iii) and (iv) address those instances in which signature consent is required, but it is not practicable to obtain the signature in person following the informed consent discussion. Former paragraph (d)(3) allowed for surrogates (who might not be available in person) to give signature consent over the telephone and/or by mail or facsimile, but it does not give this option to patients who may benefit from the same flexibility. For instance, patients may have limited mobility or live far from the VA facility, which in either case makes them unable to travel to the facility until shortly before the scheduled treatment or procedure. To ensure that patients as well as surrogates can conveniently participate in the informed consent process, the

revised language in the interim final rule permits that process to be conducted with the use of current and anticipated communication modalities when the patient (or surrogate) and the practitioner are not able to meet in person prior to a treatment or procedure. Paragraph (d)(3)(iii) permits the signed informed consent form to be transmitted to VA not only by mail or facsimile but also by secure electronic mail or other VA-approved modalities. It then requires that the form be scanned into the record. This provision does not specify which modalities are VA-approved for this purpose, because VA believes this is better placed in policy which can more easily be amended to reflect evolving forms of communications technology.

Former § 17.32(d)(3) provided, in part, that a facsimile copy of a signed consent form is adequate to proceed with treatment, and also required the surrogate to agree to submit a signed consent form to the practitioner. Requiring both the facsimile copy and the hard copy is redundant and potentially confusing. We therefore delete the language in former paragraph (d)(3) requiring that, when a signed consent form is transmitted by facsimile, "the surrogate must agree to submit a signed consent form to the practitioner." We also add to paragraph (d)(3)(iii) a requirement that a signed consent form submitted by mail, facsimile, by secure electronic mail, or other VA-approved modalities be scanned into the record. This obviates the need for VA to keep a hard copy. We also delete the specific reference to consent being obtained by telephone. We believe the other language in this paragraph establishing the conditions for use of the telephone in lieu of a signed consent form is sufficient.

As briefly alluded to above, we add the phrase "following the informed consent discussion" to paragraph (d)(3)(iii)'s treatment of circumstances where signature consent cannot be obtained in person. This language clarifies that a signed consent form submitted by mail, facsimile, transmitted by secure electronic mail, or other VA-approved modalities is not by itself sufficient to satisfy the consent requirement; rather, an informed consent discussion is a prerequisite to the validity of any signed informed consent form.

Receiving signed consent forms by mail, facsimile, secure electronic mail, or other VA-approved modalities may still, in some cases, cause undue delay. To provide VA, patients, and surrogates further flexibility, paragraph (d)(3)(iv) permits the informed consent

conversation conducted by telephone or video conference to be audiotaped, videotaped, or witnessed by a second VA employee. In addition, it specifies that 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. These actions, together, suffice to obviate the need for a signed consent form.

Obtaining Consent for Patients Who Lack Decision-Making Capacity

Former paragraph (e) addressed surrogate consent while paragraph (f) dealt with consent for patients without a surrogate. We combine former paragraphs (e) and (f) into a single paragraph (e). This change places into one paragraph how consent is to be obtained when a patient has been determined to lack decision-making capacity. Paragraph (e)(1) explains when consent is to be obtained from a surrogate decision maker and identifies who may serve as a surrogate decision maker in order of priority. Paragraph (e)(2) addresses the process for obtaining consent for a patient lacking decision-making capacity who has no such surrogate. We redesignate former paragraph (e) as paragraph (e)(1). Paragraph (e)(1) states that 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. We delete the clause in former paragraph (e) specifying that these patients are either persons judicially declared to be incompetent or minors who are otherwise incapable of giving consent. We believe this language is redundant, since we already state in paragraph (e)(1) that patients who are incapable of giving consent as a matter of law will be deemed to lack decision-making capacity for purposes of § 17.32.

Consistent with former paragraph (e), paragraph (e)(1)(i) identifies the persons authorized to act as a surrogate to consent on behalf of a patient who lacks decision-making capacity and the order of priority for surrogates. The language in the interim final rule is unchanged from former paragraph (e) except we remove "special guardian" from the list. Because "special" guardians are appointed as an outcome of a legal process, they are also "legal guardians." Including "special guardian" as a separate category of surrogate, however, suggests that there could be a special guardian who is not a legal guardian. To avoid this confusion, we remove the

designation of “special guardian.” While this is the only change to this content and is only technical in nature, VA takes this opportunity to invite public comment on whether VA should consider inclusion of emancipated minors among those listed as next-of-kin or with respect to any situations that might arise with respect to an emancipated minor (e.g., a spouse who is an emancipated minor under the age of 18). Currently, next-of-kin must be 18 years of age or older. In addition, we note that VA makes no change to the order of hierarchy of surrogates. As is currently the case, a health care agent has, and would retain here, highest priority because this is the individual selected by the patient himself/herself and so best reflects the patient’s wishes. Needed checks on the actions of a surrogate already exist in current regulation: A surrogate must make treatment decisions based on the known wishes of the patient, or in the absence thereof, based on the best interests of the patient. This standard would still apply and is addressed below, with respect to new paragraph (e)(1)(ii).

As noted, paragraph (e)(1)(i) identifies the persons authorized to act as a surrogate to consent on behalf of a patient who lacks decision-making capacity and the order of priority for surrogates. A patient with decision making capacity may select a surrogate and document that selection by designating a health care agent, and an alternate if desired, in an advance directive. VA practitioners engage patients in a discussion of the option of completing an advance directive and appointing a health care agent during goals of care conversations which occur as part of VA’s delivery of quality health care to eligible veterans. In this way, potential disputes and associated uncertainty can be avoided regarding who the patient prefers to make health care decisions in the event of loss of capacity by having already memorialized that decision in an advance directive. We further note that if a patient with decision-making capacity has a change of mind regarding appointment of a health care agent, the patient may revoke the advance directive and designate another individual in a new advance directive. See discussion below of paragraph (g)(4) which addresses revocation of an advance directive. If the patient chooses to not appoint a health care agent and subsequently loses decision making capacity, VA identifies a surrogate decision maker utilizing the priority list found in paragraph (e)(1)(i). We add new paragraph (e)(1)(ii) to consist of a

slight modification of language in former paragraph (e) describing the surrogate’s role in the consent process. Former paragraph (e) states: “the surrogate’s decision must be based on his or her knowledge of what the patient would have wanted, *i.e.*, substituted judgment.” The next sentence states: “if unknown, the surrogate’s decision must be based on the patient’s best interest.” In paragraph (e)(1)(ii), we retain these requirements but combine the two sentences into one.

Former paragraph (f)(1) explained the process for obtaining consent for a patient who lacks decision-making capacity where no surrogate is available. Former paragraph (f)(1) provided that the practitioner may request Regional Counsel assistance to obtain a special guardian for health care or follow the internal procedures in that paragraph. Former paragraph (f)(1) is redesignated as paragraph (e)(2)(i). The content remains the same with the two following exceptions: (1) The reference in former paragraph (f)(1) to “Regional Counsel” is changed in paragraph (e)(2)(i) to “District Chief Counsel” to reflect a change in title; and (2) the reference therein to a “special guardian for health care” is amended to refer to “legal guardian” for the reasons previously stated.

Former paragraph (f)(2) allowed practitioners to use a multi-disciplinary committee process for patients who lack decision-making capacity and have no surrogates, but it is very detailed and lengthy. We retain that content but bifurcate it for the sake of clarity. Paragraph (e)(2)(ii)(A) focuses on treatments and procedures that involve minimal risk, while paragraph (e)(2)(ii)(B) addresses treatments and procedures that require signature consent. The content of paragraphs (e)(2)(ii)(A) and (B) is substantively the same as former paragraph (f), with one exception. In paragraph (e)(2)(ii)(B) we now state that if the patient has valid standing orders regarding life-sustaining treatment, such as State Authorized Portable Orders, review by a multi-disciplinary committee appointed by the facility Director is not required for a decision to withhold or withdraw life-sustaining treatment. For such patients, the requirement to request the assistance of District Chief Counsel in obtaining a legal guardian for health care or to initiate the multi-disciplinary process is effectively superseded. This approach is consistent with VA’s commitment to promoting patient-centered care and ensuring that veterans’ values, goals, and treatment preferences are respected and reflected in the care they receive. Valid standing

orders should be the basis for any patient’s VA treatment plan.

Special Consent Situation

Former paragraph (g) addressed special consent situations where the patient is granted special additional procedural due process protections. We redesignate this paragraph as paragraph (f). The three “special consent situations” specifically addressed in former paragraph (g) are unusual or extremely hazardous treatments or procedures (e.g., those that may result in irreversible brain damage or sterilization), administration of psychotropic medication to an involuntarily committed patient against his or her will, and proposed procedures or courses of treatment related to approved medical research.

We delete the provisions in former paragraph (g)(1) relating to unusual or extremely hazardous treatments or procedures. This paragraph was intended to provide enhanced protection against now archaic practices of forced sterilization and lobotomy, neither of which are performed by VA. As VA no longer performs the types of treatments or procedures contemplated in this paragraph, we believe continuing to include it in our informed consent rule is unnecessary and potentially misleading to the public. VA believes that the existing informed consent processes and procedures adequately protect patients undergoing other types of procedures that carry significant risk.

Former paragraph (g)(2) is redesignated as paragraph (f)(1). In paragraph (f)(1), we state that in involuntary commitment cases where the forced administration of medications is against the patient’s will or the surrogate’s non-consent, procedural protections identified therein must be provided. These protections were already set forth together in former § 17.32(g)(2), although here we set the elements out in separate paragraphs (f)(1)(i)–(iii) for ease of reading.

Former paragraph (g)(3), relating to the need for informed consent for a proposed course of treatment or procedure that is part of approved medical research, is redesignated as paragraph (f)(2). We also make non-substantive changes to the language to enhance clarity and readability.

Advance Directives

Former paragraph (h) is titled “Advance health care planning” and addresses issues related to the VA Advance Directive. This includes general principles, patient signature and witness requirements, revocation, and

instructions given by a patient in critical situations. We make several changes to this paragraph. We redesignate this paragraph as paragraph (g) and revise the paragraph header to “Advance directives.” We also make non-substantive changes to this paragraph for the purpose of clarity and substantive changes as noted in the following discussion.

The introductory text to former paragraph (h) is redesignated as paragraph (g)(1). Paragraph (h) previously stated that 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. In redesignated paragraph (g)(1), we modify that language by inserting “within a reasonable period of time” after “regain it”. VA believes the former language could be misinterpreted to mean that the practitioner should not rely on an advance directive unless the patient is never expected to regain decision-making capacity. The amended language addresses that potential misperception. We also add introductory language to redesignated paragraph (g)(1) to reflect that a patient’s wishes are to be followed to the extent they are consistent with applicable Federal law, VA policy, and generally accepted standards of medical practice. This reflects current practice, but its codification serves to provide public notice of these practice limitations.

The introductory information in former paragraph (h) provided that an advance directive that is valid in one or more States under applicable State law will be recognized throughout the VA health care system. In redesignated paragraph (g)(1), VA modifies that language slightly for purposes of clarification. It provides that valid advance directives will be recognized throughout the VA health care system, with the exception of any components that are inconsistent with applicable Federal law, VA policy, or generally accepted standards of medical practice. This clarification is not a change in practice, as former § 17.32(h)(4) provided that clear instructions in an advance directive or instructions in critical situations will not be given effect if inconsistent with VA policy. Moreover, the terms of 38 CFR 17.38(b) require all VA care to be in accord with generally accepted standards of medical care. So, the language added to the introductory information just clarifies how, even if an advance directive is valid in a state, VA will not honor a provision therein that is inconsistent

with applicable Federal law, policy, or generally accepted standards of medical practice. This is intended to help underscore that VA is a Federal health care system with its own rules governing valid advance directives. Without this clarification, paragraph (g) could be misinterpreted to mean that VA practitioners must, in honoring a patient’s state-authorized advance directive, comply with that state’s standards and procedures. Such an interpretation could be inconsistent with the Supremacy Clause of the U.S. Constitution. U.S. Const. art. VI, cl 2.

Former paragraph (h)(1) addresses signature and witness requirements for a VA Advance Directive. We redesignate this as paragraph (g)(2). A VA Advance Directive must be signed by the patient in the presence of two witnesses. This remains VA practice.

As stated, former § 17.32(h)(1) requires the patient to sign the form. It does not, however, provide an alternative means for signing if a physical impairment prevents the patient from signing the VA Advance Directive. We remedy this by using the same approach used in paragraph (d)(3)(i), related to signature consent forms. Specifically, in paragraph (g)(2) we allow such a patient to provide signature consent by placing an “X”, thumbprint, or stamp on the form. In addition, we permit a patient to designate a third party to sign the directive at the direction of the patient and in the presence of the patient.

Under the old rule, 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. We now add language stating that neither witness may be the third party designated by the patient to sign at the patient’s direction and in the patient’s presence.

Former paragraph (h)(1) indicated that except for specific classes of employees that are listed in § 17.32, VA clinical employees are not permitted to serve as witness, with a few stated exceptions: VA employees of the Chaplain Service, Psychology Service, and Social Work Service may serve as witnesses. We remove, and do not include in paragraph (g)(2), the prior bar on these VA employees serving as witnesses, based on what the contemporary legal and ethics literature describes as an unnecessary burden to completion of advance directives. Although the originally-intended purpose of restricting who, among staff, may serve as a witness was meant to protect patients, as mentioned above, the current literature observes that there is

no evidence that the restrictions fulfill these purposes. Rather, they make it difficult for patients, especially those who are socially isolated or homeless, to complete an advance directive. In addition, the witnesses to an advance directive play no substantive role; they are attesting only to the fact that they saw the patient sign the form. Given that many clinicians play a substantial role in guiding the care of veterans, the literature does not support disqualifying them from serving as witnesses; that is, performing this non-substantive attestation.

For the same reasons, it is illogical to allow social workers and psychologists involved in the patient’s care to serve as witnesses but prohibit nurses and physicians from serving as witnesses if they are available to do so.

Finally, in addition to creating a barrier to completion of advance directives, witness restrictions can have the harmful consequence of providing narrow technical grounds for family members, who do not agree with a patient’s stated substantive treatment wishes, to challenge the validity of the patient’s directive (in toto). Such challenges undermine a patient’s use of an advance directive as an exercise of the patient’s personal autonomy. Thus, VA believes that our patients are best served by removing restrictions on which VA employees may serve as witnesses under this section.

Former paragraphs (h)(2) through (4) are redesignated as paragraphs (g)(3) through (5), respectively. The content related to instructions in critical situations essentially remain the same but for the changes reflected herein. In paragraph (g)(3), VA’s goal is to honor the unambiguous verbal or non-verbal instructions of a patient with decision-making capacity in situations when they are critically ill and their loss of decision-making capacity is imminent—even if those instructions are different from preferences expressed earlier in an advance directive. The existence of a critical clinical situation does not diminish the right of a patient with decision-making capacity to accept or refuse treatments.

We modify the requirement related to documentation of a patient’s instructions in a critical situation by co-signature, as co-signature is not a functionality in the electronic health record. Under previous rulemaking, the patient’s instructions in critical situations must be expressed to at least two members of the health care team, the substance of these instructions recorded in a progress note in the patient’s health record, and the note co-signed by at least two members of the

team who were present and who can attest to the wishes expressed by the patient. We now require when a patient provides instructions in critical situations, expressed to at least two members of the health care team, 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. Former paragraphs (h)(3) and (4) is unchanged and are redesignated as paragraphs (g)(4) and (5).

We also update the parenthetical information included at the end of § 17.32 that is related to information collection requirements to refer to the correct Office of Management and Budget (OMB) control number covering information collection related to advance care planning. OMB control number 2900-0583 expired in 2008, and the currently approved OMB control number related to this information collection is 2900-0556.

Administrative Procedure Act

The Secretary of Veterans Affairs finds that there is good cause under the provisions of 5 U.S.C. 553(b)(B), to publish this interim final rule without prior notice and the opportunity for public comment, and under 5 U.S.C. 553(d)(3), to dispense with the delayed effective date ordinarily prescribed by the Administrative Procedure Act (APA).

Pursuant to section 553(b)(B) of the APA, general notice and the opportunity for public comment are not required with respect to a rulemaking when an "agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." The Secretary finds that it is impractical to delay issuance of this rule for the purpose of soliciting prior public comment because there is an immediate and pressing need for VA to respond to the current public health crisis and national emergency by ensuring (1) effective use of health care resources as part of the announced VA contingent/crisis standards of care, including identification of which practitioners may be allowed to obtain informed consent from patients or surrogates for clinical treatments and procedures and by providing alternative methods and modalities for doing so when having the informed consent discussion or obtaining consent in-person is not practicable; (2) use of facilitated processes and procedures by which to provide patients or their surrogates with

adequate information during an informed consent discussion; (3) use of procedures and processes by which patients, their surrogates, or VA health care practitioners may effectively communicate and document informed consent for treatments and procedures through available electronic means; (4) recognition in regulation of State Authorized Portable Orders; and, (5) immediate implementation of changes to the advance care planning process (including amending signature and witness requirements for a VA advance directive) to remove barriers to veterans documenting treatment preferences in the event of a loss of decision making capacity.

Multiple provisions of this interim final rule directly support VA's response to the COVID-19 public health emergency, and improve our ability to provide timely quality health care to patients.

Changes to the definition of "practitioner" allows VA to shift health care resources as needed to meet requirements for obtaining informed consent as well as other patient needs. Adding regulatory recognition of SAPOs supports the health care needs of critically ill incoming patients with SAPOs in ensuring that the portable order is recognized and honored by VA. This definition assists VA health care providers in understanding the distinction between SAPOs and Advance Directives. VA believes recognizing SAPOs will prevent delays in translating these orders into VA orders so that they may be of-record and complied with.

This interim final rule revises multiple elements of the informed consent process and provides VA with flexibility to address the current public health emergency. In the absence of these revisions, VA cannot adequately respond to COVID-19-related issues related to informed consent because our regulation did not provide for waiver of certain regulatory requirements. Revising the general requirements for informed consent supports VA's response to COVID-19 under VA contingent/crisis standards of care where the patient needs to have all the appropriate information to make an informed consent decision for both non-COVID care and COVID care. As an example, some inpatients receiving care for other conditions need to understand the risk of getting inpatient care there amidst the current emergency such that it may be difficult to prevent possible transmission of the infection to non-infected patients. Changes to requirements related to the setting in which informed consent may be

obtained supports providing treatment and evaluation to our many outpatients receiving medical services via telehealth. These patients cannot see their provider in person under the current public health restrictions. VA needs flexibility in obtaining informed consent through these new modalities. In addition, the need to place COVID-19 inpatients in separate wards and block certain staff from accessing patients in these areas prevents some practitioners and staff from having in-person discussions with inpatients. Flexibility is needed to adjust with a continually changing delivery of care system during a pandemic.

Allowing for delegation of some duties for providing information to patients related to informed consent gives VA necessary flexibility to delegate this responsibility in a manner aligned with the current standards of care and reallocation of resources.

Delineating documentation requirements to informed consent for low risk treatments and procedures supports VA contingent/crisis standards of care by easing documentation requirements for these procedures. These changes help VA address the need for flexibility in how signature consent for low risk procedures documented. Providing a mechanism for obtaining signature consent where the patient has a physical impairment supports VA contingent/crisis standards of care because many patients unable to sign signatures due to their critical condition. These changes help VA address need for flexibility during contingent/crisis standards of care and scarce resources allocation. Allowing for third-party assistance in documentation of signature consent provides VA with necessary flexibility during contingent/crisis standards of care and scarce resources allocation. This change removes a needless procedural obstacle that hinders VA's ability to obtain valid consent when time is of the essence. Third-party assistance is needed in many COVID-19 cases where the need for treatment urgent or emergent and the patient with decision making capacity is unable to physically place an "X" on the consent form.

Removing the mandatory rescission provision for informed consent in certain situations eliminates unnecessary evaluative steps where a change in condition is de minimis and will not affect outcomes and keeps the consent process active and up-to-date. Providing for other communication modalities for completing and documenting the signature consent requirement is necessary under VA contingent/crisis standards of care

where telehealth being used for many patients, including those with suspected COVID-19 as well as other non-COVID patients. Currently, the emergency compels compliance with social distance and separation guidance, making it impossible to comply with many current procedures and requirements. Revising documentation requirements where the informed consent discussion is not held face to face supports COVID-19 response needs under VA contingent/crisis standards of care where the phone or/telehealth is more practicable for the informed consent discussion with patients, including those at home with suspected COVID-19. VA could not waive regulatory requirements under the prior rulemaking, which potentially caused disruption and created obstacles to the informed consent process where providers and patients are more and more necessarily geographically separated and unable to meet in person.

Clarifying that VA cannot honor certain preferences in an advance directive supports VA standards of care in which health care teams must be able to act on patient's advance directive in real time but still be aware that we do not enforce provisions inconsistent with Federal law, VA policy, or generally accepted standards of medical practice. Revising the rule on how a physically incapacitated patient, or a patient unable to physically sign because of medical equipment in use, may sign an advance directive provides us needed flexibility, especially with respect to use of a designated third party. Removing restrictions on who may serve as witness to the signing of an advance directive allows us to better serve patients who are in isolation wards or areas that are off-limits to non-health care team members. Under the previous rule precious time was lost trying to locate suitable VA employees and then they find work arounds whereby the remote employee can witness the patient signing the form by being in the line of sight but at a safe distance.

Removing unnecessary documentation requirements related to patient instructions given in critical situations ensures that the patient's wishes and instructions can be acted upon promptly.

For these reasons, the Secretary has concluded that ordinary notice and comment procedures would be both impracticable and contrary to the public interest, and is accordingly issuing this rule as an interim final rule. The Secretary will consider and address comments that are received within 60 days after the date that this interim final rule is published in the **Federal**

Register, and address them in a subsequent **Federal Register** document announcing a final rule incorporating any changes made in response to the public comments.

The APA also requires a 30-day delayed effective date, except for “(1) a substantive rule which grants or recognizes an exemption or relieves a restriction; (2) interpretative rules and statements of policy; or (3) as otherwise provided by the agency for good cause found and published with the rule.” 5 U.S.C. 553(d). For the reasons stated above, the Secretary finds that there is also good cause for this interim rule to be effective immediately upon publication. It is in the public interest for VA to immediately adopt the process changes noted above to provide for effective utilization of VA practitioners as it relates to the informed consent process during this period of increased demand for health care, to provide flexibility to utilize alternative modalities of communications during the COVID-19 National Emergency, and remove barriers to veterans documenting treatment preferences in an advance directive. By relieving these restrictions and barriers, and making necessary processes changes, the Secretary finds good cause to exempt this interim final rule from the APA's delayed effective date requirement.

Paperwork Reduction Act

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

This interim final rule will impose the following revised information collection requirements to an existing information collection approved by OMB under OMB Control Number 2900-0556. As required by the Paperwork Reduction Act of 1995 (at 44 U.S.C. 3507(d)), VA has submitted this rulemaking and the information collection revisions to OMB for approval. Notice of OMB approval for this information collection will be published in a future **Federal Register** document.

Information collection under OMB Control number 2900-0556 relates to collection of information related to patients documenting treatment preferences on an approved VA form. VA Form 10-0137, VA Advance Directive: Durable Power of Attorney for

Health Care and Living Will, is the VA recognized legal document that permits VA patients to designate a health care agent and/or specify preferences for future health care. The VA Advance Directive is invoked if a patient becomes unable to make health care decisions for him or herself. This rulemaking revises the information collection only as it relates to restrictions on certain VA employees serving as witness to a patient executing VA Form 10-0137.

These restrictions are reflected in the form's instructions. We note that for clarity that consent for VA medical treatment by the patient or surrogate is not a collection of information as defined by the Paperwork Reduction Act.

Title 38 CFR 17.32(g) contains a collection of information under the Paperwork Reduction Act of 1995. If OMB does not approve the collection or of information as requested, VA will immediately remove the provisions containing a collection of information or take such other action as is directed by OMB.

We are also revising the information collection, in the case of a close friend designated by VA as a surrogate decision maker, to require the signed written statement for the record that describes that person's relationship to and familiarity with the patient in the definition of a close friend who may serve as a surrogate.

Comments on the revision of the collection of information contained in this interim final rule should be submitted to the Office of Management and Budget, Attention: Desk Officer for the Department of Veterans Affairs, Office of Information and Regulatory Affairs, 727 17th St NW, Washington, DC 20503. Comments should indicate that they are submitted in response to “RIN 2900-AQ97.”

OMB will take action on the revision of the information collection contained in this rule between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment on the interim rule.

The Department considers comments by the public on proposed collections of information in—

- Evaluating whether the proposed collections of information are necessary for the proper performance of the functions of the Department, including whether the information will have practical utility;
- Evaluating the accuracy of the Department's estimate of the burden of

the proposed collections of information, including the validity of the methodology and assumptions used;

- Enhancing the quality, usefulness, and clarity of the information to be collected; and
- Minimizing the burden of the collections of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, such as permitting electronic submission of responses.

The collection of information contained in 38 CFR 17.32 is described immediately following this paragraph.

Title: Durable Power of Attorney for Health Care and Living Will, VA Advance Directive.

OMB control number 2900–0556 (amended).

Summary of collection of information: OMB Control number 2900–0556 relates to collection of information related to patients documenting treatment preferences on an approved VA form. VA Form 10–0137, VA Advance Directive: Durable Power of Attorney for Health Care and Living Will, is the VA recognized legal document that permits VA patients to designate a health care agent and/or specify preferences for future health care. The VA Advance Directive is invoked if a patient becomes unable to make health care decisions for him or herself. Former 38 CFR 17.32 stipulates that 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 your VA facility may not sign as witnesses to the advance directive unless they are your family members. The interim final rule removes restrictions on VA employees signing as a witness to execution of a VA advance directive. Witness restrictions are reflected in the instructions found in the most recent version of VA Form 10–0137, and those restrictions will be removed from the form instructions if the interim final rule becomes final. We note that revisions to the rule regarding removing the restrictions on the types of VA employees who are authorized to serve as a witness to execution of an advance directive impact time that would be expended by a veteran trying to locate a suitable witness rather than a collection of information which is defined at 5 CFR 1320.3(c) as the obtaining, causing to be obtained, soliciting, or requiring the disclosure to

an agency, third parties or the public of information by or for an agency by means of identical questions posed to, or identical reporting, recordkeeping, or disclosure requirements imposed on, ten or more persons, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit. Collection of information includes any requirement or request for persons to obtain, maintain, retain, report, or publicly disclose information.

In addition to VA Form 10–0137, the information collection would be expanded to include, in the case of a close friend designated by VA as a surrogate decision maker, the signed written statement for the record that describes that person's relationship to and familiarity with the patient in the definition of a close friend who may serve as a surrogate. For purposes of this analysis we estimate that 300 individuals each year are a close friend as that term is used in § 17.32, are designated by VA as a surrogate decision maker, and are therefore required to submit a signed written statement for the record that describes that person's relationship to and familiarity with the patient. We estimate that the signed written statement would take 10 minutes to complete.

Description of the need for information and proposed use of information: The collection of information is necessary to facilitate the process of advance care planning for veterans who elect to complete a VA advance directive to designate a health care agent and/or record their preferences for future health care. Advance directives are legal documents that allow a patient to spell out preferences about end-of-life care ahead of time. Advance directives are utilized to communicate treatment preferences and wishes to family, friends, and health care professionals and to avoid confusion later on. The document may also be used by the veteran to designate a health care agent to make decisions on behalf of the veteran following loss of decision-making capacity. Completion of an advance directive by a VA patient is entirely voluntary. The decision to complete an advance directive has no bearing on a patient's right or ability to access VA health care. If a patient completes an advance directive and the completed document is provided to a VA practitioner, the information it contains is used to identify the appropriate health care decision maker and to inform decisions about the patient's care. The form is signed by the veteran in the presence of two witnesses, and the witnesses must sign the form attesting that they were present

and witnessed the veteran signing the advance directive form. Information contained in the VA Advance Directive is used routinely in VA to help surrogates and clinicians decide what treatments or procedures to provide to patients who have lost decision-making capacity. For close friends designated as a surrogate decision maker, the signed written statement is required to document the nature of the relationship and familiarity with the patient. The following calculations represent changes to the information collection attributable to documentation required from close friends designated as a surrogate decision maker.

Description of likely respondents: Veterans who want to use the approved VA form to document their preferences for future care in the event they lose decision making capacity, and to identify the appropriate health care decision maker, and individuals who agree to serve as a surrogate decision maker and qualify under the definition of close friend.

Estimated number of respondents per year: 300.

Estimated frequency of responses per year: One response annually.

Estimated average burden per response: 10 minutes.

Estimated cost to respondents per year: VA estimates the total cost to all respondents to be \$1,286 (50 burden hours X \$25.72 per hour). The Bureau of Labor Statistics gathers information on full-time wage and salary workers. Assuming a forty (40) hour work week, the mean hourly wage is \$25.72 based on the BLS wage code—"00–0000 All Occupations." This information was taken from the following website: https://www.bls.gov/oes/current/oes_nat.htm#00-0000 May 2019.

Estimated total annual reporting and recordkeeping burden: 50 hours in FY2020 and 50 hours in FY2021.

Regulatory Flexibility Act

The Secretary hereby certifies that this interim rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601–612, because it affects only the informed consent process and use of advance directives within the VA health care system.

Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Executive Orders 12866, 13563, and 13771

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. The Office of Information and Regulatory Affairs has determined that this rule is a significant regulatory action under Executive Order 12866.

VA's impact analysis can be found as a supporting document at <http://www.regulations.gov>, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact analysis are available on VA's website at <http://www.va.gov/orpm> by following the link for VA Regulations Published from FY 2004 through FYTD. This rule is not subject to the requirements of E.O. 13771 because this rule results in no more than *de minimis* costs.

Unfunded Mandates

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This interim final rule will not result in the expenditure of \$100 million or more by State, local, and tribal governments, in the aggregate, or by the private sector.

Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs designated this rule as not a major rule, as defined by 5 U.S.C. 804(2).

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.008—Veterans Domiciliary Care; 64.011—Veterans Dental Care; 64.012—Veterans Prescription Service; 64.013—Veterans Prosthetic Appliances; 64.014—Veterans State Domiciliary Care; 64.015—Veterans State Nursing

Home Care; 64.024—VA Homeless Providers Grant and Per Diem Program; 64.026—Veterans State Adult Day Health Care; 64.029—Purchase Care Program; 64.039—CHAMPVA; 64.040—VHA Inpatient Medicine; 64.041—VHA Outpatient Specialty Care; 64.042—VHA Inpatient Surgery; 64.043—VHA Mental Health Residential; 64.044—VHA Home Care; 64.045—VHA Outpatient Ancillary Services; 64.046—VHA Inpatient Psychiatry; 64.047—VHA Primary Care; 64.048—VHA Mental Health clinics; 64.049—VHA Community Living Center; 64.050—VHA Diagnostic Care; 64.054—Research and Development.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records, Homeless, Medical and Dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Pamela Powers, Chief of Staff, Department of Veterans Affairs, approved this document on November 22, 2019, for publication.

Consuela Benjamin,

Regulation Development Coordinator, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs.

For the reasons set out in the preamble, VA amends 38 CFR part 17 as follows:

PART 17—MEDICAL

■ 1. The authority citation for part 17 is amended by adding an authority for § 17.32 in numerical order to read in part as follows:

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

Section 17.32 also issued under 38 U.S.C. 7331–7334.

* * * * *

■ 2. Revise § 17.32 to read as follows:

§ 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 in 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)

[FR Doc. 2020-10264 Filed 5-26-20; 8:45 am]

BILLING CODE 8320-01-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 27

[GN Docket No. 18-122; FCC 20-22; FRS 16735]

Expanding Flexible Use of the 3.7 to 4.2 GHz Band

AGENCY: Federal Communications Commission.

ACTION: Final rule; announcement of compliance date.

SUMMARY: In this document, the Commission announces that the Office of Management and Budget (OMB) has approved the information collection requirements associated with the eligible space station operator accelerated relocation election, eligible space station operator transition plan, and incumbent earth station lump sum payment election rules adopted in the Federal Communications Commission's (Commission) *3.7 GHz Report and Order*, FCC 20-22, and that compliance with the new rules is now required. This document is consistent with the *3.7 GHz Report and Order*, FCC 20-22, which states that the Commission will publish a document in the **Federal Register** announcing a compliance date for the new rule sections and revise the Commission's rules accordingly.

DATES: Compliance date: Compliance with 47 CFR 27.1412(c) introductory text, (c)(2), 27.1412(d) introductory text and (d)(1), and 27.1419, published at 85 FR 22804 on April 23, 2020, is required on May 27, 2020.

FOR FURTHER INFORMATION CONTACT: Anna Gentry, Mobility Division, Wireless Telecommunications Bureau, at (202) 418-7769 or Anna.Gentry@fcc.gov.

SUPPLEMENTARY INFORMATION: This document announces that OMB approved the information collection requirements in §§ 47 CFR 27.1412(c) introductory text, (c)(2), 27.1412(d) introductory text and (d)(1), and 27.1419, on May 5, 2020. These rules were adopted in the *3.7 GHz Report and Order*, FCC 20-22, published at published at 85 FR 22804 on April 23, 2020. The Commission publishes this document as an announcement of the compliance date of these new rules. OMB approval for all other new or amended rules for which OMB approval is required will be requested, and compliance is not yet required for those rules. Compliance with all new or amended rules adopted in the *3.7 GHz Report and Order* that do not require OMB approval will be required as of June 22, 2020, *see* 85 FR 22804 (Apr. 23, 2020).

If you have any comments on the burden estimates listed below, or how the Commission can improve the collections and reduce any burdens caused thereby, please contact Cathy Williams, Federal Communications Commission, Room 1-C823, 445 12th Street, SW, Washington, DC 20554, regarding OMB Control Number 3060-1272. Please include the OMB Control Number in your correspondence. The Commission will also accept your comments via email at PRA@fcc.gov.

To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an email to fcc504@fcc.gov or call the Consumer and Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY).

Synopsis

As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), the Commission is notifying the public that it received final OMB approval on May 5, 2020, for the information collection requirements contained in §§ 47 CFR 27.1412(c) introductory text, (c)(2), 27.1412(d) introductory text and (d)(1), and 27.1419. Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information