as an additional source of service information for replacing the flap transmission shafts.

Repetitive Inspections

(g) Repeat the inspection required by paragraph (f) of this AD at the applicable times specified in paragraph (g)(1), (g)(2), and (g)(3) of this AD.

(1) Before further flight after any occurrence of jamming of the flap transmission system.

(2) At intervals not to exceed 2,000 flight hours after each flap asymmetry protection test performed in accordance with 14 CFR 39.19.

(3) At intervals not to exceed 8,000 flight cycles after each flap asymmetry protection test performed in accordance with MPD task 275600–02–1.

Optional Terminating Action

(h) Replacing any flap transmission shaft with a new or reconditioned transmission shaft in accordance with the Accomplishment Instructions of Airbus Service Bulletin A310–27–2095, dated March 29, 2000, ends the inspections required for that transmission shaft only.

Actions Performed Using Previously Issued Service Information

(i) Actions performed in accordance with Airbus Service Bulletin A310–27–2092, dated April 9, 1999, or Revision 01, dated December 11, 2001, are considered acceptable for compliance with the corresponding requirements of this AD.

Alternative Methods of Compliance (AMOCs)

(j)(1) The Manager, International Branch, ANM–116, FAA, Transport Airplane Directorate, has the authority to approve AMOCs for this AD, if requested in accordance with the procedures found in 14 CFR 39.19.

(2) Before using any AMOC approved in accordance with § 39.19 on any airplane to which the AMOC applies, notify the appropriate principal inspector in the FAA Flight Standards Certificate Holding District Office.

Related Information

(k) French airworthiness directive F–2005–174, dated October 26, 2005, also addresses the subject of this AD.

Issued in Renton, Washington, on February 28, 2006.

Kalene C. Yanamura.
Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17
RIN 2900–AM19

Medical: Informed Consent—Extension of Time Period and Modification of Witness Requirement for Signature Consent

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the U.S. Department of Veterans Affairs (VA) medical regulations on informed consent by making two substantive changes. We propose to extend the period of time during which a signed consent form remains valid from 30 to 60 days and eliminate the requirement that a third party witness the patient or surrogate and practitioner signing the consent form, except in those circumstances where the patient or surrogate signs with an “X” due to a debilitating illness or disability, i.e., significant physical impairment and/or difficulty in executing a signature due to an underlying health condition(s), or is unable to read or write.

DATES: Comments must be received on or before: May 8, 2006.

ADDRESSES: Written comments may be submitted by mail or hand delivery to: Director, Regulations Management (00REG1), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1068, Washington, DC 20420; fax comments to (202) 273–9026; or e-mail comments through http://www.Regulations.gov. Comments should indicate that they are submitted in response to “RIN 2900–AM19.” All comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 273–9515 for an appointment.

FOR FURTHER INFORMATION CONTACT: Ruth Cecire, PhD., Policy Analyst, Ethics Policy Service, National Center for Ethics in Health Care (10E), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420; 202–501–2012 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: Section 7331 of title 38, United States Code (U.S.C.), directs the Secretary of Veterans Affairs to promulgate regulations to ensure that, to the maximum extent practicable, all patient care carried out under the authority of title 38 U.S.C. is accomplished with the informed consent of the patient or the patient’s surrogate. These VA medical regulations, set forth at 38 CFR 17.32 and titled “Informed Consent”, were published in the Federal Register as a final rule on October 2, 1997 (62 FR 53961).

The proposed rule would amend VA medical regulations on informed consent. Specifically, it would extend the time during which a signed consent form is valid from 30 to 60 days. Also, it would eliminate the requirement that a consent form be witnessed, except in those situations where the patient or surrogate signs with an “X”. We are specifically interested in obtaining comments from non-VA providers, patients and other concerned community members with respect to both of these changes.

Often, the informed consent discussion takes place and the requisite forms are signed before a procedure is scheduled. Under the current rule, a signed consent form is valid for 30 days. If the procedure is later scheduled for a date beyond that 30 day window, the patient and practitioner must sign and date a new consent form. In our experience a number of treatments or procedures that require signature consent are scheduled more than 30 days in advance. Extending the period during which signed consent forms remain valid would enable patients to avoid having to return to the facility just to sign a new form or to re-sign when they come for the procedure.

Under current regulations, witnesses who sign the consent form only attest to the fact that they saw the patient and the practitioner sign the form. They do not attest to the content of the informed consent discussion, or that the process was voluntary, or that the patient was capable of giving informed consent. Nor do they attest to the identity of the individuals signing the form. Experience has shown that finding an appropriate witness is sometimes difficult and creates an impediment to the timely completion of the informed consent process. Given the above, it is not clear that the witness requirement benefits the veteran, especially since there are other means to verify the signatures if there is a dispute, e.g., by comparing the signature on the form against other documents signed by the patient. Therefore, we do not think it necessary to continue this practice for general signature consent. However, two witnesses would still be required to sign the consent form when the patient or surrogate signs with an “X”.

In addition, we propose to make the following non-substantive changes to § 17.32: in paragraph (a), removing ,
e.g., a published numbered VA form (OF 522) or comparable form approved by the local VA facility”; and in paragraph (d)(2), removing “OF522”. These references to OF522, Request for Administration of Anesthesia and Performance of Operations and Other Procedures, are obsolete. Use of the OF522, which is a general form, in VA health care facilities is being phased out. Facilities now have access to procedure-specific VA-authorized consent forms.

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 an expenditure by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million or more (adjusted annually for inflation) in any given year. This rule would have no such effect on State, local, or tribal governments, or the private sector.

Paperwork Reduction Act of 1995

This rule contains no new collections of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521). The existing information collections associated with the informed consent procedures under §17.32 have been approved by OMB under 2900–0853.

Executive Order 12866

Executive Order 12866 directs agencies to assess all 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, and other advantages; distributive impacts; and equity). The Order classifies a rule as a significant regulatory action requiring review by the Office of Management and Budget if it meets any one of a number of specified conditions, including: Having an annual effect on the economy of $100 million or more; creating a serious inconsistency or interfering with an action of another agency, materially altering the budgetary impact of entitlements or the rights of entitlement recipients, or raising novel legal or policy issues. VA has examined the economic, legal, and policy implications of this proposed rule and concluded that it is a significant regulatory action because it raises novel policy issues.

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed 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. The rule will affect only individuals and will not directly affect any small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rule is exempt from the initial and final regulatory flexibility analysis requirements of sections 603 and 604.

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the programs affected by this document are 64.009, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; and 64.011, Veterans Dental Care.

List of Subjects in 38 CFR Part 17

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Foreign relations, 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, Philippines, Reporting and recordkeeping requirements, Scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: November 29, 2005.

Gordon H. Mansfield,
Deputy Secretary of Veterans Affairs.

For the reasons set out above, VA proposes to amend 38 CFR part 17 to read as follows:

PART 17—MEDICAL

1. The authority citation for part 17 is revised to read as follows:

   Authority: 38 U.S.C. 501, 1721, and as stated in specific sections.

2. Section 17.32 is amended by:

   a. Revising the section heading.
   b. In paragraph (a), in the definition of signature consent, removing “,” e.g., a published numbered VA form (OF 522) or comparable form approved by the local VA facility”.
   c. Revising paragraph (d)(2).
   d. Revising the authority citation at the end of the section.

The revisions read as follows:

§17.32 Informed consent and advance care planning.

(a) * * * *

(d) * * * *

(2) A patient or surrogate will sign with an “X” when the patient or surrogate has a debilitating illness or disability, i.e., significant physical impairment and/or difficulty in executing a signature due to an underlying health condition(s), or is unable to read or write. When the patient’s or surrogate’s signature is indicated by an “X”, two adults must witness the act of signing. By signing, the witnesses are attesting only to the fact that they saw the patient or surrogate and the practitioner sign the form. The signed form must be filed in the patient’s medical record. A properly executed VA-authorized consent form is valid for a period of 60 calendar days. If, however, the treatment plan involves multiple treatments or procedures, it will not be necessary to repeat the informed consent discussion and documentation so long as the course of treatment proceeds as planned, even if treatment extends beyond the 60-day period. If there is a change in the patient’s condition that might alter the diagnostic or therapeutic decision, the consent is automatically rescinded.

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(Authority: 38 U.S.C. 7331–7334)

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52


Approval and Promulgation of Implementation Plans; Alabama: State Implementation Plan Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is approving revisions to the Alabama State Implementation Plan (SIP), submitted by the Alabama Department of Environmental Management (ADEM) on September 11, 2003. The revisions include modifications to Alabama’s open burning rules found at Alabama Administrative Code (AAC) Chapter 335–3–3–01. These revisions are part of Alabama’s strategy to meet the national ambient air quality standards by reducing emissions of volatile organic compounds and nitrogen oxides. Open burning creates smoke that contains fine particles (PM$_{2.5}$) and precursors to ozone. ADEM has found that elevated levels of PM$_{2.5}$ mirror the months when ozone levels are highest (May–September). These rules are intended to help control levels of PM$_{2.5}$ and ozone precursors that contribute to high ozone