Harvest limits	Open season
Remainder of Unit 26	No open season.
Muskox:	
Unit 26(C)—1 bull by Federal registration permit only; up to 15 permits may be issued to rural Alaska residents of the village of Kaktovik only. Public lands are closed to the taking of muskox, except by rural Alaska residents of the village of Kaktovik during seasons identified above.	Sept. 15–Mar. 31.
Coyote:	
2 coyotes	Sept. 1–Apr. 30.
Fox, Arctic (Blue and White Phase):	
2 foxes	Sept. 1–Apr. 30.
Fox, Red (including Cross, Black and Silver Phases):	
Unit 26(A) and (B)—10 foxes; however, no more than 2 foxes may be taken prior to Oct. 1	Sept. 1–Mar. 15.
Unit 26(C)—10 foxes	Nov. 1–Apr. 15.
Hare (Snowshoe and Tundra):	
No limit	July 1–June 30.
Lynx:	
2 lynx	Nov. 1–Apr. 15.
Wolf:	
15 wolves	Aug. 10–Apr. 30.
Wolverine:	
5 wolverine	Sept. 1–Mar. 31.
Grouse (Spruce, Blue, Ruffed, and Sharp-tailed):	
15 per day, 30 in possession	Aug. 10–Apr. 30.
Ptarmigan (Rock, Willow, and White-tailed):	
20 per day, 40 in possession	Aug. 10–Apr. 30.
Trapping	
Coyote:	
No limit	Nov. 1–Apr. 15.
Fox, Arctic (Blue and White Phase):	
No limit	Nov. 1–Apr. 15.
Fox, Red (including Cross, Black and Silver Phases):	
No limit	Nov. 1–Apr. 15.
Lynx:	
No limit	Nov. 1–Apr. 15.
Marten:	
No limit	Nov. 1–Apr. 15.
Mink and Weasel:	
No limit	Nov. 1–Jan. 31.
Muskrat:	
No limit	Nov. 1–June 10.
Otter:	
No limit	Nov. 1–Apr. 15.
Wolf:	
No limit	Nov. 1–Apr. 30.
Wolverine:	
No limit	Nov. 1–Apr. 15.

Dated: June 12, 1996.

Mitch Demientieff,

Chair, Federal Subsistence Board.

Dated: June 12, 1996.

John C. Capp,

Acting Regional Forester, USDA-Forest Service.

[FR Doc. 96–18609 Filed 8–6–96; 8:45 am]

BILLING CODE 3410–1LM; 4310–55–M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AH72

Informed Consent for Patient Care

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend VA regulations concerning informed consent for patient care. It is proposed to describe the requirements for obtaining and documenting informed consent. It is also proposed to describe the types of treatments or procedures for which the patient's signature on a VA-authorized form would be required and to establish a list and priority of surrogates authorized to act on behalf of patients who lack decision-making capacity. Further, it is proposed to establish an internal decision-making process for patients who lack decision-making capacity and who have no authorized surrogate. This is intended to protect patient rights and ensure that the patient (or the patient's surrogate or representative) receives sufficient information to make an informed health-care decision.

DATE: Comments must be received on or before October 7, 1996.

ADDRESSES: Mail or hand deliver written comments to: Director, Office of Regulations Management (02D), Department of Veterans Affairs, 810 Vermont Avenue, NW, Room 1154, Washington, DC 20420. Comments should indicate that they are submitted in response to ''RIN 2900–AH72.'' All written comments will be available for public inspection at the above address in the Office of Regulations Management, Room 1158, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays).

FOR FURTHER INFORMATION CONTACT: Ruth-Ann Phelps, Ph.D., Veterans Health Administration, Office of Professional Affairs (10A2), 810 Vermont Avenue, NW, Washington, DC 20420, (202) 273–5813.

SUPPLEMENTARY INFORMATION: This document proposes to amend VA regulations concerning informed consent for patient care. Section 7331 of title 38 United States Code provides:

> The Secretary, upon the recommendation of the Under Secretary for Health * * * shall prescribe regulations establishing procedures to ensure that all medical and prosthetic research carried out and, to the maximum extent practicable, all patient care furnished under this title shall be carried out only with the full and informed consent of the patient or subject or, in appropriate cases, a representative thereof.

Current VA regulations, found at 38 CFR 17.32, set forth VA policy and describe the process for obtaining informed consent for patient care.

VA proposes to amend these regulations to clarify patient rights and responsibilities under this section and to include more detail about the process of obtaining informed consent. In addition, the proposal contains an internal decision-making process for making treatment decisions for patients who lack decision-making capacity and who have no authorized surrogate. In a medical emergency consent would be implied. This proposal describes the conditions under which the practitioner may provide necessary medical care without the patient's or surrogate's express consent.

This proposal also includes additional protections for patients when the treatment at issue is considered extremely hazardous, involves the administration of psychotropic medication to a committed patient against his or her will, or involves testing for human immunodeficiency virus (HIV). These safeguards are designed to ensure that patients receive adequate counsel and information before they undergo such procedures and that decisions made by a surrogate in this circumstance are consistent with the patient's best interest.

The proposal would also amend the definition of ''practitioner,'' which currently reads as follows:

> Practitioner includes any physician, dentist, or health care professional who has been granted specific clinical privileges to perform the diagnostic or therapeutic procedure involved.

VA proposes to include medical and dental residents in this definition of practitioner because such residents who are authorized to perform treatments or procedures would need to be involved in the informed consent process under the proposed regulations. The revised definition specifies that the term practitioner includes medical and dental residents regardless of whether they have been granted clinical privileges.

We also note that proposed § 17.32 does not address informed consent for research except to note that, in addition to the informed consent for medical treatment, the practitioner must obtain specific consent for any aspect of the treatment or procedure that involves approved medical research. There are separate regulations that govern informed consent for research (see 38 CFR Part 16—PROTECTION OF HUMAN SUBJECTS).

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act (44 U.S.C. 3504(h)). Comments on the collection of information should be sent to the Office of Management and Budget, Attention: Desk Officer for the Department of Veterans Affairs, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Director, Office of Regulations Management (02D), Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420.

The collection of information included in the proposed revision to § 17.32 in this rulemaking proceeding concerns the disclosure requirements that non-VA physicians contracting to perform services for VA must follow in conducting informed consent procedures. The provisions are consistent with standard medical practice in the community.

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

- Evaluating whether the proposed collection(s) 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 collection 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, e.g., permitting electronic submission of responses.

OMB is required to make a decision concerning the proposed collections of information contained in this document 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 to the Department on the proposed regulations.

Title: Informed Consent.

Summary of collection of information: The information collection subject to this rulemaking concerns the disclosure requirements that non-VA physicians contracting to perform services for VA must follow in conducting informed consent procedures. The information provided is designed to ensure that the patients (or in some cases, others) have sufficient information to provide informed consent.

Description of the need for information and proposed use of information: The collection of information subject to this rulemaking is designed to obtain informed consent.

Description of likely respondents: non-VA health care providers contracting to perform services for VA.

Estimated total annual reporting burden: 60,000 hours.

The estimated annual burden per respondent: ¼ hour.

Estimated number of respondents: 240,000.

Estimated annual frequency of responses: 1 per episode.

Regulatory Flexibility Act

The Secretary hereby certifies that the adoption of this proposed rule would 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 adoption of the proposed rule would affect VA beneficiaries but would not affect small businesses. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604.

The Catalog of Federal Domestic Assistance Program numbers are 64.009, 64.010, 64.011.

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 home, Philippines, Reporting and recordkeeping requirements, scholarships and fellowships, Travel and transportation expenses, Veterans.

Approved: October 11, 1995

Jesse Brown,

Secretary of Veterans Affairs.

Editorial note: This document was received at the Office of the Federal Register on July 31, 1996.

For the reasons set out in the preamble, 38 CFR part 17 is proposed to be amended as set forth below:

PART 17–MEDICAL

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

Authority: 38 U.S.C. 501, 1721, unless otherwise noted.

2. Section 17.32 is revised to read as follows:

Protection of Patient Rights

§ 17.32 Informed consent.

(a) *Definitions:*

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

Decision-making capacity: The ability to understand and appreciate the nature and consequences of health-care treatment decisions.

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

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

Practitioner: Any physician, dentist, or health-care professional who has been granted specific clinical privileges to perform the treatment or procedure involved. For the purpose of obtaining informed consent for medical treatment, the term practitioner includes medical and dental residents regardless of whether they have been granted clinical privileges.

Signature consent: The patient's signature on a VA authorized consent form, e.g., a published numbered VA form (OF 522) or comparable form approved by the local VA facility.

Special Guardian: A person appointed by a court of appropriate jurisdiction for the specific purpose of making health-care decisions.

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

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

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

(d) *Documentation of informed consent:*

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

(i) Require the use of sedation;

(ii) Require anesthesia or narcotic analgesia;

(iii) Are considered to produce significant discomfort to the patient;

(iv) Have a significant risk of complication or morbidity;

(v) Require injections of any substance into a joint space or body cavity; or

(vi) Involve testing for Human Immunodeficiency Virus (HIV).

(2) The patient's signature on a VA-authorized consent form must be witnessed. The witness' signature only attests to the fact that he or she saw the patient and the practitioner sign the form. When the patient's or surrogate's signature is indicated by an ''X'', two adults must witness the act of signing. The signed form must be filed in the patient's medical record. A properly executed OF 522 or other VA-authorized consent form is valid for a period of 30 calendar days. If, however, the patient has consented to a treatment plan that 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 30-day period. If there is a change in the patient's condition that might alter the diagnostic or therapeutic decision, the consent is automatically rescinded.

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

(e) *Surrogate consent:* If the practitioner who has primary responsibility for the patient determines that the patient lacks decision-making capacity and is unlikely to regain it within a reasonable period of time, informed consent must be obtained from the patient's surrogate. Patients who are incapable of giving consent as a matter of law, i.e., persons judicially determined to be incompetent and

minors not otherwise able to provide informed consent, will be deemed to lack decision-making capacity for the purposes of this section. If the patient is considered a minor in the state where the VA facility is located and cannot consent to medical treatment, consent must be obtained from the patient's parent or legal guardian. The surrogate generally assumes the same rights and responsibilities as the patient in the informed consent process. The surrogate's decision must be based on his or her knowledge *of what the patient would have wanted, i.e., substituted judgment.* If the patient's wishes are unknown, the decision must be based on the *patient's best interest.* The following persons are authorized to consent on behalf of patients who lack decision-making capacity in the following order of priority:

(1) Health-care agent;

(2) Legal guardian or special guardian;

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

(4) Close friend.

(f) *Consent for patients without surrogates:*

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

(2) Facilities may use the following process to make treatment decisions for patients who lack decision-making capacity and have no surrogate. For treatments or procedures that involve minimal risk, the practitioner must verify that no authorized surrogate can be located. The practitioner must attempt to explain the nature and purpose of the proposed treatment to the patient and enter this information in the medical record. For procedures that require signature consent, the practitioner must certify that the patient has no surrogate. The attending physician and the Chief of Service (or his or her designee) must indicate their approval of the treatment decision in writing. Any decision to withhold or withdraw life-sustaining treatment for such patients must be reviewed by a multi-disciplinary committee appointed by the facility Director. The committee functions as the patient's advocate and may not include members of the treatment team. The 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. After reviewing the record, the facility Director may concur with the decision to withhold or withdraw life support or request further review by Regional Counsel.

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

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

(2) Administration of psychotropic medication to an involuntarily committed patient against his or her will must meet the following requirements. The patient or surrogate must be allowed to consult with independent specialists, legal counsel or other interested parties concerning the treatment with psychotropic medication. Any recommendation to administer or continue medication against the patient's will must be reviewed by a multi-disciplinary committee appointed by the facility Director for this purpose. The facility Director must concur with the committee's recommendation to administer psychotropic medications contrary to the patient's wishes. Continued therapy with psychotropic medication must be reviewed every 90 days. The patient (or a representative on the patient's behalf) may appeal the treatment decision to a court of appropriate jurisdiction.

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

(4) Testing for Human Immunodeficiency Virus (HIV) must be voluntary and must be conducted only with the prior informed and signature (written) consent of the patient or surrogate. Patients who consent to testing for HIV must sign VA form 10–012, ''Consent for HIV Antibody Testing.'' This form must be filed in the patient's medical record. Testing must be accompanied by pre-test and post-test counseling.

(Authority: 38 U.S.C. 7331, 7332, 7333)

[FR Doc. 96–19907 Filed 8–6–96; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 260, 261, 262, 264, 268, 269 and 271

[FRL–5548–3]

Requirements for Management of Hazardous Contaminated Media (HWIR-media); Proposed Rule—Correction Notice and Notice of Data Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; Correction and notice of data availability.

SUMMARY: Since publication of the proposed rule ''Requirements for Management of Hazardous Contaminated Media (HWIR-media)'' (61 FR 18780 (April 29, 1996)), the Agency has become aware of four areas that should be clarified in the proposed rule. First, in the Appendices to Part 269, EPA is correcting the equations used to calculate the soil screening levels for inhalation of soil contaminants that are presented on page 18855 of the notice. These equations, as printed in the proposal, included a volatilization factor term that is not necessary. Second, also in the Appendices to Part 269, Exhibits 1, 2 and 3 appearing on pages 18855 and 18859 were mis-formatted. As a result,