effect upon publication, the notice is open for public comment or objection until December 16, 1997. Further, the exemptions are temporary and may be subject to change, based on the comments or objections received.

The Deputy Assistant Administrator for the Office of Diversion Control hereby certifies that this interim rulemaking will not have a significant economic impact upon a substantial number of entities whose interests must be considered under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. This interim rulemaking is an administrative action to make the regulations consistent with the law and to avoid interruption of legitimate commerce by granting temporary exemptions from registration pending promulgation, through notice and comment, of the regulations necessary to implement the provisions of the MCA pertaining to regulated drug products. Further, since this is a temporary action which provides affected persons with a means to comply with the law pending promulgation of regulations implementing the MCA, this action is not a significant regulatory action and therefore has not been reviewed by the Office of Management and Budget pursuant to Executive Order 12866.

This action has been analyzed in accordance with the principles and criteria in Executive Order 12612, and it has been determined that this interim rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects

21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, List I and List II chemicals, Security measures.

21 CFR Part 1310

Drug traffic control, List I and List II chemicals, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR parts 1309 and 1310 are amended to read as follows:

PART 1309—[AMENDED]

1. The authority citation for part 1309 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 958.

2. Section 1309.29 is revised to read as follows:

§ 1309.29 Exemption of retail distributors of regulated drug products.

The requirement of registration is waived for any retail distributor whose activities with respect to List I chemicals are restricted to the distribution of below-threshold quantities of a drug product that contains a List I chemical that is regulated pursuant to § 1300.02(b)(28)(1)(D) of this chapter to an individual for legitimate medical use.

PART 1310—[AMENDED]

1. The authority citation for part 1310 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b).

2. Section 1310.09 is amended by redesignating the existing text as paragraph (a) and adding a new paragraph (b) to read as follows:

§ 1310.09 Temporary exemption from registration.

* * * * *

(b) Each person required by section 302 of the Act (21 U.S.C. 822) to obtain a registration to distribute, import, or export a drug product that contains pseudoephedrine or phenylpropanolamine that is regulated pursuant to § 1300.02(b)(28)(1)(D) of this chapter is temporarily exempted from the registration requirement, provided that the person submits a proper application for registration on or before December 3, 1997. The exemption will remain in effect for each person who has made such application until the Administration has approved or denied that application. This exemption applies only to registration; all other chemical control requirements set forth in parts 1309, 1310, and 1313 of this chapter remain in full force and effect.

Dated: October 8, 1997.

James S. Milford,

Acting Deputy Administrator.

[FR Doc. 97–27453 Filed 10–16–97; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900–AH72

Informed Consent for Patient Care

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends VA medical regulations concerning informed consent for patient care. It describes the requirements for obtaining and documenting informed consent. It also describes the types of treatments or procedures for which the patient's or surrogate's signature on a VA-authorized form is required and establishes a list and priority of surrogates authorized to act on behalf of patients who lack decision-making capacity. Further, it establishes 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.

DATES: *Effective Date:* November 17, 1997.

FOR FURTHER INFORMATION CONTACT: Ruth-Ann Phelps, Ph.D., Veterans Health Administration, Patient Care Services (11B), 810 Vermont Avenue, NW, Washington, DC 20420, (202) 273–8473.

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** on August 7, 1996 (61 FR 41108), we proposed to amend our regulations concerning informed consent for patient care. Interested parties were invited to submit written comments on or before October 7, 1996. We received comments from one commenter, the American Psychiatric Association.

Comments

The commenter suggested that whenever the word ''patient'' appears in the document, the phrase ''or patient surrogate'' should be added. In response, we have added the words ''or surrogate'' wherever appropriate. This is intended to clarify, consistent with the intent of the proposal, that a surrogate may give informed consent on behalf of a patient who lacks decision-making capacity.

With respect to requirements regarding the administration of psychotropic medication to an involuntarily committed patient, the commenter asserted that the prescribing of such medications should be limited to psychiatrists, and further asserted that the multi-disciplinary review committee constituted for purposes of review of the decision to administer or continue the administration of such medications should be required to include a psychiatrist. We do not believe that psychotropic medication should be prescribed only by psychiatrists. We believe that patients are adequately served as long as the prescribing physician is privileged to prescribe such medication. Also, we have added the requirement that the committee must include a psychiatrist or a physician who has

psychopharmacology privileges. We believe this is adequate for the types of determinations that need to be made.

With respect to the revocation of consent (including the revocation of HIV testing consent), the commenter suggested that the regulations should require that documentation immediately be added at the place in the medical records that contained the earlier record of consent. No changes are made based on this comment. We note that the regulations provide that the informed consent process must be appropriately documented in the medical record. This requires documentation for revocations of consent, and we do not believe further instructions in the regulations are necessary (see § 17.32(d)).

The commenter suggested that consents regarding HIV testing (required to be on VA form 10–012) be filed in the patient record. No changes are made based on this comment. This already is required by these regulations (see § 17.32(g)(4)).

The proposal provided that HIV antibody testing must be accomplished by pre-test and post-test counseling. The commenter suggested that the counseling be at least equivalent to guidelines for testing from the Centers for Disease Control and Prevention and other Federal or State agencies which set HIV serologic testing policies. The commenter further suggested that the form and language of such counseling should be appropriate to the patient's or surrogate's educational level as well as cognitive and emotional state. No changes are made based on these comments. VA health-care professionals are provided with guidance commensurate with the guidelines suggested by the commenter. Further, there does not appear to be a need to specifically address the educational level and cognitive and emotional state of the patient or surrogate. This already is covered since the final rule requires that health-care professionals explain consent matters in language understandable to the patient or surrogate (see § 17.32(c)).

Paperwork Reduction Act

The collection of information contained in the notice of the proposed rulemaking was submitted to the Office of Management and Budget (OMB) for review in accordance with the Paperwork Reduction Act (44 U.S.C. 3504(h)). 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. Interested parties were invited to submit comments on the collection of information. However, no comments were received. OMB has approved this information collection under control number 2900–0583.

VA is not authorized to impose a penalty on persons for failure to comply with information collection requirements which do not display a current OMB control number, if required.

Executive Order 12866

This final rule has been reviewed by OMB under Executive Order 12866.

Regulatory Flexibility Act

The Secretary hereby certifies that the adoption of this final 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 final 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 §§ 603 and 604.

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

Lists 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, and Veterans.

Approved: September 5, 1997.

Hershel W. Gober,

Acting Secretary of Veterans Affairs.

In consideration of the foregoing, 38 CFR part 17 is amended as set forth below:

PART 17—MEDICAL

1. The authority citation for part 17 continues 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, who is familiar with the patient's activities, health, religious beliefs and values, and who has presented a signed written statement for the record that describes that person's relationship to and familiarity with the patient.

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

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

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

Practitioner. Any physician, dentist, or health-care professional who has been granted specific clinical privileges to perform the treatment or procedure 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 or surrogate'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 or surrogate must be given the opportunity to ask questions, to indicate comprehension of the information provided, and to grant permission freely without coercion. The practitioner must advise the patient or surrogate if the proposed treatment is novel or unorthodox. The patient or surrogate may withhold or revoke his or her consent at any time.

(d) *Documentation of informed consent.* (1) The informed consent process must be appropriately documented in the 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 or surrogate'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 or surrogate 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 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 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 in his or her best interest. The committee functions as the patient's advocate and may not include members of the treatment team. The committee must submit its findings and recommendations in a written report to the facility Director. The Director may authorize treatment consistent with the surrogate's decision or request that a special guardian for health care be appointed to make the treatment decision.

(2) Administration of psychotropic medication to an involuntarily committed patient against his or her will must meet the following requirements. The patient or surrogate must be allowed to consult with independent specialists, legal counsel or other interested parties concerning the treatment with psychotropic medication. Any recommendation to administer or continue medication against the patient's or surrogate's will must be reviewed by a multi-disciplinary committee appointed by the facility Director for this purpose. This committee must include a psychiatrist or a physician who has psychopharmacology privileges. The facility Director must concur with the committee's recommendation to administer psychotropic medications contrary to the patient's or surrogate's wishes. Continued therapy with psychotropic medication must be reviewed every 30 days. The patient (or a representative on the patient's behalf) may appeal the treatment decision to a court of appropriate jurisdiction.

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

(4) Testing for Human Immunodeficiency Virus (HIV) must be voluntary and must be conducted only with the prior informed and (written) signature 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.

(The information collection requirements in this section have been approved by the Office of Management and Budget under control number 2900–0583)

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

[FR Doc. 97–27565 Filed 10–16–97; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 36

RIN 2900–AI16

Loan Guaranty: Credit Standards

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: This document amends the Department of Veterans Affairs (VA) loan guaranty regulations regarding credit standards used by lenders to evaluate the creditworthiness of veteran-borrowers for home loans. VA is committed to regular review and revision of the standards used to determine the creditworthiness of veteran-applicants as issues arise and as the mortgage industry changes. These changes are designed to keep VA in step with the rest of the home mortgage industry, at least to an extent appropriate for a Government benefit-related mortgage program.

DATES: Effective Date: November 17, 1997.

FOR FURTHER INFORMATION CONTACT: Ms. Judith Caden, Assistant Director for Loan Policy (264), Loan Guaranty Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue, NW, Washington, DC 20420, (202) 273–7368.

SUPPLEMENTARY INFORMATION: In a document published in the **Federal Register** on May 7, 1997 (62 FR 24874), VA proposed to amend its loan guaranty credit standards, set forth at 38 CFR 36.4337, used by lenders to evaluate the creditworthiness of veteran-borrowers for home loans. Based on the rationale set forth in the proposed rule and this document the proposed changes are adopted, with differences explained below.

Please refer to the May 7, 1997, **Federal Register** for a complete discussion of the proposed amendments. Interested persons were given 60 days to submit comments. The comment period ended July 7, 1997. VA received three comments regarding the proposed changes.

The first commenter, an association which represents mortgage lenders, supported adoption of the proposed rule.

The second commenter, an association representing home builders, suggested that the language of proposed paragraph 36.4337(c)(5)(xii) be changed to accept other forms of tax credits in addition to those for child care as compensating factors. This was intended to cover child care tax credits of a continuing nature. VA agrees that there is no basis for distinguishing child care tax credits from other forms of tax credits of a continuing nature. The final rule at paragraph 36.4337(c)(5)(xii) is changed accordingly.

The third commenter, a lender who actively participates in the VA Guaranteed Home Loan Program, expressed general support for the proposed rule, but raised several concerns. The first concern related to proposed paragraphs 36.4337 (d) and (f), which would allow lenders to ''gross up'' income to account for the impact of tax-free income on the debt-to-income-ratio when underwriting a loan. The commenter observed that the ''grossing-up'' calculations should be kept simple and suggested that it would be helpful if VA could provide an example or formula of how ''grossing up'' calculations are performed. We agree that the ''grossing up'' calculation needs to be simple and understandable and believe that the revised regulations on this point are simple and understandable. Also, we note that the term ''grossing up'' is well understood by the mortgage industry. The mortgage industry has been ''grossing up'' income on conventional loans for many years.

Under paragraph 36.4337(f)(4), the adjustment may be made by using current income tax tables. The lender need only determine what amount of income, when taxed at the proper combination of State and Federal rates, would yield an after-tax income equivalent to the tax-free income the veteran actually receives. The purpose of allowing lenders to ''gross up'' income is to enable the lender to calculate the debt-to-income ratio as if the veteran's tax-free income were ''after-tax'' income. The arithmetic will vary by State, depending on various State and local tax rates. The lender would then use this amount to calculate the veteran's debt-to-income ratio, while using the actual tax-free income to calculate the residual income.

For example, in a State with no income tax, the lender could simply show that, for a veteran in the 15 percent Federal income tax bracket, $1,000 of tax-free income is equivalent