

with the guidelines set forth in Section 3 of the Notice of Inquiry.

Tanya Sandros,
General Counsel.

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900-AN20

Elimination of Requirements for Prior Signature Consent and Pre- and Post-Test Counseling for HIV Testing

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the Department of Veterans Affairs (VA) Informed Consent regulations to update requirements concerning testing for Human Immunodeficiency Virus (HIV) so that they are consistent with the Veterans' Mental Health and Other Care Improvements Act of 2008, which repealed provisions that had been enacted in 2003.

DATES: *Comments:* Comments must be received on or before January 28, 2009.

ADDRESSES: Written comments may be submitted through <http://www.Regulations.gov>; by mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Ave., NW., Room 1068, Washington, DC 20420; or by fax to (202) 273-9026. Comments should indicate that they are submitted in response to "RIN 2900-AN20." Copies of 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) 461-4902 for an appointment. (This is not a toll-free number.) In addition, during the comment period, comments are available online through the Federal Docket Management System (FDMS) at <http://www.Regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Ronald O. Valdiserri, MD, MPH, Chief Consultant, Public Health SHG, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420; (202) 461-7240. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: This proposed rule would amend VA's Informed Consent regulation for HIV testing in the medical regulations in 38

CFR part 17 to remove §§ 17.32(d)(1)(vi) and 17.32(g)(4). Section 124 of Public Law 100-322 (1988) ("section 124") prohibited any VA program from widespread testing to identify HIV infections unless Congress specifically appropriated funds for such a program. The statute further required VA to "provide for a program" under which VA offered HIV testing to: (1) Any patient receiving care or services for intravenous drug abuse, diseases associated with HIV, and any patient otherwise at high risk for HIV infection; and (2) any patient requesting the test, unless medically contraindicated. No testing of any patient was permissible under section 124 without the prior written informed consent of the patient and the provision of pre-and-post-test counseling.

VA originally implemented the section 124 mandates in its informed consent policy, VHA Manual M-2, part I, chapter 23 (Feb. 15, 1990). (VA's informed consent policy is currently contained in VHA Handbook 1004.1, dated Jan. 29, 2003.) A few years after the enactment of section 124, VA established its current policy, which is codified in current 38 CFR 17.32(d)(1)(vi) and (g)(4), requiring signature consent and counseling for all HIV testing conducted by VA.

In 2008, the Administration proposed to Congress the repeal of section 124 for compelling clinical and public health reasons. VA's HIV testing procedures differ from other routine clinical testing that VA conducts, most of which only requires the patient's oral informed consent. The requirements for pre-test counseling and signed consent have been widely reported to delay testing for HIV infection, which, in turn, impairs VA's ability to identify infected patients who would benefit from earlier medical intervention. Because of the delay in testing, infected patients may unknowingly spread the virus to their partners and do not present themselves for treatment until complications of the disease become clinically evident and, often, acute. Infected patients who are, or become, pregnant can unknowingly spread the virus to their fetus. This is medically unacceptable when we now have continually improving therapies with which to clinically manage the disease effectively; in many cases, their efficacy is increased if provided during the early stages of infection.

In submitting the proposal for repeal of section 124 to Congress, the Administration was aware that the scientific literature indicated that the requirements of section 124 were outdated. For example, in one peer-reviewed published study, VA's data

indicate that 50 percent of HIV-positive veterans had already suffered significant damage to their immune system by the time they were diagnosed as HIV positive. See Gandhi NR, Skanderson M, Gordon KS, Concato J, Justice AC. Delayed Presentation for Human Immunodeficiency Virus (HIV) Care Among Veterans, A Problem of Access or Screening? *Medical Care*. 2007; 45 (11): 1105-1109. These patients had, on average, 3.7 years of VA care before diagnosis, indicating that there were significant missed opportunities to make a diagnosis at a stage when HIV treatment could have prevented many of the complications experienced by these patients. *Id.*

As reported by the American Journal of Public Health, another group of VA researchers recently conducted a blinded seroprevalence survey of nearly 9,000 veteran inpatients and outpatients from 6 large VA sites. They found that the rates of previously undiagnosed HIV infection varied from 0.1 percent-2.8 percent among outpatients and from 0.0 percent-1.7 percent among inpatients. While these percentages may seem small, the CDC, based upon cost-effectiveness studies, identifies 0.1% as the threshold above which HIV testing should routinely take place in health care settings. See Owens DK, Sundaram V, Lazzeroni LC, Douglass LR, Sanders GD, *et al.* Prevalence of HIV Infection Among Inpatients and Outpatients in Department of Veterans Affairs Health Care Systems: Implications for Screening Programs for HIV. *Am J Public Health*. 2007; 97 (12): 2173-2178.

Historically, HIV testing was driven based on an assessment of risk, i.e., if the patient reported a behavior associated with HIV transmission, the test was strongly encouraged. This was a major reason for extensive pre-test counseling. However, over time, risk-based strategies for HIV testing in clinical settings proved to be inefficient, for a variety of reasons. Some patients are unwilling to share personal information about sexual and drug use behaviors with providers; some patients are unaware of their risks (e.g., someone who has a sex partner who doesn't disclose the fact that he/she is an injection drug user); risk-based testing fails to identify many HIV-infected persons until late in the course of their disease; and some patients may continue to misperceive HIV infection as a disease limited only to homosexuals, injection drug users, and persons with multiple, anonymous sexual partners.

In 2006, the Centers for Disease Control and Prevention (CDC) recommended routine HIV screening in

health-care settings for all patients aged 13–64, and further that “separate written consent for HIV testing should not be required; general consent for medical care should be considered sufficient to encompass consent for HIV testing.” Centers for Disease Control and Prevention. Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-Care Settings. *MMWR* 2006; 55 (Mp/RR–14): 1–17. The VA submitted the proposal to repeal section 124 to make its screening procedures and informed consent requirements for HIV testing in line with CDC’s recommendations.

In short, the Administration sought the repeal of section 124 to enable VA to bring its informed consent policy and procedures for HIV testing into line with current standards of practice, to improve potential health outcomes of infected patients, and to advance the country’s broader public health goals.

During the second session of the 110th Congress, the Senate and House each introduced legislation that mirrored the Administration’s legislative proposal to repeal section 124. VA testified in support of the pending legislation, while making clear that such a repeal would not erode patient rights, as VA would still be legally required to obtain the patient’s oral informed consent prior to testing.

The House Committee on Veterans’ Affairs explained its legislation would reduce existing barriers to the early diagnosis of HIV infection, recognizing that HIV testing had entered a new era. Through the repeal of section 124, the Committee intended to facilitate patients’ awareness of their HIV status to help them maintain their health and reduce further spread of the virus. The Committee also intended for the repeal to allow VA to update its informed consent procedures for HIV testing to reflect CDC guidelines, while affording VA needed flexibility to update its screening standards as necessary. See House Rep. No. 110–786, at 4, 7–9 (2008). The Senate Committee on Veterans’ Affairs similarly explained that its measure would bring VA’s statutory HIV testing requirements in line with current CDC informed consent guidelines for HIV testing, thereby benefiting patients who receive early medical intervention and advancing the country’s broader public health goals. See S. Rep. No. 110–473, at 44–45 (2008).

The repeal of section 124 was ultimately included as section 407 of S. 2162, the “Veterans’ Mental Health and Other Care Improvements Act of 2008,” which subsequently passed both chambers of Congress. The President

signed S. 2162 into law on October 10, 2008 (Pub. L. 110–387). However, by repealing section 124, Congress did not abrogate VA’s current requirements for written informed consent and counseling codified in 38 CFR 17.32(d)(1)(vi) and (g)(4). It merely repealed statutory requirements that VA’s HIV-testing policy include prior written consent and pre- and post-test counseling. VA’s current informed consent regulation governing HIV testing remains in effect contrary to the stated intentions of both the Congress and the Administration. To enable VA to bring its policy into conformance with the purpose of the legislation as well as with current medical practice, VA must remove the provisions of 38 CFR 17.32(d)(1)(vi) and (g)(4).

We note that with the changes proposed in this document, VA’s informed consent procedures for HIV testing would be governed by the requirements of 38 CFR 17.32(c), and would still be more rigorous than those generally found in the private sector. While other institutions often allow “presumed” consent or “blanket” consent for many procedures, VA regulations, as outlined in *VHA Handbook 1004.1 (VHA Informed Consent for Clinical Treatments and Procedures*, which may be viewed at http://www.ethics.va.gov/docs/policy/VHA_Handbook_1004-1_Informed_Consent_Policy_20030129.pdf), require specific informed consent for all treatments and procedures, including HIV tests. In addition to requiring that VA practitioners disclose “information that a patient in similar circumstances would reasonably want to know,” VA would specifically require VA practitioners to inform patients that they are being tested for HIV, to provide written educational materials on HIV and HIV testing, to provide patients an opportunity to decline HIV testing, and to document patients’ oral agreement to HIV testing in their health records. Furthermore, the proposed rule would not in any way alter the statutory confidentiality protections that apply to the disclosure of VA patients’ HIV test results.

In summary, after promulgation of this rule, HIV testing in VA facilities would be governed by the following:

- Providers would have to inform patients that they intend on ordering an HIV test.
- Providers would be required to give patients written educational materials that include an explanation of HIV infection and the meaning of positive and negative test results.
- The educational materials will be made available in the languages of the

most commonly encountered populations within the service area.

- Providers would be required to offer patients an opportunity to ask questions and to consent to or decline testing.

- Refusal of HIV testing would not affect a patient’s eligibility for any other care at a VA facility.

- As is the case for other tests performed in the VA, providers would be required to document the patient’s informed consent in the patient’s electronic health record.

- Definitive mechanisms would be established to inform patients of their test results.

- HIV-positive test results would always be communicated confidentially through personal contact with a health care provider.

- HIV-infected patients would be promptly referred for necessary clinical care, counseling, support, and prevention services.

Further information on VA’s policy and procedures on HIV testing may be found at <http://www.hiv.va.gov>.

Comment period

VA believes, based upon the circumstances described above, that it is consistent with the repeal of the prior legislation and in the public’s interest to bring VA’s informed consent policy and procedures for HIV testing into line with current standards of practice as quickly as possible. This will improve the potential health outcomes of infected patients and advance the country’s broader public health goals. Accordingly, VA has determined that it is not in the public’s interest to delay implementation of this regulation any longer than necessary, and we have provided that comments must be received within 30 days of publication in the **Federal Register**.

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

Paperwork Reduction Act

This document contains no provisions constituting a collection of information under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

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 Executive Order classifies a "significant regulatory action," requiring review by the Office of Management and Budget (OMB) unless OMB waives such review, as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

The economic, interagency, budgetary, legal, and policy implications of this proposed rule have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866.

Regulatory Flexibility Act

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

Catalog of Federal Domestic Assistance

This proposed rule would affect the program that has the following Catalog of Federal Domestic Assistance program number and title: 64.009—Veterans Medical Care Benefits. To the extent that VA directly provides medical care to patients under the Civilian Health and Medical Program of the Department of Veterans Affairs or other programs,

this rule would also affect those programs, which have no Catalog of Federal Domestic Assistance program numbers.

List of Subjects in 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, and Veterans.

Approved: October 31, 2008.

James B. Peake,

Secretary of Veterans Affairs.

For the reasons set forth in the preamble, the Department of Veterans Affairs proposes to amend 38 CFR part 17 as follows:

PART 17—MEDICAL

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

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

§ 17.32 [Amended]

2. Section 17.32 is amended:

- a. In paragraph (d)(1)(iv), by adding "or" after the semi-colon at the end of the paragraph.
- b. In paragraph (d)(1)(v), by removing "; or" and adding, in its place, a period at the end of the paragraph.
- c. By removing paragraph (d)(1)(vi).
- d. By removing paragraph (g)(4).

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POSTAL SERVICE

39 CFR Part 111

New Standards for Letter-Size Booklets and Folded Self-Mailers

AGENCY: Postal Service™.

ACTION: Proposed rule.

SUMMARY: On March 14, 2008, we published in the **Federal Register** (Volume 73, Number 51, pages 13812–13813) an advance notice of our intent to develop new mailing standards for folded self-mailers and booklets mailed at automation and machinable letter prices. In that advance notice, we provided justification for these changes,

announced a two-phase testing initiative, and reported the results of the first phase of testing. We invited comments from customers and asked that they suggest alternative booklet designs that could improve mailpiece performance.

The following proposed rule is based on the results of completed testing. We propose revisions to tab size, tab location, paper weight, and dimensions for folded self-mailers and booklets mailed at automation or machinable letter prices.

DATES: We must receive your comments on or before January 28, 2009.

ADDRESSES: Mail or deliver written comments to the Manager, Mailing Standards, U.S. Postal Service, 475 L'Enfant Plaza SW., Room 3436, Washington, DC 20260–3436. You may inspect and photocopy all written comments at USPS Headquarters Library, 475 L'Enfant Plaza SW., 11th Floor N., Washington, DC between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Susan Thomas, 202–268–7268.

SUPPLEMENTARY INFORMATION: Many folded self-mailers and booklets mailed at automation and machinable letter prices do not process successfully on letter-sorting machines. Unenveloped pieces tend to double feed and jam resulting in damage to the equipment and the mail. These problems and the resulting loss of machine time make it necessary to process some types of folded self-mailers and booklets on flat sorting equipment or in manual operations. Typically these operations are slower and more labor intensive resulting in higher processing costs. To improve efficiency, the USPS® worked with customers to test multiple mailpiece designs and arrived at revised standards that improve automation processing.

In addition to the controlled testing of 400 specially-manufactured mailpieces, in phase two of the testing our Engineering Department also evaluated 124 live mailings and tested 70 sample mailings provided by customers to determine optimal size, thickness, cover stock, tab style, tab strength, tab location and binding. Several customers actively participated and were present to observe the tests. When a mailpiece was nonmachinable, customers were encouraged to resubmit modified pieces for additional testing and evaluation.

We are sensitive to the current economic climate and the effect these changes may have on the mailing community. Based on the results of our tests we identified incremental