

Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3506), the agencies have reviewed the interim final rule to assess any information collections. There are no collections of information as defined by the Paperwork Reduction Act in the final rule.

Executive Order 12866

Executive Order 12866 requires federal agencies to prepare a regulatory impact analysis for agency actions that are found to be "significant regulatory actions." Significant regulatory actions include, among other things, rulemakings that "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." The OCC determined that the final rule is not a significant regulatory action under Executive Order 12866.

Unfunded Mandates Reform Act of 1995 Determination

The Unfunded Mandates Reform Act of 1995, Public Law 104-4, (2 U.S.C. 1532) (UMRA) requires that an agency prepare a budgetary impact statement before promulgating a rule that includes a federal mandate 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. If a budgetary impact statement is required, section 205 of the UMRA also requires an agency to identify and consider a reasonable number of regulatory alternatives before promulgating a rule. The OCC has determined that the final rule will not result in expenditures by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any one year. Accordingly, the OCC has not prepared a budgetary impact statement or specifically addressed the regulatory alternatives considered.

List of Subjects in 12 CFR Part 3

Administrative practice and procedure, Banks, Banking, Capital, National banks, Reporting and recordkeeping requirements, Risk.

Authority and Issuance

■ For the reasons stated in the preamble, the Office of the Comptroller of the Currency amends Part 3 of chapter I of Title 12, Code of Federal Regulations as follows:

PART 3—MINIMUM CAPITAL RATIOS; ISSUANCE OF DIRECTIVES

■ 1. The authority citation for part 3 continues to read as follows:

Authority: 12 U.S.C. 93a, 161, 1818, 1828(n), 1828 note, 1831n note, 1835, 3907, and 3909.

■ 2. In appendix A to Part 3, in section 3, add two sentences to the end of paragraph (a)(3)(iii) to read as follows:

Appendix A to Part 3—Risk Based Capital Guidelines

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Section 3. Risk Categories/Weights for On-Balance Sheet Assets and Off-Balance Sheet Items

* * * * *

(a) * * *

(3) * * *

(iii) * * * If a bank holds a first lien and junior lien on a one-to-four family residential property and no other party holds an intervening lien, the transaction is treated as a single loan secured by a first lien for the purposes of both determining the loan-to-value ratio and assigning a risk weight to the transaction. Furthermore, residential property loans made for the purpose of construction financing are assigned to the 100% risk category of section 3(a)(4) of this appendix A; however, these loans may be included in the 50% risk category of this section 3(a)(3) of this appendix A if they are the subject to a legally binding sales contract and satisfy the requirements of section 3(a)(3)(iv) of this appendix A.

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Dated: July 9, 2009.

By the Office of the Comptroller of the Currency.

Julie L. Williams,

First Senior Deputy Comptroller and Chief Counsel.

[FR Doc. E9-16882 Filed 7-15-09; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 17

RIN 2900-AN20

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

AGENCY: Department of Veterans Affairs.
ACTION: Final rule.

SUMMARY: This document adopts, without change, the proposed rule published in the **Federal Register** on December 29, 2008, updating informed consent requirements related to testing for the Human Immunodeficiency Virus (HIV) for Veterans receiving health care from the Department of Veterans Affairs

(VA). This final rule is in accordance with related provisions of the Veteran's Mental Health and Other Care Improvements Act of 2008. The final rule eliminates the regulatory requirement for written informed consent for HIV testing and specific pre- and post-test counseling of Veteran patients. VA will implement this rule through internal policy guidance specifying these requirements and how they apply to HIV testing.

DATES: *Effective Date:* This final rule is effective August 17, 2009.

FOR FURTHER INFORMATION CONTACT:

Ronald O. Valdiserri, MD, MPH, Chief Consultant (13B), Public Health Strategic Healthcare Group, Department of Veterans Affairs, 810 Vermont Avenue, NW., Washington, DC 20420, (202) 461-1040. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On December 29, 2008, VA published a proposed rule in the **Federal Register** (73 FR 79428). We proposed to amend 38 CFR 17.32(d), VA's regulation concerning documentation of informed consent, and 38 CFR 17.32(g), VA's regulation concerning special consent situations, by removing the requirement for written rather than oral informed consent for HIV testing and specific pre- and post-test counseling of Veteran patients related to HIV testing. However, nothing in this regulation changes existing statutory requirements for informed consent. These changes are in response to provisions included in section 124 of Public Law 100-322, the Veteran's Mental Health and Other Care Improvement Act of 2008. VA provided a 30-day comment period, which ended on January 28, 2009.

We received a number of comments that did not address the proposed amendments to § 17.32 and thus were outside the scope of this rulemaking proceeding. Although we appreciate those comments, we will not address them in this final rule.

We received comments concerning the proposed amendments from 10 organizations and 10 individuals. Sixteen commenters expressed support for the proposed rule. We received two comments opposing the rule, one of which was submitted jointly by four commenters, and will address each of those comments below.

VA proposed to amend the 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. 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. Section 407 of Public Law 110–387 repealed section 124 and eliminated the statutory requirements that VA’s HIV-testing policy include prior written consent and pre- and post-test counseling. To enable VA to bring its policy into conformance with the purpose of the legislation as well as with current medical practice, VA proposed to remove the provisions of 38 CFR 17.32(d)(1)(vi) and (g)(4).

One commenter opposed eliminating the requirements for pre-test counseling and signature consent because these requirements help guarantee veterans’ rights to choose their medical care, to have their privacy respected, and to be treated with dignity. VA agrees that in all of its actions, the Department should promote respect for these rights. However, other provisions in current regulations, which are not amended by this final rule, address the commenter’s concerns. Specifically, we will use oral informed consent, consistent with 38 CFR 17.32(b), which requires that all patient care furnished by VA, including HIV testing, “shall be carried out only with the full and informed consent of the patient or, in appropriate cases, a representative thereof.” 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.” 38 CFR 17.32(c). As part of the informed consent process in § 17.32(c), VA practitioners are required to “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.” Section 17.32(c) further requires that “[t]he 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,” and that the patient or surrogate “may withhold or revoke his or her consent at any time.” These regulatory requirements are grounded in Veterans’ right to choose their medical care, to have their privacy respected, and to be treated with dignity. Moreover, as noted in the Notice of Proposed Rulemaking (NPRM), the protections that we will continue to provide are still more rigorous than those generally found in the private sector.

Accordingly, we will not make any changes to the final rule based upon the comment.

Four commenters jointly opposed the proposed rule because they believed that requirements for pre- and post-test counseling and written informed consent are not meaningful barriers to promptly identifying people infected with HIV. These commenters cited several examples of organizations that have successfully increased their rates of HIV testing by streamlining their procedures for pre-test counseling and written informed consent.

Our primary purposes in eliminating these requirements are (1) to eliminate any unnecessary impediments to HIV testing, (2) to enable VA to make its informed consent and procedures for HIV testing consistent with our procedures for other routine clinical tests run by VA, and (3) to enable us to bring our procedures in line with current standards of practice as recommended by the Centers for Disease Control and Prevention while protecting the rights of patients in other health care systems. We carefully considered the alternatives available to VA, including the “streamlining” suggested by the commenters, but nonetheless concluded that there was insufficient reason to maintain the pre-test counseling and written informed consent requirements that have been shown to be associated with lower rates of HIV testing. By eliminating these requirements and replacing them with other less cumbersome procedures to ensure that patients are fully informed and have the opportunity to consent or refuse HIV testing, we believe we can increase testing rates while still protecting the rights and interests of our Veteran patients.

We note, briefly, that several studies support the proposition that eliminating

pre-test counseling and prior written informed consent may lead to increased testing rates, especially when combined with improved testing procedures. See, NM Zetola *et al.*, *Association between rates of HIV testing and elimination of written consents in San Francisco*, 297 JAMA 1061–2 (2007); PD Ehrenkrantz *et al.*, *Written Informed Consent Statutes and HIV Testing*, Am J Prev Med (May 2009) (Epub ahead of print); C. Wing, *Effects of written informed consent requirements on HIV testing rates: evidence from a natural experiment*, 99 Am J Pub Health 1087–92 (2009); RC Burke *et al.*, *Why don’t physicians test for HIV? A review of the US literature*, 21 AIDS 1617–24 (2007). This literature supports our decision that a program of prior informed oral consent, combined with better procedures, is the most efficient and effective method available at this time to achieve higher HIV testing rates, irrespective of whether other less or equally effective alternatives are available.

The commenters also argued that the current requirement for pre-test counseling should be retained because patients benefit from receiving the information VA currently provides through pre-test counseling, such as information about how HIV is spread and measures to be taken for prevention of HIV transmission. They further argued that post-test counseling should be retained because it is important for patients who test negative for HIV, especially those who engage in high-risk behaviors. Finally, they argued against eliminating the written consent requirement because written consent is needed to ensure that information has been provided to patients and that consent has been given. We will not make any changes to the final rule based upon these comments.

VA is committed to ensuring that Veterans continue to receive thorough and accurate information about HIV and HIV testing, and that HIV testing is performed only after the patient or the patient’s surrogate has received this information (see below) and specifically consented to undergo such testing. By eliminating the requirements for pre-test counseling, post-test counseling, and written informed consent for HIV testing, VA is not weakening patient protections, but merely streamlining its protocols to make them less cumbersome for practitioners and patients alike.

Specifically, VA intends to use a variety of methods, including but not limited to those recommended by the Centers for Disease Control, to ensure that the current level of protections for patients is maintained. These methods

include providing patients with written education materials that cover much of the information that was previously covered in pre-test and post-test counseling, and ensuring that patients who engage in high risk behaviors are referred to necessary prevention services. Instead of using a written consent form to ensure that the information has been provided to patients and that consent has been given, VA practitioners will be required to document the oral informed consent process in a progress note. VA will implement this rule through internal policy guidance specifying these requirements and how they apply to HIV testing. Thus the final rule enables VA to streamline its procedures by removing unnecessary barriers to HIV testing, while still ensuring that patients are provided with accurate and thorough information about HIV and HIV testing, and that HIV testing is only performed with the full and informed consent of the patient or the patient's surrogate.

Of note, VA already has on its HIV Web site (<http://www.hiv.va.gov>) extensive educational materials on HIV and HIV testing, directed at both clinical providers and patients. We will direct patients to this Web site (in addition to other available resources) which addresses topics including the benefits and risks of HIV testing; how HIV testing is performed and interpreted; available treatments for HIV; and VA confidentiality protections for HIV-infected patients. This web site receives hundreds of thousands of page views per month, and represents a resource that is widely available to providers, Veterans, and the general public. Joint commenters also assert that the title of the NPRM was confusing and misleading because it referred to elimination of pre-test counseling, implying that VA providers will not have to provide information on HIV testing to Veteran patients. The title of the notice has no substantive effect, and to the extent that anyone might find it misleading, VA's intent is clear from everything that follows the proposed rule title and as described in this final notice.

The Joint commenters also favor mandated pre-test counseling on HIV testing because of other benefits to patients, including increasing testing rates and education of patients about HIV, including methods of preventing transmission. VA agrees that these are important goals; however, it respectfully disagrees that mandated pre-test counseling is required to achieve them. VA has already encouraged providers to routinely discuss HIV risk factors and to

offer testing to all veterans who are at risk for HIV. See, e.g., Information Letter IL 10-2005-017, *Need For Routine Human Immunodeficiency Virus (HIV) Risk Assessment And Testing*. VA intends to promulgate and implement a written policy directive extending this guidance to require providers to offer HIV testing to all patients, not just those at high risk. In addition, because of its electronic medical record and computerized provider ordering entry system, VA has the capacity to utilize technologies such as electronic reminders and other mechanisms to increase testing rates. Use of such mechanisms has been shown to aid in increasing HIV testing rates in the VA system. MB Goetz et al., *A system-wide intervention to improve HIV testing in the Veterans Health Administration*. 23 J Gen Intern Med 1200-1207 (2008). However, we believe that these mechanisms alone are insufficient to adequately expand HIV testing within VA. The overall rates within VA remain low, even in facilities that have implemented these practices. RO Valdiserri et al. *Frequency of HIV screening in the Veterans Health Administration: Implications for early diagnosis of HIV infection*, 20 AIDS Educ Prev 258-264 (2008).

The commenters also assert that mandated pre-test and post-counseling are necessary to ensure linkage to care. VA respectfully disagrees. The literature cited by the commenters in support of this point is drawn from settings outside the VA; in fact, VA has an excellent record of linkage to care, with current data showing that greater than 75 percent of all HIV-infected Veterans in care within the VA system are on anti-retroviral therapy, and that over 90 percent of all HIV-infected Veterans in care within the VA system who require prophylaxis against opportunistic infections do in fact receive such prophylaxis.

The commenters also object that Congress did not intend for VA to remove requirements for written informed consent and pre-test and post-counseling, asserting that the Congress' primary goal was simply to remove the prohibition of wide-spread HIV testing. VA respectfully disagrees with this interpretation, based on the discussion of this issue in the NPRM of the plain language and history of the Veterans Mental Health Care and Other Improvements Act of 2008 (Pub. L. 110-387). As further evidence of Congress' intent, the Senate Report on the predecessor bill criticized VA for not adopting CDC's recommendations on HIV testing (which include removing requirements for written informed

consent and pre-test counseling). S. Rep. 110-85, at 56 (2008).

The commenters also argue that mandated post-test counseling should be retained because it may decrease the risk of continued high-risk behavior by patients who have a negative HIV test. VA agrees with the importance of decreasing high-risk behavior, and as part of our directives and internal guidance, we will require providers to counsel patients who are engaged in high-risk behavior and to refer them as clinically appropriate to resources to reduce such high-risk behavior. Providers will also be required to offer repeat testing to high-risk individuals at least annually, as recommended by CDC.

Finally, the same commenters argued that VA should retain the written informed consent requirement because it protects VA practitioners from liability. We disagree that this is a valid argument in support of keeping the written informed consent requirement. VA's informed consent regulations and policy are designed to benefit and protect the patient; not to benefit VA practitioners or the Department.

To the extent that the commenters requested that VA expand the scope of its testing or discuss post-test counseling, these comments were beyond the scope of this rulemaking. However, as noted earlier, VA intends to promulgate and implement a written policy on this issue. The policy guidance states that it is VHA policy that HIV testing is part of routine medical care; that providers recommend HIV testing to all veterans; that providers obtain full and informed consent of the veteran prior to testing; and that veterans who test positive for HIV infection must be referred for state-of-the-art HIV treatment, prevention of complications, and care of related conditions as soon as possible after diagnosis.

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 year. This final rule would have no such effect on State, local, and tribal governments, or on 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).

Regulatory Flexibility Act

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

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.

VA has examined the economic, interagency, budgetary, legal, and policy implications of this final rule and has determined that it is a significant regulatory action under Executive Order 12866.

Catalog of Federal Domestic Assistance

This final 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 May 15, 2009.

John R. Gingrich,

Chief of Staff, Department of Veterans Affairs.

■ For the reasons stated in the preamble, the Department of Veterans Affairs amends 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.

■ 2. Section 17.32 is amended by:

■ a. In paragraph (d)(1)(iv), adding “or” after the semicolon at the end of the paragraph.

■ b. In paragraph (d)(1)(v), removing “; or” and adding, in its place, a period at the end of the paragraph.

■ c. Removing paragraph (d)(1)(vi).

■ d. Removing paragraph (g)(4).

[FR Doc. E9–16898 Filed 7–15–09; 8:45 am]

BILLING CODE 8320–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R06–OAR–2007–0905; FRL–8931–1]

Approval and Promulgation of Implementation Plans; Texas; Revisions to General Air Quality Rules and the Mass Emissions Cap and Trade Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking a direct final action to approve portions of one revision to the Texas State Implementation Plan (SIP) submitted by the State of Texas on August 16, 2007;

these portions of the SIP revision approved: Repeal an unnecessary effective date in the Texas SIP under Title 30 in the Texas Administrative Code (TAC), Chapter 101—General Air Quality Rules, Subchapter A—General Rules; and make non-substantive changes in the Texas SIP to the Mass Emissions Cap and Trade Program (MECT) under 30 TAC Chapter 101, Subchapter H—Emissions Banking and Trading, Division 3. EPA has determined that these changes to the Texas SIP comply with the Federal Clean Air Act (the Act or CAA) and EPA regulations, are consistent with EPA policies, and will improve air quality. This action is being taken under section 110 and parts C and D of the Act.

DATES: This direct final rule is effective on September 14, 2009 without further notice, unless EPA receives relevant adverse comment by August 17, 2009. If EPA receives such comment, EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R06–OAR–2007–0905, by one of the following methods:

(1) *www.regulations.gov*: Follow the online instructions for submitting comments.

(2) *E-mail*: Mr. Jeff Robinson at robinson.jeffrey@epa.gov. Please also cc the person listed in the **FOR FURTHER INFORMATION CONTACT** paragraph below.

(3) *U.S. EPA Region 6 “Contact Us” Web site*: <http://epa.gov/region6/r6coment.htm>. Please click on “6PD” (Multimedia) and select “Air” before submitting comments.

(4) *Fax*: Mr. Jeff Robinson, Chief, Air Permits Section (6PD–R), at fax number 214–665–6762.

(5) *Mail*: Mr. Jeff Robinson, Chief, Air Permits Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733.

(6) *Hand or Courier Delivery*: Mr. Jeff Robinson, Chief, Air Permits Section (6PD–R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Such deliveries are accepted only between the hours of 8:30 a.m. and 4:30 p.m. weekdays except for legal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R06–OAR–2007–0905. EPA’s policy is that all comments received will be included in the public docket without change and may be made available online at <http://www.regulations.gov>, including any personal information provided, unless