January 28, 2009

BY FACSIMILE TRANSMISSION

Director
Regulations Management (02REG)
Department of Veterans Affairs
810 Vermont Ave., NW, Room 1068
Washington, DC 20420
Fax #: 202-273-9026

Re: Department of Veterans Affairs
Proposed Rule – RIN 2900-AN20; “Elimination of Requirements for Prior Signature Consent and Pre- and Post-Test Counseling for HIV Testing”

Dear Director:

These comments on the Department of Veterans Affairs’ Proposed Rule amending HIV testing patient protections, RIN 2900-AN20, are submitted on behalf of Lambda Legal, the American Civil Liberties Union, the Center for HIV Law and Policy, and AIDS Foundation of Chicago and the many individuals with HIV whom they represent, including those in the Department of Veterans Affairs (“VA”) system of care. The organizations submitting these comments have a long history of advocating for the interests of people with HIV/AIDS and ensuring their concerns are part of the public policy discussions on this issue.

When a government entity proposes to eliminate a patient protection that also can be characterized as a civil and human right, the burden is on the agency to show that the elimination is necessary. That burden has not been met here, and in fact the best evidence suggests that maintaining the VA’s patient protections of voluntary informed consent will also serve individual and public health, provided that the regulations are amended to clearly allow the offer of tests to all those who present for care.

Discussed in Section I are some general principles related to HIV testing that provide some background for the more detailed discussions. Section II refutes the premise that pre- and post-test counseling and written consent requirements are serious barriers to expanding testing so as to more promptly identify people infected with HIV. In Section III we specifically discuss the VA’s current requirements for pre-test counseling and relate those to the requirement for informed consent, the benefits of providing pre-test information, and the recent Congressional action related to HIV testing in VA facilities. Section IV and V, respectively, discuss the benefits of continuing to require post-test counseling for those who test negative and written consent for HIV testing.
I. Introductory Comments

We commend the VA for its commitment to expanding HIV testing, which can save lives and improve the standard of living for many individuals living with HIV. We further commend the VA’s continued commitment to “full and informed consent” to HIV testing based on, in part, “a careful explanation . . . of the proposed diagnostic procedure” in which the patient “must be given the opportunity to ask questions, to indicate comprehension of the information provided, and to grant permission freely without coercion.” 38 C.F.R. § 17.32(c). Unfortunately, portions of the proposed new rules concerning elimination of pre-test counseling are in direct conflict with this provision and therefore cannot stand, as discussed below. For the reasons addressed more fully below, we believe that the current regulations, simply amended to delete indications that HIV testing should only be offered to those considered at risk, provide an excellent model of a process that can increase patient testing without compromising patient rights and the quality of the care that veterans receive.

HIV test-related counseling should be tailored to the needs of the individual and the individual’s consent to a test should be documented. Pre-test and post-test HIV counseling, and written documentation that the testing decision was voluntary and informed, serve both the short and long term health goals of the patient and the public. As a gateway to health care, it also is essential that HIV testing be supported, directly or by referrals, with appropriate education, counseling, health care, mental health care, and social services.

This is equally true of HIV testing in the VA system of health care, with facilities across the country and in multiple jurisdictions with varied statutory requirements for counseling and consent. In order to make the most effective connection with the estimated 250,000 to 300,000 people in the U.S. living with undiagnosed HIV infection, care providers in VA facilities should initiate conversations with patients about sex and HIV risk, provide basic HIV counseling and prevention information, and offer HIV testing with informed consent to many more patients, not just those who are perceived to be members of HIV “risk groups.”

Unquestionably, regularly offering testing to patients, as the new regulations encourage, can help eliminate the distorting effect that results from providers offering HIV tests only when they assume their patients have engaged in risk activities. Provider comfort with introducing topics such as sex and HIV are central to elimination of HIV’s stigma, which is a product not only of its life-long and serious impact on health, intimate relationships, employment options and social integration, but also of its connection to populations which are still stigmatized by parts of U.S. society: gays and users of intravenous drugs. In fact, available data about HIV testing uptake in VA facilities and elsewhere strongly indicate that it is the provider’s failure to offer testing, not the process of ensuring that testing is informed and
voluntary, that keeps testing numbers unacceptably low.1 There still is no evidence that eliminating counseling and written consent requirements before testing, and counseling for all who test negative – in short, abandoning modern approaches to public health and patient autonomy – will result in earlier, better and sustained access to HIV diagnosis, treatment and medical care for individuals relying on the VA system of health care.

II. Pre-Test Information and Prior Signature Consent Are Not Barriers to Expanded HIV Testing.

The undersigned are concerned that the basic premise underlying the VA’s proposed changes to its HIV testing policy – that the primary problem with its current testing regime is the requirement of written informed consent and pre-test counseling – will erode patient autonomy with no corresponding improvement in HIV testing.2

The VA grounds its proposed changes in its belief that “[t]he requirements for pre-test counseling and signed consent have been widely reported to delay testing for HIV infection.” 73 Fed. Reg. at 79428 (Dec. 29, 2008). The VA’s reliance on such reports is misplaced. First, it is misleading to suggest that the pre-test HIV prevention counseling that the Centers for Disease Control and Prevention (“CDC”) found delayed testing bears any relation to the pre-test counseling currently done by the VA.3 In fact, as noted below, the information provided by the VA under the existing regulations is precisely the same kind of information that the CDC says must still be provided. See VA FAQs (“The purpose of pre-

1 See N. Gandhi et al., Delayed Presentation for Human Immunodeficiency Virus (HIV) Care Among Veterans – A Problem of Access of Screening?, 45 MED. CARE 1105, 1106-1107, 1108 (Nov. 2007) (discussing delayed diagnosis of HIV and delayed presentation for care among VA system patients, 39% of whom already have been receiving other VA medical care for more than a year before diagnosis/presentation for care).

2 For the same reason, while the undersigned agree with the VA that the HIV epidemic remains a matter of utmost public health importance in this country, the conclusion the VA draws from this fact – that it is necessary and appropriate to restrict the time available for public comment and input on these proposed changes to a mere thirty days – is flawed. A change of this significance requires careful consideration.

3 The CDC has recommended that “prevention counseling” should not be required. See Centers for Disease Control and Prevention, Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health-care Settings, MMWR (No. RR-14), 1-17 (2006), at http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm (“CDC Revised Recommendations”) at 1, 6, 8. The CDC defines “HIV-prevention counseling” as “[a]n interactive process of assessing risk, recognizing specific behaviors that increase the risk for acquiring or transmitting HIV, and developing a plan to take specific steps to reduce risks.” Id. at 2. The CDC concluded that there is not enough evidence to agree that this type of pre-test counseling for everyone is a good prevention tool. See id. at 6, 8.
test counseling is to provide the information the patient needs about the risks and benefits of testing in order to make an informed choice.”). Moreover, the VA already has the flexibility it needs to tailor counseling to specific patients. Id. (“Information may be tailored to meet the needs of individual patients who have varying levels of awareness and knowledge about HIV.”).

Second, public research has found that specific consent and pre-test counseling are not meaningful barriers to testing. In fact, at the recent 2008 National Summit on HIV Diagnosis, Prevention and Access to Care, a number of health care providers from busy hospital and clinic settings reported high rates of HIV testing uptake in expanded rapid test programs that included not only streamlined pre-test counseling but written documentation of consent. Providing information is more likely to encourage people to accept testing, not to deter it.

Finally, a number of successful models around the country demonstrate that it is readily possible to increase HIV testing (a goal that the undersigned share), without abandoning safeguards ensuring that testing is informed and voluntary. A key example of expanded

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5 See, e.g., Kaiser Family Foundation, Kaiser Public Opinion Spotlight, Attitudes about Stigma and Discrimination Related to HIV/AIDS (2006), at http://www.kff.org/spotlight/hivUS/index.cfm (concluding that the primary reason people reported not getting tested was because they didn’t think they were at risk, not because of a signed consent form); J. Omi, New York City Health and Hospitals Corporation, Integration of HIV Testing Within Medical Care in a Large Public Hospital System, Nov. 2008 Slide presentation, 2008 National Summit on HIV Diagnosis, Prevention and Access to Care (Nov. 19, 2008), at http://www.hivforum.org/storage/hivforum/documents/HIV%20Summit/Presentations/1120_tr_a_3_01_aberg_track.pdf (concluding that “[w]ritten informed consent has not been a significant barrier to achieving exceptional increases in the number of unique patients testing for HIV.”).


7 Surveys about pre-natal HIV testing confirm that providing greater information about HIV testing and the benefits of testing is more likely to encourage people to accept testing. See, e.g., R. Kropp et al., Unique Challenges to Preventing Perinatal HIV Transmission Among Hispanic Women in California: Results of a Needs Assessment, AIDS EDUCATION & PREVENTION 17, 22 (2005); M.I. Fernandez et al., Acceptance of HIV Testing During Prenatal Care, 115 PUBLIC HEALTH REPORTS 460-468 (2000).
testing programs that have taken place with universal post-test counseling (as well as pre-test counseling and written proof of consent) includes the “Expanded HIV Testing Initiative” undertaken by the New York Health and Hospitals Corporation (“HHC”), which, as the largest municipal health care delivery system in the United States, involves nearly 5 million annual visits and 19,000 patients with HIV infection in care. New York law requires pre-test and post-test counseling and written proof of consent. As the CDC knows from its close tracking of this initiative, HHC has substantially increased the number of individuals tested for HIV since 2006. The target was 150,000 per year. In FY 2008, the HHC documented 160,900 tested. In addition, the number of positive HIV tests has more than doubled since FY 2004, to 1,863 in FY 2008. In fact, in a November, 2008 summary of expanded testing activities across the country, the CDC reported the most impressive statistics from New York – a state that has successfully adapted and streamlined pre-test and post-test counseling, with patient documentation of informed consent, to the needs of individuals presenting for care – while noting negligible testing increases generally across the country and in many states with no such patient protections.

Other successful models of expanded testing that retains necessary safeguards are the following:

- Kaiser Permanente (“KP”) – the nation’s largest HMO, and a leading integrated health care system of 30 medical centers, 431 medical offices and 12,000 physicians – provides a compelling refutation of the position that counseling and informed written consent are a time-consuming barrier to HIV diagnosis and care. KP’s philosophy is that HIV testing is a process that includes an antibody test with pre-test and post-test counseling, patient education, and procedures to handle newly identified cases, convey test results, and discuss risk behavior, sexuality, and STD testing; counseling and the frequency of testing are determined individually. Ninety percent of KP’s HIV patients are in care within 120 days of diagnosis, and their mortality rate is lower than the national average.

8 J. Omi (2008), supra note 5.


10 B. Branson (2008), supra note 9.

11 Information provided at the 2006 National Summit on Opportunities for Expanding HIV Diagnosis, Prevention, and Access to Care in the United States (Nov. 29-30, 2006) by Dr. Michael
• Authors of one study found that routinely recommending HIV counseling and testing can be feasible and effective in an emergency department setting, despite the time constraints present in that setting, and concluded that emergency room testing can be increased by streamlining counseling and providing some information in writing, as well as by involving non-physician staff in counseling.  
  
• Perinatal transmission of HIV has been virtually eliminated in the United States, including in states that require specific written informed consent, such as Massachusetts, Pennsylvania and Michigan.  

III. The Current Requirement for Pre-test Counseling for HIV Testing Should be Retained.

The undersigned believe that the VA’s proposal to “eliminate pre-test counseling” is seriously flawed for several reasons. First and foremost, almost all of the information that the VA currently requires be provided – in an interactive exchange with the patient – must still be provided under the VA’s informed consent regulations and policies. To the extent that any is not still required, both individual patients and the public health will benefit from continued provision of virtually all of the information slated for elimination under the Proposed Rule. Moreover, Congress did not mandate that the requirement for the provision of pre-test counseling be eliminated. Furthermore, as discussed above, pre-test counseling is not a barrier to expanded HIV testing.

A. Pre-test counseling, in large part, continues to be required by the VA’s unaltered requirement for informed consent.

The requirement for informed consent prior to HIV testing – contained in portions of the regulations unchanged by the Proposed Rule and required by general legal and ethical

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Horberg, Kaiser Permanente’s Director of HIV/AIDS Policy, Quality Improvement, and Research, at http://www.hivlawandpolicy.org/resourceCategories/view/10. With over 16,000 active HIV positive patients in care, including more than 200 patients 19 years old or younger, Kaiser Permanente (KP) is the second largest provider of HIV care in the U.S. Id.


standards governing the medical profession\textsuperscript{14} – mandates that most of the VA’s “pre-test counseling” requirements continue in place. As the Supplementary Information acknowledges, informed consent will continue to be required before HIV testing occurs, and the general informed consent requirements set forth in 38 C.F.R. § 17.32 will continue to apply to HIV testing. \textsuperscript{73 Fed. Reg. at 79429.} Pursuant to those general requirements, the practitioner at the VA who has primary responsibility for the patient or who will perform the HIV test will still be required, by regulation, to provide the following information before any person is tested for HIV:

(1) the nature of the proposed HIV test;
(2) the expected benefits of having an HIV test;
(3) the reasonably foreseeable associated risks, complications or side effects from an HIV test;
(4) the reasonable and available alternatives to being tested for HIV; and
(5) the anticipated results if no HIV test is done.

\textit{See} 38 C.F.R. § 17.32(c). In addition, the patient “must be given the opportunity to ask questions, to indicate comprehension of the information provided, and to grant permission freely without coercion.” \textit{Id.} The test can only be performed after that information and opportunity have been provided to the patient and the patient consents to the test. \textit{Id.}, §§ 17.32(b), (c).

A comparison of the above iteration of the categories of information that must be provided prior to testing with the VA’s requirements for HIV “pre-test counseling” makes it clear that those counseling requirements should not be eliminated. The VA currently requires that, as part of pre-test counseling, “[a]ll elements of VA Form 10-0121 must be explained in detail by the practitioner, or professional counselor” and that other specified matters must be described. VHA Handbook 1004.1, “VHA Informed Consent for Clinical Treatments and Procedures,” at 15. Almost all of the elements set forth on VA Form 10-0121 will have to be explained pursuant to 38 C.F.R. § 17.32(c).\textsuperscript{15}

\textsuperscript{14} \textit{See}, e.g., American Medical Association, Office of the General Counsel, Division of Health Law, \textit{Informed Consent}, at http://www.ama-assn.org/ama/pub/category/4608.html; C. Hanssens, \textit{Legal and Ethical Implications of Opt-Out HIV Testing}, 45 CLINICAL INFECTION DISEASES S232 (Dec. 2007) (Suppl. 4); \textit{see also} CDC Revised Recommendations at 7, 13 (acknowledging need for informed consent prior to HIV testing).

\textsuperscript{15} \textit{See} VA Form 10-0121 (“Pre-test Counseling and Consent for HIV Testing”), at http://www.hiv.va.gov/vahiv?page=prtop02-va-01. The elements of VA Form 10-0121 are: (1) the condition or diagnosis for which the test is recommended (specifically, what the HIV test is for, what HIV and AIDS are, the fact that a person can be infected for years without knowing it yet can transmit the virus to others during that time, and the types of patients for whom the test might be recommended); (2) what the test involves; (3) the expected benefits of the test; (4) the possible risks of the test; (5) the alternatives to the test; (6) what the test results will mean (the meaning of positive,
The pre-test counseling elements not clearly enumerated in the list set forth in 38 C.F.R. § 17.32(c) are the following:

- how HIV is spread;
- Veterans Health Administration (“VHA”) policy on non-discrimination in health care services for patients with HIV infection;
- exceptions to the VHA policy for maintaining confidentiality of HIV test results including authorized disclosure to public health authorities or to a spouse and/or sexual partner;
- health care services available in the VHA;
- potential social ramifications of a positive test result;
- measures to be taken for prevention of HIV transmission; and
- identifying the types of patients for whom the test might be recommended.

However, most – if not all – of that information will continue to be required under the VA’s implementation of the informed consent requirement. As the Supplementary Information notes, if the Proposed Rule is adopted unchanged, VA practitioners will still be required to inform patients of “information that a patient in similar circumstances would reasonably want to know.” 73 Fed. Reg. at 79429 (quoting VHA Handbook 1004.1, at 4). A patient deciding whether or not to be tested for HIV is likely to want to know the extent to which the VA will be required to keep the test result confidential, what care will be available at VA facilities and the fact the patient will be able to access that care without discrimination, and the potential social ramifications if the patient is found to have HIV. Information about how HIV is spread and what measures prevent the spread of HIV is clearly relevant to a patient’s evaluation of the possible benefit of being tested to determine if HIV has been transmitted to him or her.

Thus, virtually all of what is now required as “pre-test counseling” still will be required if the Proposed Rule is adopted. But to take away the HIV-specific explication of what information will need to be provided to the patient in an interactive manner does a disservice to the patient – who deserves the safeguard of that specificity – and to the practitioner –

negative, and indeterminate test results and the generally high accuracy – but not infallibility – of the test); and (7) how HIV is spread. *Id.*

The other matters which the VA currently requires be described as part of pre-test counseling are the: “(a) VHA policy on non-discrimination in health care services for patients with HIV infection; (b) Exceptions to the VHA policy for maintaining confidentiality of HIV test results including authorized disclosure to public health authorities or to a spouse and/or sexual partner; (c) Health care services available in VHA; (d) Meaning, sensitivity and specificity of the HIV tests; (e) Potential social ramifications of a positive test result; and (f) Measures to be taken for prevention of HIV transmission.” VHA Handbook 1004.1, at 15.
who can more readily ensure that he or she meets the obligation to obtain informed consent if the current specificity is retained.

In light of this need to continue to provide virtually all of the information specified in the provision proposed for deletion, the assertion in the Proposed Rule that “pre-test counseling” is being “eliminated” is confusing and harmfully misleading. By entitling the Proposed Rule “Elimination of Requirements for Prior Signature Consent and Pre- and Post-Test Counseling for HIV Testing,” the VA risks inaccurately implying that – even if the Proposed Rule is adopted unchanged – VA personnel will no longer be required to provide the patient with particular categories of information and the opportunity to ask questions about that information before the patient’s consent can be obtained for an HIV test.

B. The current requirements for pre-test counseling should, with very few exceptions, be retained because they serve important public health and patient rights purposes.

Even if the VA believes that some of the elements currently required as part of pre-test counseling are not required by the informed consent obligation, pre-test counseling should not be eliminated because it has real value to the individual patient and to the public health.

Studies suggest that pre-test counseling that explains the nature of HIV testing and gives patients information about HIV disease provides many patients with important information they do not already know. For example, one study of patients in an urban intensive care setting revealed that patients have serious misconceptions about the nature of HIV testing. Patients doubted the accuracy of rapid HIV tests and were under the false impression that if they left the hospital and subsequently tested positive, the health department would contact them to inform them of their results. Patients were also confused about the confidentiality of HIV testing and issues of informed consent. In addition, the study revealed that many patients do not understand the importance of being tested for HIV when they do not have physical symptoms of the disease.16

An additional benefit of pre-test counseling is that such counseling increases testing consent rates among patients.17 Studies have shown that this link between pre-test counseling and consent occurs even in testing regimes where patients are routinely offered HIV tests and then given the opportunity to either accept or decline testing.18 This fact is not surprising –

16 A. Hutchinson et al., Understanding the Patient’s Perspective on Rapid and Routine HIV Testing in an Inner-City Urgent Care Center, 16 AIDS EDUC. & PREVENTION 101, 111-12 (2004).
18 See R. Kropp et al., Unique Challenges to Preventing Perinatal HIV Transmission Among Hispanic Women in California: Results of a Needs Assessment, 17 AIDS EDUC. & PREVENTION 22, 35 (2005). Nearly 40% of
when people have the benefits of HIV testing explained to them, they are far more likely to choose to protect their health. Reports on highly successful expanded testing programs in jurisdictions, such as New York, which continue to require documented counseling bear this out.19

Moreover, if requirements for pre-test information on such topics as how HIV is transmitted and how transmission can be prevented are eliminated, medical providers may lose an excellent opportunity to educate patients about HIV and how to begin to change risk behaviors – to the detriment of the individual patients and public health generally. A 2006 Kaiser Family Foundation survey about attitudes about HIV testing showed that, unfortunately, many people still lack basic information about what does, and what does not, put them at risk of getting HIV.20 This lack of knowledge is intrinsically connected to the fear and stigma that fuel the discrimination that too often follows a positive diagnosis.21

the participants in Kropp’s study were unaware that ZDV treatment could reduce the risk of mother-child transmission, but 92% indicated that such knowledge would increase their willingness to be tested. Id. These findings led the authors of the study to conclude that “[t]o improve HIV test acceptance by Hispanic women, culturally appropriate pretest counseling with information on treatment to reduce perinatal HIV transmission is needed.” Id. at 36.

19 J. Omi (2008), supra note 5.

20 Kaiser Family Foundation (2006), supra note 5; see also G. Herek et al., When Sex Equals AIDS: Symbolic Stigma and Heterosexual Adults’ Inaccurate Beliefs about Sexual Transmission of AIDS, 52 Social Problems 15-37 (2005) (2005 study revealed that 33% of male respondents and 46% of female respondents incorrectly believed HIV transmission could occur through unprotected sex between two uninfected men).

21 Stigma still attaches to an HIV diagnosis, and people living with HIV still experience discrimination. See, e.g., P.A. Vanable et al., Impact of HIV-Related Stigma on Health Behaviors and Psychological Adjustment Among HIV-Positive Men and Women, 10 AIDS AND BEHAVIOR 473-482 (2006) (reporting that 41% of the respondents in a 2006 study agreed “people often behaved negatively around them once they learned of their HIV status.”); B. Sears. & D. Ho, HIV Discrimination in Health Care Services in Los Angeles County: The Results of Three Testing Studies, The Williams Institute, UCLA School of Law (2006), at http://www.law.ucla.edu/williamsinstitute/publications/Discrimination%20in%20Health%20Care%20LA%20County.pdf. (finding that 56% of the skilled nursing facilities, 26% of the plastic and cosmetic surgeons, and 47% of the obstetricians surveyed in Los Angeles County from 2003 to 2005 refused to treat any people living with HIV); Kaiser Family Foundation (2006), supra note 5 (finding that only 1 in 4 respondents to 2006 survey reported that they would be very comfortable having a roommate who had HIV and only 29% reported that they would be very comfortable with their child having a teacher who had HIV); M.A. Schuster et al., Perceived Discrimination in Clinical Care in a Nationally Representative Sample of HIV-Infected Adults Receiving Health Care, 20 JOURNAL OF GENERAL INTERNAL MEDICINE 807-813 (2005) (noting that 26% of adults with HIV believed they had experienced discrimination from a health care provider since being diagnosed with HIV, according to a 2005 study); see also G. Herek et al., HIV-Related Stigma and Knowledge in the United States: Prevalence and...
Finally, the pre-test dialogue between practitioner and patient is important for developing or enhancing trust between the patient and the care provider, and with greater trust comes an increased likelihood that the patient will seek and continue needed treatment. Studies show that patients’ rates of adherence to prescribed treatment are higher where their trust in their physician is high.\textsuperscript{22} This is especially important given the low rates at which patients newly diagnosed as having HIV are linked to follow-up care in some settings.\textsuperscript{23} Therefore, ensuring that a patient receives the information that a patient considering an HIV test would reasonably want to know will increase the likelihood of patient-provider trust and of treatment adherence if the patient gets a positive HIV test result.

C. The proposed elimination of the requirement for pre-test counseling is not mandated by statute.

Eliminating the VA’s requirement for the provision of pre-test counseling is not mandated by the Veterans’ Mental Health and Other Care Improvements Act of 2008, Pub. L. 110-387, 122 Stat. 4110. In allowing the VA to change its approach to HIV testing, Congress appropriately focused on a real barrier to expanded testing: only offering testing to those who fit within risk profiles. With respect to HIV testing, Pub. L. 110-387 simply states as follows:

\begin{quote}
REPEAL OF LIMITATION ON AUTHORITY TO CONDUCT WIDESPREAD HIV TESTING PROGRAM.
Section 124 of the Veterans’ Benefits and Services Act of 1988 (title I of Public Law
\end{quote}


\textsuperscript{22} F.L. Altice \textit{et al., Trust and Acceptance of and Adherence to Antiretroviral Therapy}, 28 JOURNAL OF AIDS 47-58 (2001) (finding trust in a personal physician was the strongest predictor of willingness to initiate antiretroviral treatment in a population of primarily African-American and Hispanic inmates and was a strong predictor of preventive services use among African Americans); see also A.S. O’Malley \textit{et al., The Role of Trust in Use of Preventive Services Among Low-Income African-American Women}, 38 PREVENTION MEDICINE 777-785 (2004) (survey found that trust in a personal physician was strongly associated with use of preventive health services among low-income African-American women); see also D.H. Thom \textit{et al., Further Validation and Reliability Testing of the Trust in Physician Scale}, 37 MED. CARE 510-517 (1999); D.G. Safran \textit{et al., Linking Primary Care Performances to Outcomes of Care}, 47 JOURNAL OF FAMILY PRACTICE 213-218 (1998); E. Etchells \textit{et al., Bioethics for Clinicians: 1. Consent}, 155 CAN. MED. ASSOC. J. 177-180 (1996).

\textsuperscript{23} M. Lyons \textit{et al., Emergency Department HIV/Testing and Counseling: An Ongoing Experience in a Low-Prevalence Area}, 46 ANNALS OF EMERGENCY MEDICINE 22-28 (2004) (finding that only 35% to 64% of emergency department patients newly diagnosed with HIV are successfully linked to follow-up care post-diagnosis).
100-322, as amended; 38 U.S.C. 7333 note) is repealed.

122 Stat. at 4130, § 407. As a result of that statutory provision, Section 7333 of Title 38 of the United States Code now includes the following note:

Restriction on Testing for Infection With Human Immunodeficiency Virus
Section 124 of Pub. L. 100-322, as amended by Pub. L. 102-83, § 6(j)(3), Aug. 6, 1991, 105 Stat. 409 which related to a restriction on a widespread testing program to determine infection of humans with the Human Immunodeficiency Virus unless such program was specifically funded by appropriations to the Department of Veterans Affairs or such testing was offered as a voluntary service to patients already being furnished with health care or related services by the Department, was repealed by Pub. L. 110-387, Title IV, § 407, Oct. 10, 2008, 122 Stat. 4130.

38 U.S.C. § 733, note.24 Thus, it is apparent from the current statutory note that Congress’s

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24 Prior to repeal of Section 124 of Public Law 100-322, 38 U.S.C § 7333 included the following note:

Restriction on Testing for Infection With Human Immunodeficiency Virus

“(a) General rule.—Except as provided in subsection (b), the Secretary of Veterans Affairs may not during any fiscal year conduct a widespread testing program to determine infection of humans with the human immunodeficiency virus unless funds have been appropriated to the Department of Veterans Affairs specifically for such a program during that fiscal year.

“(b) Voluntary testing.— (1) The Secretary shall provide for a program under which the Department of Veterans Affairs offers each patient to whom the Department is furnishing health care or services and who is described in paragraph (2) the opportunity to be tested to determine whether such patient is infected with the human immunodeficiency virus.

“(2) Patients referred to in paragraph (1) are—

“(A) patients who are receiving treatment for intravenous drug abuse,

“(B) patients who are receiving treatment for a disease associated with the human immunodeficiency virus, and

“(C) patients who are otherwise at high risk for infection with such virus.

“(3) Subject to the consent requirement in paragraph (4) and unless medically contraindicated, the test shall be administered to each patient requesting to be tested for infection with such virus.
primary goal was to repeal language that restricted the categories of patients to whom the VA could offer an HIV test to those who requested a test and those who were considered at high risk for HIV infection. With Congress’s elimination of the requirement that the test only be offered to those considered at risk, information identifying the types of patients for whom the test might be recommended (currently part of VA Form 10-0121, Item 1) is no longer needed and the undersigned support its omission from the required pre-test information.

Moreover, the reports of the House and Senate Committees on Veterans’ Affairs did not identify elimination of pre-test counseling as a primary purpose of the legislation. In the “Purpose and Summary” portion of its report on the legislation, the House Committee Veterans Affairs stated that this section of the bill “would remove the requirement for written informed consent for HIV testing among veterans, thereby reducing existing barriers to the early diagnosis of HIV infection,” with no mention of eliminating pre-test counseling. H.R. Rep. No. 110-786, at 4 (2008); see also id. at 16 (stating, in Section-by-Section Analysis of the Bill, “[t]his section would repeal [section 124] to remove the requirement for written informed consent for HIV testing among veterans.”). Similarly, the Senate Committee on Veterans Affairs summarized the bill as “repeal[ing] the limitation on the authority of the Secretary to conduct a widespread [HIV] testing program.” S. Rep. No. 110-473, at 6 (2008). The lesser importance to both Committees of elimination of the requirement for pre-test counseling is indicated by the fact that it is only mentioned in sections providing background and cost estimates regarding the bill. See House Rep. No. 110-786, at 8, 11-12; S. Rep. No. 110-473, at 44, 88.25

Leaving intact the current specificity of what information must be provided to ensure informed consent prior to HIV testing is not only allowed by the Congressional action, but is in keeping with the desire that the VA afford its members high quality care. As discussed above, providing the information specified in the current regulations best serves the veterans who rely on the VA for care, as well as serving the public health.

“(4) A test may not be conducted under this subsection without the prior informed and separate written consent of the patient tested. The Secretary shall provide pre- and post-test counseling regarding the acquired immune deficiency syndrome and the test to each patient who is administered the test.”

25 The Senate Committee report also appends a statement by Gerald M. Cross, MD, FAAFP, Principal Deputy Under Secretary for Health, U.S. Department of Veterans Affairs, which includes discussion of the elimination of pre-test counseling. S. Rep. No. 110-473, at 100-01.
IV. Post-Test Counseling is Important for VA Patients Who Test Negative and the VA Should Continue to Provide It.

There is little disagreement that individuals who test positive for HIV should receive counseling on the meaning of the test, the availability and value of anti-retroviral treatment and other medical and social services, ways to maintain health and protect others from infection, and referrals and linkage to appropriate follow-up care. However, available evidence also supports the importance of counseling following testing even for those who test negative: to explain the meaning of test results and the importance of regular testing and care. As discussed below, this is particularly crucial to sound public health practice because the most frequently used HIV screening tests do not detect acute infection.

Primary or acute HIV infection is the period immediately following a patient’s initial infection with HIV and before development of HIV antibodies that are detectable by ELISA and Western Blot assays. Traditional antibody assays typically cannot detect the virus until a minimum of four to six weeks into infection, and sometimes as long as three to six months. However, acute HIV infection presents an important public health concern, as it is during this period when a person’s viral load spikes and the person is probably the most infectious. In fact, it is estimated that 40% of HIV-infected patients acquired HIV from someone who was in the primary infection stage and who would have tested negative on a rapid HIV test.

By definition, a person experiencing primary or acute HIV infection has engaged recently in risk activity that spreads HIV. Without some intervention, that person, armed with a negative HIV test that suggests that activity has been risk-free, is likely to continue the behavior that puts others at risk of possible infection. People are also less likely to have follow-up testing when they have received a negative HIV test. The CDC has found that one of the factors contributing to late diagnosis of HIV is a previous negative test result, because “persons who tested negative might have assumed they were safe and therefore did not retest for a long time.”


28 CDC, Late Versus Early Testing of HIV – 16 Sites, United States, 2000-2003, 52 MMWR 581-586 (June 27, 2003). The CDC report showed that compared with early testers (those who test more
on those who test positive on a rapid test is effectively ignoring this critical contributor to the HIV epidemic. Effective counseling that engages such a person in continued testing and that promotes protective sexual practices must be retained as an important part of preventive HIV care.

V. Requiring Written Consent has Value to Patients and Providers.

Because informed consent remains a critical component of HIV testing (as it is for all medical treatment), eliminating written consent for testing, as the VA proposes, is an ill-advised and unnecessary approach. Written consent is the clearest safeguard to ensure that information has been provided to patients and that consent has been given. As the VA itself has recognized correctly, use of a written consent form can also be of significant assistance to health care providers, and it is an effective way to provide information to patients.29 Further, requiring documented written consent also helps ensure that providers understand that informed consent is a valued component of HIV testing and treatment and helps mitigate the potential for coercion associated with a simultaneous effort to routinize HIV testing.30 Not only does patient documentation of informed consent provide additional insulation from provider liability for claims of coercion or involuntary testing,31 it does so without any apparent negative impact on efforts to significantly expand HIV testing.32

than 5 years before an AIDS diagnosis), later testers (those who test less than one year before an AIDS diagnosis) are significantly more likely to have tested negative for HIV previously, before their first positive test. Id.

29 See VA FAQs, supra note 4 (noting that the VA’s written consent “form provides information about HIV testing designed to answer the patient’s questions about testing, such as the HIV test procedures, the benefits and possible risks of the test, and the meaning of test results. This revised form also addresses the required elements of pre-test counseling for the provider who had not routinely provided HIV pre-test counseling in the past.”).

30 See, e.g., S. Maman & E. King, Changes in HIV Testing Policies and the Implications for Women, 53 J. MIDWIFERY & WOMEN’S HEALTH 195, 197 (May/June 2008) (noting that the CDC’s Revised Recommendations for opt-out testing have caused “widespread concern that in practice this method will lead to an erosion of voluntary consent for HIV testing” and that “given the power differentials inherent in the client-provider relationship, it is also unclear whether clients will feel enabled to opt of the services against the recommendation of their providers”).

31 See, e.g., C. Hanssens, supra note 14 at S236-7.

32 See, e.g., J. Omi (2008), supra note 5 (concluding that “Written informed consent has not been a significant barrier to achieving exceptional increases in the number of unique patients testing for HIV.”)
For all these reasons, and particularly given that providing information to a patient is a critical component of HIV testing, the VA’s position that eliminating pre-test counseling and written consent are the best way to increase testing is fundamentally flawed.

Sincerely,

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