[4410-05P]

DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 549

[BOP-1169-P]

RIN 1120-AB69

Infectious Disease Management: Voluntary and Involuntary Testing

AGENCY: Bureau of Prisons, Justice.

ACTION: Proposed rule.

SUMMARY: In this document, the Bureau of Prisons proposes two minor revisions to its regulations on the management of infectious diseases. One change would remove the requirement for HIV pre-test counseling for inmates, because the counseling requirement has become an obstacle to necessary testing. Inmates testing positive for HIV will continue to receive HIV post-test counseling. The second change would alter language regarding tuberculosis (TB) testing to clarify that it is testing for the TB infection, but not "skin testing." This would account for advances in medical technology that allow for newer testing methods.

DATES: Written comments must be submitted on or before [INSERT DATE 60 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Rules Unit, Office of General Counsel, Bureau of

Prisons, 320 First Street, NW, Washington, DC 20534.

FOR FURTHER INFORMATION CONTACT: Rules Unit, Office of General Counsel, Bureau of Prisons, phone (202) 353-8214.

SUPPLEMENTARY INFORMATION:

Posting of Public Comments

Please note that all comments received are considered part of the public record and made available for public inspection online at www.regulations.gov. Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

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SUPPLEMENTARY INFORMATION: The Bureau proposes two minor revisions to its regulations on the infectious disease management program (28 CFR, part 549, subpart A). One change would remove the requirement for HIV pre-test counseling for inmates, because the counseling requirement has become an obstacle to necessary testing. Inmates testing positive for HIV will continue to receive HIV post-test counseling. The second change would alter language regarding tuberculosis (TB) testing to clarify that it is testing for the TB infection, but not "skin testing." This would account for advances in medical technology that allow for newer testing methods.

Clarifications to inmate information procedures. 28 CFR 549.12(a)(1) currently states that the "Bureau tests inmates who have sentences of six months or more if health services staff determine, taking into consideration the risk as defined by the Centers for Disease Control Guidelines, that the inmate is at risk for HIV infection." We propose to make minor clarifying changes to this language to make it clear that such inmates will be informed orally or in writing that HIV testing will be performed unless they decline testing. This would be a minor change to be consistent with CDC Guidelines, which state that "HIV screening is recommended for patients in all health-care settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening)". In light of the CDC Guidelines, we propose to change the regulation language to clarify that HIV screening is recommended for all inmates because risk factors are present in the correctional health-care setting. The language as it currently exists in the regulation does not make it clear that inmates will be so notified, although this has already been the Bureau's longstanding procedure during Admission and Orientation of inmates.

Eliminating the requirement for HIV pre-test counseling and HIV post-test counseling for HIV-negative inmates. In 28 CFR 549.12

(Testing), subparagraph (a)(5) currently states that "Inmates being tested for HIV will receive pre- and post-test counseling, regardless of the test results." We propose altering this subparagraph to read as follows: "Inmates testing positive for HIV will receive post-test counseling." This change would eliminate the requirement that the Bureau provide pre-test counseling for inmates and post-test counseling for HIV-negative inmates. We propose these changes to bring our requirements in conformance with those recommended by the Center for Disease Control (CDC) in their report entitled "Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings"(2006, MMWR 55(RR14);1-17); **http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm**.

The CDC set forth guidelines in 1994 for counseling and testing persons with high-risk behaviors which specified prevention (pre-test) counseling to develop specific prevention goals and strategies for each person (client-centered counseling). However, in 2003, CDC introduced an initiative entitled "Advancing HIV Prevention: New Strategies for a Changing Epidemic". One key point of this initiative was to make HIV testing a routine part of medical care on the same voluntary basis as other diagnostic and screening tests. In its technical guidance, CDC acknowledged that although prevention (pre-test) counseling is desirable for all persons at risk

for HIV, such counseling might not be appropriate or feasible in all settings. Because time constraints caused some providers to perceive requirements for prevention counseling and written informed consent as a barrier to uniform testing, the initiative advocated streamlined approaches. The CDC found that although targeted testing programs, like the Bureau's infection disease management program, were implemented in acute-care settings and nearly two thirds of patients in these settings accept testing; risk assessment and prevention (pre-test) counseling are time-consuming, so only a limited proportion of eligible patients can be tested.

There are significant benefits of HIV testing for inmates because treatment for HIV can be initiated promptly preventing serious complications and death. The CDC has found that requirements for pre-test prevention counseling pose a barrier to testing and therefore CDC recommends that an "opt-out" testing protocol be utilized, in which persons are informed that they will be tested unless they choose not to be tested. Specifically CDC recommends that:

- HIV screening is recommended for patients in all health-care settings after the patient is notified that testing will be performed unless the patient declines (opt-out screening).

- 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.

- Prevention counseling should not be required with HIV diagnostic testing or as part of HIV screening programs in health-care settings.

"Revised Recommendations for HIV Testing of Adults, Adolescents, and Pregnant Women in Health Care Settings"(2006, MMWR 55(RR14); 1-17); **http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm**.

In addition to the above, the Bureau also notes that eliminating the pre-test counseling requirement would save Bureau staff approximately 20 minutes per counseling session. Since the Bureau strives to test all inmates, the time savings this would permit are substantial. We therefore propose to delete the requirement for pre-test counseling in order to conform with CDC guidelines and to remove this barrier to testing as many inmates as possible.

We also propose to remove the requirement for post-HIV-test counseling for inmates who have tested negative for HIV. Those testing positive will continue to receive post-test counseling. Those testing negative, however, have no need for further counseling, but may ask questions of Health Services staff as needed.

Eliminating the post-test counseling requirement for inmates testing HIV negative would also save 20 minutes per counseling session per inmate. Again, the time saving is quite substantial, considering that more than 98% of HIV tests performed are negative results.

Changing terminology to clarify that TB testing is no longer "skin testing." In 28 CFR 549.12(b)(4), we currently state that "[i]f an inmate refuses *skin testing*, and there is no contraindication to *tuberculin skin testing*, then, institution medical staff will test the inmate involuntarily." (Emphasis added.) We now proposed to alter this sentence to read as follows: "If an inmate refuses testing for TB infection, and there is no contraindication to testing, then institutional medical staff will test the inmate involuntarily." The only alteration we make in this language is to clarify that Tuberculosis testing is no longer "skin testing."

The Bureau currently primarily uses the tuberculin skin test for testing for latent TB infection. However, a new type of test for TB infection has become available, a blood test called the Interferon Gamma Release Assay (IGRA). In the next 5 to 10 years it is anticipated that blood tests for TB infection will replace the tuberculin skin test. These tests appear to be at least as accurate

as the skin test and have the benefit of requiring only one interaction with an inmate to draw blood (rather than place the skin test and reading it 2 to 3 days later). Using this type of test would eliminate the need for a second health care visit to conduct the test, as no "reading" would be required, which would result in great time savings to Bureau staff.

Once more, we make this change to bring the Bureau into conformance with CDC guidelines. In 2010, the CDC issued "Updated Guidelines for Using Interferon Gamma Release Assays to Detect *Mycobacterium tuberculosis* infection – United States, 2010" (MMWR 59 (RR-5)1-13; http://www.cdc.gov/mmwr/pdf/rr/rr5905.pdf. In this report, the CDC states that "[b]efore 2001, the tuberculin skin test (TST) was the only practical and commercially available immunologic test for TB infection approved in the United States."

However, several risks are associated with the use of TSTs: difficulty with the very specific administration needed, unreliable patient return to the health-care provider for the test reading, and inaccuracies and biases existing in reading the TSTs, such as false-positives. IGRAs, however, assess the presence of specific tuberculosis proteins, and therefore offer improved test specificity compared with TSTs.

For this reason, the CDC has recommended increasing use of

IGRAs. Although skin testing may still be used, it will not be used exclusively, so we propose to update our regulatory language to allow for the possibility of other kinds of testing for TB infection.

Other changes for clarity:

We also propose to make minor changes to § 549.12(a)(2), Exposure incidents, to clarify that the current language stating that the Bureau will test "when there is a well-founded reason to believe that the inmate may have transmitted the HIV infection" means the following: The Bureau tests an inmate, regardless of the length of sentence or pretrial status, when there is a well-founded reason to believe that the inmate *has been the source of a percutaneous or mucous membrane blood exposure, via an altercation or accident or other means to Bureau employees, other non-inmates who are lawfully present in a Bureau institution, or other inmates*, regardless of whether the exposure was intentional or unintentional. Exposure incident testing does not require the inmate's consent. This language more accurately reflects the intention of the regulation.

Executive Order 12866.

This proposed regulation has been drafted and reviewed in

accordance with Executive Order 12866, "Regulatory Planning and Review", section 1(b), Principles of Regulation. The Director, Bureau of Prisons has determined that this proposed regulation is a "significant regulatory action" under Executive Order 12866, section 3(f), and accordingly this proposed regulation has been reviewed by the Office of Management and Budget.

Executive Order 13132.

This proposed regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, under Executive Order 13132, we determine that this proposed regulation does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Flexibility Act.

The Director of the Bureau of Prisons, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), reviewed this proposed regulation and certifies that it will not have a significant economic impact upon a substantial number of small entities for the following reasons: This proposed regulation pertains to the correctional

management of inmates committed to the custody of the Attorney General or the Director of the Bureau of Prisons. Its economic impact is limited to the Bureau's appropriated funds.

Unfunded Mandates Reform Act of 1995.

This proposed regulation will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996.

This proposed rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 804. This proposed regulation will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 28 CFR Part 571:

Prisoners.

Charles E. Samuels, Jr.
Director, Bureau of Prisons

Under rulemaking authority vested in the Attorney General in 5 U.S.C 301; 28 U.S.C. 509, 510 and delegated to the Director, Bureau of Prisons in 28 CFR 0.96, we proposed to amend 28 CFR part 549 as follows.

SUBCHAPTER C - INSTITUTIONAL MANAGEMENT

PART 549 - MEDICAL SERVICES

1. The authority citation for 28 CFR part 549 continues to read as follows:

Authority: 5 U.S.C. 301; 10 U.S.C. 876b; 18 U.S.C. 3621, 3622, 3524, 4001, 4005, 4042, 4045, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), Chapter 313, 5006-5024 (Repealed October 12, 1984 as to offenses committed after that date), 5039; 28 U.S.C. 509, 510.

2. Amend § 549.12 by revising paragraphs (a) and (b)(4) to read as follows:

§ 549.12 Testing.

(a) *Human Immunodeficiency Virus (HIV)*—(1) *Testing.* All inmates who have sentences of six months or more will be informed upon admission either orally or in writing that HIV testing will be performed unless they refuse testing. If the inmate refuses testing and the inmate has risk factors for HIV infection as defined by the Centers for Disease Control and Prevention, staff will provide pre-test counseling, and if the inmate continues to refuse testing, staff may initiate an incident report for refusing to obey an order. Any inmate may request HIV testing during the pre-release process.

(2) *Exposure incidents.* The Bureau tests an inmate, regardless of the length of sentence or pretrial status, when there is a well-founded reason to believe that the inmate has been the source of a percutaneous or mucous membrane blood exposure, via an altercation or accident or other means to Bureau employees, other non-inmates who are lawfully present in a Bureau institution, or other inmates, regardless of whether the exposure was intentional or unintentional. Exposure incident testing does not require the inmate's consent.

(3) *Surveillance testing.* The Bureau conducts HIV testing for surveillance purposes as needed. If the inmate refuses testing, staff will offer pre-test counseling, and if the inmate continues to refuse testing, staff may initiate an incident report for refusing to obey

an order.

(4) *Inmate request.* An inmate may request to be tested. The Bureau limits such testing to no more than one per 12-month period unless the Bureau determines that additional testing is warranted.

(5) *Counseling.* Inmates testing positive for HIV will receive post-test counseling.

(b) * * *

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(4) An inmate who refuses TB screening may be subject to an incident report for refusing to obey an order. If an inmate refuses testing for TB infection, and there is no contraindication to testing, then, institution medical staff will test the inmate involuntarily.

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