

in part as to offenses committed on or after November 1, 1987), 4161–4166 (Repealed as to offenses committed on or after November 1, 1987), 5006–5024 (Repealed October 12, 1984 as to offenses committed after that date), 5039; 28 U.S.C. 509, 510.

■ 2. Revise § 501.1 to read as follows:

**SUBCHAPTER A—GENERAL
MANAGEMENT AND ADMINISTRATION**

PART 501—SCOPE OF RULES

§ 501.1 Bureau of Prisons emergencies.

(a) *Suspension of rules during an emergency.* The Director of the Bureau of Prisons (Bureau) may suspend operation of the rules in this chapter as necessary to handle an institutional emergency or an emergency affecting the Bureau. When there is an institutional emergency which the Director or Warden considers a threat to human life or safety, the Director or Warden may suspend the operation of the rules in this chapter as necessary to handle the emergency.

(b) *Responsibilities of the Warden.*

(1) *Notifying the Director.* If the Warden suspends operation of the rules, the Warden must, within 24 hours of the suspension or as soon as practicable, notify the Director by providing written documentation which:

- (i) Describes the institutional emergency that threatens human life or safety;
- (ii) Sets forth reasons why suspension of the rules is necessary to handle the institutional emergency;
- (iii) Estimates how long suspension of the rules will last; and
- (iv) Describes criteria which would allow normal rules application to resume.

(2) *Submitting certification to Director of continuing emergency.* 30 days after the Warden suspends operation of the rules, and every 30 days thereafter, the Warden must submit to the Director written certification that an institutional emergency threatening human life or safety and warranting suspension of the rules continues to exist. If the Warden does not submit this certification to the Director, or if the Director so orders at any time, the suspension of the rules will cease.

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DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 549

[BOP–1104–F]

RIN 1120–AB03

**Infectious Disease Management:
Voluntary and Involuntary Testing**

AGENCY: Bureau of Prisons, Justice.

ACTION: Final rule.

SUMMARY: In this document, the Bureau of Prisons (Bureau) finalizes regulations on the management of infectious diseases. The changes address the circumstances under which the Bureau conducts voluntary and involuntary testing for HIV, tuberculosis, and other infectious diseases. We intend this amendment to provide for the health and safety of staff and inmates.

DATES: This rule is effective on June 20, 2005.

FOR FURTHER INFORMATION CONTACT:

Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307–2105.

SUPPLEMENTARY INFORMATION: The Bureau finalizes its regulations on the infectious disease management program (28 CFR part 549, subpart A).

These regulations were first published in the **Federal Register** on October 5, 1995 (60 FR 52278) as interim final rules. We received no public comment on that interim rule. We had published an entry in the Unified Regulatory Agenda describing the finalization of that interim final rule (BOP–1017–F, RIN 1120–AA23). To clarify that this rulemaking is a change to the same interim rules, we merged that action into a proposed rule which we published on July 12, 2002 (67 FR 46136).

Why we are making this rule: The Correction Officers Health and Safety Act of 1998 gave the Bureau new statutory authority for conducting HIV tests. Additionally, the Centers for Disease Control (CDC) has issued a variety of recommendations on prevention and control of HIV, tuberculosis, and other infectious diseases. Consequently, the Bureau revises its regulations in accordance with the new statutory authority and in consideration of CDC recommendations.

Previously, Bureau regulations on the management of infectious diseases provided for mandatory HIV testing of a yearly random sample, yearly new commitment sample, new commitment re-test sample, pre-release testing, and clinically indicated testing. Any inmate

refusing an order for one of these mandatory HIV testing programs is subject to an incident report for refusing to obey an order. Previous regulations did not allow for involuntary HIV testing of an inmate following any intentional or unintentional exposure, when there is a risk of transmission of HIV infection to Bureau employees or other persons in a Bureau institution.

The Correction Officers Health and Safety Act of 1998 provides that each individual convicted of a Federal offense who is sentenced to a period of six months or more is to be tested for HIV, if such individual is determined to be at risk for HIV infection in accordance with the guidelines issued by the Bureau. The act also provides for involuntary HIV testing following any intentional or unintentional exposure when there is a risk of transmission of HIV infection to Bureau employees or other persons in a Bureau institution. Because of this new statutory authority, the Bureau amends its regulations to allow involuntary testing in those instances where an inmate refuses to be tested following any intentional or unintentional exposure. The inmate may also be subject to an incident report for refusing to obey an order.

The Bureau will continue to allow an inmate to request to be tested for HIV. Such testing is limited to no more than once per 12-month period, unless the Bureau determines that additional testing is warranted. The Bureau will also continue to provide pre- and post-test counseling, regardless of the test results.

The Bureau also amends its regulations on infectious disease management to address testing requirements for tuberculosis (TB). The Bureau's general authority to protect and provide for the safekeeping and care of inmates in Bureau custody (18 U.S.C. 4042(a)) allows us to conduct medical tests as necessary to protect the health of the inmate population. Currently, testing of inmates for TB is conducted in accordance with the recommendations and guidelines published by the Centers for Disease Control (CDC) in 1992. In response to the increased transmission of TB in correctional facilities, the CDC updated and expanded previously published recommendations for preventing and controlling TB in correctional facilities.

Based on these updated recommendations, the Bureau will screen each inmate for TB within two calendar days of initial incarceration. We intend to appropriately treat, isolate and/or protect inmates as a result of exposure in the two-day interim before testing. The Bureau will also conduct

follow-up testing for each inmate annually. In addition, the Bureau will screen an inmate for TB when health services staff determine that the inmate may be at risk for infection. An inmate who refuses TB screening may be subject to an incident report for refusing to obey an order. If an inmate refuses tuberculin skin testing, and there is no contraindication to tuberculin skin testing, institution medical staff will educate and counsel the inmate regarding the need for such testing in an institutional setting (for example, the need to identify HIV+ inmates who have not received a course of prophylaxis and are at high risk for the development of active tuberculous disease). If an inmate still refuses tuberculin testing despite education and counseling, institution medical staff will test the inmate involuntarily. The intent of this amendment is to control TB among staff and inmates in correctional facilities.

To provide for the protection, safekeeping, and care of inmates in our custody (as required by 18 U.S.C. 4042(a)), we retain, revised for clarity, regulations on diagnostics (549.12(c)); Programming, Duty and Housing Restrictions (549.13); Confidentiality of Information (549.14); and Infectious Disease Training and Preventive Measures (549.15).

Finally, the Bureau removes provisions dealing with medical isolation and quarantining as these are governed by normal medical protocols and do not need to appear in the regulations. Removing these provisions from regulation and retaining them in Bureau policy allows us the flexibility to adhere to ever-changing medical standards and Federal medical guidelines.

Public Comments and Bureau Responses: We received three comments to the proposed rule. One supported the rule, stating that it would "help control the epidemic of AIDS and other diseases in prison."

The second commenter expressed concern that using mandatory "PPD skin testing" to detect tuberculosis would contravene his Buddhist religious beliefs. The "PPD skin test" is a medical term of art referring to a test that, in earlier years, involved injecting purified pork derivative liquid under the skin. The commenter and other inmates were concerned that this would amount to consuming a pork product, which would contravene several religious beliefs, including Buddhism and Islam. The commenter further expressed concerns that there would be unnecessary follow-up testing after initial TB screening, thereby subjecting

inmates to further violation of religious beliefs.

Although the use of PPD as a screening test is routine, questions frequently arise about the required tuberculin skin test. The current version of the PPD uses a Purified Protein Derivative instead of a pork derivative. Inmates who object to the "PPD skin test" frequently cite religious reasons based on a mistaken belief that the liquid solution injected under the skin is a fat and/or animal derivative. The solution is not a fat or animal derivative, but is instead synthetic. However, the guiding principle with medical issues and religion is weighing the individual interest and the compelling government interest. TB is a highly communicable disease. The tuberculin skin test is used as an early diagnostic tool because it is highly effective in determining TB infection. Some cite that the x-ray is a least restrictive alternative because it can detect TB. However, x-rays do not provide early diagnostic information. Therefore, the safety of the institution's population, staff and inmate, is put at risk if the x-ray is used as an alternative. The compelling government interest outweighs the sincerely held religious belief and motivation of the inmate.

In response to the comment, however, we recognize that the term "PPD test" may be misleading and therefore will change the name of the test to more accurately reflect what it is: The Tuberculin Skin Test. We also eliminate references to the term "PPD" in the rule text.

Also, our previous TB testing provision had stated that after the initial screening, we would conduct follow-up testing annually. To allay the commenter's apparent concern that inmates will be tested unnecessarily every year, we clarify that we will conduct TB screening for each inmate annually only as medically indicated.

Finally, the third commenter complained that he had been subjected to seven HIV tests as part of "random" testing. This inmate had filed an administrative remedy complaint with the Bureau requesting to be removed from the HIV testing program.

Before May 2000, the Bureau conducted random HIV testing. In May 2000, the Bureau began testing a new commitment sample and, new recommitment re-test sample in addition to voluntary, pre-release, and as clinically indicated as set forth in then-current regulation (28 CFR 549.13(b)). All new commitments between October 1, 1999, and March 31, 2000, with release dates projected at 3 years or more qualified initially for the new commitment testing. If baseline

testing showed an inmate was HIV negative, new commitment re-testing was to be completed every year thereafter, until further notice.

The new commitment, new recommitment re-test sample was not a random sample. Unfortunately, when this system became effective, initial guidance referenced the testing incorrectly as a "subset of randomly selected inmates". This may have resulted in the use of the term "random" in discussing the seroconversion testing and subsequent misconceptions by staff and inmates.

Changes to § 549.14, Confidentiality of Information

After internal agency deliberation, we made changes to this part of the proposed rule for clarity and to more accurately reflect the intent of the Correction Officers Health and Safety Act (Pub. L. 105-370, codified at 18 U.S.C. 4014).

In our proposed rule, this section stated that any disclosure of test results or medical information would be made in accordance with the Privacy Act of 1974 and the HHS Standards for Privacy of Individually Identifiable Health Information promulgated pursuant to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The Bureau of Prisons is not a "covered entity" under subsequent regulations promulgated by the Department of Health and Human Services to implement HIPAA. We therefore exclude references to the Health Insurance Portability and Accountability Act of 1996.

Also, when we proposed this regulation, we described four types of routine uses of such information maintained by the Bureau in its Privacy Act systems of records.

In our revised rule, instead of singling out four routine uses of such information, we merely state that a more thorough description of routine uses allowable for inmate health records may be found in the Department of Justice Privacy Act System of Records Notice entitled "Inmate Physical and Mental Health Record System, JUSTICE/BOP-007."

In addition, we clarify that test results may be disclosed in accordance with The Correction Officers Health and Safety Act of 1998 (codified at 18 U.S.C. 4014), which authorizes the Bureau to communicate test results to a person requesting the test, the person tested, and, if the results of the test indicate the presence of HIV, to correctional facility personnel consistent with Bureau policy on this issue.

Executive Order 12866

This rule has been reviewed as a "significant regulatory action" under section 3(f) of Executive Order 12866 by the Office of Management and Budget (OMB). This rule will not impose a substantial cost on the public, the government or regulated entities. This rule change, mandated by statute and required to conform to CDC guidelines, will benefit inmates by allowing us to detect and treat infectious diseases more efficiently, thereby decreasing further infection.

Executive Order 13212

This 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, in accordance with Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Flexibility Act

The Director of the Bureau of Prisons, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities for the following reasons: This rule pertains to the correctional management of offenders committed to the custody of the Attorney General or the Director of the Bureau of Prisons, and its economic impact is limited to the Bureau's appropriated funds.

Unfunded Mandates Reform Act of 1995

This rule 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 rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule 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 549

Prisoners.

Harley G. Lappin,

Director, Bureau of Prisons.

■ Under rulemaking authority vested in the Attorney General in 5 U.S.C. 552(a) and delegated to the Director, Bureau of Prisons, we amend 28 CFR part 549 as follows.

SUBCHAPTER C—INSTITUTIONAL MANAGEMENT**PART 549—MEDICAL SERVICES**

■ 1. Revise the authority citation for 28 CFR part 549 to read as follows:

Authority: 5 U.S.C. 301; 18 U.S.C. 3621, 3622, 3624, 4001, 4005, 4014, 4042, 4045, 4081, 4082 (Repealed in part as to offenses committed on or after November 1, 1987), 4241–4247, 5006–5024 (Repealed October 12, 1984, as to offenses committed after that date), 5039; 28 U.S.C. 509, 510.

■ 2. Revise Subpart A to read as follows:

Subpart A—Infectious Disease Management

Sec.

549.10 Purpose and scope.

549.11 Program responsibility.

549.12 Testing.

549.13 Programming, duty, and housing restrictions.

549.14 Confidentiality of information.

549.15 Infectious disease training and preventive measures.

Subpart A—Infectious Disease Management**§ 549.10 Purpose and scope.**

The Bureau will manage infectious diseases in the confined environment of a correctional setting through a comprehensive approach which includes testing, appropriate treatment, prevention, education, and infection control measures.

§ 549.11 Program responsibility.

Each institution's Health Services Administrator (HSA) and Clinical Director (CD) are responsible for the operation of the institution's infectious disease program in accordance with applicable laws and regulations.

§ 549.12 Testing.

(a) *Human Immunodeficiency Virus (HIV).*

(1) *Clinically indicated.* 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. If the inmate refuses testing, staff may initiate an incident report for refusing to obey an order.

(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 may have transmitted the HIV infection, whether intentionally or unintentionally, to Bureau employees or other non-inmates who are lawfully present in a Bureau institution. 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 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 being tested for HIV will receive pre- and post-test counseling, regardless of the test results.

(b) *Tuberculosis (TB).*

(1) The Bureau screens each inmate for TB within two calendar days of initial incarceration.

(2) The Bureau conducts screening for each inmate annually as medically indicated.

(3) The Bureau will screen an inmate for TB when health services staff determine that the inmate may be at risk for infection.

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

(5) The Bureau conducts TB contact investigations following any incident in which inmates or staff may have been exposed to tuberculosis. Inmates will be tested according to paragraph (b)(4) of this section.

(c) *Diagnostics.* The Bureau tests an inmate for an infectious or communicable disease when the test is necessary to verify transmission following exposure to bloodborne pathogens or to infectious body fluid. An inmate who refuses diagnostic testing is subject to an incident report for refusing to obey an order.

§ 549.13 Programming, duty, and housing restrictions.

(a) The CD will assess any inmate with an infectious disease for appropriateness for programming, duty,

and housing. Inmates with infectious diseases that are transmitted through casual contact will be prohibited from work assignments in any area, until fully evaluated by a health care provider.

(b) Inmates may be limited in programming, duty, and housing when their infectious disease is transmitted through casual contact. The Warden, in consultation with the CD, may exclude inmates, on a case-by-case basis, from work assignments based upon the security and good order of the institution.

(c) If an inmate tests positive for an infectious disease, that test alone does not constitute sole grounds for disciplinary action. Disciplinary action may be considered when coupled with a secondary action that could lead to transmission of an infectious agent. Inmates testing positive for infectious disease are subject to the same disciplinary policy that applies to all inmates (*see* 28 CFR part 541, subpart B). Except as provided for in our disciplinary policy, no special or separate housing units may be established for HIV-positive inmates.

§ 549.14 Confidentiality of information.

Any disclosure of test results or medical information is made in accordance with:

(a) The Privacy Act of 1974, under which the Bureau publishes routine uses of such information in the Department of Justice Privacy Act System of Records Notice entitled "Inmate Physical and Mental Health Record System, JUSTICE/BOP-007"; and

(b) The Correction Officers Health and Safety Act of 1998 (codified at 18 U.S.C. 4014), which provides that test results must be communicated to a person requesting the test, the person tested, and, if the results of the test indicate the presence of HIV, to correctional facility personnel consistent with Bureau policy.

§ 549.15 Infectious disease training and preventive measures.

(a) The HSA will ensure that a qualified health care professional provides training, incorporating a question-and-answer session, about infectious diseases to all newly committed inmates, during Admission and Orientation.

(b) Inmates in work assignments which staff determine to present the potential for occupational exposure to blood or infectious body fluids will receive annual training on prevention of

work-related exposures and will be offered vaccination for Hepatitis B.

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DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Part 549

[BOP-1129-F]

RIN 1120-AB29

Over-The-Counter (OTC) Medications: Technical Correction

AGENCY: Bureau of Prisons, Justice.

ACTION: Final rule.

SUMMARY: This document finalizes a minor technical correction to the Bureau of Prisons (Bureau) regulations on Over-The-Counter (OTC) medications. Previously, our rule defined an inmate without funds as one who has had an average daily trust fund account balance of less than \$6.00 for the past 30 days. The words "average daily" in that definition resulted in incorrect classifications by the Bureau's business offices. The more accurate definition of an inmate without funds is one who has not had a trust fund account balance of \$6.00 for the past 30 days. We therefore issue this technical correction.

DATES: This rule is effective June 20, 2005.

ADDRESSES: Rules Unit, Office of General Counsel, Bureau of Prisons, 320 First Street, NW., Washington, DC 20534. Our email address is BOPRULES@BOP.GOV.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307-2105.

SUPPLEMENTARY INFORMATION: We amend our regulations on Over-The-Counter (OTC) medications (28 CFR part 549, subpart B). We published a final rule on this subject in the **Federal Register** on August 12, 2003 (68 FR 47847), and this correction as an interim final rule on September 3, 2004 (69 FR 53804). We received no comments on the interim final rule, and therefore publish it as final without change.

Previously, our rule defined an inmate without funds as one who has had an average daily trust fund account balance of less than \$6.00 for the past 30 days. The words "average daily" in that definition resulted in incorrect classifications by the Bureau's business offices. The more accurate definition of an inmate without funds is one who has

not had a trust fund account balance of \$6.00 for the past 30 days. We therefore issue this technical correction.

Executive Order 12866

This regulation has been drafted and reviewed in accordance with Executive Order 12866, "Regulatory Planning and Review", section 1(b), Principles of Regulation. The Director of the Bureau of Prisons has determined that this rule is not a "significant regulatory action" under Executive Order 12866, section 3(f), and accordingly this rule has not been reviewed by the Office of Management and Budget.

Executive Order 13132

This 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. Under Executive Order 13132, this rule does not have sufficient federalism implications for which we would prepare 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 regulation. By approving it, the Director certifies that it will not have a significant economic impact upon a substantial number of small entities because: This rule is about the correctional management of offenders committed to the custody of the Attorney General or the Director of the Bureau of Prisons, and its economic impact is limited to the Bureau's appropriated funds.

Unfunded Mandates Reform Act of 1995

This rule will not cause State, local and tribal governments, or the private sector, to spend \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. We do not need to take action under the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule 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-