



Date of Notice: October 4, 2017

**STATE OF RHODE ISLAND
DEPARTMENT OF HEALTH
PUBLIC NOTICE OF PROPOSED RULE MAKING**

In accordance with Rhode Island General Laws (RIGL) 42-35-2.7, notice is hereby given that the Rhode Island Department of Health (RIDOH) proposes to repeal the Rules and Regulations Pertaining to the Reporting and Testing of Infectious, Environmental, and Occupational Diseases [R23-10-DIS] and the Rules and Regulations Pertaining to HIV Counseling, Testing, Reporting, and Confidentiality [R23-6.3-HIV], and replace them with rules and regulations for Reporting and Testing of Infectious, Environmental, and Occupational Diseases [216-RICR-30-05-1].

REGULATION TITLE:

Rules and Regulations Pertaining to the Reporting and Testing of Infectious, Environmental, and Occupational Diseases [R23-10-DIS]

TYPE OF FILING: Repeal with associated adoption.

RULEMAKING ACTION: Public Notice of Proposed Rule Making

TIMETABLE FOR ACTION ON THE PROPOSED RULE: The public comment period ends on Monday, November 6, 2017.

SUMMARY OF PROPOSED RULE: The RIDOH is proposing rulemaking to consolidate the two regulations to be repealed into one set of regulations, provide clarity, update the list of reportable diseases, and remove any language that duplicates existing statute without additional interpretation. This consolidation is meant to delineate the reporting and testing of infectious, environmental, and occupational diseases of public health importance. Specific changes include:

- The addition of several conditions to the reportable conditions list, for example, carbapenem-resistant Enterobacteriaceae (CRE) and Acute Flaccid Myelitis (AFM).
- A requirement for laboratories to perform culture on positive Culture Independent Diagnostic Test (CIDT) specimens and submit an isolate to the RI State Health Laboratory.
- The elimination of the licensing requirement for Qualified Professional Testing Counselor (QPTC) for HIV. The course requirements remain in place.
- The expansion of the required reporters list to include persons and entities who were previously “recommended” to report.

COMMENTS INVITED: All interested parties are invited to submit written comments concerning the proposed regulations. Written comments can be submitted by mail to Paula Pullano, Rhode Island

Department of Health, 3 Capitol Hill, Providence, RI 02908-5097 or by email at paula.pullano@health.ri.gov by the close of **Monday, November 6, 2017**. Please note that comments submitted to RIDOH by other means than the prescribed mailing and email address may not be received and addressed in RIDOH's concise explanatory statement. To ensure that your comments are received, please send them to the prescribed mailing and email address.

WHERE COMMENTS MAY BE INSPECTED: Rhode Island Department of Health, 3 Capitol Hill, Providence, Rhode Island 02908-5097.

FOR FURTHER INFORMATION CONTACT: Paula Pullano, Rhode Island Department of Health, Division of Policy, Information, and Communications, 3 Capitol Hill, Providence, Rhode Island 02908-5097, 401-222-1042, paula.pullano@health.ri.gov.

AUTHORITY FOR THE RULEMAKING: Section 23-1.1 of the Rhode Island General Laws.

REGULATORY FINDINGS: In the development of the proposed amendment, consideration was given to: 1) alternative approaches; 2) overlap or duplication with other statutory and regulatory provisions; and 3) significant economic impact on small business. No alternative approach, duplication, or overlap was identified based on available information.

216-RICR-30-05-1

TITLE 216 - DEPARTMENT OF HEALTH

CHAPTER 30 – INFECTIOUS DISEASES

SUBCHAPTER 05 – INFECTIOUS DISEASES

PART 1 – Reporting and Testing of Infectious, Environmental, and Occupational Diseases

1.1 Authority

These regulations are promulgated pursuant to the authority conferred under R.I. Gen. Laws § 23-1.1 for the purpose of adopting prevailing standards for confidentiality and reporting of infectious, occupational, and environmentally related diseases in Rhode Island.

1.2 Incorporated Materials

- A. These regulations hereby adopt and incorporate HIPAA Privacy Rule and Public Health: Guidance from CDC and the U.S. Department of Health and Human Services May 2, 2003/52 (S-1); 1-12. by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.
- B. These regulations hereby adopt and incorporate The American Society of Microbiology Sentinel Level Clinical Laboratory Protocols for Suspected Biological Threat Agents and Emerging Infectious Diseases 2013 for Botulinum Toxin, Novel Influenza Viruses, Smallpox, and Staph Enterotoxin B by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.
- C. These regulations hereby adopt and incorporate The American Society of Microbiology Sentinel Level Clinical Laboratory Protocols for Suspected Biological Threat Agents and Emerging Infectious Diseases 2016 for Bacillus anthracis, Brucella, Burkholderia (mallei and pseudomallei), Coxiella burnetii, Yersinia pestis, and Francisella tularensis by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.
- D. These regulations hereby adopt and incorporate The American National Standards Institute CLSI M48-A “Laboratory Detection and Identification of Mycobacteria Approved Guideline” 2008 by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

1.3 Definitions

- A. "Asbestos" means that unique group of naturally occurring minerals that separate into fibers of high tensile strength, resistant to heat, wear, and chemicals, described as the following types: chrysotile, amosite, crocidolite, tremolite, anthophyllite, and actinolite, and every product containing any of these materials that have been chemically treated and/or altered which after manufacture are used for such products and end uses including but not limited to insulation, textiles, paper, cement, sheets, floor tile, wall covering, decorations, coating, sealants, cement pipe and reinforced plastics and other compounds.
- B. "Asbestos-related disease" means any illness or disease, other than for benign conditions of the pleura, suspected of being related to asbestos exposure, including, but not limited to, mesothelioma, asbestosis, and lung cancer believed to be caused by asbestos exposure.
- C. "Carrier" means a person or animal that harbors a specific infectious agent without discernible clinical disease and serves as a potential source of infection.
- D. "Case" or "patient" means a person who is suspected or confirmed to be ill, infected, exposed to, or diagnosed with a reportable disease.
- E. "Clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, radiobioassay, cytological, pathological, genomic, or any other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings.
- F. "Controlled substance" means a drug, substance, or immediate precursor in schedules I-V listed by R.I. Gen Laws Chapter 21-28.
- G. "Culture Independent Diagnostic Test" (CIDT) means any laboratory assay that detects the molecular or antigenic signature of pathogens independent of generating an isolate, including but not limited to microscopy, immunoassays, and NAAT.
- H. "Diagnosis of AIDS" means the most current surveillance case definition for AIDS published by the Centers for Disease Control & Prevention (CDC).
- I. "Diagnosis of HIV" means the most current surveillance case definition for HIV infection published by the CDC.
- J. "Director" means the Director of Health or his/her designee.
- K. "Disease report" means an official notice to the appropriate authority of the occurrence of a specified disease in humans or animals, in accordance with the requirements stated in these Regulations.

- L. "Emergency service worker" means a worker responding on behalf of a licensed ambulance/rescue service, fire department, or law enforcement agency.
- M. "Health care facility" means those facilities licensed by the Department in accordance with the provisions of R.I. Gen Law Chapter 23-17.
- N. "Health care provider" means a physician, physician assistant, or certified nurse practitioner licensed to practice in Rhode Island.
- O. "Infectious disease" means an illness due to a specific infectious agent or its toxic products that arises through transmission of that agent or its products from an infected person, animal, or inanimate reservoir to a susceptible host.
- P. "Occupational disease" means a disease or condition which is believed to be caused or aggravated by conditions in the individual's workplace.
- Q. "Occupational health representative" means an individual, within a health care facility, trained to respond to occupational, particularly blood borne, exposures.
- R. "RIDOH" means the Rhode Island Department of Health.
- S. "Surveillance" means the practice of monitoring the occurrence and spread of disease. Included are the systematic collection and evaluation of: morbidity and mortality reports; special reports of field investigations, epidemics and individual cases; isolations and identifications of infectious agents in laboratories; data concerning the availability and use of vaccines; immune globulin, pesticides and other substances used in disease control; information regarding immunity levels in segments of the population, and of other relevant epidemiologic data. The procedure applies to all jurisdictional levels of public health, from local to international.

1.4 Confidentiality Provisions

- A. All information concerning cases or suspected cases shall be held in confidence in accordance with the provisions of R.I. Gen Laws § 5-37-3 and all other applicable state and federal statutes and regulations.
- B. Pursuant to the HIPAA Privacy Rule, disclosures without individual authorization are permitted to RIDOH for the purpose of preventing or controlling disease, injury, or disability, including but not limited to public health surveillance, investigation, and intervention.

1.4.1 Persons and Entities Responsible for Reporting Diseases

- A. The following individuals and entities are required to report the diseases listed in § 1.5.3 of this Part:
 - 1. Physicians attending the case or suspected case or his/her designee

2. Physician assistants
3. Certified registered nurse practitioners
4. Clinical laboratories
5. Hospitals (from both inpatient and outpatient settings)
 - a. When a diagnosis or suspected diagnosis of a case is made within a hospital, the facility administrator, or his/her designee (e.g., infection control practitioner), must ensure the reporting of the case in accordance with the procedures outlined in these Regulations.
6. All other health care facilities, including but not limited to: organized ambulatory care facility, school-based health center, freestanding emergency care facility, home care/home nursing care provider, hospice, birth center, nursing facility, rehabilitation hospital center, freestanding ambulatory surgical center, kidney disease treatment center, blood centers, and prison health services.
 - a. When a diagnosis or suspected diagnosis of a case is made within a licensed health care facility, the facility administrator or medical director, or his/her designee (e.g., infection control practitioner), must ensure the reporting of the case in accordance with the procedures outlined in these Regulations.
7. Veterinarians who have knowledge of: a single case of rare and/or unusual veterinary diagnosis that has the potential to cause illness in humans, or knowledge of outbreaks of unusual zoonotic vectorborne diseases that can cause illness in humans;
8. Certified school nurse-teachers who have knowledge of a single case of rare and/or unusual diagnoses, or knowledge of outbreaks of diseases;
9. Dentists who have knowledge of a single case of rare and/or unusual diagnoses, or knowledge of outbreaks of disease;
10. Other entities or persons (such as college/university health centers, day care centers, drug treatment facilities, prison health services, travel clinics, social service agencies that serve the homeless, school health centers that treat students in grades K-12, camp counselors, funeral directors, transportation authority, assisted living facilities, community-based organizations that screen for infectious diseases, etc.) who have knowledge of a single case of rare and/or unusual diagnoses or knowledge of outbreaks of diseases.

B. Exemptions

1. Reporting of the diseases listed in §1.5.3 of this Part shall not be required in the following cases:
 - a. In research protocols and all other situations where the person conducting the research or ordering the test is unaware of the identity of the person being tested.
 - b. Anonymous HIV testing

1.5 Timeframe, Methods, and Reportable Conditions

1.5.1 Timeframes

- A. The lists cited in §1.5.3 of this Part pertain to individuals and facilities required to report pursuant to §1.4.1 of this Part. Cases due to the diseases listed below shall be reported to the RIDOH within the timelines indicated. Reportable diseases are grouped as follows:
 1. Immediately reportable diseases shall be reported within twenty-four hours of recognition or strong suspicion of disease.
 2. All other reportable conditions shall be reported within four days of recognition or suspicion.

1.5.2 Methods

- A. Case reports must be submitted on a RIDOH case report form as specified by the RIDOH website. The minimal information required when submitting a case report form includes: disease being reported, patient's full name, address, city, state, zip code, phone number, date of birth, gender, race and ethnicity, date of onset, and physicians' name and phone number.
- B. Clinical laboratories, including those outside of Rhode Island, performing examinations on any specimens derived from Rhode Island residents that yield evidence of infection due to the diseases listed in § 1.5.3 of this Part shall report such evidence of infection directly to RIDOH.
- C. The minimal information required when submitting a laboratory report includes: a laboratory contact, test results, date of specimen collection, patient's full name, date of birth, sex, address, patient's phone number and name of ordering health care provider.
- D. Reporting methods include, but are not limited to the following:
 1. Mail to: Rhode Island Department of Health, Division of Preparedness, Response, Infectious Diseases, and Emergency Medical Services, 3 Capitol Hill, Providence RI 02908-5097

2. Fax to RIDOH using fax numbers on the reporting forms.
3. Telephone: Between 8:30 am – 4:30 pm (Monday-Friday): (401) 222-2577. For telephone reporting for immediately reportable diseases after hours call (401) 272-5952
4. Electronic reporting of clinical and laboratory results to RIDOH.
5. Organizations that house reportable disease data must allow RIDOH to access the database for data mining from various data sources, including, but not limited to: electronic laboratory reports, medical records, health information exchange feeds, syndromic surveillance feeds, immunization and other disease registries, and billing data.

1.5.3 Reportable Disease and Conditions

- A. For the conditions listed below, invasive disease must be confirmed by isolation from blood, cerebral spinal fluid, pericardial fluid, pleural fluid, peritoneal fluid, joint fluid, urine, or other normally sterile site.
- B. Pregnant women with a reportable infectious disease listed in §1.5.3 of this Part that can be transmitted to the unborn child or infant must be reported within four days of recognition. For example, HIV, Zika, syphilis, Hepatitis B, Hepatitis C, rubella, etc.
- C. If testing is positive for any of the reportable conditions listed below and is performed with a Culture Independent Diagnostic Test (CIDT), the laboratory must perform reflexive culture or transport the original specimen to another laboratory to perform culture. If the culture is positive, the isolate must be recovered and sent to the RI State Health Laboratories for those organisms as indicated in §§ 1.4.3(D) and 1.4.3(E) of this Part. Both positive and negative culture results must be reported to RIDOH.
- D. Immediately Reportable Diseases and Conditions must be reported within 24 hours.
 1. Animal bites
 2. Anthrax (*Bacillus anthracis*)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
 3. Arboviral infections (e.g. West Nile, Eastern Equine Encephalitis, Powassan, Zika, Chikungunya, Yellow Fever, etc.)
 4. Botulism (*Clostridium botulinum*)

- a. Laboratories must submit the specimen to the RI State Health Laboratories
5. Brucellosis (*Brucella* species)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
6. Cholera (*Vibrio cholerae*)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
7. Ciguatera
8. *Clostridium perfringens* epsilon toxin
9. Diphtheria (*Corynebacterium diphtheriae*)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
10. Encephalitis (any infectious cause)
11. Glanders (*Burkholderia mallei*)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
12. Hantavirus (All species)
13. Hepatitis A
 - a. Laboratories must report aspartate aminotransferase (AST), alanine aminotransferase (ALT), and Bilirubin Total and Bilirubin Direct
14. Measles (Rubeola)
 - a. Laboratories must submit the specimen to the RI State Health Laboratories
15. Melioidosis (*Burkholderia pseudomallei*)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
16. Meningococcal Disease- invasive (*Neisseria meningitidis*)

Laboratories must submit isolate to the RI State Health Laboratories

17. Novel coronavirus
18. Outbreaks and clusters as defined in §1.5.4 of this Part
19. Paralytic shellfish poisoning
20. Plague (*Yersinia pestis*)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
21. Poliomyelitis (polio virus)
22. Q-Fever (*Coxiella burnetii*)
 - a. Laboratories must submit specimen to the RI State Health Laboratories
23. Rabies (animal)
 - a. Laboratories must submit the animal to the RI State Health Laboratories
24. Rabies (human)
 - a. Laboratories must submit specimen to the RI State Health Laboratories
25. Ricin Poisoning
26. Scombroid poisoning
27. Smallpox (*Variola*)
 - a. Laboratories must submit specimen to the RI State Health Laboratories
28. Staphylococcal enterotoxin B poisoning
29. Staphylococcus aureus invasive infections: Vancomycin Resistant Staphylococcus aureus (VRSA) or Vancomycin Intermediate Staphylococcus aureus (VISA)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
30. Tularemia (*Francisella tularensis*)

- a. Laboratories must submit isolate to the RI State Health Laboratories
- 31. Typhoid fever (*Salmonella typhi*)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
- 32. Unexplained deaths (possibly due to unidentified infectious causes)
- 33. Vibriosis (all *Vibrio* species)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
- 34. Viral hemorrhagic fevers (Ebola, Lassa, Marburg, etc)
 - a. Laboratories must submit specimen to the RI State Health Laboratories
- E. Other Reportable Conditions must be reported within four days
 - 1. Acute Flaccid Myelitis
 - 2. Anaplasmosis (*Anaplasma phagocytophilum*)
 - a. Laboratories must submit stained smear to the RI State Health Laboratories
 - 3. Babesiosis (all species)
 - 4. Campylobacteriosis (*Campylobacter* all species)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
 - 5. Carbapenem resistant organisms
 - a. Laboratories must submit isolate to the RI State Health Laboratories
 - 6. Chancroid (*Haemophilus ducreyi*)
 - 7. Chlamydia Trachomatis (genital and ophthalmic)
 - 8. Coccidioidomycosis (*Coccidioides immitis*)
 - 9. Cryptosporidiosis (*Cryptosporidium* all species)

10. Cyclosporiasis (*Cyclospora cayetanensis*)
11. Dengue virus infections
12. Ehrlichiosis (*Ehrlichia chaffeensis*)
 - a. Laboratories must submit stained smear to the RI State Health Laboratories
13. *Escherichia coli*, Shiga toxin-producing (STEC)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
14. Giardiasis (*Giardia lamblia*)
15. Gonorrhea (*Neisseria gonorrhoeae*)
16. Granuloma Inguinale (*Klebsiella granulomatis*)
17. *Haemophilus influenzae* disease, all serotypes- invasive
 - a. Laboratories must submit isolate to the RI State Health Laboratories
18. Hansen's disease or Leprosy (*Mycobacterium leprae*)
19. Hemolytic uremic syndrome (HUS)
20. Hepatitis B, C, D, E, and unspecified viral hepatitis
 - a. Laboratories must report all positive results.
 - b. Laboratories must report aspartate aminotransferase (AST), alanine aminotransferase (ALT), and Bilirubin Total and Bilirubin Direct
 - c. Physicians must report all acute Hepatitis cases.
 - d. Physicians must report pregnancy in a chronic Hepatitis B or Hepatitis C- positive woman using forms required by RIDOH.
21. Human Immunodeficiency Virus (HIV) 1 and 2 /Acquired Immunodeficiency Syndrome (AIDS)
 - a. Laboratories must report every CD4 cell count and HIV viral load test result performed on an HIV-positive individual.

- b. Laboratories must submit original specimens to the RI State Health Laboratories
 - c. Physicians must report pregnancy in an HIV-positive woman using forms required by RIDOH.
- 22. Influenza associated deaths (all ages)
- 23. Influenza associated hospitalizations
- 24. Influenza novel virus infections
- 25. Latent Tuberculosis Infection (LTBI) (*Mycobacterium tuberculosis*)
- 26. Legionellosis (*Legionella pneumophila*)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
- 27. Leptospirosis (*Leptospira icterohaemorrhagiae*)
- 28. Listeriosis- invasive (*Listeria monocytogenes*)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
- 29. Lyme disease (*Borrelia burgdorferi*)
- 30. Lymphogranuloma Venereum (*Chlamydia trachomatis*)
- 31. Malaria (*Plasmodium* species)
 - a. Laboratories must submit stained smear to the RI State Health Laboratories
- 32. Meningitis (aseptic, bacterial, viral, or fungal)
- 33. Mumps (*Paramyxovirus*)
 - a. Laboratories must submit the specimen to the RI State Health Laboratories
- 34. Ornithosis/Psittacosis (*Chlamydia psittaci*)
- 35. Pelvic inflammatory disease (PID): all cases, based upon clinical diagnosis
- 36. Pertussis (*Bordetella pertussis*)

37. Pneumococcal Disease- invasive (*Streptococcus pneumoniae*)
38. Rickettsiosis, including Rocky Mountain Spotted Fever (*Rickettsia*- all species)
39. Rubella (including congenital rubella)
 - a. Laboratories must submit the specimen to the RI State Health Laboratories
40. Salmonellosis (*Salmonella*- all species)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
41. Shigellosis (*Shigella*- all species)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
42. Streptococcal Disease-Group A- invasive
 - a. Laboratories must submit isolate to the RI State Health Laboratories
43. Streptococcal Disease- Group B- invasive
44. Streptococcal Toxic Shock Syndrome (*Streptococcus pyogenes*)
45. Syphilis- all stages including neurosyphilis and congenital syphilis (*Treponema pallidum*)
46. Tetanus (*Clostridium tetani*)
47. Toxic Shock Syndrome (non-Streptococcal)
48. Transmissible spongiform encephalopathies (including Creutzfeldt Jakob Disease)
49. Trichinosis (*Trichinella* species)
50. Tuberculosis Disease (*Mycobacterium tuberculosis*)
 - a. Laboratories must submit isolate to the RI State Health Laboratories
51. Varicella (*Varicella-Zoster* virus)
52. Yersiniosis (*Yersinia enterocolitica*)

- a. Laboratories must submit isolate to the RI State Health Laboratories

1.5.4 Reporting of Outbreaks

- A. Any person or entity who is required to report and has knowledge of an outbreak of infectious disease or a cluster of unexplained illness, infectious or non-infectious, whether or not listed in these regulations, shall immediately report the facts to RIDOH.
- B. Outbreaks required to be reported include, but are not limited to:
 - 1. Exotic diseases and unusual group expressions of illness which may be of public health concern.
 - 2. A single case of a disease long absent from a population or the first invasion by a disease not previously recognized in that area.
 - 3. Outbreaks or clusters identified by significant increases in the usual occurrence of the disease in the same area, among the specified population, at the same season of the year.
 - 4. The occurrence of two or more cases of a similar illness resulting from the ingestion of a common food or water source.
 - 5. A cluster of similar illness in institutional settings, including but not limited to nursing homes, hospitals, schools, and day care centers.
 - 6. A single case of rare and/or unusual diagnoses, including but not limited to avian influenza, smallpox, Ebola, SARS, Zika, Borrelia miyamotoi, or human rabies.
 - 7. Outbreaks of unusual diseases or illness that may indicate acts of terrorism using biological agents, including but not limited to anthrax and botulism. See complete list of biological agents in §1.7.2(A)(1) of this Part.
 - 8. Any condition compatible with exposure to nuclear, radiological, or chemical substances, which could be indicative of radiological or chemical terrorism events.
 - 9. Clusters of overdoses or adverse reactions to a drug, whether prescription or illicit.

1.6 Special Disease Surveillance Projects

- A. Reporting will be required for surveillance related to special and/or complex surveillance systems (e.g., Zika, latent TB infection, influenza, new and emerging

disease threats, evaluation and validation projects related to surveillance) at the discretion of RIDOH.

- B. Reporting will be required for any additional surveillance systems that may need to be developed and implemented to prepare for or respond to public health threats at the discretion of RIDOH at any time.

1.7 Instructions for Laboratories

1.7.1 General Instructions

- A. Whenever a RI licensed clinical laboratory performs tests or has the sample(s) tested out of state for those diseases cited in §1.5.3 of this Part, the laboratory shall submit to RIDOH all positive findings.
- B. Negative laboratory results must be reported for public health surveillance and investigation purposes at the discretion of RIDOH.
- C. The report shall consist of a copy of the laboratory findings submitted to the physician or other licensed health care provider who ordered the test. This report shall indicate the name of the case, address of the case, gender, date of birth, telephone number, race, ethnicity, and name of attending physician.
- D. All genotyping, molecular detection, and phylogenetic testing results on reportable conditions must be reported to RIDOH.

1.7.2 Reporting of Agents of Bioterrorism

- A. An immediate report must be made to RIDOH by telephone when an ordering provider requests a test for a potential agent of bioterrorism. After normal business hours, the RIDOH's after-hours on-call physician must be informed.
 - 1. Potential agents of bioterrorism are:
 - a. Anthrax (*Bacillus anthracis*)
 - b. Botulism (*Clostridium botulinum*)
 - c. Brucellosis (*Brucella* species)
 - d. *Clostridium perfringens* epsilon toxin
 - e. Glanders (*Burkholderia mallei*)
 - f. Melioidosis (*Burkholderia pseudomallei*)
 - g. Plague (*Yersinia pestis*)
 - h. Q-fever (*Coxiella burnetii*)

- i. Ricin Poisoning
 - j. Smallpox (Variola)
 - k. Staphylococcal enterotoxin B poisoning
 - l. Tularemia (*Francisella tularensis*)
 - m. Viral hemorrhagic fevers (Ebola, Lassa, Marburg, etc)
2. Clinical laboratories that isolate a potential agent of bioterrorism from a clinical specimen shall perform testing in accordance with the most current American Society of Microbiology (ASM) Sentinel Laboratory protocol as incorporated in §§1.2(B) and 1.2(C) of this Part, and, if unable to definitively rule out the agent, must submit the isolate to the RI State Health Laboratories for confirmation or further testing.

1.7.3 Reporting of Acid Fast Bacilli (AFB) and Mycobacterium tuberculosis (MTB)

- A. Clinical laboratories receiving clinical specimens for the purposes of performing testing for the presence of Acid Fast Bacilli (AFB) or Mycobacterium tuberculosis (MTB) testing must submit a specimen to the RI State Health Laboratories for analysis.
- 1. This requirement is waived for a RI licensed hospital laboratory, provided a written memorandum of agreement is in place between the State Health Laboratories and the hospital laboratory.
 - 2. In order to obtain a memorandum of agreement, a hospital laboratory's mycobacteriology testing methodology and practice must be consistent with national consensus standards as incorporated in §1.2(C) of this Part.
 - a. Licensed hospital laboratories that have a written memorandum of agreement with the State Health Laboratories and are performing MTB testing by any methodology shall report all positive results to RIDOH.
 - b. Positive culture results on an individual must be accompanied by all prior AFB smear results performed by the respective laboratory, and associated with the current episode of illness, whether positive or negative.
- B. As part of LTBI surveillance, Interferon Gamma Release Assay (IGRA) positive results must be reported.

1.7.4 Reporting Perinatal Exposure to HIV

Persons and entities described in § 1.4.1 of this Part must report all positive and negative HIV virologic laboratory tests on infants, zero through 12 months of age.

1.8 Reporting of Environmental Exposures and Occupational Diseases

1.8.1 Persons and Entities Responsible for Reporting Environmental Exposures and Occupational Diseases

- A. Physicians attending the case or suspected case or his/her designee
- B. Physician assistants
- C. Certified registered nurse practitioners
- D. Clinical laboratories
- E. Hospitals (from both inpatient and outpatient settings)
 - 1. When a diagnosis or suspected diagnosis of a case is made within a hospital, the facility administrator, or his/her designee (e.g., infection control practitioner), must report occupational diseases and exposures.

1.8.2 Environmental Exposures and Occupational Diseases that Must be Reported

- A. Diseases diagnosed related to exposure to:
 - 1. Arsenic
 - 2. Asbestos
 - 3. Cadmium
 - 4. Carbon monoxide
 - 5. Lead
 - 6. Mercury
- B. Any of the following occupational diseases:
 - 1. Metal fume fever
 - 2. Simple asphyxiation
 - 3. Silicosis
- C. Any cluster of occupational disease.

1.8.3 Methods and Timeframes for Reporting

- A. Reporting of Asbestos-related Diseases
 - 1. Mail report of diagnosis to RIDOH's Center for Healthy Homes and Environment, 3 Capitol Hill, Providence, RI 02908-5097, within six months of diagnosis.
 - 2. Send the patient or next of kin a dated notification of the suspected role of asbestos as it relates to the patient's condition within six months of diagnosis by certified mail with a return receipt requested.
- B. Reporting of Non-occupational Acute Carbon Monoxide Poisoning
 - 1. Submit the CO Poisoning Reporting form to RIDOH's Center for Healthy Homes and Environment according to the instructions on the form within four working days following diagnosis.
- C. Reporting of Childhood Lead Poisoning and Exposure Results
 - 1. Childhood blood lead sample results shall be reported to RIDOH's Center for Healthy Homes and Environment in accordance with the specifications in RIDOH's Lead Poisoning Prevention regulation [216-RICR-50-15-3].
- D. Reporting of Blood Lead Sample Results and all other Environmental Exposures and Occupational Diseases
 - 1. Submit all blood lead sample results to RIDOH's Center for Healthy Homes and Environment.
 - 2. For all other environmental exposures and occupational diseases, submit the Environmental Exposure and Occupational Disease reporting form to RIDOH's Center for Healthy Homes and Environment within 30 days following diagnosis according to the instructions on the form.
- E. Clinical laboratories shall submit the results of biomonitoring tests for evaluating environmental or occupational exposures to RIDOH electronically or in hard copy.

~~**RULES AND REGULATIONS PERTAINING TO THE
REPORTING OF INFECTIOUS, ENVIRONMENTAL AND
OCCUPATIONAL DISEASES**~~

~~[R23-10-DIS]~~



~~STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS~~

~~DEPARTMENT OF HEALTH~~

~~June 1966~~

~~**AS AMENDED:**~~

~~May 1970~~

~~August 1983 (E)~~

~~November 1983~~

~~April 1987~~

~~July 1989~~

~~May 1992~~

~~December 1992 (E)~~

~~February 1993 (E)~~

~~June 1993 (E)~~

~~November 1993~~

~~April 1996~~

~~January 2002 (re-filing in
accordance with the
provisions of §42-35-4.1 of
the Rhode Island General
Laws, as amended)~~

~~September 2002~~

~~February 2006~~

~~January 2007 (re-filing in
accordance with the
provisions of §42-35-4.1 of
the Rhode Island General
Laws, as amended)~~

~~July 2008~~

~~January 2012 (re-filing in
accordance with the
provisions of §42-35-4.1 of
the Rhode Island General
Laws, as amended)~~

November 2013

~~**INTRODUCTION**~~

~~These amended *Rules and Regulations Pertaining to Reporting of Infectious, Environmental and Occupational Diseases* [R23-10-DIS][†] are promulgated pursuant to the authority set forth in Chapters 23-5, 23-6, 23-10, 23-11, 23-24.6, and 23-24.5 and §§ 23-1-18 (2) and 23-8-1, of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting standards pertaining to confidentiality and reporting of infectious, occupational and environmentally related diseases in Rhode Island. Surveillance data will be used to initiate appropriate public health responses.~~

~~Pursuant to the provisions of §42-35-3(a)(3) and §42-35.1-4 of the General Laws of Rhode Island, as amended, consideration was given to:~~

- ~~(1) Alternative approaches to the regulations; and~~
- ~~(2) Duplication or overlap with other state regulations and~~
- ~~(3) Significant economic impact on small business.~~

~~Based on the available information, no known alternative approach or duplication was identified. During review of public comments it was determined that certain reporting requirements pertaining to HIV were also addressed in *Rules and Regulations Pertaining to HIV Counseling, Testing, Reporting and Confidentiality* [R23-6.3-HIV]. Specific HIV reporting requirements were removed from these Regulations and the reporting requirements of *Rules and Regulations Pertaining to HIV Counseling, Testing, Reporting and Confidentiality* have been incorporated by reference.~~

~~Upon promulgation of these amendments, these amended Regulations shall supersede all previous *Rules and Regulations Pertaining to Reporting of Infectious, Environmental and Occupational Diseases* [R23-10-DIS] promulgated by the Rhode Island Department of Health and filed with the Secretary of State.~~

[†] ~~Prior to October 2013, these Regulations were promulgated under the title *Rules and Regulations Pertaining to Reporting of Communicable, Environmental and Occupational Diseases* [R23-10-DIS]. Beginning with the October 2013 edition, the title was changed to *Rules and Regulations Pertaining to Reporting of Infectious, Environmental and Occupational Diseases* [R23-10-DIS] to reflect current terminology utilized in these Regulations.~~

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~~PART I *Definitions and Reporting Requirements*~~

~~Section 1.0 *Definitions*~~

Wherever used in these Regulations, the following terms shall be construed as follows:

- ~~1.1 *"Asbestos"* means that unique group of naturally occurring minerals that separate into fibers of high tensile strength, resistant to heat, wear and chemicals, described as the following types: chrysotile, amosite, crocidolite, tremolite, anthophyllite, and actinolite, and every product containing any of these materials that have been chemically treated and/or altered which after manufacture are used for such products and end uses including but not limited to insulation, textiles, paper, cement, sheets, floor tile, wall covering, decorations, coating, sealants, cement pipe and reinforced plastics and other compounds.~~
- ~~1.2 *"Asbestos-related disease"* is any illness or disease, other than for benign conditions of the pleura, suspected of being related to asbestos exposure, including, but not limited to, mesothelioma, asbestosis and lung cancer believed to be caused by asbestos exposure.~~
- ~~1.3 *"Carrier"* means a person or animal that harbors a specific infectious agent without discernible clinical disease and serves as a potential source of infection.~~
- ~~1.4 *"Case"* or *"patient"* means the one who is ill, infected, injured or diagnosed with a reportable disease or injury.~~
- ~~1.5 *"Clinical laboratory"* means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, radiobioassay, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings, pursuant to Chapter 23-16.2 of the Rhode Island General Laws, as amended, entitled "Laboratories."~~
- ~~1.6 *"Communicable disease"* means an illness due to a specific infectious agent or its toxic products that arises through transmission of that agent or its products from an infected person, animal or inanimate reservoir to a susceptible host.~~
- ~~1.7 *"Department"* means the Rhode Island Department of Health.~~
- ~~1.8 *"Director"* means the Director of Health.~~
- ~~1.9 *"Disease report"* means an official notice to the appropriate authority of the occurrence of a specified disease in humans or animals, in accordance with the requirements stated in these Regulations.~~
- ~~1.10 *"Disease surveillance"* means the practice of monitoring the occurrence and spread of disease. Included are the systematic collection and evaluation of: morbidity and mortality reports; special reports of field investigations, epidemics and individual cases; isolations and identifications of infectious agents in laboratories; data concerning the availability and use of vaccines; immune globulin, pesticides and other substances used in disease control; information regarding immunity levels in segments of the population, and of other relevant epidemiologic data. The procedure applies to all jurisdictional levels of public health, from local to international.~~

- ~~1.11 **"Incidence"** means a term used to characterize the frequency of new occurrences of a disease, infection, or other event over a period of time and in relation to the population in which it occurs. Incidence is expressed as a rate, commonly the number of new cases during a prescribed time in a unit of population. For example, one refers to the number of new cases of tuberculosis per 100,000 population per year.~~
- ~~1.12 **"Laboratory test diagnostic of HIV infection"** means a laboratory test approved by the U.S. Food and Drug Administration, performed by a clinical laboratory that indicates the presence of antibody to HIV, HIV structural components, or HIV ribonucleic acid in blood and other body fluid.~~
- ~~1.13 **"Manufacturers' associated laboratory"**, as used in these Regulations, means a specialized laboratory that performs initial and confirmatory HIV testing, when approved to do so by the Department.~~
- ~~1.14 **"Occupational disease"** means a disease or condition which is believed to be caused or aggravated by conditions in the individual's workplace.~~
- ~~1.15 **"Outbreak or cluster"** means the occurrence in a community or region of cases of an illness clearly in excess of the number of cases normally expected.~~
- ~~1.16 **[DELETED]**~~
- ~~1.17 **"Physician"** means any individual licensed to practice medicine in this state under the provisions of Chapter 5-37 of the General Laws of Rhode Island, as amended (i.e., M.D.s and D.O.s).~~
- ~~1.18 **"Poisoning (food)"** means a poisoning that results from eating foods contaminated with toxins. These toxins may occur naturally, as in certain mushrooms or seafoods; they may be chemical or biologic contaminants; or they may be metabolic products of infectious agents that are present in the food.~~
- ~~1.19 **"These Regulations"** mean all parts of Rhode Island *Rules and Regulations Pertaining to Reporting of Infectious, Environmental and Occupational Diseases [R23-10-DIS]*.~~

~~Section 2.0 **Reporting Requirements**~~

~~The HIPAA Privacy Rule expressly permits disclosures without individual authorization to public health authorities authorized by law to collect or receive the information for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, public health surveillance, investigation, and intervention (see Reference 19 of these Regulations).~~

~~**Responsibility for Reporting**~~

- ~~2.1 The diseases listed in these Regulations shall be reported in the manner set forth in these Regulations. Reporting of diseases listed in these Regulations is required and is the responsibility of the following:~~
- ~~➤ **Physicians** attending the case or suspected case or his/her designee;~~
 - ~~➤ **Physician assistants, certified registered nurse practitioners, and midwives;**~~
 - ~~➤ **Clinical laboratories;**~~

- ~~Hospitals (from both inpatient and outpatient settings); When a diagnosis or suspected diagnosis of a case is made within a hospital, the facility administrator, or his/her designee (e.g., infection control practitioner), is charged with the responsibility of ensuring the reporting of the case in accordance with the procedures outlined in these Regulations.~~
- ~~All other health care facilities (i.e., organized ambulatory care facility, school based health center, freestanding emergency care facility, home care/home nursing care provider, hospice, birth center, nursing facility, rehabilitation hospital center, freestanding ambulatory surgical center, kidney disease treatment center, physician office setting providing surgical treatments {office operator}); When a diagnosis or suspected diagnosis of a case is made within a licensed health care facility, the facility administrator or medical director, or his/her designee (e.g., infection control practitioner), is charged with the responsibility of ensuring the reporting of the case in accordance with the procedures outlined in these Regulations.~~
- ~~Veterinarians who have knowledge of a single case of rare and unusual veterinary diagnosis that relates to or has the potential to cause illness in humans and/or clusters or outbreaks of unusual zoonotic vectorborne diseases that can cause illness in humans;~~

2.2 ~~Reporting of diseases listed in these Regulations is recommended by and the responsibility of the following:~~

- ~~Certified school nurse teachers who have knowledge of a single case of rare and unusual diagnoses and/or clusters or outbreaks of unusual diseases or illnesses;~~
- ~~Dentists who have knowledge of a single case of rare and unusual diagnoses and/or clusters or outbreaks of unusual diseases or illnesses;~~
- ~~Other entities or persons (such as college/university health centers, day care centers, drug treatment facilities, prison health services, travel clinics, social service agencies that serve the homeless, school health centers that treat students in grades K-12, camp counselors, funeral directors, transportation authority etc.) who have knowledge of a single case of rare and unusual diagnoses and/or clusters or outbreaks of unusual diseases or illnesses.~~

2.3 ~~**Exemptions.** Reporting of the diseases listed in these Regulations shall not be required in the following case: In research protocols and all other situations where the person conducting the research or ordering the test is unaware of the identity of the person being tested. (In cases where the identity of the person being tested is known to the person, the provisions of these Regulations shall apply).~~

2.4 ~~**Public Health Response to Disease Reports.** Any disease or outbreak reported shall initiate a public health response by the Department in collaboration with the provider. The response will be in keeping with situation specific recommendations that are provided by the Division of Infectious Disease and Epidemiology.~~

2.5 ~~**Reporting of Outbreaks or Clusters.** Any person who is required or recommended to report (cited in §2.1 of these Regulations) and has knowledge of an outbreak of infectious disease or a cluster of unexplained illness, infectious or non-infectious, whether or not listed in these~~

~~regulations, shall promptly report the facts to the Department of Health. Exotic diseases and unusual group expressions of illness which may be of public health concern shall also be reported immediately. The number of cases indicating an outbreak or cluster will vary according to the infectious agent or the conditions/hazards, size and type of population exposed, previous experience or lack of exposure to the disease, and time and place of occurrence. A single case of a communicable disease long absent from a population or the first invasion by a disease not previously recognized in that area requires immediate reporting and epidemiologic investigation; two (2) cases of such a disease associated in time and place are sufficient evidence of transmission to be considered an outbreak. Outbreaks or clusters are therefore identified by significant increases in the usual incidence of the disease in the same area, among the specified population, at the same season of the year. Some examples of outbreaks are as follows:~~

- ~~(1) **Foodborne poisoning:** the occurrence of two (2) or more cases of a similar illness resulting from the ingestion of a common food;~~
- ~~(2) **Institutional:** cluster of similar illness in institutional settings, such as nursing homes, hospitals, schools, day care centers, etc.;~~
- ~~(3) **Waterborne:** at least two (2) persons experiencing a similar illness after ingestion of a common water source and epidemiologic evidence that implicates water as the probable source of the illness;~~
- ~~(4) **A single case of rare and unusual diagnoses,** such as avian influenza, smallpox, ebola, SARS, or human rabies;~~
- ~~(5) Outbreaks of **unusual diseases or illness** that may indicate **acts of terrorism** using biological agents, such as anthrax, botulism, ricinosis, epsilon toxin of *Clostridium perfringens*, and *Staphylococcus enterotoxin B*;~~
- ~~(6) Any condition compatible with exposure to nuclear, radiological, or chemical substances, which could be indicative of radiological or chemical terrorism events shall also be reportable; and~~
- ~~(7) Clusters of overdoses or adverse reactions to a drug, whether prescription or illicit.~~

~~2.6 **Confidentiality Provisions.** All information concerning cases or suspected cases shall be held in confidence in accordance with the provisions of RIGL Chapter 5-37.3 ("Confidentiality of Health Care Communications and Information Act"), all other applicable state and federal statutes and regulations, and Division of Infectious Disease and Epidemiology policies.~~

~~2.7 [DELETED]~~

~~2.8 [DELETED]~~

~~PART II Reportable Diseases and Disease Surveillance Projects~~

~~Section 3.0 Reportable Diseases and Timeframe for Reporting~~

- ~~3.1 (a) The lists cited below pertain to individuals and facilities required or recommended to report (see §2.1 in these Regulations). Cases due to the diseases listed below shall be reported to the Rhode Island Department of Health, Division of Infectious Disease and Epidemiology (IDE), within the timelines indicated. Reportable diseases are grouped as immediately reportable and non-immediately reportable. Immediately reportable diseases shall be reported within twenty four (24) hours of recognition or strong suspicion of disease. All other reportable conditions shall be reported within four (4) days of recognition or suspicion. There is no requirement to wait for laboratory confirmation for any condition.~~
- ~~(b) Case reports must be submitted on a Department of Health case report form. The minimal information required when submitting a case report form includes: disease being reported, patient's full name, address, city, state, zip code, phone number, date of birth (or age at onset), gender, race and ethnicity, date of onset, and physicians' name and phone number.~~
- ~~(c) All case report forms can be found at: <http://www.health.ri.gov/diseases/for/providers/>.~~
- ~~(d) For animal bites, TB, LTBI, HIV, and STDs case reports must be submitted on the disease-specific case report form. Case reports for all other diseases must be reported on the generic infectious disease case report form.~~
- ~~3.2 (a) Laboratories, including those outside of Rhode Island, performing examinations on any specimens derived from Rhode Island residents that yield evidence of infection due to the diseases listed below shall report such evidence of infection directly to IDE through the methods listed in §3.3 of these Regulations.~~
- ~~(b) HIV reporting guidance is detailed in *Rules and Regulations Pertaining to HIV Counseling, Testing and Reporting, and Confidentiality* [R23-6.3 HIV].~~
- ~~(c) The minimal information required when submitting a laboratory report includes: a laboratory contact, test results, date of specimen collection, case's full name, date of birth, sex, address, and name of ordering health care provider.~~
- ~~3.3 All cases, are reported to the Department via one of four (4) methods:~~
- ~~(a) **Mail.** Mail to: Rhode Island Department of Health, Division Of Infectious Disease and Epidemiology, 3 Capitol Hill, Room 106, Providence RI 02908-5097)~~
- ~~(b) **Fax.** Fax to: (401) 222 2488~~
- ~~(c) **Telephone.** Between 8:30am – 4:30pm (Monday-Friday): (401)-222-2577. For telephone reporting after hours call (401)-272-5952~~
- ~~(d) **Electronic Reporting or Data Mining Methods.** Various methods of electronic reports are required as defined in technical specifications developed by the Department. Examples of data sources include, but are not limited to electronic laboratory reports, medical records, health information exchange feeds, syndromic surveillance feeds, immunization and other disease registries, and billing data.~~

3.4 ~~List of diseases reportable to Rhode Island Department of Health, Division of Infectious Disease and Epidemiology:~~

~~***Diseases to be Reported Immediately
(within 24 hours)***~~

~~***Potential Agents of Bioterrorism***~~

- ~~➤ Anthrax~~
- ~~➤ Botulism~~
- ~~➤ Brucellosis~~
- ~~➤ Burkholderia mallei/pseudomallei~~
- ~~➤ (Glanders and Melioidosis)~~
- ~~➤ Clostridium perfringens epsilon toxin~~
- ~~➤ Plague~~
- ~~➤ Q-Fever~~
- ~~➤ Ricin Poisoning~~
- ~~➤ Smallpox~~
- ~~➤ Staphylococcal enterotoxin B poisoning~~
- ~~➤ Tularemia~~
- ~~➤ Viral Hemorrhagic Fevers (Ebola, Lassa, Marburg, etc)~~

~~***Other Conditions***~~

- ~~➤ Animal bites~~
- ~~➤ Arboviral infections (neuroinvasive)~~
- ~~➤ Cholera~~
- ~~➤ Ciguatera, Paralytic shellfish or Scombroid poisoning~~
- ~~➤ Diphtheria~~
- ~~➤ Encephalitis (any infectious cause)~~
- ~~➤ Hantavirus Pulmonary Syndrome~~
- ~~➤ Hepatitis A¹~~
- ~~➤ Measles~~
- ~~➤ Meningococcal Disease²~~
- ~~➤ Novel coronavirus~~
- ~~➤ Outbreaks and clusters (see §1.15 of these Regulations)~~
- ~~➤ Poliomyelitis~~
- ~~➤ Rabies (animal)~~
- ~~➤ Rabies (human)~~
- ~~➤ Staphylococcus aureus infections Vancomycin Resistant/Intermediate (VRSA/VISA)²~~
- ~~➤ Typhoid fever~~
- ~~➤ Unexplained deaths (possibly due to unidentified infectious causes)~~
- ~~➤ Vibrio infections~~
- ~~➤ Yellow fever~~

~~***Conditions to be Reported within four (4) days***~~

- ~~➤ Acquired Immunodeficiency Syndrome (AIDS)~~
- ~~➤ Anaplasmosis/Ehrlichiosis~~
- ~~➤ Babesiosis~~

- ~~Campylobacteriosis~~
- ~~Chancroid~~
- ~~Chlamydia Trachomatis (genital and ophthalmic)~~
- ~~Coccidioidomycosis~~
- ~~Cryptosporidiosis~~
- ~~Cyclosporiasis~~
- ~~Dengue virus infections~~
- ~~Escherichia coli, Shiga toxin producing (STEC)~~
- ~~Giardiasis~~
- ~~Gonorrhea~~
- ~~Granuloma Inguinale~~
- ~~Group A Streptococcal Disease~~
- ~~Group B Streptococcal Disease²~~
- ~~H. influenzae disease, all serotypes²~~
- ~~Hansen's disease (leprosy)~~
- ~~Hemolytic uremic syndrome (HUS)~~
- ~~Hepatitis B, C, D, E, and unspecified viral hepatitis¹ [Physicians must report all acute Hepatitis cases and surface antigen (HbsAg) and hepatitis C positive pregnant women only. Laboratories must report all positive results].~~
- ~~HIV-1 and HIV-2 infection³~~
- ~~Influenza associated deaths (all ages)~~
- ~~Influenza associated hospitalizations~~
- ~~Influenza novel virus infections~~
- ~~Legionellosis~~
- ~~Leptospirosis~~
- ~~Listeriosis²~~
- ~~Lyme disease~~
- ~~Lymphogranuloma Venereum~~
- ~~Malaria~~
- ~~Meningitis (aseptic, bacterial, viral, or fungal)²~~
- ~~Mumps~~
- ~~Ornithosis (psittacosis)~~
- ~~Pelvic inflammatory disease (PID): all cases, based upon clinical diagnosis~~
- ~~Pertussis~~
- ~~Rickettsiosis, Spotted Fever (Rocky Mountain Spotted Fever)~~
- ~~Rubella (including congenital rubella)~~
- ~~Salmonellosis~~
- ~~Shigellosis~~
- ~~Streptococcus pneumoniae²~~
- ~~Streptococcal Toxic Shock Syndrome²~~
- ~~Syphilis (all stages including neurosyphilis and congenital syphilis)~~
- ~~Tetanus~~
- ~~Toxic Shock Syndrome (non-Streptococcal)²~~
- ~~Transmissible spongiform encephalopathies (including Creutzfeldt Jakob Disease)~~
- ~~Trichinosis~~
- ~~Tuberculosis Disease and Latent Tuberculosis Infection (LTBI)~~

- ~~Varicella~~
- ~~Yersiniosis~~

NOTES:

¹ ~~Report AST, ALT, and Bilirubin also.~~

² ~~**Invasive disease:** confirmed by isolation from blood, CSF, pericardial fluid, pleural fluid, peritoneal fluid, joint fluid, or other normally sterile site.~~

³ ~~Every CD4 cell count and HIV viral load test result performed on HIV positive patients is reportable.~~

3.5 ~~List of clinical specimens from which the agent related to diseases in §3.4 that are required to be submitted to the RI State Health Laboratory by the testing laboratory:~~

Organism	Invasive disease only	Isolate	Stained smear	Specimen	Reporting to IDE and State Health Laboratory
Anaplasma phagocytophilum			X		
Bacillus anthracis		X			Immediate
Bordetella pertussis		X			
Brucella sp.		X			Immediate
Burkholderia mallei		X			Immediate
Burkholderia pseudomallei		X			Immediate
Campylobacter sp.		X			
Clostridium botulinum		X		X	Immediate
Corynebacterium diphtheriae		X			
Coxiella burnetii					Immediate
Ebola virus (VHF)				X	Immediate
E. coli Shiga toxin producing		X		(GN broth)	
E. coli 0157:H7		X		(GN broth)	
Ehrlichia sp.			X		
Francisella tularensis		X			Immediate
Haemophilus influenzae	X	X			
Legionella sp.		X			
Listeria monocytogenes		X			
Mycobacterium tuberculosis		X			
Neisseria meningitidis	X	X			
Plasmodium sp.			X		
Rabies virus				X	Immediate
Salmonella sp.		X			
Shigella sp.		X			
Staphylococcus aureus VISA/VRSA		X			
Streptococcus pyogenes (GpA Strep)	X	X			
Variola virus				X	Immediate
Vibrio cholera		X			
Vibrio parahaemolyticus		X			
Vibrio vulnificus		X			
Viral hemorrhagic fevers				X	Immediate
Yersinia enterocolitica		X			
Yersinia pestis		X			Immediate

~~*Special Disease Surveillance Projects*~~

~~3.6 Surveillance related to special and/or complex surveillance systems (e.g., West Nile Virus, latent TB infection, influenza, new and emerging disease threats, evaluation and validation projects related to surveillance) may be conducted in accordance with customized guidance issued by the Rhode Island Department of Health, Center for Epidemiology and Infectious Disease. Surveillance systems may be developed and required to prepare for or respond to public health threats on an ad hoc basis, at any time.~~

~~Section 4.0 [RESERVED]~~

~~Section 5.0 *Reporting by Laboratories*~~

~~5.1 (a) Whenever a clinical laboratory performs tests or has the sample(s) tested out of state for those diseases cited in §3.1 of these Regulations, the laboratory shall submit to the Division of Infectious Disease and Epidemiology all positive findings.~~

~~(b) Certain negative laboratory results shall be reportable to the Department as deemed essential and necessary to maintain the health, safety and welfare of the community. The Department shall specify those laboratory reports that will require negative reporting of results.~~

~~(c) The report shall consist of a copy of the laboratory findings submitted to the physician or other licensed health care professional who ordered the test. This report shall indicate the name of the case, address of the case's residence, gender, date of birth, or if unavailable, age, telephone number, attending physician's name, and race and ethnicity of the case.~~

~~5.2 [DELETED]~~

~~*Laboratory Testing and Reporting for Agents of Bioterrorism*~~

~~5.3 Clinical laboratories receiving biological specimens that are suspected to contain agents of bioterrorism, even if a bioterrorist event is not suspected, shall perform testing or refer such specimens to the State Health Laboratory for analysis in accordance with the most current Lab Response Network (LRN) protocols. Clinical laboratories that isolate a potential agent of bioterrorism from a clinical specimen shall perform testing in accordance with the most current LRN Sentinel Laboratory protocol and shall submit the isolate to the State Health Laboratory for confirmation or further testing in accordance with the current Rhode Island LRN protocol.~~

~~5.4 Clinical laboratories that receive biological specimens that are suspected to contain agents of bioterrorism, or that isolate a potential agent of bioterrorism from a clinical specimen, shall immediately report such receipt or findings to the Department's Division of Infectious Disease and Epidemiology by telephone. If the specimen is received after normal Department business hours, the Department's after hours on-call physician shall be informed.~~

~~*Laboratory Reporting of AFB and M. Tuberculosis*~~

~~5.5 Clinical laboratories receiving biological samples or specimens for the purposes of performing testing for the presence of acid fast bacilli (AFB) or M. tuberculosis testing must~~

~~submit a specimen to the State Health Laboratory for analysis. This requirement is waived for a licensed hospital laboratory, provided a written memorandum of agreement is in place between the State Laboratory and the hospital laboratory. In order to obtain a memorandum of agreement, a hospital laboratory's Mycobacteriology testing methodology and practice must be consistent with current recognized national consensus standards and/or guidelines (e.g. CLSI M48 A Laboratory Detection and Identification of Mycobacteria: Approved Guidelines).~~

- ~~5.6 Licensed hospital laboratories that have a written memorandum of agreement with the State Health Laboratory and are performing AFB testing shall report positive results to the Division of Infectious Disease and Epidemiology. Positive culture results must be accompanied by all prior AFB smear results associated with the current episode of illness on the individual whether positive or negative.~~
- ~~5.7 As part of LTBI surveillance, IGRA (Interferon Gamma Release Assay) positive results are reportable.~~

~~PART III *Other Diseases*~~

~~Section 6.0 *Childhood Lead Poisoning*~~

~~*Reporting of Cases of Childhood Lead Poisoning*~~

- ~~6.1 Any physician or employee of a licensed health care facility acting within the scope of his/her practice in making the diagnosis of childhood lead poisoning shall report such diagnosis to the Department within ten (10) business days using a form approved by the Department or by any other reporting method approved by the Department.~~
- ~~6.2 Utilization of the Department Laboratory shall constitute compliance with these reporting requirements.~~

~~*Reporting by Laboratories:*~~

- ~~6.3 Whenever a laboratory has the blood lead diagnostic sample(s) tested out of state for childhood lead poisoning, the laboratory shall submit to the Division of Community, Family Health, and Equity (CFHE) all positive and negative findings. If submitted electronically, these reports shall be in accordance with Rhode Island Department of Health standards for electronic reporting of blood lead results.~~

~~Section 7.0 *Occupational Diseases*~~

- ~~7.1 Every physician licensed pursuant to the provisions of Chapter 5-37 or other person charged with reporting (cited in §2.1 of these Regulations) attending on or called in to visit a patient whom he/she believes to be suffering from the following occupational diseases shall report such occurrences to the Rhode Island Department of Health.~~
- ~~7.1.1 Diseases diagnosed as being related to occupational exposures to any of the following substances:~~
- ~~➤ arsenic~~
 - ~~➤ cadmium~~
 - ~~➤ carbon monoxide~~
 - ~~➤ lead (defined as > 25ug/dl)~~
 - ~~➤ mercury~~
- ~~7.1.2 Any of the following occupational diseases:~~
- ~~➤ metal fume fever~~
 - ~~➤ simple asphyxiation~~
 - ~~➤ silicosis~~
- ~~7.1.3 Any unusual cluster of occupational disease.~~
- ~~7.2 Whenever a laboratory performs an analysis for, or has a blood sample tested out of state for a blood lead level in a person age sixteen (16) or over, the laboratory shall submit to the Department all results. The report, which shall be submitted electronically or in hard copy,~~

~~shall consist of a copy of the laboratory result submitted to the physician or other person charged with reporting (cited in §2.1 of these Regulations) who ordered the test.~~

Occupational Disease Reporting

~~7.3 The physician, or other person charged with reporting (cited in §2.1 of these Regulations), immediately on being called in to visit a patient with carbon monoxide intoxication or simple asphyxiation and within thirty (30) days of attending on or being called in to visit a patient with any illness or condition specified in §7.1 of these Regulations shall report the following information to the Rhode Island Department of Health:~~

~~(a) Name, address, phone number and occupation of patient;~~

~~(b) Name, address, phone number and business of employer;~~

~~(c) Nature of disease;~~

~~(d) Such other information as may be reasonably required by the Department of Health;~~

~~(e) Name and phone number of the reporting physician or other person charged with reporting (cited in §2.1 of these Regulations).~~

~~7.4 The Department of Health shall prepare and furnish standard schedule blanks for the reports required by §7.0 of these Regulations.~~

Section 8.0 *Asbestos-Related Disease*

Responsibility for Reporting

~~8.1 Any physician, facility administrator or other person charged with reporting (cited in §2.1 of these Regulations) associated with making the diagnosis of mesothelioma, asbestosis, or any other asbestos related disease, other than benign conditions of the pleura, shall report the disease to the Director of Health within six (6) months of the diagnosis.~~

~~8.2 The physician or licensed medical facility involved shall also inform the patient or patient's next of kin in a dated letter by first class mail of the suspected role of asbestos as it relates to the patient's condition.~~

~~8.3 Reporting of asbestos related diseases, such as asbestosis or any illness or disease suspected as being due to asbestos exposure, other than benign conditions of the pleura, shall be accomplished through the use of confidential reports of occupational disease, which shall be mailed directly by the attending physician or licensed health care facility to the Rhode Island Department of Health. The asbestos related disease, mesothelioma, is also reportable under the provisions of the *Rules and Regulations Pertaining to the Rhode Island Cancer Registry (R-23-12-CA)*.~~

~~8.4 Such reports of occupational disease are supplied by the Rhode Island Department of Health.~~

~~Section 9.0 *Non-occupational Acute Carbon Monoxide Poisoning*~~

~~9.1 In addition to the requirements of §7.3 of these Regulations regarding the reporting of occupational carbon monoxide (CO) intoxication, any physician licensed pursuant to the provisions of RIGL Chapter 5-37 or other person charged with reporting (cited in §2.1 of these Regulations) attending on or called in to visit a patient whom he/she believes to be suffering from acute CO poisoning shall report such occurrence(s) to the Department in accordance with the requirements of §9.3 of these Regulations.~~

~~9.2 *Case Classification*~~

~~(a) *Confirmed Case:*~~

- ~~(1) A patient with signs and symptoms consistent with acute CO poisoning[†] and a confirmed elevated carboxyhemoglobin (COHb) level, as determined by either a venous blood specimen or pulse Cooximetry; OR~~
- ~~(2) A patient with signs and symptoms consistent with acute CO poisoning (in the absence of clinical or laboratory confirmation of an elevated COHb level), with supplementary evidence in the form of environmental monitoring data suggesting exposure from a specific poisoning source; OR~~
- ~~(3) A laboratory report of a venous blood specimen (in the absence of clinical and environmental laboratory data) with a COHb level that is equal to or greater than a volume fraction of 0.12 (i.e., 12%).~~

~~(b) *Probable Case:*~~

- ~~(1) In the absence of clinical and environmental monitoring, a patient with signs and symptoms consistent with acute CO poisoning and the same history of environmental exposure as that of a confirmed case; OR,~~
- ~~(2) A patient with signs and symptoms consistent with acute CO poisoning and history of smoke inhalation secondary to conflagration; OR~~
- ~~(3) A non-smoking patient with a laboratory report of a blood specimen with a COHb level that is equal to or greater than a volume fraction of 0.09 and less than a volume fraction of 0.12 (i.e., $9 < \text{COHb}\% < 12$); OR~~
- ~~(4) A patient who has an exposure history consistent with CO, and has received hyperbaric treatment for acute CO poisoning, regardless of COHb concentration reported, and regardless of the presence or absence of symptoms.~~

[†] ~~There is no consistent constellation of signs and symptoms resulting from acute CO poisoning, nor are there any pathognomonic clinical signs or symptoms which would unequivocally indicate a case of acute carbon monoxide poisoning. The clinical presentation of acute CO poisoning varies not only with the duration and magnitude of exposure, but also between individuals with the same degree of exposure and/or same venous COHb level. Clinical signs and symptoms of acute CO poisoning include, but are not limited to: headache, nausea, lethargy (or fatigue), weakness, abdominal discomfort/pain, confusion, and dizziness. Other signs and symptoms include: visual disturbances including blurred vision, numbness and tingling, ataxia, irritability, agitation, chest pain, dyspnea (shortness of breath) on exertion, palpitations, seizures, and loss of consciousness.~~

~~(e) Suspected Case: A patient with signs and symptoms consistent with acute CO poisoning and a history of present illness consistent with exposure to CO.~~

9.3 *Timeframe for Reporting*

~~(a) A case of acute CO poisoning shall be reported to the Department's Office of Environmental Risk Assessment (3 Capitol Hill, Room 201, Providence RI 02908-5097) within four (4) working days following diagnosis.~~

~~(b) The report shall contain no less than the following information:~~

~~(1) Name, address and phone number of patient;~~

~~(2) Type of case (i.e., confirmed, probable or suspect) and the basis for case type;~~

~~(3) Such other information as may be reasonably required by the Department; AND~~

~~(4) Name and phone number of the reporting physician or other person charged with reporting (cited in §2.1 of these Regulations).~~

~~(c) The Department shall prepare and furnish standard schedule blanks for the reports required in this section.~~

~~PART IV *Confidentiality and Severability*~~

~~Section 10.0 *Confidentiality*~~

~~10.1 All information and reports relative to testing and reporting of reportable diseases shall be confidential and subject to the provisions of all laws governing the confidentiality of this information including, but not limited to, Chapters 23-6, 23-11 and 5-37.3 of the General Laws of Rhode Island, as amended.~~

~~Section 11.0 *Severability*~~

~~11.1 If any provisions of these Regulations or the application thereof to any persons or circumstances shall be held invalid, such invalidity shall not affect the provisions which can be given effect, and to this end the provisions of these Regulations are declared severable.~~

~~*DiseaseReporting_Final_November2013.doc*
Wednesday, 20 November 2013~~

REFERENCES

- ~~1. *Rules and Regulations for Asbestos Control (R23-24.5-ASB)*, Rhode Island Department of Health, September 2007~~
- ~~2. *Rules and Regulations Pertaining to HIV Counseling, Testing, Reporting, and Confidentiality (R23-6.3-HIV)*. Rhode Island Department of Health, December 2012~~
- ~~3. [DELETED]~~
- ~~4. Rhode Island General Laws, as amended:
Chapter 23-6.3 ("Prevention and Suppression of Contagious Diseases – HIV/AIDS"), Available online: <http://webservice.rilin.state.ri.us/Statutes/TITLE23/23-6.3/INDEX.HTM>
Section 28-20-4.1 ("Adoption of Regulations Pertaining to HIV and Hepatitis"); Available online: <http://www.rilin.state.ri.us/Statutes/TITLE28/28-20/28-20-4.1.HTM>~~
- ~~5. "Confidentiality of Health Care Communications and Information Act," Chapter 5-37.3 of the General Laws of Rhode Island, as amended. Available online: <http://www.rilin.state.ri.us/Statutes/TITLE5/5-37.3/INDEX.HTM>~~
- ~~6. "Board of Medical Licensure and Discipline", Chapter 5-37 of the Rhode Island General Laws, as amended. Available online: <http://www.rilin.state.ri.us/Statutes/TITLE5/5-37/INDEX.HTM>~~
- ~~7. *Rules and Regulations for the Licensure and Discipline of Physicians (R5-37-MD/DO)*, Rhode Island Department of Health, September 2012~~
- ~~8. "Laboratories", Chapter 23-16.2 of the Rhode Island General Laws, as amended. Available online: <http://www.rilin.state.ri.us/Statutes/TITLE23/23-16.2/INDEX.HTM>~~
- ~~9. *Rules and Regulations for Licensing Clinical Laboratories and Stations (R23-16.2-C&S/LAB)*, Rhode Island Department of Health, September 2007~~
- ~~10. "Nurses", Chapter 5-34 of the Rhode Island General Laws, as amended. Available online: <http://www.rilin.state.ri.us/Statutes/TITLE5/5-34/INDEX.HTM>~~
- ~~11. *Rules and Regulations for the Licensing of Nurses & Standards for the Approval of Basic Nursing Education Programs (R5-34-NUR/ED)*, Rhode Island Department of Health, March 2008~~
- ~~12. *Rules and Regulations for Licensing of Midwives (R23-13-MID)*, Rhode Island Department of Health, September 2007~~
- ~~13. "Physician Assistants", Chapter 5-54 of the Rhode Island General Laws, as amended. Available online: <http://www.rilin.state.ri.us/Statutes/TITLE5/5-54/INDEX.HTM>~~
- ~~14. *Rules and Regulations for the Licensure of Physician Assistants (R5-54-PA)*, Rhode Island Department of Health, September 2007~~
- ~~15. "Licensing of Health Care Facilities", Chapter 23-17 of the Rhode Island General Laws, as amended. Available online: <http://www.rilin.state.ri.us/Statutes/TITLE23/23-17/INDEX.HTM>~~
- ~~16. [DELETED]~~

- ~~17. Office of Minority Health and Office of Health Statistics. *Policy for Maintaining, Collecting, and Presenting Data on Race and Ethnicity*. Providence, RI: Rhode Island Department of Health. July 2000. Available online: <http://www.health.ri.gov/chic/statistics/data%20policy%20guide.pdf>~~
- ~~18. [DELETED]~~
- ~~19. HIPAA Privacy Rule and Public Health: Guidance from CDC and the U.S. Department of Health and Human Services May 2, 2003/52 (S-1); 1-12. Available online: <http://www.cdc.gov/mmwr/preview/mmwrhtml/su5201a1.htm>~~
- ~~20. *Infectious Disease Information for Providers*. Rhode Island Department of Health. Available online: <http://www.health.ri.gov/diseases/for/providers/>~~
- ~~21. RI Division of Laboratories, *Laboratory Specimen Collection Manual*. Available online: <http://www.health.ri.gov/programs/laboratory/biological/about/specimensubmission/>~~

~~The revision dates of all regulations cited above were current when these amended regulations were filed with the Secretary of State. Current copies of all regulations issued by the RI Department of Health may be downloaded at no charge from the RI Secretary of State's Final Rules and Regulations Database website: <http://www.sos.ri.gov/rules/>~~

~~RULES AND REGULATIONS PERTAINING TO
HIV COUNSELING, TESTING,
REPORTING, AND CONFIDENTIALITY~~

~~[R23-6.3 HIV]~~



~~STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS~~

~~DEPARTMENT OF HEALTH~~

~~July 1989~~

~~*As Amended:*~~

~~December 1989~~

~~September 2001~~

~~January 2002 (re-filing in
accordance with the
provisions of §42-35-4.1 of
the Rhode Island General
Laws, as amended)~~

~~January 2007 (re-filing in
accordance with the
provisions of §42-35-4.1 of
the Rhode Island General
Laws, as amended)~~

~~September 2008~~

~~July 2010~~

~~January 2012 (re-filing in
accordance with the
provisions of §42-35-4.1 of
the Rhode Island General
Laws, as amended)~~

~~**December 2012**~~

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~~INTRODUCTION~~

~~These amended *Rules and Regulations Pertaining to Counseling, Testing, Reporting and Confidentiality* [R23-6.3-HIV] are promulgated¹ pursuant to the authority conferred under Chapter 23-6.3, and §§ 11-34-10, 11-37-17, 21-28-4.20, 23-1-38, 23-11-17, 23-13-19, 23-17-31, 23-17-31.1 and 40-1-24-20 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting prevailing standards for HIV counseling, testing, reporting and confidentiality provisions in Rhode Island.~~

~~Pursuant to the provisions of §§42-35-3(a)(3) and (a)(4) of the General Laws of Rhode Island, as amended, the following were given consideration in arriving at the amended regulations: (1) alternative approached to the regulations; (2) duplication or overlap with other state regulations; and (3) significant economic impact on small business. Based on the available information, no known alternative approach, overlap or duplication was identified.~~

~~Upon promulgation of these amendments, these amended regulations shall supersede all previous *Rules and Regulations Pertaining to HIV Counseling, Testing, Reporting and Confidentiality* [R23-6-HIV] promulgated¹ by the Rhode Island Department of Health and filed with the Secretary of State.~~

¹ ~~All editions of the *Rules and Regulations Pertaining to HIV Counseling, Testing, Reporting and Confidentiality* prior to July 2010 were promulgated pursuant to authority under Chapter 23-6 of the General Laws of Rhode Island, as amended. The portions of Chapter 23-6 pertaining to HIV were repealed in their entirety by PL 2009-196 & PL 2009-289, and were replaced by Chapter 23-6.3 of the General Laws of Rhode Island, as amended. Beginning with the July 2010 edition, the *Rules and Regulations Pertaining to HIV Counseling, Testing, Reporting and Confidentiality* are promulgated pursuant to authority under Chapter 23-6.3 of the General Laws of Rhode Island, as amended.~~

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~~PART I Definitions~~

~~Section 1.0 Definitions~~

~~Wherever used in these rules and regulations, the following terms shall be construed as follows:~~

- ~~1.1 "Act" means RIGL Chapter 23-6.3 entitled "Prevention and Suppression of Contagious Diseases - HIV/AIDS".~~
- ~~1.2 "Agent" means a person empowered by the patient to assert or waive the confidentiality, or to disclose or consent to the disclosure of confidential information, as established by RIGL Chapter 5-37.3 entitled "Confidentiality of Health Care Communications and Information Act".~~
- ~~1.3 "AIDS" means the medical condition known as Acquired Immunodeficiency Syndrome, caused by infection of an individual with Human Immunodeficiency Virus (HIV).~~
- ~~1.4 "Anonymous HIV testing" means an HIV test that utilizes a laboratory generated code based system, which does not require an individual's name or other identifying information that may reveal one's identity, including information related to the individual's health insurance policy, to be associated with the test.~~
- ~~1.5 "Antibody" means a protein produced by the body in response to specific foreign substances such as bacteria or viruses.~~
- ~~1.6 "Community-based organization" means an entity that has written authorization from the Department for HIV counseling, testing and referral services (HIV CTRS).~~
- ~~1.7 "Confidential HIV testing" means an HIV test that requires the individual's name and other identifying information including information related to the individual's health insurance policy, as appropriate.~~
- ~~1.8 "Consent" means an explicit exchange of information between a person and a health care provider or qualified professional HIV test counselor through which an informed individual can choose whether to undergo HIV testing or decline to do so. Elements of consent shall include providing each individual with verbal or written information regarding an explanation of HIV infection, a description of interventions that can reduce HIV transmission, the meanings of positive and negative test results, the voluntary nature of the HIV testing, an opportunity to ask questions and to decline testing.~~
- ~~1.9 "Controlled substance" means a drug, substance, or immediate precursor in schedules I-V listed in the provisions of RIGL Chapter 21-28 entitled, "Uniform Controlled Substances Act".~~
- ~~1.10 "Department" means the Rhode Island Department of Health.~~
- ~~1.11 "Diagnosis of AIDS" means the most current surveillance case definition for AIDS published by the Centers for Disease Control & Prevention (CDC).~~

- 1.12 ~~“**Diagnosis of HIV**” means the most current surveillance case definition for HIV infection published by the CDC.~~
- 1.13 ~~“**Director**” means the Director of the Rhode Island Department of Health or his/her designee.~~
- 1.14 ~~“**ELISA result**” means Enzyme Linked Immunosorbent Assay or EIA (Enzyme Immunoassay) which is a serological technique used in immunology to detect the presence of either antibody or antigen.~~
- 1.15 ~~“**Health benefits**” include accident and sickness, including disability or health insurance, health benefit plans and/or policies, hospital, health, or medical service plans, or any health maintenance organization plan pursuant to RIGL Title 27 or otherwise.~~
- 1.16 ~~“**Health care facility**” means those facilities licensed by the Department in accordance with the provisions of RIGL Chapter 23-17.~~
- 1.17 ~~“**Health care provider**”, as used in these Regulations, means a licensed physician, physician assistant, certified nurse practitioner or midwife.~~
- 1.18 ~~“**Health care settings**” means venues offering clinical STD services including, but not limited to, hospitals, urgent care clinics, STD clinics and other substance abuse treatment facilities, mental health treatment facilities, community health centers, primary care and OB/GYN physician offices, and family planning providers.~~
- 1.19 ~~“**HIV**” means the Human Immunodeficiency Virus, the pathogenic organism responsible for HIV infection and/or the Acquired Immunodeficiency Syndrome (AIDS) in humans.~~
- 1.20 ~~“**HIV CD4 T-lymphocyte test results**” means results of any currently medically accepted and/or FDA approved test used to count CD4 T-lymphocyte cells in the blood of an HIV infected person.~~
- 1.21 ~~“**HIV counseling**” means an interactive process of communication between a person and a health care provider or qualified professional HIV test counselor during which there is an assessment of the person's risks for HIV infection and the provision of counseling to assist the person with behavior changes that can reduce risks for acquiring HIV infection.~~
- 1.22 ~~“**HIV Counseling, Testing, Referral and Services Sites (HIV CTRS)**” means sites designated and funded by the Department to provide both anonymous and confidential HIV testing and HIV counseling and referral services.~~
- 1.23 ~~“**HIV screening**” means the conduct of HIV testing among those who do not show signs or symptoms of an HIV infection.~~
- 1.24 ~~“**HIV test**” means any currently medically accepted and/or FDA approved test for determining HIV infection in humans.~~

- 1.25 ~~“**HIV viral load detection test results**” means results of any currently medically accepted test used to measure the amount of HIV in blood.~~
- 1.26 ~~“**Occupational health representative**” means an individual, within a health care facility, trained to respond to occupational, particularly blood borne, exposures.~~
- 1.27 ~~“**Opts out**” means that a person who has been notified that a voluntary HIV test will be performed, has elected to decline or defer testing. Consent to HIV testing is inferred unless the individual declines testing.~~
- 1.28 ~~“**Perinatal case report for HIV**” means the information that is provided to the Department related to a child aged less than eighteen (18) months born to an HIV-infected mother.~~
- 1.29 ~~“**Person**” means any individual, trust or estate, partnership, corporation (including, associations, joint stock companies), limited liability companies, state or political subdivision or instrumentality of a state.~~
- 1.30 ~~“**Persons at high risk for HIV infection**” means persons defined as being high risk in the CDC's most current recommendations for HIV testing of adults, adolescents and pregnant women in health care settings or through authority and responsibilities conferred on the Director by law in protecting the public's health.~~
- 1.31 ~~“**Polymerase chain reaction (PCR) test**” means a common laboratory method of creating copies of specific fragments of DNA or RNA.~~
- 1.32 ~~“**Qualified professional HIV test counselor**” means:~~
- ~~(a) A physician, physician assistant, certified nurse practitioner, midwife, or nurse licensed to practice in accordance with applicable state law;~~
 - ~~(b) A medical student who is actively matriculating in a medical degree program and who perform duties assigned to them by a physician; or~~
 - ~~(c) A person who has successfully completed an HIV counseling training program approved by the Department.~~
- 1.33 ~~“**RIGL**” means the General Laws of Rhode Island, as amended.~~
- 1.34 ~~“**Sexually transmitted diseases (STD's)**” means those diseases included in RIGL §23-11-1, as amended, entitled “*Sexually Transmitted Diseases*”, and any other sexually transmitted disease that may be required to be reported by the Department.~~
- 1.35 ~~“**These Regulations**” mean all parts of Rhode Island *Rules and Regulations Pertaining to HIV-1 Counseling, Testing, Reporting and Confidentiality [R23-6.3 HIV]*.~~

~~PART II Requirements for Offering HIV Counseling and Testing~~

~~Section 2.0 Offering of HIV Counseling and Testing~~

~~2.1 Pursuant to RIGL §§23-17-31, 23-17-31.1, 23-13-19, 40-1-24-20, and 23-11-17, the mandatory offering of HIV counseling and testing (with informed consent) shall be required in conjunction with the following:~~

- ~~(a) Services or treatment for sexually transmitted diseases (STDs);~~
- ~~(b) Clinical services for injecting drug users unless such test is deemed inappropriate by a health care provider caring for the patient.~~
- ~~(c) Every health care provider attending any person for prenatal care or family planning services shall include HIV screening in these settings so as to promote earlier detection of HIV with unrecognized or no identified risk factors.~~
- ~~(d) (1) HIV testing shall be incorporated as part of routine prenatal testing for all pregnant women as early and often as appropriate during each pregnancy after the patient has been notified that voluntary testing, in accordance with the consent and information requirements of §2.2 of these Regulations, will be performed unless the patient opts out.~~
 - ~~(2) Any woman with an undocumented HIV test status in her record at the time of labor and/or delivery shall be screened with an HIV test in accordance with the consent and information requirements of §2.2 of these Regulations, unless she opts out.~~
- ~~(e) A health care provider attending to any person who may be at risk for HIV infection shall offer the HIV test to those patients. All testing pursuant to these Regulations shall be performed in accordance with §23-6.3-7 (Confidentiality) and §23-6.3-8 (Protection of the medical Records) of the Act, and all applicable informed consent standards.~~

~~2.2 (a) Except as provided in §5.0 of these Regulations, HIV screening shall be voluntary, free from coercion, incorporated into routine medical testing, and undertaken only with the individual's knowledge and understanding that HIV testing will be performed.~~

- ~~(b) (1) No health care provider shall order or conduct a HIV test without first:~~
 - ~~(i) Providing HIV information and an opportunity for discussion, as required by §2.3(a)(1) of these Regulations;~~
 - ~~(ii) Informing the patient that he or she has a right to decline testing; and~~
 - ~~(iii) Obtaining the oral consent of the patient to be tested, or of a person authorized to consent to health care for such individual. Consent or refusal and exchange of HIV information shall be documented in the patient's medical record.~~
- ~~(2) No qualified professional HIV counselor shall order or conduct a HIV test without first:~~
 - ~~(i) Providing HIV information and counseling, as required by §2.3(a)(2) and (a)(3) of these Regulations;~~
 - ~~(ii) Informing the client that he or she has a right to decline testing; and~~

- ~~(iii) Obtaining the oral consent of the client to be tested, or of a person authorized to consent to health care for such individual. Consent or refusal and exchange of HIV information shall be documented in the client's record.~~
- ~~(c) When a person consents to anonymous testing, the health care provider and/or qualified professional HIV test counselor ordering or conducting the test shall receive only verbal confirmation from the client that the client understands all applicable information offered. Agencies performing anonymous testing shall not record acceptance using client names, but shall devise a unique identifier system or code that tracks, time, date and person administering the test.~~
- ~~(d) A person performing HIV testing shall have written protocols and procedures to record acceptance or refusal of a test, assuring non-coercion of testing, and the exchange of HIV information described in §§2.2(a) (c) of these Regulations.~~

2.3 HIV Test Counseling.

- ~~(a) (1) A health care provider may tailor HIV counseling to best meet the needs of the individual to be tested. Decisions concerning tailoring and the extent of counseling shall be made on a case-by-case basis.~~
- ~~(2) In addition to offering written information, qualified professional HIV counselors shall offer HIV prevention counseling that includes the following:~~
 - ~~(i) A client centered approach, that is, tailored to the behaviors, circumstances, and special needs of the individual being served;~~
 - ~~(ii) A personalized client risk assessment, as appropriate; and~~
 - ~~(iii) A personalized plan for the individual to use to reduce the risk of HIV infection/transmission, as appropriate.~~
- ~~(3) When an individual consents to anonymous testing and tests positive for HIV, qualified professional HIV counselors shall discuss options with the client regarding referrals and reporting of this positive screening, including the necessity of accessing a health care provider.~~
- ~~(b) In no event shall a patient be tested for HIV pursuant to these Regulations without first being provided with verbal or written information that includes the following:~~
 - ~~(1) An explanation of HIV infection;~~
 - ~~(2) A description of interventions that can reduce HIV transmission;~~
 - ~~(3) The meaning of positive and negative test results;~~
 - ~~(4) The possibility that a recent infection may not be detected; and~~
 - ~~(5) An opportunity to ask questions and to decline testing.~~

2.4 [REMOVED]

2.5 [REMOVED]

2.6 ~~[REMOVED]~~

2.7 ~~No health care provider shall discriminate against a patient because he or she is HIV positive or has declined to take an HIV test.~~

2.8 (a) ~~All persons tested under the Act and these Regulations shall be informed of the results of the HIV test.~~

(b) ~~A positive test result shall be given in person. Persons testing positive for HIV shall also be provided with linkages and referrals to HIV related counseling, health care and support.~~

(c) ~~Counselors for HIV counseling, testing and referral shall successfully complete a required training program, approved by the Department pursuant to §8.0 of these Regulations, to become a qualified professional HIV test counselor. This requirement shall not be applicable to an individual specifically exempted pursuant to §1.32(a) or (b) of these Regulations.~~

2.9 ~~**Mandatory HIV Counseling and Testing.**~~

(a) ~~In accordance with the provisions of RIGL §42-56-37, entitled “*HIV Testing*”, every individual who is committed to the adult correctional institutions to any criminal offense, after conviction, is required to be tested for HIV.~~

(b) ~~Any individual convicted of possession of any controlled substance as defined in RIGL Chapter 21-28 entitled “*Uniform Controlled Substances Act*”, that has been administered with a hypodermic instrument, retractable hypodermic syringe, needle, intra-nasally, or any similar instrument adapted for the administration of drugs shall be required to be tested for HIV unless already documented HIV positive.~~

(c) ~~Any individual convicted of a violation of any provisions of RIGL Chapter 11-34 entitled “*Prostitution and Lewdness*”, shall be required to be tested for HIV unless already documented HIV positive.~~

(d) ~~In accordance with the provisions of RIGL Chapter 11-37, entitled, “*Sexual Assault*”, any individual who has admitted to or been convicted of or adjudicated wayward or delinquent by reason of having committed any sexual offense involving penetration whether or not a sentence or fine is imposed or probation granted, shall be ordered by the court upon petition of the victim, immediate family members of the victim or legal guardian of the victim, to submit to a blood test for the presence of a sexually transmitted disease including, but not limited to, HIV.~~

(e) ~~All individuals tested under §§2.9(b), (c) or (d) of these Regulations shall be informed of their test results.~~

2.10 ~~[REMOVED]~~

2.11 ~~All individuals tested under §2.9(b) of these Regulations, who are determined to be injecting and/or intra-nasal drug users, shall be referred to appropriate substance abuse treatment as specified in §6.12 of these Regulations.~~

~~2.12 **Mandatory HIV Testing.** Mandatory HIV testing, and counseling, as appropriate, shall be performed in accordance with the following:~~

- ~~(a) Screening and testing of a potential organ donor pursuant to 42 CFR 486.344(c)(1).~~
- ~~(b) As permitted under RIGL Chapter 23-1-38 entitled “HIV Antibody Testing Sperm Collection or Donation”.~~

~~Section 3.0 *Applicability to Insurance Companies*~~

~~3.1 Pursuant to §23-6.3-16(a) of the Act, §§23-6.3-1 through 23-6.3-14 of the Act and these Regulations do not apply to the offering or sale of life insurance in Rhode Island. However, any insurance company offering or selling life insurance within Rhode Island that requires an individual to be tested for infection with human immunodeficiency virus (HIV) or any other identified causative agent of HIV for purposes of determining insurability shall be required to comply with the provisions of §23-6.3-16(a) of the Act.~~

~~3.2 Pursuant to §23-6.3-16(b) of the Act, the provisions of the Act and these Regulations apply to the offer or sale of health benefits in Rhode Island by any company regulated under the laws of Rhode Island, including, but not limited to, RIGL Title 27 and Chapter 42-62, unless specifically exempted pursuant to §§23-6.3-16(b)(1) through (b)(4) of the Act.~~

~~Section 4.0 **[REMOVED IN ENTIRETY]**~~

~~Section 5.0 *Exceptions to Consent Requirement*~~

~~5.1 A health care provider may test for the presence of HIV without obtaining consent from the individual to be tested under the following conditions:~~

- ~~(a) The individual to be tested is under one (1) year of age;~~
- ~~(b) A child is between one (1) and thirteen (13) years of age and appears to be symptomatic for HIV;~~
- ~~(c) The individual to be tested is a minor under the care and authority of the Rhode Island Department for Children, Youth, and Families, and the Director of said Department certifies that an HIV test is necessary to secure health or human services for that individual;~~
- ~~(d) **[REMOVED]**~~
- ~~(e) In a licensed health care facility or health care setting, in the event that an occupational health representative or physician, registered nurse practitioner, physician assistant, or nurse midwife, not directly involved in the exposure, determines that an employee or emergency service worker, other than one in a supervisory position to the person making the determination, had a significant exposure to the blood and/or body fluids of a patient and the patient or the patient's guardian refuses to grant consent for an HIV test to determine whether the patient has HIV; then, if a sample of the patient's blood is available, that blood shall be tested for the HIV.~~

- ~~(1) If a sample of the patient's blood is not otherwise available and the patient refuses to grant consent to draw blood, the employee or emergency service worker may petition the Superior Court for a court order mandating that the test be performed.~~
- ~~(2) Before a patient or a sample of the patient's blood is required to undergo an HIV test, the employee or emergency service worker must submit to a baseline HIV test within seventy two (72) hours of the exposure.~~
- ~~(3) No person who determines that an employee or emergency service worker has sustained a significant exposure and authorizes the HIV testing of a patient, nor any person or health care facility who acts in good faith, and recommends the test be performed, shall have any liability as a result of their actions carried out under the provisions of the Act or these Regulations, unless those persons are proven to have acted in bad faith.~~
- ~~(4) For the purposes of these Regulations, "emergency service worker" means a worker responding on behalf of a licensed ambulance/rescue service, or a fire department or a law enforcement agency, who, in the course of his/her professional duties, has been exposed to bodily fluids in circumstances that present a significant risk of transmission of HIV, and has completed a pre-hospital exposure form in accordance with RIGL §23-4-1-19.~~
- ~~(f) In an emergency, where due to a grave medical or psychiatric condition, and it is impossible to obtain consent from the patient or, if applicable under state law, the patient's parent, guardian or agent.~~
- ~~(g) In accordance with RIGL Chapter 23-8, individuals under eighteen (18) years of age may give legal consent for testing, examination, and/or treatment for any reportable communicable disease, including HIV.~~
- ~~(h) A newborn shall be tested as soon as possible at delivery without the mother's consent if the mother's HIV status is not documented, provided that:
 - ~~(1) Reasonable efforts have been made to secure voluntary consent from the mother to test the newborn; and~~
 - ~~(2) A mother is informed that HIV antibodies in the newborn indicate that the mother is infected with HIV.~~~~

~~5.2 **Reasonable Efforts to Secure Consent.** No involuntary testing for HIV shall take place under any of the exceptions set forth in §§2.9, 2.12(b), 5.1(a), 5.1(b), 5.1(c), 5.1(e) or 5.1(f) of these Regulations unless reasonable efforts have been made to:~~

- ~~(1) Secure voluntary consent from the individual to be tested, or in the case of a minor patient, from the legal parent or guardian of the minor patient; and~~
- ~~(2) Provide verbal or written information as specified in §2.2 of these Regulations.~~

~~PART III *HIV Testing*~~

~~Section 6.0 *HIV Screening and Testing of Adults, Adolescents, and Pregnant Women:* This section shall pertain to patients in all health care settings and HIV CTRS sites.~~

~~6.1 HIV screening and testing shall be based on the most current recommendations for HIV counseling, testing and referral of adults, adolescents and pregnant women issued by the Centers for Disease Control and Prevention (CDC). Provided, however, those guidelines shall be interpreted by the Department so as to best serve the individuals and patients receiving HIV testing, and shall in no event be interpreted or implemented in a manner inconsistent with the minimum informed consent standards of RIGL Title 23 or other protections of state law and regulations.~~

~~6.2 [REMOVED]~~

~~6.3 [REMOVED]~~

~~6.4 [REMOVED]~~

~~6.5 All biological samples or specimens taken for the purpose of performing laboratory analysis, utilizing any FDA approved testing methodology, for the detection of HIV, by or under the direction or order of any health care provider working within the scope of his or her practice, shall be sent to the Department of Health Laboratory for analysis. This provision shall not apply to those HIV tests performed in a hospital laboratory or to those sites performing rapid HIV testing.~~

~~6.6 Hospitals shall forward all positive confirmatory HIV test results to the Department. All sites performing HIV testing shall submit an annual HIV testing report, in electronic format, to the Department which includes data collected pursuant to §6.11(e) of these Regulations. The report shall be submitted to the Department no later than 31 March of each year, and shall cover the period January through December of the prior calendar year.~~

~~6.7 The Department of Health Laboratory shall conduct all confirmatory testing for HIV/AIDS with the exception of written waivers issued by the Department pursuant to §6.7.1 of these Regulations.~~

~~6.7.1 Sites performing non-venapuncture HIV testing (e.g. rapid testing) shall seek a waiver from the Department to provide confirmatory HIV testing from a laboratory other than the Department of Health Laboratory, and shall forward all positive and negative confirmatory HIV tests results to the Department.~~

~~6.8 Except in the case of anonymous HIV testing, a health care provider working within the scope of his or her practice providing samples or specimens for HIV testing, or results of HIV tests to the Department, shall include the name of the patient and other identifying information including information related to the individual's health insurance policy as applicable.~~

- ~~6.9 Any HIV cases reported in the previous code based system, shall remain in a code based data set. This does not prohibit a physician from submitting or requesting that an updated name case report on a patient replace a previously coded case report.~~
- ~~6.10 All individuals who desire anonymous HIV testing shall be referred to an HIV CTRS site funded by the Department that provides anonymous HIV testing.~~
- ~~6.11 All health care settings and HIV CTRS sites shall develop protocols that include no less than the following:~~
- ~~(a) Assessment for individuals at high risk for HIV infection;~~
 - ~~(b) Frequency of HIV testing;~~
 - ~~(c) Communication of HIV test results;~~
 - ~~(d) Post-test linkages to needed care and support services; and~~
 - ~~(e) A system that collects data on an annual basis regarding all HIV testing by facility conducting the testing, sex, age and test results (negative, positive, indeterminate).~~
- ~~6.12 Those adults, adolescents and pregnant women who test positive for HIV infection shall be given priority for outpatient substance abuse treatment programs that are sponsored or supported by the appropriate state agency responsible for these services, and those who test negative for HIV infection shall be referred to the appropriate state agency responsible for these services for earliest possible evaluation and treatment.~~
- ~~6.13 Anonymous and confidential HIV testing provided by HIV CTRS sites funded by the Department shall screen individuals for their ability to pay for such HIV testing, using a fee schedule and screening process available to the Department on request. HIV CTRS sites shall not deny HIV testing to any individual based on his or her inability to pay.~~

~~PART IV *Qualified Professional HIV Test Counselor Requirements*~~

~~Section 7.0 *Qualified Professional HIV Test Counselor Certification*~~

~~7.1 **Initial Certification.** Applicants for certification as a Qualified Professional HIV Test Counselor shall submit a completed application to the Department on forms provided by the Department. The application shall include all the required information on the form and documentation of successful completion of an initial Counselor training course, approved in accordance with §8.0 of these Regulations. The Department may require additional information to determine whether an application meets the requirements of these Regulations.~~

~~7.1.1 Notwithstanding the provisions of §7.1, an individual who successfully completed an HIV counselor training program, approved or conducted by the Department, prior to 1 May 2010 shall submit a completed application to the Department on forms provided by the Department. The application shall include all the required information on the form and documentation of this training. However, their certification as Qualified Professional HIV Test Counselor shall expire on 31 March 2011 unless a renewal application is submitted in accordance with §7.3.1.~~

~~7.2 **Issuance of Certification.** The Department shall grant a certificate to a Qualified Professional HIV Test Counselor who meets the certification requirements set forth in these Regulations. The certification shall be issued for a period no longer than two (2) years and shall expire on the last day of the month two (2) years from the date of issue, unless sooner suspended or revoked. The certification may be renewed in accordance with the provisions of §7.3.~~

~~7.3 **Renewal of Certifications.** A Qualified Professional HIV Test Counselor may request a certification renewal by submitting:~~

~~(a) A completed renewal application to the Department on forms provided by the Department. The application shall include all the required information on the form, without reference to any previously submitted material.~~

~~(b) Documentation of successful completion of:~~

~~(1) At least six (6) contact hours related to HIV, sexually transmitted disease, viral hepatitis, sexual behavior, prevention and/or harm reduction within the twenty-four (24) month term of their current certification; and~~

~~(2) A Department approved counseling skills assessment session within the twenty-four (24) month term of their current certification.~~

~~7.3.1 Notwithstanding the provisions of §7.3(b), an individual who was certified as a Qualified Professional HIV Test Counselor pursuant to §7.1.1 shall be required to submit:~~

~~(a) A renewal application, in accordance with §7.1 of these Regulations, without reference to any previously submitted material.~~

~~(b) Documentation of successful completion of:~~

- ~~(1) At least six (6) contact hours related to HIV, sexually transmitted disease, viral hepatitis, sexual behavior, prevention and/or harm reduction no later than 31 March 2011; and~~
- ~~(2) A Department approved counseling skills assessment session no later than 31 March 2011.~~

~~Section 8.0 *Approval of Qualified Professional HIV Test Counselor Training Programs*~~

~~8.1 **General Certification Requirements.**~~

- ~~(a) Persons and organizations offering or conducting a Qualified Professional HIV Test Counselor training program shall be certified in accordance with these Regulations.~~
- ~~(b) The criteria for successful completion of the training program shall include obtaining a passing score on the final course examination and successfully demonstrating the required counseling skills, unless the certified training course has been specifically authorized in writing by the Department to use an alternative method of determining successful completion.~~
- ~~(c) The required number of contact hours for the training course shall be construed as allowing a maximum of one (1) hour for the course final examination.~~

~~8.2 **Certification Application.** An applicant for certification of a Qualified Professional HIV Test Counselor training program shall submit the following information for review by the Department at least forty five (45) days prior to the first scheduled course date:~~

- ~~(a) The name and address of the person(s) or organization which proposes to conduct the training program; identification and affiliation of training program sponsor(s); the name of the responsible individual and his/her telephone number. If the applicant proposes to conduct the training program under a different name than shown on the application, the other name(s) shall also be provided.~~
- ~~(b) A detailed outline of the training program curriculum, including the amount of time allotted to each topic, the name and training/qualifications of the individual(s) responsible for developing the instruction program for each topic, and the name of the instructor(s) for each topic.~~
- ~~(c) Any restrictions on attendance, including minimum criteria for acceptance into the training program.~~
- ~~(d) Confirmation that the training program will adhere to the most recent guidance referencing HIV testing counselors published by CDC.~~
- ~~(e) Criteria/method(s) for evaluating the student's skills at delivering the six (6) step counseling session in role playing exercises.~~
- ~~(f) A description of the teaching methods to be used to present each topic including, where appropriate, lectures, discussions, demonstrations and audio visual materials. When applicable, include the name, producer and date of production of audio visual~~

~~materials to be used.~~

- ~~(g) A copy of the student and instructor manuals, or other materials to be used for the training program.~~
- ~~(h) Documentation that the applicant has employed or contracted instructors who meet the training and experience criteria contained in §8.4. Resumes or curricula vitae describing special training and education and/or prior experience may be submitted for the purpose of providing this documentation.~~
- ~~(i) A copy of the quality control plan to be used for maintaining and improving the quality of the training program over time. This plan shall contain at least the following elements:
 - ~~(1) Procedures for periodic revision of training materials and the final exam to reflect innovations in the field;~~
 - ~~(2) Procedures for annual review of instructor competency by the training program administrator; and~~
 - ~~(3) Procedures for administering the final exam to ensure the validity and integrity of the examination.~~~~

~~8.3 The initial training program for a Qualified Professional HIV Test Counselor shall consist of a minimum of twenty one (21) contact hours which adequately address the following topics:~~

- ~~(a) Provide a basic knowledge and understanding of the importance of integrating of HIV, STD and viral hepatitis into test counseling sufficient to allow the student to:
 - ~~(1) State at least one (1) fact about HIV and other STD infection rates;~~
 - ~~(2) State at least one (1) fact about viral hepatitis infections rates;~~
 - ~~(3) State at least one (1) fact about STD, HIV & HCV co-infection;~~
 - ~~(4) State at least three (3) reasons why ethnic, racial and sexual orientation issues are important to HIV testing;~~
 - ~~(5) List at least three (3) benefits of Partner Counseling and Referral Services; and~~
 - ~~(6) Know how to access the AIDS/HIV law and regulations at the Department of Health website~~~~
- ~~(b) Provide a basic knowledge in prevention counseling concepts sufficient to allow the student to:
 - ~~(1) State the three (3) concepts that guide the work of prevention counseling: client centered, focus on personal risk assessment and the development of a personalized action plan;~~
 - ~~(2) State at least three (3) reasons why the three (3) concepts are important; and~~
 - ~~(3) Identify and demonstrate four (4) basic counseling skills: open-ended questioning, attending, offering options, and giving information simply~~~~

~~(c) Provide a basic knowledge of the six (6) Steps of a Prevention Counseling Session:~~

- ~~(1) Introduce and orient a client to session;~~
- ~~(2) Identify client's personal risk behaviors and circumstances;~~
- ~~(3) Identify safer goal behaviors;~~
- ~~(4) Develop client action plan;~~
- ~~(5) Make referrals and provide support; and~~
- ~~(6) Summarize and close session~~

~~(d) Provide "hands on" sessions that will allow the student to:~~

- ~~(1) Describe, both verbally and in writing, the purpose for each of the six (6) Steps of a Prevention Counseling Session; and~~
- ~~(2) Demonstrate each of the six (6) Steps of a Prevention Counseling Session through practice sessions and role playing.~~

8.4 **Criteria for Instructors.** ~~The training program administrator shall ensure that all of the following education and experience criteria for the instructors are met:~~

- ~~(a) A minimum of five (5) years current relevant experience as a HIV test counselor or Qualified Professional HIV Test Counselor.~~
- ~~(b) A minimum of two (2) years experience as a trainer.~~
- ~~(c) Successful completion of fourteen (14) hour Department approved Train the Trainer course.~~
- ~~(d) Successful completion of the most current Department approved training program for a Qualified Professional HIV Test Counselor.~~
- ~~(e) An instructor who presents any portion of a training program in a language other than their native language shall have sufficient proficiency in the language used for instruction to accurately and effectively present the course material in a culturally competent manner.~~

8.5 **Record Keeping Requirements.**

- ~~(a) A certified training program shall maintain documentation of each certified course offered, which shall include as a minimum: course, date(s) and location(s) of course, class roster, results of any final examination, skills assessment and/or evaluation and the unique certificate number, for each student enrolled. The certified training program shall retain all required records for a period of at least ten (10) years and shall submit a copy of all required documentation to the Department within five (5) business days of the course.~~
- ~~(b) A certified training program shall issue unique course completion certificates to each individual who passes each course. The course completion certificate shall include, as a minimum:
 - ~~(1) The full name, a unique identification number, and address of the individual;~~~~

- ~~(2) The name of the particular course that the individual completed;~~
 - ~~(3) Date(s) of the course and date that the individual passed the course exam (if other than the last day of the course);~~
 - ~~(4) Expiration date of the certificate;~~
 - ~~(5) The name, address, and telephone number of the training program;~~
 - ~~(6) The language in which the training course was given. If the course examination was other than written English, the language and method of evaluation shall also be included.~~
- ~~(c) A certified training provider shall maintain, and make available to the Department upon request, the following records for each certified course:~~
- ~~(1) All documents that demonstrate the qualifications of the instructors;~~
 - ~~(2) Current curriculum/course materials and documents reflecting any changes made to these materials;~~
 - ~~(3) The quality control plan described in §8.2(i); and~~
 - ~~(4) Any other material not listed above that was submitted to the Department as part of the program's application for certification.~~

~~Section 9.0 [REMOVED IN ENTIRETY]~~

~~PART V *Records and Confidentiality*~~

~~Section 10.0 *Records*~~

- ~~10.1 Entries shall be made in the patient/client record of all services rendered, such as offering of test, test results, reporting, counseling, etc.~~
- ~~10.2 All forms and reports as required in accordance with these Regulations shall be maintained in the patient's/client's record by health care providers (e.g., physicians, health care facilities), including copies of any of the forms and/or reports submitted by one health care provider to another as part of the plan of care and consistent with the requirements of the Act and these Regulations.~~
- ~~10.3 Providers of health care, public health officials, and any other persons who maintain records containing information on HIV test results of individuals, shall be responsible for maintaining full confidentiality of these data as provided in §23-6.3-7 of the Act and shall take appropriate steps for their protection, including:~~
- ~~(a) Keeping records secure at all times and establishing adequate confidentiality safeguards for any such records electronically stored;~~
 - ~~(b) Establishing and enforcing reasonable policies and procedures consistent with the confidentiality requirements of these Regulations;~~
 - ~~(c) Training individuals who handle records in security objectives and techniques.~~

~~Section 11.0 *Confidentiality and Protection of Records*~~

~~11.1 **Confidentiality.**~~

- ~~(a) It is unlawful for any person to disclose to a third party the results of an individual's HIV test without the prior written consent of that individual, except for:~~
- ~~(1) A licensed laboratory or other health care facility that performs HIV tests shall report test results to the health care provider who requested the test and to the Director.~~
 - ~~(2) A health care provider shall enter HIV test results in the patient's medical record.~~
 - ~~(3) Notification to the Director of the Department of Children, Youth and Families, pursuant to §23-6.3-4(a)(3) of the Act.~~
 - ~~(4) As provided in §§23-6.3-10 and 23-6.3-14 of the Act, RIGL §5-37.3, RIGL §40-1-5-26, or as otherwise permitted by law.~~
 - ~~(5) By a health care provider to appropriate persons entitled to receive notification of individuals with infectious or communicable diseases pursuant to RIGL §23-5-9 and §23-28.36-3.~~
- ~~(b) The provisions of the Act and these Regulations chapter shall not be construed to interfere with any other federal or state laws or regulations that provide more extensive protection than provided in the Act for the confidentiality of health care information.~~

~~11.2 **Protection of Records.** Providers of health care, public health officials, and any other person who maintains records containing information on HIV test results of individuals are responsible for maintaining full confidentiality of this data and shall take appropriate steps for their protection, including:~~

- ~~(a) Keeping records secure at all times and establishing adequate confidentiality safeguards for any records electronically stored;~~
- ~~(b) Establishing and enforcing reasonable rules limiting access to these records; and~~
- ~~(c) Training persons who handle records in security objectives and technique.~~

~~Section 12.0 **Notification of Disclosure**~~

~~12.1 In all cases when an individual's HIV test results are disclosed to a third party, other than a person involved in the care and treatment of the individual, and except as permitted in §§11.1(a)(1), (a)(2), (a)(3), (a)(4) and (a)(5) of these Regulations, (permitted disclosures re: confidentiality), and permitted by and disclosed in accordance with the Federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104 191) enacted on August 21, 1996 and as thereafter amended, the person so disclosing shall make reasonable efforts to inform the individual tested in advance of:~~

- ~~(a) the nature and purpose of the disclosure;~~
- ~~(b) the date of disclosure;~~
- ~~(c) the recipient of the disclosed information.~~

~~12.2 Health care providers may inform third parties with whom an HIV infected patient is in close and continuous exposure related contact, including, but not limited to a spouse and/or partner, if the nature of the contact, in the health care providers opinion, poses a clear and present danger of HIV transmission to the third party, and if the physician has reason to believe that the patient, despite the health care provider's strong encouragement, has not and will not inform the third party that they may have been exposed to HIV.~~

~~Section 13.0 **HIV Testing and Reporting Cases of Acquired Immunodeficiency Syndrome (AIDS) and Human Deficiency Virus (HIV) Infection**~~

~~13.1 Except in the case of anonymous HIV testing, a diagnosis of HIV or AIDS shall be notifiable and reportable to the Department by name. Under this provision, the following shall be reported:~~

- ~~(a) A diagnosis of HIV, according to the most current CDC case definition of HIV, within four (4) days of testing using an official HIV/AIDS Department case reporting form.~~
- ~~(b) A diagnosis of AIDS, according to the most recent CDC case definition of AIDS, within four (4) days of testing using an official HIV/AIDS Department case reporting form.~~

- ~~(c) A positive ELISA result of any HIV test and/or other FDA approved test indicative of the presence of HIV, within four (4) days of testing.~~
- ~~(d) All CD4 counts and all viral load results (detectable and undetectable), within four (4) days of testing.~~
- ~~13.1.1 Notification of a perinatal exposure to HIV, regardless of confirmatory testing, shall be reported within four (4) days of testing.~~
 - ~~(a) Report all HIV virologic laboratory tests (positive and negative) on infants.~~
 - ~~(b) Such reporting shall occur according to procedures and format required by the Department.~~
 - ~~(c) A positive perinatal case report for HIV <18 months shall be indicated by positive results on two (2) separate specimens (not including cord blood) from one or more of these non-antibody tests:
 - ~~(1) HIV DNA or RNA detection;~~
 - ~~(2) HIV P24 Antigen test including neutralization assay for a child >1 month; and~~
 - ~~(3) HIV isolation (viral culture); and/or~~
 - ~~(4) Other U.S. Food and Drug Administration approved tests that indicate the presence of HIV in pediatric cases.~~~~
 - ~~(d) Report of pregnancy for all HIV positive women using forms as required by the Department.~~
- ~~13.2 The following persons shall report information required by this section to the Department's HIV/AIDS surveillance team:
 - ~~(a) A health care provider who diagnoses or treats HIV/AIDS;~~
 - ~~(b) The administrator of a health care facility as defined in RIGL Chapter 23-17 who diagnoses or treats HIV/AIDS; or~~
 - ~~(c) The administrator of a prison in which there is an HIV/AIDS infected person or perinatal exposure to HIV/AIDS.~~~~
- ~~13.3 Reports provided under this section shall specify the infected person's name, as well as all information required on the official Department HIV Case Report Form.~~
- ~~13.4 A person responsible for the administration of a clinical or hospital laboratory, blood bank, mobile unit, or other facility in which a laboratory examination of any specimen derived from a human body yields serological, or other evidence of HIV/AIDS, including perinatal exposure to HIV/AIDS shall notify the Department as specified in §13.1 of these Regulations.~~
- ~~13.5 All positive HIV test results shall be confirmed with a Western Blot or other FDA approved confirmatory test.~~

~~(a) All facilities obtaining blood from human donors for the purpose of transfusion or manufacture of blood products shall report HIV/AIDS consistent with this section.~~

~~(b) Any laboratory that processes specimens shall permit the Department to examine the records of said laboratory, facility, or office in order to evaluate compliance with this section.~~

~~13.6 [REMOVED]~~

~~13.7 [REMOVED]~~

~~13.8 [REMOVED]~~

~~PART VI *Violations and Remedies, and Severability*~~

~~Section 14.0 *Violations and Remedies/Penalties*~~

~~14.1 **General.** All reports and notifications made pursuant to the Act and these Regulations shall be confidential and protected from release except under the provisions of law.~~

~~(a) Any person who violates any provision of these Regulations shall be subject to the criminal, civil and/or administrative penalties prescribed by law and/or regulation.~~

~~(b) Any person aggrieved by a violation of the Act or these Regulations shall have a right of action in the superior court and may recover for each violation.~~

~~14.2 **Pertaining to Confidentiality and Protection of Records.** Any person who violates the confidentiality and/or protection of records provisions of these Regulations, shall be subject to the penalties of RIGL §5-37.3-9 which are:~~

~~(a) **Civil Penalties:** Any one who violates the confidentiality provisions of these Regulations may be held liable for actual and exemplary damages.~~

~~(b) **Criminal Penalties:** Any one who intentionally and knowingly violates the confidentiality provisions of these Regulations, shall, upon conviction, be fined not more than one thousand dollars (\$1,000.00) or imprisoned for not more than six (6) months, or both.~~

~~(c) **Commission of Crime:** The civil and criminal penalties above shall also be applicable to anyone who obtains confidential health care information through the commission of a crime.~~

~~(d) **Attorney's Fees:** Attorney's fees may be awarded, at the discretion of the court, to the successful parties in any action under the confidentiality provisions of these Regulations.~~

~~Section 15.0 *Severability*~~

~~15.1 If any provision of the Act or these Regulations is held by a court to be invalid, such invalidity shall not affect the remaining provisions of the Act or these Regulations, and to this end the provisions of these Regulations are declared to be severable.~~

REFERENCES

1. ~~"Maternal and Child Health Services for Children with Special Health Care Needs," Chapter 23-13 of the General Laws of Rhode Island, as amended.
Available online: <http://www.rilin.state.ri.us/Statutes/TITLE23/23-13/INDEX.HTM>~~
2. ~~"Licensing of Facilities and Programs for People Who Are Mentally Ill and/or Developmentally Disabled" Chapter 40.1-24 of the General Laws of Rhode Island, as amended.
Available online: <http://www.rilin.state.ri.us/Statutes/TITLE40.1/40.1-24/INDEX.HTM>~~
3. ~~"Sexually Transmitted Diseases," Chapter 23-11 of the General Laws of Rhode Island, as amended. Available online: <http://www.rilin.state.ri.us/Statutes/TITLE23/23-11/INDEX.HTM>~~
4. ~~"Corrections Department," Chapter 42-56 of the General Laws of Rhode Island, as amended.
Available online: <http://www.rilin.state.ri.us/Statutes/TITLE42/42-56/INDEX.HTM>~~
5. ~~"Prostitution and Lewdness," Chapter 11-34 of the General Laws of Rhode Island, as amended.
Available online: <http://www.rilin.state.ri.us/Statutes/TITLE11/11-34/INDEX.HTM>~~
6. ~~"Uniform Controlled Substances Act", Chapter 21-28 of the General Laws of Rhode Island, as amended. Available online: <http://www.rilin.state.ri.us/Statutes/TITLE21/21-28/INDEX.HTM>~~
7. ~~"Mental Health Law," Chapter 40.1-5 of the General Laws of Rhode Island, as amended.
Available online: <http://www.rilin.state.ri.us/Statutes/TITLE40.1/40.1-5/INDEX.HTM>~~
8. ~~"Reports of Disease and Disability," Chapter 23-5 of the General Laws of Rhode Island, as amended. Available online: <http://www.rilin.state.ri.us/Statutes/TITLE23/23-5/INDEX.HTM>~~
9. ~~"Notification of Fire Fighters, Police Officers, and Emergency Medical Technicians After Exposure to Infectious Diseases," Chapter 23-28.36 of the General Laws of Rhode Island, as amended.
Available online: <http://www.rilin.state.ri.us/Statutes/TITLE23/23-28.36/INDEX.HTM>~~
10. ~~"Quarantine Generally", Chapter 23-8 of the Rhode Island General Laws, as amended.
Available online: <http://www.rilin.state.ri.us/Statutes/TITLE23/23-8/INDEX.HTM>~~
11. ~~Revised Surveillance Case Definitions for HIV Infection Among Adults, Adolescents, and Children Aged <18 Months and for HIV Infection and AIDS Among Children Aged 18 Months to <13 Years — United States, 2008, *MMWR*, 5 December 2008 / 57(RR10);1-8 and subsequent amendments. Available online:
<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5710a1.htm>~~

~~The revision dates of all regulation cited above were current when these amended regulations were filed with the Secretary of State. Current copies of all regulations issued by the Rhode Island Department of Health may be downloaded at no charge from the RI Secretary of State's Final Rules and Regulations Database website: <http://www.sos.ri.gov/rules/>~~