



Rhode Island Department of Health

NOTICE OF PUBLIC HEARING

The Director of the Rhode Island Department of Health has under consideration proposed amendments to the *Rules and Regulations Pertaining to Reporting of Infectious, Environmental and Occupational Diseases [R23-10-DIS]* pursuant to the authority conferred under Chapters 23-10 and 42-35 of the Rhode Island General Laws, as amended. The purpose of the proposed amendments is to update the standards pertaining to confidentiality and reporting of infectious diseases in Rhode Island.

Notice is hereby given in accordance with the provisions of Chapter 42-35 of the Rhode Island General Laws, as amended, that the Director will hold a public hearing on the above mentioned matter, in the **AUDITORIUM** of the Rhode Island Department of Health (on the lower level of the Cannon Building), Three Capitol Hill, Providence, Rhode Island on **WEDNESDAY, 11 SEPTEMBER 2013 AT 1:00 PM.** at which time and place all persons interested therein will be heard. The seating capacity of the room will be enforced and therefore the number of persons participating in the hearing may be limited at any given time by the hearing officer, in order to comply with safety and fire codes.

In the development of the rules and regulations, consideration was given to the following: (1) alternative approaches; and (2) overlap or duplication with other statutory and regulatory provisions. No alternative approach, duplication, or overlap was identified based upon available information.

For the sake of accuracy, it is requested that statements to be made relative to any aspect of the regulations, including alternative approaches or overlap, be submitted in writing at the time of the hearing or in electronic format prior to the hearing date to: Christine Goulette, Chief Administrative Officer, Division of Infectious Disease and Epidemiology: by e-mail to Christine.Goulette@health.ri.gov or by calling 401-222-6868.

Copies of the regulations are available for public inspection in the Cannon Building, Room #201, Rhode Island Department of Health, 3 Capitol Hill, Providence, Rhode Island, on the Secretary of State's website: <http://www.sos.ri.gov/ProposedRules/>, by calling 401-222-7767 or by e-mail to Bill.Dundulis@health.ri.gov.

The Department of Health is accessible to the handicapped. If communication assistance (readers/ interpreters/captioners) is needed, or any other accommodation to ensure equal participation, please call 401-222-7767 or RI Relay 711 at least three (3) business days prior to the meeting so arrangements can be made to provide such assistance at no cost to the person requesting.

Signed this 9th day of August 2013

Original signed by Michael Fine, MD

Michael Fine, M.D., Director of Health

**RULES AND REGULATIONS PERTAINING TO THE
REPORTING OF ~~COMMUNICABLE~~ 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)

**September 2013
(Proposed)**

COMPILER'S NOTES:

Proposed Additions: Double-Underlined

Proposed Deletions: ~~Strikeouts~~

PUBLIC HEARING DRAFT – REVISED 7 AUGUST 2013

INTRODUCTION

These amended Rules and Regulations Pertaining to Reporting of Communicable Infectious, Environmental and Occupational Diseases [R23-10-DIS]¹ 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 ~~sections §§~~ 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 communicable, occupational and environmentally related diseases in Rhode Island ~~this state~~. Surveillance data will be used to initiate appropriate public health responses.

Pursuant to the provisions of ~~section 42-35-3(e)~~ §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, overlap or duplication nor any significant economic impact was identified, consequently the regulations are adopted in the best interest of the health, safety and welfare of the public.~~

Upon promulgation of these amendments, these ~~rules and~~ amended Regulations shall supersede all previous ~~Rules and Regulations Pertaining to Reporting of Communicable and Environmentally Related Diseases, and all previous Rules and Regulations Pertaining to Reporting of Communicable, Environmental and Occupational Diseases (R23-5-6,10,11,24.6 CD/ERD and R23-24.5 ASB)~~ 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.

¹ Prior to September 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 September 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 ~~rules and~~ 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 herein.
- 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.

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- 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 ~~herein~~, 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] "Perinatal case report for HIV"** means the information that is provided to the Department related to a child aged less than eighteen (18) months of age born to an HIV-infected mother where the child does not meet the criteria for HIV infection or the criteria for "not infected" with HIV as defined in the most current surveillance case definition for HIV infection published by the federal CDC (Centers for Disease Prevention and Control).~~
- 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 herein).

Responsibility for Reporting

- 2.1 The diseases listed in these Regulations shall be reported in the manner set forth in these Regulations herein. Reporting of diseases listed in these Regulations is required and is the responsibility of the following:

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- **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 herein.
- 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 operatory}); 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 herein.
- **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 cases:

- ~~(1) When laboratory tests are performed for insurance purposes (i.e., non diagnostic testing); and~~
- ~~(2) 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 ~~conducting the research~~, the provisions of these Regulations shall apply).~~

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- 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. ~~and/or the Department~~ The response will be in keeping with situation-specific recommendations that are provided by the Division of Infectious Disease and Epidemiology. ~~in the Guidelines for Communicable Disease Prevention and Control issued by the Rhode Island Department of Health, Center for Epidemiology and Infectious Disease.~~
- 2.5 **Reporting of Outbreaks or Clusters.** Any person who is required or recommended to report (cited in sections §2.1 of these Regulations herein) 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*; ~~and~~
 - (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 ~~of the Rhode Island General Laws, as amended,~~ ("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. ~~the HIV/AIDS Confidentiality and Security~~

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~~Policy of the Office of HIV/AIDS & Viral Hepatitis of the Rhode Island Department of Health.~~

Mechanism for Reporting

- 2.7 ~~**DELETED** Clinical providers of care responsible for reporting shall use the most current electronic or paper version of the Rhode Island Department of Health Disease Report Form, if other specialized forms are not available. Reporting shall be via secured e-mail, telephone, facsimile, U.S. mail, or other secured electronic means of communication (such as web-based systems), as approved by the Department.~~
- 2.8 ~~**DELETED** Specialized report forms for communicable disease reporting may be obtained online: ~~www.health.ri.gov~~ by calling 401-222-2577, or by writing to the Center for Epidemiology and Infectious Disease, Room 106, Three Capitol Hill, Providence, RI 02908.~~

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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) 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 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:

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

Potential Agents of Bioterrorism

- Anthrax
- Botulism
- Brucellosis
- *Clostridium perfringens*
- Glanders
- Plague
- Q-Fever
- Ricin Poisoning
- Smallpox
- *Staphylococcal enterotoxin B poisoning*
- Tularemia
- *Viral Hemorrhagic Fevers (Ebola, Lassa, Marburg, etc)*

- 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
- Mumps
- 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)

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- 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
- Streptococcal Toxic Shock Syndrome²
- Streptococcus pneumoniae²
- 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 associated deaths*

NOTES:

¹ Report AST, ALT, and Bilirubin also.

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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 specimens related to diseases in §3.4 that are required to be submitted to the RI State Health Laboratory by the testing laboratory:

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

Special Disease Surveillance Projects

~~3.2~~ 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.

~~3.1~~ The lists cited below[‡] pertain to individuals and facilities required or recommended to report (see 2.1 herein). A case shall be reported to the Department of Health, Center for Epidemiology and Infectious Disease, 3 Capitol Hill, Room 201, Providence RI 02908-5097, within four (4) working days following diagnosis, except those diseases that shall be reported **immediately** upon recognition or strong suspicion of disease cited in **bold text** below. Laboratory confirmation is not necessary prior to reporting those diseases that are required to be reported **immediately** (by fax to 401-222-2488 or by phone to 401-222-2577 during working hours/401-272-5952 after hours, or by other prescribed secured electronic means).

Invasive Diseases (Bacterial and Other Pathogens)

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

- ~~➤ **Encephalitis** (primary, including arboviral, or parainfectious)~~
- ~~➤ *H. influenzae* disease, all serotypes~~
- ~~➤ Listeriosis~~
- ~~➤ Meningitis (aseptic, bacterial, viral, or fungal)~~
- ~~➤ **Meningococcal disease (invasive)**~~
- ~~➤ Pneumococcal disease (invasive)~~
- ~~➤ Streptococcal disease: all invasive disease caused by Groups A and B streptococci (including necrotizing fasciitis)~~
- ~~➤ Streptococcal Toxic Shock Syndrome~~
- ~~➤ Toxic Shock Syndrome~~
- ~~➤ **Vancomycin resistant/intermediate *Staphylococcus aureus* (VRSA/VISA) infection**~~

Tuberculosis

- ~~➤ Tuberculous disease caused by *Mycobacterium tuberculosis*—all sites~~
- ~~➤ PPD positives (Latent Tuberculosis Infection or LTBI) in all age groups—must be reported.~~

Vaccine Preventable Diseases

- ~~➤ Death resulting from complications of varicella~~
- ~~➤ Varicella~~
- ~~➤ **Diphtheria**~~

[‡]—Note that some conditions appear under more than one heading.

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- ~~Hepatitis B surface antigen (HbsAg) positive pregnant women~~
- ~~Influenza associated pediatric deaths (<18 years ages)~~
- ~~Influenza associated hospitalizations~~

Vaccine Preventable Diseases (cont.)

- ~~Measles~~
- ~~Mumps (no longer 24-hour reportable)~~
- ~~Pertussis (no longer 24-hour reportable)~~
- ~~Poliomyelitis~~
- ~~Rubella (including congenital rubella) (no longer 24-hour reportable)~~
- ~~Tetanus~~

Blood Borne Pathogens

- ~~Acquired Immunodeficiency Syndrome (AIDS)~~
- ~~Hepatitis B, C, D, E, and unspecified viral hepatitis
(Also report AST, ALT, and bilirubin.)
Physicians must report acute cases, only. Laboratories shall report all positive results.~~
- ~~HIV 1 or HIV 2 infection~~
- ~~Name reporting shall be required on confirmatory laboratory testing forms and a unique identifier shall be required for anonymous testing. All case reports for HIV shall have names.~~

Sexually Transmitted Diseases

- ~~Chancroid~~
- ~~Chlamydia *Trachomatis* (genital and ophthalmic)~~
- ~~Gonorrhea~~
- ~~Granuloma Inguinale~~
- ~~Lymphogranuloma Venereum~~
- ~~Pelvic inflammatory disease (PID): all cases, based upon clinical diagnosis~~
- ~~Syphilis, late latent~~
- ~~Syphilis: primary, secondary, early latent~~

Vectorborne and Zoonotic Diseases

- ~~Babesiosis~~
- ~~Dengue fever~~
- ~~Ehrlichiosis~~
- ~~Hantavirus Pulmonary Syndrome~~
- ~~Leptospirosis~~
- ~~Lyme disease~~
- ~~Malaria~~

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- Ornithosis (psittacosis)
- **Rabies (human)**
- Rocky Mountain Spotted Fever
- Trichinosis
- **Yellow fever**

Enteric Diseases

- Amebiasis
- **Botulism**
- Campylobacteriosis
- **Cholera**
- **Ciguatera poisoning**
- Cryptosporidiosis
- Cyclosporiasis
- Enterohemorrhagic *E. coli* (including *E. coli* O157:H7)
- Giardiasis
- **Hepatitis A** (IgM positive, report liver function tests as well)
- **Paralytic shellfish poisoning**
- Salmonellosis
- **Scombroid poisoning**
- Shigellosis
- **Typhoid fever**
- *Vibrio vulnificus* or *V. parahaemolyticus* infection
- Yersiniosis

Agents of Bioterrorism

- **Anthrax** (includes detection of gram positive rods in CSF, blood or other normally sterile site)
- **Botulism**
- **Brucellosis**
- *Clostridium perfringens* epsilon toxin poisoning
- **Glanders**
- **Plague**
- **Q-fever**
- **Ricin poisoning**
- **Smallpox**
- *Staphylococcal enterotoxin B* poisoning
- **Tularemia**
- **Viral hemorrhagic fevers** (Ebola, Lassa, Marburg, etc)

Other Conditions

- ~~Animal bites~~
- ~~Coccidioidomycosis~~

Other Conditions (cont.)

- ~~Hansen's disease (leprosy)~~
- ~~Hemolytic uremic syndrome (HUS)~~
- ~~Legionellosis~~
- ~~Outbreaks and clusters (see section 1.15 herein)~~
- ~~Toxic Shock Syndrome~~
- ~~Transmissible spongiform encephalopathies (including Creutzfeldt Jakob Disease)~~
- ~~Unexplained deaths possibly due to unidentified infectious causes~~
- ~~Vancomycin-resistant/intermediate *Staphylococcus aureus* (VRSA/VISA), noninvasive, or invasive.~~

Section 4.0 *Special Instructions for Persons Responsible for Reporting (excluding laboratories)*

Special Instructions for Reporting of Human Immuno Deficiency Virus Infection (HIV) and Acquired Immunodeficiency Syndrome Cases (AIDS/HIV)

4.1 Perinatal exposure case report for HIV means the information that is provided to the Department related to a child aged less than eighteen (18) months of age born to an HIV-infected mother where the HIV status of the infant is undetermined. Positive and negative laboratory results, as outlined in §5.9 of these Regulations, must be reported by both clinicians and laboratories.

4.2 Pregnancy in an HIV positive woman is a reportable event.

Special instructions for Reporting LTBI

~~4.1 LTBI shall be reported on the LTBI Reporting Form, provided by the Center for Epidemiology and Infectious Disease.~~

~~4.2 Persons with a laboratory test diagnostic of HIV infection shall be reported by those persons charged with reporting (cited in section 2.1 herein). Such HIV infection shall be reported by name and include all other information on the reporting form.~~

~~4.3 AIDS cases (HIV positive persons with AIDS defining conditions as outlined in the Appendix of the most recent version of the CDC guidelines entitled, (*Guidelines for National Human Immunodeficiency Virus Case Surveillance, Including Monitoring for Human Immunodeficiency Virus Infection and Acquired Immunodeficiency Syndrome*) shall be reported by name, within two (2) weeks of diagnosis, to the Office of HIV/AIDS & Viral Hepatitis, Surveillance Unit. This includes persons with a CD4+ T-lymphocyte count less than 200 cells/uL or a CD4+ lymphocyte percent less than fourteen percent (14%) of total lymphocytes.~~

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- 4.4 ~~HIV 1 and HIV 2 cases, including perinatal case reports for HIV, as defined in section 1.16 herein, shall be reported on the most recent version of the AIDS/HIV Case Report form, within two (2) weeks of diagnosis. This form shall be mailed in a stamped envelope marked “CONFIDENTIAL” and clearly addressed to the Office of HIV/AIDS & Viral Hepatitis Surveillance Unit.~~

Special Instructions for Reporting Sexually Transmitted Diseases (STDs)

- 4.5 ~~Physicians must report gonorrhea, chlamydia and syphilis with details of treatment and partner notification activities on the Confidential Report for Sexually Transmitted Diseases form.~~

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 ~~section §3.1 of these Regulations above~~, the laboratory shall submit to the Division of Infectious Disease and Epidemiology Center for Epidemiology and Infectious Disease 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. ~~via published guidelines (see Reference 18 herein).~~
- (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. ~~(See Reference 18 herein).~~
- 5.2 ~~**[DELETED]** All laboratories must send an isolate, culture, slide or other appropriate specimen to the State Laboratory in accordance with the requirements of the most current version of the *Rhode Island Epidemiology and Laboratory Reporting and Surveillance Manual* issued by the Center for Epidemiology and Infectious Disease and State Health Laboratories (See Reference 18).~~

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

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~~Disease and Epidemiology Center for Epidemiology and Infectious Disease~~ 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 Cultures for 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 ~~portion of the specimen~~ to the State Health Laboratory for analysis. ~~Such specimens may be split to allow a portion to be analyzed at the clinical laboratory.~~ 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 ~~A clinical laboratory performing AFB smears and/or cultures and sensitivities, or having the samples tested out of state,~~ 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 Center for Epidemiology and Infectious Disease, Department of Health. Positive culture results must be accompanied by all prior AFB smear results associated with the current episode of illness on the individual whether positive ~~and~~ or negative.
- 5.7 As part of LTBI surveillance, IGRA (Interferon Gamma Release Assay) positive results are reportable.

HIV Testing and Reporting by Clinical Laboratories

- 5.8 All HIV diagnostic test results shall be confirmed by the State Health Laboratory according to the new HIV Testing algorithm stated in the most recent Clinical and Laboratory Standards Institute (CLSI) guidelines. This requirement is waived for:
- (a) The testing of initial samples (e.g., ELISA) at a hospital laboratory, (provided testing is done at the hospital laboratory);
 - (b) Sites performing rapid HIV testing
 - (c) Specimens that are analyzed for the sole purpose of assuring the safety of the blood supply
 - (d) Specimens analyzed for research purposes.
- 5.9 All licensed laboratories receiving and testing biological specimens for the purposes of HIV/AIDS testing shall report positive results with name and other identifying information to the Office of HIV/AIDS & Viral Hepatitis, regardless of the testing method being used. The following laboratory tests are reportable within four (4) days:
- (a) A positive ELISA result of any HIV test and/or other FDA approved test indicative of the presence of HIV

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- (b) All values of CD4 counts and all viral load results (detectable and undetectable).
- (c) All HIV genotyping laboratory test results
- (d) HIV DNA or RNA detection
- (e) HIV P24 Antigen test including neutralization assay for a child >1 month
- (f) HIV isolation (viral culture)
- (g) Other U.S. Food and Drug Administration approved tests that indicate the presence of HIV
- (h) Any of the above negative virologic tests results are reportable on infants eighteen (18) months or less

~~5.7 Non-hospital clinical laboratories receiving serum specimens for the purposes of HIV antibody testing must submit a portion of the specimen to the State Health Laboratory for analysis. This requirement is waived for the testing of initial samples (e.g., ELISA) at a hospital laboratory, provided testing is done at the hospital laboratory. This requirement is also waived when the specimens are analyzed for the sole purpose of assuring the safety of the blood supply or for strictly research purposes. Testing sites using alternative, FDA approved methods of testing (e.g., rapid testing) may send confirmatory samples to manufacturers' associated laboratories upon receiving written permission from the Department to do so. Otherwise, all confirmatory testing shall be done by the State Health Laboratory.~~

~~5.8 Clinical laboratories performing (or having the samples tested in reference laboratories) for HIV viral loads and CD 4 lymphocyte counts shall report counts less than 200/uL, or less than fourteen percent (14%) of the total lymphocytes as well as any positive results of viral load tests by name directly to the Office of HIV/AIDS & Viral Hepatitis Surveillance Unit at the Department.~~

~~5.9 All licensed laboratories receiving and testing biological specimens for the purposes of HIV/AIDS testing shall report positive results to the Office of HIV/AIDS & Viral Hepatitis, regardless of the testing method being used.~~

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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 ~~Family, 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 ~~section §2.1 of these Regulations herein~~) 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,

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

Occupational Disease Reporting

- 7.3 The physician, or other person charged with reporting (cited in ~~section~~ §2.1 of these Regulations herein), 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 ~~section~~ §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 ~~section~~ §2.1 of these Regulations herein).
- 7.4 The Department of Health shall prepare and furnish standard schedule blanks for the reports required by §7.0 of these Regulations ~~in this section~~.

Section 8.0 *Asbestos-Related Disease*

Responsibility for Reporting

- 8.1 Any physician, facility administrator or other person charged with reporting (cited in ~~section~~ §2.1 of these Regulations herein) 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 ~~Section~~ §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 ~~section~~ §2.1 of these Regulations ~~herein~~) 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 ~~section~~ §9.3 of these Regulations ~~herein~~.

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.

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- (c) 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 ~~section~~ §2.1 of these Regulations herein).
- (c) The Department shall prepare and furnish standard schedule blanks for the reports required in this section.

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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 ~~rules and~~ 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 ~~rules and~~ Regulations are declared severable.

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<http://www.sos.ri.gov/rules/>