Rhode Island Department of Health

NOTICE OF PUBLIC HEARING

The Director of the Rhode Island Department of Health has under consideration proposed amendments to Rules and Regulations Pertaining to HIV Counseling, Testing, Reporting, and Confidentiality [R23-6.3-HIV], promulgated pursuant to the authority conferred under Chapters 23-6.3 and 42-35 of the Rhode Island General Laws, as amended. The purpose of the proposed changes is to implement the provisions of Public Laws 2009-196 and 2009-289, enacted by the General Assembly in November 2009, which require the Department of Health to promulgate regulations regarding HIV testing. The proposed amendments also address other changes in Chapter 23-6.3 of the General Laws enacted pursuant to these Public Laws.

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 FRIDAY, 18 JUNE 2010 at 1:00 p.m. 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 mailed prior to the hearing date to: David R. Gifford, M.D., M.P.H., Director, Rhode Island Department of Health, #401 Cannon Building, 3 Capitol Hill, Providence, Rhode Island 02908-5097.

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 Department’s website: www.health.ri.gov/hsr/regulations/index.php or the Secretary of State’s website: http://www.sos.ri.gov/rules/, 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 14th day of May 2010

[Signature]

David R. Gifford, M.D., M.P.H., Director of Health
RULES AND REGULATIONS PERTAINING TO HIV COUNSELING, TESTING, REPORTING, AND CONFIDENTIALITY

[R23-6-HIV 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 section 42-35-4.1 of the Rhode Island General Laws, as amended)
January 2007 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)
September 2008
June 2010 (Proposed)

COMPILER’S NOTES:
Proposed Additions: Underlined
Proposed Deletions: Strikeouts
INTRODUCTION


Pursuant to the provisions of section § 42-35-3(c) 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; and (2) duplication or overlap with other state regulations. Based on the available information, no known alternative approach, overlap or duplication was identified.

Upon promulgation of these amendments, these amended rules and regulations shall supersede any all previous Rules and Regulations Pertaining to HIV Counseling, Testing, Reporting and Confidentiality [R23-6-HIV] promulgated by the 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 June 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 June 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.
TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>PART I</th>
<th>Definitions</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.0 Definitions</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PART II</td>
<td>Requirements For HIV Counseling and Testing</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>2.0 Mandatory Offering of HIV Counseling and Testing</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>3.0 Procedures for Offering HIV Testing Applicability to Insurance Companies</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>4.0 Informed Consent for Testing [REMOVED IN ENTIRETY]</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>5.0 Exceptions to Informed Consent Requirements</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PART III</td>
<td>HIV Testing</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>6.0 HIV Testing Screening and Testing of Adults, Adolescents, and Pregnant Women</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PART IV</td>
<td>Pre-and Post-HIV Test Counseling Qualified Professional HIV Test Counselor Requirements</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>7.0 Qualifications of HIV Counselors Qualified Professional HIV Test Counselor Certification</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>8.0 Pre-Test Counseling Approval of Qualified Professional HIV Test Counselor Training Programs</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>9.0 Post-Test Counseling [REMOVED IN ENTIRETY]</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PART V</td>
<td>Records and Confidentiality</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>10.0 Records</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>11.0 Confidentiality and Protection of Records Disclosure of Test Results</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>12.0 Notification of Disclosure</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>13.0 HIV Testing and Reporting Cases of Acquired Immunodeficiency and Human Deficiency Virus (HIV) Infection</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PART VI</td>
<td>Violations and Remedies, and Severability</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>14.0 Violations and Remedies/Penalties</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>15.0 Severability</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>References</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>Appendix “A” [REMOVED IN ENTIRETY]</td>
<td></td>
</tr>
</tbody>
</table>
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 (i) A person empowered by the patient/client to assert or to waive the confidentiality, or to disclose or consent to the disclosure of confidential information, as established by RIGL Chapter 5-37.3 of the general laws of Rhode Island, as amended, entitled "Confidentiality of Health Care Communications and Information Act". That person is not, except by explicit authorization, empowered to waive confidentiality or to disclose or consent to the disclosure of confidential information; (ii) A guardian or conservator, if the person whose right to confidentiality is protected under Chapter 5-37.3 is incompetent to assert or waive that right; or (iii) If the patient/client is deceased, his or her personal representative or, in the absence of that representative, his or her heirs at law.

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 does not require the patient’s name or signature on the consent form 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 does require the patient’s name and signature on the consent form 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 a diagnosis in adolescents and adults who are HIV infected aged greater than or equal to thirteen (13) years who have either a) less than 200 CD4positive T-lymphocytes/μL; b) a CD4positive T-lymphocyte percentage of total lymphocytes of less than 14%; or c) any of the following three clinical conditions: pulmonary tuberculosis, recurrent pneumonia, or invasive cervical cancer. This expanded definition retains the twenty-three (23) clinical conditions in the AIDS surveillance case definition published in 1987. (Please refer to the Department’s “Adult/HIV Confidential Case Report Form” for a list of those conditions). The most current surveillance case definition for AIDS published by the Centers for Disease Control & Prevention (CDC).

1.12 "Diagnosis of HIV" means the revised surveillance case definition for HIV infection published in the Morbidity and Mortality Weekly Review of reference 19 herein 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 “Duly licensed health care provider” means a licensed health professional working within his/her scope of practice.

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 subject to licensure licensed by the Department in accordance with the provisions of RIGL Chapter 23-17 of the General Laws of Rhode Island, as amended, entitled, "Licensing of Health Care Facilities", and as further defined in regulations.

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 informed consent form" means in these Regulations, a standardized form provided by the Department to those individuals offered HIV testing. Said form shall contain the information outlined in section 3.3 herein. Anonymous testing shall be exempted from the requirement to sign.

1.24 "HIV test" means any currently medically accepted and/or FDA approved diagnostic test for determining HIV infection of an individual by HIV 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 "Opt out", as used herein, means to decline HIV testing, 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–HIV/AIDS–exposure–reporting" "Perinatal case report for HIV" means filing a report, with the information that is provided to the Department, for related to a child aged less than eighteen (18) months born to an HIV-infected mother, and the child does not meet the criteria for HIV infection (H) or the criteria for “not infected with HIV as defined in the most current surveillance case definition for HIV infection published by the
"Person" means any individual, firm, trust or estate, partnership, corporation (including associations, joint stock companies), limited liability companies, company, association, or joint stock association, state or political subdivision or instrumentality of a state.

"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.

"Polymerase chain reaction (PCR) test" means a common laboratory method of creating copies of specific fragments of DNA or RNA.

"Physician" means an individual licensed to practice allopathic or osteopathic medicine pursuant to the provisions of Chapter 5-37 of the Rhode Island General Laws, as amended.

"Qualified professional HIV test counselor" means:

(a) A physicians, physician assistants, certified nurse practitioner, midwife, or nurse licensed to practice in accordance with applicable state law; licensed professional (registered) and/or practical nurses, nurse-midwives, registered nurse practitioners;

(b) A medical students who are actively matriculating in a medical degree program and who perform duties assigned to them by a physician; or

(c) A other persons who are involved with clients at risk for HIV and who have successfully completed an HIV counseling training program sponsored by the Department or who have documented evidence of completion of an HIV counseling training program approved by the Department.

"RIGL" means the General Laws of Rhode Island, as amended.

"Routinely", as used herein, shall have the same meaning as "universally."

"Services" means health care and social support services.

"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.

"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  Mandatory Offering of HIV Counseling and Testing

2.1 Pursuant to sections RIGL §§23-17-31, 23-17-31.1, 23-13-19, 40.1-24-20, and 23-11-17 of the Rhode Island General Laws, as amended, 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 physician or duly licensed health care provider caring for the patient.
(c) Every physician or duly licensed 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 included in the routine panel of prenatal tests incorporated as part of routine prenatal testing for all pregnant women unless testing is declined. Repeat testing in the third trimester is recommended if determined by the physician or duly licensed health care provider 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 physician or duly licensed health care provider attending to any person who may be at risk for HIV infection shall routinely offer the HIV test to those patients. All testing pursuant to this section these Regulations shall be performed in accordance with sections 23-6-17 §23-6.3-7 (Confidentiality) and 23-6-18 §23-6.3-8 (Protection of the medical Records) of the Act Rhode Island General Laws, as amended, and all applicable informed consent standards.

2.2 No person shall order the performance of an HIV-related test without first providing the information and counseling set forth in section 2.3 (below), informing the woman that she has a right to decline testing, and obtaining the oral consent of the patient to be tested, or of a person authorized to consent to health care for such individual. Which consent and counseling shall be documented in the patient's medical record.

(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. Prior to performing an HIV-related test, patients shall be provided
pre-test counseling. To allow greater flexibility for pre-test counseling by allowing
client-specific counseling,

(a) (1) A physician or 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 pre-
test 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 woman patient be tested for HIV pursuant to this section these
Regulations without first being provided with oral verbal or written information that
includes the following:

(a) An explanation of HIV infection;

(b) A description of the interventions that can reduce HIV transmission from mother to infant;

(c) The meaning of positive and negative test results;

(d) The possibility that a recent infection may not be detected; and

(e) An opportunity to ask questions and to decline testing.

2.4 [REMOVED] No physician or health care professional providing prenatal health services to a pregnant woman shall perform an HIV test of any woman who has not given consent to testing.

2.5 [REMOVED] In the event that a pregnant woman tests positive for HIV/AIDS, the physician, health care provider or counselor shall provide post-test counseling, which shall include information about:

(a) the meaning of the test result;

(b) the possible need for additional testing;

(c) measures to prevent the transmission of HIV;

(d) measures to prevent perinatal HIV transmission; and

(e) the availability of, and referrals for, appropriate health care services, including mental health care, and appropriate social and support services.

2.6 [REMOVED] All HIV testing pursuant to this section shall be kept confidential in accordance with section 23-6-17 of the Rhode Island General Laws, as amended, and all applicable state and federal statutes and regulations.

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

2.8 All persons tested under this section shall be counseled and tested in accordance with these regulations. Provided, however, that the counseling shall be in accordance with acceptable medical standards, and no test results shall be given by any means (e.g. phone, mail, e-mail, fax, etc.) other than in person:

(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 must undergo shall successfully complete a required training program, given 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. Pursuant to statutory provisions, mandatory HIV counseling and testing shall be required as below. No consent shall be required for testing:

(a) For any person who is convicted of any criminal offense and committed to the Adult Correctional Institution (ACI);

(b) 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 person convicted of possession of any controlled substance that has been administered with a hypodermic instrument, retractable hypodermic syringe, needle, or any similar instrument adapted for the administration of drugs shall be required to be tested for human immunodeficiency virus (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) For any person convicted of prostitution, lewdness, or any other violation of Chapter 11-34 of the Rhode Island General Laws, as amended;

(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] All persons tested under this section shall be provided pre-test and post-test counseling by individuals trained by the Department, as an HIV testing counselor, in accordance with regulations promulgated herein; provided, that the counseling shall be in accordance with acceptable medical standards:

2.11 All individuals persons who are tested under this section §2.9(b) of these Regulations, who are determined to be injecting and/or intra-nasal drug users, shall be referred to appropriate sources of substance abuse treatment by the HIV testing counselor and/or the attending
practitioner as follows: as specified in §6.12 of these Regulations.

(a) Those persons who test positive for HIV infection shall be given priority for those outpatient substance abuse treatment programs that are sponsored or supported by the appropriate state agency responsible for these services.

(b) Those persons who are injecting drug users and test negative for HIV infection shall be referred, by the HIV testing counselor and/or attending practitioner, to the appropriate state agency responsible for these services for earliest possible evaluation and treatment.

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). All human organ transplantation testing shall be conducted in accordance with 42 Code of Federal Regulations Part 486, Subpart G—(Guidelines for Preventing Transmission of HIV through Transplantation of Human Tissue and Organs) for the prevention of HIV transmission.

(b) Therapeutic donor insemination or other advanced reproductive technologies using freshly donated sperm shall conform with the guidelines and standards of the American Society for Reproductive Medicine for the prevention of HIV transmission. These standards shall not apply in situations wherein both the donor and the recipient waive the testing requirement and sign a written statement to that effect. Mandatory HIV counseling shall be required in these situations, however As permitted under RIGL Chapter 23-1-38 entitled “HIV Antibody Testing-Sperm Collection or Donation”.

Section 3.0 **Procedure for Offering HIV Test Applicability to Insurance Companies**

3.1 **Presenting the HIV Informational Brochure.** Each patient/client subject to the provisions of section 2.12 herein, shall be given an informational brochure (“Answers to Questions You May Have About the HIV Antibody Test” contained in Appendix “A” herein) on HIV infection and testing provided by the Department. Such brochure shall include the information contained in section 3.3 herein (below).

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 **Pre-Test Counseling.** A physician or other qualified professional counselor shall offer HIV information contained in the HIV informational brochure prior to testing. HIV prevention counseling should be:

- client-centered, that is, tailored to the behaviors, circumstances, and special needs of the person being served;
include a personalized client risk assessment, as appropriate;
result in a personalized plan for the client to reduce the risk of HIV infection/transmission, as appropriate.

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.

Signing the HIV Informed Consent Form for Testing

3.3 Each patient/client, with the exception of anonymous testing, shall sign and date the "HIV INFORMED CONSENT FORM" provided by the Department, which shall contain no less than the following:
(a) the public health rationale for HIV testing and information describing the nature of the HIV disease;
(b) the availability and cost of HIV testing and counseling;
(c) assurance that test results are confidential with certain exceptions;
(d) a list of exceptions to confidentiality of test results; and
(e) That the test is voluntary and that an informed consent form must be signed before testing;
(f) assurance that by signing such form the person is only acknowledging that the HIV test and counseling have been offered and/or that he or she has declined (opted-out) the offer to be tested; and

3.4 Notwithstanding the provisions of subsections (e) and (f) above, in the event an individual consents to anonymous testing, the HIV testing counselor and/or attending practitioner ordering the test shall receive only verbal confirmation from the client that the client understands all applicable information contained within the informed consent form.

3.5 In the event an individual consents to anonymous testing and tests positive for HIV, the HIV testing counselor shall discuss with the client options regarding referrals and reporting of this positive screening, including the necessity of accessing a physician or duly licensed health care provider.

3.6 With the exception of anonymous testing, when a patient/client has agreed (consented) to be tested for HIV, an "Informed Consent Form" must be signed by the patient/client, in accordance with section 4.0 hereunder in order for the testing to occur.

3.7 Each site that provides anonymous and/or confidential HIV testing, and HIV counseling and referral, shall offer free testing, counseling and referral for indigent parties and other individuals without health insurance, offer a sliding scale for payment for all other individuals and, in the case of confidential testing, screen for ability to pay through a third-party insurer. In the case of nonfunded sites for HIV testing, organizations and/or institutions performing the test shall offer free testing, counseling and referral for indigent
parties and other individuals without health insurance:

Section 4.0 **Informed Consent for Testing** [REMOVED IN ENTIRETY]

4.1 Unless otherwise exempt as set forth in section 5.0 herein, no person may be tested for the presence of HIV unless he or she has given his or her written informed consent, confirmed by his or her signature, or that of a parent, guardian, or agent on an informed consent form specifically relating to such test and after discussion with a qualified professional counselor.

4.2 Only verbal informed consent is required for anonymous testing

4.3 The written informed consent form shall include the information contained in 3.3 herein (above):

4.4 All consent forms, signed and dated, must become part of the patient's/client's record:

Section 5.0 **Exceptions to the Informed Consent Requirements**

5.1 A physician may or other duly licensed health care provider may secure a test sample for the presence of HIV without obtaining consent from the individual to be tested under the following conditions, listed below. Provided, however, reasonable efforts shall be made to secure voluntary consent:

(a) when The person individual to be tested is under one (1) year of age;

(b) when the person to be tested is A child is between one (1) and thirteen (13) years of age and appears to be symptomatic for HIV infection;

(c) when The person 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 person individual;

(d) [REMOVED] when a person (the complainant) can document significant exposure to blood or other body fluids of another person (the individual to be tested), during performance of the complainant's occupation, providing:

(i) the complainant completes an incident report within forty-eight (48) hours of the exposure, identifying the parties to the exposure, witnesses, time, place and nature of the event;

(ii) the complainant submits to a baseline HIV test within seventy-two (72) hours of the exposure, and is negative on that test for the presence of HIV;

(iii) there has been a significant percutaneous or mucus membrane exposure (i.e., needle stick; bite; splash over open wound; broken skin, or such membrane) by blood or body fluids of the person to be tested, of a type and in sufficient concentration to permit transmission of HIV, if present in those fluids; and
If a sample of the patient's blood is not otherwise available and the patient refuses to grant informed consent, then the complainant may petition the Superior Court for a court order mandating that the test be performed.

(e) In a licensed health care facility, (including hospitals), or in the private office of a physician 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 a health care provider (health worker or other individual) 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 is infected with HIV; then, if a sample of the patient's blood is available, said 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 informed consent to draw blood, then the health care 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 health care provider (health worker or other individual) 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 a health care 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 (including hospitals) 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 of reference or these Regulations, unless such 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 either the patient or, if applicable under state law, the patient's parent, guardian or agent.

(g) Persons under 18 years of age who may give legal consent for testing, examination, and/or treatment for HIV pursuant to RIGL §23-8-1.1 of the Rhode Island General Laws, as amended; or for human organ transplantation, therapeutic donor insemination or other advanced reproductive technologies using freshly donated sperm pursuant to section 23-1-38 of the Rhode Island General Laws, as amended 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) When a mother’s medical record lacks documentation of HIV status, a newborn shall be tested for HIV immediately after birth and without the consent of the parents. 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 Testing 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 Recommendations regarding HIV testing shall reference the most current guidelines 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) pertaining to HIV Counseling, Testing and Referral of Adults, Adolescents and Pregnant Women. Provided, however, those guidelines shall be interpreted by the Department so as to best serve the clients individuals and patients seeking 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] The recommendations shall emphasize that: (1) HIV screening is recommended in all health care settings, after the patient is informed, in accordance with all applicable informed consent standards, that HIV testing will be done unless the patient declines; (2) persons at high risk for HIV infection should be screened for HIV at least annually, in accordance with all applicable informed consent standards; and (3) only verbal informed consent is required for anonymous testing.

6.3 [REMOVED] HIV/AIDS shall be designated as notifiable and reportable by name. Under this provision the following shall be reported:

(a) Within four (4) days using an official HIV/AIDS Department case reporting form, a diagnosis of HIV, according to the U.S. Centers for Disease Control and Prevention case definition of HIV:

(b) Within four (4) days using an official HIV/AIDS Department case reporting form, a diagnosis of AIDS, according to the U.S. Centers for Disease Control and Prevention case definition of AIDS:

(c) Written notification to the Department of a confirmed positive ELISA result of any HIV test and/or other FDA approved test indicative of the presence of HIV within four (4) days, by name:

(d) A perinatal exposure of a newborn to HIV indicated by two positive PCR tests; <18 months; and/or other U.S. Food and Drug Administration approved tests that indicate the presence of HIV in pediatric cases.

(e) Other U.S. Food and Drug Administration approved tests indicative of the presence of HIV/AIDS, as approved by the Department.

6.4 [REMOVED] An HIV test shall be ordered by the physician or on order of any duly licensed health care provider, for those patients/clients who sign the informed consent form, and for those individuals who are subject to the provisions of section 5.0 herein.
6.5 The blood sample shall be sent for HIV testing to the Department Laboratory or a Rhode Island-licensed hospital laboratory and shall be accompanied by a Health Department Laboratory form. The physician or other duly licensed health care provider who ordered the test shall complete all required fields of the Health Department Laboratory form. 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; exceptions, for alternative testing methods, may be granted through written approval by the Department.

6.7.1 Sites performing non-venipuncture 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 physician or laboratory or duly licensed 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. The Department shall only use and require HIV name case reports submitted on or after July 1, 2006.

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  
Pre- and Post- HIV Test Counseling  
Qualified Professional HIV Test Counselor Requirements

Section 7.0  
Qualifications for HIV Counselors  
Qualified Professional HIV Test Counselor Certification

7.1  
A qualified professional counselor shall be any person as defined in section 1.21 herein:

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 Pre-Test Counseling Approval of Qualified Professional HIV Test Counselor Training Programs

8.1 Pre-test counseling shall be offered to all those individuals who are subject to the provisions of section 2.0 herein and must be provided to all those who are tested. Such pre-test counseling shall be consistent with the provisions of section 3.2 herein.

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
(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 Post-Test Counseling [REMOVED IN ENTIRETY]

9.1 Individuals with Negative HIV Tests. Each person with a negative HIV test shall be provided post-test counseling by the physician or by a qualified professional counselor as defined in section 1.21 herein. Such counseling shall consist of:

(a) informing the patient/client of the test result, its implications and the importance of retesting for individuals at high risk;
(b) instructing the patient/client on the continuing necessity to take protective measures to avoid acquiring the infection.

9.2 Individuals with Positive HIV Test. Each person with a positive HIV test shall be given post-test counseling by the physician or other qualified professional counselor. Such counseling shall consist of:

(a) the test result(s);
(b) the infectious nature of the disease and measures to prevent transmission;
(c) referral to medical, and social services;
(d) the importance of notifying his or her partner (see Department’s website: http://www.health.ri.gov/hiv/index.php for partner contact referral form); and
(e) such other information to meet the individual's needs:
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, informed consent forms, 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 reference 1 of the Act and these Regulations herein.

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 section 23-6-17 of reference 1 §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 herein of these Regulations;

(c) training individuals who handle records in security objectives and techniques.

Section 11.0  Confidentiality and Protection of Records Disclosure of Test Results

11.1 All information and reports pertaining to HIV counseling, testing, and reporting as set forth in these rules and regulations are confidential. It shall be 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, or in the case of a minor, the minor's parent, guardian or agent on a form that specifically states that HIV test results may be released, except:

(a) a licensed health care facility or laboratory:

(i) shall report HIV test results to a licensed physician or other duly licensed health care provider who ordered the test; and

(ii) shall report HIV test results to the Department as set forth in these regulations.

(b) a physician or duly licensed health care provider:

(i) may enter HIV test results in the medical record, as would be the case with any other diagnostic test;

(ii) may notify other health professionals directly involved in care of the individual testing positive on the HIV test, or to whom that individual is referred for treatment;

(iii) may notify persons exposed to blood or other body fluids of an individual who tests positive on an HIV test, in accordance with section 23-6-14 (4) through (8).
exceptions) of reference 1 and section 23-17-31 (testing of hospitalized patients) of reference 2;

(iv) may notify the Director of the Department for Children, Youth and Families, pursuant to section 23-6-14 (3) (testing of a minor to secure services) of reference 1;

(v) may inform third parties with whom an HIV-infected patient or client is in continuous exposure-related contact, including but not limited to a spouse and/or partner, if the nature of the contact, in the physician's 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 physician's strong encouragement, has not and will not inform the third party that they may have been exposed to HIV;

(e) as permitted in subsections (b) (1), (2), (5), (6), (8) through (15) of section 5-37.3-4 of the "Confidentiality of Health Care Communications and Information Act," and

(d) as permitted in section 40.1-5-26 of the "Mental Health Law" (disclosure of confidential information under mental health law), or as otherwise required by law; and

(e) by a health care provider to appropriate persons entitled to receive notification of persons with infectious or communicable diseases pursuant to section 23-5-9 of the General Laws of Rhode Island, as amended, "Reports of Disease and Disability," (report of infectious disease upon death) and section 23-28.36-3 of the General Laws of Rhode Island, as amended, "Notification of Fire Fighters, Police Officers, and Emergency Medical Technicians After Exposure to Infectious Diseases" (notification to EMT, firefighter, police officer of infectious disease).

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 Facilities and other health care providers subject to this section shall have documentation
that each person with access to any confidential information understands and acknowledges that the information may not be disclosed except as provided herein.

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 sections 11.1(a)(i), 11.1(a)(i)(ii), 11.1(b)(i), 11.1(b)(ii), 11.1(b)(iv), and 11.1(d) §§11.1(a)(1), (a)(2), (a)(3), (a)(4) and (a)(5) of these Regulations herein, (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 Physicians, facility administrators, and laboratories shall report to the Department cases of AIDS and HIV infection in a manner prescribed in the Rules and Regulations Pertaining to the Reporting of Communicable, Environmental and Occupational Diseases (R23-5-6, 10, 11, 23-24.6-CD/ERD and R23-24.5-ASB) of reference 11 herein.

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 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 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 using an official Department HIV testing report form.

(d) All CD4 counts <200 and/or less than fourteen percent (<14%), and all detectable viral load results, within four (4) days using an official Department HIV testing report form.

(e) Notification of a perinatal exposure to HIV, regardless of confirmatory testing, within four (4) days using an official Department perinatal exposure report form.

(f) A perinatal case report for HIV shall be indicated by two (2) positive polymerase chain reaction (PCR) tests; <18 months; and/or other U.S. Food and Drug Administration approved tests that indicate the presence of HIV in pediatric cases.

(g) Results of additional laboratory testing and/or case report updates, as requested by the Department, in accordance with CDC surveillance guidelines.

**Reporting of HIV/AIDS and Perinatal Exposure of Newborns**

13.2 The following persons shall report information required by this section to the Department's HIV/AIDS surveillance team:

(a) A physician/health care provider who diagnoses or treats HIV/AIDS;

(b) The administrator of a health care facility as defined in Rhode Island General Laws 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 Any high managerial agent who is 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, in a timely manner as stipulated in the rules of reference 11 herein. Reports provided under this section shall specify the name as well as all information indicated on the official Department HIV Case Report Form.

13.5 Reports as required by this section shall only be made if 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] Perinatal HIV/AIDS exposure reporting shall be made to the Department regardless of confirmatory testing.

13.7 [REMOVED] Reports required by this section shall be mailed within forty-eight (48) hours of diagnosis or treatment, to the Department using a designated envelope that shall be provided by the Department's HIV/AIDS Surveillance Team. Any other reporting method shall be approved in advance by the Department.

13.8 [REMOVED] Nothing in this section shall preclude the performance of anonymous HIV/AIDS testing.
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 herein of these Regulations, shall be subject to the penalties of section RIGL § 5-37.3-9 of reference 12 which are:

(a) Civil Penalties: Any one who violates the confidentiality provisions herein 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 herein 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 herein of these Regulations.

Section 15.0  Severability

15.1 If any provision of the Act or these Regulations or the application thereof to any facility, individual, or circumstances shall be held by a court to be invalid, such invalidity shall not affect the remaining provisions or application of the Act or these Regulations which can be given effect, and to this end the provisions of these Regulations are declared to be severable.
REFERENCES


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


Available online: http://www.rilin.state.ri.us/Statutes/TITLE23/23-1/INDEX.HTM

Available online: http://www.rilin.state.ri.us/Statutes/TITLE42/42-56/INDEX.HTM

Available online: http://www.rilin.state.ri.us/Statutes/TITLE11/11-34/INDEX.HTM


11. Rules and Regulations Pertaining to the Reporting of Communicable, Environmental and Occupational Diseases (R23-5-6, 10, 11, 23-24.6-CD/ERD and R23-24.5 ASB), as amended;
Rhode Island Department of Health.
Available online: http://www2.sec.state.ri.us/dar/regdocs/released/pdf/DOH/DOH_3844.pdf

Available online: http://www.rilin.state.ri.us/Statutes/TITLE5/5-37.3/INDEX.HTM

Available online: http://www.rilin.state.ri.us/Statutes/TITLE40.1/40.1-5/INDEX.HTM


18. *Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs* available online at: [http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm](http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.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/](http://www.sos.ri.gov/rules/)

*HIV_PublicHearingDraft_13May2010.doc*

Thursday, 13 May 2010

**ATTACHED APPENDIX A IS DELETED IN ENTIRETY**