Rhode Island Department of Health

PUBLIC NOTICE

The Director of the Rhode Island Department of Health has determined to amend the ***Rules and Regulations Pertaining to Counseling, Testing, Reporting and Confidentiality* [*R23-6.3-HIV*]** to update requirements for reporting of HIV testing. This will allow the Department to evaluate indicators of care according to the National HIV/AIDS Strategy from the Centers for Disease Control and Prevention. These amendments are proposed pursuant to the authority contained in Chapter 23-6.3 of the Rhode Island General Laws, as amended.

Notice is hereby given in accordance with the provisions of §42-35-3(1)(2) of the Rhode Island General Laws, as amended, that the Director is affording all interested persons the opportunity to submit data, views, or arguments in writing on this matter. Opportunity for public hearing shall be granted if requested by twenty-five (25) persons, by a government subdivision or agency, or by an association having not less than twenty-five (25) members. *Otherwise, no hearing shall be convened* and the regulations will be filed with the Rhode Island Secretary of State pursuant to Chapter 42-35 of the Rhode Island General Laws, as amended, shortly after the 13 November 2012 deadline (as below).

Such input or requests for public hearing must be received in writing no later than Tuesday, 13 November 2012. Such input or requests should be addressed to: Michael Fine, M.D., Director, Rhode Island Department of Health, Three Capitol Hill, Room #401, Providence, Rhode Island 02908-5097.

In the development of these amendments, 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.

Copies of the proposed regulations are available for public inspection in the Cannon Building, Room #201, Rhode Island Department of Health, Three Capitol Hill, Providence, Rhode Island 02908-5097, 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.

Signed this 12th day of October 2012

Original signed by Michael Fine, MD

Michael Fine, M.D., Director of Health

PROPOSED – REVISED 10 OCTOBER 2012

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

[R23-6.3-HIV]

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

July 1989

As Amended:

December 1989
September 2001
January 2002 (re-filing in accordance with the provisions of 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
July 2010
January 2012 (re-filing in accordance with the provisions of section 42-35-4.1 of the Rhode Island General Laws, as amended)
November 2012 (Proposed)

COMPILER'S NOTES:
Additions: Underlined
Proposed Deletions: ~~Strikeouts~~

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PROPOSED – REVISED 10 OCTOBER 2012

INTRODUCTION

These amended *Rules and Regulations Pertaining to Counseling, Testing, Reporting and Confidentiality* [*R23-6.3-HIV*] are promulgated[1] pursuant to the authority conferred under Chapter 23-6.3, and §§ 11-34-10, 11-37-17, 21-28-4.20, 23-1-38, 23-11-17, 23-13-19, 23-17-31, 23-17-31.1 and 40.1-24-20 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting prevailing standards for HIV counseling, testing, reporting and confidentiality provisions in Rhode Island.

Pursuant to the provisions of ~~§42-35-3(c)~~ §§42-35-3(a)(3) and (a)(4) of the General Laws of Rhode Island, as amended, the following were given consideration in arriving at the amended regulations: (1) alternative approached to the regulations; ~~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 was identified.

Upon promulgation of these amendments, these amended regulations shall supersede all previous *Rules and Regulations Pertaining to HIV Counseling, Testing, Reporting and Confidentiality* [*R23-6-HIV*] promulgated[1] by the Rhode Island Department of Health and filed with the Secretary of State.

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

PROPOSED – REVISED 10 OCTOBER 2012

TABLE OF CONTENTS

			Page
PART I	***Definitions***		1
	1.0	Definitions	1
PART II	***Requirements For HIV Counseling and Testing***		4
	2.0	Offering of HIV Counseling and Testing	4
	3.0	Applicability to Insurance Companies	7
	4.0	**[REMOVED IN ENTIRETY]**	
	5.0	Exceptions to Consent Requirements	7
PART III	***HIV Testing***		9
	6.0	HIV Screening and Testing of Adults, Adolescents, and Pregnant Women	9
PART IV	***Qualified Professional HIV Test Counselor Requirements***		11
	7.0	Qualified Professional HIV Test Counselor Certification	11
	8.0	Approval of Qualified Professional HIV Test Counselor Training Programs	12
	9.0	**[REMOVED IN ENTIRETY]**	
PART V	***Records and Confidentiality***		16
	10.0	Records	16
	11.0	Confidentiality and Protection of Records	16
	12.0	Notification of Disclosure	17
	13.0	HIV Testing and Reporting Cases of Acquired Immunodeficiency and Human Deficiency Virus (HIV) Infection	17
PART VI	***Violations and Remedies, and Severability***		20
	14.0	Violations and Remedies/Penalties	20
	15.0	Severability	20
	References		21

PROPOSED – REVISED 10 OCTOBER 2012

PART I ***Definitions***

Section 1.0 ***Definitions***

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

1.1 "***Act***" means RIGL Chapter 23-6.3 entitled "Prevention and Suppression of Contagious Diseases - HIV/AIDS".

1.2 "***Agent"*** means a person empowered by the patient to assert or waive the confidentiality, or to disclose or consent to the disclosure of confidential information, as established by RIGL Chapter 5-37.3 entitled "*Confidentiality of Health Care Communications and Information Act*".

1.3 ***"AIDS"*** means the medical condition known as Acquired Immunodeficiency Syndrome, caused by infection of an individual with Human Immunodeficiency Virus (HIV).

1.4 "***Anonymous HIV testing***" means an HIV test that utilizes a laboratory generated code based system, which does not require an individual's name or other identifying information that may reveal one's identity, including information related to the individual's health insurance policy, to be associated with the test.

1.5 "***Antibody***" means a protein produced by the body in response to specific foreign substances such as bacteria or viruses.

1.6 "***Community-based organization***" means an entity that has written authorization from the Department for HIV counseling, testing and referral services (HIV CTRS).

1.7 "***Confidential HIV testing***" means an HIV test that requires the individual's name and other identifying information including information related to the individual's health insurance policy, as appropriate.

1.8 "***Consent***" means an explicit exchange of information between a person and a health care provider or qualified professional HIV test counselor through which an informed individual can choose whether to undergo HIV testing or decline to do so. Elements of consent shall include providing each individual with verbal or written information regarding an explanation of HIV infection, a description of interventions that can reduce HIV transmission, the meanings of positive and negative test results, the voluntary nature of the HIV testing, an opportunity to ask questions and to decline testing.

1.9 "***Controlled substance***" means a drug, substance, or immediate precursor in schedules I-V listed in the provisions of RIGL Chapter 21-28 entitled, "Uniform Controlled Substances Act".

1.10 ***"Department"*** means the Rhode Island Department of Health.

1.11 ***"Diagnosis of AIDS"*** means the most current surveillance case definition for AIDS published by the Centers for Disease Control & Prevention (CDC).

1.12 "***Diagnosis of HIV***" means the most current surveillance case definition for HIV infection published by the CDC.

1.13 "***Director***" means the Director of the Rhode Island Department of Health or his/her designee.

1.14 ***"ELISA result"*** means Enzyme-Linked Immunosorbent Assay or EIA (Enzyme Immunoassay) which is a serological technique used in immunology to detect the presence of either antibody or antigen.

1.15 "***Health benefits***" include accident and sickness, including disability or health insurance, health benefit plans and/or policies, hospital, health, or medical service plans, or any health maintenance organization plan pursuant to RIGL Title 27 or otherwise.

1.16 ***"Health care facility"*** means those facilities licensed by the Department in accordance with the provisions of RIGL Chapter 23-17.

1.17 "***Health care provider***", as used in these Regulations, means a licensed physician, physician assistant, certified nurse practitioner or midwife.

1.18 "***Health care settings***" means venues offering clinical STD services including, but not limited to, hospitals, urgent care clinics, STD clinics and other substance abuse treatment facilities, mental health treatment facilities, community health centers, primary care and OB/GYN physician offices, and family planning providers.

1.19 "***HIV*** means the Human Immunodeficiency Virus, the pathogenic organism responsible for HIV infection and/or the Acquired Immunodeficiency Syndrome (AIDS) in humans.

1.20 ***"HIV CD4 T-lymphocyte test results"*** means results of any currently medically accepted and/or FDA approved test used to count CD4 T-lymphocyte cells in the blood of an HIV infected person.

1.21 "***HIV counseling***" means an interactive process of communication between a person and a health care provider or qualified professional HIV test counselor during which there is an assessment of the person's risks for HIV infection and the provision of counseling to assist the person with behavior changes that can reduce risks for acquiring HIV infection.

1.22 "***HIV Counseling, Testing, Referral and Services Sites (HIV CTRS)***" means sites designated and funded by the Department to provide both anonymous and confidential HIV testing and HIV counseling and referral services.

1.23 "***HIV screening***" means the conduct of HIV testing among those who do not show signs or symptoms of an HIV infection.

1.24 ***"HIV test"*** means any currently medically accepted and/or FDA approved test for determining HIV infection in humans.

1.25 "***HIV viral load detection test results***" means results of any currently medically accepted test used to measure the amount of HIV in blood.

1.26 ***"Occupational health representative"*** means an individual, within a health care facility, trained to respond to occupational, particularly blood borne, exposures.

1.27 ***"Opt~~s~~ out***" means that a person who has been notified that a voluntary HIV test will be performed, has elected to decline or defer testing. Consent to HIV testing is inferred unless the individual declines testing.

1.28 "***Perinatal case report for HIV***" means the information that is provided to the Department related to a child aged less than eighteen (18) months born to an HIV-infected mother~~, and 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 CDC~~.

1.29 ***"Person"*** means any individual, trust or estate, partnership, corporation (including, associations, joint stock companies), limited liability companies, state or political subdivision or instrumentality of a state.

1.30 "***Persons at high risk for HIV infection***" means persons defined as being high risk in the CDC's most current recommendations for HIV testing of adults, adolescents and pregnant women in health care settings or through authority and responsibilities conferred on the Director by law in protecting the public's health.

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

1.32 ***"Qualified professional HIV test counselor"*** means:

(a) A physician, physician assistant, certified nurse practitioner, midwife, or nurse licensed to practice in accordance with applicable state law;

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

(c) A person who has successfully completed an HIV counseling training program approved by the Department.

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

1.34 "***Sexually transmitted diseases (STD's)***" means those diseases included in RIGL §23-11-1, as amended, entitled "*Sexually Transmitted Diseases*", and any other sexually transmitted disease that may be required to be reported by the Department.

1.35 "***These Regulations***" mean all parts of Rhode Island *Rules and Regulations Pertaining to HIV-1 Counseling, Testing, Reporting and Confidentiality* [*R23-6.3-HIV*].

PART II *Requirements for Offering HIV Counseling and Testing*

Section 2.0 *Offering of HIV Counseling and Testing*

2.1 Pursuant to RIGL §§23-17-31, 23-17-31.1, 23-13-19, 40.1-24-20, and 23-11-17, the mandatory offering of HIV counseling and testing (with informed consent) shall be required in conjunction with the following:

(a) Services or treatment for sexually transmitted diseases (STDs);

(b) Clinical services for injecting drug users unless such test is deemed inappropriate by a health care provider caring for the patient.

(c) Every health care provider attending any person for prenatal care or family planning services shall include HIV screening in these settings so as to promote earlier detection of HIV with unrecognized or no identified risk factors.

(d) (1) HIV testing shall be incorporated as part of routine prenatal testing for all pregnant women as early and often as appropriate during each pregnancy after the patient has been notified that voluntary testing, in accordance with the consent and information requirements of §2.2 of these Regulations, will be performed unless the patient opts out.

(2) Any woman with an undocumented HIV test status in her record at the time of labor and/or delivery shall be screened with an HIV test in accordance with the consent and information requirements of §2.2 of these Regulations, unless she opts out.

(e) A health care provider attending to any person who may be at risk for HIV infection shall offer the HIV test to those patients. All testing pursuant to these Regulations shall be performed in accordance with §23-6.3-7 (Confidentiality) and §23-6.3-8 (Protection of the medical Records) of the Act, and all applicable informed consent standards.

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

(b) (1) No health care provider shall order or conduct a HIV test without first:

(i) Providing HIV information and an opportunity for discussion, as required by §2.3(a)(1) of these Regulations;

(ii) Informing the patient that he or she has a right to decline testing; and

(iii) Obtaining the oral consent of the patient to be tested, or of a person authorized to consent to health care for such individual. Consent or refusal and exchange of HIV information shall be documented in the patient's medical record.

(2) No qualified professional HIV counselor shall order or conduct a HIV test without first:

(i) Providing HIV information and counseling, as required by §2.3(a)(2) and (a)(3) of these Regulations;

(ii) Informing the client that he or she has a right to decline testing; and

(iii) Obtaining the oral consent of the client to be tested, or of a person authorized to consent to health care for such individual. Consent or refusal and exchange of HIV information shall be documented in the client's record.

(c) When a person consents to anonymous testing, the health care provider and/or qualified professional HIV test counselor ordering or conducting the test shall receive only verbal confirmation from the client that the client understands all applicable information offered. Agencies performing anonymous testing shall not record acceptance using client names, but shall devise a unique identifier system or code that tracks, time, date and person administering the test.

(d) A person performing HIV testing shall have written protocols and procedures to record acceptance or refusal of a test, assuring non-coercion of testing, and the exchange of HIV information described in §§2.2(a)-(c) of these Regulations.

2.3 **HIV Test Counseling.**

(a) (1) A health care provider may tailor HIV counseling to best meet the needs of the individual to be tested. Decisions concerning tailoring and the extent of counseling shall be made on a case-by-case basis.

(2) In addition to offering written information, qualified professional HIV counselors shall offer HIV prevention counseling that includes the following:

(i) A client-centered approach, that is, tailored to the behaviors, circumstances, and special needs of the individual being served;

(ii) A personalized client risk assessment, as appropriate; and

(iii) A personalized plan for the individual to use to reduce the risk of HIV infection/transmission, as appropriate.

(3) When an individual consents to anonymous testing and tests positive for HIV, qualified professional HIV counselors shall discuss options with the client regarding referrals and reporting of this positive screening, including the necessity of accessing a health care provider.

(b) In no event shall a patient be tested for HIV pursuant to these Regulations without first being provided with verbal or written information that includes the following:

(1) An explanation of HIV infection;

(2) A description of interventions that can reduce HIV transmission;

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

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

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

2.4 **[REMOVED]**

2.5 **[REMOVED]**

2.6 **[REMOVED]**

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

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

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

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

2.9 **Mandatory HIV Counseling and Testing.**

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

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

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

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

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

2.10 **[REMOVED]**

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

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

(a) Screening and testing of a potential organ donor pursuant to 42 CFR 486.344(c)(1).

(b) As permitted under RIGL Chapter 23-1-38 entitled "*HIV Antibody Testing-Sperm Collection or Donation*".

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

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

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

Section 4.0 **[REMOVED IN ENTIRETY]**

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

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

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

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

(c) The individual to be tested is a minor under the care and authority of the Rhode Island Department for Children, Youth, and Families, and the Director of said Department certifies that an HIV test is necessary to secure health or human services for that individual;

(d) **[REMOVED]**

(e) In a licensed health care facility or health care setting, in the event that an occupational health representative or physician, registered nurse practitioner, physician assistant, or nurse-midwife, not directly involved in the exposure, determines that an employee or emergency service worker, other than one in a supervisory position to the person making the determination, had a significant exposure to the blood and/or body fluids of a patient and the patient or the patient's guardian refuses to grant consent for an HIV test to determine whether the patient has HIV; then, if a sample of the patient's blood is available, that blood shall be tested for the HIV.

(1) If a sample of the patient's blood is not otherwise available and the patient refuses to grant consent to draw blood, the employee or emergency service worker may petition the Superior Court for a court order mandating that the test be performed.

(2) Before a patient or a sample of the patient's blood is required to undergo an HIV test, the employee or emergency service worker must submit to a baseline HIV test within seventy-two (72) hours of the exposure.

(3) No person who determines that an employee or emergency service worker has sustained a significant exposure and authorizes the HIV testing of a patient, nor any person or health care facility who acts in good faith, and recommends the test be performed, shall have any liability as a result of their actions carried out under the provisions of the Act or these Regulations, unless those persons are proven to have acted in bad faith.

(4) For the purposes of these Regulations, "emergency service worker" means a worker responding on behalf of a licensed ambulance/rescue service, or a fire department or a law enforcement agency, who, in the course of his/her professional duties, has been exposed to bodily fluids in circumstances that present a significant risk of transmission of HIV, and has completed a pre-hospital exposure form in accordance with RIGL §23-4.1-19.

(f) In an emergency, where due to a grave medical or psychiatric condition, and it is impossible to obtain consent from the patient or. if applicable under state law, the patient's parent, guardian or agent.

(g) In accordance with RIGL Chapter 23-8, individuals under eighteen (18) years of age may give legal consent for testing, examination, and/or treatment for any reportable communicable disease, including HIV.

(h) A newborn shall be tested as soon as possible at delivery without the mother's consent if the mother's HIV status is not documented, provided that:

(1) Reasonable efforts have been made to secure voluntary consent from the mother to test the newborn; and

(2) A mother is informed that HIV antibodies in the newborn indicate that the mother is infected with HIV.

5.2 **Reasonable Efforts to Secure Consent.** No involuntary testing for HIV shall take place under any of the exceptions set forth in §§2.9, 2.12(b), 5,1(a), 5.1(b), 5.1(c), 5.1(e) or 5.1(f) of these Regulations unless reasonable efforts have been made to:

(1) Secure voluntary consent from the individual to be tested, or in the case of a minor patient, from the legal parent or guardian of the minor patient; and

(2) Provide verbal or written information as specified in §2.2 of these Regulations.

PART III ***HIV Testing***

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

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

6.2 **[REMOVED]**

6.3 **[REMOVED]**

6.4 **[REMOVED]**

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

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

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

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

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

6.9 Any HIV cases reported in the previous code based system, shall remain in a code based data set. This does not prohibit a physician from submitting or requesting that an updated name case report on a patient replace a previously coded case report.

6.10 All individuals who desire anonymous HIV testing shall be referred to an HIV CTRS site funded by the Department that provides anonymous HIV testing.

6.11 All health care settings and HIV CTRS sites shall develop protocols that include no less than the following:

(a) Assessment for individuals at high risk for HIV infection;

(b) Frequency of HIV testing;

(c) Communication of HIV test results;

(d) Post-test linkages to needed care and support services; and

(e) A system that collects data on an annual basis regarding all HIV testing by facility conducting the testing, sex, age and test results (negative, positive, indeterminate).

6.12 Those adults, adolescents and pregnant women who test positive for HIV infection shall be given priority for outpatient substance abuse treatment programs that are sponsored or supported by the appropriate state agency responsible for these services, and those who test negative for HIV infection shall be referred to the appropriate state agency responsible for these services for earliest possible evaluation and treatment.

6.13 Anonymous and confidential HIV testing provided by HIV CTRS sites funded by the Department shall screen individuals for their ability to pay for such HIV testing, using a fee schedule and screening process available to the Department on request. HIV CTRS sites shall not deny HIV testing to any individual based on his or her inability to pay.

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

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

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

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

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

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

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

(b) Documentation of successful completion of:

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

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

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

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

(b) Documentation of successful completion of:

(1) At least six (6) contact hours related to HIV, sexually transmitted disease, viral hepatitis, sexual behavior, prevention and/or harm reduction no later than 31 March 2011; and

(2) A Department-approved counseling skills assessment session no later than 31 March 2011.

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

8.1 **General Certification Requirements.**

(a) Persons and organizations offering or conducting a Qualified Professional HIV Test Counselor training program shall be certified in accordance with these Regulations.

(b) The criteria for successful completion of the training program shall include obtaining a passing score on the final course examination and successfully demonstrating the required counseling skills, unless the certified training course has been specifically authorized in writing by the Department to use an alternative method of determining successful completion.

(c) The required number of contact hours for the training course shall be construed as allowing a maximum of one (1) hour for the course final examination.

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

(a) The name and address of the person(s) or organization which proposes to conduct the training program; identification and affiliation of training program sponsor(s); the name of the responsible individual and his/her telephone number. If the applicant proposes to conduct the training program under a different name than shown on the application, the other name(s) shall also be provided.

(b) A detailed outline of the training program curriculum, including the amount of time allotted to each topic, the name and training/qualifications of the individual(s) responsible for developing the instruction program for each topic, and the name of the instructor(s) for each topic.

(c) Any restrictions on attendance, including minimum criteria for acceptance into the training program.

(d) Confirmation that the training program will adhere to the most recent guidance referencing HIV testing counselors published by CDC.

(e) Criteria/method(s) for evaluating the student's skills at delivering the six (6) step counseling session in role playing exercises.

(f) A description of the teaching methods to be used to present each topic including, where appropriate, lectures, discussions, demonstrations and audio-visual materials. When applicable, include the name, producer and date of production of audio-visual

materials to be used.

(g) A copy of the student and instructor manuals, or other materials to be used for the training program.

(h) Documentation that the applicant has employed or contracted instructors who meet the training and experience criteria contained in §8.4. Resumes or curricula vitae describing special training and education and/or prior experience may be submitted for the purpose of providing this documentation.

(i) A copy of the quality control plan to be used for maintaining and improving the quality of the training program over time. This plan shall contain at least the following elements:

(1) Procedures for periodic revision of training materials and the final exam to reflect innovations in the field;

(2) Procedures for annual review of instructor competency by the training program administrator; and

(3) Procedures for administering the final exam to ensure the validity and integrity of the examination.

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

(a) Provide a basic knowledge and understanding of the importance of integrating of HIV, STD and viral hepatitis into test counseling sufficient to allow the student to:

(1) State at least one (1) fact about HIV and other STD infection rates;

(2) State at least one (1) fact about viral hepatitis infections rates;

(3) State at least one (1) fact about STD, HIV & HCV co infection;

(4) State at least three (3) reasons why ethnic, racial and sexual orientation issues are important to HIV testing;

(5) List at least three (3) benefits of Partner Counseling and Referral Services; and

(6) Know how to access the AIDS/HIV law and regulations at the Department of Health website

(b) Provide a basic knowledge in prevention counseling concepts sufficient to allow the student to:

(1) State the three (3) concepts that guide the work of prevention counseling: client centered, focus on personal risk assessment and the development of a personalized action plan;

(2) State at least three (3) reasons why the three (3) concepts are important; and

(3) Identify and demonstrate four (4) basic counseling skills: open-ended questioning, attending, offering options, and giving information simply

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

(1) Introduce and orient a client to session;

(2) Identify client's personal risk behaviors and circumstances;

(3) Identify safer goal behaviors;

(4) Develop client action plan;

(5) Make referrals and provide support; and

(6) Summarize and close session

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

(1) Describe, both verbally and in writing, the purpose for each of the six (6) Steps of a Prevention Counseling Session; and

(2) Demonstrate each of the six (6) Steps of a Prevention Counseling Session through practice sessions and role playing.

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

(a) A minimum of five (5) years current relevant experience as a HIV test counselor or Qualified Professional HIV Test Counselor.

(b) A minimum of two (2) years experience as a trainer.

(c) Successful completion of fourteen (14) hour Department-approved Train-the-Trainer course.

(d) Successful completion of the most current Department-approved training program for a Qualified Professional HIV Test Counselor.

(e) An instructor who presents any portion of a training program in a language other than their native language shall have sufficient proficiency in the language used for instruction to accurately and effectively present the course material in a culturally competent manner.

8.5 **Record Keeping Requirements**.

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

(b) A certified training program shall issue unique course completion certificates to each individual who passes each course. The course completion certificate shall include, as a minimum:

(1) The full name, a unique identification number, and address of the individual;

(2) The name of the particular course that the individual completed;

(3) Date(s) of the course and date that the individual passed the course exam (if other than the last day of the course);

(4) Expiration date of the certificate;

(5) The name, address, and telephone number of the training program;

(6) The language in which the training course was given. If the course examination was other than written English, the language and method of evaluation shall also be included.

(c) A certified training provider shall maintain, and make available to the Department upon request, the following records for each certified course:

(1) All documents that demonstrate the qualifications of the instructors;

(2) Current curriculum/course materials and documents reflecting any changes made to these materials;

(3) The quality control plan described in §8.2(i); and

(4) Any other material not listed above that was submitted to the Department as part of the program's application for certification.

Section 9.0 **[REMOVED IN ENTIRETY]**

PART V *Records and Confidentiality*

Section 10.0 *Records*

10.1 Entries shall be made in the patient/client record of all services rendered, such as offering of test, test results, reporting, counseling, etc.

10.2 All forms and reports as required in accordance with these Regulations shall be maintained in the patient's/client's record by health care providers (e.g., physicians, health care facilities), including copies of any of the forms and/or reports submitted by one health care provider to another as part of the plan of care and consistent with the requirements of the Act and these Regulations.

10.3 Providers of health care, public health officials, and any other persons who maintain records containing information on HIV test results of individuals, shall be responsible for maintaining full confidentiality of these data as provided in §23-6.3-7 of the Act and shall take appropriate steps for their protection, including:

(a) Keeping records secure at all times and establishing adequate confidentiality safeguards for any such records electronically stored;

(b) Establishing and enforcing reasonable policies and procedures consistent with the confidentiality requirements of these Regulations;

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

Section 11.0 *Confidentiality and Protection of Records*

11.1 **Confidentiality.**

(a) It is unlawful for any person to disclose to a third-party the results of an individual's HIV test without the prior written consent of that individual, except for:

(1) A licensed laboratory or other health care facility that performs HIV tests shall report test results to the health care provider who requested the test and to the Director.

(2) A health care provider shall enter HIV test results in the patient’s medical record.

(3) Notification to the Director of the Department of Children, Youth and Families, pursuant to §23-6.3-4(a)(3) of the Act.

(4) As provided in §§23-6.3-10 and23-6.3- 14 of the Act, RIGL §5-37.3, RIGL §40.1-5-26, or as otherwise permitted by law.

(5) By a health care provider to appropriate persons entitled to receive notification of individuals with infectious or communicable diseases pursuant to RIGL §23-5-9 and §23-28.36-3.

(b) The provisions of the Act and these Regulations chapter shall not be construed to interfere with any other federal or state laws or regulations that provide more extensive protection than provided in the Act for the confidentiality of health care information.

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

(a) Keeping records secure at all times and establishing adequate confidentiality safeguards for any records electronically stored;

(b) Establishing and enforcing reasonable rules limiting access to these records; and

(c) Training persons who handle records in security objectives and technique.

Section 12.0 ***Notification of Disclosure***

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

(a) the nature and purpose of the disclosure;

(b) the date of disclosure;

(c) the recipient of the disclosed information.

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

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

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

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

(c) A positive ELISA result of any HIV test and/or other FDA approved test indicative of the presence of HIV, within four (4) days of testing. ~~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 (detectable and undetectable), within four (4) days of testing ~~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.

13.1.1 Notification of a perinatal exposure to HIV, regardless of confirmatory testing, shall be reported within four (4) days of testing.

(a) Report all HIV virologic laboratory tests (positive and negative) on infants.

(b) Such reporting shall occur according to procedures and format required by the Department.

(c) A positive perinatal case report for HIV <18 months shall be indicated by positive results on two (2) separate specimens (not including cord blood) from one or more of these non-antibody tests:

(1) HIV DNA or RNA detection;

(2) HIV P24 Antigen test including neutralization assay for a child >1 month; and

(3) HIV isolation (viral culture); and/or

(4) Other U.S. Food and Drug Administration approved tests that indicate the presence of HIV in pediatric cases.

(d) Report of pregnancy for all HIV positive women using forms as required by the Department.

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

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

(b) The administrator of a health care facility as defined in RIGL Chapter 23-17 who diagnoses or treats HIV/AIDS; or

(c) The administrator of a prison in which there is an HIV/AIDS infected person or perinatal exposure to HIV/AIDS.

13.3 Reports provided under this section shall specify the infected person's name, as well as all information required on the official Department HIV Case Report Form.

13.4 A person responsible for the administration of a clinical or hospital laboratory, blood bank, mobile unit, or other facility in which a laboratory examination of any specimen derived from a human body yields serological, or other evidence of HIV/AIDS, including perinatal exposure to HIV/AIDS shall notify the Department as specified in §13.1 of these Regulations.

13.5 All positive HIV test results shall be confirmed with a Western Blot or other FDA approved confirmatory test.

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

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

13.6 **[REMOVED]**

13.7 **[REMOVED]**

13.8 **[REMOVED]**

PART VI *Violations and Remedies, and Severability*

Section 14.0 *Violations and Remedies/Penalties*

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

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

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

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

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

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

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

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

Section 15.0 *Severability*

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

REFERENCES

1. "Maternal and Child Health Services for Children with Special Health Care Needs," Chapter 23-13 of the General Laws of Rhode Island, as amended.
   Available online: http://www.rilin.state.ri.us/Statutes/TITLE23/23-13/INDEX.HTM

2. "Licensing of Facilities and Programs for People Who Are Mentally Ill and/or Developmentally Disabled" Chapter 40.1-24 of the General Laws of Rhode Island, as amended.
   Available online: http://www.rilin.state.ri.us/Statutes/TITLE40.1/40.1-24/INDEX.HTM

3. "Sexually Transmitted Diseases," Chapter 23-11 of the General Laws of Rhode Island, as amended. Available online: http://www.rilin.state.ri.us/Statutes/TITLE23/23-11/INDEX.HTM

4. "Corrections Department," Chapter 42-56 of the General Laws of Rhode Island, as amended.
   Available online: http://www.rilin.state.ri.us/Statutes/TITLE42/42-56/INDEX.HTM

5. "Prostitution and Lewdness," Chapter 11-34 of the General Laws of Rhode Island, as amended.
   Available online: http://www.rilin.state.ri.us/Statutes/TITLE11/11-34/INDEX.HTM

6. "Uniform Controlled Substances Act", Chapter 21-28 of the General Laws of Rhode Island, as amended. Available online: http://www.rilin.state.ri.us/Statutes/TITLE21/21-28/INDEX.HTM

7. "Mental Health Law," Chapter 40.1-5 of the General Laws of Rhode Island, as amended.
   Available online: http://www.rilin.state.ri.us/Statutes/TITLE40.1/40.1-5/INDEX.HTM

8. "Reports of Disease and Disability," Chapter 23-5 of the General Laws of Rhode Island, as amended. Available online: http://www.rilin.state.ri.us/Statutes/TITLE23/23-5/INDEX.HTM

9. "Notification of Fire Fighters, Police Officers, and Emergency Medical Technicians After Exposure to Infectious Diseases," Chapter 23-28.36 of the General Laws of Rhode Island, as amended.
   Available online: http://www.rilin.state.ri.us/Statutes/TITLE23/23-28.36/INDEX.HTM

10. "Quarantine Generally", Chapter 23-8 of the Rhode Island General Laws, as amended.
    Available online: http://www.rilin.state.ri.us/Statutes/TITLE23/23-8/INDEX.HTM

11. Revised Surveillance Case Definitions for HIV Infection Among Adults, Adolescents, and Children Aged <18 Months and for HIV Infection and AIDS Among Children Aged 18 Months to <13 Years --- United States, 2008, *MMWR*, 5 December 2008 / 57(RR10);1-8 and subsequent amendments. Available online:
    http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5710a1.htm

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