



Rhode Island Department of Health

PUBLIC NOTICE

The Director of the Rhode Island Department of Health has determined to amend the rules and regulations listed below to remove the specific dollar value of all fees for licensing, laboratory and administrative services provided by the Department of Health from the individual regulations and reference all such fees to a new consolidated fee regulation (to be promulgated separately). These amendments are proposed pursuant to the authority contained in Public Law 2012-241, enacted by the General Assembly on 15 June 2012, and the relevant sections of the respective professional practice and licensure acts.

The following seventy-five (75) regulations are proposed to be amended:

1. Food Code
2. Rules and Regulations Establishing Educational and Experience Requirements for Registration as a Sanitarian
3. Rules and Regulations for Asbestos Control
4. Rules and Regulations for Bottled Water
5. Rules and Regulations for Certifying Analytical Laboratories
6. Rules and Regulations for Determination of Need for New Health Care Equipment and New Institutional Health Services
7. Rules and Regulations for Lead Poisoning Prevention
8. Rules and Regulations for Licensing Assisted Living Residences
9. Rules and Regulations for Licensing Athletic Trainers
10. Rules and Regulations for Licensing Birth Centers
11. Rules and Regulations for Licensing Chemical Dependency Professionals
12. Rules and Regulations for Licensing Clinical Laboratories and Stations
13. Rules and Regulations for Licensing Clinical Social Workers and Independent Clinical Social Workers
14. Rules and Regulations for Licensing Doctors of Acupuncture and Acupuncture Assistants
15. Rules and Regulations for Licensing Home Nursing Care Providers and Home Care Providers
16. Rules and Regulations for Licensing Hospice Care
17. Rules and Regulations for Licensing Interpreters for the Deaf
18. Rules and Regulations for Licensing Kidney Disease Treatment Centers
19. Rules and Regulations for Licensing Massage Therapists
20. Rules and Regulations for Licensing Mental Health Counselors and Marriage and Family Therapists
21. Rules and Regulations for Licensing Occupational Therapists and Occupational Therapy Assistants
22. Rules and Regulations for Licensing of Hospitals
23. Rules and Regulations for Licensing of Midwives
24. Rules and Regulations for Licensing of Nursing Facilities
25. Rules and Regulations for Licensing of Nursing Home Administrators
26. Rules and Regulations for Licensing Physical Therapists and Physical Therapist Assistants
27. Rules and Regulations for Licensing Psychologists
28. Rules and Regulations for Licensing Rehabilitation Hospital Centers

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29. Rules and Regulations for Licensing Respiratory Care Practitioners
30. Rules and Regulations for Licensing Speech Pathologists and Audiologists
31. Rules and Regulations for Licensing Swimming and Wading Pools, Hot Tubs, and Spas
32. Rules and Regulations for Licensure and Discipline of Chiropractic Physicians
33. Rules and Regulations for Limited Medical Registration
34. Rules and Regulations for Radon Control
35. Rules and Regulations for the Certification of Administrators of Assisted Living Residences
36. Rules and Regulations for the Certification of Health Plans
37. Rules and Regulations for the Control of Radiation
38. Rules and Regulations for the Licensing of Freestanding Ambulatory Surgical Centers
39. Rules and Regulations for the Licensing of Freestanding Emergency Care Facilities
40. Rules and Regulations for the Licensing of Nurses and Standards for the Approval of Basic Nursing Education Programs
41. Rules and Regulations for the Licensing of Nursing Service Agencies
42. Rules and Regulations for the Licensing of Organized Ambulatory Care Facilities
43. Rules and Regulations for the Licensing of Podiatrists
44. Rules and Regulations for the Licensing of Radiographers, Nuclear Medicine Technologists, Radiation Therapists and Radiologist Assistants
45. Rules and Regulations for the Licensure and Discipline of Physicians
46. Rules and Regulations for the Licensure of Barbers, Hairdressers/Cosmeticians, Manicurists, Estheticians, and Instructors
47. Rules and Regulations for the Licensure of Clinical Laboratory Science Practitioners
48. Rules and Regulations for the Licensure of Physician Ambulatory Surgery Centers and Podiatry Ambulatory Surgery Centers
49. Rules and Regulations for the Licensure of Physician Assistants
50. Rules and Regulations for the Licensure of Veterinarians
51. Rules and Regulations for the Registration of Body Piercing Technicians and Body Piercing Establishments
52. Rules and Regulations for the Registration of Distributors of Controlled Substances in Rhode Island
53. Rules and Regulations for the Registration of Tanning Facilities
54. Rules and Regulations for the Registration of Tattoo Artists and Tattoo Parlors
55. Rules and Regulations for the Utilization Review of Health Care Services
56. Rules and Regulations Governing Vital Statistics
57. Rules and Regulations Pertaining to Certification of Managers in Food Safety
58. Rules and Regulations Pertaining to Dentists, Dental Hygienists, and Dental Assistants
59. Rules and Regulations Pertaining to Embalmers, Funeral Directors, and Funeral Service Establishments
60. Rules and Regulations Pertaining to Opticians
61. Rules and Regulations Pertaining to Optometrists
62. Rules and Regulations Pertaining to Permits for Screening Programs
63. Rules and Regulations Pertaining to Pharmacists, Pharmacies and Manufacturers, Wholesalers, and Distributors
64. Rules and Regulations Pertaining to Public Drinking Water
65. Rules and Regulations Pertaining to Rhode Island Certificates of Registration for Nursing Assistants, Medication Aides, and the Approval of Nursing Assistant and Medication Aide Training Programs
66. Rules and Regulations Pertaining to the Certification of Public Drinking Water Supply Treatment and Public Water Supply Transmission and Distribution Operators

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67. Rules and Regulations Pertaining to the Licensing of Dietitians/Nutritionists
 68. Rules and Regulations Pertaining to the Medical Examiner System
 69. Rules and Regulations Pertaining to the Newborn Metabolic, Endocrine, and Hemoglobinopathy Screening Program and the Newborn Hearing Loss Screening Program
 70. Rules and Regulations Pertaining to the Processing and Distribution of Shellfish
 71. Rules and Regulations Prescribing Minimum Standards for Processing, Storage and Transportation of Fish and Fishery Products
 72. Rules and Regulations Related to the Licensure of Hearing Aid Dealers and Fitters
 73. Rules and Regulations Related to the Medical Marijuana Program
 74. Rules and Regulations Related to the Practice of Electrolysis
 75. Rules and Regulations Relating to Emergency Medical Services
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Notice is hereby given in accordance with the provisions of §42-35-3(a)(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.* Should a hearing be requested by twenty-five (25) persons, by a government subdivision or agency, or by an association having not less than twenty-five (25) members, *a hearing shall be scheduled only for the regulation(s) for which the request for hearing was received.* All regulations for which a public hearing is not requested 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 **10 September 2012** deadline (as below).

Such input or requests for public hearing must be received in writing **no later than Monday, 10 September 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 all 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/rules/>, by calling 401-222-7767, or by e-mail to Bill.Dundulis@health.ri.gov.

Signed this 3rd day of August 2012

Original signed by Michael Fine, MD

Michael Fine, M.D., Director of Health

RULES AND REGULATIONS
PERTAINING TO PERMITS
FOR SCREENING PROGRAMS
(R23-16.2-SCRE)



STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

Department of Health
October 1990

As Amended:

July 1991 (T)
September 1991 (E)

January 1992 (E)
December 1997
June 1998

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 2007

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

August 2012 (Proposed)

COMPILER'S NOTES:

Proposed Additions: Underlined

Proposed Deletions: ~~Strikeouts~~

INTRODUCTION

These *Rules and Regulations Pertaining to Permits For Screening Programs* (R23-16.2-SCRE) are promulgated pursuant to the authority conferred under section 23-16.2-5 of the General Laws of Rhode Island, as amended, and are established for the purpose of adopting minimum standards for the issuance of permits for screening programs held in the state of Rhode Island.

Pursuant to the provisions of section 42-35 of the General Laws of Rhode Island, as amended, the following issues were considered in arriving at the regulations: (1) alternative approach; (2) duplication or overlap with other state regulations. No alternative approach, duplication or overlap was identified.

These rules and regulations shall supersede any other regulations governing the issuance of permits for screening programs held in the state of Rhode Island previously promulgated by the Department of Health and filed with the Secretary of State.

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PART I *Definitions and Procedure for Permit*

Section 1.0 *Definitions*

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

- 1.1 **"Act"** refers to Chapter 23-16.2 of the General Laws of Rhode Island, as amended, entitled, "Laboratories."
- 1.2 **"Clinical Laboratory"** means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, radiobioassay, cytological, pathological, or other examination of materials derived from the human body for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings, pursuant to the provisions of reference 1.
- 1.3 **"Department"** means the Rhode Island Department of Health.
- 1.4 **"Director"** means the Director of the Rhode Island Department of Health.
- 1.5 **"General public"** means a person as defined herein.
- 1.6 **"Limited function test"** means those tests listed in the *Federal Register* as waived tests.
- 1.7 **"Medical health professional"** means either a medical technician with a 2-year Associate's degree from an accredited educational institution, a medical technologist, with a Bachelor's degree from an accredited educational institution, or a nurse or physician who is licensed in the state.
- 1.8 **"Person"** means any individual, firm, partnership, corporation, company, association, or joint stock association.
- 1.9 **"Physician"** means a person with a license to practice allopathic or osteopathic medicine in this state under the provisions of reference 2.
- 1.10 **"Screening program or health promotion program,"** hereinafter referred to as "screening program", means a temporary or ad hoc health promotion program that offers to the general public, on a non-continual, non-permanent basis, screening procedures of biological materials (specimens) derived from the human body, for the purpose of providing information for the assessment of the health of human beings pursuant to section 23-16.2-3 of the Act and in accordance with the requirements herein.

Section 2.0 *General Requirements*

- 2.1 It shall be unlawful for any persons, corporation, or other form of entity to own, maintain, conduct or operate a temporary or ad hoc screening program in this state without meeting the requirements of the rules and regulations herein. Furthermore:

- 2.1.1 Any screening program in this state shall be conducted or operated under the overall supervision of either a physician licensed in this state, a clinical laboratory of a hospital licensed in this state, or an independent clinical laboratory licensed in this state and include appropriate personnel in accordance with the provisions of sections 6.0 and 7.0 herein.
- a) A permit shall be required for those persons seeking to operate an ad hoc screening program under the overall supervision of a physician licensed in this state.
 - i) Said permit shall be required to be obtained annually.
 - b) A permit shall *not* be required for those clinical laboratories of hospitals licensed in this state or independent clinical laboratories licensed in this state to operate an ad hoc screening program. In these cases, the screening program shall be conducted under the licensee's hospital or independent clinical laboratory license.
- 2.1.2 All persons conducting screening programs shall be required to submit a schedule of each screening site, clearly identifying the specific screening tests to be conducted, and the dates, times and locations of the screening program.
- 2.1.3 The permit fee shall be ~~seventy dollars (\$70.00)~~ as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health.*
- a) It is within the Director's discretion to waive the fee. Nothing herein shall require any licensed persons, corporations, or other entity to pay the permit fee, if the screening program is provided free of charge to the public by the licensed persons, corporation, or entity.
- 2.1.4 Any person conducting or operating a screening program shall be required to acquire liability insurance to cover any injury which may be incurred as a result of negligence.
- 2.2 A screening program shall represent itself in its advertisements, publications, or other forms of communication, as providing only those categorical screening procedures for which a screening is being conducted and shall not advertise in a manner which tends to mislead or deceive the public.

Section 3.0 *Application for Permit and Fee*

- 3.1 Persons seeking to operate an ad hoc screening program under the overall supervision of a physician licensed in this state shall submit an application for a permit to conduct or operate said screening program to the Rhode Island Department of Health, Division of Facilities Regulation, on forms provided by the Department and available through the Division. The application shall contain such information as the Department reasonably requires, including but not limited to:

- a) The name of the person and/or agency operating or conducting the screening program and the name of the person responsible for the overall medical direction of the program, the name(s) and qualifications of the on-site supervisor and other staff personnel in accordance with section 7.1 herein and the location of the site, the date, time and schedule of the screening program;
- b) Evidence of ability to comply with the requirements herein including evidence of the qualifications of staff personnel and of holding liability insurance in accordance with sections 2.1.4, 6.0 and 7.0 herein;
- c) A written description pertaining to all aspects of the administration and operation of the screening program including but not limited to:
 - i) Assurance that the specific screening test(s) to be offered will be conducted in accordance with the guidelines established by the Rhode Island Department of Health, Division of Facilities Regulation;
 - ii) The procedure(s) for monitoring, obtaining informed consents, interpretation and reporting of test results, and follow-up on positive findings, participant education, and referral of identified cases, including an explanation of results, and recommendations for appropriate treatment, prevention and control;
 - iii) Analytical method(s) to be used, type of equipment and/or instrument(s) to be used, and documented evidence to determine accuracy and precision of the instrument(s);
 - iv) A description of the supervisory methods and quality controls, in accordance with section 8.0 herein;
 - v) Staff training program and qualifications of staff;
 - vi) Copies of educational materials pertaining to specific test(s) and condition(s) to be distributed to the general public at the screening site;
 - vii) Quality control and instrument maintenance records;
 - viii) Provisions to handle emergencies; *and*
 - ix) Procedures for the disposal of waste consistent with the provisions for the management of medical waste of reference 3.

3.2 The completed application for a screening program permit shall be accompanied by the documentary requirements of section 3.1 (above) including the fee of ~~seventy dollars (\$70.00)~~ as set forth in the Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health.

- 3.2.1 The fee shall be made payable by check or money order to the General Treasurer, state of Rhode Island, and submitted along with the application form at least thirty (30) days prior to the first scheduled screening program. Said materials shall be mailed to the:

Division of Facilities Regulation
Rhode Island Department of Health
3 Capitol Hill, Room 306
Providence, RI 02908

Section 4.0 *Issuance of Permit*

- 4.1 Upon receipt of an application for a permit and accompanying fee, the Department shall issue a permit, if the applicant is found to be in compliance with the statutory and regulatory requirements herein.
- 4.2 The permit issued shall be valid only for a period of one (1) year, and only for the specific category(ies) of screening procedures specified on the permit.
- 4.3 A permit issued hereunder shall be the property of the state and loaned to the applicant. The permit shall be kept posted in a conspicuous place at the location of the screening program and is not transferable.

Section 5.0 *Denial and/or Revocation of Permit*

- 5.1 The Department is authorized to deny an application for the issuance of a permit and to revoke any permit issued, if the statutory and regulatory provisions herein are not met.
- 5.2 Whenever an action shall be proposed to deny or revoke a permit, the Department shall notify the applicant by certified mail, setting forth reasons for the proposed action, and the applicant shall be given an opportunity for a prompt and fair hearing in accordance with the provisions of section 12.0 herein.
 - 5.2.1 However, if the Department finds that public health, safety or welfare of clients requires emergency action and incorporates a finding to that effect in its order, the Department may order summary suspension of the permit pending proceedings for revocation or other action in accordance with sections 42-35-14 (c) and section 23-1-21 of the General Laws of Rhode Island, as amended.

PART II *Delivery of Services*

Section 6.0 *Medical Direction & Responsibility*

6.1 Every person conducting or operating a screening program shall enter into a provider arrangement with either a physician or an independent clinical laboratory or a clinical laboratory of a hospital, all of whom must be licensed in Rhode Island, and who will be responsible for the overall medical direction and supervision of the operation of the screening program and services and ensure the delivery of quality services, unless the person conducting or operating the screening program is either a physician, an independent clinical laboratory, or a hospital clinical laboratory licensed in this state.

6.1.1 Furthermore the person responsible for the medical direction of the screening program shall:

- a) develop and/or approve the professional components of the screening program(s) including policies and procedures governing the technical practices pertaining to no less than the provisions of section 3.1 herein; *and*
- b) ensure that the specific screening tests being offered shall be conducted in a manner consistent with the guidelines established by the Rhode Island Department of Health, Division of Facilities Regulation.

Section 7.0 *Personnel*

7.1 *Staff Personnel*

a) ***On-site Supervisor***

- i) Every screening program shall have a person designated to supervise the program and personnel;
- ii) The supervisor shall be a medical health professional, licensed and/or registered in this state, who must have the appropriate training in the specific instrumentation(s) to be used in conducting the screening program. The training shall consist of no less than one (1) day (i.e., 7 hours) training conducted by an experienced laboratory instructor (at the minimum level of a medical technologist). Said training shall consist of instruction in no less than:
 - (1) calibration and operation of the specific instrument(s) to be used in the screening program;
 - (2) detecting problems and performing usual instrument maintenance;
 - (3) handling emergencies and medical waste;
 - (4) participant education and referral protocols; *and*

(5) such other areas as may be deemed relevant.

iii) Furthermore, the on-site supervisor shall be required to be on the premises at all times during the screening program and shall be responsible to oversee the work performance of the individuals conducting the screening tests in order to ensure the accuracy of the methods and the maintenance of quality controls and the provision of appropriate education and/or referral.

b) ***Screening Personnel***

i) Individuals, other than the on-site supervisor, who will be performing the screening tests and operating the instruments shall be licensed in accordance with the requirements of the *Rules & Regulations for the Licensure of Clinical Laboratory Science Practitioners (R23-16.3-CLS)* of reference 4.

ii) Individuals performing procedures defined herein as "limited function tests" shall be required to complete a training program that shall consist of no less than a minimum of one (1) day's training (i.e., 7 hours) conducted by experienced laboratory trainer(s) and shall include no less than:

(1) calibration and operation of the specific instrument (s) to be used;

(2) detecting problems and performing usual instrument maintenance;

(3) educational and referral protocols; *and*

(4) such other areas as may be deemed relevant.

iii) In addition to this training, a minimum of one (1) week (i.e., 35 hours) supervised field experience in operating the instrument(s) shall be required. Screening personnel shall be subject to on going supervision for all aspects of their performance at the screening program.

7.2 ***First Aid or Cardiopulmonary Resuscitation (CPR)***

At least one (1) staff person shall hold a current certificate in first aid or CPR and must be on the premises and available at all times during the testing.

7.3 ***Worker Safety***

In order to protect screening personnel from occupational exposure to blood borne pathogens, procedures for workers' safety should be carried out in accordance with the Occupational Safety and Health Administration's (OSHA) Blood borne Pathogen Standards of reference 5. Work practices should be designed to minimize or eliminate exposure to blood and other body fluids.

Section 8.0 *Methodologies for Quality Control*

- 8.1 Each screening program shall establish an acceptable *internal* program of quality control covering each type of screening procedure performed for the verification and assessment of accuracy, measurement of precision, and detection of error. The factors which constitute the quality control provisions shall be based on current acceptable national standards of practice.
- 8.2 Each screening program shall establish an acceptable *external* program of quality control covering each type of screening procedure performed for the verification and assessment of accuracy, measurement of precision, and detection of error. The factors which constitute the quality control provisions shall be based on current acceptable national standards of practice.

Section 9.0 *Prohibitions Against Referral*

- 9.1 No licensed physician or clinical laboratory shall make any referral which would violate the provisions of sections 23-16.2-5.1 or 5-37-21 of the Rhode Island General Laws, as amended, or any other relevant provisions of the law.

PART III ***Practices and Procedures, Violation and Severability***

Section 10.0 ***Variance Procedure***

- 10.1 The Department may grant a variance either upon its own motion or upon request of the applicant from the provisions of any rule or regulation in a specific case, if it finds that a literal enforcement of such provision will result in unnecessary hardship to the applicant and that such variance will not be contrary to the public interest, public health and/or health and safety of the public.
- 10.2 A request for a variance shall be filed by an applicant in writing setting forth in detail the basis upon which the request is made.
 - 10.2.1 Upon the filing of each request for variance with the Department and within thirty (30) days thereafter, the Department shall notify the applicant by certified mail of its approval or in the case of a denial, a hearing date, time and place may be scheduled if the applicant appeals the denial.

Section 11.0 ***Violations***

- 11.1 Any person who violates the statutory provisions and the regulations herein shall be subject to the sanctions of section 23-16.2 of the General Laws of Rhode Island, as amended.

Section 12.0 ***Rules Governing Practices & Procedures***

- 12.1 All hearings and reviews required under the provisions of the rules and regulations herein shall be held in accordance with the *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health (R42-35-PP)* of reference 6.

Section 13.0 ***Severability***

- 13.1 If any provision of these rules and regulations or the application thereof to any individual or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of the regulations which can be given effect and to this end the provisions of the regulations are declared to be severable.

REFERENCES

1. "Laboratories", Chapter 23-16.2 of the General Laws of Rhode Island as amended.
2. "Board of Medical Licensure and Discipline", Chapter 5-37 of the General Laws of Rhode Island, as amended.
3. *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management & Disposal of Regulated Medical Waste in Rhode Island (DEM-DAH-MW-01-92)*, Rhode Island Department of Environmental Management, April 1994.
4. *Rules & Regulations for the Licensure of Clinical Laboratory Science Practitioners (R23-16.3-CLS)*, Rhode Island Department of Health, July 1996.
5. "Blood borne Pathogens", Occupational Safety and Health Administration (OSHA), *29 Code of Federal Regulations*, Part 1910-1000 to end, section 1910.1030, pp. 316-326, July 1, 1994.
6. *Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health*, Rhode Island Department of Health, May 1997.

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