216-RICR-20-10-1

TITLE 216 - DEPARTMENT OF HEALTH

CHAPTER 20 – COMMUNITY HEALTH

SUBCHAPTER 10 – SCREENING, MEDICAL SERVICES, AND REPORTING

PART 1 – Permits for Screening Programs

1.1 Authority

These rules and regulations are promulgated pursuant to the authority conferred under R.I. Gen. Laws § 23-16.2-5, 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.

1.2 Incorporated Material

A. These regulations hereby adopt and incorporate 42 C.F.R. § 493.15 (2017) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

B. These regulations hereby adopt and incorporate 29 C.F.R. § 1910.1030 (2017) by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with these regulations.

1.3 Definitions

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

1. "Act" refers to R.I. Gen. Laws Chapter 23-16.2, entitled, "Laboratories."

2. "Clinical Laboratory" means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, radiobioassey, 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.

3. "Department" means the Rhode Island Department of Health.

4. "Director" means the Director of the Rhode Island Department of Health.

5. "General public" means a person as defined herein.

6. "Limited function test" means those tests listed 42 C.F.R. § 493.15 (2017) as waived tests.

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.

8. "Person" means any individual, firm, partnership, corporation, company, association, or joint stock association.

9. "Physician" means a person with a license to practice allopathic or osteopathic medicine in this state under the provisions of R.I. Gen. Laws Chapter 5-37.

10. "R.I. Gen. Laws" means Rhode Island General Law, as amended.

11. "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 R.I. Gen. Laws § 23-16.2-3 and in accordance with the requirements herein.

1.4 Procedure for Permits

1.4.1 General Requirements

A. 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:

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 §§ through of this Part.

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.

(1) 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. 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.

3. The permit fee shall be 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.

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.

B. 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.

1.4.2 Application for Permit and Fee

A. 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:

1. 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 §) of this Part and the location of the site, the date, time and schedule of the screening program;

2. 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 §§), , and of this Part;

3. A written description pertaining to all aspects of the administration and operation of the screening program including but not limited to:

    a. 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;

    b. 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;

    c. 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);

    d. A description of the supervisory methods and quality controls, in accordance with § of this Part;

    e. Staff training program and qualifications of staff;

f. Copies of educational materials pertaining to specific test(s) and condition(s) to be distributed to the general public at the screening site;

g. Quality control and instrument maintenance records;

h. Provisions to handle emergencies; and

i. Procedures for the disposal of waste consistent with the provisions for the management of medical waste from the Department of Environmental Management's *Rules and Regulations Governing the Generation, Transportation, Storage, Treatment, Management & Disposal of Regulated Medical Waste in Rhode Island*.

B. The completed application for a screening program permit shall be accompanied by the documentary requirements of §) of this Part, including the fee 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*.

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:

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

1.4.3 Issuance of Permit

A. 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.

B. 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.

C. 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.

1.4.4 Denial and/or Revocation of Permit

A. 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.

B. 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 § of this Part.

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 R.I. Gen. Laws §§ 42-35-14(c) and 23-1-21.

1.5 Delivery of Services

1.5.1 Medical Direction & Responsibility

A. 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.

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 §) of this Part; 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.

1.5.2 Personnel

A. Staff Personnel

1. On-site Supervisor

a. Every screening program shall have a person designated to supervise the program and personnel;

b. 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.

c. 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.

2. Screening Personnel

a. 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.

b. 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 ongoing supervision for all aspects of their performance at the screening program.

3. First Aid or Cardiopulmonary Resuscitation (CPR)

a. 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.

B. Worker Safety

1. 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) Bloodborne Pathogen Standards, 29 C.F.R. §1910.1030 (2017). Work practices should be designed to minimize or eliminate exposure to blood and other body fluids.

1.5.3 Methodologies for Quality Control

A. 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.

B. 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.

1.5.4 Prohibitions Against Referral

No licensed physician or clinical laboratory shall make any referral which would violate the provisions of R.I. Gen. Laws §§ 23-16.2-5.1 or 5-37-21, or any other relevant provisions of the law.

1.6 Practices and Procedures, Violation and Severability

1.6.1 Variance Procedure

A. 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.

B. 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.

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.

1.6.2 Violations

Any person who violates the statutory provisions and the regulations herein shall be subject to the sanctions of R.I. Gen. Laws § 23-16.2.

1.6.3 Rules Governing Practices & Procedures

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.

1.6.4 Severability

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.

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