216-RICR-10-10-3

TITLE 216 - DEPARTMENT OF HEALTH

CHAPTER 10 - PUBLIC HEALTH ADMINSTRATION

SUBCHAPTER 10 - REGISTRIES

PART 3 - Rhode Island Birth Defects Registry

3.1 Authority

A. These amended Rules and Regulations Pertaining to the Rhode Island Birth Defects Registry [216-RICR-10-10-3] are promulgated pursuant to the authority conferred in R.I. Gen. Laws Chapters 23-13.3 and 42-35, as amended, and are hereby adopted for the purpose of establishing a unified procedure for the reporting of birth defects of newborns and spontaneous fetal deaths to the Rhode Island Birth Defects Registry. These specific amendments update the unified procedure for the reporting of birth defects of newborns and spontaneous fetal deaths to the Rhode Island Birth Defects Registry by requiring the use of the “International Classifications of Diseases, 10th Revision, Clinical Modification”, incorporated below at § 3.2 of this Part. Due to increasingly timely and accurate detecting methods in the prenatal stages, the amendments also require the reporting of every case up to sixty (60) months [five (5 years)] of age.

B. The Rhode Island General Assembly has found that birth defects are a major cause of infant deaths and childhood disabilities; and that early recognition and response to birth defects often prevents more serious effects; and that the epidemiological patterns of specific birth defects may provide keys to improved birth outcomes. An active birth defects surveillance and information system is essential to developing programs and disseminating information that can reduce birth defects and infant mortality. An active birth defects surveillance and information system serves to describe occurrence of birth defects in the newborn and children up to five; detect trends of morbidity and mortality, stimulate epidemiological research diminish the impact of birth defects and infant mortality; and identify newborns and children with birth defects to intervene on a timely basis for treatment.

3.2 Incorporated Materials

These regulations hereby adopt and incorporate the National Center for Health Statistics' "International Classification of Diseases, 10th Revision Clinical Modification" (2015) 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.

3.3 Definitions

A. Where used in these rules or regulations, the following terms shall construed as followed:

1. "Act" refers to R.I. Gen. Laws Chapter 23-13.3, as amended.

2. “Birth defects” include structural and chromosomal abnormalities that affect the development of organs and tissues of an infant or child and may be identified during pregnancy, at birth or following birth before a child's fifth (5th) birthday. Possible causes or contributing factors to birth defects include genetics, environmental pollutants, occupational hazards, dietary factors, medications and personal behaviors.

3. "Clinical laboratory" means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, radiobioassay, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of human beings, and licensed pursuant to R.I. Gen. Laws Chapter 23-16.2.

4. “Council” means the Birth Defects Surveillance and Information Advisory Council.

5. “Department” means the Rhode Island Department of Health.

6. “Director” means the Director of the Department of Health.

7. "Health care facility" means any institutional health service provider, facility or institution, place, building, agency, or portion thereof, whether a partnership or corporation, whether public or private, whether organized for profit or not, used, operated, or engaged in providing health care services, including but not limited to hospitals; nursing facilities; home nursing care provider (which shall include skilled nursing services and may also include activities allowed as a home care provider or as a nursing service agency); home care provider (which may include services such as personal care or homemaker services); rehabilitation centers; kidney disease treatment centers; health maintenance organizations; free-standing emergency care facilities, and facilities providing surgical treatment to patients not requiring hospitalization (surgi-centers); hospice care, and physician ambulatory surgery centers and podiatry ambulatory surgery centers providing surgical treatment. The term "health care facility" also includes organized ambulatory care facilities which are not part of a hospital but which are organized and operated to provide health care services to outpatients such as central services facilities serving more than one health care facility or health care provider, treatment

centers, diagnostic centers, outpatient clinics, infirmaries and health centers, school based health centers and neighborhood health centers. The term "health care facility" shall not apply to organized ambulatory care facilities owned and operated by professional service corporations as defined in R.I. Gen. Laws Chapter 7-5.1, as amended, or to a private practitioner's (physician, dentist, or other health care provider) office or group of the practitioners' offices (whether owned and/or operated by an individual practitioner, alone or as a member of a partnership, professional service corporation, organization, or association)

8. "Health care practitioner", as used in these Regulations, means a physician, physician assistant, certified registered nurse practitioner, or midwife who provides primary care to children five (5) years of age and younger.

9. “Primary care” means the basic or general health care furnished by a practitioner who is responsible for the overall and ongoing coordination of a patient’s health care. In most instances, primary care is focused on the point at which a patient first seeks assistance from the health care system for non-emergency services.

10. "Registrar of the Rhode Island Birth Defects Registry” hereinafter referred to as Registrar, means the person within the Department designated by the Director to be responsible for the operation of the Rhode Island Birth Defects Registry.

11. "Rhode Island Birth Defects Registry" means the central registry established within the Department by the Director pursuant to the Act as the statewide registry for the collection and recording of information on certain cases of birth defects for the purpose of describing the occurrence of birth defects in the newborn and children up to five; detecting trends of morbidity and mortality, stimulating epidemiological research, diminishing the impact of birth defects and infant mortality; and identifying newborns and children with birth defects to intervene on a timely basis for treatment.

12. “R.I. Gen. Laws” means the General Laws of Rhode Island, as amended.

13. “These Regulations” mean all parts of the Rhode Island Rules and Regulations Pertaining to the Rhode Island Birth Defects Registry [216-RICR-10-10-3].

3.4 General Reporting Requirements

A. Due to increasingly timely and accurate detecting methods in the prenatal stages all new cases of reportable birth defects as listed in § 3.5 of this Part diagnosed on and after July 1, 2016 in all unborn fetuses and children up to 60 months (five years) of age shall be reportable by health care facilities, health care

practitioners, and clinical laboratories in accordance with the Act and these Regulations. Reporting is required for all children residing in Rhode Island.

B. The administrative officer, or his/her designee, of each health care facility, health care practitioner practice setting, or clinical laboratory shall be responsible for establishing the reporting procedures at that facility or practice setting. These procedures shall ensure that every case up to sixty (60) months [five (5 years)] of age that is diagnosed either in the facility-operated inpatient or outpatient setting, or by a health care practitioner, shall be reported to the Registry. If a child is transported to another facility, the health care facility, health care practitioner practice setting, or clinical laboratory at which the reportable diagnosis is first made shall be responsible for reporting. This reporting requirement also applies in cases where the child dies before the age of five (5) or in cases where the birth defect is corrected.

C. Within sixty (60) days from the date of diagnosis or confirmation of a new case of a reportable birth defect as listed in § 3.5 of this Part, a health care facility, health care practitioner, or clinical laboratory shall report in the manner specified by the Department all the information and data requested. The originating health care facility, health care practitioner, or clinical laboratory shall retain a duplicate copy of submitted information for a two (2) year period from the date of submission.

D. Nothing under the provisions of the Act and these Regulations shall be construed to compel any individual to submit to medical or Department examination or supervision.

3.5 Reportable Defects

A. Health care facilities and clinical laboratories shall report those defects identified by the “Q” codes listed in the publication entitled, “International Classifications of Diseases, 10th Revision, Clinical Modification” incorporated above at 3.2 of this Part, as well as the following selected codes: C09-11, C22, C56-58, C62, C64-66, C68-69, C74-75, F84, H54, and H90-91. The Q codes for birth defects are separated by the following body systems:

1. Q00-Q07 – Nervous System
2. Q10-Q18 – Eye, Ear, Face, and Neck Anomalies
3. Q20-Q28 – Cardiovascular System
4. Q30-Q34 – Respiratory System
5. Q35-Q37 – Orofacial Anomalies
6. Q38-Q45 – Digestive System
7. Q50-Q56 – Reproductive System

8. Q60-Q64 – Urinary System

9. Q65-Q79 – Musculoskeletal System

10. Q80-Q89 – Other Anomalies

11. Q90-Q99 – Chromosomal Abnormalities

B. The Birth Defects Registrar shall report those defects identified by the following selected codes listed in the publication entitled, “International Classifications of Diseases, 10th Revision, Clinical Modification” incorporated above in § 3.2 of this Part.

C. Each health care facility, health care practitioner, or clinical laboratory shall submit data in such a manner as to make uniform a system of periodic reporting and shall include no less than the following detailed statistical data and information:

1. Patient's full name; parent/guardian’s full name;

2. Street address, city or town, state and zip code at the time of diagnosis;

3. Date of birth;

4. Sex;

5. Ethnicity: Hispanic/Latino; Non-Hispanic/Latino;

6. Race: White; Black/African American; Asian/Pacific Islander; American Indian/Native Alaskan; Other;

7. Primary diagnosis (text and ICD-10 codes);

8. All applicable laboratory tests by which the primary diagnosis was determined;

9. Date, place and method of diagnosis;

10. Extent/nature of disease at diagnosis;

11. Medical record number;

12. Reporting facility;

13. Date of admission;

14. Source of information [type of medical record];

15. Primary physician;

16. Such other data as may be required by the Director.

D. Data and information on cases of birth defects shall be reported electronically or by US postal mail unless reporting by another means has been approved in writing by the Director.

E. Such data and information shall be abstracted from medical charts and other sources of patient information by personnel possessing, at a minimum, a basic working knowledge of medical terminology, human anatomy, and physiology.

F. Such data and information shall be coded in a manner specified by the Director.

G. Such data and information shall be submitted with sufficient narrative substantiation to allow a visual assessment of the accuracy of coded data and information.

H. The Department shall not require the reporting of information or entering of information into the birth defects surveillance and information system regarding birth defects of a child whose parents or legal guardian objects.

I. Parents and/or guardians shall have the right to prohibit the release of individually identifiable information on their children from the birth defects surveillance and information system, and shall have the right to prohibit being contacted by the birth defects surveillance program.

J. The Department shall provide timely notification to parents and/or guardians of their rights as stated above.

K. There shall be written documentation of a parent/guardian’s prohibition of the release of their child’s individually identifiable information from the birth defects surveillance and information system, or of their objection to the reporting or entering of their child's information into the birth defects surveillance and information system. Written documentation shall include, but not be limited to: a parent/guardian’s signature maintained on file by the Department, health care facility, clinical laboratory, or health care practitioner prohibiting release of the information by the Birth Surveillance Defects Program or contact by the Birth Defects Surveillance Program; or a note regarding the prohibition of reporting of information into the birth defects surveillance and information system entered into the child’s medical record by the attending health care practitioner.

3.6 Validation of Data

To ensure the accuracy of the data and the completeness of reporting, the Registrar is authorized to review periodically patients' medical records and all other sources of patient information, including but not limited to, disease/diagnosis indices, labor and delivery logs, nursery log, newborn intensive care unit log, pediatric log, pediatric intensive care log, stillborn log, pathology/autopsy log, ultrasound reports, or cytogenetic reports as may be

necessary to substantiate the accuracy of the data and the completeness of reporting.

3.7 Confidentiality

A. The birth defects surveillance and information system shall maintain comprehensive records of all reports submitted pursuant to the Act and the rules and regulations herein. These reports shall be confidential in accordance with R.I. Gen. Laws Chapter 5-37.3 and subject to the restrictions on release incorporated in that Chapter. Provided, however, any such information shall be available only for the purposes of the Act, and any data requested for demographic or epidemiological studies shall be provided in a format without individually identifiable information.

B. All individual records and aggregate data including abstract report forms relating to the Rhode Island Birth Defects Registry are the property of the Department. The use of records and aggregate data by any person shall be subject to the approval of the Director. Furthermore, requests for access to data compiled pursuant to the provisions of these Regulations may be granted only by the Director in accordance with applicable federal and state law, rules and regulations regarding confidentiality and public access to data.

3.8 Violations/Sanctions

Failure of any health care facility or clinical laboratory to comply with the provisions of the Act and these Regulations shall be subject to sanctions and referred to the appropriate licensing and/or disciplinary body.

3.9 Exception and Severability

A. Modification of any individual rule and regulation herein may be granted by the Director upon motion of the Rhode Island Birth Defects Registry or upon request of a contracting agency and/or organization in a specific case, if the Director finds that the modification to the rule is not contrary to the purpose of the Rhode Island Birth Defects Registry nor contrary to the public interest. A request for modification of a rule shall require advance written request to the Director and written approval by the Director.

B. If any provision of these Regulations or the application thereof to any facility or provider or circumstances shall be held invalid, such invalidity shall not affect the provisions or application of these Regulations which can be given effect, and to this end the provisions of these Regulations are declared to be severable.