

RULES AND REGULATIONS
PERTAINING TO THE RHODE ISLAND
BIRTH DEFECTS REGISTRY
(R23-13.3-BD)

STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

November 2005

INTRODUCTION

These *Rules and Regulations Pertaining to the Rhode Island Birth Defects Registry*(R23-13.3-BD) are promulgated pursuant to the authority conferred in Chapters 23-13.3 and 42-35 of the General Laws of Rhode Island, 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.

The Rhode Island General Assembly has found that birth defects are a major cause of infants 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: (a) Describe occurrence of birth defects in the newborn and children up to five; (b) Detect trends of morbidity and mortality, stimulate epidemiological research diminish the impact of birth defects and infant mortality; and (c) Identify newborns and children with birth defects to intervene on a timely basis for treatment.

TABLE OF CONTENTS

	<i>Page</i>
1.0 Definitions	1
2.0 General Requirements	3
3.0 Reportable Defects	3
4.0 Validation of Data	8
5.0 Confidentiality	8
6.0 Violations/Sanctions	9
7.0 Exception and Severability	9
References	10

BIRTH DEFECTS REGISTRY

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 23-13.3 of the General Laws of Rhode Island, as amended.
- 1.2 ***"Birth defects"*** include structural, chromosomal and metabolic 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.
- 1.3 ***"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 Chapter 23-16.2 of the Rhode Island General Laws, as amended.
- 1.4 ***"Council"*** means the Birth Defects Surveillance and Information Advisory Council.
- 1.5 ***"Department"*** means the Rhode Island Department of Health.
- 1.6 ***"Director"*** means the Director of the Department of Health.
- 1.7 ***"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 chapter 5.1 of title 7, as amended (the "Professional Service Corporation Law"), 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)

- 1.8 **"Health care practitioner"**, as used herein, means a physician, physician assistant, certified registered nurse practitioner, or midwife who provides primary care to children five (5) years of age and younger.
- 1.9 **"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.
- 1.10 **"Registrar of the Rhode Island Birth Defects Registry "** hereinafter referred to as Registrar, means the person within the Department of Health designated by the Director to be responsible for the operation of the Rhode Island Birth Defects Registry.
- 1.11 **"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.

Section 2.0 *General Reporting Requirements*

- 2.1 All new cases of reportable birth defects as listed in Section 3.1 diagnosed on and after July 1, 2005 in children 20 weeks gestation, 500 grams birth weight or both, to 60 months (five years) in age shall be reportable by health care facilities, health care practitioners, and clinical laboratories in accordance with the statutory and regulatory provisions herein. Reporting is required for all children residing in RI.
- 2.2 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 from 20 weeks gestation to 60 months of age (5 years) 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.
- 2.3 Within sixty (60) days from the date of diagnosis or confirmation of a new case of a reportable birth defect as listed in section 3.1 herein, 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.
- 2.6 Nothing under the provisions of the Acts and the rules and regulations herein shall be construed to compel any individual to submit to medical or Department examination or supervision.

Section 3.0 *Reportable Defects*

- 3.1 Health care facilities and clinical laboratories shall report those defects identified by the following selected codes listed in the publication entitled, "International Classifications of Diseases, 9th Revision, Clinical Modification" of reference 1 herein:

146	146.9	147	147.9	155	155.0	181	183	183.0	186	186.0	186.9	189
189.0	190	190.5	194	194.0	195	195.0	195.2	195.3	299	299.0	369	369.0
369.00	369.01	369.02	369.03	369.04	369.05	369.06	369.07	369.08	369.1	369.10	369.11	369.12
369.13	369.14	369.15	369.16	369.17	369.18	369.2	369.20	369.21	369.22	369.23	369.24	369.25
369.3	369.4	369.6	369.60	369.61	369.62	369.63	369.64	369.65	369.66	369.67	369.68	369.69
369.7	369.70	369.71	369.72	369.73	369.74	369.75	369.76	369.8	369.9	389	389.0	389.00
389.01	389.02	389.03	389.04	389.08	389.1	389.10	389.11	389.12	389.14	389.18	389.2	389.7
389.8	389.9	740	740.0	740.1	740.2	741	741.0	741.9	742.0	742.1	742.2	742.3
742.4	742.5	742.51	742.53	742.59	742.8	742.9	743	743.0	743.00	743.03	743.06	743.1
743.10	743.11	743.12	743.2	743.20	743.21	743.22	743.3	743.30	743.31	743.32	743.33	743.34
743.35	743.36	743.37	743.39	743.4	743.41	743.42	743.43	743.44	743.45	743.46	743.47	743.48
743.49	743.5	743.51	743.52	743.53	743.54	743.55	743.56	743.57	743.58	743.59	743.6	743.61
743.62	743.63	743.64	743.65	743.66	743.69	743.8	743.9	744	744.0	744.00	744.01	744.02
744.03	744.04	744.05	744.09	744.1	744.2	744.21	744.22	744.23	744.24	744.29	744.3	744.4
744.41	744.42	744.43	744.46	744.47	744.49	744.5	744.8	744.81	744.82	744.83	744.84	744.89
744.9	745	745.0	745.1	745.10	745.11	745.12	745.19	745.2	745.3	745.4	745.5	745.6
745.60	745.61	745.69	745.7	745.8	745.9	746	746.0	746.00	746.01	746.02	746.09	746.1
746.2	746.3	746.4	746.5	746.6	746.7	746.8	746.81	746.82	746.83	746.84	746.85	746.86
746.87	746.89	746.9	747	747.0	747.1	747.10	747.11	747.20	747.21	747.22	747.29	747.3
747.4	747.40	747.41	747.42	747.49	747.5	747.6	747.60	747.61	747.62	747.63	747.64	747.69
747.8	747.81	747.82	747.83	747.89	747.9	748	748.0	748.1	748.2	748.3	748.4	748.5
748.6	748.60	748.61	748.69	748.8	748.9	749	749.0	749.00	749.01	749.02	749.03	749.04
749.1	749.10	749.11	749.12	749.13	749.14	749.2	749.20	749.21	749.22	749.23	749.24	749.25
750	750.0	750.1	750.10	750.11	750.12	750.13	750.15	750.16	750.19	750.2	750.21	750.22
750.23	750.24	750.25	750.26	750.27	750.29	750.3	750.4	750.5	750.6	750.7	750.8	750.9
751	751.0	751.1	751.2	751.3	751.4	751.5	751.6	751.60	751.61	751.62	751.69	751.7
751.8	751.9	752	752.0	752.1	752.10	752.11	752.19	752.2	752.3	752.4	752.40	752.41
752.42	752.49	752.5	752.51	752.52	752.6	752.61	752.62	752.63	752.64	752.65	752.69	752.7
752.8	752.9	753	753.0	753.1	753.10	753.11	753.12	753.13	753.14	753.15	753.16	753.17
753.19	753.2	753.20	753.21	753.22	753.23	753.29	753.3	753.4	753.5	753.6	753.7	753.8
753.9	754	754.0	754.1	754.2	754.3	754.30	754.31	754.32	754.33	754.35	754.4	754.40
754.41	754.42	754.43	754.44	754.5	754.50	754.51	754.52	754.53	754.59	754.6	754.60	754.61

754.61	754.62	754.69	754.7	754.70	754.71	754.79	754.8	754.81	754.82	754.89	755	755.0
755.00	755.01	755.02	755.1	755.10	755.11	755.12	755.13	755.14	755.2	755.20	755.21	755.22
755.23	755.24	755.25	755.26	755.27	755.28	755.29	755.3	755.30	755.31	755.32	755.33	755.34
755.35	755.36	755.37	755.38	755.39	755.4	755.5	755.50	755.51	755.52	755.53	755.54	755.55
755.56	755.57	755.58	755.59	755.6	755.60	755.61	755.62	755.63	755.64	755.65	755.66	755.67
755.69	755.8	755.9	756	756.0	756.1	756.10	756.11	756.12	756.13	756.14	756.15	756.16
756.17	756.19	756.2	756.3	756.4	756.5	756.50	756.51	756.52	756.53	756.54	756.55	756.56
756.59	756.6	756.7	756.70	756.71	756.79	756.8	756.81	756.82	756.83	756.89	756.9	757
757.0	757.1	757.2	757.3	757.31	757.32	757.33	757.39	757.4	757.5	757.6	757.8	757.9
758	758.0	758.1	758.2	758.3	758.4	758.5	758.6	758.7	758.8	758.81	758.89	758.9
759	759.0	759.1	759.2	759.3	759.4	759.5	759.6	759.7	759.8	759.81	759.82	759.83
759.89	759.9	760.71										

3.2 Health care practitioners shall report those defects identified by the following selected codes listed in the publication entitled, “International Classifications of Diseases, 9th Revision, Clinical Modification” of reference 1 herein:

Reportable Birth Defects by ICD-9-CM Codes

Selected Birth Defects	ICD-9-CM Codes
Central Nervous System	
Anencephalus	740.0-740.1
Spina Bifida without anencephalus	741.0, 741.9 w/o 740.0-740.10
Hydrocephalus without spina bifida	742.3 w/o 741.0, 741.9
Encephalocele	742.0
Microcephalus	742.1
Eye	
Anophthalmia/micropthalmia	743.0, 743.1
Congenital cataract	743.30-743.34
Aniridia	743.45
Ear	
Anotia/microtia	744.01, 744.23

Selected Birth Defects	ICD-9-CM Codes
Cardiovascular	
Common truncus	745.0
Transposition of Great Arteries	745.10-745.12, 745.19
Tetralogy of Fallot	745.2
Ventricular septal defect	745.4
Atrial septal defect	745.5
Endocardial cushion defect	745.60, 745.61, 745.69
Pulmonary valve atresia and stenosis	746.01-746.02
Tricuspid valve atresia and stenosis	746.1
Epstein's anomaly	746.2
Aortic valve stenosis	746.3
Hypoplastic left heart syndrome	746.7
Patent ductus arteriosus (include only if birth weight >2500 or note if unable to exclude <2500 grams infants)	747.0
Coarctation of aorta	747.10
Orofacial	
Cleft palate without cleft lip	749.0
Cleft lip with and without palate	749.1, 749.2
Choanal atresia	748.0
Gastrointestinal	
Esophageal atresia/tracheoesophageal fistula	750.3
Pyloric stenosis	750.5
Rectal and large intestinal atresia/stenosis	751.2
Hirshsprung's disease (congenital megacolon)	751.3
Biliary atresia	751.61
Genitourinary	
Hypospadias and epispadias	752.61, 752.62
Renal agenesis/hypoplasia	753.0
Bladder exstrophy	753.5
Obstructive genitourinary defect	753.2, 753.6
Musculoskeletal	
Congenital hip dislocation	754.30-754.31, 754.35
Varus/valgus deformities of feet	754.5-754.7
Reduction deformity, upper limbs	755.20-755.29
Reduction deformity, lower limbs	755.30-755.39
Gastroschisis	756.79
Omphalocele	756.79
Diaphragmatic hernia	756.6
Chromosomal	
Down Syndrome	758.0
Trisomy 13	758.1
Trisomy 18	758.2
Other	
Fetal alcohol syndrome	760.71
Autism	299.0

- 3.3 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:
- a) patient's full name;
parent/guardian's full name;
 - b) street address, city or town, state and zip code at the time of diagnosis;
 - c) date of birth;
 - d) sex;
 - e) ethnicity: Hispanic/Latino; Non-Hispanic/Latino;
 - f) race: White; Black/African American; Asian/Pacific Islander; American Indian/Native Alaskan; Other;
 - g) primary diagnosis (text and ICD-9 codes);
 - h) all applicable laboratory tests by which the primary diagnosis was determined;
 - i) date, place and method of diagnosis;
 - j) extent/nature of disease at diagnosis;
 - k) medical record number;
 - l) reporting facility;
 - m) date of admission;
 - n) source of information [type of medical record];
 - o) primary physician;
 - p) such other data as may be required by the Director.
- 3.4 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.
- 3.5 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.
- 3.6 Such data and information shall be coded in a manner specified by the Director.

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

Rights of Parents/Legal Guardians

- 3.8 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.
- 3.9 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.
- 3.10 The Department shall provide timely notification to parents and/or guardians of their rights as stated above.
- 3.11 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. Written documentation shall include, but not be limited to: (1) a parent/guardian's signature maintained on file by the Department, health care facility, clinical laboratory, or health care practitioner; or (2) a note regarding the prohibition of release of information entered into the child's medical record by the attending health care practitioner.

Section 4.0 Validation of Data

- 4.1 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 cyto-genetic reports as may be necessary to substantiate the accuracy of the data and the completeness of reporting.

Section 5.0 Confidentiality

- 5.1 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 Chapter 37.3 of Title 5 and subject to the restrictions on release incorporated in that Chapter. Provided, however: (1) any such information shall be available only for the purposes of the Act; and (2) any data requested for demographic or epidemiological studies shall be provided in a format without individually identifiable information.

Ownership and Publication of Data

- 5.2 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.

Section 6.0 Violations/Sanctions

- 6.1 Failure of any health care facility or clinical laboratory to comply with the provisions of the Acts and the rules and regulations herein shall be subject to sanctions and referred to the appropriate licensing and/or disciplinary body.

Section 7.0 Exception and Severability

- 7.1 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.

- 7.1.1 A request for modification of a rule shall require advance written request to the Director and written approval by the Director.

Severability

- 7.2 If any provision of the rules and regulations herein 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 the regulations which can be given effect, and to this end the provisions of the rules and regulations are declared to be severable.

REFERENCES

1. *International Classifications of Diseases, 9th Revision, Clinical Modification, 1989.*

Thursday, November 03, 2005
birth defects-final-nov05.doc