4100 Family Health Services

4101 Birth Defect Surveillance and Registry Program

1.0 Purpose

1.1 Birth defects are one of the causes of infant mortality and disabilities in Delaware. A Birth Defects Surveillance System, or Birth Defects Registry, will enable the Department of Health and Social Services (DHSS), Division of Public Health (DPH) to collect birth defects data, to create a statewide registry, and to link surveillance with tracking of individual children for the provision of services.

1.2 The purpose of the Birth Defects Registry is to provide information to Public Health officials as to the existence of previously unrecognized health and environmental hazards, help prevent certain birth defects and ultimately decrease the infant mortality rate. The Birth Defects Registry will gather data to assist with identification of risk factors, including environmental and hereditary, assist in the investigation of causes and prevalence; assist in the development of strategies to reduce the occurrence of, or prevent such defects; and track and follow-up abnormal newborn hearing screening results.

1.3 The usefulness of the data collected in the Birth Defects Registry will depend upon the full and accurate reporting of such defects by health care practitioners, health care facilities, clinics and laboratories.

1.4 The Birth Defects Registry will be a component of the Newborn Screening Case Management System, including metabolic and hearing screening. All results of metabolic and hearing screens will become part of the screening record. Tracking and follow-up of incomplete and abnormal cases will be followed by the Division of Public Health Newborn Screening Program.

2.0 Definitions

The following words shall have the meanings indicated:

"Birth Defect" means any structural or biochemical abnormality, regardless of cause, diagnosed at any time before or after birth, that requires medical or surgical intervention or that interferes with normal growth or development. This includes abnormal newborn hearing screening. Reportable birth defects are listed in Appendix A of these Regulations.

"Division" refers to the Division of Public Health under the Department of Health and Social Services.

"Registry" means a central data bank containing collected, classified, coded, and sorted data relating to defects in children under age 5, reported by health care providers.

"Surveillance" means the process of identifying and investigating birth defects in children under age 5.

3.0 Reporting Requirements

The provisions of this section shall apply to the Delaware Health and Social Services, Division of Public Health, Birth Defect Registry:

3.1 The registry shall collect information on any birth defect diagnosed in utero and postpartum on anyone who is a resident of the state of Delaware, or whose parent is a resident of Delaware, and who is diagnosed at any time prior to age five (5) as having a birth defect. For the purposes related to the registry the Division shall have access to any medical record of the child that pertains to a diagnosed or suspected birth defect. Prenatal information on the birth mother may be obtained with prior consent.

3.2 Any diagnosed birth defects shall be reported for all infants and children up to age 5, including those who have since died (if the data is still available).

3.3 For purposes of these reporting requirements, reportable diagnoses are those diagnoses, from the International Classification of Diseases (ICD), as listed in Appendix A of these regulations. The reportable diagnoses listed in Appendix A may be revised, upon notice, to

reflect changes in publications accepted for use by the Centers for Disease Control and Prevention or State.

3.4 The following persons and organizations are required to report occurrences of birth defects within 30 days of diagnosis to the Division of Public Health.

3.4.1 Any physician, surgeon, dentist, podiatrist, certified nurse midwife, or other health care practitioner who diagnoses or provides treatment, or both, for a child under age 5 with birth defects who is not known to be previously reported;

3.4.2 The designated representative of any clinical laboratory that performs any test which identifies a child or children under age 5 with birth defects not known to be previously reported; and

3.4.3 The designated representative of any hospital, dispensary, clinic, or other similar public or private institution that diagnoses or provides treatment, or both, for a child or children under age 5 with birth defects who is not known to be previously reported.

3.4.4 This section of the regulations shall not apply to any person or private institution that, as an exercise of religious freedom, treats the sick or suffering by spiritual means through prayer alone.

3.5 The administrative officer of every health care facility shall be responsible for establishing reporting procedures at that facility, using the identified Birth Defect Registry reporting form. Reporting procedures must ensure that each infant initially diagnosed as having a birth defect shall be reported to the Division. Any presumptive or actual diagnosis in a child up to the age of 5 must be reported to the Division.

3.6 Reporting sources shall complete the Division of Public Health Birth Defects Surveillance Form for each reported case, and forward the completed form to the Division of Public Health Director or designee.

3.7 Reporting sources are required to submit annual follow-up information as requested through Birth Defect Program.

4.0 Confidentiality of Reports

4.1 No report of a diagnosis or treatment of a birth defect shall be disclosed in such a way as to identify the child who is the subject of the report, or as to identify the child's family. However, patient-identifying information may be exchanged among authorized agencies as approved by the Department and upon receipt by the Department of satisfactory assurances by those agencies of the preservation of the confidentiality of such information. Agencies will maintain the confidentiality of any information exchanged for the purpose of delivery of program services, evaluation, early intervention and epidemiological investigation.

4.2 Any parent, custodian or guardian of any infant having any birth defect may refuse disclosure to the surveillance system and registry of the infant’s name and identifying information on the grounds that such birth defect identification is contrary to the religious tenets and practices of the infant’s parent, custodian or guardian.

4.3 No individual or organization providing information pursuant to these regulations shall be held liable for divulging such information to the Division.

5.0 Penalties

Any person or organization required to report the diagnosis or treatment of a birth defect pursuant to these regulations, and who violates these regulations, shall be subject to a fine of up to $100 for each violation, pursuant to 16 **Del.C.** Sec. 206**.** Justices of the Peace Courts have jurisdiction over such violations.

6.0 Severability

In the event any particular clause or section of the regulations should be declared invalid or unconstitutional by any court of competent jurisdiction, the remaining portions shall remain in full force and effective.

Table 1: APPENDIX A October 2002

DELAWARE BIRTH DEFECTS REGISTRY REPORTABLE DIAGNOSES		
Broad Categories	**Specific Categories**	**ICD-9 Codes**
Congenital Infections		
	Congenital syphilis	090.0 - 090.3
	Congenital rubella	771.0
	Congenital cytomegalovirus	771.1
	Congenital toxoplasmosis (not specific code)	771.2
Other infections specific to perinatal period		771.80
	Other congenital infections	771.x
Neoplasms	Neurofibromatosis	237.70
Endocrine, Nutritional, Metabolic, Immunological Diseases		
	Congenital hypothyroidism	243.00
	Phenylketonuria	270.10
	Galactosemia	271.1
	Cystic Fibrosis	277.00.01
	Other Metabolic diseases	
Diseases of Blood		
	Sickle Cell Disease	282.60
	Other hemoglobinopathies	282.63, 282.69, 282.4
Developmental Disorders		
	Developmental Language Disorder	315.31-315.39
	Coordination Disorder	315.40
	Mental Retardation	317 - 319
Congenital Anomalies of 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
	Holoprosencephaly/Porencephaly	742.2
	Other Congenital Anomalies of Nervous System	742.4 - 742.9
Congenital Anomalies of the Eye		
	Anophthalmia/microphthalmia	743.0,743.1
	Congenital cataract	743.30 -743.34
	Aniridia	743.45
	Glaucoma	743.20 -743.22
	Coloboma	743.46*
Congenital Anomalies of the Ear		

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DELAWARE BIRTH DEFECTS REGISTRY REPORTABLE DIAGNOSES		
	Anotia/microtia	744.01,744.23
Congenital Anomalies of the Cardiovascular System		
	Common truncus	745.0
	Transposition of great arteries	745.10,745.11, 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
	Single Ventricle	745.3
	Pulmonary valve atresia and stenosis	746.01,746.02
	Tricuspid valve atresia and stenosis	746.1
	Ebstein's anomaly	746.2
	Aortic valve stenosis	746.3
	Hypoplastic left heart syndrome	746.7
	Patent ductus arteriosus >2500 gms	747.0
	Coarctation of aorta	747.10
	Pulmonary artery anomalies	747.3
Congenital anomalies of the Respiratory System		
	Anomalies of larynx/trachea/ bronchus	748.30
	Lung agenesis/hypoplasia	748.5
	Other respiratory anomalies	
Congenital Anomalies of the Orofacial Area		
	Cleft palate without cleft lip	749.00 -749.04
	Cleft lip with or without cleft palate	749.1,749.2
	Choanal atresia	748.0
Congenital Anomalies of the Gastrointestinal Tract		
	Esophageal atresia/ tracheoesophageal fistula	750.3
	Atresia/stenosis of intestine and rectum	751.10,751.2
	Hirschsprung's disease (congenital megacolon)	751.3
	Anomalies of internal fixation of bowel	751.40
	Biliary atresia	751.61
	Malrotation of intestine	751.4*
	Pyloric stenosis	750.5
	Anorectal malformation	751.4*
Congenital Anomalies of the Genitourinary System		

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DELAWARE BIRTH DEFECTS REGISTRY REPORTABLE DIAGNOSES		
	Renal Agenesis/hypoplasia	753.0
	Bladder exstrophy	753.5
	Cloacal exstrophy	*
	Cystic/dysplastic kidneys	753.10,753.15
	Obstructive genitourinary defect	753.2,753.6
	Hypospadias and Epispadias	752.6
	Ambiguous genitalia	752.9*
	Polycystic kidneys	753.12 -753.14
Congenital Anomalies of the Musculoskeletal Regions		
	Reduction defect, upper limbs	755.20 -755.29
	Polydactyly/ Syndactyly/ Adactyly	755.00 -755.02 755.10 -755.14 755.4*
	Reduction defect, lower limbs	755.30-755.39
	Arthrogryposis multiplex congenital	754.89*
	Achondroplasia	756.4
	Osteogenesis imperfecta	756.51
	Other skeletal dysplasia Gastroschisis	756.7
	Omphalocele	756.7
	Diaphragmatic hernia (moved up)	756.6
	Scoliosis/Lordosis/Kyphosis	754.0, 756.19
	Congenital hip dysplasia	754.30, 754.31
		754.35*
	Club Foot	754.50, 51, 53, 60, 70, 79
	Craniosynostosis	756.0*
Chromosomal Disorders		
	Trisomy 21 (Down syndrome)	758.0
	Trisomy 13	758.1
	Trisomy 18	758.2
	Autosomal deletion syndromes	758.30
	Other conditions due to autosomal anomalies	758.50
	Gonadal dysgenesis (Turner's syndrome)	758.60
	Klinefelter's syndrome	758.70
	Other conditions due to sex chromosome anomalies	758.80
	Conditions due to anomaly of unspecified Chromosome	758.90
	Fragile X Syndrome	759.83
Other Congenital Malformations		
	Amniotic bank disruption complex	no code
Embryopathy from Toxic Exposure in Utero		

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DELAWARE BIRTH DEFECTS REGISTRY REPORTABLE DIAGNOSES		
	Fetal Alcohol syndrome	760.71
	Phenytoin	760.79*
	Isotretinoin	760.79*
	Warfarin	760.79*
	Other toxic exposures	760.7x
Conductive hearing loss, external ear		389.01
Conductive hearing loss, middle ear		389.03
Ear disorder, unspecified		388.9
Hearing loss, noise-induced		388.12
Hearing loss, sudden, unspecified		388.2
Hearing loss, unspecified		388.9
Sensorineural hearing loss, unspecified		389.10