

DEPARTMENT OF HEALTH AND SOCIAL SERVICES

DIVISION OF PUBLIC HEALTH

Statutory Authority: 16 Delaware Code, Section 203 (16 Del.C. §203)
16 DE Admin. Code 4101

PROPOSED

PUBLIC NOTICE

4101 Birth Defect Surveillance and Registry Program

Pursuant to 16 Del.C. §203, the Department of Health and Social Services, Division of Public Health is proposing revisions to regulation 4101 Birth Defect Surveillance and Registry Program and intends to hold them open for public comment per Delaware law. The revisions include technical changes to bring the regulation into compliance with the *Delaware Administrative Code Style Manual*, updates to Appendix A (Delaware Birth Defects Registry Reportable Diagnoses), and Appendix B (Registry Reporting Form).

Copies of the proposed regulation are available for review in the February 1, 2026 issue of the *Delaware Register of Regulations*, accessible online at: <http://regulations.delaware.gov> or by calling the Division of Public Health at 302-744-4951.

Public comments will be accepted until 4:30 PM on March 3, 2026. Comments will be accepted in written form via email to DHSS_DPH_regulations@delaware.gov, or by U.S. mail to the following address:

Vicki Schultes, Hearing Officer
Division of Public Health
417 Federal Street
Dover, DE 19901

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 The Birth Defects Surveillance System, or Birth Defects Registry, will enable~~ enables the Delaware Department of Health and Social Services (DHSS), Division of Public Health (DPH) to collect birth defects data, ~~to create~~ 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~~ provides information to ~~Public Health~~ public health officials as to the existence of previously unrecognized health and environmental hazards, ~~help~~ helps prevent certain birth defects ~~defects~~, and ultimately ~~decrease~~ decreases the infant mortality rate. The Birth Defects Registry ~~will gather~~ gathers data to assist with identification of risk factors, including environmental and ~~hereditary, assist~~ hereditary; assists in the investigation of causes and ~~prevalence; assist~~ prevalence; and assists in the development of strategies to reduce the occurrence of, or prevent such defects; ~~and track and follow-up abnormal newborn hearing screening results; birth defects.~~
- 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.~~
- 1.4.1.3 ~~The Birth Defects Registry will be~~ is a component of the Newborn Screening Case Management System, ~~including~~ and includes 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~~ is completed by the Division of Public Health Newborn Screening Program staff.

2.0 Definitions

The following words ~~and terms, when used in this regulation,~~ have the meanings indicated following meaning:

"Birth Defect~~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~~ this regulation.

"Department" means the State of Delaware Department of Health and Social Services.

"Division" ~~refers to~~ means the Division of Public Health ~~under~~ within the Delaware Department of Health and Social Services.

"Registry" means a central data bank containing collected, classified, coded, and sorted data relating to birth defects in children under age 5 diagnosed in utero and postpartum for 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 5 as having a birth defect, 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 for anyone who is a resident of the state of Delaware, Delaware; or whose parent is a resident of Delaware, Delaware~~ and who is diagnosed at any time prior to age ~~five (5) 5~~ as having a birth defect. ~~For the purposes related to the registry the~~ 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~~ Reportable diagnoses are those diagnoses, from the International Classification of Diseases (ICD), as listed in Appendix A of these regulations this regulation. 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 the State of Delaware.

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. ~~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~~ 3.5 This section of the regulations Section 3.0 of this regulation 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~~ 3.6 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 Form (Appendix B of this regulation). 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~~ 3.7 Reporting sources shall complete the Division of Public Health Birth Defects Surveillance Form for each reported ~~case, case~~ and forward the completed form to the Division of Public Health Director or designee.

~~3.7~~ 3.8 Reporting sources are required to submit annual follow-up information as requested ~~through Birth~~ through the 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 patient-identifying~~ information. Agencies will maintain the confidentiality of any information exchanged for the purpose of delivery of program services, evaluation, early ~~intervention~~ intervention, and epidemiological investigation.

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

4.3 No individual or organization providing birth defect/patient-identifying information pursuant to ~~these regulations~~ this regulation shall be held liable for divulging ~~such~~ the 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~~ this regulation, and who violates ~~these regulations~~ this regulation, shall be subject to a fine of up

to \$100 for each violation, pursuant to 16 ~~Del.C. Sec. 206.~~ §206. Justices of the Peace Courts have jurisdiction over such ~~these~~ violations.

6.0 Severability

In the event any particular clause or section of ~~the regulations~~ this regulation 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		
	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		
	Renal Agensis/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
	Craniostynostosis	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		
	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

APPENDIX A

Birth Defect Surveillance and Registry

<https://regulations.delaware.gov/register/February2026/8E5A18FC-4863-49F5-BEEB-1A4443D8B794>

APPENDIX B

Birth Defects Registry Reporting Form

<https://regulations.delaware.gov/register/February2026/4851FA50-87C4-46BE-B2A9-7DBA57391913>