

STATE OF MAINE

MAINE BIRTH DEFECTS PROGRAM RULE

**10-144 CMR
Chapter 280**



**Department of Health and Human Services
Maine Center for Disease Control and Prevention
11 State House Station
Augusta, Maine 04333-0011**

Last Amended: December 13, 2017, filing 2017-194

10 DEPARTMENT OF HEALTH AND HUMAN SERVICES

144 MAINE CENTER FOR DISEASE CONTROL AND PREVENTION

Chapter 280: MAINE BIRTH DEFECTS PROGRAM RULE

SUMMARY STATEMENT

This rule establishes the responsibilities of hospital administrators, physicians and other health care providers with regard to the reporting of the presence of birth defects in infants and fetuses and the referral of cases from the Maine Birth Defects Program to related programs in the Maine Center for Disease Control and Prevention, and to comply with part C of the I.D.E.A. (The Individuals with Disabilities Education Act), which directs the State of Maine to ensure cooperation among state agencies in delivering supports and services to infants, toddlers and preschoolers with disabilities or developmental delay and their families. This rule establishes the confidentiality requirements of the Maine Birth Defects Program and provides for parental objection to birth defect reporting or participation in the birth defect registry.

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SECTION 1. PURPOSE

This rule implements the Maine Birth Defects Program, as established pursuant to Title 22, Chapter 1687 of the *Maine Revised Statutes*.

SECTION 2. DEFINITIONS

1. **Birth hospital** means any hospital licensed under the provisions of Title 22 M.R.S. which provides health care services to pregnant woman and those who give birth.
2. **Birthing center** means any non-hospital health facility, institution, or place designed to accommodate mothers giving birth away from home at the culmination of normal, uncomplicated pregnancies.
3. **Birth defect** means a major structural abnormality which impacts upon a fetus, newborn or infant's ability to function or survive. For reporting purposes, only those birth defects included in the Appendix to this rule need be reported.
4. **Part C Agency** means an agency that meets the definition in the federal I.D.E.A. (*Individuals with Disabilities Education Act*, Public Law No. 94-142). In Maine, Child Development Services (CDS), under the supervision of the Maine Department of Education, is the Part C Agency providing both Early Intervention (birth through two years) and Free Appropriate Public Education (FAPE for ages three through five years).
5. **Reportable birth defects** means those birth defects which hospitals, physicians and other health care providers licensed under the provisions of Title 22 M.R.S. or Title 32 M.R.S. are required to report. These reportable birth defects are identified in the Appendix to this rule.
6. **Specialty provider** means an individual licensed under Title 32 M.R.S. who has additional certification by or eligibility for one of the disciplines of the American Board of Medical Specialties and is registered and certified by the appropriate specialty boards.

SECTION 3. RESPONSIBILITY FOR REPORTING

1. All administrators of hospitals licensed by the Department of Health and Human Services, all health professionals licensed pursuant to Title 32 M.R.S. engaged by a birthing center and individuals licensed to practice midwifery as Certified Midwives are responsible to report all cases involving a diagnosis of a reportable birth defect involving any fetus or infant born in the State of Maine to a Maine resident. Reporting shall be made to the Department of Health and Human Services, Maine Center for Disease Control and Prevention, Maine Birth Defects Program ("Maine Birth Defects Program"). This reporting requirement extends to any live born or stillborn infant diagnosed at birth or to any infant one year of age or younger admitted to the hospital or outpatient office/clinic for diagnosis or treatment related to a reportable birth defect.
2. Individuals licensed to practice midwifery as Certified Professional Midwives are responsible to report all cases when they recognize a reportable birth defect involving any fetus or infant born in the state of Maine to a Maine resident. Reporting shall be made to the Maine Birth Defects Program.

3. Each administrator of a hospital or other health facility subject to licensing requirements established under either Title 22 M.R.S. or Title 32 M.R.S., which provides health care for pregnant woman or for infants, shall designate a contact person responsible for coordinating the reporting of birth defects by the facility to the Maine Birth Defects Program. Such designee should be a clinical person with appropriate experience in either obstetrics or newborn care, unless the Maine Birth Defects Program authorizes another designee. Each such administrator shall advise the Maine Birth Defects Program of the identity of the contact person for his or her facility.
4. The designated contact person shall also be responsible for the submission of appropriate reports to the Maine Birth Defects Program regarding any infant or fetus diagnosed with a reportable birth defect.
5. The administrator of any hospital licensed pursuant to Title 22 M.R.S. shall also designate a contact person within its medical records department to coordinate the provision of all relevant medical records and other information pertaining to an infant or fetus diagnosed with a reportable birth defect to the Maine Birth Defects Program. The administrator shall also furnish the name of such contact person to the Maine Birth Defects Program.
6. Each hospital, birthing center, and licensed midwife subject to this rule will be provided a report form by the Maine Birth Defects Program, which will identify the required reporting data pertaining to the mother and infant/fetus, along with a listing of reportable birth defects under this rule.
7. The administrator of each hospital licensed by the Department of Health and Human Services or licensed health professionals subject to this rule is responsible for assuring that all facility staff, with responsibility for obstetrical or newborn care, are informed of their respective responsibilities under this rule.

SECTION 4. RESPONSIBILITY OF THOSE PROVIDING PEDIATRIC SERVICES

1. Any primary care physician, specialty physician or other health care provider licensed pursuant to Title 32 M.R.S. who diagnoses or recognizes a reportable birth defect in a newborn or infant in the first year of life shall report to the Maine Birth Defects Program such birth defect. The physician or other health care provider shall report on a form provided by the Maine Birth Defects Program, if possible.
2. The reporting requirements under this subsection extend to the presence of a birth defect in any fetus, newborn or infant delivered by Maine residents.

SECTION 5. RESPONSIBILITY OF THOSE PROVIDING OBSTETRICAL SERVICES

1. Any physician or other health care provider licensed pursuant to Title 32 M.R.S. who diagnoses or recognizes a fetus with a reportable birth defect shall submit a report regarding the birth defect to the Maine Birth Defects Program, regardless of the outcome of the pregnancy.

2. In the event the subject pregnancy results in other than a live birth, any such physician or other health care provider who provides care to the mother shall submit to the Maine Birth Defects Program a report confirming the presence of a birth defect in the fetus or stillborn.

SECTION 6. TIMING OF REPORTING THE PRESENCE OF A BIRTH DEFECT IN AN INFANT OR FETUS

1. The required report is to be submitted to the Maine Birth Defects Program, either within 24 hours of the time the infant is discharged or transferred, or within seven days of the diagnosis or recognition of a reportable birth defect, whichever occurs first.
2. Diagnosis of a birth defect in a fetal death shall be reported within seven days of the diagnosis or confirmation of a reportable birth defect.

SECTION 7. CONFIDENTIALITY OF ALL REPORTING DATA

1. All data reported to the Maine Birth Defects Program, which contains either direct or indirect individually identifiable information, shall be confidential.
2. Except as otherwise provided in this rule, individually identifiable information submitted to the Maine Birth Defects Program shall only be available to qualified organizations with a documented history of scientific research or other researchers determined to be appropriate by the Maine Birth Defects Program. In any event, disclosure of any individually identifiable information will be in conformity with applicable state and federal law.
3. Any organization or individual which requests individually identifiable information from the Maine Birth Defects Program may be required to execute such confidentiality agreements as the Maine Birth Defects Program deems appropriate.
4. Institutional Review Board approval is required for any research plan which involves either the use or release of any information contained in the Maine Birth Defects Program. Any such Institutional Review Board must be established in conformity with applicable state and federal laws including regulations established by the U.S. Department of Health and Human Services regarding the Protection of Human Subjects..
5. In the event a proposed research plan involves contacting family members, written consent of the parent or guardian of any infant or fetus will be required as a predicate for use or release of any information from the Maine Birth Defects Program.

SECTION 8. CONTACT WITH FAMILIES

1. The Maine Birth Defects Program may contact families to provide information about available services.

2. Referrals shall be made to the Department of Health and Human Services, Children with Special Health Needs Program and/or Public Health Nursing within 30 days upon confirmation of the birth defect, and in compliance with Part C of The I.D.E.A. (Individuals with Disabilities Education Act) the Maine Birth Defects Program will refer a newborn with a confirmed birth defect that has the potential to develop a developmental delay to the Part C Agency.
3. No family will be required to accept any services offered by the Maine Birth Defects Program, including any nursing visit or referral.
4. In the event of a prenatal diagnosis of a reportable birth defect, the Maine Birth Defects Program will not contact the family, unless requested to do so by the family or physician or other health care provider subject to this rule.

SECTION 9. PARENTAL OBJECTION TO PARTICIPATION

1. In the event of parental objection on the basis of sincerely held religious beliefs the hospital, birthing center, licensed midwife, or health care provider subject to this rule shall not be required to report the presence of any birth defect.
2. Parental objection to reporting and participation in the Maine Birth Defects Program based on sincerely held religious beliefs shall be clearly documented in writing, and incorporated into the medical records of the mother, infant and newborn.
3. In the event of documented parental objection to participation in the Maine Birth Defects Program, based upon sincerely held religious beliefs, the Maine Birth Defects Program shall not collect or gather any medical records relating to birth defects of the fetus, newborn or infant.

APPENDIX**Central Nervous System**

Anencephalus
 Spina bifida without anencephalus
 Hydrocephalus without Spina Bifida
 Encephalocele
 Microcephalus
 Holoprosencephaly

Eye

Anophthalmia/microphthalmia
 Congenital cataract
 Aniridia

Ear

Anotia/microtia

Cardiovascular

Common truncus
 Transposition of great arteries
 Tetralogy of Fallot
 Ventricular septal defect
 Atrial septal defect
 Endocardial cushion defect
 Pulmonary valve atresia and stenosis
 Tricuspid valve atresia and stenosis
 Ebstein's anomaly
 Aortic valve stenosis
 Hypoplastic left heart syndrome
 Patent ductus arteriosus
 Coarctation of aorta
 Double outlet right ventricle (DORV)
 Interrupted aortic arch (IAA)
 Total anomalous pulmonary venous connection
 Single ventricle

Orofacial

Cleft palate without cleft lip
 Cleft lip with and without cleft palate
 Choanal atresia

Gastrointestinal

Esophageal atresia/tracheoesophageal fistula
 Rectal and large intestinal atresia/stenosis
 Pyloric stenosis
 Hirschsprung's disease (congenital megacolon)
 Biliary atresia
 Small intestinal atresia/stenosis

Genitourinary

Renal agenesis/hypoplasia
 Bladder exstrophy
 Obstructive genitourinary defect
 Hypospadias and Epispadias
 Cloacal exstrophy
 Congenital posterior urethral valves

Musculoskeletal

Reduction deformity, upper limbs
 Reduction deformity, lower limbs
 Gastroschisis
 Omphalocele
 Congenital hip dislocation
 Diaphragmatic hernia
 Clubfoot
 Craniosynostosis

Chromosomal

Trisomy 13
 Down syndrome (Trisomy 21)
 Trisomy 18
 22q11.2 deletion
 Turner syndrome

Other

Fetal alcohol syndrome
 Amniotic bands

STATUTORY AUTHORITY: 22 M.R.S. §§ 8943 and 8944

EFFECTIVE DATE:

May 1, 2003 - filing 2003-95

AMENDED:

May 17, 2008 – filing 2008-198

April 1, 2011 – filing 2011-77

December 13, 2017 – filing 2017-194