

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
MAINE CENTER FOR DISEASE CONTROL
DIVISION OF FAMILY HEALTH
MAINE BIRTH DEFECTS PROGRAM**

Chapter 280: RULES RELATING TO THE MAINE BIRTH DEFECTS PROGRAM

SUMMARY: These rules establish 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, require the referral of cases from the Maine Birth Defects Program to related programs in the Maine Center for Disease Control and Prevention, and comply with part C of the I.D.E.A. (The Individuals with Disabilities Education Act) which directs the State to ensure cooperation among state agencies in delivering supports and services to infants, toddlers and preschoolers with disabilities or developmental delay and their families. These rules establish the confidentiality requirements of the Maine Birth Defects Program and provide for parental objection to birth defect reporting or participation in the birth defect registry.

SECTION 1. PURPOSE

These rules implement 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 of the Maine Revised Statutes 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 these rules need be reported.
4. **“Reportable birth defects”** means those birth defects which hospitals, physicians and other health care providers licensed under the provisions of Title 22 or Title 32 of the Maine Revised Statutes are required to report. These reportable birth defects are identified in the Appendix to these rules.
5. **“Specialty provider”** means those licensed under Title 32 who have additional certification by or eligibility for one of the disciplines of the American boards of certification 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 and all health professionals licensed pursuant to MRS Title 32 engaged by a birthing center 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 Maine 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. Each administrator of a hospital or other health facility subject to licensing requirements established under either M.R.S.A. Title 22 or Title 32, 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 Birth Defects Program authorizes another designee. Each such administrator shall advise the Birth Defects Program of the identity of the contact person for his or her facility.
3. 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.
4. The administrator of any hospital licensed pursuant to M.R.S.A. Title 22 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 Program.
5. Each hospital or birthing center subject to these Rules will be provided a report form by the 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 these Rules.
6. The administrator of each hospital licensed by the Department of Health and Human Services or licensed health professionals engaged by a birthing center subject to these Rules is responsible for assuring that all facility staff, with responsibility for obstetrical or newborn care, are informed of their respective responsibilities under these Rules.

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 of the Maine Revised Statutes who diagnoses 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 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 of the Maine Revised Statutes who diagnose 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 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 7 days of the diagnosis of a reportable birth defect, whichever occurs first.
2. Diagnosis of a birth defect in a fetal death shall be reported within 7 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 these Rules, individually identifiable information submitted to the 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 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 Birth Defects Program may be required to execute such confidentiality agreements as the 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 Birth Defects Program. Any such Institutional Review Board must be established in conformity with applicable regulations established by the U.S. Department of Health and Human Services including but not limited to *45 CFR, Subtitle A, Part 46, §§ 46.101-46.409.* (Revised as of Oct. 1, 2002).
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 Birth Defects Program.

SECTION 8 CONTACT WITH FAMILIES

1. The 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 Birth Defects Program, including any nursing visit or referral.
4. In the event of a prenatal diagnosis of a reportable birth defect, the 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 these Rules.

SECTION 9 PARENTAL OBJECTION TO PARTICIPATION

1. In the event of parental objection on the basis of sincerely held religious beliefs, neither the hospital, birthing center, nor health care provider subject to these Rules may be required to report the presence of any birth defect.
2. Parental objection to reporting and participation in the 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 Birth Defects Program, based upon sincerely held religious beliefs, the 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

Eye

Anophthalmia/microphthalmia
 Congenital cataract
 Aniridia

Ear

Anotia/microtia

Cardiovascular

Common truncus
 Transportation 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
 (include only if weight=>2500 grams or note
 if unable to exclude <2500 grams infants.)
 Coarctation of aorta

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
 Hirshsprung's disease (congenital megacolon)
 Biliary atresia

Genitourinary

Renal agenesis/hypoplasia
 Bladder exstrophy
 Obstructive genitourinary defect
 Hypospadias and Epispadias

Musculoskeletal

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

Chromosomal

Trisomy 13
 Down syndrome (Trisomy 21)
 Trisomy 18

Other

Fetal alcohol syndrome
 Amniotic bands

STATUTORY AUTHORITY: 22 M.R.S.A. c1687; 22 M.R.S.A. §§ 1532 and 1533

EFFECTIVE DATE:

May 1, 2003 - filing 2003-95

AMENDED:

May 17, 2008 – filing 2008-198

April 1, 2011 – filing 2011-77