**10-144 MAINE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**MAINE CENTER FOR DISEASE CONTROL & PREVENTION**

**DIVISION OF POPULATION HEALTH**

**CHILDREN WITH SPECIAL HEALTH NEEDS: CRITICAL CONGENITAL HEART DEFECTS SCREENING**

**Chapter 709 (new): CRITICAL CONGENITAL HEART DEFECTS SCREENING**

**SUMMARY:** These rules and regulations define the responsibilities of hospital administration and staff, physicians and other health care providers, midwives and other “principal birthing attendants,” and others, with regard to the screening of newborn infants for critical congenital heart defects which if left untreated could cause critical incidents or death. These rules and regulations address the designation of a contact person in each hospital, timing and method of CCHD screening, parental refusal of tests, types of records to be maintained, responsibilities for follow-up and reporting of data collection.

1. **PURPOSE**

These rules implement 22 M.R.S.A. §1532, which requires screening of newborns to detect critical congenital heart defects and submission of data to the Department. Unless the infant’s parent(s) objects on religious grounds, the responsible hospital, birthing center, physician, midwife, principal birthing attendant or other health care provider shall screen each infant either born in the State of Maine or moving to Maine within one month of birth (see Section 5.1 for infants not born in Maine) for critical congenital heart defects.

**2.0 DEFINITIONS**

* 1. “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.
	2. “Birth hospital” means any hospital licensed under the provisions of Title 22 of the Maine Revised Statues which provides health care services to pregnant women and those who give birth.
	3. “CCHD” means Critical Congenital Heart Defects, also known as Critical Congenital Heart Disease, including, but not limited to 7 specific heart defects: hypoplastic left heart syndrome, pulmonary atresia (with intact septum), tetralogy of fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia and truncus arteriosus that may be detectable by pulse oximetry screening.
	4. “Department” means the Maine Department of Health and Human Services including the Maine Center for Disease Control and Prevention (Maine CDC). The Maine CDC Birth Defects Program performs the functions related to these rules.
	5. “ECHO” means echocardiogram, a non-invasive diagnostic method using ultrasound to visualize heart structures
	6. “Health care provider” means a physician, advanced practice nurse or other licensed professional acting as primary health care provider or specialty health care provider caring for an infant or child with a critical congenital heart defect included in the Maine CDC Birth Defects Program.
	7. “Part C Agency” is an agency that meets the definition in the I.D.E.A. (Individuals with Disabilities Education Act). 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 - two years) and Free Appropriate Public Education (FAPE for ages three - five years)
	8. “Principal birthing attendant” means any adult who acts as the principal attendant during a delivery that occurs at a site other than a hospital or birthing center. This may be a midwife or other adult attendant.
	9. “Screening technology” shall be pulse oximetry testing in the right hand and either foot. Screening can occur concurrently or sequentially.

**3.0 RESPONSIBILITY FOR CCHD SCREENING FOR INFANTS BORN IN HOSPITALS OR BIRTHING CENTERS IN MAINE.**

**3.1** The administrator of the hospital or birthing center involved in testing under these regulations shall be responsible for assuring that the hospital has a protocol for screening that includes timing and documentation of screening results as well as risk related protocols for followup of any abnormal screening result (See Section 8 for timing of screening and Section 11 for followup).

**3.2** The administrator of the hospital or birthing center shall be responsible for assuring a screening test for CCHD is performed for each newborn infant prior to his/her discharge from the facility (see Section 8 for timing of the screening, including screening of babies that are preterm, sick or suspected/known to have a heart defect).

**3.3** Each administrator of a hospital or birthing center shall appoint, and provide to the Maine CDC Birth Defects Program, Division of Population Health, Maine Department of Health and Human Services, the name of a contact person at the facility, who shall be responsible for coordinating the facility’s screening activities.

**3.4** No infant shall be discharged until his/her chart is checked to assure that a CCHD screening has been performed and documented including date, time and screening results. The facility employee who assembles the discharge papers before the infant leaves the facility shall check that the screening test has been performed and that this fact has been recorded in the infant’s medical record. If an infant has had a previous ECHO or a known CCHD diagnosis, this shall be noted in the chart documenting the CCHD screen was not required. The fact that the infant has had a CCHD screen shall be included in any discharge instructions that are given to the parent(s) or guardian(s).

**3.5** The contact person shall determine the screening status of all infants admitted to the hospital. If any infant is identified as having been discharged without testing, the contact person shall notify the infant’s physician or other primary health care provider (within 24 hours) and the Maine CDC Birth Defects Program (within 5 working days) of discovering that fact. The health care provider shall then take appropriate steps to have the infant screened within 5 working days.

**3.6** If an infant is transferred to a second facility during the first 48 hours of life, the CCHD screening should be performed at the second facility. The first facility shall clearly indicate in the papers accompanying the infant that the child needs to be screened (see Section 8) and notify the Maine CDC Birth Defects Program of the transfer within 5 working days. This notification can be provided in conjunction with notification to the Maine CDC Newborn Bloodspot Screening Program.

**3.7** All screening results will be recorded in the individual infant’s medical record and provided to the infant’s healthcare provider.

**3.8** The administrator of the hospital or birthing center shall ensure that at least 10% of infants’ medical records are reviewed within 8 weeks after discharge, to assure that screening information, including result, has been recorded

**3.9** The administrator of the hospital or birthing center shall ensure that all employees are informed of their responsibilities with respect to these regulations.

1. **REPORTING**

 **4.1** Suspected or confirmed heart defects shall be reported to the Maine CDC Birth Defects Program as required by 22 M.R.S.A. § 1687, and Chapter 280, Rules related to Maine Birth Defects Program

**4.2** All infants born, transferred to or admitted to a hospital shall have their screening status reported to the Maine CDC Birth Defects Program.

**4.3** Hospitals, birthing facilities and other providers of CCHD screening shall provide the following information to the Maine CDC Birth Defects Program on a weekly to bi-monthly basis:

1. the number of infants born in that hospital or location;
2. the number of infants born in that hospital or location who had a heart defect suspected or diagnosed prenatally;
3. the number of infants born in that hospital or location who received a CCHD screening;
4. the number of infants who received a CCHD screening at that hospital or location who received a negative screen “pass” from the test;
5. the number of infants who received a CCHD screening at that hospital or location who received one or more indeterminate screen results from the test;
6. the number of infants who received one or more indeterminate screen results who were referred for clinical assessment;

# the number of infants who received a CCHD screening at that hospital or location who received a positive screen “fail” from the test;

1. the number of infants with a positive “fail” screen that were referred for clinical assessment and pediatric cardiology consultation and
2. the number of infants whose parents or guardians declined/refused the CCHD screening.

**4.4** The birthing hospital, birthing center or other provider of CCHD screening shall include the information necessary to allow identification of the infant for appropriate tracking and follow-up when reporting to the Department.

**5.0 RESPONSIBILITY FOR CCHD SCREENING FOR INFANTS BORN IN MAINE BUT NOT IN A HOSPITAL OR BIRTHING CENTER.**

**5.1** If an infant is delivered outside a hospital or birthing center by a midwife or other principal birthing attendant who is prepared to perform CCHD screening at the appropriate time (Section 7.0), that person shall do so and report screening results to the Department.

**5.2** This midwife or principal birthing attendant shall record in the infant’s record the fact that CCHD screening was performed, including date, time and screening results.

**5.3** If the midwife or principal birthing attendant is not prepared to perform CCHD screening, he or she shall:

1. inform the parent(s) or guardian(s) about the importance of thescreening test and the State law governing it;
2. direct the parent(s) or guardian(s) to see an individual prepared to perform the CCHD screening test by the 3rd day of life;
3. contact the parent(s) or guardian(s) by the 5th day of life to verify that the infant has been screened; and
4. keep a written record of each of the actions required under this rule.

**6.0 RESPONSIBILITY FOR CCHD SCREENING FOR INFANTS NOT BORN IN MAINE**

**6.1** If an infant is not born in the State of Maine but is, or subsequently becomes, a resident of Maine, the first primary health care provider in Maine who examines the infant in the first month of life should verify whether the infant has been screened, and if not, shall perform a CCHD screen and report the results to the Department unless the parents or guardians refuse the CCHD screening based on religious grounds. The health care provider may rely upon the information in the infant’s medical record to determine whether screening has been done.

1. **RESPONSIBILITY OF THOSE PROVIDING PEDIATRIC SERVICES**

**7.1** Any primary health care provider in Maine who examines an infant for the first time in the first month of life should determine whether the child has been screened for CCHD by checking the infant’s medical records or, if necessary, contacting the Maine CDC Birth Defects Program. If the health care provider determines that no screening has been performed, the provider shall screen the infant for CCHD and report the results to the Department unless the parents or guardians refuse the CCHD screening based on religious grounds.

* 1. Any physician or other health care provider subject to these rules who has identified a case of a child presenting with, or suspected of having, a critical congenital heart defect or other heart defect shall notify the Maine CDC Birth Defects Program of such condition including method of determining diagnosis, by submitting a Confidential Medical Report to the Maine CDC Birth Defects Program within 5 working days of the identification.

**8.0 TIMING OF CCHD SCREENING**

**8.1** For term infants not requiring supplemental oxygen and with no signs of heart defects, the CCHD screen shall be performed between 24 and 48 hours of life.

**8.2** For infants who are discharged within 24 hours of birth, the administrator of the hospital or birthing center shall assure:

1. that the infant’s parent(s) are notified of what they need to do to complete the screening test;
2. that the infant’s primary health care provider is notified of the early discharge and that the required CCHD screen has not been performed; and
3. that such notifications are made a part of the infant’s medical records.

**8.3** For preterm, sick or other infants in intensive care,

* 1. Infants with a previous ECHO or known CCHD diagnosis do not require screening.
	2. Infants not requiring supplemental oxygen and with no signs of heart defects shall be screened as a well infant between 24 and 48 hours of life.
	3. Infants requiring oxygen should be screened 24 hours after weaning to room air unless a previous ECHO has been performed or infant is known to have a CCHD diagnosis.

 **8.4** For infants who have had a suspected or heart defect diagnosed prenatally or postnatally, pulse oximetry screening is not required. Suspected or confirmed heart defects shall be documented in the medical record and reported to the Maine CDC Birth Defects Program.

**9.0 SCREENING TEST PERFORMED**

**9.1** Screening for CCHD shall be performed by pulse oximetry using equipment approved for neonatal use by the FDA (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm)

**9.2** Screening is performed in the right hand and either foot. Screening can occur concurrently or sequentially.

**10.0 PARENTAL REFUSAL OF THE SCREENING TESTS**

**10.1** In the instance of parental refusal of the CCHD screening tests on religious grounds, the parental refusal shall be stated in writing using the refusal form provided or available on the Maine CDC Birth Defects Program website at www.mainepublichealth.gov/birthdefectsand made a part of the infant’s medical record.

**10.2** The administrator of hospitals and birthing centers, principal birthing attendants and primary healthcare providers shall ensure that the Maine CDC Birth Defects Program, Maine Department of Health and Human Services is notified in writing of the parental refusal within 5 days of the infant’s birth.

**11.0 FOLLOW-UP**

**11.1** The administrator of the hospital or birthing center shall assure a protocol is in place to respond to abnormal screening results based on the level of urgency and clinical presentation.

**11.2** For the purpose of coordinating efforts to detect, prevent, and treat CCHD the Department may share individually identifiable health information related to the potential or actual presence of CCHD, with other public health programs and agencies whose mission is to detect, prevent and treat these disorders such as a health department of another state in which a child resides.

**11.3** In order to assess and ensure timely and ongoing treatment related to critical congenital heart defects, and to evaluate the effectiveness of screening and health care services in reducing the morbidity and mortality caused by screened disorders, the Department will collect short and long-term information on individuals confirmed to have a condition included in the program. Healthcare providers will provide requested information within 30 days of request or as otherwise indicated in the request relative to the level of clinical urgency. As needed to ensure patient access to timely and ongoing medical treatment, providers may disclose medical information to the Department in the minimum amount necessary to accomplish the purposes of this regulation. Consent is not required for this disclosure because this rule and the statutes it is based on are made to protect the public health and welfare.

**12.0 REFFERAL**

**12.1** In compliance with part C of The I.D.E.A. (Individuals with Disabilities Education Act), the Maine CDC Birth Defects Program screening will refer a newborn with a confirmed heart defect that has the potential to develop a developmental delay to the Part C agency.

**13.0 PROGRAM’S RESPONSIBILITY TO MAINTAIN CONFIDENTIALITY OF ALL DATA**

**13.1** All data reported to the Program, which contains either direct or indirectly individually identifiable information shall be confidential and is not considered a public record.

**13.2** Unless the person or his/her legal authorized representative specifically prohibits such use in writing, the information obtained during the screening process may be used for program evaluation or program related research.

**13.3** Any report produced from data collection will be in a form that does not allow direct or indirect identification of individuals.

**13.4** A standard Institutional Review Board process conforming to all applicable state and federal laws is required for any proposed research plan that involves the use of any Maine CDC Birth Defects Program data. Approval by the Maine CDC Institutional Review Board must be documented prior to the release of any data.

STATUTORY AUTHORITY: 22 MRSA § 42, 1532 and 1533

EFFECTIVE DATE:

AMENDED:

EFFECTIVE DATE (ELECTRONIC CONVERSION):

AMENDED: