

**R398. Health, Family Health and Preparedness, Children with Special Health Care Needs.**

**R398-5. Birth Defects and Critical Congenital Heart Disease Reporting.**

**R398-5-1. Authority and Purpose.**

(1) This rule is authorized by sections 26-1-30(5), (6), (7), (9), (18), (22), 26-10-1(2), 26-10-2, and 26-10-6(1)(d).

(2) This rule establishes reporting requirements for birth defects, critical congenital heart disease, and stillbirths in Utah and for related test results.

**R398-5-2. Definitions.**

As used in this rule:

(1) "Birth defect" means any medical disorder of organ structure, function or biochemistry which is of possible genetic or prenatal origin. This includes any congenital anomaly, indication of hypoxia or genetic metabolic disorder listed in the ICD-9-CM (International Classification of Diseases, 9th Revision, Clinical Modification, established by the United States Center for Health Statistics) with any of the following diagnostic codes: 243, 255.2, 255.4, from 269.2 to 279.9, from 740.0 to 759.9, 760.72, from 768.0 to 768.9, and 779.5 or listed in the ICD-10 (International Classification of Diseases, 10th Revision, established by the World Health Organization) with any of the following diagnostic codes: A92.5, E03, E25, from E70 to E90, from D55 to D58, H90.0 to H90.8, H90.A, H91.0 to H91.9, J96.00 to J96.91, P09, P35.1, P35.4, P96.1 to P96.2 and from Q00 to Q99.

(2) "Birthing center" means a birthing center licensed under Title 26, Chapter 21.

(3) "CCHD" means Critical Congenital Heart Disease.

(4) "Clinic" means physician-owned or operated clinic which regularly provide services for the diagnosis or treatment of birth defects, genetic counseling, or prenatal diagnostic services.

(5) "Critical Congenital Heart Disease (CCHD) Screening" is a non-invasive test using pulse oximetry measuring how much oxygen is in the blood and can help to identify newborns affected with CCHD. Screening should begin after 24 hours of age or shortly before discharge if the baby is less than 24 hours of age.

(6) "Department" means the Utah Department of Health, Utah Birth Defect Network and Critical Congenital Heart Disease programs.

(7) "Hospital" means general acute hospital, children's specialty hospital, remote-rural hospital licensed under Title 26, Chapter 21.

(8) "Institution" means a hospital, alternate birthing facility, or midwife service providing maternity or nursery services or both.

(9) "SpO2" stands for peripheral capillary oxygen saturation, an estimate of the amount of oxygen in the blood.

(10) "Stillbirth" means a pregnancy resulting in a fetal death at 20 weeks gestation or later.

### **R398-5-3. Birth Defects Reporting.**

Each hospital, clinic, institution, or birthing center which admits a patient and detects or screens for a birth defect as a result of any outcome of pregnancy, or admits a child under 24 months of age with a birth defect, or is presented with the event of a stillbirth shall report or cause to report to the department within 40 days of discharge the following:

- (1) if live born, child's name;
  - (a) last name;
  - (b) first name;
- (2) child's date of birth (or date of delivery);
- (3) child's medical record number;
- (4) child's gender;
- (5) mother's name;
  - (a) last name;
  - (b) first name;
  - (c) maiden name;
- (6) mother's date of birth;
- (7) mother's medical record number;
- (8) delivery institution;
- (9) ICD - 9 - CM or ICD - 10 birth defect codes;
- (10) mother's state of residency at delivery; and
- (11) mother's zip code of residency at delivery.

### **R398-5-4. Birth Defects Reporting by Laboratories.**

Each laboratory operating in the state which identifies a human chromosomal or genetic abnormality or other evidence of a birth defect shall report the following on a calendar quarterly basis to the department within 40 days of the end of the preceding calendar quarter:

- (1) if live born, child's name;
  - (a) last name;
  - (b) first name;
- (2) child's date of birth;
- (3) mother's name;
  - (a) last name;
  - (b) first name;
- (4) mother's date of birth;
- (5) date the sample is accepted by the laboratory;
- (6) test conducted;
- (7) test result; and
- (8) mother's state of residency at delivery.

**R398-5-5. Critical Congenital Heart Disease (CCHD) Screening Reporting.**

CCHD Screening results shall report or cause to report to the department within 40 days of discharge the following:

- (1) newborn's name;
  - (a) last name;
  - (b) first name;
- (2) newborn's date of birth;
- (3) newborn's gender;
- (4) newborn's gestational age;
- (5) newborn's birth weight;
- (6) newborn's medical record number;
- (7) newborn's newborn screening kit number;
- (8) newborn's delivery institution;
- (9) newborn's discharge unit (if applicable);
- (10) newborn's CCHD Screening result for each attempt:
  - (a) date;
  - (b) time;
  - (c) probe location;
  - (d) SpO2 result; and
  - (e) outcome of attempt.
- (11) Newborn's first echocardiogram (if indicated):
  - (a) date; and
  - (b) time.
- (12) mother's name;
  - (a) last name;
  - (b) first name;
  - (c) maiden name;
- (13) mother's date of birth; and
- (14) mother's medical record number.

**R398-5-6. Record Abstraction.**

Hospitals, birthing centers, institutions, and clinics as well as community health care providers shall allow personnel from the department or its contractors to abstract information from the mother's and child's files on their demographic characteristics, family history of birth defects, prenatal and postnatal procedures or treatments (including diagnostics) related to the birth defect or stillbirth, and outcomes of this and other pregnancies of the mother. Hospitals, birthing centers, institutions, and clinics as well as community health care providers shall allow personnel from the department or its contractors to abstract information from the affected child's files, throughout their lifespan.

**R398-5-7. Liability.**

As provided in Title 26, Chapter 25, persons who report,

either voluntarily or as required by this rule, information covered by this rule may not be held liable for reporting the information to the Department of Health.

**R398-5-8. Penalties.**

Pursuant to Section 26-23-6, any person that willfully violates any provision of this rule may be assessed an administrative civil money penalty not to exceed \$1,000 upon an administrative finding of a first violation and up to \$3,000 for a subsequent similar violation within two years. A person may also be subject to penalties imposed by a civil or criminal court.

**KEY: birth defects, birth defect reporting, critical congenital heart disease (CCHD), CCHD screening**

**Date of Enactment or Last Substantive Amendment: March 11, 2019**

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**Authorizing, and Implemented or Interpreted Law: 26-1-30(2)(c), (d), (e), (g), (p), (t); 26-10-1(2); 26-10-2; 26-25-1**