

APA-1  
4/18

**TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION**

Control 420 Alabama Department of Public Health

Rule Number 420-10-3

Rule Title Birth Defects Surveillance Program

XXXX New  Amend  Repeal  Adopt by Reference

Would the absence of the proposed rule significantly harm or endanger the public health, welfare or safety? Yes

Is there a reasonable relationship between the state's police power and the protection of the public health, safety or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved and, if so, to what degree? No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule? No

Are all facts of the rulemaking process designed solely for the purpose of and so they have as their primary effect, the protection of the public? Yes

Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? No

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of §41-22-23, Code of Alabama, 1975.

**Certification of Authorized Official**

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama, 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of Certifying Officer *P. Ron Hale*

Date 7/10/19 2019 JUL 18 PM 3:57

LEGISLATIVE SVC AGENCY

**FORM APA2**  
**10/17**

**STATE BOARD OF HEALTH**  
**NOTICE OF INTENDED ACTION**

AGENCY NAME: Alabama Department of Public Health

RULE NUMBER AND TITLE: 420-10-3, Birth Defects Surveillance Program

INTENDED ACTION: To create a birth defects registry

SUBSTANCE OF PROPOSED ACTION: This new rule will allow for the Department to create a birth defects registry in children birth to 3 years of age for the purpose to conduct surveillance of birth defects.

TIME, PLACE, AND MANNER OF PRESENTING VIEWS: A public hearing will be held on August 22, 2019, at 10:00 a.m., at the RSA Tower, Suite 1540, 201 Monroe Street, Montgomery, AL 36104.

FINAL DATE FOR COMMENTS AND COMPLETION OF NOTICE: Written or oral comments will be received until the close of the record at 5:00 p.m. on September 4, 2019. All comments and requests for copies of the proposed amendments should be addressed to the contact person listed below.

CONTACT PERSON AT AGENCY: Rachael Montgomery, Office of Family Health Services, Department of Public Health, P.O. Box 303017, Montgomery, Alabama 36130-3017, Telephone number: (334) 206-5955.



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P. Brian Hale, Agency Secretary

ALABAMA STATE BOARD OF HEALTH  
ALABAMA DEPARTMENT OF PUBLIC  
HEALTH BUREAU OF FAMILY HEALTH  
SERVICES ADMINISTRATIVE CODE

CHAPTER 420-10-3  
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BIRTH DEFECTS SURVEILLANCE PROGRAM

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**420-10-3-.01 Purpose.**

The State Department of Health shall establish and maintain a birth defects registry which shall contain a confidential record of all birth defects that occur in Alabama in children ages birth to 3 years and any other information that the department deems necessary and appropriate in order to conduct thorough and complete surveillance of birth defects and assist with health and early intervention services to children with birth defects and their families.

**Authors:** Rachael N. Montgomery, B.S.N., R.N.

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2, 22-20-3, 22-11A-1.

**History:** New Rule: Filed XX-XX-XXXX.

**420-10-3-.02 Definitions.**

- (1) **Birth Defect** - structural, functional, or biochemical abnormality regardless of cause and irrespective of any known genetic or environmental association(s); whether manifest prenatally, at delivery, or at a later date up to 3 years of age and that may interfere with normal growth or development.
- (2) **Birth Defects Registry** - the central databank containing collected, classified, and coded stored data relating to reported diagnoses of birth defects.
- (3) **Department** - the Alabama Department of Public Health.
- (4) **Diagnosis** - a physician's opinion, derived from physician observation, procedures, or tests of a patient, which identifies a birth defect.
- (5) **Health Care Facility** - any facility or institution located in Alabama, whether public or private, proprietary or not for profit, including but not limited to hospitals and other

outpatient facilities such as clinics that provide services for the diagnosis or treatment of birth defects to pregnant women, newborns, and children up to 3 years of age.

(6) **Individually Identifiable Health Information** - information that is a subset of health information, including demographic information, and is created or received by the department that identifies the individual.

(7) **Health Care Provider** - any licensed physician or practitioner who makes a diagnosis.

(8) **Public Health Authority** - an agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, or an indian tribe, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.

(9) **Report** - an official notice to the department of a diagnosis of a birth defect using such forms and means as determined by the State Health Officer.

**Authors:** Rachael N. Montgomery, B.S.N., R.N.

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2, 22-20-3.

**History:** New Rule: Filed XX-XX-XXXX.

#### **420-10-3.03      Reporting.**

(1) Responsibility for Reporting. Each health care facility, health care provider, or physician who diagnoses the birth defect or provides treatment to the infant or child for the birth defect shall be responsible to report diagnoses of the designated birth defects made prenatally, at delivery, and up to 3 years of age to the department as the State Health Officer considers necessary and appropriate for the prevention and early detection of birth defects to facilitate health surveillance of the incidence and prevalence of birth defects in Alabama. Each report shall include the following data categories:

- a. Mother's individual identifiable health information and demographics;
- b. Child (birth to 3) or fetal death identifiable health information and demographics;
- c. Health care provider and facility contact information;
- d. Specific birth defects identification;
- e. Diagnosis; and
- f. Other information as necessary to identify the patient and ensure accuracy and completeness.

(2) Every diagnosis of a birth defect detected prenatally, at delivery, or within the first 3 years of life is required to be reported to facilitate epidemiological investigation and health

surveillance of the incidence and prevalence of birth defects in Alabama.

(3) A diagnosis regarding an Alabama resident is required to be reported within 30 days of diagnosis by an Alabama health care provider treating a resident child up to 3 years of age, irrespective of whether the birth occurred inside or outside Alabama.

(4) A diagnosis regarding a non-resident child who may come to Alabama for specialty treatment, evaluation, or consultation is not required to be reported.

(5) The department may not require a health care provider or health care facility to report the name of an infant or child for whom a report is made if the parent or guardian of the infant or child states in writing that he or she refuses to release the name or address of the infant or child.

(6) No health care facility, health care provider, or physician need report a birth defect if that person knows that another health care facility, health care provider, or physician has already reported to the department the required information with respect to the same birth defect of the same infant or child.

**Authors:** Rachael N. Montgomery, B.S.N., R.N.

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2, 22-11A-1.

**History:** New Rule: Filed XX-XX-XXXX.

**420-10-3-.04 Designation of Birth Defects.**

The State Board of Health hereby designates the following as birth defect diagnoses subject to reporting and notification requirements herein below specified and maintains the authority for adding or deleting conditions as needed.

| <b>Birth Defect</b>   |
|---|
| <b>Central Nervous System</b>                               |
| Anencephalus  |
| Spina bifida without anencephalus                           |
| Encephalocele   |
| <b>Eye and Ear</b>  |
| Anophthalmia /microphthalmia                                |
| Anotia/microtia   |
| <b>Cardiovascular</b>                                       |
| Aortic valve stenosis                                       |
| Atrial septal defect  |
| Atrioventricular septal defect (Endocardial cushion defect) |
| Coarctation of the aorta                                    |
| Common truncus (truncus arteriosus)                         |
| Double outlet right ventricle (DORV)                        |
| Ebstein anomaly   |

|  |
|--|
| Hypoplastic left heart syndrome              |
| Interrupted aortic arch                      |
| Pulmonary valve atresia and stenosis         |
| Single Ventricle                             |
| Tetralogy of Fallot                          |
| Total anomalous pulmonary venous connection  |
| Transposition of the great arteries          |
| Tricuspid valve atresia and stenosis         |
| Ventricular septal defect                    |
| <b>Craniofacial</b>                          |
| Choanal atresia                              |
| Cleft lip with cleft palate                  |
| Cleft lip alone (without cleft palate)       |
| Cleft palate alone (without cleft lip)       |
| <b>Gastrointestinal</b>                      |
| Esophageal atresia/tracheoesophageal fistula |
| Rectal and large intestinal atresia/stenosis |
| Small intestinal atresia/stenosis            |
| <b>Genitourinary</b>                         |
| Bladder exstrophy                            |
| Cloacal exstrophy                            |
| Congenital Posterior Urethral Valves         |
| Hypospadias                                  |
| Renal agenesis/hypoplasia                    |
| <b>Musculoskeletal</b>                       |
| Clubfoot                                     |
| Diaphragmatic hernia                         |
| Gastroschisis                                |
| Limb deficiencies (reduction defects)        |
| Omphalocele                                  |
| <b>Chromosomal</b>                           |
| Trisomy 13                                   |
| Trisomy 18                                   |
| Trisomy 21 (Down syndrome)                   |

Others as identified by the State Board of Health.

**420-10-3-.05 Access to Data and Records.**

(1) When a reported birth defect diagnosis occurs in Alabama in the office of an individual health care provider or in a health care facility with a maternal-newborn service, neonatal intensive care unit, special care nursery service, continuing care nursery service, pediatric service, pediatric intensive care unit or with a medical specialty service and when an individual health care provider or his or her agent has not provided complete information that the State Health Officer

requires for reporting, authorized abstractors shall be given access to those parts of the medical records which are necessary to obtain information of children suspected or diagnosed as having birth defects, including the medical records of their mothers.

(2) Information from medical records of children and their parents relating to diagnostic information regarding designated birth defects diagnosed prenatally, at delivery, and up to 3 years of life is required to be reported to the department without patient consent.

(3) The department shall require for reporting no more information than the State Health Officer considers necessary and appropriate to conduct surveillance activities to include preventative treatment and control measures for birth defects. The department shall not require reporting of social security numbers.

(4) Access to the central Birth Defects Registry information is limited to authorized department employees. The Department shall maintain a listing of each person who is given access to the information in the registry that shall include:

- a. The name of the person authorizing access;
- b. The name, title, and organizational affiliation of each person given access;
- c. The dates of access; and
- d. The specific purpose for which the information was used.

(5) The department shall maintain confidentiality of reports or information submitted to the Birth Defects Registry and shall comply with applicable statewide records retention schedules in the event that a decision is made that the information maintained or stored in connection with this registry is no longer needed.

(6) Under federal law, Health Information Portability and Accountability Act, the department is permitted to disclose birth defects registry information to other public health authorities, for the "purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions" (45 CFR §164.512 (b) (1) (i)).

**Authors:** Rachael N. Montgomery, B.S.N., R.N.

**Statutory Authority:** Code of Ala. 1975, §§ 22-2-2, 22-20-3.

**History:** New Rule: Filed XX-XX-XXXX.