DEPARTMENT OF HEALTH AND HUMAN SERVICES

DIVISION FOR VITAL RECORDS AND HEALTH STATISTICS

BIRTH DEFECTS REPORTING

Filed with the Secretary of State on December 19, 2017

These rules become effective immediately upon filing with the Secretary of State unless adopted under section 33, 44, or 45a(6) of 1969 PA 306. Rules adopted under these sections become effective 7 days after filing with the Secretary of State.

(By authority conferred on the department of health and human services by section 5721 of 1978 PA 368, MCL 333.5721 and Executive Reorganization Order No. 1996-1, MCL 330.3101.)

R 325.9071, R 325.9072, R 325.9075 are amended; and R 325.9077 is added to the Michigan Administrative Code as follows:

R 325.9071 Definitions.

Rule 1. (1) As used in these rules:

(a) "Birth defect" means an abnormality of the body's structure or inherent function present at birth, whether the abnormality is detected in utero at the time of delivery or becomes apparent at a later date.

(b) "Birth defects registry" means the data base that contains individual case level demographic and diagnostic information maintained by the department.

(c) "Department" means the department of health and human services.

(d) "Institutional Review Board for the Protection of Human Research Subjects (IRB)" means the board within the department of health and human services that is established under 45 CFR 46.

(e) "Registrant" means a child who is diagnosed with a reportable birth defect.

(f) "Reporting entity" means a hospital, clinical laboratory, physician, genetic counselor, health clinic, and other health professional or health facility required to report birth defects under R 325.9072.

(2) The terms "clinical laboratory" and "hospital," as defined in sections 20104 and 20106, 1978 PA 368, MCL 333.20104 and 333.20106 have the same meanings when used in these rules.

R 325.9072 Reportable birth defects.

Rule 2. (1) Reportable birth defects are those birth defects identified in the following list of medical conditions:

(a) Congenital anomalies of the central nervous system.

(b) Congenital anomalies of the eye.

(c) Congenital anomalies of the ear, face, and neck.

(d) Congenital anomalies of the heart and circulatory system.

(e) Congenital anomalies of the respiratory system.

(f) Cleft palate and cleft lip.

(g) Congenital anomalies of the upper alimentary canal/ digestive system.
(h) Congenital anomalies of the genital and urinary systems.
(i) Congenital anomalies of the musculoskeletal system.
(j) Congenital anomalies of the integument.
(k) Chromosomal anomalies.
(2) Other congenital anomalies, including the following:
(a) Infectious conditions occurring in the perinatal period, including the following:
(i) Syphilis.
(ii) Congenital rubella.
(iii) Cytomegalovirus.
(iv) Listeriosis.
(v) Herpes simplex.
(vi) Malaria.
(vii) Toxoplasmosis.
(viii) Tuberculosis.
(ix) Zika.
(b) Familial/congenital neoplasms.
(c) Endocrine/metabolic disorders.
(d) Diseases of the blood and blood forming organs including the following:
(i) Hereditary hemolytic anemias.
(ii) Familial hypoplastic anemia.
(iii) Coagulation defects.
(iv) Primary thrombocytopenia.
(e) Diseases of the central and peripheral nervous system, including the following:
(i) Cerebral lipidoses.
(ii) Cerebral degeneration.
(iii) Hereditary spastic paraplegia.
(iv) Cerebral palsy.
(v) Werdnig-hoffman disease.
(vi) Disorders of the autonomic nervous system.
(vii) Cerebral palsy and spasms.
(viii) Cerebral cysts.
(ix) Polyneuritis cranialis.
(x) Hereditary and idiopathic peripheral neuropathy.
(xi) Myoneural disorders.
(xii) Muscular dystrophies and other myopathies.
(f) Diseases of the eye, including the following:
(i) Retinal disorders.
(ii) Chorioretinitis.
(iii) Blindness and low vision.
(iv) Hereditary optic atrophy and nystagmus.
(v) Any other irregular movement of the eye.
(g) Hearing deficiency, including structural and functional deficiencies.
(h) Diseases of the heart and circulatory system including the following:
(i) Cardiomyopathy.
(ii) Conductive cardiac disorders.

(iii) Dysrhythmias.
(iv) Occlusions of coronary arteries.
(v) Budd-chiari syndrome.
(i) Diseases of the gastrointestinal system, including the following:
(i) Anomalies of teeth, jaw, or hernia.
(ii) Stricture.
(iii) Volvulus.
(iv) Fistula of organs.
(j) Diseases of the genital and urinary systems involving fistula and obstruction.
(k) Fetal/placental anomalies.
(l) Musculoskeletal system diseases involving abnormal bone growth.
(m) Maternal causes of fetal morbidity, including the following:
(i) Infections, including those infections specified in subrule (2)(a) of this rule.
(ii) Alcohol use including fetal alcohol spectrum disorders.
(iii) Cocaine use, opioid use, and other toxic or medicinal agents affecting the fetus.
(n) Autism spectrum disorders, including Asperger syndrome and Rett syndrome.

(2) Diagnoses of birth defects that occur in children from birth to 2 years of age shall be reported to the department by those entities listed in subrules (3), (4), and (5) of this rule in a manner that is consistent with these rules. This subrule applies whether or not a child dies 2 years of age. The director of the department may designate the reporting of birth defects, diagnosed up to and including 12 years of age, for medical conditions that require surveillance and are commonly diagnosed after 2 years of age, including, but not limited to, any of the following:
(a) Fetal alcohol spectrum disorders.
(b) Cystic fibrosis.
(c) Muscular dystrophy.
(d) Autism.
(e) Cerebral palsy.

(3) Hospitals shall report diagnoses of birth defects. The administrative officer of each reporting facility shall establish the reporting procedures at that facility. These procedures shall ensure that every child from birth to 2 years of age, or up to 12 years of age for defects designated under subrule (2) of this rule, who is diagnosed either in the facility operated inpatient or outpatient setting as having a birth defect is reported to the birth defects registry. If a child is transported to another facility, the health care facility at which a reportable diagnosis is first made is responsible for reporting.

(4) Clinical laboratories shall report diagnoses of birth defects. The director of a laboratory that conducts postmortem examinations or cytogenetic tests shall report to the department any potential registrant who has a reportable birth defect.

(5) The director may designate diagnoses of birth defects to be reported by physicians, genetic counselors, health clinics, and other health professionals or health facilities involved in the diagnosis or treatment of children with birth defects as necessary to assure efficient and comprehensive surveillance of birth defects.

(6) Diagnoses of birth defects may be reported by local public health officials, other programs within the department, and by programs in other departments that provide treatment, services, medical, or other benefits to children with birth defects and their families.

(7) Reports shall be submitted within 30 days of a diagnosis in a form prescribed and approved by the department.

(8) Reports that are submitted on forms provided by the department or by electronic media shall meet data quality, format, and timeliness standards prescribed by the department, as described in the manual for completing the birth defects registry report form.

R 325.9075 Scientific advisory panel; release of information for research.

Rule 5. (1) The director of the department shall appoint a scientific advisory panel of not less than 3 scientists to review research proposals for which a release of information which is maintained by the department and which identifies an individual reported to have a diagnosis of a birth defect is required.

(2) The scientific advisory panel shall review a research proposal that requires the release of information that identifies an individual who has a reported diagnosis of a birth defect.

(3) The panel shall, in writing, advise the director on the merits of the study.

(4) The study or research project shall not publish the name of any individual who is or was the subject of a report of a birth defect that was submitted to the department. The study or research project shall not release any identifying number, mark, or description that can be readily associated with an individual who is or was the subject of a report of a birth defect that was submitted to the department. A formal memorandum of agreement that is signed by an authorized representative of the department and the director of the research project shall include all of the following provisions:

(a) That electronic files, optical files, or hard copy of the data provided by the department shall not be copied for retention, resold, or otherwise provided to another person or agency and will be returned to the department upon completion of processing of the study.

(b) That any reports or published papers relying in whole or in part on the data furnished by the department to the study or research project shall acknowledge the Michigan birth defects registry of the Michigan department of health and human services as the source of the data.

(c) That a prepublication copy of all resulting papers shall be sent to the department at least 15 days before to the expected date of publication.

R 325.9077 Exchange of records.

Rule 7. The department, by agreement, may transmit transcripts or copies of reports of birth defects diagnoses to state or national birth defects registries when the reports relate to residents of other states or countries. The agreement shall require that the transcripts or records be used only for statistical or research purposes, or to offer referrals to medical and other support services.