DEPARTMENT OF COMMUNITY HEALTH

DIVISION FOR VITAL RECORDS AND HEALTH STATISTICS

BIRTH DEFECTS REPORTING

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

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 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 community health.

(d) "Institutional Review Board for the Protection of Human Research Subjects (IRB)" means the board within the department of community health 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.

History: 1991 AACS; 2011 AACS.

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.

(b) Familial/congenital neoplasms.

(c) Endocrine/metabolic disorders.

(d) Diseases of the blood & 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 & circulatory system including the following:
(i) Cardiomyopathy.
(ii) Conductive cardiac disorders.
(iii) Dysrhythmias.
(iv) Icclusions 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.
(ii) Alcohol use including fetal alcohol spectrum disorders.
(iii) Cocaine use and other toxic or medicinal agents affecting the fetus.
(n) Autism spectrum disorders, including Asperger's syndrome and Rett's syndrome.

(2) Diagnoses of birth defects that occur in children from birth to 2 years old shall be reported to the department in a manner that is consistent with these rules. This subrule applies whether or not a child dies before the age of 2. 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 the age of 2 years, 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) Diagnoses of birth defects shall be reported by hospitals. 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 age 12 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 shall be 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) Diagnoses of birth defects shall be reported by clinical laboratories. 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.

History: 1991 AACS; 2011 AACS.

R 325.9073 Quality assurance.

Rule 3. (1) For the purposes of assuring the quality of submitted data, each reporting entity shall allow the department or an authorized agent of the department, with not less than 5 working days' notice and during reasonable working hours, to inspect the parts of a patient's medical records as necessary to verify the accuracy of the submitted data.

(2) A reporting entity shall, upon the request of the department, supply missing information, if known, or clarify information submitted to the department.

(3) Upon mutual agreement between a reporting entity and the department, the reporting entity may elect to submit copies of medical records instead of on-site inspection of the records by the department. Each copy of a medical record or part thereof that is submitted to the department under this rule shall be used only for verification of corresponding reported data, shall not be recopied by the department, and shall be kept in a locked file cabinet when not being used. The copies shall be promptly destroyed following verification of the corresponding reported data or, if the reported data appears to be inaccurate, following clarification or correction of the reported data.

(4) Both of the following provisions shall be complied with to preserve the confidentiality of each patient's medical records:

(a) Each reporting entity, when requested, shall provide the department with, for inspection only, all of the following records and reports:

(i) Reports of diagnoses of birth defects and notations of the reasons for such diagnoses, including the primary clinician's reports and consultation reports.

(ii) Those parts of medical records that contain the specific information required to be reported.

(b) A reporting entity shall not be required by this rule to allow the inspection of any part of any patient's record other than those parts specified in subrule (1) of this rule. A reporting entity may allow the inspection of medical records from which parts, other than those specified, have been deleted, masked, crossed out, or otherwise rendered illegible.

History: 1991 AACS; 2011 AACS.

R 325.9074 Confidentiality of reports.

Rule 4. (1) The department shall maintain the confidentiality of all reports of birth defects submitted to the department and shall not release such reports or any information which, because of name, identifying number, mark, or description, can be readily associated with a particular individual, except in

accordance subrules (2), (3), (4), (5), and (6) of this rule. The department shall not release any information that would indicate if the name of a particular person is listed in the registry, except in accordance with subrules (2), (3), (4), (5), and (6) of this rule.

(2) A report of birth defects that is submitted to the department concerning a particular individual, and any other information maintained in the birth defects registry reporting system which, because of name, identifying number, mark, or description, can be readily associated with a particular individual, shall be released only as follows:

(a) To the particular individual upon compliance with both of the following provisions:

(i) Receipt of a written request which is signed by the particular individual and which is witnessed or notarized as required by subrule (3) of this rule.

(ii) Presentation by the particular individual of suitable identification as required by subrule (4) of this rule.

(b) If the particular individual is a minor, to a parent of the particular individual upon compliance with all of the following provisions:

(i) Receipt of a written request which is signed by the parent and which is witnessed or notarized as required by subrule (3) of this rule.

(ii) Receipt of a certified copy of the birth certificate of the particular individual.

(iii) Presentation by the parent of suitable identification as required by subrule (4) of this rule.

(c) If the particular individual has a court-appointed guardian or if the particular individual is deceased, then to the court-appointed guardian or to the executor or administrator of the particular individual's estate upon compliance with all of the following provisions:

(i) Receipt of a written request which is signed by the court-appointed guardian, executor, or administrator and which is witnessed or notarized as required subrule (3) of this rule.

(ii) Receipt of a certified copy of the order or decree which appoints the guardian, executor, or administrator.

(iii) Presentation by the guardian, executor, or administrator of suitable identification as required by subrule (4) of this rule.

(d) To an attorney or other person who is designated by the particular individual upon compliance with both of the following provisions:

(i) Receipt of a written request which is signed by the particular individual, which is witnessed or notarized as required by subrule (3) of this rule, and which requests release of the information to the attorney or other person.

(ii) Presentation by the attorney or other person of suitable identification as required by subrule (4) of this rule.

(e) To an attorney or other person who is designated by the court-appointed guardian of the particular individual or who is designated by the executor or administrator of the estate of the particular individual upon compliance with all of the following provisions:

(i) Receipt of a written request which is signed by the court-appointed guardian, executor, or administrator, which is witnessed or notarized as required by subrule (3) of this rule, and which requests release of the information to the attorney or other person.

(ii) Receipt of a certified copy of the order or decree which appoints the guardian, executor, or administrator.

(iii) Presentation by the attorney or other person of suitable identification as required by subrule (4) of this rule.

(f) If the particular individual is a minor, to an attorney or other person who is designated by the parent of the particular individual upon compliance with all of the following provisions:

(i) Receipt of a written request which is signed by the parent, which is witnessed or notarized as required by subrule (3) of this rule, and which requests release of the information to the attorney or other person.

(ii) Receipt of a certified copy of the birth certificate of the particular individual.

(iii) Presentation by the attorney or other person of suitable identification as required by subrule (4) of this rule.

(3) Every written request for the release of information that is submitted under subrule (2) of this rule shall be signed by the person who makes the written request. The signature shall comply with either of the following provisions:

(a) Be witnessed by an employee of the department who has been designated to witness such requests and to whom the person making the request presents suitable identification as required by subrule (4) of this rule.

(b) Be notarized by a notary public or magistrate.

(4) Any person who is required by subrule (2) or (3) of this rule to present suitable identification shall present an identification document, such as a driver's license, or other document which contains both a picture of the person and the signature or mark of the person.

(5) The director may, under R 325.9074 and R 325.9075, release information from the birth defects registry to an authorized representative of a study or research project that shall be reviewed by a scientific advisory panel, reviewed and approved by the department's IRB, and approved by the director. The process for release of information that identifies the registrant shall be as set forth in this subrule for any research proposals that require contact with the family of the child including direct contact with the child. After the proposal for the research has been reviewed and approved under R 325.9075, and before any information is released to the researcher, information shall be sent to the parent or parents or legal guardian of the registrant or to the registrant, if an adult, that describes the goals and process of the research project. The parent, parents, or legal guardian or registrant, as appropriate, shall be asked to indicate if he or she wishes to participate in the project. The name of the registrant shall only be released to the director of the research project when the parent, parents, or legal guardian grants approval for such release. The department shall not release any part of a patient's medical record obtained under R 325.9073.

(6) The director may authorize information from the birth defects registry to be used within the department or by an authorized agent of the department, including a local health department, to offer medical and other support services to the registrant. The department may contact the parent, parents, or legal guardian or registrant, if an adult, who is identified in the birth defects registry to offer referral to medical and other support services as appropriate. The department shall not release any part of a patient's medical record obtained under R 325.9073.

History: 1991 AACS; 2011 AACS.

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) A research proposal that requires the release of information that identifies an individual who has a reported diagnosis of a birth defect shall be reviewed by the scientific advisory panel.

(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 public health 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 prior to the expected date of publication.

History: 1991 AACS.

R 325.9076 Rescinded.

History: 1991 AACS; 2011 AACS.