CHAPTER 4
CONGENITAL AND INHERITED DISORDERS

[Prior to 7/29/87, Health Department[470]]

Chapter rescission date pursuant to Iowa Code section 17A.7: 8/1/30

641—4.1(136A) Definitions. For the purposes of this chapter, the following definitions apply:

"Anonymized specimen" means a specimen that cannot be traced back to or linked with the particular individual from whom the specimen was obtained.

"Attending health care provider" means the same as defined in Iowa Code section 136A.2.

"Birth defect" means any major structural abnormality or metabolic disorder that may adversely affect a child's health and development. The abnormality or disorder must be diagnosed or its signs and symptoms must be recognized within the first two years of life.

"Birthing facility" means a private or public facility licensed pursuant to Iowa Code chapter 135B that has a licensed obstetric unit or is licensed to provide obstetric services.

"Central laboratory" means the state hygienic laboratory (SHL), which is designated as the screening laboratory to perform testing and reporting for the Iowa newborn screening and Iowa maternal prenatal screening programs.

"Central registry" means the Iowa registry for congenital and inherited disorders (IRCID).

"Congenital condition" means a condition that exists at birth and may be hereditary, result from an action or exposure occurring during pregnancy or at birth, or may be due to a combination of both factors.

"Consulting physician" means a physician designated by the center for congenital and inherited disorders to interpret screen results and provide consultation to a licensed health care provider.

"Council" means the council on health and human services.

"Critical congenital heart disease" or *"CCHD"* means the presence of one or more of the following specific heart lesions: hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus.

"Discharge" means a release of an infant from a hospital or birth center.

"Early ACCESS" means the statewide, comprehensive, interagency system of integrated early intervention services that supports eligible children and their families as defined in 281—Chapter 120.

"Early hearing detection and intervention program" means Iowa's newborn hearing screening and follow-up program, which ensures that all newborns and toddlers with hearing loss are identified as early as possible and provided with timely and appropriate audiological, educational and medical intervention and family support.

"Follow-up program" means the services provided to follow up on an abnormal screening result.

"Guardian" means a person who is not the parent of a minor child, but who has legal authority to make decisions regarding life or program issues for the child.

"Health care provider" means a licensed physician, nurse practitioner, certified nurse midwife, registered nurse, or physician assistant providing medical care to an individual.

"Iowa maternal prenatal screening program" or *"IMPSP"* means a program that provides a screening test designed to identify increased risk of having a baby with a congenital or inherited disorder or developing a problem later in pregnancy.

"Iowa newborn screening panel" or *"newborn screening panel"* means the list of disorders for which the department screens Iowa newborns.

"Iowa newborn screening program" or *"INSP"* means a program that provides screening of live-born Iowa newborns for the disorders listed on the Iowa newborn screening panel.

"Neuromuscular disorder" means Duchenne, Becker, congenital, distal, Emery-Dreifuss, facioscapulohumeral, limb-girdle, myotonic, and oculopharyngeal muscular dystrophy.

"Newborn critical congenital heart disease (CCHD) screening" means the screening of newborns for seven targeted heart conditions (hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot,

total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus) using pulse oximetry or other means to detect blood oxygen saturation levels.

"Primary health care provider" means a licensed physician, physician assistant, nurse practitioner, or certified nurse midwife providing ongoing primary medical care to a patient.

"Receiving facility" means the facility receiving an infant from a birthing facility.

"Residual maternal prenatal serum screening specimen" means the portion of the specimen that may be left over after all necessary activities of the Iowa maternal prenatal screening program are completed.

"Residual newborn screening specimen" means the portion of the dried blood spot specimen that may be left over after all activities necessary for the Iowa newborn screening program are completed.

"Specialty genetics provider" means a medical geneticist, genetic nurse, genetic physician assistant, genetic nurse practitioner, or genetic counselor.

"State hygienic laboratory" or *"SHL"* means the designated central testing laboratory.

"Stillbirth" means the same as defined in Iowa Code section 136A.2.

"Transferring facility" means the birthing facility that transfers the infant to another facility.

[**ARC 9319C**, IAB 5/28/25, effective 8/1/25]

641—4.2(136A) Iowa newborn screening program (INSP). This program provides comprehensive newborn screening services for hereditary and congenital disorders for the state.

4.2(1) *Newborn screening policy.*

a. All newborns and infants born in the state of Iowa shall be screened for all congenital and inherited disorders on the Iowa newborn screening panel as specified by the department.

b. As new disorders are recognized and new technologies and tests become available, the department will develop and follow protocols for the addition of disorders to or the deletion of disorders from the screening panel.

c. The department may monitor individuals identified as having a genetic or metabolic disorder for the purpose of conducting public health surveillance or intervention and for determining whether early detection, treatment, and counseling lead to the amelioration or avoidance of the adverse outcomes of the disorder. Birthing facilities and health care providers shall provide patient data and records to the department upon request to facilitate the monitoring. Any identifying information provided to the department shall remain confidential pursuant to Iowa Code section 22.7(2).

d. For purposes of newborn screening, the department will collect newborn screening specimens and data, test the specimens for disorders on the universal screening panel, conduct follow-up on abnormal screening results, conduct quality improvement and quality assurance activities, and store specimens for a time period determined by its policies.

4.2(2) *Newborn blood spot screening procedure for facilities and providers.*

a. Educating parent or guardian. Before a specimen from an infant is obtained, a parent or guardian will be informed of the type of specimen, how it is obtained, the nature of the disorders for which the infant is being screened, the consequences of treatment and nontreatment, and the retention, use and disposition of residual specimens.

b. Refusal of screening. Should a parent or guardian refuse the screening, said refusal shall be documented in the infant's medical record, and the parent or guardian shall sign the refusal of screening form. The birthing facility or attending health care provider shall submit the signed refusal of screening form to the INSP within six days of the refusal. The birthing facility or attending health care provider may submit refusal forms via the courier service established for the transportation of newborn screening specimen collection forms or via secure fax.

c. Collection of specimens. A filter paper blood specimen shall be collected from the infant between 24 to 48 hours after the infant's birth. A specimen shall not be collected from an infant less than 24 hours after birth except as follows:

(1) A blood specimen must be collected before any initial transfusion, even if the infant is less than 24 hours old.

(2) A blood specimen must be collected before the infant leaves the hospital, whether by discharge or by transfer to another hospital, even if the infant is less than 24 hours old.

d. Submission of specimens. All specimens shall be delivered to the SHL via courier service or, if courier service is not available, overnight postage, overnight express delivery service, or other appropriate means within 24 hours after collection.

4.2(3) *Primary health care provider responsibility.*

a. The health care provider or a designee shall ensure that infants under the provider's care are screened.

b. Procedures for specimen collection for newborn blood spot screening shall be followed in accordance with subrule 4.2(2).

c. A physician or other health care professional who undertakes primary pediatric care of an infant delivered in Iowa shall arrange for the newborn screening if a newborn screening result is not in the infant's medical record.

d. The primary care provider of an infant delivered in Iowa shall discuss the newborn screening results with the parent or guardian of the newborn, including follow-up on abnormal results.

4.2(4) *Birthing facility.* The birthing facility shall ensure that all infants receive newborn screening.

a. Designee. Each birthing facility shall designate an employee to be responsible for the newborn screening program in that institution.

b. Procedures for specimen collection for newborn screening shall be followed in accordance with subrule 4.2(2).

c. Transfer. The following apply if an infant is transferred:

(1) If an infant is transferred within the hospital for acute care, the newborn nursery shall notify the acute care unit of the status of the newborn screening. The acute care unit shall then be responsible for the status of the newborn screening prior to discharge of the infant.

(2) If the infant is transferred to another facility within the state, the facility shall notify the receiving facility of the status of the newborn screening. The receiving facility shall then be responsible for completion of the newborn screening prior to discharge of the infant.

d. Discharge. Each birthing facility shall collect a newborn screening specimen on every infant prior to discharge, including under the following circumstances:

(1) The infant is discharged or transferred to another facility before the infant is 24 hours old.

(2) The infant is born with a condition that is incompatible with life.

(3) The infant has received a transfusion.

e. Notification. The birthing facility shall report the newborn screening results to the health care provider who has undertaken ongoing primary pediatric care of the infant.

4.2(5) *SHL responsibility.* The SHL will:

a. Contract with a courier service to provide transportation and delivery of newborn screening specimens.

b. Contact all birthing facilities to provide education on ordering specimen transport from the courier.

c. Process specimens within 24 hours of receipt.

d. Notify the submitting health care provider, birthing facility, or drawing laboratory of an unacceptable specimen and the need for another specimen.

e. Report a presumptive positive screen result within 24 hours to the consulting physician or the physician's designee.

f. Distribute specimen collection forms, specimen collection procedures, refusal of newborn screening forms, and other materials to drawing laboratories, birthing facilities, and health care providers.

g. Report normal and abnormal screening results to the submitting facility or provider.

h. Submit a written annual report of the previous calendar year to the department by July 1 of each year. This report will include:

(1) Number of infants screened,

(2) Number of repeat screens,

(3) Number of presumptive positive results by condition and disorder,

(4) Number of rejected specimens,

(5) Number of waivers,

(6) Results of quality assurance testing, including any updates to the INSP quality assurance policies, and

(7) Screening and educational activity details.

i. In collaboration with the program consulting physicians, submit a proposed budget and narrative justification for the upcoming state fiscal year by January 31 of each year.

j. Act as fiscal agent for program expenditures encompassing the analytical, technical, administrative, educational, and follow-up costs for the screening program.

k. Submit a fiscal expenditures report to the department within 90 days after the end of the state fiscal year.

4.2(6) *Follow-up program responsibility.* Follow-up programs will be available for all individuals identified by the newborn screening as having an abnormal screen result.

a. The follow-up activities will include care coordination, consultation, genetic counseling or recommendations for treatment when indicated, case management, education and quality assurance.

b. The follow-up programs shall submit a written annual report of the previous calendar year by July 1 of each year. The report shall include:

(1) The number of presumptive positive results and confirmed positive results by condition and disorder,

(2) Number of confirmed cases receiving follow-up,

(3) A written summary of educational and follow-up activities.

c. In collaboration with the SHL, the follow-up programs shall submit a proposed budget and narrative justification for the upcoming fiscal year to the department by January 31 of each year.

d. The follow-up programs shall submit a fiscal expenditures report to the department within 90 days of the end of the state fiscal year.

4.2(7) *Information sharing and confidentiality.* Reports, records, and other information collected by or provided to the Iowa newborn screening program relating to an infant's newborn screening results and follow-up information are confidential records pursuant to Iowa Code sections 22.7 and 136A.7. INSP data may be retained for 19 years.

a. Personnel of the program shall maintain the confidentiality of all information and records used in the review and analysis of newborn screening and follow-up, including information that is confidential under Iowa Code chapter 22 or any other provisions of state law.

b. The program shall not release confidential information, except to the following persons and entities under the following conditions:

(1) The parent or guardian of an infant or child or the adult individual for whom the report is made.

(2) A primary health care provider, birthing facility, or submitting laboratory.

(3) A representative of a state or federal agency or agents of tribes and tribal public health authorities to the extent that the information is necessary to perform a legally authorized function of that agency or the department. No data shall be furnished to state or federal agencies or agents of tribes or tribal public health agencies until the department has prepared in writing the conditions under which the data may be used and has received an agreement signed by a responsible agent of the state or federal agency agreeing to meet and conform to such conditions.

(4) A researcher, upon documentation of parental consent obtained by the researcher, and only to the extent that the information is necessary to perform research authorized by the department.

c. Newborn screening information shall not be released to any person or entity for commercial purposes or law enforcement purposes or to establish a database for forensic identification.

4.2(8) *Retention, use and disposition of residual newborn screening specimens.*

a. A newborn screening specimen collection form consists of a filter paper containing the dried blood spots (DBS) specimen and the attached requisition that contains information about the infant and birthing facility or drawing laboratory. The DBS specimen can be separated from the information contained in the requisition form. The INSP is the custodian of the specimens and related data for purposes of newborn screening, quality improvement and quality assurance activities.

(1) The residual DBS specimen shall be held for five years in a locked area at the SHL.

(2) The residual DBS specimen shall be stored for the first year at –75 to –80 degrees C.

(3) After one year, the residual DBS specimen shall be archived for four additional years at room temperature.

(4) The residual DBS specimen shall be incinerated after completion of the retention period.

b. The program shall not release a residual newborn screening specimen except to the following persons and entities:

(1) The parent or guardian of the infant or the individual adult upon whom the screening was performed.

(2) A health care provider acting on behalf of the patient.

(3) A medical examiner authorized to conduct an autopsy on a child or an investigation into the death of a child.

(4) A researcher, upon documentation of parental consent obtained by the researcher, and only to the extent that the information is necessary to perform research authorized by the department.

(5) The newborn screening program, for operations as provided in this rule.

c. Research. A residual newborn screening specimen may be released for research purposes only if written consent has been received by the researcher from a parent or guardian of the child, or the individual adult upon whom the screening was performed, and each of the following conditions is satisfied:

(1) Investigators shall submit proposals to use residual newborn screening specimens to the department. Any intended use of the requested specimens as part of the research study must be clearly delineated in the proposal.

(2) Before research can commence, proposals shall be approved by the researcher's institutional review board and the department.

(3) Research on residual newborn screening specimens shall be allowed only in instances where research would further: newborn screening activities; the health of an infant or child for whom no other specimens are available or readily attainable; general medical knowledge for existing public health surveillance activities; public health purposes; or medical knowledge to advance the public health.

d. Newborn screening program operations. Residual newborn screening specimens and related data may be used for activities, testing, and procedures directly related to the operation of the newborn screening program, including confirmatory testing, laboratory quality control assurance and improvement, equipment calibration, evaluation and improvement of the accuracy of newborn screening tests, and equipment and screening methods validation, and for the use of linked specimens in feasibility studies approved by the council for the purpose of incorporating new tests or evaluating new test methodologies.

e. Prohibited uses. A residual newborn screening specimen shall not be released to any person or entity for commercial purposes or law enforcement purposes or to establish a database for forensic identification.

f. Return or destruction of specimens. A parent or guardian may request return or destruction of the parent's or guardian's newborn's residual newborn screening specimen by contacting the department.

4.2(9) *Newborn screening for critical congenital heart disease.* All newborns and infants born in Iowa shall receive newborn screening for CCHD, by pulse oximetry or other means in accordance with subparagraph 4.2(9)*"b"*(3). The purpose of newborn screening for CCHD is to identify newborns with structural heart defects usually associated with hypoxia in the newborn period that could have significant morbidity or mortality early in life with the closing of the ductus arteriosus or other physiological changes early in life.

a. Newborn CCHD screening procedure for providers and facilities.

(1) Educating parent or guardian. Before newborn screening for CCHD on an infant is conducted, a parent or guardian shall be informed of the type of screening, how it is performed, the nature of the conditions and disorders for which the infant is being screened, and the follow-up procedure for an abnormal screen result.

(2) Refusal. Should a parent or guardian refuse the screening, said refusal shall be documented in the infant's medical record, and the parent or guardian shall sign the refusal of screening form. The birthing facility or attending health care provider shall submit the signed refusal form to the central laboratory within six days of the refusal. The birthing facility or attending health care provider may submit refusal

forms via the courier service established for the transportation of newborn screening specimen collection forms or via secure fax.

b. Newborn CCHD screening for newborns in low-risk or intermediate nurseries or out-of-hospital births.

(1) Screening should not begin until the newborn is at least 24 hours of age, or as late as possible if earlier discharge is planned, and should be completed on the second day of life.

(2) Screening shall be conducted using pulse oximeters or other means in accordance with subparagraph 4.2(9)*"b"*(3). Pulse oximeters shall:

1. Be motion tolerant;
2. Report functional oxygen saturation;
3. Be validated in low-perfusion conditions;
4. Be cleared by the Food and Drug Administration (FDA) for use on newborns; and
5. Have a 2 percent root-mean-square accuracy.

Disposable or reusable probes may be used. Reusable probes must be appropriately cleaned between uses according to manufacturer's instructions.

(3) Newborn CCHD screening shall be conducted by pulse oximetry or other means in accordance with the most recently published guidelines, algorithms, and protocols as outlined by the American Academy of Pediatrics, the American College of Cardiology Foundation and the American Heart Association, or subsequent guidance by the organizations listed in this subparagraph. Materials are available on the department's website.

c. Newborn CCHD screening for high-risk newborns in neonatal intensive care unit (NICU). Until such time that an evidence-based protocol for CCHD screening in infants discharged from the NICU is available, the attending health care provider shall conduct a comprehensive examination of the newborn to screen the infant for CCHD prior to discharge.

d. Primary health care provider responsibility. The health care provider shall ensure that infants under the provider's care are screened.

e. Reporting results of newborn CCHD screening. Results of newborn CCHD screening shall be reported in a manner consistent with other newborn screening reporting.

4.2(10) *INSP and IMPSP fees.*

a. In consultation with the department, the SHL shall establish the newborn screening fee schedule in a manner sufficient to support the newborn screening system of care, including but not limited to laboratory screening costs, short-term and long-term follow-up program costs, the newborn screening developmental fund, and the cost of the department's newborn screening data system.

b. The SHL shall include as part of the INSP fee an amount to fund the provision of special medical formula and foods for eligible individuals with inherited diseases of amino acids and organic acids who are identified through the programs.

c. Funds collected through newborn screening fees will be used for newborn screening program activities only.

d. Funds collected through maternal prenatal screening fees will be used for maternal prenatal screening activities only.

e. In order to support newborn and maternal prenatal screening activities, the department will authorize the expenditure and exchange of newborn screening and maternal prenatal screening developmental funds between the SHL (as designated fiscal agent) and the department.

f. A portion of INSP and IMPSP fees will be distributed to the department to support activities of the INSP and the IMPSP.

4.2(11) *Special medical formula and foods program.*

a. A special medical formula and foods program for individuals with inherited diseases of amino acids and organic acids who are identified through the Iowa newborn screening program is provided by the University of Iowa.

b. Payments received from clients based on third-party payment, sliding fee scales and donations shall be used to support the administration of and the purchase of special medical formula and foods.

c. The funding allocation from the Iowa newborn screening program fee will be used as the funder of last resort after all other available funding options have been pursued by the special medical formula and foods program.

d. Provisions of special medical formula and foods through this funding allocation shall be available to an individual only after the individual has shown that all benefits from third-party payers, including but not limited to health insurers; health maintenance organizations; Medicare; Medicaid; Special Supplemental Food Program for Women, Infants and Children program (WIC); and other government assistance programs have been exhausted. In addition, a full fee and a sliding fee scale shall be established and used for those persons able to pay all or part of the cost. Income and resources shall be considered in the application of the sliding fee scale. Individuals whose income is at or above 185 percent of the federal poverty level shall be charged a fee for the provision of special medical formula and foods. Placement of individuals on the sliding fee scale shall be determined and reviewed at least annually.

e. The SHL will act as the fiscal agent.

f. The University of Iowa Health Care Medical Center under the control of the state board of regents shall not receive indirect costs from state funds appropriated for this program.

[**ARC 9319C**, IAB 5/28/25, effective 8/1/25]

641—4.3(136A) Iowa maternal prenatal screening program (IMPSP). This program provides comprehensive maternal prenatal screening services for the state.

4.3(1) *Maternal screening.* The IMPSP provides a risk assessment for certain congenital or inherited conditions and disorders of a newborn. The department will identify the minimum conditions included in the assessment on the department's website.

a. If a patient desires this screening test, the health care provider shall direct that a specimen be drawn and submitted to the SHL or a laboratory with the capacity to provide screening for the minimum type of prenatal screening services.

b. As new technologies and tests become available, the department will develop and follow protocols for the addition or deletion of conditions and disorders from the screening program.

4.3(2) *Maternal screening procedure.*

a. Specimen collection. A serum or clotted blood specimen shall be collected from the patient within the appropriate gestational range indicated by the requested screen.

b. Specimen processing. The SHL will test specimens within three working days of receipt.

c. Reporting abnormal results. Abnormal screen results shall be reported within 24 hours to the consulting physician or the physician's designee, who shall then notify the primary health care provider. On the next working day, this initial report shall be followed by a written report to the primary health care provider.

4.3(3) *Consulting physician responsibility.* A consulting physician shall be designated by the department to provide interpretation of screen results and consultation to the submitting health care provider. This physician shall provide consultation for abnormal screen results, assist with questions about management of identified cases, provide education and assist with quality assurance measures. The screening program, with assistance from the consulting physician, shall:

a. In collaboration with the SHL, submit a proposed budget and narrative justification for the upcoming fiscal year to the department by January 31 of each year, and

b. Submit a written annual report of the previous calendar year's activity to the department by July 1 of each year. The report will include:

(1) Number of persons screened,
(2) Number of repeat screens,
(3) Number of abnormal results by condition and disorder,
(4) Number of rejected specimens,
(5) Results of quality assurance testing, and
(6) Screening and educational activity details.

4.3(4) *SHL responsibility.* The SHL will:

a. Contract with a courier service to provide transportation and delivery of maternal prenatal serum specimens.

b. Contact all entities submitting specimens to recommend use of the courier service to transport specimens to the SHL.

c. Test specimens within seven working days of receipt.

d. Distribute specimen collection kits and other materials to health care provider offices and drawing facilities as required.

e. Inform the submitting health care provider or drawing facility of an unacceptable specimen and request another specimen.

f. Provide educational materials concerning specimen collection procedures to health care provider offices.

g. Have available for review a written quality assurance program covering all aspects of its screening activity.

h. Act as a fiscal agent for program charges encompassing the analytical, technical, administrative, educational and follow-up costs for the screening program.

4.3(5) *IMPSP fee determination.* The department will annually review and determine the fee to be charged for all activities associated with the IMPSP. The review and determination of the fee will be completed at least one month prior to the beginning of the fiscal year.

4.3(6) *Information sharing and confidentiality.* Reports, records, and other information collected by or provided to the IMPSP relating to a patient's maternal prenatal screening results and follow-up information are confidential records pursuant to Iowa Code section 22.7.

a. Personnel of the program shall maintain the confidentiality of all information and records used in the review and analysis of maternal serum screening and follow-up, including information that is confidential under Iowa Code chapter 22 or any other provisions of state law.

b. The program shall not release confidential information except to the following persons and entities, under the following conditions:

(1) The patient for whom the report is made.

(2) A primary health care provider or submitting laboratory.

(3) A representative of a state or federal agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The state or federal agency will be subject to confidentiality regulations that are the same as or more stringent than those in the state of Iowa.

c. Maternal prenatal information shall not be released to any person or entity for commercial purposes or law enforcement purposes or to establish a database for forensic identification.

4.3(7) *Retention, use and disposition of residual maternal prenatal screening specimens.* The residual serum specimens shall be held for a specified period of time in a locked area at the SHL in accordance with SHL policy and procedures.

[**ARC 9319C**, IAB 5/28/25, effective 8/1/25]

641—4.4(136A) Regional genetic consultation service (RGCS). This program provides comprehensive genetic and genomic services statewide through outreach clinics.

4.4(1) Provision of comprehensive genetic and genomic services. The department will contract with the division of medical genetics and genomics within the department of pediatrics at the University of Iowa to provide genetic and genomic health care and education outreach services for individuals and families within Iowa.

4.4(2) The University of Iowa Health Care Medical Center under the control of the state board of regents shall not receive indirect costs from state funds appropriated for this program.

[**ARC 9319C**, IAB 5/28/25, effective 8/1/25]

641—4.5(136A) Neuromuscular and other related genetic disease program (NMP). This program provides comprehensive services statewide for individuals and families with neuromuscular disorders through outreach clinics and statewide, active surveillance for selected neuromuscular disorders.

4.5(1) Comprehensive service provision. The department will contract with the department of pediatrics at the University of Iowa to provide neuromuscular health care, case management and education outreach services for individuals and families within Iowa.

4.5(2) The University of Iowa Health Care Medical Center under the control of the state board of regents shall not receive indirect costs from state funds appropriated for this program.
[**ARC 9319C**, IAB 5/28/25, effective 8/1/25]

641—4.6(136A) Iowa registry for congenital and inherited disorders (IRCID). This program provides active statewide surveillance for congenital and inherited conditions and disorders. These may include birth defects, neuromuscular disorders, metabolic disorders, and all stillbirths. The program also may conduct active statewide surveillance of live births without a reportable congenital or inherited condition or disorder to serve as controls for epidemiological surveys. Surveillance activities for specific congenital and inherited conditions and disorders and maternal and congenital infections will be conducted for the period of time that adequate financial support is available.

A reportable congenital or inherited condition or disorder occurring in a miscarriage or pregnancy may be included in the IRCID.

4.6(1) *Surveillance policy.*

a. Congenital conditions and disorders, including birth defects, occurring in Iowa are reportable conditions, and records will be abstracted pursuant to rule 641—1.3(139A) and maintained in the IRCID. Congenital conditions and disorders surveillance will be performed in order to determine the occurrence and trends of such conditions and disorders, to determine co-occurring conditions and treatments through annual follow-up abstraction, to conduct thorough and complete epidemiological surveys to identify environmental and genetic risk factors for congenital conditions and disorders, to contribute to prevention strategies, and to assist in the planning for and provision of services to children with congenital conditions and disorders and their families.

b. Records for neuromuscular disorders will be abstracted pursuant to rule 641—1.3(139A) and maintained in the IRCID. Neuromuscular disorders surveillance for individuals of all ages shall be performed to determine the occurrence and trends of the selected neuromuscular disorders, to determine co-occurring conditions and treatments through annual follow-up abstraction, to conduct thorough and complete epidemiological surveys through annual long-term follow-up, and to assist in the planning for and provision of services to individuals with selected neuromuscular disorders and their families.

c. Stillbirths occurring in Iowa are reportable conditions, and records of these stillbirths will be abstracted pursuant to rule 641—1.3(139A) and maintained in the IRCID. Stillbirth surveillance will be performed to determine the occurrence and trends of stillbirths, to conduct thorough and complete epidemiological surveys to identify environmental and genetic risk factors for stillbirths, and to assist in the planning for and provision of services to prevent stillbirths.

4.6(2) *IRCID activities.*

a. The department will establish an agreement with the University of Iowa to implement the activities of the IRCID.

b. The IRCID will use the birth defects, neuromuscular disorders, and stillbirth coding schemes developed by the Centers for Disease Control and Prevention (CDC).

c. The IRCID staff will review hospital records, clinical charts, physician's records, vital records, prenatal records, and fetal death evaluation protocols pursuant to rule 641—1.3(139A), information from the INSP, RGCS, NMP, and the IMPSP, and any other information that the IRCID deems necessary and appropriate for congenital and inherited conditions and disorders surveillance.

4.6(3) *Department responsibility.*

a. When a live infant's medical records are ascertained by the IRCID, the department or its designee will inform the parent or legal guardian by letter that this information has been collected and provide the parent or guardian with information about services for which the child and family may be eligible.

b. The department and the IRCID will annually release aggregate medical and epidemiological information to medical personnel and appropriate state and local agencies for the planning and monitoring of services for children with congenital or inherited conditions and disorders and their families.

4.6(4) *Confidentiality and disclosure of information.* Reports, records, and other information collected by or provided to the IRCID relating to a person known to have or suspected of having a congenital or inherited condition or disorder are confidential records pursuant to Iowa Code sections 22.7 and 136A.7.

a. Personnel of the IRCID and the department shall maintain the confidentiality of all information and records used in the review and analysis of congenital or inherited conditions and disorders, including information that is confidential under Iowa Code chapter 22 or any other provisions of state law.

b. IRCID staff are authorized pursuant to rule 641—1.3(139A) to gather all information relevant to the review and analysis of congenital or inherited conditions and disorders. IRCID staff are permitted to review hospital records, clinical charts, physician's records, vital records, and prenatal records, information from the INSP, RGCS, NMP, and IMPSP and any other information the IRCID deems necessary and appropriate for live births without a reportable congenital or inherited condition and disorder to serve as controls for epidemiological surveys.

c. No individual or organization providing information to the IRCID in accordance with this rule shall be deemed or held liable for divulging confidential information.

4.6(5) *Access to information in the IRCID.* The IRCID and the department shall not release confidential information except to the following, under the following conditions:

a. The parent or guardian of an infant or child for whom the report is made and who can demonstrate that the parent or guardian has received the notification letter.

b. An Early ACCESS service coordinator or an agency under contract with the department to administer the children with special health care needs program, upon receipt of written consent from the parent or guardian of the infant or child.

c. A local health care provider, upon receipt of written consent from the parent or guardian of the infant or child.

d. A representative of a federal agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The information provided shall not include the personal identifiers of an infant or child with a reportable congenital or inherited condition or disorder.

e. Researchers. All proposals for research using the IRCID data to be conducted by persons other than program staff shall first be submitted to and accepted by the researcher's institutional review board. Proposals shall then be reviewed and approved by the department before research can commence.

f. A representative of a state agency, to the extent that the information is necessary to perform a legally authorized function of that agency or the department. The state agency will be subject to confidentiality regulations that are the same as or more stringent than those in the state of Iowa.

[**ARC 9319C**, IAB 5/28/25, effective 8/1/25]

These rules are intended to implement Iowa Code chapter 136A.

[Filed November 20, 1970]
[Filed 2/12/82, Notice 12/23/81—published 3/3/82, effective 4/7/82]
[Filed emergency 7/15/83—published 8/3/83, effective 7/15/83]
[Filed emergency 9/23/83—published 10/12/83, effective 9/23/83]
[Filed emergency 5/11/84—published 6/6/84, effective 5/11/84]
[Filed 11/15/85, Notice 8/14/85—published 12/4/85, effective 1/8/86]
[Filed 12/8/86, Notice 9/24/86—published 12/31/86, effective 2/4/87]
[Filed emergency 7/10/87—published 7/29/87, effective 7/10/87]
[Filed 11/30/87, Notice 10/21/87—published 12/16/87, effective 1/20/88]
[Filed 1/10/92, Notice 8/7/91—published 2/5/92, effective 3/11/92]
[Filed emergency 7/14/95 after Notice 6/7/95—published 8/2/95, effective 7/14/95]
[Filed 9/14/01, Notice 8/8/01—published 10/3/01, effective 11/7/01]
[Filed 9/11/02, Notice 8/7/02—published 10/2/02, effective 11/6/02]
[Filed 9/12/03, Notice 8/6/03—published 10/1/03, effective 11/5/03]
[Filed 7/16/04, Notice 6/9/04—published 8/4/04, effective 9/8/04]
[Filed emergency 7/13/05 after Notice 5/25/05—published 8/3/05, effective 7/13/05]
[Filed emergency 7/27/06 after Notice 6/21/06—published 8/16/06, effective 7/27/06]
[Filed 9/13/07, Notice 8/1/07—published 10/10/07, effective 11/14/07]
[Filed ARC 7981B (Notice ARC 7791B, IAB 5/20/09), IAB 7/29/09, effective 9/2/09]
[Filed ARC 0664C (Notice ARC 0572C, IAB 1/23/13), IAB 4/3/13, effective 5/8/13]

[Filed ARC 1747C (Notice ARC 1471C, IAB 5/28/14; Amended Notice ARC 1567C, IAB 8/6/14), IAB 12/10/14, effective 1/14/15]
[Filed ARC 2929C (Notice ARC 2819C, IAB 11/23/16), IAB 2/1/17, effective 3/8/17]
[Filed ARC 6554C (Notice ARC 6432C, IAB 7/27/22), IAB 10/5/22, effective 11/9/22]
[Filed ARC 9319C (Notice ARC 8543C, IAB 12/11/24), IAB 5/28/25, effective 8/1/25]