

CHAPTER 4
CENTER FOR CONGENITAL AND INHERITED DISORDERS

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

641—4.1(80GA, HF2362) Program explanation. The center for congenital and inherited disorders within the department of public health provides administrative oversight to the following: Iowa neonatal metabolic screening program, expanded maternal serum alpha-fetoprotein screening program, regional genetic consultation service, neuromuscular and related genetic disease program and Iowa registry for congenital and inherited disorders. The center for congenital and inherited disorders advisory committee represents the interests of the people of Iowa and assists in the development of programs that ensure the availability of and access to quality genetic health care services by all residents. The committee advises the director of the department of public health regarding issues related to genetics and hereditary and congenital disorders and makes recommendations about the design and implementation of the center's programs. Committee membership is made up of representatives of professional groups, agencies, legislators, consumers and individuals with an interest in promoting genetic services for the residents of Iowa.

641—4.2(80GA, HF2362) Definitions. For the purposes of this chapter, the following definitions shall apply:

"Anonymized specimen" means a specimen that cannot be traced back to or linked with the particular infant from whom the specimen was obtained. Specimens shall be anonymized by removing the dried blood spot portion from the infant information portion of the specimen collection form.

"Attending health care provider" means the licensed physician, nurse practitioner, certified midwife or physician assistant providing care to an infant at birth.

"Birth center" means "birth center" as defined in Iowa Code section 135.61.

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

"Center" means the center for congenital and inherited disorders within the Iowa department of public health.

"Central laboratory" means the University Hygienic Laboratory, which is designated as the screening laboratory to perform testing and reporting for the Iowa neonatal metabolic screening and expanded maternal serum alpha-fetoprotein screening programs.

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

"Committee" means the center for congenital and inherited disorders advisory committee.

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

"Department" means the Iowa department of public health.

"Director" means the director of the Iowa department of public health.

"Discharge" means a release of an infant from a hospital to the infant's parent or legal guardian.

"Early ACCESS" means Iowa's Individuals with Disabilities Education Act (IDEA), Part C, program for infants and toddlers. Early ACCESS is a statewide, comprehensive, interagency system of integrated early intervention services that supports eligible children and their families as defined in 281—Chapter 120.

"Follow-up program" means the designated individuals from the divisions of endocrinology, hematology, and medical genetics of the department of pediatrics of the University of Iowa.

"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, or physician assistant providing care to an individual.

“*Receiving hospital*” means the hospital receiving an infant from a birthing hospital.

“*Residual neonatal metabolic screening specimen*” means a portion of the specimen left over after the completion of newborn screening services by the Iowa neonatal metabolic screening program.

“*Specialty genetics provider*” means a geneticist, genetic nurse, or genetic counselor.

“*Tandem mass spectrometry*” means the use of tandem mass spectrometer and associated software to test a newborn screening sample.

“*Transferring hospital*” means the birthing hospital that transfers the infant to a hospital.

641—4.3(80GA, HF2362) Iowa neonatal metabolic screening program (INMSP). This program provides comprehensive neonatal metabolic screening services for hereditary and congenital disorders for the state to allow children and their families the earliest possible opportunity to receive appropriate early intervention services. The program includes the following: birthing hospitals, birth centers, health care providers, central laboratory, follow-up consultants, and consulting physicians.

4.3(1) Newborn screening policy.

a. All newborns and infants born in the state of Iowa shall be screened for medium chain acyl Co-A dehydrogenase deficiency, phenylketonuria, and other amino acid, organic acid, and fatty oxidation disorders detectable by tandem mass spectrometry; hypothyroidism; galactosemia; hemoglobinopathies; congenital adrenal hyperplasia; and biotinidase deficiency.

b. As new disorders are recognized and new technologies and tests become available, the center shall follow protocols developed by the department in regard to the addition of disorders to or deletion of disorders from the screening panel. The state board of health shall provide final approval for the addition of new disorders to the screening panel.

c. The center may monitor individuals identified as having a genetic or metabolic disease 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 disease. Birthing hospitals or birth centers and health care providers shall provide patient data and records to the center upon request to facilitate the monitoring. Any identifying information provided to the center shall remain confidential pursuant to Iowa Code section 22.7(2).

4.3(2) Neonatal metabolic screening procedure.

a. *Educating parent or guardian.* Before a specimen from an infant is obtained, a parent or guardian shall be informed of the type of specimen, how it is obtained, the nature of the disorders for which the infant is being screened, and the consequences of treatment and nontreatment.

b. *Waiver.* Should a parent or guardian refuse the screening, said refusal shall be documented in writing on the Iowa neonatal metabolic screening program waiver for newborn screening refusal form. The parent or guardian and licensed attending health care provider shall sign the waiver. The birthing hospital, birth center, or attending health care provider shall provide the Iowa neonatal metabolic screening program with a copy of the waiver within six days of the refusal. The original copy of the waiver shall become a part of the infant’s medical record.

c. *Collection of specimens.* A filter paper blood specimen shall be collected from the infant at least 24 hours after the infant’s birth, but not later than five days after the infant’s birth.

EXCEPTIONS:

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

(2) Every infant shall be screened prior to discharge even if the infant is less than 24 hours old.

(3) An infant transferred to another hospital must be screened by the receiving hospital unless the infant has already been screened. The transferring hospital is responsible for notifying the receiving hospital of the status of neonatal metabolic screening.

d. Submission of specimens. All specimens shall be delivered via courier service or forwarded by first-class mail or other appropriate means within 24 hours after collection to the University Hygienic Laboratory, the center's designated central laboratory.

e. Processing of specimens. The central laboratory shall process specimens within 24 hours of receipt. The central laboratory shall notify the submitting health care provider, birthing hospital, birth center, or drawing laboratory of an unacceptable specimen and the need for another specimen.

f. Reporting of presumptive positive test results. A presumptive positive test result shall be reported within 24 hours to the consulting physician, or the physician's designee, who shall then notify the attending health care provider and the birthing hospital, birth center, or drawing laboratory. This initial report shall be followed by a written report to the attending health care provider and the birthing hospital, birth center, or drawing laboratory.

4.3(3) Health care provider responsibility.

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

b. Procedures for specimen collection for neonatal metabolic screening shall be followed in accordance with 4.3(2).

c. Beginning November 1, 2004, a physician or other health care professional who undertakes primary pediatric care of an infant delivered in Iowa shall order the neonatal metabolic screening for completion if a neonatal metabolic screening result is not in the infant's medical record. The health care professional who undertakes primary pediatric care of the infant shall arrange for the neonatal metabolic screening.

4.3(4) Birthing hospital or birth center responsibility. The birthing hospital or birth center shall ensure that all infants receive neonatal metabolic screening.

a. Designee. Each birthing hospital or birth center shall designate an employee to be responsible for the neonatal metabolic screening program in that institution.

b. Procedures for specimen collection for neonatal metabolic screening shall be followed in accordance with 4.3(2).

c. Transfer. The following shall 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 neonatal metabolic screening. The acute care unit shall then be responsible for the status of the neonatal metabolic screening prior to discharge of the infant.

(2) If the infant is transferred out of house, the birthing hospital or birth center shall notify the receiving hospital of the status of the neonatal metabolic screening. The receiving hospital shall then be responsible for completion of the neonatal metabolic screening prior to discharge of the infant.

d. Discharge. Each birthing hospital or birth center shall collect a neonatal metabolic screening specimen on every infant prior to discharge, including under the following circumstances:

(1) The infant is discharged 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 hospital or birth center shall report the neonatal metabolic screening results in written form to the licensed attending health care provider.

4.3(5) Central laboratory responsibility. The central laboratory shall:

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

b. Contact all birthing hospitals and birth centers to inform them of the courier schedule.

c. Process specimens within 24 hours of receipt.

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

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

f. Distribute specimen collection forms, specimen collection procedures, screening waivers, and other materials to drawing laboratories, birthing hospitals, birth centers, and health care providers.

g. Report normal and abnormal screening results to birthing hospitals, birth centers, or drawing laboratories.

h. Submit a proposed budget and narrative for the upcoming fiscal year on or before March 31 of each year. Central laboratory shall submit a written annual report to the center by July 15 of each year. This report shall include:

- (1) Number of infants screened,
- (2) Number of repeat screens,
- (3) Number of presumptive positive results by disorder,
- (4) Number of rejected specimens,
- (5) Number of waivers,
- (6) Results of quality assurance testing including any updates to the INMSP quality assurance policies,
- (7) Screening and educational activity details, and
- (8) A fiscal expenditures report.

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

4.3(6) *Follow-up program responsibility.* Under the direction of consulting physicians, metabolic, endocrine, and hemoglobinopathy follow-up programs shall be available for all individuals identified by metabolic screening.

a. The follow-up activities shall include consultation, treatment when indicated, case management, education and quality assurance.

b. The follow-up programs shall submit an INMSP proposed budget and narrative for the next fiscal year by March 31 of each year. Follow-up programs shall submit metabolic screening data to the center by July 15 of each year. The information shall include:

- (1) The number of presumptive positive results and confirmed positive results by disorder,
- (2) Each individual's age at confirmation of disorder,
- (3) Each individual's age when treatment began,
- (4) Type of treatment for each disorder,
- (5) A written summary of educational and follow-up activities, and
- (6) A fiscal expenditure report for the fiscal year.

c. The consulting physician will oversee the respective follow-up programs.

4.3(7) *Sharing of information and confidentiality.* Reports, records, and other information collected by or provided to the Iowa neonatal metabolic screening program relating to an infant's neonatal metabolic 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 neonatal metabolic 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 for whom the report is made.
- (2) A local health care provider, birthing hospital, birth center, or submitting laboratory.
- (3) A local birth-to-three coordinator with the Early ACCESS program or with 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.

(4) 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.

(5) 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 which are the same as or more stringent than those in the state of Iowa.

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

4.3(8) *Retention, use and disposition of residual neonatal metabolic screening specimens.* Beginning January 1, 2005, the following policy shall be implemented.

a. A neonatal metabolic screening specimen collection form consists of dried blood spots on filter paper and attached information about the infant and birthing hospital, birth center, or drawing laboratory.

(1) Specimen collection forms shall be held for five years in a locked area at the central laboratory.

(2) The specimen collection forms shall be retained for the first year at -70 degrees C.

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

(4) The specimen collection forms shall be incinerated after five years of retention.

b. Research use.

(1) Investigators shall submit to the center proposals to use specimens. Any intent to utilize information associated with the residual neonatal metabolic screening specimen for 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, the congenital and inherited disorders advisory committee, and the department.

(3) Personally identifiable residual specimens or records shall not be disclosed without documentation of informed parental consent.

(4) Research on anonymized or identifiable residual specimens shall be allowed in instances where research would further: neonatal metabolic screening activities; the health of an infant or child for whom no other specimens are available or readily attainable; or general medical knowledge for existing public health surveillance activities.

4.3(9) *Neonatal metabolic screening fee.*

a. Sixty days prior to the end of the fiscal year, the central laboratory and the consulting physicians shall submit a combined program proposal and budget to the center for the coming year.

b. The department shall annually review and determine the fee to be charged for all activities associated with the INMSP. The review and fee determination shall be completed at least one month prior to the beginning of the fiscal year. The neonatal metabolic screening fee is \$77.

c. The department shall include as part of this fee an amount determined by the committee and department to fund the provision of special medical formula for eligible individuals with inherited diseases of amino acids and organic acids who are identified through the program.

d. Provisions of special medical formula 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, 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 a 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. The placement on the sliding fee scale shall be determined and reviewed at least annually.

4.3(10) *Special medical formula program.*

- a. A special medical formula program for individuals with inherited diseases of amino acids and organic acids who are identified through the Iowa neonatal metabolic 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.
- c. The funding allocation from the INMSP fee will be used as the funder of last resort after all other available funding options have been pursued by the special medical formula program.
- d. The central laboratory shall act as the fiscal agent.

641—4.4(80GA, HF2362) Expanded maternal serum alpha-fetoprotein screening program.

This program provides comprehensive second trimester maternal screening services for the state.

4.4(1) *Maternal screening policy.* It shall be the policy of the state of Iowa that all pregnant women are offered the Iowa expanded maternal serum alpha-fetoprotein (MSAFP)/Quad Screen. The Iowa expanded MSAFP/Quad Screen measures the maternal serum levels of alpha-fetoprotein, unconjugated estriol, human chorionic gonadotropin, and inhibin-A to provide a risk assessment for open neural tube defects, ventral wall defects, Down syndrome, Trisomy 18, and Smith-Lemli-Opitz. If a patient desires this screening test, the specimen shall be drawn and submitted by her health care provider to the University Hygienic Laboratory, the center's designated central laboratory.

4.4(2) *Maternal screening procedure.*

- a. *Collection of specimens.* A serum or clotted blood specimen shall be collected from the patient during 15 to 20 weeks of gestation.
- b. *Processing of specimens.* The central laboratory shall test specimens within three working days of receipt.
- c. *Reporting of abnormal results.* Abnormal test results shall be reported within 24 hours to the consulting physician or the physician's designee who shall then notify the submitting health care provider. On the next working day, this initial report shall be followed by a written report to the submitting health care provider.

4.4(3) *Consulting physician responsibility.* A consulting physician shall be designated by the center in collaboration with the central laboratory to provide interpretation of test results and consultation to the submitting health care provider. This physician shall provide consultation for abnormal test 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 submit to the center annual reports detailing program activities.

4.4(4) *Central laboratory responsibility.* The central laboratory shall:

- a. Test specimens within three working days of receipt.
- b. Distribute specimen collection kits and other materials to health care provider offices and drawing facilities as required.
- c. Inform the submitting health care provider or drawing facility of an unacceptable specimen and request another specimen.
- d. Provide educational materials concerning specimen collection procedures.
- e. Have available for review a written quality assurance program covering all aspects of its screening activity.
- f. Act as a fiscal agent for program charges encompassing the analytical, technical, administrative, educational and follow-up costs for the screening program.
- g. Act as a fiscal agent for program charges encompassing the analytical, technical, administrative, educational and follow-up costs for the screening program.

4.4(5) Iowa expanded MSAFP/Quad Screen fee determination. Sixty days prior to the end of the fiscal year, the central laboratory and the consulting physician shall submit a combined program proposal and budget to the center for the coming year. The department shall annually review and determine the fee to be charged for activities associated with this program. The review and fee determination shall be completed at least one month prior to the beginning of the fiscal year.

641—4.5(80GA, HF2362) Regional genetic consultation service (RGCS). This program provides comprehensive genetic services statewide through outreach clinics.

4.5(1) Provision of comprehensive genetic services. The department shall contract with the division of medical genetics within the department of pediatrics at the University of Iowa to provide genetic health care and education outreach services for individuals and families within Iowa. The contractor shall provide annual reports to the department as specified in the contract.

4.5(2) Clinical services. The services provided may include, but are not limited to: diagnostic evaluations, confirmatory testing, consultation by board-certified geneticists, genetic counseling, medical case management, and referral to appropriate agencies.

4.5(3) Patient fees. A sliding fee scale for specialty genetics provider services shall be established for patients attending the outreach clinics. The parameters for the sliding fee scale shall be based on federally established percent of poverty guidelines and updated annually.

Families/clients seen in the regional genetic consultation service clinics shall have bills submitted to third-party payers where applicable. Families/clients shall be billed on a sliding fee scale after third-party payment is received. Payments received from receipts of service based on the sliding fee scale or from the third-party payers shall be used only to support the RGCS.

641—4.6(80GA, HF2362) 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.

4.6(1) Provision of comprehensive services. The department shall 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. The contractor shall provide annual reports to the department as specified in the contract.

4.6(2) Clinical services. The services provided may include, but are not limited to: diagnostic evaluations, confirmatory testing, physical therapy, consultation by board-certified neurologists, genetic counseling, medical case management, supportive services and referral to appropriate agencies.

4.6(3) Patient fees. A sliding fee scale for specialty genetic provider services shall be established for patients attending the outreach clinics. The parameters for the sliding fee scale shall be based on federally established percent of poverty guidelines and updated annually.

Families/clients seen in neuromuscular outreach clinics shall have bills submitted to third-party payers where applicable. Families/clients shall be billed on a sliding fee scale after third-party payment is received. Payments received from receipts of service based on the sliding fee scale or from the third-party payers shall be used only to support the neuromuscular outreach clinics.

4.6(4) Surveillance for selected neuromuscular disorders. Rescinded IAB 8/4/04, effective 9/8/04.

4.6(5) Definition. Rescinded IAB 8/4/04, effective 9/8/04.

4.6(6) Central registry activities. Rescinded IAB 8/4/04, effective 9/8/04.

641—4.7(80GA, HF2362) Iowa registry for congenital and inherited disorders. The central registry provides active statewide surveillance for selected congenital and inherited disorders. Selected congenital and inherited disorders include birth defects and neuromuscular disorders.

4.7(1) Definitions.

a. Birth defects shall be defined as any structural or genetic abnormality that may adversely affect a child's health and development. The abnormality must be diagnosed or its signs and symptoms must be recognized within the first year of life.

b. Neuromuscular disorders include diagnoses involving the muscle, nerve, or neuromuscular junction.

4.7(2) Surveillance policy for birth defects and neuromuscular disorders.

a. Birth defects occurring in Iowa are reportable conditions, and records of these birth defects shall be abstracted pursuant to 641—1.3(139A) and maintained in a central registry.

b. Birth defects surveillance shall be performed in order to determine the occurrence and trends of birth defects, to conduct thorough and complete epidemiological surveys, to assist in the planning for and provision of services to children with birth defects and their families, and to identify environmental and genetic risk factors for birth defects.

c. Records for selected neuromuscular disorders shall be abstracted pursuant to 641—1.3(139A) and maintained in a central registry. Selected neuromuscular disorders include Duchenne and Becker muscular dystrophies. Selected neuromuscular disorders surveillance shall be performed in order to determine the occurrence and trends of the selected neuromuscular disorders, 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 children with selected neuromuscular disorders and their families for the period of time that adequate financial support is available for this project.

4.7(3) Central registry activities.

a. The center shall establish an agreement with the University of Iowa to implement the activities of the central registry.

b. The central registry shall use the birth defects and neuromuscular coding schemes defined by the Centers for Disease Control and Prevention (CDC).

c. The central registry staff shall review hospital records, clinical charts, physician's records, vital records and prenatal records pursuant to 641—1.3(139A) and any other information that the central registry deems necessary and appropriate for birth defects surveillance.

d. A reportable birth defect or neuromuscular disorder occurring in a fetal death or pregnancy termination may be included in the central registry.

4.7(4) Department responsibility.

a. When a live infant's medical records are ascertained by the central registry, the department or its designee shall 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 center and the central registry shall 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 birth defects.

4.7(5) Confidentiality and disclosure of information. Reports, records, and other information collected by or provided to the central registry relating to a person known to have or suspected of having a birth defect or neuromuscular disorder are confidential records pursuant to Iowa Code section 22.7.

Personnel of the central registry and the department shall maintain the confidentiality of all information and records used in the review and analysis of birth defects or neuromuscular disorders, including information which is confidential under Iowa Code chapter 22 or any other provisions of state law.

Central registry personnel are authorized pursuant to 641—1.3(139A) to gather all information relevant to the review and analysis of birth defects or neuromuscular disorders. This information may include, but is not limited to, hospital records, physician's records, clinical charts, birth records, death records, fetal death records, prenatal records, vital records, and other reports relevant and necessary for birth defects and neuromuscular disorders surveillance.

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

4.7(6) *Access to information in the central registry.* The central registry 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 birth defect or neuromuscular disorder.

e. Researchers, in accordance with the following:

(1) All proposals for research using the central registry 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 and the central registry's internal advisory committee before research can commence.

(2) The central registry shall submit to the central registry's internal advisory committee for approval a protocol describing any research conducted by the central registry in which the central registry deems it necessary to contact case subjects and controls.

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.

These rules are intended to implement 2004 Iowa Acts, House File 2362.

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