

641—4.3 (136A) 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, UHL, 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 all congenital and inherited disorders specified by the center and approved by the state board of health.

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 the deletion of disorders from the screening panel. The state board of health shall provide final approval for the addition of disorders to or the deletion of disorders from the screening panel.

c. The center 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 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 for facilities and providers.*

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, the consequences of treatment and nontreatment, and the retention, use and disposition of residual specimens.

b. Waiver. Should a parent or guardian refuse the screening, said refusal shall be documented in the infant's medical record. The birthing hospital, birth center, or attending health care provider shall notify the central laboratory of the waiver within six days of the refusal.

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; however, a specimen collected up to five days after the infant's birth is valid. 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 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 via courier service or, if courier service is not available, forwarded by first-class mail or other appropriate means within 24 hours after collection to the UHL.

e. Processing of specimens. The UHL shall process specimens within 24 hours of receipt. The UHL 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 report to the birthing hospital, birth center, or drawing laboratory and, subsequently, to the health care provider who undertakes primary pediatric care of the newborn at the birthing facility.

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

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 within the state, 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 or transferred to another hospital 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 to the health care provider who has undertaken primary pediatric care of the infant.

4.3(5) UHL responsibility. The UHL 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 written annual report of the previous fiscal year to the center by September 30 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, 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 center within 90 days after the end of the state fiscal year.

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

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

b. The follow-up programs shall submit a written annual report of the previous fiscal year by September 30 of each year. The report shall include:

- (1) The number of presumptive positive results and confirmed positive results by disorder,
- (2) Method and timing of referrals made to the follow-up programs,
- (3) Each individual's age at confirmation of disorder,
- (4) Each individual's age when treatment began,
- (5) Type of treatment for each individual with a disorder, and
- (6) A written summary of educational and follow-up activities.

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

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

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

(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 and the state board of health.

4.3(8) *Retention, use and disposition of residual neonatal metabolic screening specimens.*

a. A neonatal metabolic 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 hospital, birth center, or drawing laboratory. The DBS specimen can be separated from the information contained in the requisition form.

- (1) The residual DBS specimen shall be held for five years in a locked area at the UHL.
- (2) The residual DBS specimen shall be stored for the first year at -70 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. Research use.

(1) Investigators shall submit proposals to use residual DBS specimens to the center. Any intent to utilize information associated with 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, 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 obtained by the researcher.

(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) *INMSP fee determination.*

a. 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 \$112.

b. 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.

4.3(10) *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 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 and foods.

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 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, 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 UHL shall act as the fiscal agent.

f. The University of Iowa Hospitals and Clinics under the control of the state board of regents shall not receive indirect costs from state funds appropriated for this program.