

641—4.3 (136A) Iowa newborn screening program (INSP). This program provides comprehensive newborn screening services for hereditary and congenital disorders for the state.

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 facilities 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).

d. For purposes of newborn screening, the department shall 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 policies established by the CIDAC and the department.

4.3(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 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. 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 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.

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 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 SHL.

e. Informed consent for the release of residual specimens for research use. Rescinded ARC 2929C, IAB 2/1/17, effective 3/8/17.

4.3(3) *Primary health care provider responsibility.*

a. The health care provider 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 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 newborn screening if a newborn screening result is not in the infant's medical record.

4.3(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 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 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.

4.3(5) SHL responsibility. The SHL shall:

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

b. Contact all birthing facilities to inform them of the courier schedule.

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 center by July 1 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 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 center within 90 days after the end of the state fiscal year.

4.3(6) *Follow-up program responsibility.* Follow-up programs shall be available for all individuals identified by the newborn screening as having an abnormal screen result.

- a.* The follow-up activities shall include care coordination, consultation, 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 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 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 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 indefinitely.

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, 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.

4.3(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 center. 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, the congenital and inherited disorders advisory committee, 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.
- (4) For specimens collected prior to January 1, 2016, a parent or guardian may send a letter stating that the newborn's specimen is not to be released for research purposes. This letter shall include the parent's or guardian's name, the newborn's name at birth, and the newborn's date of birth. The letter of notice shall be sent to the State Hygienic Laboratory at Newborn Screening Program, State Hygienic Laboratory, 2220 S. Ankeny Blvd., Ankeny, Iowa 50023-9093.

d. Newborn screening program operations. Residual newborn screening specimens 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, calibration of equipment, evaluation and improvement of the accuracy of newborn screening tests, and validation of equipment and screening methods, and the use of linked specimens in feasibility studies approved by the Congenital and Inherited Disorders Advisory Committee 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 executive officer of the center for congenital and inherited disorders by calling 1-800-383-3826, or by mail to Executive Officer, Center for Congenital and Inherited Disorders, Iowa Department of Public Health, 321 E. 12th Street, Lucas State Office Building, Des Moines, Iowa 50319-0075.

4.3(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 4.3(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 which 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 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.

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 4.3(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 CCID Web page at <http://idph.iowa.gov/genetics/public/newborn-screening> .

c. Newborn CCHD screening for high-risk newborns in neonatal intensive care settings (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 (formerly referenced as metabolic screening) reporting.

4.3(10) INSP and IMPSP fees.

a. The department shall annually review and determine the fee to be charged for all activities associated with the INSP and the IMPSP. The review and fee determination shall be completed at least one month prior to the beginning of the fiscal year. The newborn screening fee is \$122.

b. The department shall include as part of the INSP fee an amount determined by the committee and department 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 shall be used for newborn screening program activities only.

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

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

f. Upon department approval of proposed budgets, a portion of INSP and IMPSP fees shall be distributed to the department to support activities of the INSP and the IMPSP at the center for congenital and inherited disorders (CCID).

4.3(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, 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 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.