PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Proposing rule making related to congenital and inherited disorders
and providing an opportunity for public comment

The Public Health Department hereby proposes to amend Chapter 4, “Center for Congenital and Inherited Disorders,” Iowa Administrative Code.

Legal Authority for Rule Making

This rule making is proposed under the authority provided in Iowa Code section 136A.8 and 2022 Iowa Acts, Senate File 2345.

State or Federal Law Implemented

This rule making implements, in whole or in part, Iowa Code chapter 136A and 2022 Iowa Acts, Senate File 2345.

Purpose and Summary

The proposed amendments will accomplish the following:

- Add definitions of “Iowa newborn screening panel,” “Iowa newborn screening program,” and “federal recommended uniform screening panel” (pursuant to 2022 Iowa Acts, Senate File 2345).
- Rescind language requiring State Board of Health approval to add disorders to or remove disorders from the newborn screening panel.
- Provide a fax number for the submission of refusal forms.
- Indicate that collection of the newborn screening specimen shall not delay critical care to the newborn.
- Describe who is responsible for informing the parent or guardian of the newborn screening procedure.
- Establish a cap on the amount that a facility or provider can charge for the newborn screening panel.
- Require a physician or other health care professional who undertakes primary pediatric care of a newborn delivered in Iowa to be available on an emergency basis to follow up on time-critical newborn screening results for newborns in the physician’s or health care professional’s care.
- Remove language indicating the newborn screening fee and describe the authority given to the State Hygienic Laboratory (SHL) to establish the newborn screening fee, pursuant to Senate File 2345.
- Move responsibility for reporting on the number of refusals of newborn screening from the SHL to the short-term follow-up program.
- Update language in subrule 4.3(7) regarding the release of newborn and maternal prenatal screening data to build consistency with Department data-sharing policies, HIPAA regulations, and the Common Rule; and allow an agent of a state or federal agency to receive the same information as the state or federal agency.
- Replace the term “written” with “informed” to allow researchers to obtain consent from a parent/guardian for use of the infant’s residual dried blood spot specimen by means other than written, e.g., telephonic or electronic “in-app” consent.
- Move references to the Iowa maternal prenatal screening program funding to the Iowa maternal prenatal screening program fee section.
- Remove language regarding income guidelines of 185 percent of the federal poverty level for the medical formula and medical foods program to allow the fiscal administrator (University of Iowa
Hospitals and Clinics) of the program to place individuals on the sliding fee schedule according to the fiscal administrator’s established guidelines and policy.

- Expand the list of disorders or conditions for which the Iowa Registry for Congenital and Inherited Disorders (IRCID) may conduct surveillance to include surveillance of pregnancy outcomes in order to understand the effects of emerging and reemerging threats on pregnant women and their infants.
- Describe the authority given through Senate File 2345 to the Congenital and Inherited Disorders Advisory Committee (CIDAC) to review newborn screening conditions on the federal recommended uniform screening panel (U.S. Department of Health and Human Services Recommended Uniform Screening Panel (RUSP)) for addition to Iowa’s newborn screening panel.
- Establish timelines for CIDAC’s review and consideration of RUSP conditions (within 12 months of the addition of the condition to the RUSP) and for the Department to add the condition(s) to the state newborn screening panel (within 18 months of CIDAC’s recommendation).
- Add a description of CIDAC membership pursuant to Senate File 2345.

**Fiscal Impact**

This rule making may have a fiscal impact to the State of Iowa. There will be additional expenses for laboratory equipment and infrastructure to support the testing including test supplies, education materials and training provided to expecting parents and providers. 2022 Iowa Acts, Senate File 2345, gives authority to the SHL to establish a newborn screening fee schedule in a manner sufficient to support the newborn screening system of care.

The costs of the additional jobs, equipment, supplies, trainings and educational materials are dependent on the type of disorders added to the newborn screening panel; each disorder comes with its specific testing methodology and expertise requirements, so costs are unknown until such time as the capacity of the current system and the administration, laboratory, clinical, and follow-up needs for expansion of the panel for the specific disorder(s) can be as assessed.

**Jobs Impact**

The addition of disorders to the newborn screening panel as required by 2022 Iowa Acts, Senate File 2345, will create additional jobs for those with expertise in the disorder(s) added, such as laboratory scientists, bioinformaticians, medical geneticists, genetic counselors, and follow-up nurses.

**Waivers**

Any person who believes that the application of the discretionary provisions of this rule making would result in hardship or injustice to that person may petition the Department for a waiver of the discretionary provisions, if any, pursuant to the Department’s waiver provisions contained in 641—Chapter 178.

**Public Comment**

Any interested person may submit written comments concerning this proposed rule making. Written comments in response to this rule making must be received by the Department no later than 4:30 p.m. on June 7, 2022. Comments should be directed to:

Kimberly Piper  
Department of Public Health  
Lucas State Office Building  
321 East 12th Street  
Des Moines, Iowa 50319  
Email: kimberly.piper@idph.iowa.gov
Public Hearing

No public hearing is scheduled at this time. As provided in Iowa Code section 17A.4(1)“b,” an oral presentation regarding this rule making may be demanded by 25 interested persons, a governmental subdivision, the Administrative Rules Review Committee, an agency, or an association having 25 or more members.

Review by Administrative Rules Review Committee

The Administrative Rules Review Committee, a bipartisan legislative committee which oversees rule making by executive branch agencies, may, on its own motion or on written request by any individual or group, review this rule making at its regular monthly meeting or at a special meeting. The Committee’s meetings are open to the public, and interested persons may be heard as provided in Iowa Code section 17A.8(6).

The following rule-making actions are proposed:

ITEM 1. Amend subrule 4.1(1) as follows:

4.1(1) Advisory committee. 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 and genomic health care services by all residents. The advisory 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.

ITEM 2. Adopt the following new definitions of “Federal recommended uniform screening panel,” “Iowa newborn screening panel” and “Iowa newborn screening program” in rule 641—4.2(136A):

“Federal recommended uniform screening panel” means the list of disorders for which the U.S. Department of Health and Human Services recommends states screen as part of their state newborn screening panels.

“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.

ITEM 3. Amend rule 641—4.2(136A), definitions of “Committee” and “Specialty genetics provider,” as follows:

“Committee Advisory committee” means the congenital and inherited disorders advisory committee (CIDAC).

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

ITEM 4. Amend paragraphs 4.3(1)“a” and “b” as follows:

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 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.

ITEM 5. Amend subrules 4.3(2) and 4.3(3) as follows:

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, the prenatal care provider, the attending health care provider, or a representative of either shall inform a parent or guardian 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 or its designee 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 facsimile to (319)384-5116.

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, unless collection of the blood specimen would delay critical care to the infant.

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, 1AB 2/1/17, effective 3/8/17. The facility or health care provider collecting and submitting the newborn screening specimen shall charge a fee for the newborn screening panel that does not exceed the newborn screening fee listed in the fee schedule established by the SHL.

4.3(3) Primary health care provider responsibility.

a. The attending 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.

d. A primary health care provider, or the provider’s designee, who undertakes primary pediatric care of an infant delivered in Iowa shall be available on an emergency basis to follow up on time-critical newborn screening results for the infant in the provider’s care.

Item 6. Amend subparagraph 4.3(4)“d”(1) as follows:
(1) The infant is discharged or transferred to another facility before the infant is 24 hours old.

Item 7. Rescind paragraphs 4.3(5)“i” to “k.”

Item 8. Reletter paragraphs 4.3(5)“a” to “h” as 4.3(5)“a” to “i.”

Item 9. Adopt the following new paragraph 4.3(5)“a”:

a. Establish the newborn screening fee schedule pursuant to Iowa Code section 136.3A(6) as enacted by 2022 Iowa Acts, Senate File 2345, section 2.

Item 10. Rescind subparagraph 4.3(5)“h”(5).

Item 11. Renumber subparagraphs 4.3(5)“h”(6) and (7) as 4.3(5)“h”(5) and (6).

Item 12. Renumber subparagraph 4.3(6)“b”(3) as 4.3(6)“b”(4).

Item 13. Adopt the following new subparagraph 4.3(6)“b”(3):
(3) Number of refusals for screening,
ITEM 14. Amend subparagraphs 4.3(7)“b”(3) and (4) as follows:

(3) A representative or agent 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 and its agents 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 permission for the use of data from the Iowa newborn screening program for research purposes subject to conditions the department may impose to ensure the use of the data is limited to such research purposes. No data shall be furnished from the Iowa newborn screening program for research purposes 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 a research organization agreeing to meet and conform to such conditions.

ITEM 15. Amend paragraph 4.3(8)“c” as follows:

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) to (4) No change.

ITEM 16. Amend subparagraph 4.3(9)“a”(2) as follows:

(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 facsimile to (319)384-5116.

ITEM 17. Amend subrule 4.3(10) as follows:

4.3(10) INS P and IMPSP fees.

a. The department shall annually review and determine the fee to be charged for all activities associated with the INS P 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. 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 department shall include as part of the INS P 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 developmental funds between the SHL (as designated fiscal agent) and the department.
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).

ITEM 18. Amend paragraph 4.3(11)“d” as follows:

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, Women, Infants, and Children (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.

ITEM 19. Amend rule 641—4.7(136A), introductory paragraph, as follows:

641—4.7(136A) Iowa registry for congenital and inherited disorders (IRCID). This program provides active statewide surveillance for congenital and inherited disorders. These disorders may include birth defects, neuromuscular disorders, metabolic or other inherited disorders, and all stillbirths. The program also may conduct active statewide surveillance of pregnancy outcomes to understand the effects of emerging and reemerging threats on pregnant women and their infants and conduct active statewide surveillance of live births without a reportable congenital or inherited disorder to serve as controls for epidemiological surveys. Surveillance activities for specific congenital and inherited disorders will be conducted for the period of time that adequate financial support is available.

ITEM 20. Amend paragraph 4.7(1)“a” as follows:

a. Birth defects shall be defined as any major structural abnormality or metabolic heritable 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.

ITEM 21. Reletter paragraphs 4.7(1)“d” and “e” as 4.7(1)“c” and “d.”

ITEM 22. Reletter paragraph 4.7(2)“d” as 4.7(2)“c.”

ITEM 23. Amend paragraph 4.7(3)“b” as follows:

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

ITEM 24. Amend paragraph 4.7(6)“e” as follows:

e. Researchers, in accordance with the following:

(1) 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 and the IRCID’s internal advisory committee CIDAC before research can commence.

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

ITEM 25. Amend rules 641—4.11(136A) and 641—4.12(136A) as follows:

641—4.11(136A) Purpose. CIDAC 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 and genomic health care services by all residents. The committee advises the director regarding issues related to genetics and hereditary and congenital disorders. A congenital and inherited disorders advisory committee (CIDAC or advisory committee) is established to assist the center for congenital and inherited disorders and the
department in the development of programs that ensure the availability of and access to quality genetic and genomic health care services for all Iowans.

641—4.12(136A) Duties of the advisory committee. CIDAC shall perform the following duties:

4.12(1) Make recommendations about the design and implementation of the center’s programs, including but not limited to:
   a. The Iowa newborn screening program, including management of the Iowa newborn screening panel.
      (1) The advisory committee shall assist the center for congenital and inherited disorders and the department in designating the conditions to be included in the newborn screening and in regularly evaluating the effectiveness and appropriateness of the newborn screening.
      (2) Beginning July 1, 2022, the advisory committee shall ensure that all conditions included in the federal recommended uniform screening panel as of January 1, 2022, are included in the newborn screening.
      (3) Within 12 months of the addition of a new condition to the federal recommended uniform screening panel, the advisory committee shall consider and make a recommendation to the department regarding inclusion of the new condition in the newborn screening panel, including the current newborn screening capacity to screen for the new condition and the resources necessary to screen for the new condition going forward.
      (4) If the advisory committee recommends inclusion of a new condition, the department shall include the new condition in the newborn screening panel within 18 months of receipt of the recommendation;  
      b. The regional genetics consultation service;
      c. The maternal prenatal screening program;
      d. The neuromuscular and related genetic disorders program; and
      e. The Iowa registry for congenital and inherited disorders.

4.12(2) Support the development of special projects and conferences regarding genetic and genomic health care services and issues.

4.12(3) Advocate for quality genetic and genomic health care services for all residents in the state of Iowa.

ITEM 26. Amend rule 641—4.13(136A) as follows:

641—4.13(136A) Membership. The members of the advisory committee shall be appointed by the director and shall include persons with relevant expertise and interest including parent representatives. Membership will be comprised of representatives of professional groups, agencies, legislators, parents, consumers, and professional health care providers.

4.13(1) CIDAC shall be comprised of regular, ex officio, and honorary members membership.
   a. to e. No change.

4.13(2) No change.

4.13(3) The director will appoint regular and honorary advisory committee members for three fiscal years. Reappointment of regular and honorary members shall be at the discretion of the director.

ITEM 27. Amend subrule 4.14(1) as follows:

4.14(1) Meetings of the advisory committee will be held as necessary and at the call of the director or the chairperson. There shall be a minimum of four meetings per year.

ITEM 28. Amend subparagraph 4.14(6)“b”(1) as follows:

(1) A designee of similar standing must be able to reasonably fulfill the member’s role on the advisory committee in discussions.