ARC 1471C

PUBLIC HEALTH DEPARTMENT[641]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)*"b."*

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 136A.8, the Department of Public Health hereby gives Notice of Intended Action to amend Chapter 4, "Center for Congenital and Inherited Disorders," Iowa Administrative Code.

The proposed amendments add the newborn hearing screening program, Iowa Early Hearing Detection and Intervention, to the purview of the Center for Congenital and Inherited Disorders; describe the authority of the Department to collect, test, and store newborn screening specimens and conduct follow-up and quality assurance activities; include a new rule that describes newborn screening for critical congenital heart disease; define the time frame for retention of newborn screening data; describe ownership of the dried blood spot specimen; and amend a paragraph to require informed consent of the parent or guardian prior to the release of specimens for research use. Paragraph 4.6(3)"a" requiring the use of a sliding fee scale by the neuromuscular and related disorders program is rescinded.

These proposed amendments have been reviewed by the Congenital and Inherited Disorders Advisory Committee and interested individuals within the field.

Any interested person may make written comments or suggestions on the proposed amendments on or before June 17, 2014. Such written comments should be directed to Kimberly Noble Piper, State Genetics Coordinator, Center for Congenital and Inherited Disorders, Department of Public Health, Lucas State Office Building, 321 East 12th Street, Des Moines, Iowa 50319; fax (515)725-1760. E-mail may be sent to kimberly.piper@idph.iowa.gov.

After analysis and review of this rule making, the impact on jobs is anticipated to be minimal.

These amendments are intended to implement Iowa Code chapter 136A and Iowa Code section 135.131.

The following amendments are proposed.

ITEM 1. Amend rule 641—4.1(136A), introductory paragraph, as follows:

641—4.1(136A) Program overview. The center for congenital and inherited disorders within the department of public health provides administrative oversight to the following: Iowa newborn screening program, ~~expanded maternal serum alpha-fetoprotein screening~~ Iowa maternal prenatal screening program, regional genetic consultation service, neuromuscular and related genetic disease program, ~~and~~ Iowa registry for congenital and inherited disorders, and Iowa early hearing detection and intervention program.

ITEM 2. Adopt the following **new** definitions of "Critical congenital heart disease," "Newborn critical congenital heart disease (CCHD) screening" and "Early hearing detection and intervention program" in rule **641—4.2(136A)**:

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

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

"Newborn critical congenital heart disease (CCHD) screening" means the screening of newborns for seven targeted heart conditions (hypoplastic left heart syndrome, pulmonary atresia, tetrology of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosis) using pulse oximetry to detect blood oxygen saturation levels.

ITEM 3. Amend rule **641—4.2(136A)**, definitions of "Committee" and "Primary health care provider," as follows:

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

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

ITEM 4. Adopt the following **new** paragraph **4.3(1)"d"**:

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.

ITEM 5. Amend subrule 4.3(2), catchwords, as follows:

4.3(2) ~~*Neonatal metabolic*~~ *Newborn blood spot screening procedure for facilities and providers.*

ITEM 6. Amend paragraph **4.3(2)"b"** as follows:

b. ~~*Waiver*~~ *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 waiver. The birthing facility or attending health care provider shall submit the signed refusal of screening waiver 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 dried blood spot collection forms.

ITEM 7. Amend paragraph **4.3(2)"e"** as follows:

e. ~~*Waiver for the*~~ *Refusal of release of residual specimens for research use.* The department shall establish policies and procedures, including a refusal for research ~~waiver~~ form, to allow a parent or guardian the ability to refuse the release of the newborn's residual newborn screening specimen for research purposes. The birthing facility or attending health care provider shall submit the signed refusal for research ~~waiver~~ form to the central laboratory pursuant to established policy and procedure.

ITEM 8. Amend paragraph **4.3(3)"b"** as follows:

b. Procedures for specimen collection for newborn blood spot screening shall be followed in accordance with 4.3(2).

ITEM 9. Amend paragraph **4.3(4)"e"** as follows:

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.

ITEM 10. Amend paragraph **4.3(6)"b"** as follows:

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) No change.

(2) ~~Method and timing of referrals made to the follow-up programs~~ Number of confirmed cases receiving follow-up,

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

ITEM 11. Amend subrule 4.3(7), introductory paragraph, as follows:

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 ~~section~~ sections 22.7 and 136A.7. INSP data shall be retained indefinitely.

ITEM 12. Amend subparagraph **4.3(7)"b"(1)** as follows:

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

ITEM 13. Amend paragraph **4.3(8)"a,"** introductory paragraph, as follows:

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 DBS specimen is the property of the newborn's parent or guardian until the child reaches 18 years of age, at which point the specimen becomes the property of the individual upon whom the screening was performed. The INSP is the custodian of the specimens and related data for purposes of newborn screening, quality improvement and quality assurance activities and may release residual specimens to researchers upon consent of the parent, guardian, or individual adult.

ITEM 14. Reletter paragraph **4.3(8)"b"** as **4.3(8)"c."**

ITEM 15. Adopt the following **new** paragraph **4.3(8)"b"**:

b. The program shall not release a residual DBS 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, birthing facility, or submitting laboratory.

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

(4) A researcher for research purposes, under the terms and conditions provided in this rule.

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

ITEM 16. Amend relettered paragraph **4.3(8)"c"** as follows:

c. Research ~~use~~. A residual DBS specimen may be released for research purposes only if written consent has been received 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 DBS specimens to the center. Any ~~intent to utilize information associated with~~ intended use of the requested ~~specimens~~ DBS 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)~~ (3) Research on anonymized or identifiable residual DBS 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; ~~or~~ general medical knowledge for existing public health surveillance activities; public health purposes; or medical knowledge to advance the public health.

ITEM 17. Adopt the following **new** paragraphs **4.3(8)"d"** and **"e"**:

d. Newborn screening program operations. Residual DBS 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.

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

ITEM 18. Renumber subrules **4.3(9)** and **4.3(10)** as **4.3(10)** and **4.3(11)**.

ITEM 19. Adopt the following **new** subrule 4.3(9):

4.3(9) *Newborn screening for critical congenital heart disease.* 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. Screening for CCHD is through the use of pulse oximetry monitoring. All newborns and infants born in Iowa shall receive newborn screening for CCHD.

a. Newborn CCHD screening procedure for providers and facilities.

(1) Educating parent or guardian. Before pulse oximetry 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 dried blood spot collection forms.

b. Newborn CCHD screening using pulse oximetry method 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 that are motion tolerant; report functional oxygen saturation; have been validated in low-perfusion conditions; have been cleared by the Food and Drug Administration (FDA) for use on newborns; and 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 in accordance with the most recently published guidelines, algorithms, and protocols from the American Academy of Pediatrics (AAP) or the department. Materials are available on the CCID web page at http://idph.state.ia.us/genetics/newborn_screening.asp.

c. Newborn CCHD screening using pulse oximetry method 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, including pulse oximetry, 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 and the results are communicated to the parent or guardian.

e. Reporting results of newborn CCHD screening. When a newborn CCHD reporting system is established by the department, providers and birth facilities shall report newborn CCHD screening information in accordance with department policy.

ITEM 20. Amend subrule 4.6(3) as follows:

4.6(3) ~~*Patient fees.*~~

~~*a.* 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.~~

~~*b.* 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.~~

~~*c.*~~ 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.

ITEM 21. Adopt the following **new** rule 641—4.8(135):

641—4.8(135) Iowa's early hearing detection and intervention program. The goal of universal hearing screening of all newborns and infants in Iowa is the early detection of hearing loss to allow children and their families the earliest possible opportunity to obtain appropriate early intervention services. All newborns and infants born in Iowa, except those born with a condition that is incompatible with life, shall be screened for hearing loss. Early hearing detection and intervention programming and services will be provided pursuant to 641—Chapter 3.