ARC 7791B

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 sections 135.11 and 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.

These proposed amendments provide for an increase in the neonatal metabolic screening fee; require birthing providers to retain documentation of neonatal metabolic screening waivers and provide notification to the Department; and rename the Expanded Maternal Serum Alpha-Fetoprotein Screening Program to reflect the broader scope of testing available. Finally, technical amendments for the purpose of clarifying program acronyms are included.

Any interested person may make written comments or suggestions on the proposed amendments on or before June 9, 2009. 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. E-mail may be sent to kpiper@idph.state.ia.us.

A public hearing will be held by conference call on June 9, 2009, from 10 to 11 a.m. Individuals may participate by calling 1-866-685-1580 and entering the following pass code: 5152816466#.

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

The following amendments are proposed.

ITEM 1. Amend rule **641—4.2(136A)**, definitions of "Central laboratory," "Central registry," "Residual neonatal metabolic screening specimen" and "Transferring hospital," as follows:

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

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

"Residual neonatal metabolic screening specimen" means ~~a~~ the portion of the specimen that may be left over after ~~the completion of newborn screening services by~~ all activities necessary for the Iowa neonatal metabolic screening program are completed.

"Transferring hospital" means the birthing hospital that transfers the infant to ~~a~~ another hospital.

ITEM 2. Adopt the following **new** definitions in rule **641—4.2(136A)**:

"Iowa maternal prenatal screening program" or *"IMPSP"* means a screening test designed to identify women with an increased risk of having a baby with a congenital or inherited disorder or women at risk of developing a problem later in pregnancy.

"Residual maternal prenatal serum screening specimen" means the portion of the specimen that may be left over after all necessary activities of the Iowa maternal prenatal screening program are completed.

"University hygienic laboratory" or *"UHL"* means the designated central testing laboratory.

ITEM 3. Amend rule 641—4.3(136A), introductory paragraph, as follows:

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, ~~central laboratory~~ UHL, follow-up consultants, and consulting physicians.

ITEM 4. Amend subrule 4.3(1) as follows:

4.3(1) *Newborn screening policy.*

a. No change.

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 ~~new~~ disorders ~~to~~ from the screening panel.

c. The center may monitor individuals identified as having a genetic or metabolic ~~disease~~ 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 ~~disease~~ 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).

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

4.3(2) *Neonatal metabolic screening procedure for facilities and providers.*

a. No change.

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~~ in the mother's medical record. ~~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~~ notify the central laboratory ~~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. No change.

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 ~~University Hygienic Laboratory, the center's designated central laboratory~~ UHL.

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

ITEM 6. Amend paragraph **4.3(3)"c"** as follows:

c. ~~Beginning November 1, 2004, a~~ A physician or other health care professional who undertakes primary pediatric care of an infant delivered in Iowa shall ~~order~~ arrange for 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.~~

ITEM 7. Amend paragraph **4.3(4)"e"** as follows:

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 who has undertaken primary pediatric care of the infant.

ITEM 8. Amend subrule **4.3(5)**, introductory paragraph, as follows:

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

ITEM 9. Amend subrule 4.3(6) as follows:

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 ~~affected~~ having an abnormal screen result.

a. No change.

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,

~~(2)~~ (3) Each individual's age at confirmation of disorder,

~~(3)~~ (4) Each individual's age when treatment began,

~~(4)~~ (5) Type of treatment for each individual with a disorder, and

~~(5)~~ (6) A written summary of educational and follow-up activities.

c. In collaboration with the ~~central laboratory~~ 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. No change.

~~*e.* The consulting physician will oversee the respective follow-up programs.~~

ITEM 10. Amend paragraph **4.3(8)"a"** as follows:

a. A neonatal metabolic screening specimen collection form consists of a filter paper containing the dried blood spots ~~on filter paper~~ (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) ~~Specimen collection forms~~ The residual DBS specimen shall be held for five years in a locked area at the ~~central laboratory~~ UHL.

(2) The residual DBS specimen ~~collection forms~~ shall be ~~retained~~ stored for the first year at −70 degrees C.

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

(4) The residual DBS specimen ~~collection forms~~ shall be incinerated after ~~five years of~~ completion of the retention period.

ITEM 11. Amend subparagraph **4.3(8)"b"(1)** as follows:

(1) Investigators shall submit ~~to the center~~ proposals to use residual DBS specimens to the center. Any intent to utilize information associated with the ~~residual neonatal metabolic screening specimen for~~ requested specimens as part of the research study must be clearly delineated in the proposal.

ITEM 12. Amend subrule 4.3(9) as follows:

4.3(9) ~~*Neonatal metabolic screening*~~ *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 ~~$97~~ $112.

b. No change.

~~*c.* 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.~~

ITEM 13. Amend subrule 4.3(10) as follows:

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.

~~*d.*~~ *e.* The ~~central laboratory~~ UHL shall act as the fiscal agent.

~~*e.*~~ *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.

ITEM 14. Amend rule 641—4.4(136A) as follows:

641—4.4(136A) ~~Expanded~~ Iowa maternal ~~serum alpha-fetoprotein~~ prenatal screening program (IMPSP). This program provides comprehensive ~~second trimester~~ maternal prenatal 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~~ maternal prenatal screening. The Iowa ~~expanded MSAFP/Quad Screen measures the maternal serum levels of alpha-fetoprotein, unconjugated estriol, human chorionic gonadotropin, and inhibin A to provide~~ maternal prenatal screening program provides a risk assessment for open neural tube defects, ventral wall defects, Down syndrome, and Trisomy 18~~, and Smith-Lemli-Opitz~~.

a. If a patient desires this screening test, ~~the specimen shall be drawn and submitted by~~ her health care provider shall direct that a specimen be drawn and submitted to the ~~University Hygienic Laboratory, the center's designated central laboratory~~ UHL.

b. As new technologies and tests become available, the center shall follow protocols developed by the department with regard to the addition of disorders to or the deletion of disorders from the screening program.

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~~ within the appropriate gestational range indicated by the requested screen.

b. Processing of specimens. The ~~central laboratory~~ UHL shall test specimens within three working days of receipt.

c. No change.

4.4(3) *Consulting physician responsibility.* A consulting physician shall be designated by the center in collaboration with the ~~central laboratory~~ UHL 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:

a. In collaboration with the ~~central laboratory~~ UHL, submit a proposed budget and narrative justification for the upcoming fiscal year to the center by January 31 of each year, and

b. No change.

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

a. Contract with a courier service to provide transportation and delivery of maternal prenatal serum specimens.

b. Contact all entities submitting specimens to inform them of the courier's schedule.

~~*a.*~~ *c.* Test specimens within three working days of receipt.

~~*b.*~~ *d.* Distribute specimen collection kits and other materials to health care provider offices and drawing facilities as required.

~~*c.*~~ *e.* Inform the submitting health care provider or drawing facility of an unacceptable specimen and request another specimen.

~~*d.*~~ *f.* Provide educational materials concerning specimen collection procedures.

~~*e.*~~ *g.* Have available for review a written quality assurance program covering all aspects of its screening activity.

~~*f.*~~ *h.* 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*~~ *IMPSP fee determination.* The department shall annually review and determine the fee to be charged for all activities associated with the ~~MSAFP/Quad Screen~~ IMPSP. The review and determination of the fee shall be completed at least one month prior to the beginning of the fiscal year.

4.4(6) *Sharing of information and confidentiality.* Reports, records, and other information collected by or provided to the ~~Iowa expanded MSAFP/Quad screening program~~ IMPSP relating to a patient's maternal ~~serum~~ prenatal screening results and follow-up information are confidential records pursuant to Iowa Code section 22.7.

a. No change.

b. The program shall not release confidential information except to the following persons and entities, under the following conditions:

(1) to (3) No change.

(4) A researcher, upon documentation of ~~parental~~ patient 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.

4.4(7) *Retention, use and disposition of residual maternal ~~serum~~ prenatal screening specimens.*

a. A maternal serum screening specimen collection consists of laboratory tubes with maternal serum ~~screening specimens and attached~~ and associated information about the patient, health care provider, or drawing laboratory.

(1) ~~Maternal serum screening~~ The residual serum specimens shall be held for a specified period of time in a locked area at the ~~central laboratory~~ UHL in accordance with ~~central laboratory~~ UHL policy and procedures.

(2) Reserved.

b. Research use.

(1) Investigators shall submit ~~to the center~~ proposals to use ~~maternal serum screening~~ residual serum specimens to the center. Any intent to utilize information associated with the ~~residual maternal serum screening specimen for~~ requested specimens as part of the research study must be clearly delineated in the proposal.

(2) and (3) No change.

(4) Research on anonymized or identifiable residual specimens shall be allowed in instances where research would further maternal ~~serum~~ prenatal screening activities or general medical knowledge for existing public health surveillance activities.

ITEM 15. Amend rule 641—4.6(136A) as follows:

641—4.6(136A) 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) to **4.6(3)** No change.

~~**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.~~

ITEM 16. Amend rule 641—4.7(136A) as follows:

641—4.7(136A) Iowa registry for congenital and inherited disorders (IRCID). ~~The central registry~~ This program provides active statewide surveillance for ~~selected~~ congenital and inherited disorders. ~~Selected congenital and inherited~~ These disorders include birth defects, ~~and~~ neuromuscular disorders, metabolic disorders, and all stillbirths. The program also may 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.

4.7(1) *Definitions.*

a. Birth defects shall be defined as any major 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~~ shall be defined as Duchenne and Becker muscular dystrophies.

c. Metabolic disorders shall be defined as those disorders included in the INMSP screening panel.

d. Stillbirths shall be defined as an unintended fetal death occurring after a gestational period of 20 completed weeks or an unintended fetal death of a fetus with a weight of 350 or more grams. Stillbirth is synonymous with fetal death.

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

a. ~~Birth defects~~ Congenital disorders, including birth defects, occurring in Iowa are reportable conditions, and records of these ~~birth defects~~ disorders shall be abstracted pursuant to 641—1.3(139A) and maintained in ~~a central registry~~ the IRCID. Congenital disorders surveillance shall be performed in order to determine the occurrence and trends of such disorders, to conduct thorough and complete epidemiological surveys to identify environmental and genetic risk factors for congenital disorders, to contribute to prevention strategies, and to assist in the planning for and provision of services to children with congenital disorders and their families.

~~*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.*~~ *b.* Records for selected neuromuscular disorders shall be abstracted pursuant to 641—1.3(139A) and maintained in ~~a central registry~~ the IRCID. 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~~.

c. Records for selected metabolic disorders shall be abstracted pursuant to 641—1.3(139A) and maintained in the IRCID. Selected metabolic disorders surveillance shall be performed in order to determine the occurrence and trends of the selected metabolic 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 metabolic disorders and their families.

d. Stillbirths occurring in Iowa are reportable conditions, and records of these stillbirths shall be abstracted pursuant to 641—1.3(139A) and maintained in the IRCID. Stillbirth surveillance shall be performed in order to determine the occurrence and trends of stillbirths, to conduct thorough and complete epidemiological surveys to identify environmental and genetic risk factors for stillbirths, and to assist in the planning for and provision of services to prevent stillbirths.

4.7(3) ~~*Central registry*~~ *IRCID activities.*

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

b. The ~~central registry~~ IRCID shall use the birth defects, ~~and~~ neuromuscular disorders, metabolic disorders, and stillbirth coding schemes ~~defined~~ developed by the Centers for Disease Control and Prevention (CDC).

c. The ~~central registry~~ IRCID staff shall review hospital records, clinical charts, physician's records, vital records, ~~and~~ prenatal records, and fetal death evaluation protocols pursuant to 641—1.3(139A), information from the INMSP, RGCS, NMP, and the IMPSP, and any other information that the ~~central registry~~ IRCID deems necessary and appropriate for ~~birth defects~~ congenital and inherited disorders 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~~ IRCID, 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~~ IRCID 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~~ congenital or inherited disorders and their families.

4.7(5) *Confidentiality and disclosure of information.* Reports, records, and other information collected by or provided to the ~~central registry~~ IRCID relating to a person known to have or suspected of having a ~~birth defect or neuromuscular~~ congenital or inherited disorder are confidential records pursuant to Iowa Code ~~section~~ sections 22.7 and 136A.7.

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

b. ~~Central registry personnel~~ IRCID staff are authorized pursuant to 641—1.3(139A) to gather all information relevant to the review and analysis of ~~birth defects or neuromuscular~~ congenital or inherited disorders. This information may include, but is not limited to, hospital records, physician's records, clinical charts, ~~birth records, death records, fetal death records,~~ vital records, prenatal records, ~~vital records, and other reports relevant and necessary for birth defects and neuromuscular disorders surveillance.~~ fetal death evaluation protocols, information from the INMSP, RGCS, NMP, and the maternal prenatal screening program, and any other information that the IRCID deems necessary and appropriate for congenital and inherited disorders surveillance. IRCID staff are permitted to review hospital records, clinical charts, physician's records, vital records, and prenatal records, information from the INMSP, RGCS, NMP, and IMPSP and any other information that the IRCID deems necessary and appropriate for live births without a reportable congenital and inherited disorder to serve as controls for epidemiological surveys.

c. No individual or organization providing information to the ~~central registry~~ IRCID 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~~ IRCID.* The ~~central registry~~ IRCID and the department shall not release confidential information except to the following, under the following conditions:

a. to *c.* No change.

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~~ congenital or inherited disorder.

e. Researchers, in accordance with the following:

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

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

f. No change.