PUBLIC HEALTH DEPARTMENT [641]

Notice of Intended Action

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 revise the timeline for the development of policies and procedures for obtaining informed consent for the storage and release of residual newborn screening specimens, and clarifies the use of linked specimens in feasibility studies approved by the Congenital and Inherited Disorders Advisory Committee (CIDAC) for the purpose of incorporating new tests or evaluating new test methodologies when the clinical validity and reliability of the test methodologies have previously been determined. The proposed amendments also replace the defunct Iowa Registry for Congenital and Inherited Disorders (IRCID) internal advisory committee with CIDAC for the review of proposals for research as well as correcting a grammatical error of the word congenital.

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 suggestions or comments on these proposed amendments prior to December 29, 2015. 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 rulemaking, no impact on jobs has been found.

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

The following amendments are proposed.

ITEM 1 Amend paragraph **4.3(2)"e"** as follows:

e. Informed consent for the storage and *release of residual specimens for research use.* By July 1, 2017, ~~The~~ the department shall establish policies and procedures, including an informed consent procedure for the storage and release of specimens for research, to allow a parent or guardian the ability to provide informed consent prior to the release of the newborn's residual newborn screening specimen for research purposes. The parent or guardian, birthing facility or attending health care provider shall submit ~~the informed consent form~~ documentation of informed consent to the ~~central laboratory~~ State Hygienic Laboratory or its designee pursuant to established policy and procedure. The informed consent procedure shall apply to all specimens collected on or after ~~January 1, 2016~~ July 1, 2017. For specimens collected prior to ~~January 1, 2016~~ July 1, 2017 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~~ State Genetics Coordinator at the Iowa Department of Public Health, 321 E. 12th Street, Des Moines, IA 50319-0075.

ITEM 2. Amend paragraph **4.3(8)"*c*"** as follows:

c. Research. A residual newborn screening specimen may be released for research purposes only if ~~written~~ informed 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:

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

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, 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 when clinical validity and reliability of the test methodologies have previously been determined.

ITEM 4. Amend subparagraphs **4.7(6)"e"(1)** and **(2)** as follows:

(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 CIDAC and the department ~~and the IRCID's internal advisory committee~~ before research can commence.

(2) The IRCID shall submit to ~~the IRCID's internal advisory committee~~ CIDAC and the department 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 5. Amend subrule 4.11(136A), introductory paragraph, 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 ~~congential~~ congenital disorders.