DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

1) Heading of the Part: Newborn Metabolic Screening and Treatment Code

2) Code Citation: 77 Ill. Adm. Code 661

3)

Section Numbers:	Proposed Action:
661.10	Amend
661.15	Amend

4) Statutory Authority: Implementing and authorized by the Newborn Metabolic Screening Act [410 ILCS 240].

5) A Complete Description of the Subjects and Issues Involved: The Department of Public Health Division of Laboratories provides testing to support the Newborn Screening Program. After testing is complete, specimens will be retained for a period of time (at least two months) in case repeat testing or supplemental testing of the specimen is necessary to complete the screening. When this supplemental testing is not performed by the Division of Laboratories, it may be necessary to engage the services of other clinical laboratories to perform this additional testing. Retained specimens are also used to provide quality control material to ensure the accuracy of current methods and those methods under development. If the specimen is determined to be normal, it will be retained for not longer than four months. Since abnormal specimens provide a special opportunity for quality control and are rarely encountered, they will be retained for a longer period of time. Abnormal specimens will be retained for a maximum of six years. After storage by the Division of Laboratories, all specimens will be destroyed.

The economic effect of this proposed rulemaking is unknown. Therefore, the Department requests any information that would assist in calculating this effect.

The Department anticipates adoption of this rulemaking approximately six to nine months after publication of the Notice in the *Illinois Register*.

6) Published studies or reports, and sources of underlying data, used to compose this rulemaking: None

7) Will this rulemaking replace any emergency rulemaking currently in effect? No

8) Does this rulemaking contain an automatic repeal date? No

9) Does this rulemaking contain incorporations by reference? No

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

10) Are there any other proposed rulemakings pending on this Part? No

11) Statement of Statewide Policy Objectives:

This rulemaking does not create or expand any state mandates on units of local government.

12) Time, Place and Manner in which interested persons may comment on this proposed rulemaking:

Written or e-mail comments may be submitted within 45 days after this issue of the *Illinois Register* to:

Susan Meister
Division of Legal Services
Illinois Department of Public Health
535 W. Jefferson St., 5th floor
Springfield, Illinois 62761

(217) 782-2043
e-mail: dph.rules@illinois.gov

13) Initial Regulatory Flexibility Analysis:

A) Types of small businesses, small municipalities and not for profit corporations affected: None

B) Reporting, bookkeeping or other procedures required for compliance: No additional bookkeeping will be required.

B) Types of professional skills necessary for compliance: None

14) Regulatory Agenda on which this rulemaking was summarized: This rulemaking did not appear on either of the Department's most recent Regulatory Agendas because the need for the rulemaking was not apparent when the Regulatory Agendas were prepared.

The full text of the Proposed Amendments begins on the next page:

DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENTS

TITLE 77: PUBLIC HEALTH
CHAPTER I: DEPARTMENT OF PUBLIC HEALTH
SUBCHAPTER i: MATERNAL AND CHILD HEALTH

PART 661
NEWBORN METABOLIC SCREENING AND TREATMENT CODE

Section

AUTHORITY: Implementing and authorized by the Newborn Metabolic Screening Act [410 ILCS 240].

SOURCE: Adopted December 14, 1973; emergency rules at 3 Ill. Reg. 28, p. 224, effective June 28, 1979, for a maximum of 150 days; rules repealed and new rules adopted at 3 Ill. Reg. 48, p. 42, effective November 20, 1979; amended at 5 Ill. Reg. 4593, effective April 15, 1981; amended and codified at 8 Ill. Reg. 19041, effective September 26, 1984; amended at 11 Ill. Reg. 12921, effective August 1, 1987; amended at 13 Ill. Reg. 15079, effective October 1, 1989; amended at 14 Ill. Reg. 13292, effective August 15, 1990; amended at 17 Ill. Reg. 13609, effective August 1, 1993; amended at 19 Ill. Reg. 15720, effective November 1, 1995; expedited correction at 20 Ill. Reg. 3590, effective November 1, 1995; amended at 22 Ill. Reg. 20639, effective November 10, 1998; amended at 26 Ill. Reg. 10676, effective July 1, 2002; amended at 26 Ill. Reg. 18412, effective January 1, 2003; amended at 31 Ill. Reg. 13203, effective August 28, 2007; amended at 34 Ill. Reg. 940, effective December 31, 2009; amended at 36 Ill. Reg. 1753, effective January 19, 2012; amended at 37 Ill. Reg. 13452, effective July 31, 2013; amended at 38 Ill. Reg. _____, effective _____.

Section 661.10 Responsibility for Screening

a) The physician in attendance at or immediately after the birth of the newborn

infant shall have primary responsibility for seeing that a specimen of the infant's blood is screened in accordance with this Part. Newborn screening includes tests for the following disorders: classical phenylketonuria (PKU) and certain other amino acid, organic acid, and fatty acid oxidation disorders; primary hypothyroidism; classical galactosemia; congenital adrenal hyperplasia due to 21-hydroxylase deficiency; biotinidase deficiency; sickle cell disease/trait; cystic fibrosis; lysosomal storage disorders; and severe combined immunodeficiency. Specific diseases in the categories of amino acid, organic acid, and fatty acid oxidation disorders and lysosomal storage disorders shall be reviewed by the Genetic and Metabolic Diseases Advisory Committee. The Department will consider the recommendations of the Genetic and Metabolic Diseases Advisory Committee in determining to include an additional disorder in the screening panel. Implementation of the Department's determination is subject to that determination's adoption by rule. For a current list of disorders, refer to the Illinois Department of Public Health Newborn Screening Practitioner's Manual. A blood specimen meeting the requirements for testing shall suffice for all tests (see Section 661.20). The physician may delegate this responsibility to the hospital administrator or to the administrator's designated representative, such as a member of the pediatrics staff, the laboratory director, the obstetrical supervisor, or other hospital official.

b) If the infant is not born in or admitted to a hospital or when there is no physician in attendance at or immediately after the birth, the physician caring for the infant during the first month of life shall be the individual responsible for seeing that a blood specimen for newborn screening is submitted. When there is no physician caring for the infant during this period, the parents or guardian is responsible. Local health authorities or the Department will assist the parents or guardian in having a blood specimen submitted for testing.

c) All specimens collected pursuant to this Part shall be submitted for testing to the Newborn Screening Section, Division of Laboratories, Illinois Department of Public Health, 2121 West Taylor Street, Chicago, Illinois 60612 (see Section 661.20).

d) When a retest is determined to be necessary pursuant to Section 661.30 of this Part, the ~~Illinois~~ Department ~~of Public Health~~ will notify the physician or his or her designee who is responsible for obtaining another specimen and having the specimen tested.

e) Specimens received by the Department for newborn screening will be retained for a minimum of two months. If all test results obtained from a specimen are determined to be within normal range, the specimen will be retained for a maximum of four months. If any test result obtained from a specimen is determined to be abnormal (i.e., out of normal range), the specimen will be retained for a maximum of six years. Specimens that the Department retains may be used within the Department for quality control purposes as required under the Clinical Laboratory Improvement Amendments (CLIA). Based on the Department's testing capabilities, specimens with an abnormal result may be referred to other clinical laboratories for supplemental testing to further characterize the abnormality. After the maximum time period for retention, the Department will destroy all specimens.

(Source: Amended at 38 Ill. Reg. _____, effective _____)

Section 661.15 Definitions

"Act" means the Newborn Metabolic Screening Act [410 ILCS 240].

"Advisory Committee" means the Genetic and Metabolic Diseases Advisory Committee appointed by the Director.

"Clinical and Laboratory Standards Institute" or "CLSI" means a global nonprofit standards-developing organization that promotes the development and use of voluntary consensus standards and guidelines within the health care community.

"Clinical Laboratory Improvement Amendments" or "CLIA" means federal regulations (Centers for Medicare and Medicaid Services, United States Department of Health and Human Services) providing standards applicable to all facilities or sites in the United States that test human specimens for health assessment or to diagnose, prevent, or treat disease.

"Department" or "DPH" means the Department of Public Health.

"Director" means the Director of the Department of Public Health.

"Formula" means a medically prescribed treatment substance that has been designed to treat a specific metabolic disorder.

"Lysosomal storage disorders" or "LSD" means disorders including, but not limited to, the following: Krabbe, Pompe, Gaucher, Fabry, Niemann-Pick and Mucopolysaccharidosis Type I (Hurlers syndrome) and Mucopolysaccharidosis Type II (Hunters syndrome), which are inherited metabolic disorders caused by lysosomal dysfunction, usually as a consequence of deficiency of a single enzyme required for the metabolism of lipids, glycoproteins or mucopolysaccharides.
"Newborn screening" or "testing" means the testing of a blood sample for classical phenylketonuria (PKU) and certain other amino acid, organic acid, and fatty acid oxidation disorders, primary hypothyroidism, classical galactosemia, congenital adrenal hyperplasia due to 21-hydroxylase deficiency, biotinidase deficiency, sickle cell disease/trait, cystic fibrosis, lysosomal storage disorders, and severe combined immunodeficiency. At times, variant forms of some disorders, or related conditions, may also be identified.

"Quality Control" means a procedure or set of procedures to assure the accuracy of results reported by the laboratory.

"Tandem mass spectrometry" or "MS/MS" means use of a tandem mass spectrometer and associated software to test a newborn screening sample.

"Severe combined immunodeficiency and T cell lymphopenia or "SCID" means a primary immune deficiency characterized by a severe defect in both the T and B lymphocyte systems.

"Supplemental Test" means any test approved by the United States Food and Drug Administration or validated under a laboratory's CLIA certification that is used to further characterize a newborn screening specimen that had received a positive (i.e., abnormal) result when initially screened by the laboratory.

"Using accepted statistical techniques" means using techniques that have been published in peer reviewed scientific literature.

(Source: Amended at 38 Ill. Reg. _____, effective _____)