

ILLINOIS REGISTER

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DEPARTMENT OF PUBLIC HEALTH

NOTICE OF PROPOSED AMENDMENT

- 1) Heading of the Part: Newborn Metabolic Screening and Treatment Code
- 2) Code Citation: 77 Ill. Adm. Code 661
- 3) Section Numbers:                      Proposed Action:  
661.15    Amend
- 4) Statutory Authority: Newborn Metabolic Screening Act [410 ILCS 240]
- 5) A Complete Description of the Subjects and Issues Involved: The amendment is necessary to ensure that the definition of “Lysosomal Storage Disorders” (LSDs) corresponds with the expansion of screening testing specified in P.A. 97-0532 which became effective on August 23, 2011. The amendment to the Act adds Mucopolysaccharidosis Type I (Hurlers syndrome) and Mucopolysaccharidosis Type II (Hunters syndrome) to the list of disorders included in the Lysosomal Storage Disorders category.  
  
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
- 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 a State Mandate.

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

Interested persons may present their comments concerning this rulemaking within 45 days after the publication of this issue of the *Illinois Register* to:

Susan Meister  
Division of Legal Services  
Illinois Department of Public Health  
535 W. Jefferson St., 5<sup>th</sup> floor  
Springfield, IL 62761  
217-782-2043  
e-mail: [dph.rules@illinois.gov](mailto:dph.rules@illinois.gov)

- 13) Initial Regulatory Flexibility Analysis:

- A) Types of small businesses, small municipalities and not for profit corporations affected: Birthing hospitals in Illinois.
- B) Reporting, bookkeeping or other procedures required for compliance: No changes are required.
- C) Types of professional skills necessary for compliance: Same as now exist for other disorders included in the Illinois newborn screening panel.

- 14) Regulatory Agenda on which this rulemaking was summarized: The rulemaking was not included on the most recent Regulatory Agenda because the need for the rulemaking was not apparent when the Regulatory Agenda was prepared.

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

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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	
661.10	Responsibility
661.15	Definitions
661.30	Interpretation of Results
661.35	Designation of Medical Specialists
661.40	Reports
661.50	Diagnosis and Treatment
661.70	Fee Assessment and Payment

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 29, 2012; amended at 37 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.

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~~"CF" means cystic fibrosis.~~

~~"CLSI" means "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.~~

"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 "LSD" means lysosomal storage disorders" or "LSD" means disorders, including, but not limited to, the following: Krabbe, Pompe, Gaucher, Fabry, and 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.

~~"PKU" means classical phenylketonuria.~~

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

~~"MS/MS" means Tandem Mass Spectrometry.~~

~~"Severe "SCID" means severe combined immunodeficiency and T cell~~

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lymphopenia “or SCID” means a primary immune deficiency characterized by a severe defect in both the T and B lymphocyte systems.

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

(Source: Amended at 37 Ill. Reg. \_\_\_\_\_, effective \_\_\_\_\_)