**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 Department 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. 12509, effective June 2, 2014)