**Section 661.35 Designation of Medical Specialists**

a) The Newborn Screening Program Manager, with the advice of the Director of the University of Illinois Division of Specialized Care for Children, and the Chairman of the Advisory Committee, will designate qualified professionals to serve as medical specialists in specified disease categories within the Newborn Screening Program. These medical specialists should provide care to children identified through newborn screening in collaboration with the primary care provider.

b) Equivalency in all qualifications specified in this Section will be determined by the Newborn Screening Program Manager, with the advice of the Director of the University of Illinois Division of Specialized Care for Children and the Chairman of the Advisory Committee.

c) The minimum qualifications required for designation as a medical specialist are a license to practice medicine in all its branches in Illinois, or licensure in the state of practice, and certification by the American Board of Pediatrics or equivalent board from another country. In addition, to be designated to serve in specified disease categories, medical specialists shall also have the following qualifications:

1) Phenylketonuria (PKU) and All Other Disorders of Amino Acid and Organic Acid Metabolism: certification by the American Board of Medical Genetics in Clinical Biochemical Genetics or certification by the American Board of Medical Genetics in Clinical Genetics with at least one year of experience post-training in the diagnosis and treatment of amino acid and organic acid disorders. The medical specialist shall have the capacity to provide a multidisciplinary approach to care, including the availability on site of specially trained metabolic dieticians and a biochemical genetics laboratory; for citrullinemia and argininosuccinic aciduria, medical specialists should have on-site availability of required medical therapies, such as hemodialysis, that are necessary for the treatment of patients with these disorders.

2) Primary Hypothyroidism: training in Pediatric Endocrinology with membership in the Lawson Wilkins Pediatric Endocrinology Society or certification of special competence in Pediatric Endocrinology by the American Board of Pediatrics.

3) Galactosemia: certification by the American Board of Medical Genetics in Clinical Biochemical Genetics or certification by the American Board of Medical Genetics in Clinical Genetics with at least one year of experience post-training in the diagnosis and treatment of galactosemia and inborn errors of metabolism. Medical specialists should have the capacity to provide a mulitidisciplinary approach to care, including the availability on site of specially trained metabolic dieticians.

4) Congenital Adrenal Hyperplasia: training in Pediatric Endocrinology with membership in the Lawson Wilkins Pediatric Endocrinology Society or certification of special competence in Pediatric Endocrinology by the American Board of Pediatrics.

5) Biotinidase Deficiency: certification by the American Board of Medical Genetics in Clinical Biochemical Genetics or certification by the American Board of Medical Genetics in Clinical Genetics with at least one year of experience post-training in the diagnosis and treatment of biotinidase deficiency and inborn errors of metabolism. Medical specialists should have the capacity to provide a multidisciplinary approach to care, including the availability on site of specially trained metabolic dieticians.

6) Sickle Cell Disease: training in Pediatric Hematology and certification of special competence in Pediatric Hematology-Oncology by the American Board of Pediatrics.

7) Fatty Acid Oxidation Disorders: certification by the American Board of Medical Genetics in Clinical Biochemical Genetics or certification by the American Board of Medical Genetics in Clinical Genetics with at least one year of experience post-training in the diagnosis and treatment of fatty acid oxidation disorders. Medical specialists should have the capacity to provide a multidisciplinary approach to care, including the availability on site of specially trained metabolic dieticians.

8) Cystic Fibrosis: certification by the American Board of Pediatrics in Pediatric Pulmonology or Pediatric Gastroenterology. Medical specialists should provide prompt access to quantitative pilocarpine iontophoresis sweat chloride testing in a laboratory that meets all CLSI standards. Medical specialists should provide a multidisciplinary approach to care, including the availability of on-site genetic counselors, dieticians, respiratory therapists and social workers. Medical specialists should provide access to microbiology laboratories that use CF-specific protocols for detection of respiratory tract infection.

9) Lysosomal Storage Disorders: certification by the American Board of Medical Genetics in Clinical Biochemical Genetics or certification by the American Board of Medical Genetics in Clinical Genetics with at least one year of experience post-training in the diagnosis and treatment of LSDs. Medical specialists should have the capacity to provide enzyme replacement infusion therapies and to provide a multidisciplinary approach to care, including the availability of pediatric specialists in neurology, cardiology and pulmonology. In addition to the above requirements, for Krabbe disease, medical specialists should be affiliated with a facility that has experience in performing stem cell transplantation.

10) Severe Combined Immunodeficiency and T Cell Lymphopenia: certification by the American Board of Allergy and Immunology with at least one year post-training in the diagnosis and treatment of primary immunodeficiency diseases. Medical specialists should have the capacity to diagnose SCID, DiGeorge syndrome or other causes of T cell lymphopenia and to provide a multidisciplinary approach to treatment, including access to specialists in stem cell transplantation, and be affiliated with a facility that has experience in performing stem cell transplantation.

(Source: Amended at 36 Ill. Reg. 1753, effective January 19, 2012)