**Section 661.10 Definitions**

"Adrenoleukodystrophy" or "ALD" means a rare inborn disorder that affects the brain, nervous system, and adrenal glands because the body cannot break down certain fatty acids.

"Advanced practice registered nurse" means a person who is licensed as an advanced practice registered nurse underthe Nurse Practice Act.

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

"Amino acid disorder" means a rare inborn disorder that prevents the proper processing of amino acids, the building blocks of proteins.

"ASHA 2019 Guidelines" means the "Year 2019 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs" created by the Joint Committee on Infant Hearing of the American Speech-Language-Hearing Association (ASHA) and incorporated by reference in Section 661.20(c)(4).

"Audiologist" means a person who is licensed as an audiologist by the Illinois Department of Financial and Professional Regulation to provide audiological services under the Illinois Speech-Language Pathology and Audiology Practice Act.

"Auditory Brainstem Response (ABR)", as used in the ASHA 2019 Guidelines, means electrophysiologic measurement of the brainstem's response to the acoustic stimulation of the ear.

"Automated Auditory Brainstem Response (AABR)", as used in the ASHA 2019 Guidelines, means objective electrophysiologic measurement of the brainstem's response to acoustic stimulation of the ear, obtained with equipment that automatically provides a pass/refer outcome.

"Authorized user" means an individual who has signed an Individual User Agreement and Confidentiality Statement, and for whom the Department has provided credentials authorizing that person access to the Registry.

"Bilateral Pass", as used in the ASHA 2019 Guidelines, means there is a low likelihood of significant hearing loss in both or either ear on the day of the screening.

"Biotinidase deficiency" means a rare inborn disorder that prevents proper use of a vitamin called biotin.

"Caregiver" means a person who directly attends to the needs or concerns of a newborn, infant or child.

"Child" means a person between the ages of 12 months through six years.

"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.

"Congenital adrenal hyperplasia" or "CAH" means a rare inborn disorder in which the body cannot produce enough of the hormone cortisol or a salt-retaining hormone.

"Congenital hypothyroidism" or "CH" means an inborn disorder in which the body does not make enough thyroid hormone.

"Critical Congenital Heart Disease" or "CCHD" includes, but is not limited to, the following heart defects present at birth: hypoplastic left heart syndrome; pulmonary atresia with intact septum; tetralogy of Fallot; total anomalous pulmonary venous return; transposition of the great arteries; tricuspid atresia; truncus arteriosus, coarctation of the aorta, double outlet right ventricle, Ebstein anomaly, interrupted aortic arch, single ventricle, and other critical CHDs requiring treatment in the first year of life.

"Cystic fibrosis" or "CF" means an inborn disorder in which the body produces thick, sticky mucus that causes respiratory and digestive problems.

"Department" or "DPH" or "IDPH" means the Illinois Department of Public Health or its designee.

"Director" means the Director of the Illinois Department of Public Health or the Director's designee.

"Discharge" means a newborn, infant or child's release from the premises of a medical care facility and into the care of the parent or legal guardian.

"DSCC" means the Division of Specialized Care for Children at the University of Illinois at Chicago.

"Early Hearing Detection and Intervention" or "EHDI" means the program established to screen every infant for hearing loss prior to one month of age, diagnose hearing loss prior to three months of age, and provide intervention services prior to six months of age.

"Early Hearing Detection and Intervention Act" or "EHDI Act" means the Early Hearing Detection and Intervention Act [410 ILCS 213].

"Early Hearing Detection and Intervention (EHDI) Service Providers" means Physicians, advanced practice nurses, physician assistants, otolaryngologists, audiologists, ancillary health care providers, early intervention programs and providers, parent support, parent-to-parent support programs, the Department of Human Services, and the University of Illinois at Chicago Division of Specialized Care for Children.

"Early Intervention" means the Department of Human Services' program described at 89 Ill. Adm. Code 500.10.

"Early intervention provider" means an individual providing developmental services to a child with a suspected or confirmed hearing loss and their family as part of a Part C or non-Part C early intervention service delivery plan.

"Fatty acid oxidation disorder" means a rare inborn disorder that causes the body to have trouble burning fat for energy.

"Formula" means a medically prescribed nutritional product that is designed and used to treat an inborn metabolic disorder.

"Galactosemia" means a rare inborn disorder that impairs digestion of a certain part of milk sugar called galactose.

"Guardian" means a person or entity legally responsible for a newborn, infant or child.

"Hearing loss" or "atypical hearing", as used in the ASHA 2019 Guidelines, means a dysfunction of the auditory system of any type and degree in one or both ears that is sufficient to interfere with the acquisition of communication and language skills.

"Hearing screening" means the completion of one or more objective, physiologic tests administered to screen the newborn, infant or child's hearing in each ear. The screening automatically provides a pass/refer outcome in each ear suggesting the need for further testing. The screening shall be performed by individuals who have been appropriately trained and utilize instrumentation and protocols recommended by the Joint Committee on Infant Hearing.

"Hearing screener" means an individual who is trained in the equipment and procedures to conduct newborn hearing screening.

"Hemoglobinopathies" means rare inborn disorders that impair the red blood cells' ability to carry oxygen to the body's organs and tissues.

"Homebirth" means any birth outside of a medical care facility or a birth where the newborn is not admitted to a medical care facility after birth.

"Hospital" means a facility licensed by the State of Illinois under the Hospital Licensing Act [210 ILCS 85] and for the purposes of this Part, that provides obstetrical and neonatal services. Also, for purposes of this Part, "hospitals" include children's hospitals and free standing birth centers that provide obstetrical and newborn nursery services. (See "Medical care facility".).

"Incomplete hearing screening" means the required number of screening sessions were not conducted prior to discharge.

"Individual user agreement" means a signed agreement stating that the Registry user agrees that information that identifies a patient will not be released to any other person without the written consent of the patient.

"Infant" means a baby up to 1 year (through 12 months) of age.

"Institutional Review Board" or "IRB" means the Department of Public Health committee authorized to review research studies to ensure the rights and well-being of people who are subjects in research are protected; investigators are provided with thorough and timely review of their research proposals; and persons participating in research are assured research is conducted in an ethical and accountable manner.

"Lysosomal storage disorders" or "LSDs" means rare inborn disorders in which the body is unable to break down or recycle certain types of complex fats, proteins, and sugars, due to lysosomal dysfunction.

"Medical care facility" means a hospital, birthing center or any other licensed facility that provides obstetrical and newborn nursery services.

"Medical Diagnostic Evaluation" means, for the purposes of this Part, the examination and medical procedures provided by personnel qualified and licensed to perform the procedures prescribed for the specified medical conditions for which an infant is being referred.

"Missed" means a newborn, infant or child did not complete newborn screening.

"Neonatal Intensive Care Unit" or "NICU" means an intensive care unit for high-risk newborns.

"Newborn" means a baby in the first month of life.

"Newborn blood spot screening" or "newborn blood spot testing" means the testing of a dried blood spot sample for conditions defined in the Newborn Metabolic Screening Act. At times, variant forms of some disorders, or related conditions, may also be identified.

"Newborn hearing screening" means the completion of one or more objective, physiologic, electronic tests administered as defined by the Early Hearing Detection and Intervention Act to determine the infant's hearing status in each ear and the need for further diagnostic testing by an audiologist.

"Newborn heart screening" or "CCHD screening" means the completion of one or more objective, physiologic tests administered to determine the newborn's blood oxygen level and the need for further diagnostic testing by a cardiologist.

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

"Newborn Screening Registry" or "Registry" or "Registries" means a data collection, follow-up, tracking, and reporting information system that is designed to support the Department's newborn screening program, including blood spot screening, hearing screening, and heart screening.

"Organic acid disorder" means a rare inborn disorder in which the body cannot remove certain waste products from the blood.

"Otoacoustic Emissions Testing", as used in the ASHA 2019 Guidelines, means a specific test method that elicits a physiologic response from the outer hair cells in the cochlea, and may include Transient Evoked Otoacoustic Emissions (TEOAE) and/or Distortion Product Otoacoustic Emissions (DPOAE).

"Otolaryngologist" means a physician trained in the medical and surgical management and treatment of patients with diseases and disorders of the ear, nose, throat (ENT), and related structures of the head and neck.

"Otologist" means a physician who specializes in treatment of the ear.

"Outpatient newborn hearing screening" means hearing screening completed after the newborn, infant or child is discharged to home.

"Parent support" means support services provided to parents and families of children who are deaf or hard of hearing by trained providers who support the EHDI principals.

"Parent-to-parent support" means support services provided to parents and families of children who are deaf or hard of hearing by trained providers who are also parents of children who are deaf or hard of hearing and who support the EHDI principals.

"Part C" is a section of the Individuals with Disabilities Education Act (IDEA) that defines the rights of a parent of a child, birth through age two with disabilities, who is receiving early intervention services.

"Pediatric audiologists" means audiologists with the equipment and experience to test children birth through six years of age for hearing loss and related issues, and who perform hearing tests and evaluations to determine the presence, extent, and reason for hearing loss in accordance with best practices and the Year 2019 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs.

"Plan of care" means an outline of care showing the newborn, infant or child's needs and the steps to take in meeting those needs.

"Primary healthcare provider" means the physician, physician assistant, advanced practice registered nurse or their agent who provides the newborn, infant, or child's routine medical care in the area where they reside after discharge.

"Provider site" means a health care provider or certified local health department to which the Department may release information from the Registry.

"Provider site enrollment" means the agreement that is signed by the provider or designee, who assumes responsibility for the proper use and protection of Registry data at the site.

"Public health surveillance" means the ongoing, systematic collection, analysis, and interpretation of health-related data essential to planning, implementation, and evaluation of public health practice.

"Risk factor" means an indicator associated with a higher risk of congenital, late-onset or acquired childhood hearing loss.

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

"Severe combined immunodeficiency" or "SCID" means a group of rare inborn disorders affecting the white blood cells responsible for fighting off infections.

"Sickle cell disease" and "sickling disorder" means a rare inborn disorder that impairs the red blood cells' ability to carry oxygen to the body's organs and tissues. A change in the shape of the red blood cells may occur, at times resembling a sickle shape.

"Significant Hearing Loss" means a dysfunction of the auditory system of any type or degree that is sufficient to interfere with the acquisition of speech and language skills.

"Site manager" means the person at the provider site who assumes responsibility for the proper use and protection of the Registry at the site.

"Special Care Baby Unit" or "SCBU" means a nursery that provides intermediate intensive care to newborns and infants.

"Spinal muscular atrophy" or "SMA" means a genetic disorder characterized by muscle weakness and atrophy caused by a loss of motor neurons.

"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.

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

"T-cell lymphopenia" means a state in which there is a reduced level of thymus derived lymphocyte count in the bloodstream.

"Total parenteral nutrition" or "TPN" means a method of feeding that bypasses the gastrointestinal tract by infusing nutrient solution directly into a blood vessel.

"Transfer" means that the newborn, infant, or child is moved from the birth location to the responsible medical care facility or moved between medical care facilities.

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

(Source: Amended at 48 Ill. Reg. 5175, effective March 12, 2024)