**Section 661.20 Incorporated and Referenced Materials**

1. The following federal and State statutes and rules guidelines are referenced in this Part:

1) Illinois Statutes:

1. Newborn Metabolic Screening Act [410 ILCS 240]
2. Early Hearing Detection and Intervention Act [410 ILCS 213]
3. Genetic and Metabolic Diseases Advisory Committee Act [410 ILCS 465]
4. Nurse Practice Act [225 ILCS 65]
5. Illinois Speech-Language Pathology and Audiology Practice Act [225 ILCS 110]
6. Early Intervention Services System Act [325 ILCS 20]
7. Illinois Health Statistics Act [410 ILCS 520]
8. Medical Studies Act [735 ILCS 5/8-2100]

2) Illinois Rules

Early Intervention Program (89 Ill. Adm. Code 500)

Illinois Clinical Laboratories Code (77 Ill. Adm. Code 450)

3) Federal Statutes

1. Family Educational Rights and Privacy Act (FERPA) (20 U.S.C. 1232(g))
2. Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. 1320d-2)
3. Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. 263a)
4. Individuals with Disabilities Education Act (20 U.S.C. 1400)
5. The following federal regulation is incorporated by reference in this Part:

Privacy Rule (Standards for Privacy of Individually Identifiable Health Information) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (45 CFR 164.512(a) and (k)(6) (October 1, 2007), 45 CFR 164.506 (October 15, 2002) and 45 CFR 164.501 (October 15, 2002)).

1. The following standards and guidelines are incorporated in this Part:

1) "Newborn Screening for Preterm, Low Birth Weight, and Sick Newborns", available at: Clinical and Laboratory Standards Institute (CLSI), 950 West Valley Road, Suite 2500, Wayne, PA 19087, 2009

2) "Strategies for Implementing Screening for Critical Congenital Heart Disease". Pediatrics, vol. 128, Pages 1259-1267, Copyright 2011 by the AAP.

3) "Overview of Cutoff Determinations and Risk Assessment Methods used in Dried Blood Spot Newborn Screening − Role of Cutoffs and Other Methods of Data Analysis", Association of Public Health Laboratories, Version Two, July 2022, available at: https://www.aphl.org/programs/newborn\_screening/Documents/Cutoff-Determinations-and-Risk-Assessment-Methods.pdf#search=cutoff.

4) "Year 2019 Position Statement: Principles and Guidelines for Early Hearing Detection and Intervention Programs", Joint Committee on Infant Hearing (JCIH), available at: American Speech-Language-Hearing Association (ASHA), 2200 Research Boulevard, Office 309, Rockville, MD 20850 or https://digitalcommons.usu.edu/jehdi/vol4/iss2/1/.

d) All incorporations by reference of federal regulations and guidelines and the standards of nationally recognized organizations refer to the regulations, guidelines and standards on the date specified and do not include any later amendments or editions.