SUBPART A: GENERAL PROVISIONS

Section

661.10 Definitions

661.20 Incorporated and Referenced Materials

661.30 General Procedures for Newborn and Infant Screening

661.40 Genetic and Metabolic Diseases Advisory Committee

661.50 Exemption

661.60 Fee Assessment and Payment

SUBPART B: NEWBORN SCREENING REGISTRIES

Section

661.100 Newborn Screening Registries

661.110 Early Hearing Detection and Intervention (EHDI) Registry

661.120 Confidentiality and Access to Data in Newborn Screening Registries

661.130 Data Submission

661.140 Provider Sites

661.150 Individual User Agreement

SUBPART C: NEWBORN SCREENING

Section

661.200 Collection and Submission of Specimens

661.210 Blood Spot Reporting

661.220 Retention of Specimens

661.230 Designation of Medical Specialists

SUBPART D: DETAILED PROCEDURES FOR BLOOD SPOT SCREENING

Section

661.300 Adrenoleukodystrophy (ALD)

661.310 Biotinidase Deficiency

661.320 Congenital Adrenal Hyperplasia (CAH)(Secondary to 21-hydroxylase deficiency)

661.330 Congenital Hypothyroidism (CH)

661.340 Cystic Fibrosis (CF)

661.350 Galactosemia

661.360 Lysosomal Storage Disorders (LSDs)

661.370 Amino Acid, Organic Acid and Fatty Acid Oxidation Disorders

661.380 Severe Combined Immunodeficiency (SCID)and T-Cell Lymphopenia

661.390 Sickle Cell Disease/Trait and Other Hemoglobinopathies

661.400 Spinal Muscular Atrophy (SMA)

SUBPART E: DETAILED PROCEDURES FOR NON-BLOOD SPOT SCREENING

Section

661.500 Critical Congenital Heart Disease (CCHD)

SUBPART F: EARLY HEARING DETECTION AND INTERVENTION (EHDI)

Section

661.599 Newborn Hearing Screening Program Goals

661.600 Newborn Hearing Screening

661.610 Responsibilities of Medical Care Facilities

661.620 Responsibilities of Service Providers

661.630 Access to Diagnostic Testing