AN ACT relating to newborn screening for spinal muscular atrophy (SMA).

Be it enacted by the General Assembly of the Commonwealth of Kentucky:

➔Section 1. KRS 214.155 is amended to read as follows:

(1) The Cabinet for Health and Family Services shall operate a newborn screening program for heritable and congenital disorders that includes but is not limited to procedures for conducting initial newborn screening tests on infants twenty-eight (28) days or less of age and definitive diagnostic evaluations provided by a state university-based specialty clinic for infants whose initial screening tests resulted in a positive test. The secretary of the cabinet shall, by administrative regulation promulgated pursuant to KRS Chapter 13A:

(a) Prescribe the times and manner of obtaining a specimen and transferring a specimen for testing;

(b) Prescribe the manner of procedures, testing specimens, and recording and reporting the results of newborn screening tests; and

(c) Establish and collect fees to support the newborn screening program.

(2) The administrative officer or other person in charge of each institution caring for infants twenty-eight (28) days or less of age and the person required in pursuance of the provisions of KRS 213.046 shall register the birth of a child and cause to have administered to every such infant or child in its or his care tests for heritable disorders, including but not limited to phenylketonuria (PKU), sickle cell disease, congenital hypothyroidism, galactosemia, medium-chain acyl-CoA dehydrogenase deficiency (MCAD), very long-chain acyl-CoA deficiency (VLCAD), short-chain acyl-CoA dehydrogenase deficiency (SCAD), maple syrup urine disease (MSUD), congenital adrenal hyperplasia (CAH), biotinidase disorder, and cystic fibrosis (CF), 3-methylcrotonyl-CoA carboxylase deficiency (3MCC), 3-OH 3-CH3 glutaric aciduria (HMG), argininosuccinic acidemia (ASA), beta-ketothiolase deficiency (BKT), carnitine uptake defect (CUD), citrullinemia (CIT), glutaric acidemia type I

(GA I), Hb S/beta-thalassemia (Hb S/Th), Hb S/C disease (Hb S/C), homocystinuria (HCY), isovaleric acidemia (IVA), long-chain L-3-OH acyl-CoA dehydrogenase deficiency (LCAD), methylmalonic acidemia (Cbl A,B), methylmalonic acidemia mutase deficiency (MUT), multiple carboxylase deficiency (MCD), propionic acidemia (PA), trifunctional protein deficiency (TFP), tyrosinemia type I (TYR I), ***spinal muscular atrophy (SMA),*** and krabbe disease. The listing of tests for heritable disorders to be performed shall include all conditions consistent with the recommendations of the American College of Medical Genetics.

(3) The administrative officer or other person in charge of each institution caring for infants twenty-eight (28) days or less of age and the person required in pursuance of the provisions of KRS 213.046 shall register the birth of a child and cause to have administered to every such infant or child in its or his care a screening for critical congenital heart disease (CCHD) prior to discharge unless CCHD has been ruled out or diagnosed with prior echocardiogram or prenatal diagnosis of CCHD.

(4) Each health care provider of newborn care shall provide an infant's parent or guardian with information about the newborn screening tests required under subsections (2) and (3) of this section. The institution or health care provider shall arrange for appropriate and timely follow-ups to the newborn screening tests, including but not limited to additional diagnoses, evaluation, and treatment when indicated.

(5) Nothing in this section shall be construed to require the testing of any child whose parents are members of a nationally recognized and established church or religious denomination, the teachings of which are opposed to medical tests, and who object in writing to the testing of his or her child on that ground.

(6) The cabinet shall make available the names and addresses of health care providers, including but not limited to physicians, nurses, and nutritionists, who may provide postpartum home visits to any family whose infant or child has tested positive for a

newborn screening test.

(7) A parent or guardian shall be provided information by the institution or health care provider of newborn care about the availability and costs of screening tests not specified in subsections (2) and (3) of this section. The parent or guardian shall be responsible for costs relating to additional screening tests performed under this subsection, and these costs shall not be included in the fees established for the cabinet's newborn screening program under subsection (1) of this section. All positive results of additional screening of these tests shall be reported to the cabinet by the institution or health care provider.

(8) (a) For the purposes of this subsection, a qualified laboratory means a clinical laboratory not operated by the cabinet that is accredited pursuant to 42 U.S.C. sec. 263a, licensed to perform newborn screening testing in any state, and reports its screening results using normal pediatric reference ranges.

(b) The cabinet shall enter into agreements with public or private qualified laboratories to perform newborn screening tests if the laboratory operated by the cabinet is unable to screen for a condition specified in subsection (2) of this section.

(c) The cabinet may enter into agreements with public or private qualified laboratories to perform testing for conditions not specified in subsection (2) of this section. Any agreement entered into under this paragraph shall not preclude an institution or health care provider from conducting newborn screening tests for conditions not specified in subsections (2) and (3) of this section by utilizing other public or private qualified laboratories.

(9) The secretary for health and family services or his or her designee shall apply for any federal funds or grants available through the Public Health Service Act and may solicit and accept private funds to expand, improve, or evaluate programs to provide screening, counseling, testing, or specialty services for newborns or children at risk

for heritable disorders.

(10) This section shall be cited as the James William Lazzaro and Madison Leigh Heflin Newborn Screening Act.