TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

Emergency Rule
LSA Document #18-277(E)

DIGEST

Temporarily amends 410 IAC 3-3-3 to add spinal muscular atrophy and severe combined immunodeficiency syndrome to the list of disorders for which all newborns shall be screened. Temporarily amends 410 IAC 3-3-13 to increase the fee charged for newborn screening to cover the cost of the additional screening. Effective June 29, 2018.

SECTION 1. **(a) This SECTION supersedes 410 IAC 3-3-3.**

(b) Except as provided for in section 2(c) of this section *[410 IAC 3-3-2(b)]* **, all newborns and infants born in the state of Indiana shall be screened for the following:**

(1) Phenylketonuria.
(2) Hypothyroidism.
(3) Galactosemia.
(4) Homocystinuria.
(5) Maple syrup urine disease.
(6) Hemoglobinopathies, including sickle cell anemia.
(7) Congenital adrenal hyperplasia.
(8) Biotinidase deficiency.
(9) Cystic fibrosis.
(10) Hearing impairment.
(11) Other genetic conditions that are detectable at birth via newborn screening methods, including, but not limited to, the following:
(A) Tandem mass spectrometry (MS/MS).
(B) High volume radioimmunoassay.
(C) Hemoglobin electrophoresis.
(D) Isoelectric focusing.
(E) Bacterial inhibition assays.
(F) Immunoreactive trypsin (IRT).
(G) DNA testing.
(12) Spinal muscular atrophy.
(13) Severe combined immunodeficiency syndrome.

(c) The responsible physician, midwife, birthing center, or hospital shall collect a specimen of the newborn or infant's blood on a filter paper kit approved by the department. The specimen shall consist of capillary blood obtained by heel puncture and applied directly to the special filter paper. All circles shall be saturated with blood from one (1) side of the filter paper only. All information requested on the form attached to the special filter paper shall be provided. The specimen shall be air dried and then inserted into the protective envelope with complete data. If multiple specimens are forwarded in one (1) envelope, care must be taken to avoid cross-contamination. Completed specimens shall be forwarded to a designated laboratory within twenty-four (24) hours after collection.

(d) The newborn or infant's blood for these tests shall be collected not earlier than forty-eight (48) hours after birth and not before the newborn or infant has been on a protein diet for at least twenty-four (24) hours, except as stated in subsection (e), and not later than one hundred twenty (120) hours after birth, except as stated in subsection (g).

(e) When a live birth occurs in a hospital or birthing center, the responsible physician or midwife shall have a specimen of the newborn or infant's blood taken prior to the newborn or infant's discharge from the hospital. If the newborn is discharged from the hospital before forty-eight (48) hours after birth, or before being on a protein diet for twenty-four (24) hours, a blood specimen shall be collected regardless, but collection shall be repeated after forty-eight (48) hours and not later than one hundred twenty (120) hours after birth. The hospital or birthing center shall provide a written notice to the parents, at or before discharge, of the requirements for the newborn to be tested again prior to one hundred twenty (120) hours after birth.

(f) When a live birth occurs in a facility other than a licensed hospital or birthing center, it shall be the responsibility of the physician or midwife in attendance at the birth to assure that the newborn or infant is referred to an appropriate facility, such as a physician office, hospital, birthing center, or local health department, and to make the arrangements to obtain and submit a satisfactory blood specimen in accordance with this section. In the absence of an attending physician or midwife, the registrar of births shall refer the newborn or infant immediately to the parent's physician or to the local health department for submission of a specimen in accordance with this section and notify the MCH/NBS immediately.

(g) For preterm newborns or infants, the specimen shall be taken on the day of discharge or on the sixth day if nursery stay is prolonged beyond six (6) days. Prematurity and transfusion status shall be noted on the request form in the space provided. If the newborn or infant is to receive total exchange transfusion, then the specimen for the newborn screening test is to be obtained from the first draw, which represents the newborn or infant's own blood.

(h) For newborns or infants within the neonatal intensive care unit (NICU), the responsible physician or hospital shall follow the routine NICU rescreening guidelines and collect specimens as specified by the department.

SECTION 2. **(a) This SECTION supersedes 410 IAC 3-3-13.**

(b) The program involving the department and MCH/NBS as described in this rule *[410 IAC 3-3]* shall be funded by the collection of a newborn screening fee for each initial newborn screening performed. The designated laboratory shall assess and collect the full amount of the newborn screening fee from hospitals, birthing centers, public health nurses, physicians, and midwives submitting newborn screening specimens. No surcharge will be assessed, collected, or reported for newborns or infants receiving repeat screens. The accumulated collections from the newborn screening fees shall be submitted on a monthly basis by the designated laboratory to the division of finance at the department. Payments shall be postmarked not later than five (5) days after the close of the preceding month. The designated laboratory shall also submit a monthly report on the number of newborns screened. Revenues submitted by the laboratory shall correspond with the number of newborns screened.

(c) The newborn screening fee shall be one hundred dollars ($100) based on the projected cost of the program described in this rule *[410 IAC 3-3]* and the estimated number of newborns per year. The fees shall be deposited in the newborn screening fund. Funds for the program described in this rule *[410 IAC 3-3]* shall be disbursed by the department in accordance with normal procedures prescribed by the state budget agency and the state board of accounts. The fee shall be reviewed annually by the department.

SECTION 3. SECTIONS 1 through 2 of this document take effect June 29, 2018.

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