

IC 16-41-17**Chapter 17. Prevention and Treatment Programs:
Examination of Infants for Phenylketonuria, Hypothyroidism,
and Other Disorders**

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IC 16-41-17-1 Waste blood specimen

Sec. 1. As used in this chapter, "waste blood specimen" means a blood sample or a solid, liquid, or semiliquid blood product that:

- (1) has served the intended purpose under section 4 of this chapter; or
- (2) has served the natural, biological, medical, or intended purpose and has been discarded or accumulated for discard from a use other than as provided under section 10(a)(5) of this chapter.

[Pre-1993 Recodification Citation: 16-8-6-1.6.]

As added by P.L.2-1993, SEC.24.

IC 16-41-17-2 Examinations; religious exemption

Sec. 2. (a) Subject to subsection (d), every infant shall be given examinations at the earliest feasible time for the detection of the following disorders:

- (1) Phenylketonuria.
- (2) Hypothyroidism.
- (3) Hemoglobinopathies, including sickle cell anemia.
- (4) Galactosemia.
- (5) Maple Syrup urine disease.
- (6) Homocystinuria.
- (7) Inborn errors of metabolism that result in an intellectual disability and that are designated by the state department.
- (8) Congenital adrenal hyperplasia.
- (9) Biotinidase deficiency.
- (10) Disorders detected by tandem mass spectrometry or other technologies with the same or greater detection capabilities as tandem mass spectrometry, if the state department determines that the technology is available for use by a designated laboratory under section 7 of this chapter.
- (11) Spinal muscular atrophy.
- (12) Severe combined immunodeficiency.
- (13) Beginning July 1, 2020, Krabbe disease.
- (14) Beginning July 1, 2020, Pompe disease.
- (15) Beginning July 1, 2020, Hurler syndrome (MPS1).
- (16) Adrenoleukodystrophy (ALD).

(b) Subject to subsection (d), every infant shall be given a physiologic hearing screening examination at the earliest feasible time for the detection of hearing impairments.

(c) Subject to subsection (d), every infant shall be given a pulse oximetry screening examination in accordance with rules adopted by the department for the detection of low

oxygen levels. Section 10(a)(2) of this chapter does not apply to this subsection.

(d) If a parent of an infant objects in writing, for reasons pertaining to religious beliefs only, the infant is exempt from the examinations required by this chapter.

[Pre-1993 Recodification Citation: 16-8-6-1.]

As added by P.L.2-1993, SEC.24. Amended by P.L.91-1999, SEC.2; P.L.149-2001, SEC.3; P.L.229-2011, SEC.165; P.L.117-2015, SEC.34; P.L.17-2018, SEC.1; P.L.1-2019, SEC.1; P.L.19-2020, SEC.1.

IC 16-41-17-3 Educational program

Sec. 3. The state department shall conduct an intensive educational program among physicians, hospitals, public health nurses, and the public concerning the disorders listed in section 2 of this chapter. The educational program must include information about:

- (1) the nature of the disorders; and
- (2) examinations for the detection of the disorders in infancy;

so that measures may be taken to prevent the intellectual disabilities, medical complications, or mortality resulting from the disorders.

[Pre-1993 Recodification Citation: 16-8-6-2.]

As added by P.L.2-1993, SEC.24. Amended by P.L.117-2015, SEC.35.

IC 16-41-17-4 Tests

Sec. 4. After consultation with medical authorities, the state department shall require appropriate tests to be used in the detection of disorders listed in section 2 of this chapter.

[Pre-1993 Recodification Citation: 16-8-6-3.]

As added by P.L.2-1993, SEC.24.

IC 16-41-17-5 Detection plans and procedures

Sec. 5. The state department and all local boards of health shall encourage and promote the development of plans and procedures for the detection of the disorders listed in section 2 of this chapter in all local health jurisdictions of Indiana.

[Pre-1993 Recodification Citation: 16-8-6-4.]

As added by P.L.2-1993, SEC.24.

IC 16-41-17-6 Reports

Sec. 6. (a) The state department shall provide forms on which the results of tests performed on each child for the disorders listed in section 2 of this chapter shall be reported to the state department by physicians and hospitals.

(b) The state department shall ascertain at least quarterly the extent of such testing and the findings shall be reported to all hospitals, physicians, and other groups interested in child welfare.

[Pre-1993 Recodification Citation: 16-8-6-5.]

As added by P.L.2-1993, SEC.24.

IC 16-41-17-7 Testing laboratories

Sec. 7. (a) The state department shall designate at least one (1) laboratory for testing for disorders listed in section 2(a) of this chapter.

(b) The designated laboratories shall perform tests on all infants for the detection of disorders under section 2(a) of this chapter.

(c) This section does not prevent other facilities from conducting tests for disorders under this chapter.

[Pre-1993 Recodification Citation: 16-8-6-6(a).]

As added by P.L.2-1993, SEC.24. Amended by P.L.91-1999, SEC.3.

IC 16-41-17-8 Blood sample; collection; exceptions

Sec. 8. (a) Each hospital and physician shall:

- (1) subject to subsection (b), take or cause to be taken a blood sample from every infant born under the hospital's and physician's care; and
- (2) transport or cause to be transported each blood sample described in subdivision (1) to a laboratory designated under section 7 of this chapter;

for testing for the disorders listed in section 2(a) of this chapter.

(b) This subsection does not apply to preterm infants or newborn infants who receive a total exchange blood transfusion. Except as provided in subsection (c), a newborn infant's blood sample taken under subsection (a)(1) must be collected not earlier than twenty-four (24) hours after birth.

(c) If a newborn infant is discharged before the time set forth in subsection (b), the blood sample must be collected not earlier than immediately before the infant's discharge, and a second blood sample must be collected after forty-eight (48) hours but not later than one hundred twenty (120) hours after birth.

[Pre-1993 Recodification Citation: 16-8-6-6(b).]

As added by P.L.2-1993, SEC.24. Amended by P.L.91-1999, SEC.4; P.L.38-2018, SEC.1.

IC 16-41-17-9 Rules

Sec. 9. The state department shall adopt rules under IC 4-22-2 to carry out this chapter, including rules to ensure the following:

- (1) Proper and timely sample collection and transportation under section 8 of this chapter.
- (2) Quality testing procedures at the laboratories designated under section 7 of this chapter.
- (3) Uniform reporting procedures.
- (4) Centralized coordination, tracking, and follow-up.
- (5) Appropriate diagnosis and management of affected newborns and counseling and support programs for newborns' families.

[Pre-1993 Recodification Citation: 16-8-6-7.]

As added by P.L.2-1993, SEC.24.

IC 16-41-17-10 Follow-up programs; newborn screening fees; waste blood specimen confidentiality

Sec. 10. (a) The state department shall develop the following:

- (1) A registry for tracking and follow-up of all newborns and individuals for screening.
- (2) A centralized program that provides follow-up, diagnosis, management, and family counseling and support, including equipment, supplies, formula, and other materials, for all infants and individuals identified as having one (1) of the disorders listed in section 2 of this chapter.
- (3) A laboratory quality assurance program, including proficiency testing.
- (4) A statewide network of genetic evaluation and counseling services.
- (5) A system for using, for epidemiological survey and research purposes, any waste blood specimen generated under this chapter.

(b) The program described in subsection (a) shall be funded by collection of a newborn screening fee for each newborn screened by a designated laboratory.

(c) The state department shall set the fee and procedures for disbursement under rules adopted under IC 4-22-2. The fee must be based upon the projected cost of the program. The proposed fee must be approved by the budget agency before the rule is adopted.

(d) The designated laboratory shall assess, collect, and deposit the fees established under subsection (c) in the newborn screening fund established under section 11 of this chapter.

(e) The state department shall annually review the newborn screening fee.

(f) Waste blood specimens used for the purpose of implementing the system described under subsection (a)(5) may not include the name or other identifying characteristics that

would identify the individual submitting the specimen.

[Pre-1993 Recodification Citation: 16-8-6-8 part.]

As added by P.L.2-1993, SEC.24.

IC 16-41-17-11 Newborn screening fund

Sec. 11. (a) The newborn screening fund is established for the purpose of carrying out this chapter. The state department shall administer the fund.

(b) The expenses of the newborn screening program shall be paid from money in the fund.

(c) Money in the fund at the end of a state fiscal year does not revert to the state general fund.

[Pre-1993 Recodification Citation: 16-8-6-9.]

As added by P.L.2-1993, SEC.24.