ARTICLE 3. MATERNAL AND CHILD HEALTH

Rule 1. Vision Acuity Testing

NOTE: This rule was promulgated jointly with the state board of education and also appears at 511 IAC 4-2-1.

410 IAC 3-1-1 Testing

Authority: IC 20-34-3-12
Affected: IC 20-34-3-12

Sec. 1. (a) All school corporations shall conduct an annual screening test of the visual acuity of all children enrolled in or transferred to grades 3 and 8 and all other school children suspected of having a visual defect.

(b) Equipment for testing visual acuity shall consist of the following:

(1) The minimum equipment to be used shall be a Snellen Chart illuminated by two (2) sixty (60) watt bulbs.

(2) The Snellen E Chart shall be used for grade 3.

(3) The Snellen Alphabetical Chart shall be used for grade 8.

(4) The use of testing equipment equivalent to or more elaborate than the Snellen test is at the discretion of the local school system and shall be based on the recommendations of the school's professional health advisory sources.

(Indiana State Department of Health; Reg MCH 1,A; filed Mar 21, 1960: Rules and Regs. 1961, p. 217; filed May 11, 1988, 4:30 pm: 11 IR 3539; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 3-1-2 Testing procedures; standards

Authority: IC 20-34-3-12
Affected: IC 20-34-3-12

Sec. 2. Procedures for vision testing are as follows:

(1) Equipment shall be used as follows:

(A) The Snellen Chart (E or Alphabetical) shall be used at a distance of twenty (20) feet.

(B) The lamps used to illuminate the chart shall be placed one (1) foot from the chart.

(2) The following standards apply:

(A) Children in grade 3 who are unable to read with each eye the 20/30 line of the Snellen Chart shall be recommended for further examination based upon the recommendations of the professional advisors of a school's eye screening program.

(B) Children in grade 8 who are unable to read with each eye the 20/20 line of the Snellen Chart shall be recommended for further examination.

(C) Parents of children with corrective lenses or other ocular devices shall be informed of the eye screening program but these children need not be referred for further examination.

(Indiana State Department of Health; Reg MCH 1,B; filed Mar 21, 1960: Rules and Regs. 1961, p. 217; filed May 11, 1988, 4:30 pm: 11 IR 3539; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 3-1-3 Qualification of testers

Authority: IC 20-34-3-12
Affected: IC 20-34-3-12

Sec. 3. The school administrator shall assign the best qualified person in the school system or school health service to supervise eye screening tests. *(Indiana State Department of Health; Reg MCH 1,C; filed Mar 21, 1960: Rules and Regs. 1961, p. 218; filed May 11, 1988, 4:30 pm: 11 IR 3539; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)*

410 IAC 3-1-4 Reports

Authority: IC 20-34-3-12
Affected: IC 20-34-3-12

Sec. 4. Reporting of School Testing Program

(1) Each school corporation shall submit an annual report of its vision testing program to the Indiana state board of health.

(2) The report shall include the following:

(A) the number of children in each grade tested;

(B) the number of children in each grade requiring further examination;

(C) the number of children receiving further professional attention;

(D) the type of screening test used;

(E) the person or department supervising the testing program.

(3) The school's testing program shall be subject to review and approval by the state board of education and the state board of health.

(Indiana State Department of Health; Reg MCH 1,D; filed Mar 21, 1960: Rules and Regs. 1961, p. 218; filed May 11, 1988, 4:30 pm: 11 IR 3539; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

Rule 1.1. Visual Acuity Testing; Modified Clinical Technique

NOTE: This rule was promulgated jointly with the state board of education and also appears at 511 IAC 4-2-1.1.

410 IAC 3-1.1-1 Annual vision test

Authority: IC 20-34-3-12
Affected: IC 20-34-3-12

Sec. 1. Every school corporation shall conduct an annual visual test, using the modified clinical technique, of children when they enroll in either kindergarten or grade 1 unless an eye care professional requests, in writing, that the child not be tested. The modified clinical technique consists of testing for vision acuity, refractive error, ocular health, and binocular coordination. The school corporation shall use the suggested equipment unless the professional health personnel of the school recommend other equivalent or superior equipment. *(Indiana State Department of Health; 410 IAC 3-1.1-1; filed May 11, 1988, 4:30 pm: 11 IR 3540; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)*

410 IAC 3-1.1-2 Visual acuity

Authority: IC 20-34-3-12
Affected: IC 20-34-3-12

Sec. 2. To test for visual acuity, the school corporation shall use the Snellen Alphabetical, Stycar (HOTV) Chart or equivalent test. The chart shall be calibrated at ten (10) to twenty (20) feet for distance vision and fourteen (14) inches for near vision. For testing distance vision, the chart shall be illuminated by two (2) sixty (60) watt bulbs and for near vision, by one (1) sixty (60) watt bulb. The chart shall be located at a distance of ten (10) to twenty (20) feet from the student and calibrated accordingly. Lamps shall be placed one (1) foot from the chart. The school shall recommend for further examination those students who:

(1) are unable to read the 20/40 line with either eye;

(2) with one (1) eye can read a line that is two (2) or more lines higher or lower on the chart than the line that can be read with the other eye; or

(3) are unable to read the 20/30 line at 14 inches using both eyes.

(Indiana State Department of Health; 410 IAC 3-1.1-2; filed May 11, 1988, 4:30 pm: 11 IR 3540; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 3-1.1-3 Refractive error

Authority: IC 20-34-3-12
Affected: IC 20-34-3-12

Sec. 3. To test for refractive error, a retinoscope with loose lenses or a lens bar shall be used. The child shall focus on an object at twenty (20) feet for distance vision of 3/4 meter (29.53 inches) for near vision. A school corporation shall recommend for further examination a student who has:

(1) refraction of + 2.00D or greater;
(2) refraction of - 1.00D or greater;
(3) astigmatism of 1.00D or greater;
(4) anisometropia of 1.00D or greater.

(Indiana State Department of Health; 410 IAC 3-1.1-3; filed May 11, 1988, 4:30 pm: 11 IR 3540; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 3-1.1-4 External health of eye

Authority: IC 20-34-3-12
Affected: IC 20-34-3-12

Sec. 4. To determine the external health of the eyes, the ocular adnexa, conjunctiva and cornea of the eyes shall be observed in a room with normal illumination and the illumination from a pen light. *(Indiana State Department of Health; 410 IAC 3-1.1-4; filed May 11, 1988, 4:30 pm: 11 IR 3540; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)*

410 IAC 3-1.1-5 Internal health of eye

Authority: IC 20-34-3-12
Affected: IC 20-34-3-12

Sec. 5. To determine the internal health of the eyes, the anterior chamber, iris, posterior chamber, lens, vitreous, optic nerve head, and retina shall be observed with a direct ophthalmoscope with rheostat, variable aperture and variable plus and minus lenses. *(Indiana State Department of Health; 410 IAC 3-1.1-5; filed May 11, 1988, 4:30 pm: 11 IR 3540; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)*

410 IAC 3-1.1-6 Binocularity

Authority: IC 20-34-3-12
Affected: IC 20-34-3-12

Sec. 6. Binocularity shall be tested respectively at twenty (20) feet (distance) and fourteen (14) inches (near). To test the binocularity of the eyes, any of the following equipment may be used:

(1) A paddle occuluder *[sic.]* to alternately cover the eyes while the opposite eye fixates on a target.
(2) Plastic or glass prisms loose or in a bar or rotary pedestal to measure manifest or latent deviation.
(3) Stereopsis targets with appropriate testing spectacles. Disparity shall be recorded in seconds of arc.

(Indiana State Department of Health; 410 IAC 3-1.1-6; filed May 11, 1988, 4:30 pm: 11 IR 3540; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 3-1.1-7 Further examination

Authority: IC 20-34-3-12
Affected: IC 20-34-3-12

Sec. 7. The school corporation shall recommend for further examination those students who demonstrate:
(1) a manifest deviation of any size;
(2) a latent deviation of 10 prism diopters of exodeviation;
(3) a latent deviation of 8 prism diopters of esodeviation; or
(4) a lack of stereo acuity.

(Indiana State Department of Health; 410 IAC 3-1.1-7; filed May 11, 1988, 4:30 pm: 11 IR 3541; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 3-1.1-8 Eye health care professional; qualifications

Authority: IC 20-34-3-12
Affected: IC 20-34-3-12

Sec. 8. Qualification of testers:
(1) The school administrator shall be responsible for assigning the best qualified person(s) in the school system or school health service for conducting, supervising, and assisting in eye screening.
(2) The school administration shall be responsible for obtaining the services of a licensed eye health care professional to conduct testing using the modified clinical technique (internal and external diseases of the eye, testing of refraction and binocularity using paddle occlusion test with prism measurement) for students upon first entrance into the school.

(Indiana State Department of Health; 410 IAC 3-1.1-8; filed May 11, 1988, 4:30 pm: 11 IR 3541; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

Rule 2. Lead Poisoning Testing; Sickle Cell Anemia Testing

NOTE: This rule was promulgated jointly with the state board of education and also appears at 511 IAC 4-2-2.

410 IAC 3-2-1 Lead poisoning testing

Authority: IC 20-34-3-1; IC 20-34-3-11
Affected: IC 20-34-3-11

Sec. 1. Lead Poisoning Test. Lead poisoning test methods shall include one or more of the following acceptable quantitative test procedures for screening or confirmatory purposes to determine the content of lead in blood, urine or other clinial specimen from human sources.

(a) The acceptable quantitative test procedures for the detection of blood lead shall include the following methods: dithizone, colorimetric, atomic absorption spectrophotometric, emission spectroscopic, anodic stripping voltametric, fluorimetric test for free erythrocyte porphyrins (indirect test for blood lead), or any other procedure shown to be accurate and reliable.

(b) Also acceptable is the quantitative test on urine to measure elevated urinary ALA (delta-aminolevulnic acid) as an indirect test for lead poisoning or any other accurate and reliable test on urine, specimens of hair or other clinical specimen from human sources.

(Indiana State Department of Health; Rule MCH 2,Sec 1; filed Apr 10, 1974, 2:00 pm: Rules and Regs. 1975, p. 342; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

410 IAC 3-2-2 Sickle cell anemia testing

Authority: IC 20-34-3-1; IC 20-34-3-10
Affected: IC 20-34-3-10

Sec. 2. Sickle Cell Anemia.

(a) The sickle cell anemia testing equipment shall be of a type generally recognized as suitable to provide accurate test results by one or more of the test procedures indicated in (c). The equipment may be of manual or automated design, subjected to whatever periodic preventive maintenance and quality control measures are necessary to assure satisfactory operation and accurate test results.

(b) The qualifications of the sickle cell anemia testing personnel shall indicate sufficient training and experience in the techniques of the tests employed to assure competency in operation of the testing equipment and accuracy in the test results obtained.

(c) The sickle cell anemia testing procedures shall consist of one or more test methods generally recognized as dependable and accurate for the detection of sickle cell anemia. The test procedures may be of manual or automated type. The screening tests and/or confirmatory tests recognized as useful include the sodium metabisulfite method, the solubility or dithionite-type tests, hemoglobin electrophoresis procedures, and other tests which detect sickle cell anemia.

(Indiana State Department of Health; Rule MCH 2,Sec 2; filed Apr 10, 1974, 2:00 pm: Rules and Regs. 1975, p. 342; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; readopted filed Sep 11, 2013, 3:19 p.m.: 20131009-IR-410130346RFA)

Rule 3. Newborn Screening

410 IAC 3-3-1 Definitions

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 1. The following definitions apply throughout this rule:

(1) "Audiologist" means an audiologist licensed by the state of Indiana pursuant to the Indiana professional licensing agency board who meets the requirements outlined in Indiana's Best Practice Guidelines for Assessment and who administers short-term and long-term early hearing detection and intervention (EHDI) program follow-up.

(2) "Birthing center" means any nonhospital facility in which live births routinely take place.

(3) "Child" means an individual twelve (12) months to eighteen (18) years of age.

(4) "Department" means the Indiana state department of health.

(5) "Diagnostic audiology Level 1 facility" means a facility as defined by the department that has and uses the recommended test battery and equipment for provision of comprehensive audiological assessment of newborns and infants.

(6) "EHDI follow-up" means follow-up that occurs subsequent to newborn hearing screening. Children in need of EHDI follow-up include the following:

(A) Newborns or infants not yet screened (for any reason).

(B) Newborns or infants who did not pass newborn hearing screening.

(C) Newborns or infants who passed newborn hearing screening but have a risk indicator that could lead to late-onset hearing loss.

(7) "Galactosemia" means an inherited error in the metabolism of galactose.

(8) "Health care provider" means the medical professional providing care after birth.

(9) "Hearing loss" means an impairment that is a dysfunction of the auditory system of any type or degree sufficient to interfere with acquisition and development of speech and language.

(10) "Hearing screening" means a bilateral, physiological measurement of hearing on a newborn or infant.

(11) "Hemoglobinopathy" means a condition where a person has abnormal hemoglobin that results from an inherited defect, some of which may produce a sickling phenomenon in erythrocytes.

(12) "Homocystinuria" means an inherited error in the metabolism of methionine.

(13) "Hospital" means a licensed hospital with obstetric services.
(14) "Hypothyroidism" means a deficient amount or activity of thyroid hormone.
(15) "Infant" means an individual who is thirty (30) days to twelve (12) months of age.
(16) "Maple syrup urine disease" means an inherited error in the metabolism of leucine, isoleucine, and valine.
(17) "MCH/CSHCS clinics" means clinics affiliated with the children's special health care services program of the division of maternal and child health of the department that provide services to women, children, and children with special health care needs.
(18) "MCH/NBS" means division of maternal and child health, genomics and newborn screening program, at the department.
(19) "Midwife" means an individual licensed under IC 25-23-1-13.1.
(20) "Metabolic formula" means a nutritional supplement provided to patients diagnosed with metabolic newborn screening conditions.
(21) "Newborn" means an individual who is up to twenty-nine (29) days of age.
(22) "Parent" means a natural (birth) parent, stepparent, adoptive parent, legal guardian, or other legal custodian of an individual.
(23) "Phenylketonuria" means an inherited error in the metabolism of phenylalanine.
(24) "Physician" means an individual licensed under IC 25-22.5-5.
(25) "Satisfactory blood specimen" means a blood specimen on which an accurate laboratory analysis can be performed for the disorder for which it is submitted.
(26) "Unsatisfactory blood specimen" means any of the following:
(A) A filter paper kit on which an insufficient quantity of blood is obtained.
(B) A filter paper kit on which an accurate analysis or interpretation cannot be performed due to improper collection, handling, or submission or a technical or laboratory problem.
(C) Cord blood.
(D) Blood from any transfused neonate.
(E) A filter paper kit that does not provide all of the information regarding the patient as required. The blood specimen within such a filter paper kit may be satisfactory according to section 3 of this rule.

(Indiana State Department of Health; 410 IAC 3-3-1; filed Nov 7, 1986, 3:30 p.m.: 10 IR 415; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

410 IAC 3-3-2 Provision of testing information; religious objection

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 2. (a) The department shall provide public educational materials, including descriptions of the disorders and of the screening program, to hospitals, birthing centers, physicians, midwives, and other health care providers for distribution to patients. Physicians and midwives engaged in providing prenatal or perinatal care, or both, shall provide pregnant women, prior to the estimated date of delivery, with this information. Hospitals and birthing centers shall provide each pregnant woman admitted for delivery with a copy of this information prior to collection of the blood specimen. If a woman is unable to read the material, it shall be translated or read to her in a language she understands.

(b) Any parent who objects to the testing for reasons pertaining to religious beliefs only shall so indicate by signing a statement of informed refusal. The objection shall become part of the medical record, and the newborn or infant shall be exempted from the testing. *(Indiana State Department of Health; 410 IAC 3-3-2; filed Nov 7, 1986, 3:30 p.m.: 10 IR 416; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)*

410 IAC 3-3-2.5 Equipment and supplies for newborn screening

Authority: IC 16-41-17
Affected: IC 16-41-17

Sec. 2.5. (a) The state-contracted newborn screening laboratory will furnish filter paper kits, without additional cost, annually to hospitals, midwives, birthing centers, and other collections sources. Manufacturer and lot number for the filter paper must be included on the filter paper section of the kit in accordance with the Clinical Laboratory Standards Institute (CLSI)-approved national standard. Sequential system control numbers for each collection kit must be printed on each information section of the collection card and on the filter paper section, if that section is detachable.

(b) The state-contracted newborn screening laboratory must provide filter paper kits, without additional cost, to local health departments, MCH/CSHCS clinics, or other outside organizations/individuals as designated by the department for the collection of newborn screening specimens.

(c) The department's newborn screening program will ensure that all Indiana residents who are diagnosed with one (1) of the metabolic conditions included in the newborn screening panel have access to the appropriate metabolic formula necessary for treatment as follows:

(1) A single brand of metabolic formula for each metabolic condition on the newborn screen will be designated by the state-contracted metabolic geneticist and made available to all Indiana residents as appropriate.

(2) The appropriate metabolic formula will be made available to all Indiana residents diagnosed with one (1) of the metabolic conditions included on Indiana's newborn screening panel, regardless of the individual's ability to pay or socioeconomic status as follows:

(A) Payment for metabolic formula will be based on a sliding-fee scale as designated by the department.

(B) All efforts will be made to collect payment for metabolic formula from private insurance companies or other third-party payers.

(C) The department's newborn screening program will serve as a payer of last resort for patients without private insurance coverage or for whom reimbursement cannot be obtained from another third-party payer.

(d) All other costs related to purchasing equipment or supplies that are required to perform mandated newborn screening must be covered by the hospital, birthing center, midwifery, or physician practice. *(Indiana State Department of Health; 410 IAC 3-3-2.5; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)*

410 IAC 3-3-3 Screening for certain disorders; collection procedures

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 3. (a) Except as provided for in section 2(b) of this rule, all newborns and infants born in the state of Indiana shall be screened for the following:

(1) The following endocrine disorders:

(A) Congenital adrenal hyperplasia (CAH).

(B) Hypothyroidism.

(2) The following hemoglobinopathies:

(A) Sickle cell anemia Hb SS.

(B) Hb S/C.

(C) Hb S/beta-thalassemia.

(D) Other Hb variant including genetic trait.

(3) The following metabolic conditions:

(A) The following amino acid (AA) disorders (include urea cycle disorders):

(i) Arginase deficiency (argininemia).

(ii) Argininosuccinic aciduria.

(iii) Biopterin cofactor defects.

(iv) Citrullinemia, type I.
(v) Citrullinemia, type II (also called Citron deficiency).
(vi) Homocystinuria (HCY).
(vii) Hypermethioninemia.
(viii) Hyperphenylalaninemia (also called H-Phe).
(ix) Maple syrup urine disease (MSUD).
(x) Phenylketonuria (PKU).
(xi) Tyrosinemia type I.
(xii) Tyrosinemia type II.
(xiii) Tyrosinemia type III.

(B) The following fatty acid oxidation (FAO) disorders:
(i) 2, 4-dienoyl-CoA reductase deficiency.
(ii) Carnitine-Acylcarnitine translocase deficiency (CACT).
(iii) Carnitine palmitoyltransferase deficiency I (CPT IA).
(iv) Carnitine palmitoyltransferase deficiency II (CPT II).
(v) Carnitine uptake defect (CUD).
(vi) Glutaric acidemia type II.
(vii) Long chain hydroxyacyl-CoA dehydrogenase deficiency (LCHAD).
(viii) Medium chain acyl-CoA dehydrogenase deficiency (MCAD).
(ix) Medium/short chain L-3-hydroxyacyl-CoA dehydrogenase deficiency (M/SCHAD).
(x) Trifunctional protein deficiency.
(xi) Very long chain acyl-CoA dehydrogenase deficiency (VLCAD).
(xii) Medium-chain ketoacyl-CoA thiolase deficiency (MCAT).

(C) The following organic acidemia (OA):
(i) 2-Methylbutyrylglycinuria (2-MBG).
(ii) 3-Hydroxy-3-methyl glutaric aciduria (HMG).
(iii) 3-Methylcrotonyl-CoA carboxylase deficiency (3-MCC deficiency).
(iv) 3-Methylglutaconic acidemia (3-MGA).
(v) Beta-ketothiolase deficiency.
(vi) Glutaric acidemia type I (GA type I).
(vii) Isobutyrylglycinuria (IBG).
(viii) Isovaleric acidemia (IVA).
(ix) Malonic aciduria (MAL).
(x) Methylmalonic acidemia (MUT or methylmalonyl-CoA mutase).
(xi) Methylmalonic acidemia with cobalamin disorders (CblA and CblB).
(xii) Methylmalonic acidemia with homocystinuria (CblC and CblD).
(xiii) Propionic acidemia.
(xiv) 2-Methyl-3-hydroxybutyric aciduria (2M3HBA).

(4) The following other inborn errors of metabolism:
(A) Biotinidase deficiency.
(B) Galactosemia (classic galactosemia or G/G, galactosemia D/G variant and other galactosemia variants).

(5) The following other genetic conditions:
(A) Cystic fibrosis.
(B) Severe combined immunodeficiencies (SCID).
(C) Spinal muscular atrophy (SMA).

(6) Other genetic conditions that are detectable at birth via newborn screening methods, including, but not limited to, the following:
(A) Tandem mass spectrometry.
(B) High performance liquid chromatography.

(C) Isoelectric focusing.
(D) Time resolved fluoroimmunoassay: immunoreactive trypsinogen (IRT) measurement.
(E) Other enzymatic assay.
(F) Fluorometric assay.
(G) DNA mutation analysis.

(b) 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.

(c) The newborn or infant's blood for these tests shall be collected not earlier than twenty-four (24) hours after birth and not later than forty-eight (48) hours after birth, except as stated in subsections (f) and (g).

(d) 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 twenty-four (24) hours after birth, 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.

(e) 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 ensure 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.

(f) For preterm or low birth weight (less than two thousand (2,000) grams) newborns or infants, the initial specimen shall be taken not earlier than twenty-four (24) hours after birth and not later than forty-eight (48) hours after birth. A repeat specimen collection shall be taken not earlier than fourteen (14) days and not later than thirty (30) days after birth or the day of discharge, whichever comes first. Prematurity and transfusion status shall be noted on the request form in the space provided. If the newborn or infant is to receive transfusion, then the specimen for the newborn screening test is to be obtained prior to transfusion, which represents the newborn or infant's own blood. If the pre-transfusion collection occurred before twenty-four (24) hours after birth, a repeat collection shall be taken not earlier than twenty-four (24) hours post-transfusion start time. Additional repeat collection shall be taken at fourteen (14) days and thirty (30) days or day of discharge, whichever comes first.

(g) Except for newborns and infants described in subsection (f), for newborns or infants within the neonatal intensive care unit (NICU), the initial collections shall be taken not earlier than twenty-four (24) hours after birth and not later than forty-eight (48) hours after birth. A repeat collection shall be taken at fourteen (14) days and thirty (30) days or day of discharge, whichever comes first. *(Indiana State Department of Health; 410 IAC 3-3-3; filed Nov 7, 1986, 3:30 p.m.: 10 IR 416; filed Sep 17, 1999, 10:42 a.m.: 23 IR 324; errata filed Nov 19, 1999, 9:31 a.m.: 23 IR 814; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA; filed Sep 28, 2018, 2:04 p.m.: 20181024-IR-410180158FRA)*

410 IAC 3-3-3.5 Pulse oximetry measurement for critical congenital heart disease

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 3.5. (a) Except as provided for in section 2(b) of this rule, every newborn shall be given a pulse oximetry screening examination:

(1) not earlier than twenty-four (24); and

(2) not later than forty-eight (48);

hours after birth. Preterm newborns or infants shall be given a pulse oximetry screening, including repeat screenings, at or near the time the specimen is taken as provided for in section 3(f) of this rule.

(b) Pulse oximetry screenings shall be taken from pulse oximetry readings on the right hand and one (1) foot.

(c) A passing pulse oximetry reading is an initial reading or repeat readings, which is:

(1) greater than or equal to ninety-five percent (95%) on the right hand or foot; and

(2) less than or equal to three percent (3%) variance between the right hand and foot.

(d) Except as provided in subsection (e), newborns who do not pass the initial pulse oximetry reading as described in subsection (c) shall have up to three (3) repeat readings performed at one (1) hour increments. If the newborn does not pass one (1) three (3) repeat readings as described in subsection (c), the newborn shall be immediately referred for cardiology evaluation.

(e) Newborns with an initial pulse oximetry reading of less than ninety percent (90%) on right hand or foot shall be immediately referred for cardiology evaluation.

(f) Newborns referred for cardiology evaluation as required in either subsection (d) or (e) shall be given, at a minimum, diagnostic testing via echocardiogram. *(Indiana State Department of Health; 410 IAC 3-3-3.5; filed Sep 28, 2018, 2:04 p.m.: 20181024-IR-410180158FRA)*

410 IAC 3-3-4 Designated laboratories; requirements to perform screening tests for disorders

Authority: IC 16-19-3-4; IC 16-41-17-9

Affected: IC 16-41-17

Sec. 4. An approved laboratory must meet the following requirements in order to perform screening tests for disorders on dried blood samples from newborns or infants:

(1) Complies with Public Law 90-174, the Federal Clinical Laboratory Improvement Act of 1988, and is accredited by the College of American Pathologists, or is accredited by the Joint Commission on Accreditation of Hospitals.

(2) Performs or makes reasonable assurances that it will perform each one of the above screening tests on all newborns or infants born in the state of Indiana.

(3) Performs repeat newborn screening on blood specimens annually as a follow-up to abnormal screens or screens that are not legally valid as described above.

(4) Uses laboratory procedures and values for normal and abnormal test results that have been submitted to and approved by the department.

(5) Initiates the approved tests within twenty-four (24) hours of receipt of the specimen and completes all approved tests within seventy-two (72) hours of receipt of the specimen.

(6) Reports findings in a timely manner and maintains records of the results of all screening and follow-up testing in accordance with the requirements of the department.

(7) Provides reports of its screening activities to the department in the format and time frame specified by the department.

(8) Maintains a written quality assurance program covering all aspects of its newborn screening activity, which is approved yearly by the department.

(9) Cooperates with other relevant agencies concerned with newborn or infant health care.

(10) Participates in a laboratory quality assurance program, including proficiency testing, approved by the department.

(Indiana State Department of Health; 410 IAC 3-3-4; filed Nov 7, 1986, 3:30 p.m.: 10 IR 417; filed Feb 25, 1988, 4:30 p.m.: 11 IR 2579; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

410 IAC 3-3-5 Laboratory reports

Authority: IC 16-19-3-4; IC 16-41-17-9

Affected: IC 16-41-17

Sec. 5. Specific reporting/follow-up requirements vary based on whether the analysis indicated whether the specimen met all requirements for a valid screening test and whether the screening results were normal, unsatisfactory, abnormal, presumptive positive, or confirmed positive. The laboratory shall report as follows:

(1) Negative test results shall be reported within seven (7) days of the date of receipt of the specimen to the following:

(A) MCH/NBS.

(B) The hospital or birthing center submitting the specimens.

(C) The responsible physician or midwife.

The report of the test results shall become part of the patient's clinical record.

(2) Presumptive positive tests shall be reported immediately by telephone to the hospital, birthing center, responsible physician, midwife, or collection source. The notification shall be recorded in the laboratory's records, specifying date and time of notification, person notified, and information provided. This shall be followed by an official report within three (3) days. The report of the test result shall become part of the patient's clinical record. If there is no known responsible physician or midwife, the appropriate state-contracted newborn screening follow-up specialist shall be notified.

(3) Confirmed positive tests shall be reported immediately by telephone to the hospital, birthing center, responsible physician, or midwife and MCH/NBS. The notification shall be recorded in the laboratory's records specifying date and time of notification, person notified, and information provided. This shall be followed by an official report within three (3) days. The report of the test result shall become part of the patient's clinical record. If there is no known responsible physician or midwife, the local health officer in the county of the mother's residence shall be notified.

(4) Unsatisfactory specimens shall be reported immediately by telephone to the hospital or birthing center and responsible physician, midwife, or other health care provider submitting the specimen with an explanation about the reason for rejection. In the event that the responsible physician, midwife, or health care provider who submitted the specimen is no longer the primary health care provider, he or she shall be responsible for notifying the current primary health care provider.

(5) In the event a specimen is rejected for any reason as unsatisfactory, the health care provider responsible for the newborn or infant's care at the time of the report shall be responsible for the submission of an acceptable specimen within forty-eight (48) business hours. If the laboratory does not receive the repeat specimen within five (5) days, it shall send the collection source and responsible health care provider notification of the requirement for a repeat screen, with a copy provided for MCH/NBS. A reminder will be sent five (5) business days after the initial notification if no repeat specimen has been received. The laboratory will notify MCH/NBS immediately by telephone if no repeat specimen has been received seven (7) to ten (10) business days after the reminder letter has been sent so that public health nurse assistance can be obtained.

(6) The designated laboratories performing the tests shall maintain records of the results of all screening and follow-up testing of newborns or infants for these conditions in accordance with Indiana requirements for records management.

(7) The laboratory shall provide newborn heel-stick, pulse oximetry, and hearing screening reports to the department in the format, media, and time frame specified by the department.

(Indiana State Department of Health; 410 IAC 3-3-5; filed Nov 7, 1986, 3:30 p.m.: 10 IR 417; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA; filed Sep 28, 2018, 2:04 p.m.: 20181024-IR-410180158FRA)

410 IAC 3-3-6 Maintenance of screening logs; follow-up of missing results; monthly reports as submitted by hospitals, birthing centers, midwives, and physicians providing home birth services

Authority: IC 16-19-3-4; IC 16-41-17-9

Affected: IC 16-41-17

Sec. 6. (a) Each hospital or birthing center, and midwife or physician submitting screening tests on newborns or infants born outside a hospital or birthing center shall maintain a newborn screening log that shall contain the following:

(1) Name of newborn or infant.

(2) Attending physician or midwife.

(3) Medical record number.

(4) Form number of sample sent.

(5) Date sample collected.
(6) Date sample sent.
(7) Date results received.
(8) What the results were.
(9) Name of person notified of positive results and date and time of notification.

All such information and records shall be confidential but shall be open to examination by the department personnel or its designated agents for any purpose directly connected with the administration of the newborn screening program.

(b) The log shall be reviewed daily to determine that the results of required tests have been recorded within fourteen (14) days of discharge, or that a parent's signed religious waiver has been filed in the infant or newborn's medical record.

(c) Whenever a hospital, birthing center, physician, or midwife determines that a discharged newborn or infant has not received the mandated tests, the hospital, birthing center, physician, or midwife shall immediately contact the responsible health care provider by telephone to inform him or her that a specimen must be obtained and immediately send a written notification to the responsible health care provider and MCH/NBS. If the responsible health care provider cannot be contacted within three (3) days or will not obtain a specimen, the hospital, birthing center, physician, or midwife shall notify MCH/NBS immediately by telephone and shall send written notification within three (3) days to MCH/NBS. MCH/NBS shall then immediately notify the local health officer, who shall arrange collection of a specimen.

(d) Whenever a hospital, birthing center, physician, or midwife determines that a specimen has been obtained but there are no results available in the infant or newborn's medical record within fourteen (14) days of discharge, the hospital, birthing center, physician, or midwife shall obtain the results from the laboratory by telephone and request that another written copy be sent. The hospital, birthing center, physician, or midwife shall also notify MCH/NBS that results have not been received. If no results are available from the laboratory, then the hospital, birthing center, physician, or midwife shall proceed as in section 7(c) of this rule.

(e) When the responsible health care provider is notified by telephone by the hospital, birthing center, physician or midwife that a newborn or infant was discharged before a specimen was taken, or if the health care provider determines from his or her own records that no test has been performed or that no results are available, the responsible health care provider shall make every reasonable effort to have a specimen obtained within three (3) days of notification. If the responsible health care provider cannot obtain the specimen, the health care provider shall notify MCH/NBS immediately by telephone. The telephone notification shall be noted in the responsible health care provider's record, specifying the date of notification, the person notified, and the information provided.

(f) When the responsible health care provider is notified by the laboratory by telephone that a specimen is inadequate, the health care provider so notified shall make every reasonable effort to have an adequate repeat specimen obtained within forty-eight (48) hours of notification. If the responsible health care provider so notified cannot obtain the repeat specimen, the health care provider shall notify MCH/NBS immediately by telephone. The telephone notification shall be noted in the responsible health care provider's records specifying the time and date of notification, the person notified, and the information provided.

(g) All repeat specimens shall be forwarded to a designated laboratory within twelve (12) hours after they have been obtained.

(h) MCH/NBS shall make every reasonable effort to follow up on all newborns and infants that have been reported as not having received a completed screening in an attempt to ensure that all newborns and infants born in the state of Indiana will have received the required screening for disorders.

(i) Hospitals, birthing centers, midwives, and physicians providing home birth services shall provide monthly reports to the department indicating the total number of live births and the number of newborns or infants for whom specimens were submitted for initial newborn screening. *(Indiana State Department of Health; 410 IAC 3-3-6; filed Nov 7, 1986, 3:30 p.m.: 10 IR 418; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)*

410 IAC 3-3-7 Follow-up of positive results, recommendations

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 7. (a) When the responsible health care provider is notified by telephone by the laboratory of an initial presumptive positive test result, the responsible health care provider shall obtain the department approved repeat blood specimen from the

newborn or infant and submit it to the designated laboratory within forty-eight (48) hours. If the blood specimen cannot be obtained within forty-eight (48) hours, the responsible health care provider shall notify MCH/NBS by telephone. The telephone notification shall be noted in the responsible health care provider's records, specifying the date of notification, the person notified, and the information provided. MCH/NBS will notify the local health officer and provide the necessary follow-up to ensure that the repeat blood specimen is obtained.

(b) It shall be the responsibility of the responsible health care provider or, if none, the local health officer to report the following immediately to the newborn or infant's parent:

(1) All abnormal results from the newborn screening test in order to recommend appropriate diagnostic and possible therapeutic procedures.

(2) Any diagnosis of a disorder in order to recommend appropriate therapeutic procedures and psychosocial support.

(c) When the repeat blood specimen supports a presumptive diagnosis of a disorder, the laboratory shall notify MCH/NBS and the responsible health care provider or local health officer, as appropriate.

(d) When the responsible health care provider is notified of a presumptive positive or abnormal newborn screening result for a newborn or infant in the neonatal intensive care unit (NICU), regardless of whether the specimen was an initial or routine repeat specimen, the responsible health care provider shall provide follow-up as outlined above.

(e) The responsible health care provider retains responsibility for the newborn, infant, or child's case management as the primary health care provider and shall make arrangements for the necessary diagnosis, therapy, and genetic counseling about the clinical and etiologic nature of the disorder, the chance of recurrence in subsequent children and other family members, existing resources for comprehensive clinical management, and family emotional and financial support. These can be provided directly by the responsible health care provider or by referral to appropriate specialists.

(f) The department shall advise the responsible health care provider of the available referrals and programs for further evaluation, genetic counseling, and management available to the patient and family. These shall include, but are not limited to, care by the following:

(1) A clinical biochemical geneticist for newborns, infants, or children with the following:

(A) Phenylketonuria.

(B) Galactosemia.

(C) Maple syrup urine disease.

(D) Homocystinuria.

(E) Other metabolic conditions included on the newborn screen.

(2) A pediatric hematologist for newborns, infants, or children with a clinically significant hemoglobinopathy.

(3) A pediatric pulmonologist for newborns, infants, or children with cystic fibrosis.

(4) A pediatric endocrinologist for newborns, infants, or children with hypothyroidism or congenital adrenal hyperplasia.

(5) An audiologist, otolaryngologist, or other specialist for newborns, infants, or children with hearing loss.

In the case of newborns, infants, or children identified as carriers of an inherited hemoglobin abnormality (individuals with trait), the department shall recommend further evaluation of parents and appropriate counseling.

(g) All physicians and audiologists making an initial diagnosis of a treatable disorder for which testing is required under IC 16-41-17 shall report such diagnosis and the information necessary for follow-up to the department. The reporting is mandatory for physicians and audiologists making the initial diagnosis and should be reported in the format and media approved by the department. Physicians and audiologists caring for Indiana newborns, infants, or children who have been diagnosed outside the state of Indiana with a disorder for which testing is required under IC 16-41-17 shall report in a similar manner.

(h) The department shall maintain the following:

(1) A tracking system for follow-up of newborn screening results.

(2) A confidential registry of every newborn or infant born for whom the diagnosis of:

(A) phenylketonuria;

(B) hypothyroidism;

(C) galactosemia;

(D) maple syrup urine disease;

(E) homocystinuria;

(F) hemoglobinopathy;

(G) cystic fibrosis;
(H) hearing loss; or
(I) another metabolic or endocrine condition;

has been confirmed.

These records shall be utilized only for the purpose of service delivery and program administration and shall be managed in accordance with 410 IAC 21-3.

(i) The department shall develop and maintain a statewide network of genetic evaluation and counseling services. Regional genetic services centers and outreach services from these centers shall serve as local evaluation and counseling resources for the follow-up program described in this section. *(Indiana State Department of Health; 410 IAC 3-3-7; filed Nov 7, 1986, 3:30 p.m.: 10 IR 419; filed Feb 25, 1988, 4:30 p.m.: 11 IR 2579; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; readopted filed May 22, 2007, 1:44 p.m.: 20070613-IR-410070141RFA; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)*

410 IAC 3-3-7.1 Newborn screening fund; fees; disposition; reporting requirements (Repealed)

Sec. 7.1. *(Repealed by Indiana State Department of Health; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR- 410100504FRA)*

410 IAC 3-3-8 Grounds for filing a complaint (Repealed)

Sec. 8. *(Repealed by Indiana State Department of Health; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR- 410100504FRA)*

410 IAC 3-3-9 Newborn hearing screening responsibilities

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 9. (a) The department's early hearing and detection intervention (EHDI) program is:

(1) located organizationally within the department's newborn screening program; and
(2) the program responsible for ensuring that all newborns or infants born in the state of Indiana receive appropriate newborn hearing screening and follow-up as necessary.

As the responsibilities, protocols, and reporting requirements for hearing screening differ from those for traditional heel-stick newborn screening, separate sections were created for newborn hearing screening.

(b) As outlined in section 3 of this rule, all newborns and infants born in the state of Indiana shall be screened for hearing loss.

(c) The department's EHDI program shall be the lead coordinating agency in Indiana responsible for development, implementation, and coordination of the EHDI system and oversight of the EHDI process. The department shall administer the EHDI program in a manner consistent with the 2007 joint committee on infant hearing (JCIH) position statement.

(d) Hospitals, physicians, audiologists, and all other personnel shall comply with these timelines by assisting the department's EHDI program through early assessment, prompt referral, and prompt reporting via the specified reporting method or methods to the department's EHDI program.

(e) Each hospital or birthing center shall do the following:

(1) Designate a person to be responsible for the universal newborn hearing screening (UNHS) program in that facility. This person will act as the single point of contact between the hospital or birthing center and the department. This person shall ensure all personnel performing UNHS are appropriately trained and develop a quality assurance/performance improvement component of the hospital or birthing center's UNHS program to ensure compliance with all EHDI program rules, regulations, and guidelines.
(2) Make a reasonable effort to do the following:
(A) Perform newborn hearing screening for each newborn or infant prior to the newborn or infant's discharge.
(B) Rescreen newborns or infants that do not pass the initial newborn hearing screening prior to the newborn or infant's discharge.

(3) Report newborn hearing screening results to the newborn or infant's health care provider and to the department as specified in section 12 of this rule.

(Indiana State Department of Health; 410 IAC 3-3-9; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

410 IAC 3-3-10 Equipment and supplies for newborn hearing screening

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 10. (a) All materials and supplies required to perform newborn hearing screening are the responsibility of the screening facility.

(b) Each screening facility shall calibrate the screening equipment annually or according to the manufacturer's guidelines. Each screening facility shall provide a copy of the manufacturer's guidelines to the department upon request.

(c) Educational materials, including a hearing screening certificate, shall be provided to the newborn or infant's parent by the screening facility. *(Indiana State Department of Health; 410 IAC 3-3-10; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)*

410 IAC 3-3-11 Hearing screening protocols for hospital birthing facilities and midwives

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 11. (a) Prior to the hearing screening of a newborn or infant, the hospital or birthing center shall provide information explaining the importance of newborn hearing screening and follow-up in writing to the newborn or infant's parents.

(b) The responsible physician, midwife, birthing center, or hospital shall conduct a hearing screening of the newborn or infant's ears via the recommended method or methods as accepted by the department. Hearing screening shall mean a test to detect hearing thresholds of thirty (30) decibels (dB) or greater in the speech frequency range of each ear.

(c) The newborn or infant's hearing should be screened after six (6) hours of age and prior to discharge as follows:

(1) Preterm newborns or infants (born prior to thirty-five (35) weeks gestational age) who stay in the nursery greater than five (5) days should have hearing screening when the newborn or infant is medically stable, but prior to discharge.

(2) Newborns or infants who reside for greater than five (5) days in the neonatal intensive care unit (NICU), especially those who have complicated birth factors, are considered to be at significantly greater risk for types of neural hearing loss, such as auditory neuropathy/dyssynchrony. These newborns or infants should receive hearing screening or diagnostic testing, or both, as recommended by the department.

(3) When possible, inpatient diagnostic testing shall be made available to long-stay newborns or infants who do not pass the initial newborn hearing screening and one (1) rescreen (for a total of two (2) hearing screenings).

(d) The only acceptable reason for not screening the hearing of a newborn or infant is if the parent of the newborn or infant objects, in writing, to the screening based on religious beliefs.

(e) If a newborn or infant is transferred to a hospital prior to receiving newborn hearing screening, the responsibility for completing the newborn hearing screening is shared between the birth and transferred facilities. If newborn hearing screening occurs at the transferred hospital, hearing screening results should be shared with the birth hospital or birthing center via the reporting method and format specified by the department's early hearing and detection intervention (EHDI) program.

(f) If a newborn or infant is not successfully screened or did not receive a newborn hearing screening prior to discharge, the hospital or birthing center shall provide an outpatient hearing screening for this newborn or infant.

(g) For newborns or infants who do not pass the initial newborn hearing screening, hearing should be rescreened one (1) additional time in both ears (regardless of previous screening results) prior to and as close to discharge as possible (for a total of two (2) hearing screenings). Preterm infants or newborns (born prior to thirty-five (35) weeks gestational age) who do not pass the initial newborn hearing screening should be rescreened one (1) additional time in both ears (regardless of previous screening results) prior to and as close as possible to discharge (for a total of two (2) hearing screenings).

(h) If a newborn or infant does not pass:

(1) his or her newborn hearing screening; and

(2) the rescreen prior to discharge;

for a total of two (2) hearing screenings, the birthing center or hospital shall contact an approved diagnostic audiology Level 1 facility to schedule an appointment for an outpatient diagnostic hearing test. The birthing center or hospital shall provide the location, date, and time of the appointment to the infant or newborn's parent, health care provider, and the department's EHDI program.

(i) Inpatient diagnostic testing shall be made available, when possible, for long-stay newborns or infants who do not pass the initial newborn hearing screening and one (1) rescreen (for a total of two (2) hearing screenings).

(j) If a newborn or infant passes the newborn hearing screening, but has risk indicators for late-onset or progressive hearing loss, the hospital shall do the following:

(1) Inform the newborn or infant's parent in writing of the risk indicator.

(2) Provide written documentation of language and hearing milestones.

(3) Recommend a follow-up test at an approved diagnostic audiology Level 1 facility to be done when the infant is between nine (9) and twelve (12) months of age.

This information shall also be provided in writing to the newborn or infant's health care provider and to the department's EHDI program via the reporting method and format specified by the department's EHDI program.

(k) Midwives shall follow all newborn hearing screening protocols as outlined for birthing centers and hospitals. Newborn hearing screening should be performed on all newborns prior to one (1) month of age, using portable equipment if needed.

(1) If midwives cannot provide direct screening for the newborns in their care, they shall have a designated referral site for these newborns to receive the hearing screening prior to one (1) month of age.

(2) If a newborn or infant does not pass:

(A) his or her newborn hearing screening; and

(B) a second hearing screening;

the midwife shall contact an approved diagnostic audiology Level 1 facility to schedule an appointment for an outpatient diagnostic hearing test. The midwife shall provide the location, date, and time of the appointment to the newborn or infant's parent, health care provider, and the department's EHDI program.

(l) Diagnostic audiology Level 1 facilities must meet the following requirements in order to perform diagnostic hearing evaluations on newborns or infants referred from newborn hearing screening programs:

(1) The audiologist or audiologists:

(A) must be licensed by the state of Indiana; and

(B) shall have experience in performing diagnostic audiological assessments of newborns and infants.

(2) The facility:

(A) shall conduct the assessment in accordance with Indiana's Best Practice Guidelines For Audiologic Assessment, Pediatric Amplification, and Intervention of the Infant dated October 2010; and

(B) must have and routinely use recommended equipment for newborn and infant diagnostic testing.

(Indiana State Department of Health; 410 IAC 3-3-11; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)

410 IAC 3-3-12 Newborn hearing screening reports

Authority: IC 16-19-3-4; IC 16-41-17-9

Affected: IC 16-41-17

Sec. 12. (a) Hearing screening results shall be provided in writing to the newborn or infant's parent prior to discharge.

(b) Hearing screening results (from the hearing screening equipment or from the heel-stick card) for every newborn, infant, or child that receives a screen shall be provided to the department's early hearing detection and intervention (EHDI) program in the format, media, and time specified by the department's EHDI program.

(c) The birthing center or hospital shall report all screening exceptions within five (5) business days, including the following:

(1) Newborns or infants who are not screened due to equipment or hospital error.

(2) Newborns or infants who do not pass the initial newborn hearing screening and one (1) additional rescreen prior to

discharge (for a total of two (2) hearing screenings).

(3) Newborns or infants at risk for late-onset hearing loss.

(d) If a newborn or infant is not successfully screened or did not receive a newborn hearing screening prior to discharge, the birthing center or hospital shall report these results as follows:

(1) To the newborn or infant's parent orally and in writing.

(2) To the newborn or infant's health care provider and the department's EHDI program.

(e) If a newborn or infant does not pass his or her newborn hearing screening and does not pass the rescreen prior to discharge (for a total of two (2) hearing screenings), the birthing center or hospital shall report these results as follows:

(1) To the newborn or infant's parent orally and in writing.

(2) To the newborn or infant's health care provider and the department's EHDI program.

(3) The birthing center or hospital shall also contact an approved diagnostic audiology Level 1 facility and schedule an appointment for an outpatient diagnostic hearing test. The location, date, and time of the appointment shall be provided to the newborn or infant's health care provider and the department's EHDI program.

(f) If a newborn or infant passes the newborn hearing screening, but has risk indicators for late-onset or progressive hearing loss, the birthing center or hospital shall do the following:

(1) Inform the newborn or infant's parent of the risk indicator in writing.

(2) Provide the newborn or infant's parent with written documentation of language and hearing milestones.

(3) Recommend a follow-up test at an approved diagnostic audiology Level 1 facility to be done when the infant is between nine (9) and twelve (12) months of age.

(4) Provide documentation of the hearing screening results, risk indicator, language and hearing milestones, and recommendation for follow-up test to the newborn, infant, or child's health care provider in writing.

(5) Report the hearing screening results and risk indicator to the department's EHDI program.

(g) Each birthing center or hospital shall complete and submit to the department's EHDI program a monthly summary report (MSR) by the fifteenth day of the following month. MSR data shall be submitted in the format and media specified by the department's EHDI program.

(h) Newborn hearing screening reports to be completed by physicians or midwives providing home birth services shall comply with the following:

(1) Midwives or physicians shall report all newborn hearing screening results to the newborn, infant, or child's health care provider (if designated) and to the department's EHDI program.

(2) Midwives or physicians shall report all newborns or infants who:

(A) did not receive a newborn hearing screening;

(B) did not pass a newborn hearing screening; or

(C) passed the newborn hearing screening but have a risk indicator for late-onset hearing loss;

to the department's EHDI program.

(3) Each midwife or physician providing home birth services must complete an MSR by the fifteenth day of the following month.

(i) Diagnostic audiology Level 1 facilities shall report results of diagnostic audiological evaluations as follows:

(1) Results shall be reported for each ear separately.

(2) Assessment results shall be reported to the department's EHDI program, regardless of audiological findings.

(3) Results shall include a statement of the severity and type of hearing loss identified.

(4) Results shall be reported within five (5) business days following the assessment.

(j) Each screening facility shall make available the following items to the department's EHDI program in the reporting method and format specified by the department:

(1) The name of the current person at the screening facility designated as the point of contact.

(2) The type of hearing screening equipment utilized.

(3) Equipment calibration records.

(4) Whether the hearing screening program at that screening facility is conducted by screening facility personnel or is contracted to an outside entity.

(5) Hearing screening protocols.

(6) Test procedure or procedures used by the screening facility's universal newborn hearing screening program.

(7) Pass criteria that minimally meet guidelines established by the department's EHDI program.

(8) A description of the screening facility quality assurance/quality improvement program.

(k) By reporting all audiologic findings to the department as outlined above, audiologists meet the reporting requirements of the Indiana birth defects and problems registry (IBDPR) for children who are diagnosed with permanent hearing loss between birth and three (3) years of age. *(Indiana State Department of Health; 410 IAC 3-3-12; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)*

410 IAC 3-3-13 Newborn screening fund; fees; disposition; reporting requirements

Authority: IC 16-19-3-4; IC 16-41-17-9; IC 16-41-17-10
Affected: IC 16-41-17

Sec. 13. (a) The program involving the department and MCH/NBS as described in this rule 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.

(b) The newborn screening fee shall be one hundred dollars ($100) based on the projected cost of the program described in this rule 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 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. *(Indiana State Department of Health; 410 IAC 3-3-13; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA; filed Sep 28, 2018, 2:04 p.m.: 20181024-IR-410180158FRA)*

410 IAC 3-3-14 Grounds for filing a complaint

Authority: IC 16-19-3-4; IC 16-41-17-9
Affected: IC 16-41-17

Sec. 14. The willful or repeated failure of any:

(1) physician;

(2) midwife;

(3) laboratory;

(4) hospital;

(5) birthing center; or

(6) other health care provider;

to comply with the provisions of this rule shall, in addition to any other penalty prescribed by law, constitute grounds for filing a complaint with the individual's or institution's licensing board in addition to other legal remedies. *(Indiana State Department of Health; 410 IAC 3-3-14; filed Apr 25, 2012, 3:46 p.m.: 20120523-IR-410100504FRA; readopted filed Sep 26, 2018, 2:48 p.m.: 20181024-IR-410180328RFA)*

*