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)

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)

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)*

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)

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)*

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)

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)

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)*

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)*

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)

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)

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)

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)

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)

Rule 3. Examination of Infants for Disorders

410 IAC 3-3-1 Definitions

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

Sec. 1. As used in 410 IAC 3-3:

"Birthing center" means any non-hospital facility in which live births routinely take place.

"Board" means the Indiana state board of health.

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

"Hemoglobinopathy" means an abnormal hemoglobin which results from an inherited defect, some of which may produce a sickling phenomenon in erythrocytes.

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

"Hospital" means a licensed hospital with obstetric services.

"Hypothyroidism" means a deficient amount or activity of thyroid hormone.

"Maple syrup urine disease" means an inherited error in the metabolism of leucine, isoleucine and valine.

"MCH" means division of maternal and child health, genetic diseases section, at the Indiana state board of health.

"Phenylketonuria" means an inherited error in the metabolism of phenylalanine.

"Satisfactory blood specimen" means a blood specimen on which an accurate laboratory analysis can be performed for the disorder for which it is submitted.

"Unsatisfactory blood specimen" means any of the following:

(1) A filter paper kit on which an insufficient quantity of blood is obtained.

(2) A filter paper kit on which an accurate analysis or interpretation cannot be performed due to improper collection, handling, submission, or a technical or laboratory problem.

(3) Cord blood.

(4) Blood from any transfused neonate.

(5) A filter paper kit which 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 the criteria above.

(Indiana State Department of Health; 410 IAC 3-3-1; filed Nov 7, 1986, 3:30 pm: 10 IR 415; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

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 board 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 and/or perinatal care 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 such material, it shall be translated or read to her in a language she understands.

(b) Any parent or guardian who objects to the testing for reasons pertaining to religious beliefs only shall so indicate by signing a statement of informed refusal. Such objection shall become part of the medical record and the infant shall be exempted from the testing. *(Indiana State Department of Health; 410 IAC 3-3-2; filed Nov 7, 1986, 3:30 pm: 10 IR 416; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3-3-3 Screening for phenylketonuria, hypothyroidism, galactosemia, homocystinuria, maple syrup urine disease, hemoglobinopathies, congenital adrenal hyperplasia, and biotinidase deficiency; collection procedures

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

Sec. 3. (a) All newborn infants born in the state of Indiana shall be screened for:
(1) phenylketonuria;
(2) hypothyroidism;
(3) galactosemia;
(4) homocystinuria;
(5) maple syrup urine disease;
(6) hemoglobinopathies;
(7) congenital adrenal hyperplasia; and
(8) biotinidase deficiency;
except as provided for in section 2(b) of this rule.

(b) The responsible physician, midwife, or hospital shall collect a specimen of the infant's blood on a filter paper kit approved by the board. 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 infant's blood for these tests shall be collected not earlier than forty-eight (48) hours after birth and not before the infant has been on a protein diet for at least twenty-four (24) hours, except as stated in subsection (d), and no later than one hundred twenty (120) hours after birth, except as stated in subsection (f).

(d) When a live birth occurs in a hospital, the responsible physician shall have a specimen of the infant's blood taken prior to the infant's discharge from the hospital. If the infant 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 no later than one hundred twenty (120) hours after birth. The hospital administrator or a designated representative shall provide a written notice to the parents, guardian, or other legally responsible person, at or before discharge, of the requirements for such 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, it shall be the responsibility of the physician or midwife in attendance at the birth to assure that the newborn is referred to an appropriate facility, such as a physician office, hospital, 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 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 immediately.

(f) For preterm 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 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 infant's own blood. *(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)*

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: (a) Complies with Public Law 90-174, the Federal Clinical Laboratory Improvement Act of 1967, or is accredited by the College of American Pathologists, or is accredited by the Joint Commission on Accreditation of Hospitals.

(b) Performs or makes reasonable assurances that it will perform each one of the above screening tests on a minimum of 25,000 newborns annually.

(c) Uses laboratory procedures and values for normal and abnormal test results which have been submitted to and approved by the board.

(d) Initiates the approved tests within twenty-four (24) hours of receipt of the specimen and the tests shall be completed within seventy-two (72) hours.

(e) Reports findings in a timely manner and maintains records in accordance with the requirements of the board.

(f) Provides at least monthly reports of its screening activities to the board.

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

(h) Cooperates with other relevant agencies concerned with newborn health care.

(i) Participates in a laboratory quality assurance program, including proficiency testing, approved by the board. *(Indiana State Department of Health; 410 IAC 3-3-4; filed Nov 7, 1986, 3:30 pm: 10 IR 417; filed Feb 25, 1988, 4:30 pm: 11 IR 2579; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

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. The laboratory shall report as follows: (a) Negative test results shall be reported within seven (7) days of the date of analysis by mail to MCH and to the hospital submitting the specimens. A copy for the responsible physician shall be included for distribution by the hospital. The report of the test results shall become part of the patient's clinical record.

(b) Confirmed positive tests shall be reported immediately by telephone to the hospital, responsible physician and to MCH. Such 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 a written 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, the local health officer in the county of the mother's residence shall be notified.

(c) Unsatisfactory specimens shall be reported immediately by telephone to the hospital and responsible physician or other health care provider submitting the specimen with an explanation about the reason for rejection. In the event that the responsible physician 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.

(d) In the event a specimen is rejected for any reason as unsatisfactory, the physician responsible for the infant's care at the time of the report shall be responsible for the submission of an acceptable specimen within forty-eight (48) hours. If the laboratory does not receive the repeat specimen within five (5) days, it shall notify MCH immediately by telephone.

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

(f) The laboratory shall also provide at least a monthly report to the board which shall contain:

(1) The number of infants tested.

(2) The number of repeat tests.

(3) The number of unacceptable specimens by hospital, birthing center, physician, or other health care provider submitting the specimen.

(4) Presumptive positive results by test.

(5) Confirmed positive results by test, including patient names and identifying information.

(Indiana State Department of Health; 410 IAC 3-3-5; filed Nov 7, 1986, 3:30 pm: 10 IR 417; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)

410 IAC 3-3-6 Maintenance of screening logs; follow-up of missing results; monthly reports

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

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

(1) Name of infant.

(2) Attending physician.

(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 board 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 or legal guardian's signed refusal has been filed in the newborn's medical record.

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

(d) Whenever a hospital, birthing center or midwife determines that a specimen has been obtained but there are no results available in the newborn's medical record within fourteen (14) days of discharge, the hospital, birthing center or midwife shall obtain the results from the laboratory by telephone and request that another written copy be sent. The hospital, birthing center or midwife shall also notify MCH that results have not been received. If no results are available from the laboratory, then the hospital, birthing center or midwife shall proceed as in 410 IAC 3-3-7(c).

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

(f) When the responsible physician is notified by the laboratory by telephone that a specimen is inadequate, the physician so notified shall make every reasonable effort to have an adequate repeat specimen obtained within forty-eight (48) hours of notification. If the responsible physician so notified cannot obtain the repeat specimen, the physician shall notify MCH immediately by telephone. Such telephone notification shall be noted in the responsible physician'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 shall make every reasonable effort to follow up on all newborns who have been reported as not having received a completed screening in an attempt to ensure that all infants born in the state of Indiana will have received the required screening for disorders.

(i) Hospitals and birthing centers, and midwives and physicians providing home birth services shall provide monthly reports to the board indicating the total number of live births and the number of newborns for whom specimens were submitted for initial screening for phenylketonuria, hypothyroidism, galactosemia, maple syrup urine disease, homocystinuria and hemoglobinopathy, and the total number of positive results by test with patient identifying information. *(Indiana State Department of Health; 410 IAC 3-3-6; filed Nov 7, 1986, 3:30 pm: 10 IR 418; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

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 physician is notified by telephone by the laboratory of an initial presumptive positive test result, the responsible physician shall obtain the board approved repeat blood specimen from the newborn 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 physician shall notify MCH by telephone. Such telephone notification shall be noted in the responsible physician's records, specifying the date of notification, the person notified and the information provided. MCH 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 physician or, if none, the local health officer to report immediately to the parent or guardian:

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

(2) any diagnosis of a disorder in order to recommend appropriate therapeutic procedures and psycho-social support.

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

(d) The responsible physician retains responsibility for the child's case management as the primary health care provider, and shall make arrangements for the necessary diagnosis, therapy and 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 physician or by referral to appropriate specialists.

(e) The board shall advise the responsible physician of the available referrals and programs for further evaluation, counseling, and management available to the patient and family. These shall include, but are not limited to, care by a clinical biochemical geneticist for children with phenylketonuria, galactosemia, maple syrup urine disease and homocystinuria, care by a pediatric hematologist for children with a clinically significant hemoglobinopathy, and care by a pediatric endocrinologist for children with hypothyroidism. In the case of children identified as carriers of an inherited hemoglobin abnormality (individuals with trait), the board shall recommend further evaluation of parents and appropriate counseling.

(f) All physicians making an initial diagnosis of a treatable disorder for which testing is required under IC 16-8-6 *[IC 16-8 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]* shall report such diagnosis and the information necessary for follow-up to the board. Physicians caring for Indiana newborns who have been diagnosed outside the state of Indiana with a disorder for which testing is required under IC 16-8-6 *[IC 16-8 was repealed by P.L.2-1993, SECTION 209, effective April 30, 1993.]* shall report in a similar manner.

(g) The board shall maintain a tracking system for follow-up of newborn screening results, and shall maintain a confidential registry of every infant born for whom the diagnosis of phenylketonuria, hypothyroidism, galactosemia, maple syrup urine disease, homocystinuria, or hemoglobinopathy 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 the procedures described in 410 IAC 1-2-2 *[410 IAC 1-2 was repealed filed Jul 27, 1988, 2:50 pm: 11 IR 4098. See 410 IAC 1-2.1.]*.

(h) The board 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 pm: 10 IR 419; filed Feb 25, 1988, 4:30 pm: 11 IR 2579; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

410 IAC 3-3-7.1 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. 7.1. (a) The program involving the Indiana state department of health and MCH as described in this rule shall be furnished by a collection of a newborn screening fee for each newborn screened by a designated laboratory. The designated laboratory shall assess and collect the fees from hospitals, birthing centers, physicians, and midwives. 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 Indiana state department of health. 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 fees shall be deposited in the newborn screening fund. Funds for the program described in this rule shall be disbursed by the Indiana state department of health in accordance with normal procedures prescribed by the state budget agency and the state board of accounts.

(c) The newborn screening fee shall be thirty dollars ($30) based on the projected cost of the program described in this rule and the estimated number of newborns per year. The fee shall be reviewed annually by the Indiana state department of health.

(Indiana State Department of Health; 410 IAC 3-3-7.1; filed Feb 25, 1988, 4:30 p.m.: 11 IR 2580; filed Aug 9, 1991, 11:00 a.m.: 14 IR 2223; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234; filed Dec 12, 2003, 10:45 a.m.: 27 IR 1568)

410 IAC 3-3-8 Grounds for filing a complaint

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

Sec. 8. The willful or repeated failure of any physician, midwife, laboratory, hospital, birthing center, or other health care provider to comply with the provisions of 410 IAC 3-3 shall, in addition to any other penalty prescribed by law, constitute grounds for filing a complaint with said individual's or institution's licensing board in addition to other legal remedies. *(Indiana State Department of Health; 410 IAC 3-3-8; filed Nov 7, 1986, 3:30 pm: 10 IR 420; readopted filed Jul 11, 2001, 2:23 p.m.: 24 IR 4234)*

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