

CABINET FOR HEALTH AND FAMILY SERVICES

Department for Public Health

Division of Laboratory Services

(Amendment)

902 KAR 4:030. Newborn screening program.

RELATES TO: KRS 194A.050, 211.090, 211.180(1), 214.155

STATUTORY AUTHORITY: KRS 194A.050(1), 211.090(3), 214.155

NECESSITY, FUNCTION, AND CONFORMITY: KRS 214.155 requires the Cabinet for Health and Family Services to operate a newborn screening program for inborn errors of metabolism and other inherited and congenital disorders and conditions, and to establish a schedule of fees to cover the actual costs to the cabinet for the program. This administrative regulation requires that infants be tested for inborn errors of metabolism and other inherited and congenital disorders and conditions as specified in KRS 214.155, and establishes the schedule of fees to cover actual costs of the newborn screening program. The selection of screened conditions is based upon the recommended uniform screening panel as authored by the American College of Medical Genetics and commissioned by the Health Resources and Services Administration, U.S. Department of Health and Human Services.

Section 1. Definitions.

- (1) "Blood spot testing" means laboratory testing that is performed on newborn infants to detect a wide variety of inherited and congenital disorders and conditions by using a laboratory-authorized filter paper specimen card.
- (2) "Critical congenital heart disease" or "CCHD" means an abnormality in the structure or function of the heart that exists at birth and places an infant at significant risk of disability or death if not diagnosed and treated soon after birth.
- (3) "Diagnostic echocardiogram" means a test that uses ultrasound to provide an image of the heart that is performed by a technician trained to perform pediatric echocardiograms.
- (4) "Laboratory" means the Division of Laboratory Services within the Cabinet for Health and Family Services, Department for Public Health.
- (5) "Pediatric cardiologist" means a pediatrician that is board-certified to provide pediatric cardiology care.
- (6) "Program" means the Newborn Screening Program for inherited and congenital disorders and conditions operated by the Cabinet for Health and Family Services, Department for Public Health.
- (7) "Pulse oximetry testing" means a noninvasive test that estimates the percentage of hemoglobin in blood that is saturated with oxygen.
- (8) "Submitter" means a hospital, primary care provider, health department, birthing center, laboratory, or midwife submitting an infant's blood specimen for the purpose of newborn screening.

Section 2. Tests for inborn errors of metabolism or other inherited or congenital disorders and conditions for newborn infants as part of newborn screening shall be consistent with the U.S. Department of Health and Human Services' Recommended Uniform Screening Panel and include the following:

- (1) 2-Methyl-3-hydroxybutyric aciduria (2M3HBA);
- (2) 2-Methylbutyryl-CoA dehydrogenase deficiency (2MBDH);
- (3) 3-Methylcrotonyl-CoA carboxylase deficiency (3MCC);
- (4) 3-Methylglutaconic aciduria (3MGA);
- (5) 3-Hydroxy 3-Methylglutaric aciduria (HMG);
- (6) Argininemia (ARG);

- (7) Argininosuccinic acidemia (ASA);
- (8) Beta-ketothiolase deficiency (BKT);
- (9) Biotinidase disorder (BIOT);
- (10) Carnitine acylcarnitine translocase deficiency (CACT);
- (11) Carnitine palmitoyltransferase deficiency I (CPT-I);
- (12) Carnitine palmitoyltransferase deficiency II (CPT-II);
- (13) Carnitine uptake defect (CUD);
- (14) Citrullinemia type I (CIT-I);
- (15) Citrullinemia type II (CIT-II);
- (16) Congenital adrenal hyperplasia (CAH);
- (17) Congenital hypothyroidism (CH);
- (18) Critical congenital heart disease (CCHD);
- (19) Cystic fibrosis (CF);
- (20) Ethylmalonic encephalopathy (EE);
- (21) Galactosemia (GAL);
- (22) Glutaric acidemia type I (GA I);
- (23) Glutaric acidemia type II (GA-II);
- (24) Glycogen storage disease type II (GSD-II, Pompe Disease);
- (25) Guanidinoacetate methyltransferase deficiency (GAMT);
- ~~(26)~~ Homocystinuria (HCY);
- ~~(27)~~ ~~(26)~~ Hypermethioninemia (MET);
- ~~(28)~~ ~~(27)~~ Hyperphenylalaninemia (H-PHE);
- ~~(29)~~ ~~(28)~~ Isobutyryl-CoA dehydrogenase deficiency (IBG);
- ~~(30)~~ ~~(29)~~ Isovaleric acidemia (IVA);
- ~~(31)~~ ~~(30)~~ Long-chain hydroxyacyl-CoA dehydrogenase deficiency (LCHAD);
- ~~(32)~~ ~~(31)~~ Malonic acidemia (MAL);
- ~~(33)~~ ~~(32)~~ Maple syrup urine disease (MSUD);
- ~~(34)~~ ~~(33)~~ Medium-chain acyl-CoA dehydrogenase deficiency (MCAD);
- ~~(35)~~ ~~(34)~~ Methylmalonic acidemia (Cbl A,B);
- ~~(36)~~ ~~(35)~~ Methylmalonic acidemia (Cbl C,D);
- ~~(37)~~ ~~(36)~~ Methylmalonic acidemia mutase deficiency (MUT);
- ~~(38)~~ ~~(37)~~ Mucopolysaccharidosis type I (MPS-I, Hurler's Disease);
- ~~(39)~~ Mucopolysaccharidosis type II (MPS-II, Hunter's Disease);
- ~~(40)~~ ~~(38)~~ Multiple carboxylase deficiency (MCD);
- ~~(41)~~ ~~(39)~~ Non-ketotic Hyperglycinemia (NKHG);
- ~~(42)~~ ~~(40)~~ Phenylketonuria (PKU);
- ~~(43)~~ ~~(41)~~ Propionic acidemia (PA);
- ~~(44)~~ ~~(42)~~ Severe combined immunodeficiency (SCID);
- ~~(45)~~ ~~(43)~~ Short-chain acyl-CoA dehydrogenase deficiency (SCAD);
- ~~(46)~~ ~~(44)~~ Sickle cell disease (Hb S/S);
- ~~(47)~~ ~~(45)~~ Sickle cell hemoglobin C disease (Hb S/C);
- ~~(48)~~ ~~(46)~~ Sickle cell S Beta Thalassemia (Hb S/Th);
- ~~(49)~~ ~~(47)~~ Spinal muscular atrophy (SMA);
- ~~(50)~~ ~~(48)~~ Trifunctional protein deficiency (TFP);
- ~~(51)~~ ~~(49)~~ Tyrosinemia type I (TYR-I);
- ~~(52)~~ ~~(50)~~ Tyrosinemia type II (TYR-II);
- ~~(53)~~ ~~(51)~~ Tyrosinemia type III (TYR-III);
- ~~(54)~~ ~~(52)~~ Various Hemoglobinopathies (includes Hb E);
- ~~(55)~~ ~~(53)~~ Very long-chain acyl-CoA deficiency (VLCAD); and
- ~~(56)~~ ~~(54)~~ X-linked adrenoleukodystrophy (X-ALD).

Section 3. Tests for inborn errors of metabolism or other inherited or congenital disorders and conditions for newborn infants as part of newborn screening shall include the following disorder that is not recommended by the U.S. Department of Health and Human Services, but is required by Kentucky law: Krabbe Disease (KD).

Section 4. Submitter Responsibilities.

(1) Except as provided in KRS 214.155(3) and (5), the administrative officer or other person in charge of the hospital or institution caring for newborn infants and the attending primary care provider or midwife shall administer to, or verify administration of tests to, every infant in its care prior to hospital discharge:

(a) A blood spot test to detect inborn errors of metabolism and other inherited and congenital disorders and conditions identified in Sections 2 and 3 of this administrative regulation; and

(b) Pulse oximetry testing to detect critical congenital heart disease.

(2) If a baby is not born in a hospital or institution, the attending primary care provider or midwife shall ensure that both tests required by subsection (1) of this section are:

(a) Administered between twenty-four (24) and forty-eight (48) hours of age;

(b) Acted upon if abnormal; and

(c) Reported to the program by fax or by the cabinet's web-based system.

(3) A capillary blood spot specimen shall be obtained from a newborn infant not requiring an extended stay due to illness or prematurity between twenty-four (24) and forty-eight (48) hours of age.

(4) If the infant is to remain in the hospital due to illness or prematurity, the hospital shall obtain the capillary blood spot specimen from that infant after twenty-four (24) and before seventy-two (72) hours of age.

(5) Except as provided by subsection (6) of this section, the pulse oximetry testing shall be performed when the infant is twenty-four (24) hours of age or older and shall occur prior to discharge.

(6) If the infant is discharged prior to twenty-four (24) hours of age, the blood spot and pulse oximetry testing shall be performed as close to twenty-four (24) hours of age as possible.

(7) If an infant is transferred from the birth hospital to another hospital during the newborn hospital stay, the requirements established in this subsection shall apply.

(a) The sending hospital shall obtain the capillary blood spot specimen for the newborn screening blood test and the pulse oximetry testing for CCHD if the infant is twenty-four (24) hours of age or more when the infant is transferred to another hospital.

(b) The receiving hospital shall ensure the newborn screening blood spot test and the pulse oximetry testing are performed if the infant is less than twenty-four (24) hours of age when the infant is transferred.

(8) If an infant expires before the newborn screening blood spot test and pulse oximetry test have been performed, the program shall be notified within five (5) calendar days.

(9) If the information on the filter paper specimen card obtained by the submitter and sent to the laboratory is incomplete or inadequate, then the submitter, upon request of the program, shall:

(a) Attempt to locate the infant and obtain a complete and adequate specimen within ten (10) days; and

(b) Report to the program a specimen that is unable to be obtained within ten (10) days.

(10) A submitter that is responsible for the collection of the initial blood spot specimen and pulse oximetry testing for newborn screening shall:

(a) Provide to an infant's parent or guardian educational materials regarding newborn screening and pulse oximetry testing;

(b) Designate a newborn screening coordinator and physician responsible for the coordination of the facility's newborn screening compliance by having a newborn screening protocol;

(c) Notify the program of the name of the individuals designated in paragraph (b) of this subsection each year in January and if the designated individual changes; and

(d) Develop a written protocol for tracking newborn screening compliance, which shall:

1. Be submitted to the program each year in January; and

2. Include, at a minimum:

a. A requirement that the name of the primary care provider that will be attending the infant after birth or discharge or, if known, the primary care provider who will be caring for the infant after discharge, shall be placed on the filter paper specimen card sent with the initial blood spot specimen to the laboratory. If the infant is in the neonatal intensive care unit, the name of the attending neonatologist may be placed on the filter specimen card sent with the initial blood spot specimen to the laboratory;

b. Verification that:

(i) Each infant born at that facility has had a specimen obtained for newborn screening and pulse oximetry testing on or before discharge;

(ii) All information on the specimen card has been thoroughly completed; and

(iii) The specimen has been submitted appropriately;

c. A process to ensure that final results of the pulse oximetry screening are entered into the cabinet's web-based system; and

d. A procedure to assure the hospital or facility that identifies that an infant has not had a specimen obtained for newborn screening and pulse oximetry testing prior to discharge shall:

(i) Notify the program;

(ii) Use every reasonable effort to locate the infant;

(iii) Notify the parent or guardian and the primary care provider immediately; and

(iv) Recommend that the infant present to the hospital or primary care provider immediately for a newborn screening blood spot specimen and pulse oximetry testing.

(11) A hospital or facility shall report each written refusal, in accordance with KRS 214.155(5), to the program within five (5) calendar days.

Section 5. Blood Specimen Collection.

(1) A capillary blood spot specimen required by Section 4 of this administrative regulation shall be obtained by a heel stick.

(2) Blood from the heel stick shall be applied directly to the filter paper specimen card.

(3) All circles shall be saturated completely using a drop of blood per circle on a filter paper specimen card.

(4) The specimen collector shall provide, on the filter paper specimen card, information requested by the laboratory.

(5) The capillary blood spot specimen shall be air dried for three (3) hours and then shall be mailed or sent to the laboratory:

(a) Within twenty-four (24) hours of collection of the specimen; or

(b) The next business day in which mail or delivery service is available.

(6) A submitter sending a blood spot specimen via regular mail services shall send the specimen to the following address: Cabinet for Health and Family Services, Department for Public Health, Division of Laboratory Services, 100 Sower Boulevard, Frankfort, Kentucky 40602.

(7) A submitter sending a blood spot specimen via expedited mail services shall ensure the specimen is sent to the following address: Cabinet for Health and Family Services, Department for Public Health, Division of Laboratory Services, 100 Sower Boulevard, Suite 204, Frankfort, Kentucky 40602.

(8) Specimens processed or tracked under the newborn screening program shall be limited to specimens on infants less than six (6) months of age.

Section 6. Unsatisfactory or Inadequate Blood Specimen.

(1) If a specimen is unsatisfactory or inadequate to produce a valid result, the laboratory shall notify the submitter and the parent on the filter paper specimen card that the newborn screen needs to be repeated as soon as possible.

(2) If a requested repeat specimen has not been received within ten (10) business days from the date the repeat request was issued, the program shall notify the parent by mail of the need for a repeat screening test.

Section 7. Special Circumstances - Blood Transfusion. If a newborn infant requires a blood transfusion, the requirements for newborn screening established in this section shall apply.

(1) The hospital shall obtain a capillary blood spot specimen for newborn screening prior to the infant being transfused, except in an emergency situation.

(2) If the pre-transfusion blood spot specimen was obtained before twenty-four (24) hours of age, or if it was not obtained due to an emergency situation, then the hospital or primary care provider shall use all reasonable efforts to obtain a repeat capillary blood specimen from the transfused infant and submit it to the laboratory according to the following schedule:

(a) Seventy-two (72) hours after the last blood transfusion, rescreen for inborn errors of metabolism and inherited and congenital disorders and conditions listed in Sections 2 and 3 of this administrative regulation; and

(b) Ninety (90) days after the last blood transfusion, rescreen for any disorder that relies on red blood cell analysis such as hemoglobinopathies, galactosemia, and biotinidase deficiency.

Section 8. Reporting Results of Newborn Screening Blood Tests.

(1) Normal Results. Upon receipt of a normal lab result, the laboratory shall send the result to the primary care provider and the submitter.

(2) Abnormal Results.

(a) The laboratory shall report abnormal, presumptive positive, or equivocal results of tests for inborn errors of metabolism, inherited and congenital disorders and conditions to the program.

(b) The submitter and primary care provider shall receive a copy of all abnormal, presumptive positive, and equivocal results.

(c) In addition, a primary care provider shall be notified of an abnormal, presumptive positive, or equivocal result in the manner established in this paragraph.

1. Upon receipt of an abnormal, equivocal, or a presumptive positive lab result, the laboratory shall notify the primary care provider listed on the filter paper specimen card within two (2) business days of the result and the need for follow-up testing.

2. Upon receipt of a presumptive positive lab result, the program shall notify the primary care provider listed on the filter paper specimen card of the result and recommend immediate consultation with a university pediatric specialist.

3. If the program is unable to determine the infant's primary care provider to notify them of an abnormal, presumptive positive, or equivocal result and the need for follow-up, the program shall use every available means to notify the infant's parent.

(d) The Cabinet for Health and Family Services shall share pertinent test results with a state university-based specialty clinic or primary care provider who informs the cabinet

they are treating the infant who received the test.

(e) The cabinet may share pertinent test results with the local health department in the infant's county of residence that conducts newborn screening follow-up activities.

(f) A specialty clinic or primary care provider shall report results of diagnostic testing to the program within thirty (30) days or earlier upon request.

(g) If a requested repeat specimen has not been received within ten (10) business days from the date the repeat request was issued, the program shall notify the parent by mail of the need for a repeat screening test.

Section 9. Pulse Oximetry Screening for Critical Congenital Heart Disease. Pulse oximetry screening for critical congenital heart defects required by Section 2 of this administrative regulation shall be consistent with the standard of care according to national recommendations by the American Academy of Pediatrics.

Section 10. Pulse Oximetry Screening Process.

(1) Except as provided by KRS 214.155(3) and subsections (2) and (4) of this section, pulse oximetry testing shall be performed when the infant is between twenty-four (24) and forty-eight (48) hours of age and shall occur no later than the day of discharge.

(2) If the infant is discharged prior to twenty-four (24) hours of age, the blood spot and pulse oximetry testing shall be performed as close to twenty-four (24) hours of age as possible.

(3) An infant in a neonatal intensive care unit shall be screened when medically appropriate after twenty-four (24) hours of age but prior to discharge.

(4) An infant who has been identified with critical congenital heart disease prior to birth or prior to twenty-four (24) hours of age shall be exempt from the pulse oximetry screening process.

(5) Pulse oximetry screening shall be performed by placing pediatric pulse oximetry sensors simultaneously on the infant's right hand and either foot to obtain oxygen saturation results.

(6) If using a single pediatric pulse oximetry sensor, pulse oximetry screening shall be performed on the infant's right hand and either foot, one after the other, to obtain oxygen saturation results.

Section 11. Pulse Oximetry Testing Results.

(1) A passed result shall not require further action if:

(a) The pulse oximetry reading in both extremities is greater than or equal to ninety-five (95) percent; and

(b) The difference between the readings of both the upper and lower extremity is less than or equal to three (3) percent.

(2)

(a) A pending result shall:

1. Occur if:

a. The pulse oximetry reading is between ninety (90) and ninety-four (94) percent; or

b. The difference between the readings of both the upper and lower extremity is greater than three (3) percent; and

2. Be repeated using the pulse oximetry screening in one (1) hour.

(b) If a repeated pulse oximetry screen is also interpreted as pending, it shall be performed again in one (1) hour.

(c) If the pulse oximetry result on the third screen continues to meet the criteria as pending after three (3) screenings have been performed, it shall be considered failed and the procedures established in subsection (3) of this section shall be followed.

(3) A failed result shall:

- (a) Occur if:
 - 1. The initial pulse oximetry reading is less than ninety (90) percent in the upper or lower extremity; or
 - 2. The provisions of subsection (2)(c) of this section apply; and
- (b) Require the following actions:
 - 1. The primary care provider shall be notified immediately;
 - 2. The infant shall be evaluated for the cause of the low saturation reading; and
 - 3. If CCHD cannot be ruled out as the cause of the low saturation reading, the attending physician or advanced practice registered nurse shall:
 - a. Order a diagnostic echocardiogram to be performed without delay;
 - b. Ensure the diagnostic echocardiogram be interpreted as soon as possible; and
 - c. If the diagnostic echocardiogram results are abnormal, obtain a consultation with a pediatric cardiologist prior to hospital discharge.

Section 12. Reporting Results of Pulse Oximetry Screening.

- (1) Final results of the pulse oximetry screening shall be entered into the cabinet's web-based system.
- (2) A failed result shall be immediately reported to the program by fax or by the cabinet's web-based system.

Section 13. Newborn Screening Fees.

- (1)
 - (a) A submitter obtaining and sending a blood spot specimen to the laboratory shall be billed a fee of \$200[150] for the initial newborn screening test.
 - (b) A midwife obtaining and sending a blood spot specimen to the laboratory shall be billed a fee of fifty (50) dollars for the initial newborn screening test.
- (2) A submitter obtaining and sending a repeat blood spot specimen to the laboratory shall not be charged an additional fee.
- (3) Fees due the Cabinet for Health and Family Services shall be collected through a monthly billing system.

STEVEN J. STACK, MD, MBA, Commissioner
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: May 23, 2024

FILED WITH LRC: June 10, 2024 at noon

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on August 26, 2024, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by August 19, 2024, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until August 31, 2024. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-7476; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Krista Quarles or Julie Brooks

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation requires that infants be tested for inborn errors of metabolism and other inherited and congenital disorders and conditions as specified in KRS 214.155 and establishes the schedule of fees to cover actual costs of the newborn screening program.

(b) The necessity of this administrative regulation:

The Newborn Screening Program helps determine if a baby has certain health disorders. A healthy newborn can have serious metabolic or genetic disorders that cannot be detected without specific screening. If left undetected and untreated, these disorders can lead to slow growth, blindness, brain damage or possibly death.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

KRS 214.155 requires the Cabinet for Health and Family Services to operate a newborn screening program for inborn errors of metabolism and other inherited and congenital disorders and conditions, and to establish a schedule of fees to cover the actual costs to the cabinet for the program.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This administrative regulation will assist in the identification of newborns who have inborn errors of metabolism and other inherited and congenital disorders and conditions.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

The amendment to this administrative regulation adds guanidinoacetate methyltransferase deficiency and mucopolysaccharidosis type II to the list of screened conditions, increases the fee for hospitals submitting newborn screening tests to the state laboratory to \$200 and establishes a fee of fifty (50) dollars for midwives to submit newborn screening tests to the state laboratory.

(b) The necessity of the amendment to this administrative regulation:

The amendment to this administrative regulation is necessary because guanidinoacetate methyltransferase deficiency and mucopolysaccharidosis type II were added to the recommended universal screening panel in 2022. The tiered fee structure is necessary to offer an incentive to midwives to submit screening tests to the state laboratory. In 2022 there were 1,027 reported home births in Kentucky. However, less than half of these newborns had a screening test submitted to the state laboratory.

(c) How the amendment conforms to the content of the authorizing statutes:

KRS 214.155 requires the Cabinet for Health and Family Services to operate a newborn screening program for inborn errors of metabolism and other inherited and congenital disorders and conditions, and to establish a schedule of fees to cover the actual costs to the cabinet for the program.

(d) How the amendment will assist in the effective administration of the statutes:

The amendment to this administrative regulation will ensure all newborns have proper screening to identify genetic and metabolic conditions that may impact growth and development.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

The amendment to this administrative regulation will impact the forty-six (46) birthing hospitals and thirty (30) midwives practicing in Kentucky.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

Hospitals will need to be aware of the increased fee amount and submit the correct reimbursement. Midwives will need to be aware of the lowered fee amount.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

Hospitals will pay an additional fifty (50) dollars per initial screening test submitted. Midwives will pay a fifty (50) dollar fee.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

Birthing hospitals will continue to submit newborn screening test. Midwives will be incentivized to submit newborn screening test to the state laboratory. This will ensure all newborns are screened in accordance with KRS 214.155.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

The total cost of the newborn screening program is \$9.7 million.

(b) On a continuing basis:

Assuming program operations continue as they are, there is no anticipated increase in cost on an ongoing basis.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

Agency funds and fees collected from submitters are used for the implementation and enforcement of this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

An increase in funding is not needed to implement the amendment to this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

The amendment to this administrative regulation raises the fee for hospitals submitting newborn screening tests to the state laboratory to \$200. The fee for midwives to submit newborn screening tests to the state laboratory is lowered to \$50. The fees are only assessed on the initial tests submitted. There is no fee for submitting repeat tests.

(9) TIERING: Is tiering applied?

Tiering is applied. The amendment to this administrative regulation establishes a tier fee structure by lowering the fee for midwives to submit testing to the state laboratory.

FISCAL IMPACT STATEMENT

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 194A.050(1), 211.090(3), and 214.155.

(2) Identify the promulgating agency and any other affected state units, parts, or divisions:

The Department for Public Health, Division of Laboratory Services is the promulgating agency.

(a) Estimate the following for the first year:

Expenditures:The combined cost of the newborn screening program is approximately \$9.7 million per year. This is a combination of the state laboratory cost and the case management program cost.

Revenues:The amendment to this administrative regulation will generate approximately \$2,000,000 in the first year.

Cost Savings:The amendment to this administrative regulation does not generate cost savings for the promulgating agency.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

Changes in expenditures and revenues in subsequent years will be dependent upon the number of live births and the number of newborn screening test submitted to the state laboratory.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts):

There are no affected local entities.

(a) Estimate the following for the first year:

Expenditures:Not applicable.

Revenues:Not applicable.

Cost Savings:Not applicable.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

Not applicable.

(4) Identify additional regulated entities not listed in questions (2) or (3):

Additional regulated entities include the forty-six (46) birthing hospitals and thirty (30) midwives practicing in Kentucky.

(a) Estimate the following for the first year:

Expenditures:Birthing hospitals will be assessed \$200 per initial newborn screening test submitted to the Division of Laboratory Services. Midwives will be assessed \$50 per initial newborn screening test submitted to the Division of Laboratory Services.

Revenues:This administrative regulation does not generate revenue for the regulated entities.

Cost Savings:Midwives will have a cost saving of \$150 per initial newborn screening test submitted.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

The expenditures and cost savings will not change in subsequent years.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:

This administrative regulation will have minimal fiscal impact on the regulated entities.

(b) Methodology and resources used to determine the fiscal impact:

There will be a fee increase of fifty (50) per initial test for hospitals. Midwives will pay a much lower fee for submitting testing to the state laboratory. The revenue generated by the change in fee structure will help offset the program operating cost resulting in budget neutrality for the department.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). (\$500,000 or more, in aggregate)

This administrative regulation will not have an overall negative or adverse major economic impact.

(b) The methodology and resources used to reach this conclusion:

While the approximate amount of revenue exceeds \$500,000 this will not be paid by any one regulated entity.