NOTICE OF INTENT

Department of Health
Office of Public Health

Newborn Heel Stick Screening and Laboratory Services
(LAC 48:V.6303 and LAC 48:V.13703)

Under the authority of R.S. 40:29, R.S. 40:1081.1 and 1081.2 and in accordance with the Administrative Procedure Act, R.S. 49:950 *et seq*, the Louisiana Department of Health, Office of Public Health (LDH-OPH) proposes to amend Section 6303 (Purpose, Scope Methodology) of Chapter 63 (Newborn Heel Stick Screening). This Chapter is under Subpart 18 (Disability Prevention Program) of Part V (Preventive Health Services) of Title 48 (Preventive Health Services) of LAC 48 (Public Health−General). The proposed rule adds Severe Combined Immunodeficiency (SCID) to the panel of tests for which infants are screened at birth to detect genetic diseases. It also proposes to update procedures to reflect modern laboratory testing methodologies for some screening tests as well as updating addresses, phone numbers and fax numbers of the OPH Laboratory and Genetic Diseases Program.

In accordance with law, LDH has consulted with medical geneticists from each of Louisiana's medical schools prior to the publication of this Notice of Intent. In 2011, an ad hoc meeting of the Louisiana Newborn Screening Advisory Committee,recommended to add SCID to the newborn screening panel once funding became available.

Finally, Section 13703 (Applicability) of Chapter 137 (Laboratory Services) under Subpart 49 (Community Based and Rural Health Services) of Part V of Title 48 of LAC 48 is proposed to be amended to correct an apparent error of applicability (likely dating back to a June 1989 amendment of Section 13703) as it relates to fees currently being collected to assist in funding for the newborn heel stick screening program.

TITLE 48
PUBLIC HEALTH—GENERAL
Part V. Preventive Health Services
Subpart 18. Disability Prevention Program

Chapter 63. Newborn Heel Stick Screening

§6303. Purpose, Scope, and Laboratory Testing Methodology

A. R.S. 40:~~1299.1.2.3~~1081.1 and 1081.2 requires physicians to test Louisiana newborns for the disorders listed below along with the abbreviations used by the American College of Medical Genetics (ACMG).

1. Disorders of amino acid metabolism:
   a. ~~P~~phenylketonuria (PKU);
   b. ~~M~~maple ~~S~~syrup ~~U~~urine ~~D~~disease (MSUD);
   c. ~~H~~homocystinuria (HCY~~);~~
   d. ~~C~~citrullinemia, type I (CIT);

e. ~~Argininosuccinic Aciduria~~argininosuccinate acidemia (ASA); and

f. ~~T~~tyrosinemia, type I (TYR I).

2. Disorders of fatty acid metabolism:

a. ~~M~~medium-~~C~~chain ~~A~~acyl-CoA dehydrogenase ~~D~~deficiency (MCAD);

b. ~~T~~trifunctional protein deficiency (TFP);

c. ~~V~~very ~~L~~long-~~C~~chain ~~A~~acyl-CoA ~~D~~dehydrogenase ~~D~~deficiency (VLCAD);

d. ~~C~~carnitine ~~U~~uptake ~~D~~defect (CUD); and

e. ~~L~~long ~~C~~chain-3-~~H~~hydroxy-acyl-CoA ~~D~~dehydrogenase ~~D~~deficiency (LCHAD).

3. Disorders of organic acid metabolism:

a. ~~I~~isovaleric ~~A~~acidemia (IVA);

b. ~~M~~methylmalonic ~~A~~acidemia (methylmalonyl-CoA mutase, MUT),(cobalamin disorders, CBL A, B);

c. ~~G~~glutaric ~~A~~acidemia ~~T~~type 1 (GA1);

d. ~~P~~propionic ~~Aciduria~~acidemia (PROP);

e. 3-~~H~~hydroxy-3-~~M~~methylglutaryl–CoA ~~L~~lyase deficiency (HMG);

f. ~~M~~multiple ~~C~~carboxylase ~~D~~deficiency (MCD) including, but not limited to, holocarboxylase synthetase deficiency;

g. ~~β~~beta-~~K~~ketothiolase ~~D~~deficiency (BKT); and

h. 3-~~M~~methylcrotonyl CoA ~~C~~carboxylase ~~D~~deficiency (3-MCC).

4. Other metabolic disorders:

a. ~~B~~biotinidase ~~D~~deficiency (BIOT); and

b. ~~C~~classic ~~G~~galactosemia (GALT).

5. Endocrine disorders:

a. ~~C~~congenital ~~H~~hypothyroidism (CH); and

b. ~~C~~congenital ~~A~~adrenal ~~H~~hyperplasia (CAH).

6. Hemoglobinopathies (~~S~~sickle ~~C~~cell diseases):

a. hemoglobin S,S disease (~~S~~sickle ~~C~~cell ~~A~~anemia) (Hb SS);

b. hemoglobin S,C disease (Hb SC);

c. hemoglobin S,~~B~~ beta-~~T~~thalassemia disease (Hb S/βTH); and

d. ~~O~~other sickling diseases.

7. Pulmonary disorders:

a. ~~C~~cystic ~~F~~fibrosis (CF).

8. Immune Disorders:

a. ~~S~~severe ~~C~~combined ~~I~~immunodeficiency (SCID).

B. Methodology

1. Filter Paper Specimen Form~~,~~ (Lab-10), used in blood specimen collection for neonatal screening, can be obtained ~~at parish health units~~from the Genetic Diseases Program by calling 504-568-8254. There are two different types of Lab-10 forms which are color-coded.

a. For patients covered by Medicaid or Managed Care Plans, ~~including those in the Kid-Med Program,~~ blue border Lab-10 forms are used. There is no charge to private providers for these blue border forms. The patient's Medicaid number (or mother's number, if the patient has not been issued one) ~~must~~shall be indicated on the form.

b. For private and non-Medicaid patients, red border Lab-10 forms are used. These red border Lab-10 forms are $~~18~~ 30 each. The name of the insurance company and policy number ~~must~~shall be included on the form.

2. Private providers should order a mix of red and blue Lab-10 forms from ~~their local parish health unit (or OPH Regional Office for certain areas)~~the Genetic Diseases Program to match the Medicaid/non-Medicaid composition of newborns to be screened at their facility. The Lab-10 forms ~~must~~shall be completely filled out.

3. For non-Medicaid patients with a financial status of greater than 100 percent of the ~~P~~poverty ~~G~~guidelines as established by the Louisiana Department of Health ~~and Hospitals~~ (LDH~~H~~) and who attend a parish health unit for just the newborn screening service, the parent or guardian ~~will~~shall be charged $~~18~~ 30 upon registering at the parish health unit.

4. To ensure that specimens for testing are received within ~~two~~2 to ~~three~~3 days by the laboratory approved by the Office of Public Health (OPH) to perform newborn screening pursuant to the ~~pertaining~~ requirements of this Chapter, all such laboratories ~~must~~shall provide mailing envelopes to submitting hospitals which guarantee a delivery time no longer than ~~three~~3 days from mailing. An example of an acceptable minimum option would be the use of the United States Postal Service's Flat Rate Priority Mailing Envelopes. The use of all other companies and courier services providing ~~this~~the required level of service stated herein are acceptable.

C. Policy for Pre-Discharge, Repeat Screening and Education to Parents on Repeat Screening

1. Pre-Discharge Screening. All hospitals that have maternity units shall institute and maintain a policy of screening all newborns before discharge regardless of their length of stay in the hospital. ~~Newborns remaining in the hospital for an extended period should be screened initially no later than seven days after birth.~~ The initial screen should occur at greater than 24 hours of birth but shall occur no later than 7 days after birth.

2. Repeat Screening for Specimens Collected before 24 Hours. There is a greater risk of false negative results for specimens collected from babies younger than 24 hours of age. Therefore, full-term, healthy newborns screened prior to 24 hours of age must be rescreened at the first medical visit, preferably between ~~one~~1 and ~~two~~2 weeks of age, but no later than the third week of life. Repeat screening should be arranged by the primary pediatrician; however, it may be done by any primary healthcare provider or clinical facility qualified to perform newborn screening specimen collection. For preterm, low birth weight, and sick infants admitted to the neonatal intensive care unit (NICU), an initial specimen should be collected upon admission, a second

specimen shall be collected at 48-72 hours after admission and a final specimen shall be collected at 28 days or upon discharge, whichever comes first.

3. Education to Parents on Repeat Screening. To ensure that newborns who need rescreening ~~(due to initial unsatisfactory specimen or an initial collection performed on a baby less than 24 hours old)~~ actually receive the repeat test, hospitals with maternity units must establish a system for disseminating information to parents about the importance of rescreening. This includes infants with an initial unsatisfactory specimen, infants with an initial collection performed at less than 24 hours of age, and infants admitted to the NICU.

D. Notification of Screening Results

1. The Genetic Diseases Program follow-up staff shall notify the appropriate medical provider of the positive screening result by telephone. Otherwise, submitters should receive ~~the~~test result~~s slip~~ from the State Public Health Laboratory within ~~two weeks~~5 days after collection. Test ~~R~~results are ~~also~~ available to submitters 24 hours a day, 365 days a year through the ~~Voice Response System~~web--based ~~with Fax (VRS)~~ Secure Remote View~~w~~er (SRV) which is accessed ~~by using a touch tone telephone~~ via computer. Information on signing up for and ~~using VRS~~ the SRV can be obtained by calling the Genetic Diseases Program Office at (504) ~~219-4413~~568-8254. If test results are not available, medical providers may fax in their requests to the following numbers: (~~504~~225) 219-~~4694~~4905 (Public Health Biochemistry Laboratory) or (504) ~~219-4452~~ 568-8253 (Genetics Office). ~~To assist the pediatrician's office in the retrieval of the results on the initial specimen of the infant at the first medical visit, the phlebotomist or nurse collecting the initial specimen should tear off the blue carbon of the Lab-10 form and give this to the parent. The parent should be instructed to bring this copy to the first medical visit.~~ In order to retrieve test results from the SRV, the provider must have the infant's date of birth plus one of the following: mother's first name, mother's last name, baby's first name or baby's last name. Test results can also be found by the infant's medical record number or by the Lab 10 form number.

E. Unsatisfactory Specimens. The accuracy of a test depends on proper collection of the blood spot. Specimens of unsatisfactory quality for testing ~~will~~shall be indicated on the test result slip. Training on collecting adequate specimens can be arranged by calling the Genetics ~~Nurse~~ Diseases Program at telephone number (504) 568-~~5070~~8254.

F. Medical/Nutritional Management

1. In order for a patient with PKU or other rare inborn errors of metabolism to receive the special formulas for the treatment of these disorders from the state's Genetic Diseases Program and/or Special Supplemental Nutrition Program for Infants, Women, and Children (WIC), the following guidelines ~~must~~shall be met:

a. The patient ~~must~~shall be a resident of the State of Louisiana.

b. The patient ~~must~~shall receive clinical and dietary management services through a metabolic center to include a medical evaluation at least once annually by a physician who is board certified in biochemical genetics or a medical geneticist physician with written documentation of a medical evaluation and continuing consultation with a physician board certified in biochemical genetics. A licensed registered dietitian must also be on staff and be readily available for both acute and chronic dietary needs of the patient. Children less than ~~one~~1 year of age ~~must~~shall be seen by the dietitian and medical geneticist at least twice a year. Children greater than ~~one~~1 year of age ~~must~~shall be seen at least once per year by the dietitian and medical geneticist.

c. The patient ~~must~~shall provide necessary blood specimens for laboratory testing as requested by the treating physician meeting the above requirements. Laboratory test result values for phenylalanine and tyrosine ~~must~~shall be submitted to the Genetics Program Office by the treating medical center within 15 working days after data reduction and interpretation.

d. The patient ~~must~~shall include dietary records with the submission of each blood specimen.

e. All insurance forms relative to charges for special formula ~~must~~shall be signed and submitted by the parent or appropriate family member.

f. The parent or guardian ~~must~~shall inform the Genetics Program Office immediately of any changes in insurance coverage.

g. If a patient fails to comply with these requirements, he/she ~~will~~shall not be able to receive metabolic formula, medications and medical services through the Office of Public Health.

G. Acceptable Newborn Screening Testing Methodologies and Procedures for Medical Providers Not Using the State Laboratory. Laboratories performing or intending to perform the state mandated newborn screening battery on specimens collected on Louisiana newborns ~~must~~shall meet the conditions specified below pursuant to R.S. 40:~~1299.1~~1081.2.

1. The testing battery ~~must~~shall include testing for the disorders listed in ~~Subpart~~Subsection A above.

2. The laboratory ~~must~~shall perform the newborn screening testing battery on at least 50,000 specimens a year unless the said laboratory has been routinely performing the full screening battery since January 1, 1995.

3. A laboratory ~~must~~shall perform the complete battery at one site. Using two laboratories for completion of the total battery is unacceptable as this increases the risk of error and delay in reporting.

4. When using dried blood spots, only specimen forms using filter paper approved by the Centers for Disease Control and Prevention (CDC) are acceptable.

5. Only the following testing methodologies listed in Table 6303.G.5 are acceptable without prior written approval from the Genetic Diseases Program.

Table 6303.G.5

Disease	Testing Methodology
Disorders of Amino Acid Metabolism	Tandem Mass Spectrometry (MS/MS)
Disorders of Fatty Acid Metabolism	
Disorders of Organic Acid Metabolism	
(Specific disorders include those as listed under ~~part~~Subsection A)	

Table 6303.G.5	
Disease	**Testing Methodology**
Biotinidase Deficiency	Time-Resolved Immunofluorescence assay Qualitative or Quantitative Enzymatic Colorimetric or Fluorometric
Galactosemia	Galt enzyme assay Total Galactose
Hemoglobinopathies (Sickle Cell Diseases)	Cellulose acetate/citrate agar Capillary isoelectric focusing (CIEF) Gel isoelectric focusing (IEF) High Pressure Liquid Chromatography (HPLC) DNA Mutational Analysis Sickle Dex – is NOT Acceptable Controls must include: F, A, S, C, D, E If controls for hemoglobins D and E are not included in the ~~1st~~first tier testing methodology, then the ~~2nd~~second tier testing must be able to identify the presence of these hemoglobins. Result Reporting: by phenotype Positive/negative is NOT acceptable
Congenital Hypothyroidism	Radioimmunoassay (RIA), Fluorescent Immunoassay (FIA) time resolved fluoroimmunoassay, Enzyme Immunoassay (EIA) methods for T4 and/or Thyroid Stimulating Hormone (TSH) which have been calibrated for neonates
Congenital Adrenal Hyperplasia	17 hydroxyprogesterone (17OHP), time resolved fluoroimmunoassay
Cystic Fibrosis	Primary: Immunoreactive Trypsinogen; Time-Resolved fluoroimmunoassay Second Tier: Deoxyribonucleic Acid (DNA) mutation analysis Qualitative Sweat Conductivity Test is NOT acceptable as a primary screening methodology. Confirmatory Test Methodologies: Quantitative Pilocarpine Iontophoresis Sweat Chloride Test Qualitative Sweat Conductivity Test is NOT recommended.
Severe Combined Immunodeficiencies (SCID)	Real Time Quantitative ~~Quick~~ Polymerase Chain Reaction (RTQPCR) ~~and time-resolved fluorescence resonance energy transfer~~

Table 6303.G.5	
Disease	**Testing Methodology**
~~New Food and Drug Administration approved methodologies may be used if found to be acceptable by the Genetic Diseases Program. Approval should be requested in writing 60 days before the intended date of implementation (see Genetic Diseases Program mailing address below) Requests for approvals will be based on documentation of FDAapproval and an in-house validation study of said methodology.~~	

a.) Alternative Methodologies not listed in Table 6303.G.5. New Food and Drug Administration (FDA)-approved methodologies may be used if first found to be acceptable by the Genetics Diseases Program. Approval shall be requested from the Genetic Diseases Program in writing 60 days before the intended date of implementation by mailing the request to:

LDH OPH Genetic Diseases Program
1450 Poydras Street, Suite 2046
New Orleans, Louisiana 70112

b.) Approval Process. Requests for approvals of methodologies not listed in Table 6303.G.5 shall be based on documentation of FDA-approved methodologies or on documentation of OPH Laboratory-developed test methodologies, as well as an in-house OPH Laboratory validation study of the applicable methodology proposed for use.

6. The laboratory ~~must~~shall comply with the regulations for proficiency testing as mandated in the Clinical Laboratory Improvement Amendments of 1988 (CLIA 88 Section §493.1707). When using dried blood spots, the laboratory must participate in a~~the~~ proficiency testing program ~~of the Centers for Disease Control and Prevention (CDC)~~. The laboratory must report all proficiency testing results to the Genetic Diseases Program Office within ~~one~~1 month of receiving the report from the proficiency testing provider.

7. The laboratory ~~must~~shall be able to provide test result data to physicians and nurses on their specific patients by telephone and by FAX or by use of the internet, 24 hours a day 365 days a year.

8. Mandatory Reporting of Positive Test Results Indicating Disease

a. To ensure appropriate and timely follow-up, positive results ~~must~~shall be reported, along with patient demographic information as specified below to the Genetic Diseases Program Office by fax at (504)~~-219-4452~~568-8253. Receipt of faxed results ~~must~~shall be verified by call~~ing to~~ the Genetics Office at (504) ~~219-4413~~568-8254.

b. Described below are specific time deadlines after data reduction and interpretation for reporting positive results indicating probable disease to the Genetics Diseases Program Office. Laboratories ~~must~~shall make arrangements with the Genetics Diseases Program Office for reporting after hours, weekends and holidays for positive test results from tandem mass spectrometry and the assays for galactosemia, and congenital adrenal hyperplasia~~ and congenital hypothyroidism~~. Notification of presumptive positive results for biotinidase deficiency, sickle cell disease, congenital hypothyroidism and cystic fibrosis ~~will~~shall be made at the beginning of the next business day.

i. ~~M~~metabolic disorders identified by tandem mass spectrometry and for ~~g~~galactosemia—report results ~~by~~within 2 hours~~.~~;

ii. ~~B~~biotinidase ~~D~~deficiency—report results within 24 hours~~.~~;

iii. ~~S~~sickle ~~C~~cell ~~D~~disease—report results of FS, FSC, FSA from initial specimens within 24 hours~~.~~;

iv. ~~C~~congenital ~~H~~cypothyroidism—report within 24 hours~~.~~;

v. ~~C~~congenital ~~A~~adrenal ~~H~~hyperplasia—report within 2 hours~~.~~; and

vi. ~~C~~cystic ~~F~~fibrosis—report within 24 hours.

c. The specified information to be reported:

i. – xiii. …

xiv. transfusion given~~.~~?

Yes ___ ~~Date of last transfusion (if available)~~ No ___
If yes, date of last transfusion (if available): _____

9. Provision of Follow-up Services. To ensure that reporting time deadlines specified under Subparagraph b of Paragraph 8 of this Subsection are met for ~~every~~ positive test result indicating probable disease ~~under b above~~, a follow-up system must be in operation. The protocol for a follow-up system may rely on the submitting hospital for the follow-up action which must include the following.

a. – a.iii. …

iv. if there is no response to mail within 5 days, a home visit should be made; and,

a.v. – b.ii. …

10. Reporting requirements of private laboratories to the Genetic Diseases Program Office for public health surveillance and quality assurance purposes.

a. The laboratory ~~must~~shall submit quarterly statistical reports to the Genetic Diseases Program Office that indicate the number of specimens screened by method, the number of specimens unsatisfactory for testing, the number normal and positive, and for screening of hemoglobinopathies, the number by phenotype ~~(~~[see the Genetics Diseases Program Office's address ~~in Subsection G.7~~near the end of the Diseases/Testing Methodology table (which may be found under Paragraph 5 of this Subsection)].

b. The laboratory ~~must~~shall electronically report newborn screening results on all Louisiana newborns screened to the Genetic Diseases Program Office on a monthly basis. The file format and data layout ~~will~~shall be determined by the Genetic Diseases Program. Essential patient data is the following and is required to be reported unless "optional" is indicated:

i. – xiii. …

xiv. mother's Social Security number (format: 999-99-9999); and

xv. …

11. The laboratory ~~must~~shall register by letter with the OPH's Genetic Diseases Program ~~of the Office of Public Health~~ each year. This letter ~~must~~shall contain the following and shall be received in the Genetic Diseases Program Office by February 1 each year:

a. assurance of compliance with the requirements described in Subsection G. 1. – G.9. of this Subsection;

b. – c. …

d. the type of specimen(s) used, *i.e.*, filter paper or whole blood; and

G.11.e. – H.2. …

3. If the specimen was not collected before transfusion, the laboratory reporting the results to the submitter mustshall indicate that transfusion may alter all newborn screening results and include the above times for repeat screening.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1299, et seq.1018.1 and 1081.2

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Preventive and Public Health Services, LR 13:246 (April 1987), amended by the Department of Health and Hospitals, Office of Public Health, LR 17:378 (April 1991), LR 18:1131 (October 1992), LR 20:1386 (December 1994), LR 23:301 (March 1997), LR 27:545 (April 2001), LR 29:1490 (August 2003), LR 32:248 (February 2006), LR 34:442 (March 2008)., amended by the Louisiana Department of Health, Office of Public Health, LR 44:

Subpart 49. Community Based and Rural Health Services

Chapter 137. Laboratory Services

§13703. Applicability

A. Except as otherwise provided under this Title, Tthese laboratory fees shall not be charged:

1. to the Office of Public Health of the Louisiana Department of Health and Hospitals (LDH) or for laboratory services for a patient at a clinic or health unit operated by the Office of Public Health or to any physician, nurse, dentist, veterinarian, sanitarian or other licensed health care provider who is treating a patient or providing services in an official capacity in relation to the treatment of a patient of the Office of Public Health of the Louisiana Department of Health, including the network of parish health units operated by the Office of Public Health;

2.–3. …

4. to any state hospital or institution when the secretary of the Louisiana Department of Health and Hospitals requires the Office of Public Health laboratory to act for such institution in case of emergency.

B. These fees shall be charged for all tests, procedures, functions, or any operations performed by each laboratory independently operated by the Office of Public Health of the Louisiana Department of Health and Hospitals as a state laboratory on human specimens, environmental samples, cultures, analytical and research procedures and related services which are submitted by any physician, hospital, clinic or health unit not operated by the Office of Public Health, nurse, veterinarian, sanitarian or any other licensed health care provider authorized to submit specimens for scientific analysis by the Division of Laboratories of the Office of Public, LDHH. The charges or fees for these services will be assessed according to the following schedule.

Test Description	Fee
1. – 98. …	…

Test Description	Fee
99. Newborn Screening Panel	$ ~~31~~30
100. – 373. …	…

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:29.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Health Services and Environmental Quality, LR 3:245 (May 1977), amended by the Department of Health and Hospitals, Office of the Secretary, LR 15:477 (June 1989), amended by the Office of Public Health, LR 24:942 (May 1998), amended by the Louisiana Department of Health, Office of Public Health, LR 44:

Family Impact Statement

(1) The effect on the stability of the family. The purpose of newborn screening is to identify genetic conditions which are treatable, life enhancing and potentially life-saving. Newborn screening is a very important service to families in detecting diseases at birth which can be identified through proper and available screening. Adding SCID to the newborn screening panel would enhance the stability of the family by detecting this devastating condition early and preventing the negative health consequences.

(2) The effect on the authority and rights of parents regarding the education and supervision of their children. This will not affect the authority, rights or supervision of parents over their children. Parents have the choice to "opt out" of the testing.

(3) The effect on the functioning of the family. If detected and treated early, children affected by this disorder can lead long and fulfilling lives. This will contribute to a positive family structure.

(4) The effect on the family earnings and family budget. Testing for SCID is life-saving as well as cost saving. Testing for SCID is approximately $4. However, an undiagnosed or late diagnosed case of SCID can result in up to 1 million dollars per case in medical bills and can ultimately lead to death in the first year of life. Treatment for SCID is approximately $200,000 and is covered by most health insurance plans and results in a typical life.

(5) The effect on the behavior and personal responsibility of children. The addition of SCID would help children affected with this condition to lead typical lives.

(6) The ability of the family or local government to perform the function as contained in the proposed rule. All children in Louisiana are tested at birth for most conditions recommended by the U.S. Department of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children. The addition to SCID to the newborn screening panel will not call for any additional effort of families or local governments.

Poverty Impact Statement

(1.) The effect on household income, assets, and financial security. There will be a positive effect on household income, assets and financial security through the avoidance of health issues for families of children who have Severe Combined Immune Deficiency (SCID) and were detected at birth. Health issues, if not treated early in life, can have huge financial impact to a family as they will have extreme medical costs.

(2.) The effect on early childhood development and preschool through postsecondary education development. If detected and treated early, children can develop without the burden of

continued medical issues. When the disease is not identified early, illness and eventually death, will likely occur before the child ever reaches pre-school.

(3.) The effect on employment and workforce development. There could be effect on the employment and workforce development of parents of children with SCID. Caring for a very sick child could make employment for both parents difficult.

(4.) The effect on taxes and tax credits. There will be no effect on taxes and tax credits.

(5.) The effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance. There will be a positive effect on child and dependent care, housing, health care, nutrition, transportation, and utilities assistance. Early detection and treatment mean that a child, and their family, can operate without the burden of increased health care costs. Additionally, lost employment and strained resources for utilities can be avoided, as well as increased difficulties for child and dependent care, due to frequent illnesses.

Small Business Impact Statement

The impact of the proposed rule on small businesses as defined in the Regulatory Flexibility Act has been considered. The proposed action includes revision of LAC 48:V.6303 to include Severe Combined Immunodeficiency (SCID) on the newborn screening panel of tests. Testing for this condition is a life-saving and a cost saving measure that will result in a positive impact on affected citizens. The Office of Public Health's Genetic Diseases Section does not expect that adoption of the proposed amendments will have a significant economic impact on small business entities.

Provider Impact Statement

The proposed Rule should have minimal impact on providers as defined by HCR 170 of 2014 Regular Legislative Session. Per HCR 170, "provider" means an organization that provides services for individuals with developmental disabilities. In particular, the impact is anticipated as follows:

(1.) No impact on the effect on the staffing level requirements or qualifications required to provide the same level of service;

(2.) The incidence of SCID is 1 per 58,000 births. For that 1 case, the provider will have additional responsibility in following up on the positive result, referring the patient for confirmation testing and referring the patient to a more specialized provider for treatment. The goal of testing newborns is to capture positive cases early in life and institute treatment as soon as possible; thus, more costly interventions later in life to babies who are not tested and are later found to exhibit symptoms of this disease are averted. Delay in knowing if a newborn has this disease will likely lead to an increase of costs to providers, as well as possibly the State.

(3.) Due the low incidence, particularly when found early because of such testing, the total direct and indirect effect on the cost to the providers to provide the same level of service is minimal; and

(4.) There will be no impact on the overall effect on the ability of the provider to provide the same level of service.

Request for Comments

Interested persons may submit written comments on the proposed rule. Such comments must be received no later than Wednesday, August 29, 2018 at COB, 4:30 pm, and should be addressed to Cheryl Harris, Program Administrator, Genetic Diseases Program, Office of Public Health, 1450 Poydras Street, Suite 2046, New Orleans, LA 70112, or faxed to (504) 568-8253.

Public Hearing

Interested persons may submit a written request to the Genetic Diseases Program to conduct a public hearing; however, such request must received no later than August 10, 2018 at COB, 4:30 pm. If request(s) for public hearing is received by this deadline date and it (or they) meets the minimum criteria specified in R.S. 49:953(A)(2)(a) for holding a public hearing, LDH-OPH will conduct a public hearing at 10 am on Tuesday, August 28, 2018, in Room 173 of the Bienville Building, 628 North 4th Street, Baton Rouge, LA. Before attending, interested persons should first call Ms. Cheryl Harris at (504) 568-8254 after August 10, 2018 to confirm whether or not a public hearing will be held. If a public hearing is to be held, all interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing. If held, persons attending the hearing may have their parking ticket validated when one parks in the 7-story Galvez Parking Garage which is located between N. 6th and N. 5th / North and Main Streets. (cater-corner and across the street from the Bienville Building).

Rebekah E. Gee MD, MPH
Secretary