

## DEPARTMENT OF HEALTH

**NOTICE OF PROPOSED RULEMAKING**

The Director of the Department of Health, pursuant to the authority set forth in section 5 of the Newborn Hearing Screening Act of 2000, effective April 4, 2001 (D.C. Law 13-276; D.C. Official Code § 7-854), Mayor's Order 2002-12, dated January 25, 2002, section 4 of the District of Columbia Newborn Screening Requirement Act of 1979, effective April 29, 1980 (D.C. Law 3-65; D.C. Official Code § 7-833), Mayor's Order 2004-172, dated October 20, 2004, sections 2003(e) and 2006 of the Childhood Lead Poisoning Screening and Reporting Act of 2002, Title XX of the Fiscal Year 2003 Budget Support Act of 2002, effective October 1, 2002 (D.C. Law 14-190; D.C. Official Code §§ 7-1033(e) and 7-1036), and Mayor's Order 2005-23, dated January 25, 2005, hereby gives notice of his intent to adopt the following amendments to Title 22 of the District of Columbia Municipal Regulations (DCMR) in not less than thirty (30) days from the date of publication of this notice in the *D.C. Register*.

The proposed rule will clarify and consolidate the portions of Chapters 22 and 73 of Title 22, DCMR that relate to the screening of newborns. Specifically, the rule will amend section 2099 to add definitions, rename section 2204 as "Neonatal Screening Services", add new metabolic disorders to the list of disorders that newborns are tested for, move the text of existing Chapter 73 to the renamed section 2204 and clarify these provisions, add subsections 2204.10 through 2204.13 to establish standards for indigency and residency for parents to qualify to receive benefits for metabolic disorder testing, amend § 2600.8 to require maternity centers to comply with the requirements of section 2204, and rename Chapter 73 as "Childhood Lead Poisoning Prevention".

The renamed Chapter 73 will add provisions establishing the requirements for universal childhood lead screening, diagnostic and follow-up testing for a child with an elevated blood lead level, case management for a lead-poisoned child, and the reporting of all blood lead level results for each child less than six (6) years of age residing in the District of Columbia. The universal lead screening, testing, and case management provisions in this proposed rulemaking are based on the guidelines issued by the United States Centers for Disease Control and Prevention in *Preventing Lead Poisoning in Young Children* (October 1991) and *Screening Young Children for Lead Poisoning: Guidance for State and Local Public Health Officials* (November 1997). Revised chapter 73 implements the provisions of the Childhood Lead Poisoning Screening and Reporting Act of 2002, effective October 1, 2002 (D.C. Law 14-403; D.C. Official Code § 7-1031 *et seq.*), and provides the minimum standards for the periodicity of blood lead level screenings. These standards are in addition to the requirements of the Student Health Care Act of 1985, effective December 3, 1985, as amended (D.C. Law 6-66; D.C. Official Code § 38-601 *et seq.*), for childhood blood lead screening for a child who attends a school or child development center located in the District of Columbia.

**Title 22 (Public Health and Medicine) (August 1986) of the DCMR is amended as follows:**

**I. The table of contents is amended as follows:**

A. Strike the phrase "2204: NEWBORN HEARING SCREENING SERVICE" and insert the phrase "2204: NEONATAL SCREENING SERVICES" in its place.

B. Strike the phrases "CHAPTER 73. NEONATAL TESTING FOR METABOLIC DISORDERS" and "22-7300. NEONATAL TESTS; INFORMED CONSENT" and insert the following phrases in their place:

Chapter 73 CHILDHOOD LEAD POISONING PREVENTION

7300 GENERAL PROVISIONS

7301 UNIVERSAL CHILDHOOD LEAD SCREENING

7302 TESTING AND CASE MANAGEMENT FOR A CHILD WITH AN ELEVATED BLOOD LEAD LEVEL

7303 REPORTING BLOOD LEAD LEVEL TEST RESULTS

7304-7398 RESERVED

**II. Section 2099 of Chapter 20 (Hospitals and Clinics) is amended by adding or amending the following terms with the ascribed meanings as follows:**

**2,4-Dienoyl-CoA reductase deficiency**-an autosomal recessive genetic disorder characterized by a deficiency of 2,4 Dienoyl CoA Reductase necessary for the degradation of unsaturated fatty acids with an even number of double bonds. Symptoms include sepsis, hypotonia, decreased feeding, and intermittent vomiting. Low carnitine levels can be detected and respiratory acidosis may occur.

**2-Methylbutryl-CoA dehydrogenase deficiency**-an autosomal recessive genetic disorder resulting from a defect in the metabolism of the branched chain amino acid isoleucine. Symptoms include poor feeding, lethargy, hypoglycemia, and metabolic acidosis. Symptomatic patients display developmental delay, seizure disorders, and progressive muscle weakness in infancy and childhood.

**3-Methylcrotonyl-CoA carboxylase deficiency (3MCC)**-a progressive autosomal recessive genetic disorder characterized by failure to thrive, hypotonia, muscle atrophy, seizures, mental retardation, and dermatological changes.

**3-Methylglutaconyl-CoA hydratase deficiency**-an autosomal recessive genetic disorder involving an enzyme in the metabolism of the amino acid leucine. Symptoms

appear in a wide range of clinical severity and may include acute life-threatening cardiopulmonary symptoms soon after birth, psychomotor retardation, hypotonia, failure to thrive, microcephaly, seizures, and spasticity. Some patients may have acute episodes of vomiting, metabolic acidosis, and lethargy progressing to coma.

**3-OH 3-CH<sub>3</sub> glutaric aciduria or 3-hydroxy-3-methylglutaryl-CoAlyase deficiency (HMG)**-an autosomal recessive genetic disorder. Symptoms may include metabolic acidosis, hypoglycemia, sensitivity to dietary leucine, carnitine deficiency, hepatomegaly, fever, somnolence, and coma. If this disorder is untreated, it is likely to result in death during childhood.

**5-Oxoprolinuria (pyroglutamic aciduria)**-a group of autosomal recessive genetic conditions including glutathione synthetase deficiency, glutamylcysteine synthetase deficiency, and 5-oxoprolinase deficiency caused by a deficiency of one (1) of three (3) enzymes in the gamma glutamyl cycle and characterized by metabolic acidosis, hemolytic anemia, electrolyte imbalance, and jaundice.

**Argininemia**-an autosomal recessive genetic condition that presents from two (2) months to four (4) years of age. Symptoms include progressive spastic paraplegia, failure to thrive, delayed milestones, hyperactivity, and irritability, with episodic vomiting, hyperammonemia, seizures, microcephaly, and cerebral atrophy resulting in mental retardation.

**Argininosuccinic acidemia (ASA)**-an autosomal recessive genetic disorder of the urea cycle. Symptoms are hyperammonemia accompanied by lack of appetite, vomiting, listlessness, seizures, and coma. Onset is usually at birth, but symptoms may not be noticeable for days or weeks. The build up in ASA, if too high, ultimately causes a build up in ammonia. Build up of ammonia is toxic and can cause brain damage. ASA is also characterized by excessive urinary excretion of argininosuccinic acid, epilepsy, ataxia, mental retardation, liver disease, and friable, tufted hair.

**Beta-ketothiolase deficiency (BKT)**-an autosomal recessive genetic disorder characterized by recurrent severe metabolic acidosis. Symptoms include increased plasma glycine level, metabolic acidosis, episodic ketosis, vomiting, dehydration, coma, and cardiomyopathy, with on average onset of five (5) to twenty-four (24) months.

**Biotinidase deficiency (BIOT)**-an autosomal recessive genetic disorder characterized by a lack of the enzyme biotinidase that can lead to seizures, developmental delay, eczema, and hearing loss that are treated with free biotin. Symptoms include hypotonia, ataxia, alopecia, seborrheic dermatitis, and optic nerve atrophy. Metabolic acidosis can result in coma and death.

**Carbamoylphosphate synthetase deficiency (CPS def.)**-an autosomal recessive genetic condition that presents within seventy-two (72) hours with symptoms of lethargy, vomiting, hypothermia, respiratory alkalosis, and seizures progressing to coma. Survivors of the newborn period have recurrent episodes of hyperammonemia

associated with viral infections or increased dietary protein intake. Some patients have a later onset with less severe symptoms.

**Carnitine uptake defect (CUD)**-a class of autosomal recessive genetic disorders characterized by hypoketotic hypoglycemia, seizures, vomiting, lethargy progressing to coma, cardiomyopathy, and hepatomegaly. This disorder includes carnitine palmitoyl transferase deficiency type I and carnitine acylcarnitine translocase deficiency.

**Citrullinemia (CITR)**-an autosomal recessive genetic disorder characterized by a deficiency of argininosuccinic acid synthetase, hyperammonemia accompanied by lack of appetite, vomiting, listlessness, seizures, and coma. Onset is usually at birth, but symptoms may not be noticeable for days or weeks. When left untreated, brain damage, coma, and death will occur.

**Congenital adrenal hyperplasia (CAH)**-a set of inherited disorders that occurs in both males and females as a result of the excess production of male hormones and an underproduction of the enzyme 21-hydroxylase, severe acne, excess facial or body hair, early development of pubic hair, receding scalp hairline, menstrual disturbances in females, and infertility in males and females in its mild form and ambiguous genitalia in newborn girls and salt and hormonal imbalances in girls and boys in more severe forms. If not treated, CAH can cause heart failure and death within a few days from birth. CAH can not be cured; however, it can be effectively treated.

**Cystic fibrosis (CF)**-an autosomal recessive genetic disorder characterized by progressive chronic damage to the respiratory system, chronic digestive system problems, and can affect other organs. CF affects mucus-producing glands producing thick mucus that can obstruct air passages in the lungs, affects sweat and salivary glands, and blocks enzymes secreted by the pancreatic duct. Cystic Fibrosis can cause lung disease, failure to grow, clubbed fingers and toes, muscular weakness, and visual impairment.

**Galactosemia**-a condition involving the inability to convert galactose to glucose.

**Glucose-6-phosphate dehydrogenase deficiency (G6PD)**-a condition resulting in anemia or jaundice that is made worse by certain medications and some foods.

**Glutaric acidemia type I (GA-I)**-an autosomal recessive enzyme deficiency genetic disorder characterized by hypoglycemia, dystonia, and dyskinesia. After a period of apparently normal development, the disorder may appear suddenly and present as vomiting, metabolic acidosis, hypotonia, and central nervous system degeneration. It is not yet known how or why Glutaric Acid causes brain damage, yet damage occurs when a crisis causes an acidic environment in the blood created by excess protein byproducts. Crises can be provoked by common childhood illnesses such as colds, flu, ear infections, stomach virus, fever, etc.

**Homocystinuria**-a condition resulting from one of several genetically determined errors of methionine metabolism.

**Hemoglobinopathy**-a class of disorders caused by the presence of abnormal hemoglobin production in the blood, due to genetic variations that can result in production of hemoglobin with different structures or thalassemias and reduction in the amount of normal hemoglobin produced. This term includes the following hemoglobin variants: HbS, HbC, HbE, HbD, and alpha-thalassemias.

**Hyperammonemia, hyperornithinemia, homocitrullinemia syndrome (HHH)**-an autosomal recessive genetic disorder that may present at birth or in later childhood. Newborns on high protein formulas or foods may vomit with feeding, refuse to eat, become lethargic, or develop hyperammonemic coma. Patients gravitate to diets low in milk and meat during childhood.

**Hyperornithine with gyrate deficiency**-an autosomal recessive genetic disorder characterized by slow progressive vision loss leading to blindness. Myopia and decreased night vision appear as early symptoms in the patient's teens and early twenties.

**Hypothyroidism**-those clinical conditions that result from abnormally low circulating levels of thyroid hormone.

**Isobutyryl-CoA dehydrogenase deficiency**-an autosomal recessive genetic disorder involving the inability to metabolize valine with a highly variable presentation.

**Isovaleric acidemia (IVA)**-an autosomal recessive genetic disorder caused by a defect in the breakdown of the molecule isovaleryl-CoA that presents in acute or intermittent episodes. IVA can present as an acute episode of illness during the first few weeks of a newborn's life, or it may present chronically with intermittent episodes of illness throughout life. Both forms of IVA are caused by the same biochemical defect. Infants who survive an acute neonatal episode will go on to exhibit the chronic intermittent form. Symptoms of acute IVA are attacks of vomiting, lack of appetite, and listlessness; lethargy, neuromuscular irritability, and hypothermia are other characteristics. Episodes can be triggered by upper respiratory infections or by excessive consumption of high-protein foods. Early detection through newborn screening and good treatment of IVA generally leads to normal development. Permanent neurologic damage can occur if an acute episode is not prevented or is misdiagnosed.

**Long-chain L-3-OH acyl-CoA dehydrogenase deficiency (LCHADD)**-an autosomal recessive genetic disorder characterized by failure to oxidize fatty acids due to a missing or malfunctioning enzyme. Symptoms include hypoglycemia, lethargy, failure to thrive, cardiomyopathy and developmental delay. Early identification and treatment can prevent life-threatening episodes.

**Malonic aciduria**-an autosomal recessive genetic disorder caused by a deficiency of malonyl-CoA decarboxylase (MCD) with a variable presentation ranging from acute neonatal onset to later in childhood. Symptoms include developmental delay, seizures, hypotonia, diarrhea, vomiting, metabolic acidosis, hypoglycemia, and ketosis.

**Maple syrup urine disease**-a condition resulting from the impairment of branched chain alpha-ketoacid dehydrogenase.

**Maternity center**-a facility or other place, other than a hospital or the mother's home, that provide antepartal, intrapartal, and postpartal care for both mother and newborn infant during and after normal, uncomplicated pregnancy.

**Medium chain acyl-CoA dehydrogenase deficiency (MCADD)**-an autosomal recessive genetic disorder characterized by inability to convert fat to energy. Fasting is not tolerated well in people with MCADD. Symptoms generally begin in infancy or early childhood, however, there are some with no apparent symptoms at birth. Low blood sugar, seizures, brain damage, cardiac arrest and serious illness can occur very quickly in children who are not feeding well. Some experience recurrent episodes of metabolic acidosis, hypoglycemia, lethargy, and coma. If not detected and treated appropriately, MCADD can result in mental retardation and death. Those treated are expected to have normal life expectancy.

**Metabolic disorder**-a disorder that results in a defect in the function of a specific enzyme or protein.

**Methylmalonic acidemia**-one of two variations of an autosomal recessive genetic disorder caused by an enzymatic defect in the oxidation of amino acids characterized by lethargy, failure to thrive, vomiting, dehydration, respiratory distress, hypotonia, and hepatomegaly. Acute episodes may include drowsiness, coma, and seizures, with subsequent developmental delays. This disorder includes methylmalonic acidemia CblA, methylmalonic acidemia CblB, and methylmalonic acidemia mutase deficiency.

**Multiple acyl-CoA dehydrogenase deficiency (MADD)**-an autosomal recessive genetic disorder, also known as glutaric acidemia type T1, with three (3) different clinical presentations. Symptoms include hypotonia, hepatomegaly, severe nonketotic hypoglycemia, metabolic acidosis, and variable body odor of sweaty feet.

**Multiple carboxylase deficiency (MCD)**-an autosomal recessive genetic disorder characterized by a biotin deficiency. Symptoms include seizures, developmental delay, eczema, and hearing loss. Other symptoms are immune system impairment, skin rashes, hair loss and mental retardation that are treatable with oral biotin supplements.

**Neonatal carnitine palmitoyl transferase deficiency-type I1 (CPT-IT)**-an autosomal recessive genetic disorder of mitochondria1 fatty acid oxidation that presents in three (3) forms. The classic form has adult onset of exercise-induced muscle weakness, often with rhabdomyolysis and myoglobinuria that may be associated with renal failure.

A second form that is often fatal between three (3) and eighteen (18) months of age with symptoms of hepatomegaly, non-ketotic hypoglycemia, cardiomyopathy, hypotonia, and muscle weakness. A severe form presents in newborns with non-ketotic hypoglycemia, cardiomyopathy, hypotonia, muscle weakness, and renal dysgenesis in some patients.

**Newborn**--an infant under four (4) weeks of age.

**Phenylketonuria (PKU)**--the metabolic disease of the newborn in which metabolites of phenylalanine appear in the urine.

**Propionic acidemia (PROP)**--an autosomal recessive genetic disorder characterized by protein intolerance, vomiting, failure to thrive, lethargy, and profound metabolic acidosis. If not treated early, brain damage, coma, seizures and death can occur.

**Short chain acyl-CoA dehydrogenase deficiency (SCAD)**--an autosomal recessive genetic disorder of fatty acid beta oxidation with a usual clinical onset between the second (2nd) month and second (2nd) year of life, with some presenting within a few days of birth and some in adulthood. Symptoms include hypotonia, progressive muscle weakness, developmental delay, and seizures. Symptoms worsen with seemingly innocuous illness that may lead to lethargy, coma, apnea, cardiopulmonary arrest, or sudden unexplained death.

**Short chain hydroxy acyl-CoA dehydrogenase deficiency (SCHAD)**--an autosomal recessive genetic disorder of mitochondrial fatty acid beta oxidation for which a complete spectrum of presentation has not been defined. Most patients have hypoglycemia as the major symptom along with seizures, neurologic sequelae or death as the outcome. Several present in the first days or months of life with hypoglycemic seizures secondary to hyperinsulinism. Some patients present after one (1) year with acute onset of vomiting, lethargy, and hyponatremic seizures.

**Sickle Hemoglobinopathy**--repealed.

**Trifunctional protein deficiency (TFP)**--an autosomal recessive mitochondrial fatty acid oxidation genetic disorder characterized by an inability to break down long-chain fatty acids into an energy source. Metabolic crises can occur when fasting, as well as hypoglycemia, lethargy, hypotonia, myopathy, failure to thrive, cardiomyopathy, and neuropathy. Severe untreated cases may present as SIDS.

**Tyrosinemia, type I (TYRO-I)**--an autosomal recessive genetic disorder that causes severe liver disease in infancy. Affected persons develop cirrhosis of the liver and eventually require liver transplantation. The most severe form causes symptoms within the first months of life. These infants experience poor weight gain, enlarged liver and spleen, swelling of the legs, increased tendency of bleeding. Even with therapy death frequently occurs within six (6) to nine (9) months of life for those with the severe form.

Children with a less severe form also suffer from enlargement of the liver, spleen, poor weight gain, vomiting and diarrhea.

**Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD)**-an autosomal recessive genetic disorder in which the body cannot oxidize fatty acids because of a missing or mal-functioning enzyme. Symptoms include hypoketotic hypoglycemia, hepatocellular disease, and cardiomyopathy. Fatal infantile encephalopathy may be the only indication of the condition.

**III. Section 2204 of Chapter 22 (Categories of Hospital Services) is amended to read as follows:**

### **2204 Neonatal Screening Services**

- 2204.1 Each institution shall establish a Newborn Hearing Screening Service according to the following requirements:
- (a) Each institution shall designate a person to be responsible for the newborn hearing screening service in that institution.
  - (b) An audiologist, otolaryngologist, or other qualified person, including a neonatal nurse or a hospital technician, shall oversee each newborn hearing screening service. The person assigned to oversee the newborn hearing screening service may be full or part time, on or off site, an employee of the institution, or under contract or other arrangement that allows him or her to oversee the newborn hearing screening service. This person shall advise the institution about all aspects of the newborn hearing screening service, including screening, and recommendations for follow-up testing and treatment.
  - (c) Each institution shall provide hearing screening services pursuant to this section, unless any of the following occurs:
    - (1) The procedure is contrary to the parents' religious beliefs;
    - (2) The parents withhold consent to perform the screening; or
    - (3) The institution transfers the newborn to another institution for treatment before hearing screening can be completed, provided that the transferring institution informs the Maternal and Family Health Administration of the Department within twenty- four (24) hours.
  - (d) Newborn hearing screening may be performed by any of the following:

- (1) An audiologist;
- (2) An otolaryngologist;
- (3) A neonatal nurse appropriately trained to perform hearing screening and under supervision by an audiologist or otolaryngologist;
- (4) A hospital technician appropriately trained to perform hearing screening and under supervision by an audiologist or otolaryngologist; or
- (5) A hospital volunteer appropriately trained to perform hearing screening and under supervision by an audiologist or otolaryngologist.

2204.2 Before discharging the newborn, each institution shall do the following:

- (a) Provide the newborn's parents with oral information and written materials that describe the benefits and purpose of hearing screening, the procedures used for hearing screening, and the consequences of hearing loss;
- (b) Provide the newborn's parents with oral and written information about whether it performed a hearing screening on the newborn;
- (c) After performing the hearing screening, provide the newborn's parents, the newborn's primary care provider, if known, and the Maternal and Family Health Administration of the Department with oral and written results of the hearing screening; and
- (d) After performing the hearing screening, recommend to the newborn's parents and the newborn's primary care provider, if known, appropriate follow-up testing and treatment that may be necessary.

2204.3 If the parents do not understand English well enough to comprehend the information, the institution shall provide the information required by § 2204.2 in the parents' native language.

2204.4 For newborns that require additional procedures to complete the screening after being discharged from the institution, the institution shall provide the newborn's parents and the newborn's primary care provider, if known, with written notice about the availability and importance of additional screening procedures.

2204.5 An institution that completes a newborn hearing screening and finds that the newborn did not pass the screening shall provide the newborn's parents, the Department, and the newborn's primary care provider, if known, with written results of the screening, recommended diagnostic procedures, and resources available for newborns with hearing impairment.

2204.6 Each institution shall make available to each newborn delivered or cared for at the institution blood tests to screen for the following metabolic disorders:

- (a) 2,4-Dienoyl-CoA reductase deficiency;
- (b) 2-Methylbutryl-CoA dehydrogenase deficiency;
- (c) 3-Methylcrotonyl-CoA carboxylase deficiency (3MCC);
- (d) 3-Methylglutaconyl-CoA hydratase deficiency;
- (e) 3-OH 3-CH<sub>3</sub> glutaric aciduria (HMG);
- (f) 5-Oxoprolinuria (pyroglutarnic aciduria);
- (g) Argininemia;
- (h) Argininosuccinic acidemia (ASA);
- (i) Beta-ketothiolase deficiency (BKT);
- (j) Biotinidase deficiency (BIOT)
- (k) Carbamoylphosphate synthetase deficiency (CPS def.)
- (l) Carnitine uptake defect (CUD)
- (m) Citrullinemia (CITR)
- (n) Congenital adrenal hyperplasia (CAH);
- (o) Cystic fibrosis (CF);
- (p) Galactosemia (GALT);
- (q) Glucose-6-Phosphate Dehydrogenase Deficiency (GGPD);

- (r) Glutaric acidemia type I (GA I);
- (s) Hemoglobinopathy;
- (t) Homocystinuria (HCY)
- (u) Hyperammonemia, hyperomithinemia, homocitrullinemia syndrome (HHH);
- (v) Hyperornithine with gyral atrophy;
- (w) Hypothyroidism;
- (x) Isobutyryl-CoA dehydrogenase deficiency;
- (y) Isovaleric acidemia (IVA);
- (z) Long-chain L-3-OH acyl-CoA dehydrogenase deficiency (LCHADD);
- (aa) Malonic aciduria;
- (bb) Maple Syrup Urine Disease (MSUD);
- (cc) Medium chain acyl-CoA dehydrogenase deficiency (MCAD);
- (dd) Methylmalonic acidemia;
- (ee) Multiple acyl-CoA dehydrogenase deficiency (MADD);
- (ff) Multiple carboxylase deficiency (MCD);
- (gg) Neonatal carnitine palmitoyl transferase deficiency-type I1 (CPT-11);
- (hh) Phenylketonuria (PKU);
- (ii) Propionic acidemia (PROP)
- (jj) Short chain acyl-CoA dehydrogenase deficiency (SCAD);
- (kk) Short chain hydroxy acyl-CoA dehydrogenase deficiency (SCHAD);
- (ll) Trifunctional protein deficiency (TFP);

(mm) Tyrosinemia type I (TYRO-I); and

(nn) Very long-chain acyl-CoA dehydrogenase deficiency (VLCAD).

- 2204.7 Each institution shall inform the parent or parents of the availability and purpose of the tests for the conditions set forth in subsection 2204.6 and shall document in the newborn's health record that the parent or parents were properly informed and understood the purpose of the tests.
- 2204.8 Each institution shall provide the parent or parents a reasonable opportunity to object to performance of the tests and shall document in the newborn's health record whether the parent or parents consented or withheld consent to have the testing done.
- 2204.9 Each institution that has obtained parental consent to have the newborn tested shall take from the newborn a blood sample of sufficient quantity to enable a laboratory designated by the Mayor to analyze the sample for the tests identified in subsection 2204.6, unless an identical test has been performed. Each institution shall send the sample to the designated laboratory.
- 2204.10 A newborn's parent is indigent for the purpose of § 9 of the District of Columbia Newborn Screening Requirement Act of 1979, effective April 29, 1980 (D.C. Law 3-65; D.C. Official Code § 7-838), if the parent does not have coverage by Medicaid or third party medical or health insurance coverage and has a total pre-tax household income, including child support payments, alimony, rent payments received, and any other income received on a regular basis, equal to or less than three hundred per cent (300%) of the federal poverty level.
- 2204.11 A newborn's parent shall document income to satisfy the requirements of § 2204.10 as follows:
- (a) For a person whose source of income is earned income, one of the following:
- (1) Originals or copies of all earnings statements received within the previous thirty (30) days;
  - (2) A copy of the first two (2) pages of a District of Columbia tax return for the most recent tax year;
  - (3) A copy of the first page of a Federal tax return for the most recent tax year; or

- (4) For a newly employed parent, a copy of an offer of employment that states the amount of salary to be paid.
- (b) For a parent whose source of income is unearned income, one of the following;
  - (1) A copy of a Social Security or worker's compensation benefit statement;
  - (2) Proof of child support or alimony received; or
  - (3) A copy of a Federal tax return for the most recent tax year, including all schedules and attachments.

2204.12 A newborn is a resident of the District of Columbia for the purpose of § 9 of the District of Columbia Newborn Screening Requirement Act of 1979, effective April 29, 1980 (D.C. Law 3-65; D.C. Official Code § 7-838), if the newborn's mother is a resident of the District of Columbia on the date on which the newborn was born.

2204.13 The mother of a newborn shall document residency to satisfy the requirements of § 2204.12 by providing one of the following:

- (a) A valid motor vehicle operator's permit issued by the District;
- (b) A non-driver's identification card issued by the District;
- (c) A voter registration card issued by the District of Columbia Board of Elections and Ethics;
- (d) A copy of a lease or a rent receipt for real property located in the District;
- (e) A utility bill for real property located in the District; or
- (f) A copy of the most recent federal income tax return or Earned Income Credit Form.

**IV. Subsection 2600.8 of Chapter 26 (Maternity Centers) is amended to read as follows:**

2600.8 Each maternity center shall, in addition to the other requirements of this chapter, comply with the requirements of section 2004 regarding newborn hearing screening and newborn testing for metabolic disorders.

**V. Chapter 73 is amended to read as follows:**

**CHAPTER 73 -- CHILDHOOD LEAD POISONING PREVENTION**

Sections

7300 General Provisions  
7301 Universal Childhood Lead Screening  
7302 Testing and Case Management  
7303 Reporting  
7304-  
7398 Reserved  
7399 Definitions

**7300 GENERAL PROVISIONS**

7300.1 Each health care provider or health care facility shall inform the parent or guardian of every child under the age of six (6) years residing in the District of Columbia, served by the provider or the facility, of the requirement for periodic blood lead level (BLL) screening tests, as required by this chapter. Each health care provider or health care facility shall document in the child's health record that the parent or guardian was informed of this requirement and understood the purpose of the tests.

7300.2 Each health care provider or health care facility offering care to pregnant women and breast feeding mothers shall inform the patient of the risks of lead poisoning, specifically the risks from lead-based paint hazards, including lead-contaminated dust, lead-contaminated soil, and lead-contaminated paint that is deteriorated or present in accessible surfaces; lead in drinking water; and lead in improperly prepared or unsafe foods, folk remedies, toys, and other consumer products.

**7301 UNIVERSAL CHILDHOOD LEAD SCREENING**

7301.1 Each health care provider or health care facility that has obtained parental consent shall, as part of a well-child care visit, perform a BLL screening test on every child who resides in the District of Columbia and who is served by the provider or facility, unless an identical test was performed not more than twelve (12) months before the well-child visit. Blood lead level screening tests shall be performed according to the following schedule:

- (a) Once between the ages of six (6) and nine (9) months;
- (b) Once between the ages of twenty-two (22) and twenty-six (26) months; and

- (c) At least twice if a child over the age of twenty-six (26) months has not previously been tested for BLL. The tests for children over the age of twenty-six (26) months shall be conducted before the child attains the age of six (6) years and shall be conducted at least twelve (12) months apart, or according to a schedule determined appropriate by the health care provider or health care facility.

7301.2 When a health care provider or health care facility required to provide testing pursuant to this chapter does not administer a BLL test during a well-child visit and according to the schedule provided in subsection 7301.1, the health care provider or health care facility shall document in the child's health record the reason for not performing the BLL test.

7301.3 Each health care provider and health care facility shall conduct additional BLL screening when any of the following circumstances are present:

- (a) When a child is at risk for high-dose lead exposure based on the child's living conditions, a parent's occupational exposure to lead, a history of lead poisoning in siblings or playmates, or as indicated because of the child's behavior or development. In determining whether a child is at risk for high-dose lead exposure, each health care provider and health care facility shall determine, through the use of a personal-risk questionnaire or by other appropriate means, whether any of the following risk indicators are present:
  - (1) The child lives in, or frequently visits, deteriorated housing built before 1978;
  - (2) The child lives in, or frequently visits, housing built before 1978, with recent, ongoing, or planned renovation or remodeling;
  - (3) The child's siblings, housemates, or playmates have confirmed lead poisoning;
  - (4) The child's parent, guardian, or other household members participate in occupations or hobbies that may result in exposure to lead; or
  - (5) The child lives, or has lived, near industrial facilities or operations that may release atmospheric lead;
- (b) The child exhibits pica, which consists of repeated ingestion of nonfood substances, or has frequent hand-to-mouth activity; or

- (c) The child has unexplained seizures, neurological symptoms, abdominal pain, or other symptoms consistent with lead poisoning, including growth failure, developmental delay, attention deficit, hyperactivity, behavioral disorders, school problems, hearing loss, or anemia.

7301.4 Each health care provider or health care facility shall provide family lead education and appropriate referrals for social and environmental services to the family of a child with an elevated blood lead level.

## **7302 TESTING AND CASE MANAGEMENT**

7302.1 This section establishes best practices for providing diagnostic, follow-up testing, and case management when a child under the age of six (6) has a BLL screening that indicates an elevated BLL.

7302.2 Each health care provider or health care facility should provide:

- (a) Diagnostic and follow-up testing, treatment, and care for a child with an elevated BLL; and
- (b) Case management for a lead-poisoned child, according to generally accepted medical standards and the guidelines established in this section. The guidelines in this section should be applied in conjunction with pertinent information regarding the child's medical condition and risk of exposure to lead hazards.

7302.3 Each health care provider or health care facility should give a child with an elevated blood level, based on the ELL in a screening test, a diagnostic test according to the following schedule:

- (a) If the results of a BLL screening test are equal to ten (10) micrograms per deciliter ( $\mu$ /dL), or between ten (10) and nineteen (19) micrograms per deciliter ( $\mu$ /dL), the child should receive a diagnostic test within three (3) months after the screening test; and
- (b) If the results of a BLL screening test are equal to or greater than twenty (20) micrograms per deciliter ( $\mu$ /dL), the child should receive a diagnostic test according to the following schedule:
  - (1) Between one (1) week and one (1) month after the screening test when the BLL was between twenty (20) and forty-four (44) micrograms per deciliter ( $\mu$ /dL);

- (2) Not later than forty-eight (48) hours after the screening test when the BLL was between forty-five (45) and fifty-nine (59) micrograms per deciliter ( $\mu$ /dL);
- (3) Not later than twenty-four (24) hours after the screening test when the BLL was between sixty (60) and sixty-nine (69) micrograms per deciliter ( $\mu$ /dL); or
- (4) Immediately, as an emergency laboratory test, when the BLL was equal to or greater than seventy (70) micrograms per deciliter ( $\mu$ /dL).

7302.4 If a child twelve (12) months of age or younger has an elevated BLL on a screening test, or the health care provider has reason to believe that the child's BLL is increasing rapidly, the health care provider may provide the diagnostic test sooner than indicated in subsection 7302.3. Generally, there is a direct correlation between the elevation of the BLL and the urgency for performing a diagnostic test.

7302.5 Each health care provider or health care facility should provide a child with an elevated BLL equal to or greater than ten (10) micrograms per deciliter ( $\mu$ /dL), as indicated in a diagnostic test, with the following services:

- (a) Case management; and
- (b) Follow-up testing within two (2) months of the diagnostic test.

7302.6 A child receiving case management pursuant to this section should receive follow-up testing at not sooner than thirty (30) days and not more than sixty (60) day intervals until all of the following conditions are met:

- (a) The child's BLL is less than ten (10) micrograms of lead per deciliter ( $\mu$ /dL) for at least two (2) follow-up-tests;
- (b) The lead hazards that caused, or that are likely to have caused, the child's elevated BLL have been removed; and
- (c) There is no new exposure and no increased likelihood of exposure to lead hazards.

7302.7 After all the conditions in § 7302.6 have been met, the child should be tested approximately once every three (3) months, until the child reaches thirty-six (36) months of age and typically no longer requires follow-up testing.

## **7303 REPORTING**

- 7301.1 Each time a health care provider or health care facility draws blood or orders a blood draw for a BLL test for a child residing in the District of Columbia, the health care provider or health care facility shall collect and record the information listed in § 7303.3. The provider or facility shall transmit the information to the laboratory performing the BLL analysis at the same time the provider or facility transmits the blood specimen to the laboratory.
- 7303.2 Each laboratory that analyzes a blood sample taken from a child residing in the District of Columbia shall, immediately upon completion of the analysis, submit a report that meets the requirements in § 7303.3, as follows:
- (a) The laboratory shall submit a written report to the health care provider or the health care facility where the sample was taken;
  - (b) The laboratory shall submit a report to the Childhood Lead Poisoning Prevention Program (Program), both in writing and through the Program's electronic reporting system; and
  - (c) The laboratory shall immediately notify the health care provider or the health care facility and the Childhood Lead Poisoning Prevention Program of the results by telephone and fax if the child's BLL equals or exceeds ten (10) micrograms of lead per deciliter ( $\mu$ /dL).
- 7303.3 The laboratory reports for BLL tests shall include the following information:
- (a) Full name, date of birth, gender, and race of the child;
  - (b) Social Security Number of the child;
  - (c) Medicaid Identification Number of the child, if applicable;
  - (d) Complete home address of the child at the time the blood sample was drawn, including the house or apartment number, street, and zip code;
  - (e) Full name, address, and telephone number of the parent or guardian;
  - (f) Name, address, and telephone number of the health care provider or health care facility, including the name and telephone number of the physician ordering the test;

- (g) Type of specimen (venous or capillary), and date on which the specimen was drawn;
- (h) Draw site name, address, and telephone number, if different from the health care provider or health care facility;
- (i) Laboratory identification number, name, address, and telephone number;
- (j) Blood lead level, in micrograms per deciliter ( $\mu$ /dL);
- (k) Name, address, and telephone number of any insurance company that may provide coverage for the child, and the group number and member identification number of the primary insured; and
- (l) Any other information that may be required in any reporting forms or instructions that the Childhood Lead Poisoning Prevention Program may issue.

7303.4 Immediately upon receipt of a laboratory report indicating an elevated BLL in a child, the health care provider or health care facility shall inform the child's parent or guardian of the results and the measures recommended for follow-up treatment and care. Upon request, the provider or facility shall furnish the parent or guardian with a copy of the laboratory report free of charge.

7303.5 Each health care provider or health care facility shall report a lead-poisoned child to the Childhood Lead Poisoning Prevention Program (Program) as follows:

- (a) Report a lead-poisoned child by telephone within seventy-two (72) hours after receiving information of a lead-poisoned child from a laboratory or another health care provider or health care facility;
- (b) Supply the child's name and address; and
- (c) Supply the name and telephone number of the child's parent or guardian.

7303.6 The health care provider or health care facility shall, upon a parent's or guardian's request, provide to the child's parent or guardian, a certificate of testing for lead poisoning that includes the date of the test and the test results.

- 7303.7 Except as provided in this section, each health care provider, health care facility, laboratory, and the Childhood Lead Poisoning Prevention Program shall keep confidential the laboratory report prepared pursuant to this section and the underlying transmittal information from the health care provider or health care facility to the laboratory.
- 7303.8 An employee or agent of the District of Columbia Government may disclose the following information concerning a child with an elevated BLL to the Department, to the owner of the affected property, and to the owner's attorney:
- (a) The name of the child;
  - (b) The child's home address;
  - (c) The name and telephone number of the child's parent or guardian; and
  - (d) Any other information contained in a laboratory report prepared pursuant to this section, except that the child's Social Security Number shall not be disclosed to the owner of the affected property or the owner's attorney.
- 7303.9 An employee or agent of the District of Columbia Government may disclose the address of an affected property, but not the name of a child who may have become lead-poisoned at the affected property, or any other information contained in a laboratory report prepared pursuant to this section concerning that child, to the following:
- (a) The Department of Housing and Community Development;
  - (b) The Department of Consumer and Regulatory Affairs;
  - (c) The Housing Authority;
  - (d) The Water and Sewer Authority; and
  - (e) An individual or business entity retained to conduct lead-based paint activities at the affected property, provided the individual or business entity is certified pursuant to the Lead-Based Paint Abatement and Control Act of 1996, effective April 9, 1997, as amended (D.C. Law 11-221, D.C. Official Code § 8-1 15.01 *et seq.*).
- 7303.10 Except as provided in this section, no person other than an employee or agent of the Department of Health may disclose the name of the child or

any other information contained in a laboratory report prepared pursuant to this section, to any other person without the express consent of the parent or guardian.

**7304-7398 RESERVED**

**7399 DEFINITIONS**

7399.1 When used in this chapter, the following terms have the meanings ascribed:

**Affected property** - a residence where a child with an elevated blood lead level resides or regularly visits and which is a likely source of the lead contributing to the elevated blood lead level.

**Blood lead level or BLL** - the concentration of lead in a sample of whole blood expressed in micrograms per deciliter ( $\mu$ /dL).

**Child** - a person under six (6) years of age.

**Childhood Lead Poisoning Prevention Program or Program** - the office in the Department of Health or a successor program or agency responsible for receiving reports and results concerning a child's blood lead level.

**Case management** - the interdisciplinary treatment and care of a child with an elevated blood lead level, consisting of coordinated medical, social, and environmental services. This term includes diagnostic testing and medical evaluation for complications of lead poisoning; pharmacological treatment, if appropriate; follow-up testing at appropriate intervals; family lead education, housekeeping, and nutritional intervention; appropriate referrals, including referral to the Childhood Lead Poisoning Prevention Program and referral for child development and social services; environmental investigation and assessment; and the elimination or reduction of lead hazards, including source control measures necessary to eliminate or control any lead-based paint hazard to which a lead-poisoned child is exposed.

**Department** - unless otherwise indicated, the Department of Health.

**Diagnostic test** - the first venous blood level test performed within six (6) months on a child with a previously elevated blood level of lead on a screening test. A test performed more than six (6) months after the original screening test is a new screening test, with decisions about further testing and treatment based on the new screening test.

**Elevated blood lead level** - the concentration of lead in a sample of whole blood equal to or greater than ten (10) micrograms of lead per deciliter ( $\mu$ /dL).

**Follow-up test** - a venous blood lead level test used to monitor the status of a child with a prior diagnostic test indicating an elevated blood lead level.

**Health care facility** - a facility providing individual care or treatment of diseases or other medical, physiological, or psychological conditions, including hospitals, clinics, laboratories, nursing homes, or homes for the aged or chronically ill, but excluding private medical offices.

**Health care provider** - a physician, clinic, hospital, or neighborhood health center, licensed by the District of Columbia, that is responsible for providing primary care and coordinating referrals, when necessary, to other health care providers.

**Lead-based paint activities** - that term as used in § 2(9) of the Lead-Based Paint Abatement and Control Act of 1996, effective April 9, 1997, as amended (D.C. Law 11-221; D.C. Official Code § 8-115.01(9)).

**Lead-poisoned child** - a child with a confirmed blood lead level equal to or greater than fifteen (15) micrograms per deciliter ( $\mu\text{dL}$ ), or any other lower threshold that the United States Centers for Disease Control and Prevention may establish in written guidance or regulation.

**Lead hazard** - any source or pathway that results, or that may result, in exposure to lead, including lead-based paint; lead-contaminated dust or soil; sources related to occupations or work sites of parents, guardians, and caregivers (take-home exposure); airborne lead; and lead in water, food, ceramics, traditional remedies, cosmetics, and materials used in hobbies and other home activities.

**Owner** - a person who, alone or jointly or severally with others, meets either of the following criteria:

- (a) Has legal title to any building arranged, designed, or used (in whole or in part) to house one or more dwelling or rooming units: or
- (b) Has charge, care, or control of any building arranged, designed, or used (in whole or in part) to house one or more dwelling or rooming units, as owner or agent of the owner, as fiduciary of the estate of the owner, or as an officer appointed by the court.

**Person** - an individual, corporation, partnership, firm, conservator, receiver, trustee, executor, or legal representative.

**Screening test** - a laboratory test for lead poisoning that is performed on a blood sample from an asymptomatic child to determine the child's blood lead level.

Comments on the proposed rules should be sent in writing to the Department of Health, Office of the General Counsel, 4<sup>th</sup> Floor, 825 North Capitol Street, NE, Washington, DC 20002, not later than thirty (30) days from the date of publication of this notice in the D.C. Register. Copies of the proposed rules may be obtained Monday through Friday, excepting holidays, between the hours of 8:30 A.M. and 4:45 P.M. at the same address.