C. LABORATORY TESTS

Hereditary/Metabolic Screening

Maryland hospitals and birthing centers are required to offer newborn screening for hereditary/metabolic diseases. Most of the tests require that the infant have a minimum of 24 hours of milk feedings prior to the collection of the specimen. The minimum length of stay in the hospital following delivery has been extended to at least 48 hours; however, the mother may request shorter length of stay. Early maternal/infant discharge can interfere with effective screening. If the infant is discharged before having 24 hours of milk feedings, the primary care provider (PCP) should repeat the test before the infant is 2 weeks old.

The Healthy Kids Program requires a second routine hereditary/metabolic screen at 2-4 weeks of age with documentation of the results in the medical record. A *List of the Most Common Metabolic Disorders* included in the hereditary/metabolic screen is available (Refer to Section 3, Table 4).

Obtain newborn screening results for children born in Maryland from the *DHMH Maryland's Public Health Laboratory*. A paper copy of the newborn screening report can be obtained by sending a fax using your practice coversheet to **443-681-4505**. The faxed request should include the baby's birth name, mother's name at the time of birth, the baby's birth date, and hospital of birth. Results can also be obtained by contacting **443-681-3900**. Have the information listed above when calling.[1]

Document results in the child's medical record. A positive screening test does not establish a diagnosis, but is an indication for further evaluation. Consult the *DHMH Maryland State Newborn Screening Follow-Up Unit* [2] at **443-681-3900** for assistance with interpretation of results and arranging an appropriate evaluation. Additionally, the DHMH *Office for Genetics and People with Special Health Care Needs*[3] (OG/PSHCN) at **410-767-6730** can provide clinical information to assist in the management of a child diagnosed with sickle cell disease. Immunization records and other clinical history may also be available through the OG/PSHCN for newly established patients with a known history of sickle cell disease.

Hemoglobinopathy Screening

It is important to screen all infants for hemoglobin disorders, regardless of apparent racial or ethnic group. Tests for both sickle cell disease and trait have been included in the initial newborn screen since 1985. A negative sickle cell test documented on the newborn

[1] For more information, refer to *http://dhmh.maryland.gov/laboratories/Pages/nbs_provider.aspx*.

[2] See *http://dhmh.maryland.gov/laboratories/SitePages/Newborn%20Screening.aspx*.

[3] See *http://phpa.dhmh.maryland.gov/genetics/Pages/home.aspx*.

screen for hereditary/metabolic diseases is sufficient. Screen any infant who does not have a documented negative hemoglobinopathy screen. Document attempts to get test results from prior PCPs.

If using the State Lab and the infant is under 3 months of age, use the *Hereditary Metabolic Disorders Lab Slip (DHMH 79)* for isoelectric focusing test. Be sure to mark "Hemoglobin Test" in red on the slip. After 3 months of age, use a *Hemoglobin Disorder Lab Slip (DHMH 189).* The **Maryland's Public Health Laboratory** at **410-681-3900** will provide lab slips to providers who have their tests analyzed by the Maryland State lab.

Hemoglobinopathy Testing

Review sickle cell trait results at 12 years of age. If a negative sickle cell trait result is not documented in the child's medical record, and the child/adolescent was born in Maryland, contact the *Maryland's Public Health Laboratory* at **410-681-3900** for assistance in determining the results. If results are not available or the child was not born in Maryland, a hemoglobin electrophoresis is recommended, regardless of apparent racial or ethnic group. Refer the adolescent for genetic counseling if sickle cell trait is present.

Anemia Screening

Perform a hematocrit (Hct) or hemoglobin (Hgb) determination to screen for the presence of anemia at 12 months and 24 months of age.[4] Additionally, complete an anemia screen on the initial visit for all children up to 6 years of age unless results are available from the previous provider. Age specific hematocrit and hemoglobin values for healthy children are available (Refer to Section 3, *Table 5: Maximum Hemoglobin Concentration and Hematocrit Values for Anemia*). Periodic anemia screens are not required for a Healthy Kids visit after 2 years of age, unless clinically indicated, or the results of a previous test are not available (Refer to Section 4, *Adolescent Anemia Screening*). [5]

Critical Congenital Heart Disease Screening (CCHD)

CCHD is defined as a heart defect that is present at birth and can cause serious illness or even death if not detected the first few weeks of life. According to CDC CHDs are a leading cause of birth defect-associated infant illness and death.[6] Since 2012, all

[4] American Academy of Pediatrics (AAP). (2010). *Diagnosis and Prevention of Iron Deficiency and Iron Deficiency Anemia in Infants and Young Children (0-3 Years of Age).* 126(5), 1040-1050. Retrieved on 09/22/14, from *http://pediatrics.aappublications.org/content/126/5/1040.full*.

[5] CDC (1998). *Recommendations to prevent and control iron deficiency in the United States*, MMWR, 47(RR-3), 1-36. Retrieved on 12/01/14, from *http://www.cdc.gov/mmwr/preview/mmwrhtml/00051880.htm*.

[6] CDC. *Congenital Heart Defects (CHDs): Data and Statistics*. Retrieved on 06/16/2015, from *http://www.cdc.gov/ncbddd/heartdefects/data.html*.

hospitals and birthing centers in Maryland are required to screen babies within 24-48 hours of age for CCHD.[7]

Not all CCHD can be detected at birth, but some types of CCHD can be detected most of the time using pulse oximetry screening. If a newborn does not pass the pulse oximetry test, further evaluation is needed immediately to see if the newborn have a CCHD. This evaluation should be done before the newborn leaves the hospital. For more information, contact the *OG/PSHCN Critical Congenital Heart Disease Prevention Program*[8] at **410-767-6736.**

Lead Risk Assessment and Blood Lead Testing

A lead risk assessment is a series of questions used to determine if the child is at risk for high-dose lead exposure. The *Preventive Screen Questionnaire* (Refer to Section 7, Appendix II for the *English* and *Spanish* versions) can be used for this assessment. A lead risk assessment is required at each preventive health care visit starting at 6 months of age up to 6 years of age. Consider a "yes" or "I don't know" response to any of the questions a positive risk assessment. Documented results of the lead risk assessment must be in the clinical record at each well child visit. Document the results of the lead risk assessment on either the visit sheet or the Preventive Screen Questionnaire.

Lead Risk Assessment Follow-Up

If the child is at risk, i.e., if the response to any of the lead risk assessment questions is "yes" or "don't know" or if there is any history, symptoms, or signs that may be related to possible lead poisoning, a blood lead level must be done.

Blood Lead Level (BLL) Testing and Laboratory Information

Regardless of the results of the lead risk assessments or zip code of residence, all MA children must have a BLL at 12 months of age and again at 24 months of age. Additionally, obtain a baseline blood lead level on the initial visit for all children up to 6 years of age, if the child has not been previously tested or if results are not available. As noted above, initiate testing at any age, whenever a child is determined to be at risk for lead exposure using a lead risk assessment. The PCP must document that a blood lead level was ordered. Direct any questions regarding the lead testing requirements for Medicaid children to the **Healthy Kids Program** at **410-767-1903**.

The PCP may refer the child to a CLIA (Clinical Laboratory Improvement Amendments of 1988) certified laboratory to obtain and process the blood lead specimen. All laboratories must be CLIA certified to participate in the Maryland Medical Assistance Program. The Managed Care Organizations (MCOs) have contracts with specific

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[7] See COMAR 10.52.15.

[8] See *http://phpa.dhmh.maryland.gov/genetics/SitePages/CCHD_Program.aspx*.

laboratories in your geographical area. Contact each MCO to determine which laboratory to use.

Based on MCO contracts, the PCP may have the option of collecting the blood lead specimen in his/her office. The venipuncture method for specimen collection is recommended to minimize false positive results.

State law requires that all laboratories send blood lead results to the *Childhood Lead Registry* at the *Maryland Department of the Environment, Childhood Lead Poisoning Prevention Program* (CLPPP). Laboratory slips should contain all patient demographic information: name, complete street address, and zip code. This information is used to track children exposed to lead and identify areas at risk for lead poisoning.

Maryland Targeting Plan for Childhood Lead Poisoning

In addition to the blood lead testing requirements for MA participants, there are requirements for all children, regardless of insurance coverage. To review the revised **2015 *Maryland Targeting Plan***, follow the link *http://phpa.dhmh.maryland.gov/IDEHASharedDocuments/MD%202015%20Lead%20Targeting%20Plan.pdf*.

Elevated Blood Lead Level Follow-Up

Lead poisoning is a serious disease, and elevations require confirmation, assessment of increasing/decreasing trend, and prompt follow-up. The child's PCP is responsible for the child's medical case management. When children have documented blood lead levels between 1-5 mcg/dl, venous and capillary, the child's caregiver needs health education and anticipatory guidance about lead and lead poisoning. The second blood lead level at 24 months is still required, even if the blood lead level at 12 months is between 0-9 mcg/dl. Continue to conduct lead risk assessments at every visit up to 6 years of age. Perform additional testing if lead risk has increased.

Children who have blood lead levels between 5-9 mcg/dl must be retested in 3 months. In addition, families whose children have a confirmed level of 5 mg/dl and above should receive lead and nutritional education, and be assessed for possible sources of lead exposure[9]. Children who have blood lead levels of 10 mcg/dl and above need follow-up according to the protocols established by the Centers for Disease Control and Prevention (CDC) and the Maryland Department of the Environment, CLPPP (Refer to Section 3, *Table 6: Maryland Childhood Lead Poisoning Prevention Blood Lead Follow-Up for Children*, and *Table 7: Maryland DOE Case Coordination Guidelines for Lead Poisoned Children*). For assistance in locating tertiary centers that provide chelation treatment for BLL over 40, contact the *Department of the Environment* at **1-800-776-2706/ 410-537-3000.** The *Community Health Nurses* at the local Health Departments provide

[9] See *http://phpa.dhmh.maryland.gov/IDEHASharedDocuments/factsheets/LeadProviderLetterJune2012.pdf*.

environmental inspections, nursing case management and individualized health education to families with lead poisoned children (Refer to Section 8).

Additional Health Risk Assessments

Health risk assessments are used to determine risks for a variety of health-related problems. A risk assessment consists of a series of questions asked to determine if the child/adolescent needs counseling, education, testing, and/or referral to a specialty care provider. The age appropriate risk assessments are described below.

Tuberculosis Risk Assessment

Diagnosis of tuberculosis in children is difficult and poses problems that are not present in adults. Children are less likely to have obvious symptoms of tuberculosis. Tuberculosis in infants and children younger than four years of age is much more likely to spread throughout the body through the bloodstream. As a result, children are at much greater risk of developing life-threatening forms of TB disease (e.g., disseminated TB, TB meningitis).

Perform a tuberculosis risk assessment annually at the Healthy Kids preventive visit beginning at 1 month of age or on the first visit and yearly thereafter, to determine if the child is at risk. The questions for the tuberculosis risk assessment are on the *Preventive Screen Questionnaire* (Refer to Section 7, Appendix II for the *English* and *Spanish* versions). A "yes" response to any of the questions indicates a "positive" tuberculosis risk assessment. Document the result of the tuberculosis risk assessment, "positive" or "negative", on the questionnaire form or on the visit sheet. Be sure to date and sign off on the questionnaire after review. If a child has a "positive" tuberculosis risk assessment, perform testing. Routine Tuberculine Skin Testing (TST) is discouraged for low risk children, because of possible false-positive skin tests. If the practice is completing a pediatric health form requesting TST results for a child assessed as low risk, document "not indicated" on the form.

Current Professional Recommendations Regarding TB:

- Carefully screen for risk of tuberculosis exposure; tuberculin skin testing for low risk children is NOT recommended
- Selectively and appropriately test those at risk for tuberculosis using intra-dermal TST
- Use only trained health care providers to administer and read the results
- Implement prompt medical evaluation for anyone with positive a TST

Targeted TB testing discourages screening of children from low risk populations and focuses on identifying children and adolescents at risk for latent tuberculosis infection (LTBI), who would benefit from drug treatment to prevent progression to TB disease.[10]

[10] Pediatric TB Collaborative Group (2004). *Targeted tuberculin skin testing and treatment of latent tuberculosis infection in children and adolescents.* Retrieved from *http://pediatrics.aappublications.org/content/pediatrics/114/Supplement_4/1175.full.pdf*

Children/adolescents with LTBI have inactive TB bacteria in their body. They do not have TB disease symptoms, and cannot spread TB disease to others. However, they can develop TB disease in the future and then may be capable of spreading active TB bacteria. For further clarification of LTBI vs. TB disease, refer to the ***CDC's Basic TB Facts*** webpage at: *http://www.cdc.gov/tb/topic/basics/default.htm*.

Testing: Determine the frequency and timing of tuberculin skin testing (Refer to Section 3, *Table 8: Priority Groups for Targeted Testing and Treatment of Latent TG Infection with TST Cut-Points and Recommended Testing Frequency)* based on individual health history and evidence of risk factors. Use only the Mantoux TST test (5 tuberculin units of purified protein derivative placed intra-dermally). Multiple puncture or Tine tests are inadequate for TST and should not be used.
A child who has received a TST must return within 48-72 hours to have the injection site inspected or "read" by a trained health care provider.

Use a ruler to measure, in millimeters, the induration (not erythema). Record the results in the medical record based on correct interpretation of skin-test reactions (Refer to Section 3, *Table 9: Tuberculin Skin Test Cut-Points by Age Low Risk Persons*). Do not allow parents or other caregivers to read the skin test. A history of BCG vaccinations is not a contraindication to tuberculin skin testing and is generally not a factor in interpretation of results. For more information about the BCG vaccination and the testing for TB in BCG vaccinated children refer to ***CDC's BCG Vaccine Fact Sheet*** webpage at *http://www.cdc.gov/tb/publications/factsheets/prevention/BCG.htm.*

Treatment: A positive skin test requires further assessment for tuberculosis, including a chest X-ray to rule out active disease. Children with negative chest X-rays and positive skin test are considered latently infected and should receive isoniazid prophylaxis for a minimum of nine months to prevent active disease in the future (Refer to Section 3, *Table 10: Regiments for Treatment of Latent TB Infection and Recommended Monitoring*). Treat a child/adolescent with active disease according to Maryland and national standards. Contact the *DHMH Center for Tuberculosis Control and Prevention* at **410-767-6698** for further information. Administer medications via Directly Observed Therapy (DOT). Notify the *TB Control Coordinators* at the local Health Departments (Refer to Section 8) of anyone with a positive TST and an abnormal chest x-ray, or a child with symptoms of tuberculosis.[11]

[11] See Maryland Guidelines for the Treatment and Prevention of Tuberculosis — 2007 at *http:ideha.dhmh.maryland.gov/OIDPCS/CTBCP/CTBCPDocuments/tbguidelines.pdf.*

Cholesterol/Heart Disease Risk Assessment

The Maryland Healthy Kids Program requires cholesterol/heart disease risk assessment by questionnaire starting at 2 years of age. Since family health history can change, the risk assessment is required annually. The *Preventive Screen Questionnaire* (Refer to Section 7, Appendix II for the *English* and *Spanish* versions) is provided to assist providers in determining risk for heart disease. A "yes" response to any question indicates a "positive" risk. Be sure to date and sign off on the questionnaire after review. Document the result of the cholesterol/heart disease risk assessment, positive or negative, on the questionnaire form or on the visit sheet.

When a child has a positive cholesterol/heart disease risk assessment, the first fasting lipid profile test (FLP) should be completed minimally at 2 years of age, but no later than 10 years of age based on the 2008 guidelines of the American Academy of Pediatrics[12] and the 2007 Expert Committee on the Assessment, Prevention, and Treatment of Child and Adolescent Overweight and Obesity[13]. Test children and adolescents:

- With a positive family history of dyslipidemia or premature cardiovascular disease beginning at ≤ 55 years of age for men and ≤65 year of age for women (this includes documented angioplasty, coronary artery bypass surgery, diagnosed coronary atherosclerosis, myocardial infarction, angina pectoris, peripheral vascular disease, or sudden cardiac death,
- Whose family history is unknown for CVD risks,
- Whose parent has TC≥240 mg/dL or known dyslipidemia,
- Who are overweight and obese-above the 85% on the BMI chart,
- With hypertension, BMI≥95th %ile, or smokes cigarettes,
- With a moderate- or high-risk medical conditions-(diabetes mellitus, chronic kidney disease/end-stage renal disease/post renal transplant, postorthotopic heart transplant, Kawasaki diseases, chronic inflammatory disease, HIV, nephritic syndrome),
- Who have FLP results in the normal range, but who continue to be at risk, every 3-5 years

[12]AAP. (2008). Lipid Screening and Cardiovascular Health in Childhood, *Pediatrics;* 122,198-208; Retrieved on 12/22/2014, from *http://pediatrics.aappublications.org/content/122/1/198.full*.

[13] AAP. (2007). Expert Committee Recommendations Regarding the Prevention, Assessment, and Treatment of Child and Adolescent Overweight and Obesity: Summary Report . *Pediatrics*. 120 (4), 164-192. Retrieved on 08/18/2014 from *http://pediatrics.aappublications.org/content/120/Supplement_4/S164.full?sid=96871aff-5e0c-4c9b-ad26-d97d2b61e47b*.

The physician must measure the FLP on two separate occasions at least 2, but not more than 12 weeks apart and average the values.

Effective January 1, 2016, the DHMH added a new requirement of dyslipidemia lab tests. One test is required between the ages 9-11, and a second one between the ages of 18-21. For more information, refer to the AAP-endorsed *2011 Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents* from the National Heart Blood and Lung Institute.[14]

For management of hypercholesterolemia in children, refer to the AAP -endorsed *2011 Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents* from the National Heart Blood and Lung Institute[15] (Refer to Section 3, *Table 11: Acceptable, Borderline-High and High Plasma Lipid, Lipoprotein and Apolipoprotein Concentrations (mg/dL) for Children and Adolescents*). Children with persistent elevated blood cholesterol levels should receive a referral to a nutritionist for further dietary intervention. Drug therapy should be considered in children 10 years of age and older with an:

- No CVD risk factors, but with LDL-C≥190 mg/dL after 6 months of lifestyle/diet changes, or
- LDL-C 160-189 mg/dL with positive family history or presence of 2 or more additional risk factors (obesity, smoking or hypertension), after 6 months of lifestyle/diet changes, or
- LDL of ≥ 130 mg/dL if diabetes mellitus is present, or
- Average fasting TG level ≥500 mg/dL or average LDL≥250 mg/dL.

Children younger than 10 years of age should not be treated with a medication unless they have:

- Severe primary hyperlipidemia, or
- High-risk condition associated with serious medical morbidity (LDL-C ≥400 mg/dL; TG≥500 mg/dL; evident CVD; post-cardiac transplantation)

Please note: The goal of LDL-lowering therapy in childhood and adolescence is LDL-C below the 95th percentile (≥130 mg/dL)

[14] National Heart, Blood and Lung Institute. (2011). *Integrated Guidelines for Cardiovascular Health and Risk Reduction in Children and Adolescents.* Retrieved on 09/18/2014, from *http://www.nhlbi.nih.gov/guidelines/cvd_ped/index.htm*.

[15] *Ibid.*

STI/HIV Risk Assessment

The Maryland Healthy Kids Program currently requires PCPs to conduct risk assessments for Sexually Transmitted Infections/Human Immunodeficiency Virus (STI/HIV) at each Healthy Kids visit beginning at 11 years of age or earlier if indicated by the child's history. The questions for the STI/HIV risk assessment are on the *Preventive Screen Questionnaire* (Refer to Section 7, Appendix II for the *English* and *Spanish* versions). Document results of the assessment on the questionnaire form or on the visit sheet. Be sure to date and sign off on the questionnaire after review. A "yes" response to any of the questions indicates a positive risk and the need for further assessment and appropriate testing with results documented in the medical record. The CDC recommendation is to screen, through opt-out testing, all patients aged 13 to 64 years in all healthcare settings.[16]

Diagnosis of a STI often requires multiple specific diagnostic tests and all sexually active adolescents should be counseled and tested for sexually transmitted infections, and educated about safe sex and contraception. Effective contraceptive management is important for the sexually active adolescent but if the PCP does not perform these services, an appropriate specialty referral is indicated to a gynecologist for female adolescents or adolescent medicine specialist for males and/or females.[17] For more information about contraceptives, refer to *Contraceptive Options* subsection of Section 4 of this Manual.

The US Preventive Task Force recommends that pap smears be deferred until the female adolescent turns 21 years of age. This recommendation is based in part on the very low incidence of invasive cancer and the potential for adverse effects of the follow-up of abnormal cytology screening results. [18]

Indications for pelvic examinations prior to age 21 are noted in the 2010 AAP statement "*Gynecologic Examination for Adolescents in the Pediatric Office Setting*".[19]

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[16] CDC (2006). *Revised Recommendations for HIV Testing of Adults, Adolescents and Pregnant Women in Health-Care Settings.* Retrieved on 11/25/14, from *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5514a1.htm.*

[17] See U.S Preventive Services Task Force. (2014). *Sexually Transmitted Infections: Behavioral Counseling.* Retrieved on 11/24/14, from *http://www.uspreventiveservicestaskforce.org/Page/Topic/recommendation-summary/sexually-transmitted-infections-behavioral-counseling1*.

[18] See U.S. Preventive Services Task Force. (2012). Cervical Cancer: Screening. Retrieved on 11/24/14, from *http://www.uspreventiveservicestaskforce.org/uspstf/uspscerv.htm*.

[19] AAP. (2010). Gynecologic Examination for Adolescents in the Pediatric Office Setting. *Pediatrics*. 126 (3), 583-590. Retrieved on 09/05/2014, from *http://pediatrics.aappublications.org/content/pediatrics/126/3/583.full.pdf*.