

Summary of Changes to New York State Public Health Law and Regulations: Blood Lead Testing, Reporting and Follow-up

The New York State Department of Health (NYSDOH) recently adopted changes to Administrative Rules and Regulations Subparts 67-1 and 67-3 regarding childhood lead poisoning screening, reporting and follow-up. The Notice of Adoption was published in the State Register on May 6, 2009, and the amendments are **effective on June 20, 2009**.

In addition, several changes to New York State Public Health Law related to lead testing and reporting were recently enacted as part of the 2009 state budget process. Unless otherwise stated, these changes are effective immediately.

This guidance document summarizes the combined statutory and regulatory changes. It is a companion document to another guidance document currently under development that summarizes changes that directly affect laboratories that conduct blood lead testing, including Physician Office Laboratories and Limited Service Laboratory Registrants. These guidance documents and complete copies of the amended Public Health Law and regulations will be available on the NYSDOH Web site at: www.nyhealth.gov/environmental/lead.

Childhood lead testing and reporting

The amended public health law and regulations:

- 1) **Clarify that statewide requirements for lead screening include blood lead testing.** State law and regulations require health care providers to test all children's blood lead levels at or around ages one year and two years, and to assess all children six months to six years of age for risk of lead exposure at least annually as part of routine care, with blood lead testing for children at risk for lead exposure based on those assessments. In the past, some health care providers have noted confusion over the use of the term "screening" to refer to blood lead testing. (*PHL Section 1370-a*)
- 2) **Authorize Physician Office Laboratories (POLs) and Limited Service Laboratory Registrants to conduct blood lead testing, using devices of complexity appropriate for their level of certification.** These changes were made to recognize the availability of, and encourage access to blood lead testing using simple, portable "point-of-care" testing technologies, such as the CLIA-waived LeadCareII™. **NOTE:** even with these changes, all entities that perform blood lead testing must still have the appropriate level of approval to conduct testing on human specimens, as determined by NYSDOH's Wadsworth Center, as summarized below. (*NYCRR Subpart 67-1.3*)
- 3) **Require POLs and Limited Service Laboratory Registrants that conduct blood lead testing to report all results to the New York State Department of Health (NYSDOH).** Reporting of all blood lead test results is essential to assure timely and appropriate follow-up and complete data for public health surveillance purposes. The amendments specify the information that must be reported, the timeframes for reporting and the mechanisms for reporting, which vary by type of laboratory. Additional information about reporting

requirements for laboratories will be detailed in a separate document. (*PHL Sections 1370-e and 2168-a; NYCRR Subparts 67-1.2 and 67-1.3*)

- 4) **Require that health care providers confirm capillary blood lead test results ≥ 10 micrograms per deciliter ($\mu\text{g}/\text{dL}$) using venous blood samples.** This updates the previous regulation, which required confirmation of capillary test results above 15 mcg/dL, and is consistent with national guidelines from the Centers for Disease Control and Prevention (CDC) to maximize the identification of children with lead poisoning. Note that for point-of-care testing using waived test methods, such as the LeadCare II™ device, NYS DOH has established a confirmation threshold level of ≥ 8 mcg/dL. See practice standards for use of CLIA-waived point of care test devices at www.nyhealth.gov/environmental/lead. (*NYCRR Subpart 67-1.2*)
- 5) **Eliminate use of the term “certificate of lead screening”.** This term has caused confusion because there is no specific certificate format that must be utilized. The revised regulations clarify that any written statement signed by a health care provider satisfies the requirement for providing documentation of lead screening to parents and child care providers. (*NYCRR Subparts 67-1.2 and 67-1.4*)
- 6) **Authorize the exchange of information between the statewide childhood lead registry (LeadWeb) and the New York State Immunization Information System (NYSIIS).** This data exchange will integrate children’s lead testing and immunization information to reinforce lead testing requirements for clinicians and provide new information tools for state and local health departments to target lead testing improvement activities. The amendments specify the persons and organizations that can access the lead information in NYSIIS and for what purposes. The amendments also establish NYSIIS as the vehicle for private physician office laboratories that conduct blood lead testing on children to submit test reports to the statewide lead registry, with anticipated implementation in fall 2009. Additional information about these system enhancements and the reporting requirements will be shared with LHDs, health care providers, laboratories and other partners in the near future. (*PHL Sections 1370-a and 2168*)

Follow-up services for children with elevated blood lead levels (EBLLs)

The amended public health law and regulations:

- 1) **Require health care providers to provide comprehensive follow-up services for all children with blood lead levels (BLLs) ≥ 15 $\mu\text{g}/\text{dL}$.** Comprehensive follow-up services include: lead exposure assessment, developmental screening, nutritional assessment, medical management as necessary and referral to the state or local health departments for environmental management. This expands previous criteria, which required these services for children with BLLs ≥ 20 $\mu\text{g}/\text{dL}$. Health care providers are responsible for the provision of follow-up services other than environmental management, while LHDs are required to institute measures to identify and track children with EBLLs to assure follow-up services are provided. (*NYCRR Subpart 67-1.2*)
- 2) **Require LHDs to provide environmental management for all children with BLLs ≥ 15 mcg/dL (or, for partial service counties, to make referrals to the NYSDOH District Offices for environmental management).** All children identified with BLLs ≥ 15 mcg/dL

on or after June 20, 2009 must receive environmental management services. Children who were previously identified with BLLs 15-19 mcg/dL prior to June 20, 2009 should be re-tested at the next recommended time, in accordance with current guidelines for follow-up testing of children with EBLs. Environmental management must be provided for any children identified with BLLs \geq 15 mcg/dL at the next follow-up test. (*NYCRR Subparts 67-1.1, 67-1.2 and 67-1.6*)

- 3) **Clarify that follow-up services are required for all children with EBLs up to age eighteen years.** Although routine blood lead testing is **not** recommended or required for children age six years and older, health care providers may choose to test older children and youth for specific reasons, such as a diagnostic work up, suspected occupational exposure, or refugee status. LHDs should communicate and coordinate with health care providers to appropriately tailor follow-up services for older children with EBLs. Additional guidelines and optional protocols to assist LHDs in providing and tailoring follow up services for older children are included in forthcoming guidance documents. (*NYCRR Subparts 67-1.1, 67-1.2 and 67-1.6*)
- 4) **Expand the requirements for immediate notification of critically elevated BLLs to include all children less than eighteen years of age.** Laboratories must notify the health care providers ordering the tests of BLLs \geq 45 μ g/dL for all children under the age of eighteen years within 24 hours of analysis. Health care providers in turn must notify the local health departments of BLLs \geq 45 μ g/dL for all children under the age of eighteen years within 24 hours of notification by the laboratories. Previous regulations required these urgent notifications only for children less than six years of age. Note that current New York City Health Code reporting requirements, which require that blood lead test results \geq 10 mcg/dL for children residing in New York City be reported to the New York City Department of Health and Mental Hygiene (NYCDOHMH) within 24 hours of receipt of analysis, remain unchanged. (*NYCRR Subparts 67-3.1 and 67-3.2*)