Fiscal Note for Readoption and Amendment of 10A NCAC 41C .0701-.0703

Agency:	NC Commission for Public Health Dept. Of Health and Human Services, Division of Public Health, Epidemiology Section, Occupational and Environmental Epidemiology Branch
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Rule Citations:	10A NCAC 41C .0701 Definition (Readopt) 10A NCAC 41C .0702 Reportable Diseases Illnesses and Injuries (Amend) 10A NCAC 41C .0703 Method of Reporting (Readopt)
Purpose of Addition:	Require laboratories and/or physicians to report all blood lead laboratory test results for individuals age 16 and older to the NC Division of Public.
Relevant Statutes:	GS 130A, Article 20 – Occupational Health, Sections 455–460.
State Agency Impact:	Yes
Local Agency Impact:	No
Private-Sector Impact	Yes
Substantial Economic Impact:	No

Reason for Proposed Readoption/Amendment

Adult Blood Lead and Epidemiology Surveillance Program

The Adult Blood Lead Epidemiology and Surveillance Program (ABLES), in the Occupational and Environmental Epidemiology Branch, NC Division of Public Health, has been in operation since 1994 and allows public health to collect data to determine the magnitude, distribution and risk factors for adult lead poisoning. In addition, findings are used to identify at-risk populations, formulate appropriate public health interventions, and evaluate the effectiveness of public health and regulatory programs. State data is shared annually with the Centers for Disease Control and Prevention (CDC), National Institute of Occupational Safety and Health (NIOSH) to evaluate national lead poisoning trends and inform policy change. Most of blood lead testing in NC is driven by the Occupational Safety and Health Administration (OSHA) lead regulations. Current NC Public Health statutes and rules allow ABLES to collect adult blood lead results from commercial laboratories and physicians do not have to report if laboratories have done so. ABLES is currently restricted to obtaining adult blood lead levels at $\geq$ 40 µg/dL for those 18 years and older. This is insufficient for conducting effective surveillance and protecting people.

Elevated Blood Lead Levels - Definition

Lead is a heavy metal. Routes of exposure for inorganic lead are inhalation and ingestion. Adults are primarily exposed in the workplace. Acute toxicity from lead exposure is well known. Once absorbed lead affects multiple body systems and can cause permanent damage. Those systems commonly affected are the brain, nervous system, kidneys, musculoskeletal system and gastrointestinal system. Acute health effects can range from mild, nonspecific symptoms such as fatigue, irritability and sleep disturbances to delirium, seizures and coma at high levels of intoxication. In general, the severity of symptoms worsens with increasing blood lead level. In some instances, adult exposure may result in family exposure. If not diligent about personal hygiene, workers may inadvertently take lead dust home on their hair, skin, cloths and shoes and potentially contaminate family cars and homes. Pregnant women and children are at risk for exposure. Lead easily crosses the placenta in pregnant woman and can adversely affect the fetus. Small children are very sensitive to low levels of lead and typically engage in behaviors favoring ingestion of lead. Common childhood adverse health effects include IQ deficits, changes in attention-related behaviors, and poor academic achievement.

Collection of blood lead data allows ABLES to identify at risk populations and formulate prevention strategies to reduce risk of exposure. These include:

- Tracking adult blood lead levels to find out who is exposed to lead;
- Conducting follow-up interviews with workers and employers to learn more about exposure circumstances and provide information about exposure control;
- Performing work-site evaluations;
- Providing technical assistance to employers and others;
- Making referrals to regulatory agencies for consultation and enforcement; and
- Developing educational materials and outreach programs

The current definition of a reportable, elevated blood lead level in North Carolina is $\geq$ 40 ug/dL. This means that labs and/or physicians are only required to report blood lead levels $\geq$ 40 ug/dL. The reporting rule was developed 25 years ago, and recent science indicates lead toxicity and adverse health effects can occur at much lower blood lead levels. Chronic, low level lead exposure (e.g. < 10 µg/dL) has adverse health effects in adults such as kidney damage, reduced fetal growth, and hypertension; and, no safe blood lead threshold for these effects has been identified. In response to recent findings, the CDC, NIOSH and the Council of State and Territorial Epidemiologists (CSTE) now define an adult elevated blood lead as BLL $\geq$ 5 µg/dL and NIOSH recommends ABLES state programs collect all blood lead levels on adults. Of the 40 states conducting adult blood lead surveillance across the country 70% (28 states) require all blood lead tests be reported to the state's public health division. North Carolina and South Carolina have the highest reporting thresholds in the country at $\geq$ 40 µg/dL. Currently 43% of southeastern states (FL, GA and TN) require all blood lead levels be reported to state's departments of public health.

The current blood lead level reporting language compromises NC Division of Public Health's ability to access, characterize and respond to blood lead levels that may cause harm. Both adults and unborn children are at risk. In the rule, the definition of "elevated blood lead" should reflect the need to collect all elevated adult blood lead levels in NC. The rule also asks for non-elevated blood lead levels (e.g. 0 ug/dL, fractions, below level of detection or not detected); these thresholds vary based on the differences in testing capability at commercial laboratories. Obtaining non-elevated blood lead levels is necessary because these are needed to accurately compute incidence and prevalence rates for periodic analysis and reporting of adult blood lead trends.

Age required for reporting elevated blood lead levels

NIOSH stipulates an adult in the ABLES program is defined as 16 years and older. This was set to correspond with childhood lead which collects blood lead data for individuals < 16 years old. That way evaluation of blood lead is covered for the lifespan between the two programs. In the rule, under Rule .0720 (a), (b) and (c), the age requirement for reporting should be 16 years of age and above.

Addition of ethnicity to information required from physicians and commercial laboratories

Just like race, public health practitioners need to collect this information to identify vulnerable groups. NIOSH requires this variable to be collected.

Laboratory reporting

ABLES is a hybrid reporting system where the program receives blood lead levels electronically and through paper reports. By 2019 most blood leads will be received electronically.

Required Readoption

In addition, 10A NCAC 41C .0701 and .0703 are being readopted with substantive changes pursuant to GS § 150B-21.3A, Periodic Review and Expiration of Existing Rules. The Commission for Public Health, Rules Review Commission, and the Joint Legislative Administrative Procedure Oversight Committee approved a periodic review report for 10A NCAC 41C listing .0701 and .0703 as necessary with substantive public interest.

Opportunity Cost

State Agency Impact
A revised reporting rule will ensure the state can meet the federal reporting requirement for all blood lead levels and be able to identify and implement risk reduction strategies for lower blood lead levels meeting or exceeding the NIOSH elevated blood lead threshold (≥ 5 µg/dL) for individuals age 16 years and older. With a few exceptions, commercial laboratories and doctor's offices are compliant with providing all blood lead levels for those age 16 years and older to the state. Most of blood lead results received are below 5 µg/dL (79%) and go into the database with little to no staff effort so lowering the reporting threshold will require minimal additional staff time. Lastly, continued reliance on electronic reporting frees up staff time for other program tasks. All these features of the program result in no change in the hours or wages needed to handle extra reports.

Receipt of all adult lead results from physicians will require minimal data entry time for staff.

Local Agency Impact
The proposed amendment has no fiscal impact on the local health departments as they are not involved in ABLES.

Private-Sector Impact
The proposed amendment will have limited fiscal impact on the private sector. Based on historical blood level test reporting, staff has estimated that on average one to two physician offices will report yearly approximately 30 blood test results. Staff has estimated the fiscal impact based on 60 projected number of new tests being reported, which is on the upper end of the projection. There will be a small increase in clinic staff time (60 minutes per year total for each physician office at rate of $ 70/hour for a private practice nurse) to provide data on an estimated 62 blood lead tests per year that fall below our current reporting rule of are 40 ug/dL). Most physician offices are set up to capture ethnicity.

Laboratories are not mandated to initiate electronic lab reporting with this amendment. However, upon initiating ELR to transmit reportable disease test results to public health, laboratories must meet this reporting requirement. No unique actions are required for reporting adult lead results via ELR. Therefore, the requirement to transmit blood lead results poses no additional burden on laboratories. Commercial laboratories are set up to capture ethnicity in their systems. Also, since all blood tests will be reportable, the new NC blood lead reporting language will reduce the possibility of non-compliance of laboratories or physician offices going forward.

Table 1. Resources and costs associated with the reporting of all positive blood lead test results used to identify lead poisoning in North Carolina.

Resources	Cost
A. Impact on State Agency	
Upgrades to NC EDSS* to receive all blood lead case reports	None needed
Maintenance cost	NA
Total one-time cost to State Agency	None
Impact on State Agency: Division of Public Health, Epidemiology Section, Occupational and Environmental Epidemiology Health Branch	$5,593.64

# Reported	Total Hours per Event Reported	Hourly Salary (including fringe) of State Epidemiologist [1]	Cost to State Agency
62	1	$90.22	$5,593.64

B. Impact on Local Agencies	
None	$None
C. Impact on Private Sector	
Hourly wage for private practice nurse ($47/hr. including 49% fringe uplift to total $ 70.03/hr.) times estimated number of tests per year (60) time 1 hour to report the test results.	$4,341.86
Total cost	
Total one-time cost	None
Total annual cost	$ 9,935.50

*North Carolina Electronic Disease Surveillance System

Appendix: Proposed Rule Amendments

10A NCAC 41C .0701 is proposed for readoption with substantive changes as follows:

SECTION .0700 - OCCUPATIONAL HEALTH SURVEILLANCE

10A NCAC 41C .0701 DEFINITION

"Adult" for the purposes of this section means a person age 16 or older.

"Elevated blood lead level" means a blood lead of ~~40 ug/dL or greater.~~ >0 µg/dL.

"Non-elevated blood lead level" means all blood lead levels that are not elevated regardless of threshold.

History Note: *Authority G.S. 130A-455;*
Eff. January 4, 1994.

10A NCAC 41C .0702 is proposed for amendment as follows:

10A NCAC 41C .0702 REPORTABLE DISEASES, ILLNESSES, AND INJURIES

(a) The following named diseases, illnesses, and injuries are declared to be dangerous to the public health and shall be reported by a physician within the time period specified after the disease, illness, and injury is diagnosed:

(1) asbestosis - 15 ~~working~~ business days;

(2) silicosis - 15 ~~working~~ business days;

(3) elevated blood lead levels for adults ~~aged 18 years of age and above~~ - 15 ~~working~~ business days;

(4) injuries caused by tractors, farm equipment, or farm machinery that occur while working on a farm and require medical care - 15 ~~working~~ business days;

(5) carbon monoxide poisoning - 15 ~~working~~ business days.

(b) All laboratories providing diagnostic service in North Carolina shall report to the Occupational and Environmental Epidemiology Branch within the Division of Public Health elevated blood lead levels for adults. ~~adults aged 18 years of age and above.~~

(c) Physicians shall not be required to report elevated blood lead levels for adults ~~aged 18 years of age and above~~ when a laboratory providing diagnostic service in North Carolina reports elevated blood lead levels.

(d) Non-elevated blood lead levels shall be reported in same manner for surveillance purposes.

History Note: *Authority G.S. 130A-455; 130A-456; 130A-457; 130A-458;*
Eff. January 4, 1994;
Amended Eff. December 1, 2016.
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 16, 2019.

10A NCAC 41C .0703 is proposed for readoption with substantive changes as follows:

10A NCAC 41C .0703 METHOD OF REPORTING

(a) When a physician makes a report of a disease, illness, injury, or elevated blood lead level for adults ~~aged 18 years of age and above~~ pursuant to G.S. 130A-456 or a medical facility makes such a report pursuant to G.S. 130A-457, the report shall be made to the Occupational Health Section as follows:

(1) The report shall be made on the surveillance forms provided by or approved by the Occupational Health Section and shall include the following information:

(A) The name, address, telephone number, date of birth, ~~social security number,~~ race, ethnicity, gender, and job title of the person;

(B) The name, address, telephone number, and type of business of the person's employer;

(C) The name of the disease, illness, or injury being reported; and

(D) The name, address, and telephone number of the physician, laboratory, or medical facility.

(2) Surveillance forms are available from the ~~SENSOR Program, Division of Public Health, 1915 Mail Service Center, Raleigh, North Carolina 27699-1915.~~ Occupational and Environmental Epidemiology Branch, Epidemiology Section, Division of Public Health, N.C. Department of Health and Human Services, 1912 Mail Service Center, Raleigh, NC 27699-1912. The form can also be downloaded from the following website: https:epi.publichealth.nc.gov/oee/pest/reporting.html.

(b) When a laboratory providing diagnostic service in North Carolina reports laboratory findings related to occupational disease or illness pursuant to G.S. 130A-458, the report shall include:

(1) the specimen collection date;

(2) the person's name, ~~age,~~ date of birth, gender, race, and ethnicity; ~~and social security number;~~

(3) the submitting physician/employer name, address, and telephone number; and

(4) the name, address, and telephone number of the laboratory.

History Note: *Authority G.S. 130A-455; 130A-456; 130A-458;*
Eff. January 4, 1994.