

PRELIMINARY SIGNIFICANT ANALYSIS

WAC 246-101-010

Definitions within the Notifiable Conditions Regulations

January 28, 2014

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Section 1: Introduction

Lead is toxic to most organ systems in the body. Children and pregnant women have the highest risk for health effects from lead exposure. In pregnant women lead exposure can cause miscarriage, reduced growth of the fetus, and premature birth. Lead is highly toxic to children's developing nervous systems. Low level exposures in children cause IQ loss, poor academic performance, and behavioral problems. At high exposure levels it can cause seizures, coma, and death.

The Washington State Department of Health (department) has been conducting surveillance for lead poisoning since 1993. At that time the Centers for Disease Control and Prevention (CDC) defined elevated blood lead levels in children as at or above the 'level of concern' of 10 µg/dL. This level of concern was the value used to create the definition of elevated blood lead for children in Washington State's notifiable conditions rule. In 2012 the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) recommended that the CDC change the 'level of concern' of 10 µg/dL to a 'reference value' of 5 µg/dL. The CDC endorsed the recommendations later that same year. The recommendation was based on research that demonstrated no safe level of lead for children. The reference value was set at the 97.5th percentile of blood lead levels from the National Health and Nutrition Examination Survey (NHANES) which is 5 µg/dL. The reference value will be revised and possibly updated every four years by the CDC so that it remains at the 97.5th percentile nationally. The next CDC review will be in 2016 when it is likely that a lower reference value will be set.

The ACCLPP recommends that parents of children with blood lead levels over 5 µg/dL receive:

- Education about lead poisoning, nutrition, exposure sources, and renovations to reduce lead in the home;
- Home visits by childhood lead poisoning prevention staff; and
- Assistance navigating landlord tenant issues regarding lead in pre-1978 structures.

The CDC's National Institute for Occupational Safety and Health (NIOSH) administers the Adult Blood Lead Epidemiology and Surveillance program (ABLES). The ABLES elevated level of 25 µg/dL or greater was used to create the definition of elevated blood lead level for adults in Washington State's notifiable conditions rule. In 2009 the Council for State and Territorial Epidemiologists published a position paper that recommended lowering the definition of elevated adult blood lead level to 10 µg/dL. The ABLES program endorsed that recommendation that same year.

Reducing lead exposure to children and adults aligns with national and state strategies:

- **Healthy People 2020:** EH-8: Reduce blood lead levels in children
- **Healthy People 2020:** EH-20.3: Reduce exposure to lead in the population
- **State Board of Health Strategic Goals:** #5 Promote healthy and safe environments
- **DOH Strategic Plan:** *Core Activities:* Protecting the public from unsafe environments
- **DOH Strategic Plan:** *Ten Essential Public Health Services:* Detecting and investigating health problems and health hazards in the community

Screening for elevated blood lead levels takes place at hospitals, clinics, head start programs, and occasionally at health fairs. Blood lead tests are done from either capillary or venous blood draws. Capillary draws are primarily done at the point of care and are generally for screening purposes only. Venous draws are analyzed at laboratories, are more accurate, and are used to confirm elevated capillary tests. All facilities that conduct these screenings are considered laboratories under chapter 246-101 WAC, Notifiable conditions, and must report elevated blood lead levels to the department within 2 business days and all other blood lead levels monthly. The revised rule would require laboratories that test for lead to report more results in a 2 day timeframe instead of monthly as more results would be considered elevated under the new definition. This will provide faster response times by case managers at the county level for children under the age of 15 with blood lead levels between 5.0 µg/dL and 9.9 µg/dL. For adults this rule revision will allow the Department of Labor and Industries to have more up to date information on elevated adult blood lead levels to inform workplace investigations.

Section 2: What is the scope of the rule?

For the purposes of this rule, adult means “persons aged fifteen years or older” and child means persons “less than fifteen years of age.” The proposed revision of the definition of “elevated blood lead level” is in response to guidance adopted by the CDC on adult and childhood blood lead poisoning. In 2009 the CDC revised their guidance on adult lead levels down from 25 µg/dL to 10 µg/dL. In 2012 the CDC revised their guidance on childhood lead levels down to a reference level of 5 µg/dL. The proposed rule revises the definition of “elevated blood lead level” to be consistent with these CDC standards. The proposed rule reflects current scientific knowledge about the danger of lead exposure even at low levels and reflects mounting evidence that there is no safe level of lead for children or adults.

Two housekeeping changes are also proposed. The first clarifies the definition of “laboratory” by including a cross-reference to the requirements of chapter 246-388 WAC, Medical test site rules. The second updates the definition of “health care facility” by replacing the term “boarding home” with “assisted living facility” to be consistent with SHB 2056, Chapter 10, Laws of 2012.

Section 3: What are the general goals and specific objectives of the proposed rule’s authorizing statute?

The general goal and specific objective of the authorizing statute is found in RCW 43.20.050(2)(f) which states in part that “In order to protect public health, the state board of health shall adopt rules for the prevention and control of infectious and noninfectious diseases...” Lead is an environmental contaminant that is proven to be hazardous to human health at very low levels. Increasing the number of lab results reported to the department within 2 business days as opposed to monthly, allowing faster intervention, supports the goal of the statute to protect Washington State residents from environmental exposures that cause noninfectious disease.

Changing the definition of “laboratory” to reference chapter 246-338 WAC, Medical test site rules, provides clarification on who must report elevated blood lead levels and when the report must be submitted to the Department of Health and supports the goal of the statute to protect Washington State residents.

Section 4: What is the justification for the proposed rule?

RCW 34.05.328(1)(b) requires the department to determine the rule is needed to achieve the general goals and specific objectives of the statute and analyze alternatives to rulemaking and the consequences of not adopting the rule.

The proposed rule will achieve the authorizing statute’s goals and objectives to protect public health by reducing the effects of exposure to environmental hazards. There is no alternative to rulemaking as the statute requires the State Board of Health (board) to adopt standards for protecting the public health in rule.

Section 5: What are the Probable Costs and Benefits of the Rule?

Children and adults with elevated blood lead levels will benefit from the rule change. Laboratories may incur costs associated with this rule. The costs and benefits for each group are considered separately:

Costs

Some laboratories currently use <5 µg/dL as their reporting level. These labs use equipment that is capable of detecting blood lead levels in the 1-2 µg/dL range. Although this detection level is within the range necessary to comply with the proposed rule, a laboratory may decide to update its testing procedures to achieve greater accuracy and more confidence in complying with the proposed rule. If a lab chose to do this, it would incur minimal staff time costs.

Under the current rule, labs must report blood lead results for children below 10 µg/dL monthly and above that level within 2 business days. For adults, they must report blood lead results below 25 monthly and above that level within 2 business days. Under the proposed rule, all laboratories will be required to submit blood lead results in the 5 to 9.9 µg/dL range for children, and the 10 to 24.9 µg/dL range for adults in 2 business days. For labs that report electronically, the cost will be negligible. For labs that submit by mail or fax, there may be marginal staff time costs to fax or mail the report on a shortened timeframe.

Benefits

The revised rule would require laboratories that test for lead to report more results in a 2 day timeframe instead of monthly as more results would be considered elevated under the new definition. The primary benefit of this proposed rule is in timeliness of interventions designed to reduce lead exposure. Case managers at the county level will have data earlier and will be able to conduct investigations to determine appropriate interventions,

potentially reducing the detrimental effects of lead poisoning for these children. The number of children potentially impacted by this rule revision varies by year. Data from the past decade indicate a range from 224 children in 2011 to 628 children in 2009.

A rigorous scientific justification for changing the definition of elevated blood lead level is presented in the ACCLPP's report "Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention¹." As more research has been conducted on the health effects of lead exposure the blood lead level of concern has steadily fallen from 60 µg/dL in 1960 down to 5 µg/dL in the 2012 revision. During that time, period average blood lead levels have dropped significantly leading researchers to study the health effects of blood lead at increasingly lower levels. From that research, Healy et. al. 2010 conclude "the preponderance of evidence supports an inverse association, with no clear threshold, between blood lead concentrations and children's scores on tests of psychometric intelligence."² Emerging research has found negative effects on children's intelligence at levels as low as 0.5 µg/dL and effects on neonatal intelligence when the mother's blood lead concentration rose from 0.28 to 1.18 µg/dL.³ The most rapid loss of IQ occurs at blood lead concentrations less than 10 µg/dL.

Economic benefits of lead poisoning prevention are typically calculated by using the present value of IQ points multiplied by an estimation of the number of IQ points lost to lead poisoning. The Washington State Chemical Action Plan for Lead prepared by the Dept. of Ecology estimates that lead exposures over 2 µg/dL costs the state between \$675 million and \$2.3 billion annually. The model assumed a net present value of \$9,076 for an IQ point for a 12 month old based on associations between IQ and lifetime earnings. There is insufficient scientific evidence to conclude that the type of interventions provided by Washington State counties improve outcomes in terms of IQ.

The benefits to adults would be better informed workplace investigations by Labor and Industries made possible by improved surveillance data maintained by the Department of Labor and Industries.

The proposed rule would allow the department to provide county lead contacts with the information necessary to begin their interventions more quickly and potentially reduce the effects of lead exposure on children. Adults with occupational exposure to lead will be better served because the Department of Labor and Industries will have access to more timely data to inform their investigations. Based on this analysis, the board has determined that the probable benefits of the proposed rule outweigh the probable costs.

¹ The Center for Disease Control and Prevention. "Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention." Advisory Committee on Childhood Lead Poisoning Prevention. January 4th, 2012

² Healey et. al. 2010. Toxicological Review and Recommended Toxicological Reference Values for Environmental Lead Exposure in Canada. Healthy Environment and Consumer Safety Branch, Health Canada, Ottawa

³ Ibid.

Section 6: What alternative versions of the rule were considered? Is the proposed rule the least burdensome approach?

Three alternative versions of the rule were considered including:

- Retaining the rule as currently written,
- Changing the definition of childhood elevated blood lead level and not changing the definition of adult elevated blood lead level, and
- Creating a more protective definition of childhood elevated blood lead level than the CDC recommends.

While retaining existing requirements is the least burdensome alternative, current scientific knowledge about the danger of lead exposure indicates the need to revise the rule to protect public health. And although there are measurable health effects below 5 µg/dL, there is no research that suggests an appropriate intervention strategy for children in the <5 µg/dL range. In addition, it is unlikely that any county in the state has the resources to respond to such a high volume of cases making this lower standard unusable and ineffective.

Based on this analysis, the board has determined that the minimal cost of achieving the greater level of protection provided by the proposed rule is the least burdensome approach.

Section 7: Does the rule require those to whom it applies to take an action that violates requirements of another federal or state law?

No. The proposed rule does not require those to whom it applies to take an action that violates requirements of federal or state law.

Section 8: Does the rule require more stringent performance requirements on private entities than on public entities unless the difference is required in federal or state law?

No. The proposed rule does not impose more stringent performance requirements on private entities than on public entities.

Section 9: Does the rule differ from any federal regulation or statute applicable to the same activity or subject matter? If so, is the difference justified by an explicit state statute or by substantial evidence that the difference is necessary?

No. The proposed rule does not differ from any applicable federal regulation or statute.

Section 10: Is the rule coordinated to the maximum extent possible with other federal, state, and local laws applicable to the same activity or subject matter?

Yes. The department coordinated with the Department of Labor and Industries, Department of Ecology, and U.S. Environmental Protection Agency in developing this proposed rule. Local health jurisdictions, Department of Commerce, Health Care Authority, Department of Fish and Wildlife, Department of Early Learning, Office of the Superintendent of Public Instruction, U.S. Department of Housing and Urban Development, and other interested parties were provided an opportunity to comment on the regulation during the informal comment period in November 2013.