

Health and Human Services Agency California Department of Public Health



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Gavin Newsom
Governor

NOTICE OF PROPOSED RULEMAKING Title 17, California Code of Regulations DPH-18-007 Childhood Lead Poisoning Prevention Program Lead Exposure Risk Factors Notice Published on May 23, 2025

Notice is hereby given that the California Department of Public Health (Department) is proposing the regulation described below. This notice of proposed rulemaking commences a rulemaking to make the regulations permanent after considering all comments, objections, and recommendations regarding the regulation.

PUBLIC PROCEEDINGS

Public Comment Period

The Department will hold a virtual public hearing on July 9, 2025 (See "Public Hearing" for further details).

Written comments will be accepted from May 23, 2025 until 5:00pm on July 9, 2025. Written comments must be submitted as follows:

- 1. By email to: Regulations@cdph.ca.gov;
- 2. By fax transmission to: (916) 440-5747;
- 3. By postal service or hand delivered to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All comments, including email or fax transmissions, should include the regulation package identifier "**DPH-18-007 Lead Exposure Risk Factors**" in the subject line to facilitate the timely identification and review of the comment.

For the Department to provide copies of any notices for proposed changes to the regulation text of which additional comments may be solicited, include your name and your mailing address or email address with your written comment.

Public Hearing

The hearing will be held via Microsoft Teams ®, on July 9, 2025, from 10:00am to 12:00pm, and may be accessed at the following link:

California Department of Public Health
Office of Legal Services • 1415 L Street, Suite 500, Sacramento, CA 95814
(916) 558-1710 • (916) 440-5747 FAX

<u>Department Website</u> (www.cdph.ca.gov)

Microsoft Teams

Meeting ID: 215 110 278 300

Passcode: S5sk3dR6

Dial in by phone: +1 916-306-8051,778021574# United States, Sacramento

Find a local number: < https://dialin.teams.microsoft.com/78c43e68-2867-4a4f-af8d-

e771e376b3ee?id=778021574>

Phone conference ID: 778 021 574#

During the hearing, any person may present oral statements or arguments relevant to the proposed action described in this notice. The Department requests but does not require persons who make oral comments during the hearing to also submit a written copy of their testimony as follows:

- 1. By email to: Regulations@cdph.ca.gov;
- 2. By fax transmission to: (916) 440-5747;
- 3. By postal service or hand delivered to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All comments, including email or fax transmissions, should include the regulation package identifier "**DPH-18-007 Lead Exposure Risk Factors**" in the subject line to facilitate the timely identification and review of the comment.

For the Department to provide copies of any notices for proposed changes to the regulation text of which additional comments may be solicited, include your name and your mailing address or email address with your written comment.

An agenda for the public hearing will be made available upon request. For individuals with disabilities, the Department shall provide, upon request, assistive services such as sign-language interpretation, real-time captioning, note takers, reading or writing assistance, and conversion of written public hearing materials into Braille, large print, and audiocassette or computer disk.

Note: The range of assistive services available may be limited if requests are received without adequate preparation time prior to the public hearing.

Authority and Reference

Authority for the proposed regulatory change is provided in sections 20, 100275, 105280, 105285, 105286, 105300, 105301, 124165, 131050, 131051, 131052, and 131200, Health and Safety Code.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Summary of the Proposed Regulations

The California Department of Public Health (Department) proposes to amend chapter 9 (sections 37000 to 37100) of division 1, title 17 of the California Code of Regulations (CCR). These regulations would expand the existing standard of care for screening children at risk of lead poisoning to include significant environmental risk factors, and would clarify health care providers' duties under this standard of care.

A definitions section is also proposed to be added to the existing regulations.

By expanding the existing standard of care for childhood lead screening, these regulations would implement requirements established by Assembly Bill 1316 (AB 1316), effective January 1, 2018, and Assembly Bill 2276 (AB 2276), effective January 1, 2021, which amended and broadened the provisions of the Childhood Lead Poisoning and Prevention Act of 1991 (CLPPA).

Additionally, the Department proposes amendments to the Childhood Lead Poisoning Prevention (CLPP) Program's lead screening regulations to incorporate updates from the most current federal guidelines from the Centers for Disease Control and Prevention (CDC).

Background and Summary of Existing Laws and Regulations

Pursuant to sections 100275, subdivision (a) and 131200 of the Health and Safety Code (HSC), the Department is authorized to adopt and enforce regulations as may be necessary for the execution of its duties. The Department also has broad regulatory authority to implement the CLPPA pursuant to HSC section 105300.

The CLPP Program is the state program created by CLPPA and administered by the Department, including services provided by a contracted local health jurisdiction (LHJ). A contracted LHJ may also be referred to as local CLPP Program (local CLPPP). Not all LHJs opt to contract with the Childhood Lead Poisoning Prevention Branch (CLPPB). For those jurisdictions, services are provided by the state CLPPB.

The CLPPA charges the Department with collecting and analyzing childhood lead poisoning information, developing protocols to screen for childhood lead poisoning, identifying lead-poisoned children, ensuring appropriate case management, and reducing childhood exposure to lead. Additionally, the CLPPA directs the Department to establish standard of care regulations "at least as stringent" as CDC guidelines, requiring children to be evaluated for the risk of lead poisoning, among other requirements. (HSC, § 105285, subd. (b)(1).)

The Legislature gave the Department discretion to determine the minimum blood lead level (BLL) constituting a health risk, as well as the discretion to base this level upon either the CDC guidelines or a determination by the Department. (HSC, §§ 105280, subd. (b), 105300.) In October 2021, the CDC updated the blood lead reference value (BLRV) of a BLL considered elevated in children from 5 micrograms of lead per deciliter of blood (mcg/dL) to 3.5 mcg/dL. This is much less than the 10 mcg/dL specified in the Department's existing regulations.

To establish standard of care regulations "at least as stringent" as the most recent CDC guidelines, the Department's proposed regulations would amend the minimum BLL considered elevated in children from 10 mcg/dL to 3.5 mcg/dL.

The Department's existing regulations focus on identifying children who are at the greatest risk for lead poisoning, specifically children under 72 months of age who either 1) receive services through a publicly funded health program for low-income children, or 2) who have been exposed to buildings built before 1978 that have deteriorated paint or that have recently been renovated.

Health care providers are currently required to perform an evaluation of these two risk factors to determine if screening for lead exposure is necessary. However, AB 1316 requires the Department to revise its standard of care regulations to "consider the most significant environmental risk factors," including:

- 1) A child's time spent in a home, school, or building built before 1978;
- 2) A child's proximity to a former lead or steel smelter or an industrial facility that historically emitted or currently emits lead;
- 3) A child's proximity to a freeway or heavily traveled roadway; and
- 4) Other potential risk factors for lead exposure and known sources of lead contamination.

In 2020, AB 2276 was introduced in the state legislature, requiring the Department to consider six additional "significant environmental risk factors" as part of its standard of care regulations:

- 1) A child's residency in or visit to a foreign country;
- A child's residency in a high-risk ZIP Code;
- 3) A child whose sibling or playmate has lead poisoning;
- 4) The likelihood of a child placing nonfood items in their mouth;
- 5) A child's proximity to current or former lead-producing facilities; and
- 6) The likelihood of a child using food, medicine, or dishes from other countries.

Under the proposed regulations, children would continue to be screened for lead poisoning if they are enrolled in a publicly funded program for low-income children. If they do not receive such assistance, they would then be screened if they reside in a high-risk ZIP Code. This ZIP Code inquiry combines many statutorily required risk factors into one query for the ease of the health care provider.

If a child is not already screened for lead poisoning due to receiving services from a publicly funded program for low-income children, or living in a high-risk ZIP Code, these regulations would require that health care providers evaluate the child for additional risk factors to determine if screening for lead exposure is necessary.

To determine these additional risk factors, the Department considered the remaining significant risk factors of AB 1316 and AB 2276 not previously addressed by the proposed regulations, and identified seven potential risk factors for inclusion in a child's lead-risk evaluation:

- 1) Living or spending time in a home, school, or building built before 1978;¹
- 2) Living with a household member who works in a job that may involve exposure to lead, or who participates in an activity that may involve exposure to lead, including soldering, hunting, fishing, shooting, painting, or ceramics;²
- 3) Pica behavior;³
- 4) Living or extended travel outside of the United States;⁴
- 5) Having a sibling, playmate, or other close contact who has a BLL ≥ 3.5 mcg/dL;⁵
- 6) Exposure to dishware or pottery that is worn or chipped, was made before 1970, or was made outside of the United States;⁶ and
- 7) Ingestion of or exposure to traditional remedies or medicines; traditional religious powders, chalks, cosmetics, liquids, or creams; or foods made outside of the United States.⁷

Policy Statement Overview

Problem Statement:

Although instances of lead poisoning in California have significantly decreased since enactment of the CLPPA, the state's children continue to suffer from elevated blood lead levels (BLLs) and lead poisoning. AB 1316 and AB 2276 require the Department to include additional environmental risk factors in the standard of care for health care providers who treat children at risk of lead poisoning. By increasing screening, additional children with lead exposure may be identified and receive interventions. Unknown sources of lead exposure may also be identified and eliminated, mitigating the risk of lead poisoning for many more children in California.

Objectives:

¹ (HSC, § 105285, subd. (b)(2)(A).)

² (HSC, § 105285, subd. (b)(2)(D); see <u>Cal. State Auditor, Childhood Lead Levels</u> – <u>Millions of Children in Medi-Cal Have Not Received Required Testing for Lead Poisoning (2020) p. 38 "risk factors commonly considered in other states."</u>)

<information.auditor.ca.gov/reports/2019-105/index.html> (Accessed October 16, 2024).

³ (HSC, § 105285, subd. (b)(2)(H).)

⁴ (HSC, § 105285, subd. (b)(2)(E).)

⁵ (HSC, § 105285, subd. (b)(2)(G).)

⁶ (HSC, § 105285, subd. (b)(2)(D) & (J).)

⁷ (HSC, § 105285, subd. (b)(2)(J).)

The broad objectives of this proposed regulatory action are:

- Alignment of the Department's current regulations with legislatively enacted changes to the CLPPA.
- Expansion of the CLPP Program's standard of care to include the most significant environmental risk factors.
- Alignment of the BLL standards for follow-up care consistent with federal CDC guidelines.

Benefits:

The expected benefits of this proposed regulatory action are:

- The prevention of ongoing harm to California's children and Californians of all ages from exposure to lead and its associated life-long adverse health effects.
- The reduction of economic costs associated with lead exposure, which would yield an estimated \$45 to \$90 million in economic benefit statewide over the lifetime of each annual cohort of children receiving intervention under this regulatory action.
- An increase in the number of at-risk children screened for lead poisoning.
- An increase in the number of children receiving treatment and follow-up care to reduce lead exposure and elevated BLLs.
- Increased abatement of environmental lead hazards.
- The expansion of business opportunities for medical/clinical laboratories.

<u>Evaluation as to Whether the Proposed Regulations are Inconsistent or Incompatible with Existing State and Federal Regulations</u>

The Department has determined that the proposed regulations are compatible and consistent with existing state and federal laws.

In developing the regulations, the Department reviewed the most recent CDC guidelines. To assist states with their lead programs, the CDC publishes guidelines related to the assessment, monitoring, and treatment of lead poisoning in children. While the CDC guidelines do not have the force of law, they represent the most current national standards. Under the CLPPA, the Department's standard of care regulations are required to be "at least as stringent" as the most recent CDC guidelines. (HSC, § 105285, subd. (b)(1).) Thus, the Department's proposed regulations incorporate updated CDC guidance and revise its standard of care regulations in compliance with this mandate.

Substantial Difference from Federal Regulation or Statute

The Department has determined these regulations are not substantially different from either a federal regulation or statute.

Local Mandate Determination

The Department has determined this regulatory action would not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by part 7 (commencing with Section 17500) of division 4 of the Government Code.

Fiscal Impact Estimate:

A. Cost or savings to any local agency or school district:

Local activities are funded by the Department. The Department uses a three-year contract cycle, and funding allocations are re-calculated prior to each cycle. Funding provided to contracted LHJs (or local CLPPPs) cover the cost of all mandated activities, including nurse case management activities tied to the subset of children identified with childhood lead poisoning. The Department uses an allocation formula incorporating data from each local CLPPP. Cost estimates of state funds in support of local government activities are discussed below.

B. Cost or savings to any state agency: Following the expansion of risk factors associated with these regulations, the Department may need up to 25 additional staff to provide services to the estimated 231,844 children now in-scope for screening/testing. This represents 1.91 times as many children who will be subject to testing, and it is expected that 1.46 times as many cases will be identified as a result. Specifically, the Department would need additional staff to:

- Carry out data management, tracking, analysis, and follow-up for reported blood lead level tests.
- Increase capacity for, and provide: follow-up, case management, public health nursing visit, and environmental investigation services to children meeting full case definition; and outreach, education, and BLL monitoring for children meeting basic case definition.
- Educate health care providers and LHJs about new regulatory guidelines and changed testing requirements.
- Create and/or modify screening questionnaires and outreach materials.
- Conduct laboratory testing of environmental samples for lead exposure source determination.

The Department estimates that the fiscal year 2024-25 state costs associated with the expansion of risk factors will be \$4,416,762. This includes personnel-related expenses and one-time costs of \$259,945 for equipment purchases. For fiscal year 2025-26, costs are expected to be \$4,247,204. For fiscal year 2026-27, costs are expected to be \$4,336,628. There are no one-time equipment purchases associated with fiscal years 2025-26 or 2026-27. Looking at the three-year average, and excluding one-time equipment purchases, the Department projects that the expansion of risk factors will cost the State approximately \$4,246,883 per year.

Impact on the Department includes covering expenses of contracted LHJs. Following the expansion of risk factors associated with these regulations, the Department estimates that the fiscal year 2024-25 LHJ incremental change in costs CLPPB will reimburse will be \$11,410,106. For fiscal year 2025-26, incremental costs of \$11,609,607 are expected. For fiscal year 2026-27, incremental costs of \$11,924,185 are expected. Looking at the three-year average, the Department projects that the expansion of risk factors will cost LHJs approximately \$11,647,966 per year. These

estimates assume that 100% of all children are screened. Additional context is provided below.

The Department contracts out mandated activities to LHJs. Local CLPP Programs (local CLPPPs) may need additional staff to provide services to the larger population that is proposed due to the expanded risk factors associated with new regulations. This expanded population is expected to be 1.46 times larger due to these new risk factors. The larger in-scope population will mean more screenings and more cases. Specifically, local CLPPPs would need additional staff to: increase capacity for, and provide; follow-up, case management, public health nursing visit, and environmental investigations to children meeting full case definition; outreach, education, and BLL monitoring for children meeting basic case definition; education to health care providers about new regulatory guidelines and testing requirements; and distribution of screening questionnaires and outreach materials. In counties without contracts, the state Childhood Lead Poisoning Prevention Branch (CLPPB) provides direct services.

Additional use of state-provided XRF instruments for local environmental investigations will be needed. Finally, subcontracting for laboratory analysis and testing of environmental samples, XRF maintenance, and source replacement of XRF instruments will be increased at the local level.

- C. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: None.
- **D.** Cost or savings in federal funding to the state: The Department estimates federal costs in support of the regulations expansion to be commensurate with funding provided to the Department and LHJs. The federal government provides support to California state and local governments for childhood lead poisoning prevention services via federal financial participation under Title XIX of the US Social Security Act. Implementation under the Social Security Act is facilitated through California's Medicaid program. Federal funding under Title XIX is anticipated to increase. Any federal funding to the state is contingent upon federal approval.

Evidence Supporting No Significant Adverse Economic Impact on Business

The Department has made an initial determination that the proposed regulatory action would have no significant adverse economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states. There will be an increase in screening costs for the health insurance industry. The health care providers' offices that are considered small businesses and laboratories will be reimbursed for additional blood lead testing. There will likely be an expansion of business for these offices and laboratories.

Cost Impacts on Representative Person or Business

The Department estimates that there would be a cost impact upon the Medical/Clinical Laboratories, Health Insurance Agencies, Environmental Consulting/Remediation Industry, and owners of housing units under this regulatory action.

Economic Impact Assessment

The Department has made an initial determination that these regulations would not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. There may be a moderate increase in screening costs for the health insurance industry. The Department has determined that the regulations may affect the following:

- 1. The creation or elimination of jobs within the State of California. Health care providers already assess children for risk of lead exposure and order blood lead testing; laboratories already draw, analyze and report results for blood lead samples; and abatement services are already being performed, in accordance with current statutory and regulatory requirements. The proposed regulations do not significantly add or remove new types of responsibilities for California physicians or medical/clinical laboratories. However, they will increase the number of children tested, with an associated increase in necessary lead hazard abatements. The increase in testing could potentially result in the need for additional staff hours for physicians and is expected to increase private sector employment needs for phlebotomists and laboratory technicians.
- 2. The creation of new businesses or elimination of existing businesses within the State of California. The proposed regulations primarily impact the health care industry (health insurance, health care providers, and laboratories). Some health care providers' practices may be classified as small businesses; however, there are no proposed regulations that would necessitate the creation or elimination of these private entities.
- 3. The expansion of businesses currently doing business within the State of California. There will be anticipated increased costs as a result of expanded blood lead testing. Expanded blood lead testing will increase demand for services of medical/clinical laboratories, with costs for expanded testing as the responsibility of California health insurance agencies as a mandated covered benefit. However, there are no proposed regulations that would require the use of new types of services.
- **4.** The benefits of the regulation to the health and welfare of Californians, worker safety, and the state's environment. This proposal will result in better identification of children who have been exposed to lead, allowing for early intervention and follow-up.

Housing Costs

The Department has determined that the regulations will not have an impact on housing costs.

Small Business

The laboratories and health care providers' offices that are considered to be small businesses will be reimbursed for additional blood lead testing. There will likely be an expansion of business for these offices and laboratories. The environmental consulting/remediation companies that are small businesses would potentially have

increased business opportunities associated with an anticipated increase in necessary lead hazard abatements

Consideration of Alternatives

The Department must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Department invites interested persons to submit alternatives with respect to the proposed regulation during the comment period. Alternatives that the Department itself considered are discussed in the Initial Statement of Reasons.

AVAILABILITY STATEMENTS

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, will be the custodian of public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

Contact Persons

Inquiries concerning the proposed regulation, including requests for copies of the public notice, the regulation text, and the initial statement of reasons, or alternate formats for mailing these documents, can be made by contacting:

David Martin Office of Regulations 1415 L Street, Suite 500, Sacramento, CA 95814 **Phone:** (916) 440-7673

Email: david.martin@cdph.ca.gov or Regulations@cdph.ca.gov, or use the California

Relay Service by dialing 711.

Backup contact: Hannah Strom-Martin

Office of Regulations 1415 L Street, Suite 500, Sacramento, CA 95814

Phone: (279) 217-0764

Email:hannah.strom-martin@cdph.ca.gov

Upon specific request, these documents will be made available in Braille, large print, audio format, or computer disk.

The full text of any regulation which is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

Final Statement of Reasons:

A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

INTERNET ACCESS

Materials regarding the action described in this notice (including this public notice, the text of the proposed regulations, and the initial statement of reasons) that are available via the Internet may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: Decisions Pending & Opportunities for Public Participation, Proposed Regulations.