# INITIAL STATEMENT OF REASONS

## 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).

## 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 screen 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:***

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.

**Evaluation as to Whether the Proposed Regulations are Inconsistent or Incompatible with Existing State and Federal Regulations**
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.

**Background**
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 a local CLPP Program (local CLPPP). Not all LHJs have a contracted 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).)

Lead poisoning is "present when the concentration of lead in whole venous, arterial, or cord blood reaches or exceeds levels constituting a health risk, as specified in the most recent… [CDC] guidelines for lead poisoning as determined by the [D]epartment, or when the concentration of lead in whole venous, arterial, or cord blood reaches or exceeds levels constituting a health risk as determined by the [D]epartment pursuant to Section 105300." (HSC, § 105280, subd. (b).) The Legislature gave the Department discretion to determine the minimum 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 BLL considered elevated in children from 5 micrograms of lead per deciliter of blood (mcg/dL) to 3.5 mcg/dL.[1] 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 proposes to amend the minimum BLL considered elevated in children from 10 mcg/dL to 3.5 mcg/dL. This more stringent 3.5 mcg/dL threshold ensures that childhood lead poisoning cases are identified earlier and that steps are taken to prevent further poisoning of lead-burdened children. This is an important step forward for achieving reduced rates of elevated BLLs across the state. Department recommendations and management guidelines for health care providers are already consistent with the 3.5 mcg/dL threshold; current contractual scope of work between the local health jurisdictions and the Department uses the 3.5 mcg/dl threshold in terms of case definitions.

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. These evaluations are required at the child's periodic health assessment at 12 months old, 24 months old, or up to 72 months old, if the evaluation was not performed prior to 72 months. All children

[1] Centers for Disease Control (CDC), CDC Updates Blood Lead Reference Value <archive.cdc.gov/#/details?q=updates-blood-lead-reference&start=0&rows=10&url=https://www.cdc.gov/media/releases/2021/p1028-blood-lead.html> (Accessed April 2, 2024).

identified as at-risk by these evaluations are then screened for lead poisoning and provided with treatment and follow-up care as appropriate. Failure of health care providers to comply with this standard of care can result in disciplinary action by the appropriate licensing agency.

The authors of AB 1316 did not consider the existing regulations to be sufficient as "many children not on government assistance programs and not living in old houses may actually be exposed to lead and not getting an appropriate evaluation for lead risk and screened as-needed."[2] "To address this gap in lead exposure evaluations,"[3] 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;
2) 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.

***Standard of Care Overview:***

The Department's proposed regulations would expand the Department's current standard of care regulations as mandated under AB 1316 and AB 2276. The table below provides an overview of the significant environmental risk factors the Department must consider (Column 1), and how the Department intends to implement them in its regulations (Column 2). The Department determined these risk factors after careful consideration of the mandates of AB 1316 and AB 2276, the CDC guidelines, analysis of California data, current scientific studies, and the regulatory schemes of other states.

[2] (Sen. Rules Com. Off. Of Sen. Floor Analyses, 3d reading analysis of Assem. Bill No. 1316 (2017-2018 Reg. Sess.) Sept. 4, 2017, p. 4.) <leginfo.legislature.ca.gov/faces/billAnalysisClient.xhtml?bill_id=201720180AB1316#> (Accessed October 16, 2024).

[3] *Ibid.*

**Table 1: HSC Section 105285's Statutory Risk Factors in the Proposed Regulations**

| Source Legislation | Statutory Mandates<br>*When determining the risk factors, the [D]epartment shall consider the most significant environmental risk factors, including, but not limited to, the following:* | Correlating Proposed Regulation Text |
|---|---|---|
| AB 1316 | *(A) A child's time spent in a home, school, or building built before 1978.* | Proposed section 37100, subdivision (a)(3): High-risk ZIP Codes[4] and included in the list of risk factors in proposed section 37100, subdivision (a)(4). |
| AB 1316 | *(B) A child's proximity to a former lead or steel smelter or an industrial facility that historically emitted or currently emits lead.* | Proposed section 37100, subdivision (a)(3): High-risk ZIP Codes. |
| AB 1316 | *C) A child's proximity to a freeway or heavily traveled roadway.* | Proposed section 37100, subdivision (a)(3): High-risk ZIP Codes. |
| AB 1316 | *(D) Other potential risk factors for lead exposure, and known sources of lead contamination.* | Proposed section 37100, subdivision (a)(3): High-risk ZIP Codes and included in the list of risk factors in proposed section 37100, subdivision (a)(4). |
| AB 2276 | *(E) A child's residency in or visit to a foreign country.* | Included in the list of risk factors in proposed section 37100, subdivision (a)(4). |
| AB 2276 | *(F) A child's residency in a high-risk ZIP Code.* | Proposed section 37100, subdivision (a)(3): High-risk ZIP Codes. |
| AB 2276 | *(G) A child who has a sibling or playmate with lead poisoning.* | Included in the list of risk factors in proposed section 37100, subdivision (a)(4). |
| AB 2276 | *(H) The likelihood of a child placing nonfood items in the mouth.* | Included in the list of risk factors in proposed section 37100, subdivision (a)(4). |
| AB 2276 | *(I) A child's proximity to current or former lead-producing facilities.* | Proposed section 37100, subdivision (a)(3): High-risk ZIP Codes. |
| AB 2276 | *(J) The likelihood of a child using food, medicine, or dishes from other countries.* | Included in the list of risk factors in proposed section 37100, subdivision (a)(4). |

[4] As part of its high-risk ZIP Code analysis, the Department mapped areas where at least 25% of the housing stock was built before 1978, because of the longstanding recognition of the risk of lead hazards in all homes built before 1978. See also Determination of High-risk ZIP Codes, below.

***Expansion of Risk Factors:***
Currently, a child is screened for lead poisoning if they are enrolled in a publicly funded program for low-income children (such as Medi-Cal),[5] or if they live or spend time in a building constructed before 1978 that has deteriorated paint or that has recently been renovated.

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 this public assistance, they would then be screened if they reside in a high-risk ZIP Code. As demonstrated in Table 1, the ZIP Code inquiry combines many statutorily required risk factors into one query for the ease of the health care provider. Since the vast majority of California's ZIP Codes are high-risk, this means that the evaluation would be completed for 99 percent of participants after determination of only two factors.[6] These regulations are intended to provide a three-step (or less) roadmap for health care providers to meet their obligations under HSC section 105285 while not being overly burdensome.

Under the Department's proposed regulations, the small number of children not ruled out based on the first two risk factors would then be evaluated regarding their exposure to any of the risk factors proposed by the Department in section 37100, subdivision (a)(4). An affirmative or uncertain response to any one factor would require the health care provider to screen the child for lead poisoning. It is therefore unlikely that a provider would need to ask about every proposed risk factor. This three-step evaluation is meant to reduce the potential burden on health care providers per input received during stakeholder engagement.

**Determination of High-Risk ZIP Codes:**
AB 2276 requires the Department to consider a "child's residency in a high-risk ZIP Code" as a significant risk factor. Pursuant to HSC section 124125, subdivision (c)(1)(B), the Department already identifies and posts annually on its Publications for Providers website (www.cdph.ca.gov/Programs/CCDPHP/DEODC/CLPPB/Pages/Publications-for-Providers.aspx) a list of high-risk geographic areas. The Department supplies this information in terms of both census tracts and ZIP Codes. The Department provides this data in terms of census tracts in compliance with the census tract language found in HSC section 124125, subdivision (c)(1)(B). The Department also provides the same information in terms of ZIP Codes due to stakeholder feedback that more people are

[5] Screening for lead poisoning in children enrolled in Medi-Cal is a long-standing federal requirement, and usually eliminates the need for further questions for approximately 50 percent of participating children.
[6] Please see the list of ZIP Codes the Department identifies and posts annually on its Publications for Providers website (www.cdph.ca.gov/Programs/CCDPHP/DEODC/CLPPB/Pages/Publications-for-Providers.aspx).

aware of which ZIP Code they live in than they are of the census tract in which they live. This high-risk ZIP Code data can now be used for compliance with AB 2276's requirement to consider a child's residency in a high-risk ZIP Code. Moreover, the Department's list of high-risk ZIP Codes gives health care providers a quick and easy way to evaluate whether a child lives in a High-Risk ZIP Code and needs to be screened.

The Department defines a high-risk ZIP Code as any ZIP Code in California that meets the criteria of at least one geospatial risk factor that puts the population at a higher risk for lead poisoning (for example: ZIP Codes where a disproportionate number of children have previously been identified as having elevated BLLs). To determine what constitutes a high-risk ZIP Code, the Department undertook comprehensive data gathering, including analysis of California data, consultation with medical experts, environmental experts, subject matter experts, stakeholders, and a review of the most current literature and analysis on the topic.

As part of its analysis, the Department also considered the following risk factors from AB 1316: 1) "proximity to a former lead or steel smelter or an industrial facility that historically emitted or currently emits lead"; 2) "proximity to a freeway or heavily traveled roadway"; and 3) "[o]ther potential risk factors for lead exposure, and known sources of lead contamination." Similarly, per AB 2276, the Department considered "proximity to current or former lead-producing facilities."[7]

As a result of its research and as described in further detail below, the Department determined that ZIP Codes where ≥ 2.5 percent of children tested had BLLs ≥ 3.5 mcg/dL were high-risk. The Department also identified seven specific manmade environments which were high-risk:

1) Areas where 25 percent or more of the residential buildings were built before 1978;
2) Locations within 1.7 miles of a former lead or steel smelter or a facility that historically emitted or currently emits lead;
3) Locations within 1,000 feet of a state highway;
4) Locations within 1 km[8] of an airport where leaded aviation fuel is used;
5) Locations within 1 km of a railroad;
6) Locations within 1,000 feet of a speedway; and
7) Areas serviced by a community water system with at least one known lead service line or lead fitting.

[7] (HSC, § 105285, subds. (b)(2)(B)-(D) amended by Stats. 2017, ch. 507 § 3 and (l) amended by Stats. 2020, ch. 216 § 1. (See also Table 1.)

[8] The CLPP Program based its analysis upon multiple resources. Some reports expressed measurement units in Metric while some used U.S. Customary. To remain consistent with the cited resources, this ISOR uses the measurement system from the source to which it is citing.

The presence of any one of these factors in a ZIP Code causes the ZIP Code to be considered high-risk. Please see below for a full discussion and justification of these geospatial risk factors.

- *ZIP Codes where ≥ 2.5 percent of children tested had BLLs ≥ 3.5 mcg/dL*. In making this determination, the Department looked to the American Academy of Pediatrics' (AAP) recommendations, CDC guidance, and HSC mandates. The AAP is the largest professional organization of pediatricians in the United States. In mapping these areas, the Department first looked to the AAP's recommendation of screening children in communities where ≥ 5 percent of children have BLLs of ≥ 5 mcg/dL.[9]

  Instead of ≥ 5 percent and ≥ 5 mcg/dL, the Department will use ≥ 2.5 percent and ≥ 3.5 mcg/dL, to ensure the Department's standard of care regulations will be "at least as stringent" as the CDC guidelines. (HSC, § 105285, subd. (b)(1).) The CDC bases its reference value of ≥ 3.5 mcg/dL for childhood lead poisoning on the 97.5$^{th}$ percentile of the blood lead distribution in U.S. children less than six years of age. Thus, communities where ≥ 2.5 percent of children have BLLs above the reference value have a higher prevalence of childhood lead poisoning than the nation as a whole.[10]

  This determination is also consistent with the Department's obligation under HSC section 124125, subdivision (c)(1)(B), to report the areas where "children test higher than the national average for blood lead in exceedance of the [CDC's] reference level." The Department reports this data for the most recent calendar year available. Thus, by following the AAP's mapping approach with parameters consistent with CDC guidance and the Department's own statutory reporting requirements, the Department determined the ZIP Codes where ≥ 2.5 percent of children tested in the most recent calendar year for which data is available had BLLs ≥ 3.5 mcg/dL to be high-risk.

- *Areas where 25 percent or more of the residential buildings were built before 1978.* The AAP recommends blood lead testing for children ages 12 to 24 months living in communities where at least 25% of the housing stock was built before 1960.[11] In mapping these areas the Department used 1978 instead of

[9] American Academy of Pediatrics (AAP) Council on Environmental Health, Prevention of Childhood Lead Toxicity, Pediatrics, vol. 138 (2016), p.12.
[10] See also: Ruckart, et al., Update of the Blood Lead Reference Value-United States, Morbidity and Mortality Weekly Report (MMWR), vol. 70 (2021).
[11] AAP Council on Environmental Health, Prevention of Childhood Lead Toxicity, Pediatrics, vol. 138 (2016), p 12.

1960 to acknowledge the generally recognized risk of lead hazards in all homes built before 1978.[12] (See also HSC, § 105285, subd. (b)(2)(A).)

- *Locations within 1.7 miles of a former lead or steel smelter or a facility that historically emitted or currently emits lead.* Lead and steel smelters directly emit lead into the air. A variety of other facilities emit lead as a byproduct of their operations, including military bases, mines, recycling plants, and manufacturers of batteries, steel, glass, pipes, and fittings. Emitted lead can then be deposited into the soil.

  The Department was able to map facilities that have emitted lead from 1988 to the present by using the United States Environmental Protection Agency (US EPA)'s Toxic Release Inventory.[13] (Although estimating soil contamination boundaries is very difficult due to the variations of each facility (size, emissions, topography, wind direction, presence of and number of stacks, etc.)), the Department was able to use the analysis and related literature regarding two major emitters with large cleanup efforts to determine that a 1.7-mile limit would be appropriate. Specifically, the California Department of Toxic Substances Control determined a potential for soil lead contamination up to 1.6 miles away from the Ecobat (formerly Quemetco) battery recycling plant.[14] Similarly, the Department found that living up to 1.7 miles away from the former Exide Technologies battery recycling plant was associated with increased odds of a BLL ≥ 4.5 mcg/dL.[15] Reviewing these studies and related literature and considering that the CDC's relevant BLL is even lower than 4.5 mcg/dL (≥ 3.5 mcg/dL), the Department determined that a distance of 1.7 miles would be the appropriate boundary.

  For facilities that closed before 1988, the Department had to perform manual research. Many facilities that closed before 1988 either did not have a usable street number and name-specific address, or they had one that no longer

[12] Data accessed via Digital Map Products/LightBox, SmartParcels, on October 12, 2022. <www.lightboxre.com/product/smartparcels/> (Accessed October 15, 2024).
[13] United States Environmental Protection Agency (US EPA). TRI Customized Search <www.epa.gov/enviro/tri-customized-search> (Accessed July 27, 2023).
[14] Zielinski, Department of Toxic Substances Control (DTSC) Hotspots Analysis and Reporting Program (HARP) Air Dispersion Model 2. 0 for the Quemetco Facility at 720 S. 7th Avenue, City of Industry, California (California Department of Toxic Substance Control ed. , 2018, page 35-43). <www.envirostor.dtsc.ca.gov/getfile?filename=/public%2Fdeliverable_documents%2F8338642954%2FQuemetco%20Inc_DTSC%20Review%20of%20and%20Determinations%20Regarding%20RCRA%20Facility%20Investigation%20Report_121718.pdf> (Accessed on October 15, 2024).
[15] DTSC, Removal Action Plan (Cleanup Plan): Offsite Properties within the Exide Preliminary Investigation Area. (2017), p. ES 3. <ceqanet.opr.ca.gov/2016061032/2> (Accessed on October 15, 2024).

existed. For this reason, the distance of 1.7 miles around the site could not be used to identify locations at risk, so the entire city of these facilities was used.

- *Locations within 1,000 feet of a state highway.* Although automotive leaded gasoline was banned in the 1990s, contamination from historical emissions can still be found in the soil surrounding freeways and heavily trafficked roadways. When children play in this contaminated soil, they may ingest it directly, or dirt from their hands can taint their food. In its consideration of "proximity to a freeway or heavily traveled roadway," ideally, the Department would employ a dataset of historic traffic volume on all roadways in California at the time leaded gas was in use, but the Department was unable to find or compile such a dataset. Thus, the Department mapped these areas using the best analogous data source currently available – the California State Highway Network data from the Transportation System Network database maintained by the California Department of Transportation (accessed December 31, 2017).[16]

  The 1,000-foot buffer is based on a California Air Resources Board Technical Advisory stating that emissions from freeways can be detected up to a distance of 1,000 feet.[17] Additionally, the Department conducted its own analysis showing increased risk of lead poisoning within 1 kilometer (roughly 3,200 feet) of a state highway. In its analysis, the Department was unable to separate the effect of the highways from other factors that are associated with lead poisoning. Consequently, the Department determined that, based on the current data, it would be more appropriate to use the 1000-foot limit here.

- *Locations within 1 km of an airport where leaded aviation fuel is used.* In contrast to gasoline for automobiles, leaded aviation fuel (avgas) is still used for small-craft airplanes. In 2023, the US EPA issued "its final determination that emissions of lead from aircraft that operate on leaded fuel cause or contribute to air pollution which may reasonably be anticipated to endanger public health and

[16] California Department of Transportation (CalTrans), State Highway Network (SHN) and Postmile System (2018) <postmile.dot.ca.gov/PMQT/PostmileQueryTool.html?> (Accessed October 15, 2024).
[17] California Environmental Protection Agency (CA EPA), Technical Advisory: Strategies to Reduce Air Pollution Exposure Near High-Volume Roadways (Research Division of the Air Resources Board ed. (2017), p. 19. <ww2.arb.ca.gov/resources/fact-sheets/strategies-reduce-air-pollution-exposure-near-high-volume-roadways> (Accessed October 15, 2024).

welfare under the Clean Air Act."[18] [19] Using the Federal Aviation Administration's Airport Data and Information Portal, the Department mapped California airports where avgas has been used.[20] [21] [22] The Department elected to use 1 km as the boundary because children within 1 km of these airports have been found to be at the greatest risk.[23] [24] [25]

- *Locations within 1 km of a railroad.* Coal transported via freight train is often uncovered, allowing coal dust containing lead to travel into the areas surrounding the tracks. Such dust contains many heavy metals, including arsenic, mercury, and lead.[26] [27] To map these areas, the Department used freight route data (excluding passenger-only tracks) from the California Department of Transportation's California Rail Network and used a 1 km boundary because

[18] US EPA. Petitions and EPA Response Memorandums related to Lead Emissions from Aircraft that Operate on Leaded Fuel. (updated October 20, 2023). <www.epa.gov/regulations-emissions-vehicles-and-engines/regulations-lead-emissions-aircraft> (Accessed October 15, 2024).
[19] US EPA, EPA Determines that Lead Emissions from Aircraft Engines Cause or Contribute to Air Pollution (October 18, 2023). <www.epa.gov/newsreleases/epa-determines-lead-emissions-aircraft-engines-cause-or-contribute-air-pollution> (Accessed October 15, 2024).
[20] Federal Aviation Administration (FAA), Airport Data and Information Portal Advanced Facility Search. <adip.faa.gov/agis/public/#/public> (Accessed March 24, 2021).
[21] *Id.* (Accessed July 13, 2023).
[22] CalTrans. Airport Runways website. <gis-calema.opendata.arcgis.com /datasets/52ba234076a84ceb8aebacade070d8fe/explore> (Accessed February 16, 2022).
[23] Miranda, et al., A geospatial analysis of the effects of aviation gasoline on childhood blood lead levels, Environmental Health Perspective vol. 119 (2011), p. 1513.
[24] Zahran et al., Leaded aviation gasoline exposure risk and child blood lead levels, PNAS Nexus, vol. 2 (2023).
[25] Zahran et al., The effect of leaded aviation gasoline on blood lead in children, Journal of the Association of Environmental and Resource Economists, vol. 4 (2017).
[26] Wilkomirski, et al., Railway transportation as a serious source of organic and inorganic pollution, Water, Air, & Soil Pollution vol. 218 (June 2011), p. 33.
[27] Jian-Hua, et al., Heavy Metal Pollution in Soils on Railroad Side of Zhengzhou-Putian Section of Longxi-Haizhou Railroad, China, Pedosphere vol. 19 (2009), p. 121.

lead-contaminated dust has been found up to 1 km away from railroad tracks.[28] [29] [30] [31]

- *Locations within 1,000 feet of a speedway.* The EPA noted in its 2006 report on sources of lead that populations living in the vicinity of racetracks were at an increased risk of lead exposure.[32] Indeed, while leaded fuel for on-road vehicles was banned in the 1990s, leaded gas was allowed in race car fuel into the 2000s.[33] Using the assumption that on-road vehicles on highways and race cars on speedways emit lead particles in a similar manner, the Department mapped these areas using the same 1,000-foot boundary for state highways discussed above.

- *Areas serviced by a community water system with at least one known lead user service line or lead fitting.* Water service lines that contain lead or have lead fittings pose a risk of drinking water contamination. Using data from the California State Water Resources Control Board, the Department mapped where children living in affected water districts could be at increased risk for lead poisoning.[34] [35] [36]

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[28] Li and Liao, Spatial Characteristics of Heavy Metals in Street Dust of Coal Railway Transportation Hubs: A Case Study in Yuanping, China, International Journal of Environmental Research and Public Health, vol. 15 (2018), p.121.
[29] CalTrans, California Rail Network <data.ca.gov/dataset/california-rail-network> (Accessed 2013).
[30] *Id*. (Accessed January 27, 2020).
[31] *Id*. (Accessed June 20, 2023).
[32] US EPA, Air Quality Criteria for Lead § I (National Center for Environmental Assessment - RTP Division ed. 2006), pp. 2-50. <semspub.epa.gov/work/HQ/190966.pdf> (Accessed October 15, 2024).
[33] Bernstein, *Nascar Plans to Switch to Unleaded Fuel in '08*, New York Times (Jan. 20, 2006). <www.nytimes.com/2006/01/20/sports/othersports/nascar-plans-to-switch-to-unleaded-fuel-in-08.html> (Accessed October 15, 2024).
[34] Division of Drinking Water (DDW) California Water Boards. Lead Service Line Replacement Inventory Status. (Data extracted on February 3, 2021 from 2019 Electronic Annual Report by DDW staff). <gispublic.waterboards.ca.gov/portal/apps/storymaps/stories/c129b6a5cc324eea807f716efac2b54a> (Accessed October 15, 2024).
[35] DDW California Water Boards. 2022 Updated Replacement Plans. Sim, Alison. "RE: Update to Lead Service Line Replacement Inventory Status data" Received by Stephanie Fisher, June 29, 2023 and July 25, 2023.
[36] DDW California Water Resources Control Board, California Drinking Water Service Area Boundaries. (Item updated May 23, 2023) <gispublic.waterboards.ca.gov/portal/home/item.html?id=fbba842bf134497c9d611ad506ec48cc> (Accessed October 15, 2024).

- *Alternatives considered.* In response to stakeholder concern that ports might be a potential source of lead exposure, the Department also considered ports in its analysis of geospatial risk factors for high-risk ZIP Codes. In a review of the relevant literature, however, the Department was unable to find lead exposure sources connected to ports. Nonetheless, in mapping out California's ports, the Department determined that California's ports are located in ZIP Codes already determined to be high-risk under the Department's analysis of the geospatial risk factors discussed above.

**Determination of Additional Risk Factors:**
Under the Department's proposed regulations, 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, health care providers are required to evaluate 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 in the proposed regulations. (See Table 1.) The Department reviewed data from case investigations of lead poisoned California children, consulted with medical, environmental, and subject matter experts; reviewed CDC guidelines, scientific studies, and the regulatory schemes of other states; and conferred with professional organizations and stakeholders to make its determinations.

As a result of its analysis, the Department 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;[37]
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;[38]
3) Pica behavior (ingesting non-food items);[39]
4) Living or traveling outside of the United States;[40]
5) Having a sibling, playmate, or other close contact who has a BLL ≥ 3.5 mcg/dL;[41]
6) Exposure to dishware or pottery that is worn or chipped, was made before 1970, or was made outside of the United States;[42] and

[37] (HSC, § 105285, subd. (b)(2)(A).)
[38] (HSC, § 105285, subd. (b)(2)(D); see Cal. State Auditor, Childhood Lead Levels – Millions of Children in Medi-Cal Have Not Received Required Testing for Lead Poisoning (2020) p. 38 "risk factors commonly considered in other states.") <information.auditor.ca.gov/reports/2019-105/index.html> (Accessed October 16, 2024).
[39] (HSC, § 105285, subd. (b)(2)(H).)
[40] (HSC, § 105285, subd. (b)(2)(E).)
[41] (HSC, § 105285, subd. (b)(2)(G).)
[42] (HSC, § 105285, subd. (b)(2)(D) & (J).)

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.[43]

The full discussion and justification for the Department's adoption of these additional risk factors can be found in the discussion of regulatory changes, below.

**Stakeholder Engagement:**
Between March and July 2019, the Department held feedback sessions to inform the development of these regulations. The stakeholder feedback received was applicable to both AB 1316 and AB 2276. These sessions included stakeholders, local CLPP Programs, and health care providers affiliated with the California Medical Association, the American Academy of Family Practice, the American Academy of Pediatrics (AAP), federally qualified health centers, major medical centers, and other major medical groups in California, such as Kaiser Permanente. Additional review and analyses were completed based on information received during the feedback sessions.

**Detailed discussion of each regulatory provision proposed to be amended**
The Department proposes to adopt, repeal, and amend the following sections of the CCR, title 17, to implement AB 1316 and AB 2276, and to make necessary updates.

**Repeal sections 37000, 37020, and 37025**
The Department proposes to repeal the above-named sections and replace them with section 37030: Definitions. This is necessary to maintain stylistic consistency with the Department's other regulations and to create a comprehensive definitions section for the ease of the regulated population.

**Adopt section 37030. Definitions.**
The Department proposes to adopt the following definitions to govern this chapter:

**(a)** ***Blood Lead Level***. The definition of "blood lead level" (BLL) is necessary to create a standard for the method of measuring the level of lead in a child's blood sample. BLLs analyze blood that has not been separated into its constituent parts and are considered by the CDC as the best way to measure exposure to lead.

**(b)** ***Child***. The definition of "child" is necessary to specify the population to whom these regulations apply. The Department's proposed definition differs from the generally accepted definition of a child as someone between the ages of birth to 18 years old and extends the definition to include individuals under 21 years of age. Because individuals under 21 years of age are eligible for Medi-Cal health coverage in California (CCR, tit. 22, § 50030, subd. (a)), the Department determined that this approach would provide

[43] (HSC, § 105285, subd. (b)(2)(J).)

consistency with related state departments. For example: California Children's Services provides services for low-income lead-poisoned children under the age of 21.

The Department's regulations would provide individuals 18, 19, and 20 years of age an opportunity to obtain state services for lead poisoning even if their parents did not seek out or declined these services when the child was under 18 years of age and unable to consent to medical care.

The Department considered using the traditional definition of a child, but rejected this approach as it would not align with existing departmental regulations and practices or comply with the legislative intent to expand lead poisoning screening to more children. The Department also considered applying the expanded age range only to individuals enrolled in Medi-Cal or receiving other services from DHCS, but rejected this approach as it would deny screening to a portion of the population due to their economic status.

**(c)** ***Childhood Lead Poisoning Prevention Program****.* The definition of "Childhood Lead Poisoning Prevention Program" is necessary to specify that this term refers not only to the state administrated program but also to services provided by a contracted local health jurisdiction (LHJ).

**(d)** ***Confirmatory Venous Blood Lead Test***. The definition of "confirmatory venous blood lead test" is necessary to specify that the test to confirm a BLL in a prior blood lead test must be a venous blood test.

The initial step to determine if a child has lead in their blood is typically a capillary sample, such as a finger or heel-prick, because this is a simpler blood draw and may have quicker results depending on the analysis method. In contrast, a venous sample is taken from the child's vein. A capillary sample can often be tested quickly at the point of care, while a venous sample typically takes a few days to receive the results.

Capillary samples can provide artificially high results if lead on the skin is captured in the sample. This sort of contamination is less likely with blood collected from the vein. For this reason, if a child's capillary sample shows an elevated BLL of ≥ 3.5 mcg/dL, it must be confirmed with a venous test.

The CDC refers to this second test as a "confirmatory venous sample'" or a "confirmatory test."[44] The CDC also refers to a venous test (even an initial venous test) as a "confirmed venous blood lead level,"[45] or a "confirmed test." These terms are so similar that, without more explanation, they could be confusing and subject to more than one interpretation. Further, the term "confirmatory test," does not make clear that the test must be done via a venous sample. For these reasons, the Department has

[44] CDC, Recommended Actions Based on Blood Lead Level (2022). <www.cdc.gov/lead-prevention/hcp/clinical-guidance/index.html> (Accessed October 15, 2024).
[45] *Ibid*.

determined to use the more specific term "confirmatory venous blood lead test" in its regulations.

**(e)** ***Department***. The definition of "Department" is necessary to align the regulations with HSC section 105280, subdivision (c) and to provide clarity to the regulated public.

**(f)** ***Follow-up Venous Blood Lead Test.*** The definition of "follow-up venous blood lead test" is necessary to specify that a venous blood lead test performed to monitor BLLs after a previous venous blood test result shows a BLL of ≥ 3.5 mcg/dL is called a "follow-up venous blood lead test." This term is consistent with the CDC terms for these tests.

After a child's BLL is established via a venous sample, the child's BLL is monitored during treatment and follow-up care. "Follow-up test" or "follow-up blood lead test" are the CDC terms for these subsequent tests.[46] Due to the reliability of venous tests, these follow-up tests are done via a venous sample. However, as with the CDC term "confirmatory test," "follow-up test" or "follow-up blood lead test" does not specify that the test must be done via a venous sample. The term "follow-up venous blood lead test" is consistent with CDC nomenclature and guidance and provides clarity to the regulated population because it specifies that this follow-up testing must be done with a venous test.

**(g)** ***Health Care Provider***. The definition of "health care provider" is moved from the existing regulation at CCR, title 17, section 37000. As stated previously, the Department proposes to repeal section 37000 to move this definition to this proposed comprehensive definition section. Non-substantive changes have been made to streamline and simplify the existing definition for the ease of the reader.

**(h)** ***Lead Poisoning***. The definition of "lead poisoning" is necessary to align the regulations with the definition of "lead poisoning" imported from HSC section 105280, subdivision (b) for the ease of the reader.

**(i)** ***Parent or Guardian***. The definition of "parent or guardian" is necessary to specify who may consent to screening and follow-up health care for a child. In recognition of non-traditional family structures, the Department's definition includes both biological and adoptive parents as well as legal guardians and other persons with legal authority to authorize medical care for a child. This definition is also necessary because the proposed regulations require health care providers to educate, provide guidance to parents and guardians on the risks of lead exposure, and to include the parent or guardian in their evaluation of the child's risk of lead exposure.

[46] CDC, Recommended Actions Based on Blood Lead Level (2022) <www.cdc.gov/lead-prevention/hcp/clinical-guidance/index.html> (Accessed October 15, 2024).

The Department considered including caregivers in this definition but rejected this alternative to ensure that only individuals with the legal authority over the child may consent to the child's medical care and treatment.

**(j)** ***Publicly Funded Program for Low-Income Children***. The definition of "publicly funded program for low-income children" is moved from CCR, title 17, section 37020 (proposed to be repealed) and updated. Language relating to the Child Health and Disability Program (CHDP) in previous subdivision (b) has been removed because this program transitioned to Medi-Cal effective July 1, 2024. (See HSC, §§124024 & 124110.5.) Similarly, the Department also removed the reference to the Healthy Families Program in prior subdivision (c) because the Healthy Families Program transitioned to Medi-Cal in February 2014.[47] (See also Welf. & Inst. Code, § 14005.27.)

Proposed subdivision (3) replaces the phrase "medical services or preventative healthcare" from the previous version of this provision with "need-based services or assistance." This change is necessary so that more low-income children can be screened for lead. The CDC has identified low-income children as part of the demographic having "the greatest risk of lead exposure."[48] The Department's previous regulations have already covered children in Medi-Cal; however, the Department did not include, for example, children enrolled in Head Start, which is primarily a need-based program but not a health program. This amendment is necessary to ensure that as many at-risk children as possible are screened,[49] and that the Department can comply with its mandate to create a standard of care "at least as stringent" as the CDC guidelines (HSC, § 105285, subd. (b)(1).)

Non-substantive changes have been made to this provision for the ease of the reader.

**(k)** ***Screening***. The definition of "screening" to mean "testing a child for lead poisoning by performing a blood lead test" is imported from CCR, title 17, section 37025 (proposed to be repealed) with the removal of the term "asymptomatic" and non-substantive changes for the ease of the reader. "Asymptomatic" is removed from this definition as, in the Department's experience, it could be too restrictive and "screen," as used in HSC section 105280, subdivision (e), is not limited to asymptomatic situations.

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[47] California Department of Health Care Services (DHCS), *Healthy Families Program Transition to Medi-Cal Final Comprehensive Report* (February 4, 2014). <www.dhcs.ca.gov/provgovpart/Documents/Waiver%20Renewal/AppendixCHFP.PDF> (Accessed October 15, 2024).

[48] CDC, People at Increased Risk for Childhood Lead Poisoning, <www.cdc.gov/ lead-prevention/ risk-factors/index.html#:~:text=Children%20from%20low-income% 20households%20and%20those%20who%20live% 20in,more%20likely%20to% 20contain%20lead> (Accessed April 10, 2024).

[49] Under HSC section 105285 subdivision (a), it is the goal of the state that all child at risk of lead exposure receive blood lead screening tests.

**Amend** Pursuant to sections 100275, **citations** to update these citations to reflect the Department's 2007 reorganization and to provide additional authority. Specifically, the Department proposes adding[50] the following to the cited authorities:

- HSC sections 20, 131050, 131051, and 131052 to reflect the Department's reorganization in 2007;
- HSC section 131200, to reflect the Department's reorganization in 2007 and its authority to adopt and enforce regulations for the execution of its duties.
- HSC section 105280, granting authority to the Department to determine the minimum BLL constituting a health risk under HSC 105280(b); and
- HSC section 124165, authorizing the Department, through the CLPP Program, "to take steps that it determines are necessary to reduce the incidence of excessive childhood lead exposure in California."

The Department also proposes adding the following to the cited references:

- HSC section 105280, as these definitions implement, interpret, or make specific the definitions found in HSC section 105280, subdivisions (b) and (c);
- HSC section 105300, as these definitions implement, interpret, or make specific HSC section 105300, subdivisions (a) and (e); and
- HSC section 105301, as the definition of Childhood Lead Poisoning Prevention Program implements, interprets, or makes specific this provision.

**Amend Article 2. Standard of Care on Screening for Childhood Lead Poisoning**
The Department proposes the following amendments to Article 2.

**Amend Section 37100. Standard of Care on Screening for Childhood Lead Poisoning**
The Department proposes amendments to this section's title to specify that the following provisions relate to the standard of care on screening for childhood lead poisoning. The previous title of this section, "Requirements" is overly broad, making this amendment necessary to ensure clarity for the regulated population. The following discussion lists the regulatory provisions as they are proposed to be amended.

Amend subdivision (a) to make non-substantive corrections to punctuation and to the term "subsection," and to replace "standard of care" with "requirements" to avoid duplication of the section title.

Amend subparagraph (a)(1) to comply with HSC 105286 and to include the most significant sources of lead exposure for California children. Under HSC 105286, the Department must require health care providers to inform parents and guardians of the

[50] HSC sections 100275, 105285, and 105300 are included in the proposed authorities, but are not discussed above as they were previously cited as authority for existing regulation definitions imported into this definition section. Similarly, HSC section 105285 is included in the proposed references, but is not discussed above as it was previously cited as the reference for existing regulation definitions imported into this section.

Department's screening requirement. The existing regulation does not include this obligation. The proposed amendment adds language to correct this omission.

Further, the Department proposes revising the listed lead hazards from "deteriorating or disturbed lead-based paint and the dust from it" to "deteriorating or disturbed lead-based paint and lead-contaminated dust and soil" as paint, dust, and soil are the most likely sources of exposure for California children, and dust may contain lead from paint, lead-contaminated soil, or other sources. Other non-substantive changes are made to this subparagraph for the clarity of the reader.

Subparagraph (a)(2) No changes to text.

Amend subparagraph (a)(3) to establish the use of high-risk ZIP Codes in determining the need for screening a child for lead poisoning if the child is not found to be at risk of lead exposure under provision (a)(2). This is necessary to comply with the mandate of AB 2276 that the Department consider a child's residency in a high-risk ZIP Code as a significant risk factor for lead poisoning. As discussed above, this ZIP Code inquiry also encapsulates additional statutory risk factors from both AB 1316 and AB 2276.

Adopt subparagraph (a)(4) to require that, if a child is not found to be at risk of lead exposure under provision (a)(2) or (3), the health care provider must evaluate if the child has experienced, or if it is uncertain whether the child has experienced, any of the risk factors in provisions (A)-(G). If, in the professional judgement of the health care provider, the child is at risk of lead poisoning based on these risk factors, the health care provider must order the child screened for lead poisoning. This requirement is necessary to comply with AB 1316 and AB 2276, for the reasons previously discussed.

Adopt subparagraph (a)(4)(A) to specify living or spending time in a home, school, or building built before 1978. Per AB 1316, this is one of the "most significant environmental risk factors." The CDC has identified children who live in housing built before 1978 as part of the demographic having "the greatest risk of lead exposure."[51] Older housing is associated with an increased risk for childhood lead poisoning due to the use of lead-based paint. Federal law effectively banned the use of such paint in 1978, after which its use declined, however, children may still be at-risk for lead poisoning if they live or spend time in a home, school, or building built prior to 1978.

The Department recognizes the phrase "spending time in" is broad, however, less prescriptive language allows health care providers discretion to decide on a case-by-case basis if the amount of time a child has been exposed to a high-risk building is

[51] CDC, People at Increased Risk for Childhood Lead Poisoning, <www.cdc.gov/ lead-prevention/ risk-factors/index.html#:~:text=Children%20from%20low-income% 20households%20and%20those%20who%20live% 20in,more%20likely%20to% 20contain%20lead> (Accessed April 10, 2024).

sufficient to require testing. If a child lives in, or spends time in, a home, school, or building built before 1978, they face a significant risk factor for childhood lead poisoning and should be screened if their health care provider deems it appropriate.

Adopt subparagraph (a)(4)(B) to specify 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. The Department proposes to add this as a risk factor in compliance with AB 1316's mandate to consider "known sources of lead contamination," because persons employed in lead-related occupations or engaging in lead-related hobbies can unintentionally transport lead dust home from a worksite through clothing, shoes, tools, or vehicles.[52] [53] Further, per the California State Auditor: "[p]roximity to adults who work with lead" is a lead risk factor "commonly considered in other states."[54] In California, possible take-home lead exposure was identified in 16 percent of new cases from July 1, 2015 to June 30, 2016.[55]

The Department includes art supplies used in hobbies such as painting and ceramics because they are known to contain lead and have been recalled by the Federal Consumer Product Safety Commission.[56] Stained-glass, for example, uses metal came or solder to hold the pieces of glass together, both of which are often made of lead. Glazes found on ceramics often contain lead and are a potential source of lead exposure to children.[57] CDPH has confirmed that some California children with elevated BLLs have a history of exposure to fishing sinkers, pellets, and art supplies that were found to contain lead.[58]

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[52]CDC, Occupational and take-home lead poisoning associated with restoring chemically stripped furniture – California., 1998, MMWR, vol. 50 (2001), p. 247.
[53] CDC, Childhood lead poisoning associated with lead dust contamination of family vehicles and child safety seats - Maine, 2008, MMWR vol. 58 (2009), p. 890.
[54] California State Auditor, *Childhood Lead Levels – Millions of Children in Medi-Cal Have Not Received Required Testing for Lead Poisoning* (2020) p. 38. <information.auditor.ca.gov/reports/2019-105/index.html> (Accessed October 16, 2024).
[55] California Department of Public Health (CDPH), California's Progress in Preventing and Managing Childhood Lead Exposure (2020). <www.cdph.ca.gov/Programs/CCDPHP/DEODC/CLPPB/CDPH%20Document%20Library/CLPPBReport2020.pdf> (Accessed October 15, 2024).
[56] United States Consumer Product Safety Commission, Recall List. <www.cpsc.gov/Recalls> (Accessed December 11, 2019).
[57] United States Food and Drug Administration (US FDA), Questions and Answers on Lead-Glazed Traditional Pottery, (2010), p.1. <www.fda.gov/food/environmental-contaminants-food/questions-and-answers-lead-glazed-traditional-pottery> (Accessed October 15, 2024).
[58] CDPH, California's Progress in Preventing and Managing Childhood Lead Exposure (2020).

The Department includes hunting and shooting as a risk factor in this provision because most bullets contain lead. The CDC has found that indoor firing range are a source of lead exposure and elevated BLLs among employees, their families, and customers.[59] [60] Among recreational shooters, women and children are at special risk and do not receive the same health protections as occupational users of firing ranges.[61] Further, there is a possibility either lead shot or lead-containing bullets may not be completely removed from game meat prior to consumption, resulting in a risk that the child might ingest the lead.[62]

The Department recognizes the phrase "may involve lead exposure to lead" is broad, however, it is not possible to define every, job, hobby, or free time activity that might involve lead. The Department opted to use less prescriptive language to encourage conversation between a child's parent or guardian and health care providers, and to permit the health care provider discretion in deciding if a child should be screened.

Adopt subparagraph (a)(4)(C) to specify pica behavior. Per AB 2276, "the likelihood of a child placing nonfood items in the mouth" is one of the "most significant environmental risk factors." For this reason, the Department proposes to use the medical term "pica behavior" instead of "placing nonfood items in the mouth" to distinguish the medical term for eating or chewing nonfood items from a normal developmental stage in young children. Otherwise, this risk factor could result in universal screening of all children who have reached the developmental stage of putting nonfood items—most of which are unlikely to contain lead—in their mouths. Universal screening is inconsistent with HSC section 105285's risk factor analysis.

Pica behavior is a significant cause of lead poisoning that must be promptly recognized and treated.[63] In California, eating paint chips or soil was identified in 29 percent of new lead poisoning cases in children who received full case management from July 1, 2015 to June 30, 2016 based on Department data. Similarly, pregnant people may be at risk

[59] Beaucham, et al., Indoor firing ranges and elevated blood lead levels-United States, 2002-2013, MMWR, vol. 63 (2014), p.347.

[60] McLaughlin and Gessner, State of Alaska Epidemiology Bulletin Blood Lead Epidemiology and Surveillance, Non-Occupational Exposures in Adults and Children-Alaska, 1995–2006 (Department of Health and Human services ed. State of Alaska 2008), p. 1. <health.alaska.gov/dph/Epi/Pages/bulletins/default.aspx> (Accessed January 31, 2019). Note: This document is no longer available online.

[61] Laidlaw, et al., Lead exposure at firing ranges-a review, Environmental Health, vol. 16 (2017), p.10.

[62] Iqbal, et al., Hunting with lead: association between blood lead levels and wild game consumption, Environmental Research, vol. 109 (2009), p. 952.

[63] Leung and Hon, Pica: A common condition that is commonly missed - An update review, Current Pediatric Reviews (2019), pp.164-169.
<pubmed.ncbi.nlm.nih.gov/30868957/> (Accessed October 15, 2024).

of pica behavior and of subsequent lead poisoning for various reasons.[64] Among pregnant women with lead poisoning in New York City, pica behavior was associated with higher peak BLLs.[65] Therefore, exhibiting pica behavior is a significant risk factor for childhood lead poisoning.

Additionally, by listing several high-risk items such as dishware or traditional religious powders in other provisions in this regulatory section, the Department has accounted for the most likely lead-containing household items that children might put in their mouths, in further satisfaction of AB 2276.

Adopt subparagraph (a)(4)(D) to specify living or traveling outside of the United States. Per AB 2276, "residency in or visit to a foreign country" is one of the "most significant environmental risk factors." Accordingly, the Department proposes to add "living or extended travel outside of the United States" as a risk factor based on evidence from the CDC, the American Academy of Pediatrics (AAP), and other scientific data and peer-reviewed studies.

According to the CDC, the risk for lead exposure is much higher in countries from which children are adopted than in the United States.[66] The 2013 AAP Policy Statement on improving care for immigrant and migrant children recommends such children be screened for lead whether screening is required for school entry or not.[67]. Further, a case-control study of New York City children found that both being born outside the United States and residing in a foreign country less than six months before their blood test, showed an elevated risk of lead poisoning compared with US-born children with no foreign residential history before their blood test.[68] To avoid stigmatization of immigrant or migrant children by pointing out specific high-risk countries, the Department has determined that being born in or having previous residence in any country other than the United States should be considered a significant risk factor for childhood lead poisoning and should trigger screening.

Additionally, while it is generally accepted that a child can be exposed to lead during international travel, the Department determined that "extended travel" would be more appropriate than "visit" or "travel" to differentiate from travel for any amount of time because there is evidence to suggest that the amount of time may be a factor that

[64] Thihalolipavan, et al., Examining pica in NYC pregnant women with elevated blood lead levels, Maternal and Child Health Journal vol. 17 (2013), p.52.
[65] *Id*. p. 49.
[66] CDC, Elevated blood lead levels among internationally adopted children, United States, 1998, MMWR, vol. 49 (2000), p. 97.
[67] Pediatrics Council on Community, Providing care for immigrant, migrant, and border children, Pediatrics, vol. 131 (2013).

[68] Tehranifar, et al., Immigration and risk of childhood lead poisoning: findings from a case control study of New York City children, American Journal of Public Health, vol. 98 (2008), p. 292.

health care providers should consider in exercising their professional judgement. For example, in the case-control study of New York City children referenced above,[69] there was a significant correlation of lead poisoning in children with time abroad of at least two months compared to the control group. In other words, as little as two months could lead to significant exposure. The Department considered using a two-month threshold but ultimately determined this would be too restrictive as every child's situation and potential for exposure can be different based on the totality of circumstances. The New York City study noted that significant exposure could occur within two months. "Extended travel" is less prescriptive language that allows health care providers discretion to decide on a case-by-case basis if the amount of time a child has been outside of the United States is sufficient to require testing.

Adopt subparagraph (a)(4)(E) to specify having a sibling, playmate, or other close contact who has a BLL equal to or greater than 3.5 mcg/dL. Per AB 2276, having a sibling or playmate with lead poisoning is one of the "most significant environmental risk factors." The Department also proposes to add this as a risk factor at the recommendation of the CDC.[70] As discussed previously, the BLL ≥ 3.5 mcg/dL level is used here per the CDC guidelines.

In the Department's experience, "sibling," "playmate" and "close contact" are all proxies for environmental lead exposure. In other words, if someone whom the child frequently spends time with has a BLL of 3.5 or higher, there is a high likelihood that the child was also exposed to the same source of lead. The Department considered defining "sibling," "playmate," and "close contact," but decided that a strict definition could lead to an at-risk child being overlooked for screening due to a relationship the Department had not considered. "Close contact" in this case does not have the same meaning as in CCR, title 8, section 3205, which was defined due to the COVID-19 pandemic but is a commonly used term in the regulated community that includes household members and other individuals with whom the child frequently spends time.

Adopt subparagraph (a)(4)(F) to specify exposure to dishware or pottery that is worn or chipped, was made before 1970, or was made outside of the United States. Per AB 2276, the "likelihood of a child using … dishes from other countries" is one of the "most significant environmental risk factors." In addition, the Department proposes to include exposure to "dishware or pottery that is worn or chipped, was made before 1970" as a risk factor in compliance with AB 1316's mandate to consider "known

[69] *Ibid.*
[70] CDC, CDC Response to Advisory Committee on Childhood Lead Poisoning Prevention Recommendation in "Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention" (2012), p. 32. <www.cdc.gov/mmwr/preview/mmwrhtml/mm6120a6.htm> (Accessed October 15, 2024).

sources of lead contamination." The Department determined this risk factor pursuant to scientific studies,[71] FDA reports, and the Department's own findings.

In North America, the ceramics industry only moved away from leaded glazes in the 1970s, but, even in ceramics made more recently, lead can leach out if the glaze is not intact.[72] Dishware containing lead has been identified as a source of lead exposure in California's children, [73] as have glazes found on ceramics, earthenware, bone China, and porcelain.[74] Dishware or pottery made outside of the United States is a known risk of lead exposure. For example, In 2010, the FDA reported that traditional pottery from Mexico labeled "lead free" was found to contain extractable lead.[75]

Adopt subparagraph (a)(4)(G) to specify 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. Per AB 2276, "the likelihood of a child using food [or] medicine … from other countries" is one of the "most significant environmental risk factors." The Department also proposes to include (a)(4)(G) as a risk factor because, in California, children with lead poisoning often have a history of ingesting traditional[76] ethnic remedies such as:

- *Ayurvedic medications.* The CDC recommends providers ask patients, especially foreign-born or pregnant patients, about any use of foreign health products or

[71] Dignam, et al. Control of Lead Sources in the United States, 1970-2017: Public Health Progress and Current Challenges to Eliminating Lead Exposure, Journal of Public Health Management Practice, vol. 25 (Supplement Lead Poisoning Prevention (2019).
[72] US FDA, Questions and Answers on Lead-Glazed Traditional Pottery, (2010). <www.fda.gov/food/environmental-contaminants-food/questions-and-answers-lead-glazed-traditional-pottery#:~:text=In%20most%20kits%2C%20if%20the,or%20storing%20food%20or%20drinks> (Accessed October 15, 2024)
[73] CDPH, California's Progress in Preventing and Managing Childhood Lead Exposure (2020). <www.cdph.ca.gov/Programs/CCDPHP/DEODC/CLPPB/CDPH%20Document%20Library/CLPPBReport2020.pdf> (Accessed October 15, 2024).
[74] US FDA, Questions and Answers on Lead-Glazed Traditional Pottery, (2010), p.1. <www.fda.gov/food/environmental-contaminants-food/questions-and-answers-lead-glazed-traditional-pottery#:~:text=In%20most%20kits%2C%20if%20the,or%20storing%20food%20or%20drinks> (Accessed October 15, 2024)
[75] *Ibid*.
[76] "Traditional" is a term widely used and understood in the regulated community. (See, e.g., US FDA, Questions and Answers on Lead-Glazed Traditional Pottery, (2010), p.1 and CDC, Lead poisoning associated with use of traditional ethnic remedies--California, 1991-1992, MMWR, vol. 42 (1993), p. 521.)

supplements.[77] [78] A study reported in the Journal of the American Medical Association found over 19 percent of Ayurvedic medicines sold on the internet contained lead.[79]

- *Azarcon and greta.* Both azarcon and greta are traditional Mexican remedies used for gastrointestinal complaints. (Azarcon is an orange powder that can contain 86 percent to 95 percent lead, and that has been responsible for children with BLLs as high as 137 mcg/dL.)[80] Greta, a yellow powder with a high percentage of lead, also creates a risk for elevated BLLs.[81]
- *Pay-loo-ah.* This southeast Asian remedy consisting of red and orange powders is commonly given to California children to reduce fever or rash, and has been found to contain up to 90 percent lead.[82]
- Some traditional Chinese remedies also have high lead content responsible for causing lead poisoning in California's children.[83]

Similarly, the Department proposes to include (a)(4)(G) as a risk factor because, in California, children with lead poisoning often have a history of using traditional religious powders, chalks, cosmetics, liquids, or creams such as:

- *Surma, kajal, and kohl.* Traditional powders and liquids believed to provide protection and promote health, such as surma and kajal in Asia, and kohl in the Middle East, are sometimes applied to the eyes of infants and young children,

[77] CDC, Lead poisoning in pregnant women who used Ayurvedic medications from India--New York City, 2011-2012, MMWR, vol. 61 (2012), p.641.
[78] Meiman, et al., Lead Poisoning and Anemia Associated with Use of Ayurvedic Medications Purchased on the Internet-Wisconsin, 2015, MMWR, vol. 64 (2015), p.883.
[79] Saper, et al., Lead, mercury, and arsenic in US and Indian-manufactured Ayurvedic medicines sold via the Internet, JAMA, vol. 300 (August 27, 2008), p.918.
[80] Bose, et al., Azarcon por empacho-another cause of lead toxicity, Pediatrics, vol. 72 (1983), pp.106, 107.
[81] CDC, Lead poisoning associated with use of traditional ethnic remedies--California, 1991-1992, MMWR, vol. 42 (1993), p. 521.
[82] CDC, Folk remedy-associated lead poisoning in Hmong children–Minnesota, MMWR, vol. 32 (1983), p. 555.
[83] CDPH, California's Progress in Preventing and Managing Childhood Lead Exposure (2020). <www.cdph.ca.gov/Programs/CCDPHP/DEODC/CLPPB/CDPH%20Document%20Library/CLPPBReport2020.pdf> (Accessed October 15, 2024).

and can contain very high levels of lead.[84] These products have all been identified as a source of lead exposure in California children.[85]

- *Sindoor*. This orange or red powder used for religious and cultural purposes on the Indian subcontinent. One use of Sindoor identified during Department investigations of lead exposed children is as an additive to diaper creams. Sindoor brought to and sold in the US has been found to contain more than 30 percent lead,[86] and has been identified as a source of lead exposure in California children.[87]

The Department considered compiling a comprehensive list of traditional remedies or medicines, however, a comprehensive list is not possible as California is a large and culturally diverse state, and many cultures have their own unique "traditional" or "natural" cures. For the same reason, it is impossible to compile a complete list of traditional religious powders, chalks, cosmetics, liquids, or creams. Further, to limit this risk factor to the examples listed above would be constrictive. The Department opted for less prescriptive language so that a child's parent or guardian and health care provider may consider items that the Department might not have anticipated. This will permit health care providers more discretion on deciding if an individual child's history with these items warrants screening.

The Department also proposes to include (a)(4)(G) as a risk factor because the CDC recommends that health care providers be aware of the potential hazards of certain food products.[88] [89] A recent CDC report found an average lead level of more than 1 mg/kg (milligrams of lead per kilogram of food or spice) in many of the samples collected during lead investigations North Carolina.[90] These foods included:

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[84] CDC, Childhood lead exposure associated with the use of kajal, an eye cosmetic from Afghanistan-Albuquerque, New Mexico, 2013, MMWR, vol. 62 (2013), p. 917.
[85] CDC, California's Progress in Preventing and Managing Childhood Lead Exposure (2020).
[86] Shah, et al., Lead Content of Sindoor, a Hindu Religious Powder and Cosmetic: New Jersey and India, 2014-2015, American Journal of Public Health, vol. 107 (2017), p.1630.
[87] CDPH, California's Progress in Preventing and Managing Childhood Lead Exposure (2020). <www.cdph.ca.gov/Programs/CCDPHP/DEODC/CLPPB/CDPH%20Document%20Library/CLPPBReport2020.pdf> (Accessed October 15, 2024).
[88] CDC, Childhood lead poisoning associated with tamarind candy and folk remedies-California, 1999-2000, MMWR, vol. 51 (2002), p.684.
[89] Woolf and Woolf, Childhood lead poisoning in 2 families associated with spices used in food preparation, Pediatrics, vol. 116 (2005), p.2004.
[90] Angelon-Gaetz, et al., Lead in Spices, Herbal Remedies, and Ceremonial Powders Sampled from Home Investigations for Children with Elevated Blood Lead Levels-North Carolina, 2011-2018, MMWR, vol. 67 (2018), p. 1290.

- Imported chili powder (average lead level 12. 6 mg/kg), and turmeric (average lead level 66. 4 mg/kg).[91]
- Chapulines (grasshopper snacks) brought to the US from Oaxaca, Mexico (found to contain lead levels up to 2,300 mg/kg.)

Additionally, some candies manufactured outside the US have been found to have large amounts of lead such that the California Food and Drug Branch has established a Lead in Candy program to prevent the sale of adulterated candy to infants, young children, and pregnant women.[92]

While the Department considered compiling a complete list of products to include under this provision, a comprehensive list is not possible. The Department opted for a less prescriptive approach for the reasons previously discussed.

Amend subdivision (b) to make non-substantive changes to ensure consistency of language in this regulatory section and to eliminate needless words.

Amend subparagraph (b)(1) to revise the term “anticipatory guidance” to “actions,” and to change the age at which a health care provider must perform subdivision (a)(1)’s requirements. As explained above, for compliance with HSC section 105286, the Department added a requirement for health care providers to inform parents about the screening requirement, in section 37100 of these proposed regulations, to subdivision (a)(1)’s existing language. With this addition to subdivision (a)(1), the term “anticipatory guidance” in (b)(1) is now insufficient and the term “actions” is proposed to encompass both the screening notification and the anticipatory guidance requirements of subdivision (a)(1). The Department also proposes to change the age at which subdivision (b)(1) applies from six months to birth. This is necessary because a child younger than six months can still be at risk of lead poisoning. For example, if a child’s mother has a BLL ≥ 5 mcg/dL at the time the child is born or has a history of lead exposure. As lead can easily cross the placenta from the mother to the fetus,[93] it is advisable to have the child tested for lead poisoning at birth, rather than waiting until the child is six months old.

Non-substantive changes have also been made to ensure consistency of language.

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[91] *Id.* pp. 1290-1294.
[92] CDPH, Food and Drug Branch, Lead in Candy. <www.cdph.ca.gov/Programs/CEH/DFDCS/Pages/FDBPrograms/FoodSafetyProgram/LeadInCandy.aspx> (Accessed December 11, 2019.)
[93] CDC, Guidelines for the Identification and Management of Lead Exposure in Pregnant and Lactating Women (2010), p. 27. <stacks.cdc.gov/view/cdc/147837> (Accessed October 15, 2024).

Amend subparagraph (b)(2) to add references to subdivision (a)(4). This is necessary to implement the Department's updated standard of care as discussed below. The Department also proposes the non-substantive correction of revising "screening and evaluation" to "evaluation and screening" as the evaluation of the child would occur before any screening. In addition, non-substantive changes have been made to ensure consistency of language.

Amend subparagraph (b)(2)(C) and (b)(2)(D) to add references to subdivision (a)(4). This is necessary due to the Department's updated standard of care as discussed below.

Adopt subparagraph (b)(3) to logically group together situations where a screening would be performed without further evaluation under subdivisions (a)(2), (3), or (4).

Amend subparagraph (b)(3)(A) to renumber and move existing subparagraph (b)(2)(E) to this subparagraph, along with related non-substantive changes in punctuation, because a situation where "a change of circumstances has put the child at risk of lead poisoning" would logically require screening without further evaluation under subdivisions (a)(2), (3), or (4).

Adopt subparagraph (b)(3)(B) to add a provision for screening whenever the health care provider becomes aware that the child may be at risk of lead poisoning without restriction to 72 months of age or to a situation where there has been a "change in circumstances" as in subparagraph (b)(3)(A). This provision, implementing the Department's definition of "child" as an individual from birth to under 21 years old, is necessary because a child younger than 12 months or older than 72 months can be at risk of lead poisoning and there could be a situation where a child is at risk of lead exposure, but would not be covered under the screening situations above. Thus, this provision is needed as a "catch all" to ensure compliance with the statutory mandate that "all children at risk of lead exposure receive blood lead screening tests." (HSC, § 105285, subd. (a).)

There are risks of lead exposure that affect children of any age, and older children can be exposed to different sources of lead by different avenues than young children.[94] The language specifically identifying a "newborn or infant whose mother may have been exposed to lead before giving birth," is included here for clarity, to highlight for health care professionals that these children may also be "at risk," and to specify that a health care provider has discretion to act if they determine that the child's mother may have been exposed to lead prior to giving birth. Lead can pass from mother to fetus through the placenta and, to a lesser extent, to the baby through breastmilk, and newborns and

[94] CDC, Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention (2012), p.46. <stacks.cdc.gov/view/cdc/11859> (Accessed October 15, 2024).

infants can be exposed to environmental sources of lead exposure.[95] Further, according to the AAP, blood lead concentrations of children who live in lead-contaminated environments typically increase rapidly between six and 12 months of age.[96]

Even if a child is older than 72 months, it is still important that a lead-exposed child is identified and treated.[97] [98] [99] For example, children with developmental conditions such as autism spectrum disorder and other neurological syndromes who have persistent pica behaviors or poor cognitive discriminatory recognition are at increased risk of lead contamination which may persist beyond the age when children are routinely screened for elevated BLLs.[100] To illustrate, a study looking at behavior problems found that even low blood lead concentrations at seven to eight years of age are associated with more autistic behaviors at 11 to 12 years of age, underscoring the need for continued efforts to reduce lead exposure in children over 72 months.[101] Finally, the Department has experience with even older children being exposed to lead from sources such as firing ranges and lead contaminated remedies.

Adopt subparagraph (b)(3)(C) to require screening to be performed at the request of the parent or guardian of a child under 18 years of age, or upon the request of a child 18, 19, or 20 years of age, if the request is medically appropriate in the professional judgment of the health care provider.

This provision is necessary to ensure that "all children at risk of lead exposure receive blood lead screening tests." (HSC, § 105285, subd. (a).) Due to the detrimental consequences lead exposure has on a child's health, if a parent, guardian, or child 18, 19, or 20, has any concern regarding lead exposure, then the Department believes the best course is to have the child screened.

The Department specifies "if the request is medically appropriate in the professional judgment of the health care provider" in this provision to give the health care provider

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[95] CDC, Guidelines for the Identification and Management of Lead Exposure in Pregnant and Lactating Women (2010), pp. 27, 29 and 57. <stacks.cdc.gov/view/cdc/147837> (Accessed October 15, 2024).
[96] AAP, Council on Environmental Health, Prevention of Childhood Lead Toxicity, Pediatrics, vol. 138 (2016), p. 5.
[97] *Id*. pp. 3 and 4.
[98] CDC, Lead exposure from indoor firing ranges among students on shooting teams--Alaska, 2002-2004, MMWR, vol. 54 (2005), pp.557 and 559.
[99] Kazi, et al., Occupational and environmental lead exposure to adolescent workers in battery recycling workshops, Toxicology and Industrial Health, vol. 31 (2015), p.1288.
[100] Hauptman, et al., An Update on Childhood Lead Poisoning, 18 Clinical Pediatric Emergency Medicine, vol. 18 (2017), p. 3.
[101] Kim, et al., Low-level lead exposure and autistic behaviors in school-age children, Neurotoxicology, vol. 53 (2016), p.193.

discretion to determine any need for evaluation or screening, and to account for the rare circumstances in which a request might be unreasonable or frivolous.

Amend subdivision (c) to specify that a child, 18, 19, or 20 years of age can withhold consent to screening. This is necessary to update the regulations to reflect the Department's definition of "child." The phrase "of the child, or other person with legal authority to withhold consent" is deleted as the proposed definition of "parent or guardian" renders it superfluous.

Amend subdivision (d) to make non-substantive changes for the clarity of the reader, to ensure consistency of language across the proposed regulations, and to eliminate needless words. The word "reasons" is changed to "reason(s)" to clarify that, while all reasons must be documented, one reason would be sufficient.

Amend subdivision (e) to maintain consistency with CDC guidelines. Under current CDC guidance, the blood lead reference value considered elevated in children is 3.5 mcg/dL. The CDC has also identified 3.5 mcg/dL as the minimum level for providing follow-up care.[102] The CDC guidelines are national standards that are widely understood by the regulated population. Further, per HSC section 105285, subdivision (b)(1), the Department's standard of care regulations must be "at least as stringent" as the most recent CDC guidelines. Accordingly, the Department proposes changing the minimum BLL in this regulatory provision concerning follow-up care from 10 mcg/dL to 3.5 mcg/dL.

This change is not only necessary to align the standard of care for treatment of children exposed to lead with the CDC guidelines, but also to ensure that more children receive beneficial follow-up care. Early treatment and follow-up care of children with exposure to lead is the most effective method of preventing the permanent developmental effects of lead poisoning.[103] Therefore, revising the BLL to the lower CDC BLL level will help more children receive this beneficial follow-up care.

This amendment makes other non-substantive changes for the ease of the reader.

Amend subparagraph (e)(1) to include the education of a child, if 18, 19, or 20 years of age. Children aged 18, 19, and 20 may make their own medical decisions, and education regarding lead hazards and childhood lead poisoning should be provided to them, just as it is provided to a parent or guardian.

Other non-substantive changes have been made for the ease of the reader.

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[102] CDC, Recommended Actions Based on Blood Lead Level (2022) <www.cdc.gov/lead-prevention/hcp/clinical-guidance/index.html> (Accessed October 15, 2024).
[103] AAP, Council on Environmental Health, Prevention of Childhood Lead Toxicity, Pediatrics, vol. 138 (2016), p. 5.

Amend subparagraph (e)(2) to make non-substantive changes.

Amend subparagraph (e)(3) to insert requirements regarding confirmatory venous blood lead tests into the standard of care regulations. This is necessary to align the Department's regulations with the CDC's *Recommended Actions Based on Blood Lead Level*[104] and for these standard of care regulations to be presented in a logical reading order as confirmatory venous blood lead tests are done before follow-up venous blood lead tests.

Looking to the CDC guidelines, this amendment provides that, if a child's BLL of ≥ 3.5 mcg/dL was based on a capillary sample,[105] the healthcare provider must order a confirmatory venous blood lead test. As discussed previously, the initial step to determine if a child has elevated blood levels is typically a capillary sample instead of a venous sample. Per the *Recommended Actions Based on Blood Lead Level,* if a child's capillary sample shows an elevated BLL of ≥ 3.5 mcg/dL, the next step is to confirm the result from the capillary sample with a venous test. The term in these regulations for this test is "confirmatory venous blood lead test."

Adopt subparagraphs (e)(3)(A)-(F) to establish the schedule for ordering confirmatory venous blood lead tests. This is necessary because, per CDC guidelines: "[t]he higher the BLL is on the initial screening capillary test, the more urgent it is to get a venous sample for confirmatory testing."[106] This is a national standard widely understood by the regulated population. Per HSC section 105285, subdivision (b)(1), the Department's standard of care regulations must be "at least as stringent" as the most recent CDC guidelines. In developing this schedule, the Department has mirrored the schedule provided in the CDC's *Recommended Actions Based on Blood Lead Level* [107] with the following minor revisions:

- In subparagraph (e)(3), the Department specifies that a health care provider must "order" rather than "obtain" the confirmatory venous blood lead test within certain time periods after a BLL ≥ 3.5 mcg/dL. The Department considered requiring that the tests be "obtained" (i.e. performed) as in the CDC guidance but determined that it would be more appropriate to hold health care providers accountable for ordering tests since they may not be the person who ends up performing the test.

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[104] CDC, Recommended Actions Based on Blood Lead Level (2022) <www.cdc.gov/lead-prevention/hcp/clinical-guidance/index.html> (Accessed October 15, 2024).
[105] If a child's BLL of ≥ 3.5 mcg/dL was established via a venous sample, a confirmatory venous blood lead test would not typically be needed.
[106] CDC, Recommended Actions Based on Blood Lead Level (2022) <www.cdc.gov/lead-prevention/hcp/clinical-guidance/index.html> (Accessed October 15, 2024).
[107] *Ibid.*

Additionally, while health care providers can control when they order tests, they may have less control as to when the test is performed.

Where the CDC uses whole numbers for BLLs (10, 11, 12, etc.) in its guidance for all BLLs (other than 3.5 mcg/dL) in its schedule, the Department uses rational numbers to the tenths place (3.5 mcg/dL or 4.6 mcg/dL, etc.) since laboratories report BLLs using rational numbers. The Department correlates these BLLs to the CDC schedule using standard mathematical rounding principles. (Under standard mathematical rounding principles, any result ≤ 0.4 is rounded down and any result ≥ 0.5 is rounded up.) For example, if a child has a BLL of 9.5-19.4 mcg/dL this would correlate to a BLL of 10-19 mcg/dL on the CDC schedule. Due to this rounding, the Department's schedule is more protective than the CDC's, which is appropriate because the Department's standard of care must be "at least as stringent" as the most recent CDC guidelines.

- The Department's proposed schedule is expressed in terms of greatest urgency to least urgency while the CDC schedule is expressed in terms of least urgency to greatest urgency. The Department considered expressing the schedule in the same order as the CDC, but ultimately determined that, given the greatest urgency for the highest BLLs, that the most exigent tests should be at the top of the list.

- Due to the need for rapid confirmatory venous blood lead tests after very high BLLs, the Department included two additional levels of urgency in its schedule. The CDC's current schedule recommends obtaining a confirmatory venous blood lead test within 48 hours if a child has a BLL ≥ 45 mcg/dL. The Department follows this time frame for BLLs of 44.5-59.4 mcg/dL. However, the Department determined it would be more protective to order testing within 24 hours if a child's BLL is 59.5 to 69.4 mcg/dL, and to order testing immediately if the child's BLL is ≥ 69.5 mcg/dL. In determining to include these two additional levels, the Department looked to a prior version of the CDC confirmatory testing schedule that recommended testing within 24 hours if a child's BLL is 60 to 69 mcg/dL and testing "urgently as an emergency test" if a child's BLL is ≥ 70 mcg/dL. This prior schedule can be found on the CDC testing schedule website (www.atsdr.cdc.gov/csem/leadtoxicity/diagnostic_testing.html#anchor_1589476190).

Amend subparagraph (e)(4) to replace the existing schedule for follow-up venous blood lead tests with *Table 1-Schedule for Follow-up Venous Blood Lead Testing* to better align with current CDC guidance in compliance with HSC section 105285 subdivision (b)(1)'s requirement that the Department's standard of care regulations be "at least as stringent" as the most recent CDC guidelines. Thus, this proposed schedule

is based on the CDC's schedule for follow-up blood testing[108] with the following minor revisions:

- As explained above with the confirmatory venous blood lead testing schedule, the Department elected to use rational numbers to the tenths place instead of whole numbers and, in turn, the Department rounds a BLL to the closest whole number in the CDC chart.

- For early testing, the Department requires "at least 2 tests," instead of using the CDC's chart language of "2-4 tests" because, in the Department's experience, a limitation of four tests would be inappropriate, as the Department has had instances where more than four early tests were needed.

- Two side notes from the CDC table are included here instead of in the regulatory text as explanatory notes are generally more appropriate here than in regulatory text. Specifically, the CDC notes that changes in BLLs due to seasonal weather changes may be more apparent in colder climate areas and greater exposure in the summer months may necessitate more frequent follow-up. Moreover, some case managers or health care providers may choose to repeat early blood lead tests on all new patients within a month as repeated testing may confirm that the child's BLL is decreasing.

- Non-substantive changes were made to the CDC table to correct spelling errors and provide consistent language across the regulations. (For example: the CDC table uses "µg/dL" while the Departments uses "mcg/dL.") Further, the CDC table uses the abbreviation BLL or BLLs. Although we have used this abbreviation in this document (after defining the term) for the clarity of the regulated public, the proposed regulations contain the full term "blood lead level," instead.

Adopt and amend subparagraph (e)(5) to update the Department's scheduling requirements for follow-up venous blood lead testing. The Department's existing regulations (in former subparagraphs (e)(3)(A) and (e)(3)(B), proposed to be deleted) direct the provider to test at "one-to-two-month intervals" until the child's venous BLL remains less than 15 mcg/dL of blood for at least six months. The Department's proposed amendments replace the "one-to-two-month intervals" language by requiring the health care provider to refer to Table 1. The amendments continue the practice of requiring testing to continue until a child's venous BLL remains less than 15 mcg/dL for at least six months but amend 15 mcg/dL to 3.5 mcg/dL to conform with the CDC guidelines. In a non-substantive change, the phrase "six calendar months" is replaced with "six months" to maintain consistency with the rest of the Department's proposed

[108] See Table 2: Schedule for follow-up blood lead testing on the CDC's Childhood Lead Poisoning Prevention web page, Recommended Actions Based on Blood Lead Level, Childhood Lead Poisoning Prevention, <www.cdc.gov/lead-prevention/hcp/clinical-guidance/index.html> (Accessed May 22, 2024).

regulations. The phrase “micrograms of lead per deciliter” is shortened to mcg/dL to provide consistency of language across the proposed regulations and with *Table 1 – Schedule for Follow-up Venous Blood Lead Testing.*

Existing regulations provide for additional tests at set three-month intervals until the child reaches 36 months of age. The Department proposes removing the 36-month age limit on retesting because, depending on the age at which the child is identified with lead poisoning, they may begin required follow-up testing after 36 months of age. The follow-up testing timeline will also depend on the length of time needed for the child’s BLL to drop below 3.5 mcg/dL.

This revised provision also specifies that additional testing may occur even after the venous blood lead level has remained less than 3.5 mcg/dL for at least six months and the source of the lead poisoning has been removed or remediated, as medically appropriate. In the Department’s experience, at this late stage in the child’s treatment, there can be variability in each child’s individual needs; thus, instead of retaining a set three-month testing interval, the Department’s amendments allow the health care provider discretion to retest the child as medically appropriate. This language allows health care providers to determine the best treatment plan for the individual child based on the provider’s professional judgment and current medical standards.

Adopt subparagraph (e)(6) to specify that health care providers should refer a child with a BLL ≥ 3.5 mcg/dL to the CLPP Program. Existing language in the CCR (former provision (e)(4) proposed to be deleted) specifies that providers should refer families to a local childhood lead poisoning prevention program (local CLPPP) or LHJ. However, in practice, it is the child and not the family that would receive the referral and, additionally, not all LHJs have a contracted local CLPPP. For those jurisdictions, services are provided by the state. The CLPP Program maintains information on both state and local lead program contacts on its website. Adding language specifying the CLPP Program is necessary to ensure that children living in jurisdictions without a local CLPPP can still obtain services.

Amend subparagraph (e)(7) to specify that the healthcare provider should either order medically necessary treatment for the child, or refer the child for medically necessary treatment, including chelation therapy, if deemed appropriate in the professional judgment of the health care provider.

These revisions are necessary to be inclusive of all medically necessary treatments. As currently written, the Department’s regulations could be interpreted as excluding all treatments except chelation therapy from the standard of care. Medically necessary treatment will depend on the child’s specific BLL and other unique facts and circumstances particular to the child. For example, the CDC’s *Recommended Actions*

*Based on Blood Lead Level*[109] provides different recommendations depending on the child's specific BLL, with chelation therapy usually recommended for cases where a child has a venous BLL ≥ 45 mcg/dL.

Language specifying "order or refer" in the proposed amendment is necessary since not all treatments are within the scope of practice of all health care providers. For example, the CDC recommends consultation with a pediatric toxicologist if the child's BLL is ≥ 45.

Non-substantive changes have been made to this provision to retain logical numbering.

Amend subdivision (f) to define the overall scope of a health care provider's responsibilities under this section. This is needed for the clarity of the regulated public and to comply with HSC section 105285, subdivision (e). This language is required by statute and has been duplicated here with non-substantive changes for the ease of the reader.

Amend subdivision (g) to make non-substantive changes to renumber, update, and simplify existing language, and to simplify the reference to the disciplinary provisions of the Business and Professions Code, consistent with the proposed simplification of the definition for health care provider.

Amend authority and reference citations to update these citations to reflect the Department's 2007 reorganization and the Department's proposed adoptions and amendments to this section. Non substantive changes have been made to correct punctuation and delete an unnecessary subdivision reference.

Specifically, the Department proposes adding the following to the cited authorities:

- HSC sections 20, 131050, 131051, and 131052 to reflect the Department's reorganization in 2007;
- HSC section 131200, to reflect the Department's reorganization in 2007 and its authority to adopt and enforce regulations for the execution of its duties.
- HSC section 105280 (authorizing the Department to determine the minimum BLL constituting a health risk);
- HSC 105286 (mandate that the Department require health care providers to inform parents and guardians of section 37100's screening requirement and the "risks and effects of childhood lead exposure"); and
- HSC section 124165 (authorizing the Department, through the CLPP Program, "to take steps that it determines are necessary to reduce the incidence of excessive childhood lead exposure in California.")

The Department also proposes to adopt the following cited references:

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[109] CDC, Recommended Actions Based on Blood Lead Level (2022) <www.cdc.gov/lead-prevention/hcp/clinical-guidance/index.html> (Accessed April 17, 2024).

- HSC 105286 because HSC 105286 not only mandates that the Department require health care providers to inform parents and guardians of section 37100's screening requirement and the "risks and effects of childhood lead exposure," but these standard of care regulations also serve to implement, interpret, or make specific this mandate; and
- HSC section 124165 because HSC section 124165 not only authorizes the Department "to take steps that it determines are necessary to reduce the incidence of excessive childhood lead exposure in California," but these standard of care regulations also serve to implement, interpret, or make specific these steps.

**Documents Relied Upon**

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5. Ruckart, et al., Update of the Blood Lead Reference Value – United States, MMWR, vol. 70 (2021).
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9. DTSC, Removal Action Plan (Cleanup Plan): Offsite Properties within the Exide Preliminary Investigation Area (2017). ), p. ES 3. <ceqanet.opr.ca.gov/2016061032/2> (Accessed October 15, 2024).

10. California Department of Transportation (CalTrans), State Highway Network (SHN) and Postmile System (2018). <postmile.dot.ca.gov/PMQT/PostmileQueryTool.html?> (Accessed October 15, 2204).

11. California Environmental Protection Agency (CA EPA), Technical Advisory: Strategies to Reduce Air Pollution Exposure Near High-Volume Roadways (Research Division of the Air Resources Board ed., 2017). <ww2.arb.ca.gov/resources/fact-sheets/strategies-reduce-air-pollution-exposure-near-high-volume-roadways> (Accessed October 15, 2024).

12. US EPA. Petitions and EPA Response Memorandums related to Lead Emissions from Aircraft that Operate on Leaded Fuel. (updated October 20, 2023) <www.epa.gov/regulations-emissions-vehicles-and-engines/regulations-lead-emissions-aircraft> (Accessed October 15, 2024).

13. US EPA. EPA Determines that Lead Emissions from Aircraft Engines Cause or Contribute to Air Pollution (October 18, 2023) <www.epa.gov/newsreleases/epa-determines-lead-emissions-aircraft-engines-cause-or-contribute-air-pollution> (Accessed October 15, 2024).

14. Federal Aviation Administration (FAA). Airport Data and Information Portal Advanced Facility Search. <adip.faa.gov/agis/public/#/public> (Accessed March 24, 2021).

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16. Miranda, et al., A geospatial analysis of the effects of aviation gasoline on childhood blood lead levels, Environmental Health Perspective, vol. 119 (2011).

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**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.

**Statements of Determination**

**Effect on Small Business**

The Department has determined that there would be the following impacts on small businesses. The laboratories and health care providers' offices that are considered 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.

**Reasonable Alternatives**
As discussed, the Department considered numerous alternatives to the various elements of this action. The Department has made the initial determination 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 while equally effective in implementing the statutory policy or other provisions of law.

**Mandated Use of Specific Technologies, Equipment, Actions, or Procedures**
There is no change in the specific technologies, equipment, actions or procedures required.

**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.