SUPPLEMENT TO THE INITIAL STATEMENT OF REASONS

The California Department of Public Health (Department) has instituted changes to its proposed regulations which are discussed below. These changes are either initiated by the Department or in response to comments that were received during the 45-day public comment period, which ended on July 9, 2025. Additional discussion and rationale to the Initial Statement of Reasons (ISOR), identified below, are added to the rulemaking file.

Overview of Changes

- Clarification that the obligations under the standard of care regulations are limited to activities that health care providers are permitted to perform as licensed health care professionals.
- Grouping all risk factors, other than enrollment in a publicly funded program for low-income children, into one subdivision for ease of reference.
- Revision of the proposed regulations to further streamline the risk factor
 evaluation process and to reduce the potential burden on the regulated public.
 Because the risk factors for lead poisoning impact almost every child statewide,
 the proposed regulations have been revised to clarify that if a child is not
 screened for lead poisoning due to enrollment in a publicly funded program for
 low-income children, the health care provider is permitted to screen the child for
 lead poisoning without further analysis of the risk factors specified under these
 regulations. Although this election is already permitted, this change makes this
 option clear.
- Revision of specific risk factors to include: lead poisoning cases in the same dwelling, including multi-unit dwellings; spices made outside of the United States; and wording changes for additional clarity and consistency.
- Added requirement to provide guidance to a person who refuses to consent to screening.
- Throughout the text various changes were made to reflect the movement, deletion, or addition of regulatory text to accomplish the above revisions. In addition, typographical errors were corrected.

Detailed Discussion of Changes

Update to Repeal of Section 37020

Amend reference to remove typographical error referencing the repeal of Section 37025.

Update to Adoption of Section 37030

Amend authority to insert "Note:"

Updates to Section 37100: Standard of Care on Screening for Childhood Lead Poisoning

Amend subdivision (a). During the 45-day comment period, the American Academy of Pediatrics, California (AAP-CA) sought to clarify that the scope of the requirement that providers take steps that are "reasonable and medically necessary to reduce . . . the child's blood lead level" in subdivision (e) and be responsible for "medically necessary follow-up services" in subdivision (f) does not include exposure investigation, case management, and environmental mitigation. The AAP-CA recognized the importance of these activities but shared concerns that these components exceeded the capacity of the health care provider offices and would pose an undue burden, particularly for solo and small group practices.

In response to these comments, the phrase "within their scope of practice" was added to subdivision (a) to clarify that health care providers are only responsible, under the standard of care regulations, for activities they are permitted to perform as licensed health professionals.

Amend subdivision (a)(3). The Department moved previously noticed language in this provision relating to high-risk ZIP Codes to new subdivision (a)(6)(A) so that all risk factors, other than enrollment in a publicly funded program for low-income children, could be grouped into one subdivision for ease of reference. In its place, the Department has added language to this provision specifying that, if the child is not screened due to enrollment in a publicly funded program for low-income children, then the health care provider may order the child screened for lead poisoning as the risk factors listed in subsequent subdivision (a)(6) are known to impact almost every child statewide.

The addition of this new language is the result of feedback received during the 45-day comment period from the Center for Environmental Health, Children Now, and a retired director of Alameda County Healthy Homes and Child Poisoning Prevention Department.

The new language is intended to further streamline the risk factor evaluation process to reduce the potential burden on the regulated public. Under the initially proposed regulations, the evaluation for screening was intended to operate as follows: First, children would continue to be screened if they are enrolled in a publicly funded program for low-income children. Second, if not screened under this first step, they would be screened if they reside in a high-risk ZIP Code. As the ZIP Code inquiry combines many statutorily required risk factors into one query, and the vast majority of California's ZIP Codes are high-risk, it was anticipated that 99 percent of participants would be screened due to these first two steps. Third, 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 remaining risk factors proposed by the Department in section 37100.

During public comments, stakeholders, including the Center for Environmental Health, Children Now, the AAP-CA, and a retired director of Alameda County Healthy Homes and Child Poisoning Prevention Department, pointed out that current data demonstrates even higher impact numbers than previously envisioned, and expressed concerns that the proposed regulations could be impractical to implement. Further analysis demonstrates that all or nearly all children in California are at risk of lead poisoning because the Department's proposed risk factors for lead poisoning - based on statutory requirements and the Department's own research - impact almost every child statewide. The Department also received input from the AAP-CA that evaluation for high-risk ZIP Codes alone would require extensive work with electronic medical record systems, and that evaluation for all risk factors could be so cumbersome as to potentially delay the meaningful implementation of these regulations by years.

In response to these concerns, and in furtherance of the legislative pronouncement that it is the state's goal that "all children at risk of lead exposure receive blood lead screening tests" the proposed regulations have been revised to clarify that if a child is not screened for lead poisoning due to enrollment in a publicly funded program for low-income children, the health care provider is permitted to screen the child for lead poisoning without further analysis under these risk factors. As these regulations reflect minimum standards, this election was previously permitted, and this change makes this option clear.

With this revision, the evaluation process operates as follows: First, children would continue to be screened if they are enrolled in a publicly funded program for low-income children. Second, if a child is not screened under this first step, the health care provider may elect to screen the child for lead poisoning without further evaluation because the risk factors for lead poisoning impact almost every child statewide. Third, if the child is not screened under step one, or because the health care provider has not elected to screen the child under step two, the health care provider must evaluate the child for lead poisoning under the risk factors proposed by the Department in section 37100.

¹ (HSC, § 105285, subd. (a).)

In making these revisions, the word "tested" has been replaced by the word "screened" to avoid confusion and provide consistent language across the regulations.

Adopt subdivision (a)(4) to require that, if a child is not screened under provision (a)(2) or (a)(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)(6). The word "tested" has been replaced by the word "screened" to avoid confusion and provide consistent language across the regulations. This section is broken out from the originally noticed section (a)(4) for the ease of the reader.

Adopt subdivision (a)(5) to require that, if in the professional judgment of the health care provider, the child is at risk of lead poisoning based on any of the risk factors listed in subdivision (a)(6), the health care provider shall order the child screened for lead poisoning. This section is broken out from originally noticed section (a)(4) for the ease of the reader.

Adopt subdivision (a)(6)(A)

As stated above, the Department has moved previously noticed language, with slight revisions, from subdivision (a)(3) relating to high-risk ZIP Codes to new section (a)(6)(A) so that all risk factors, other than enrollment in a publicly funded program for low-income children, are grouped into one subdivision for ease of reference. The previous language was revised slightly for greater conformity in syntax with the other risk factors listed in this subdivision.

Adopt subdivisions (a)(6)(D) and (a)(6)(E) for consistency with the Informative Digest. Specifically, to remove the parenthetical "(ingesting non-food items)" after "Pica behavior" in the subdivision previously numbered as (a)(4)(C) and to revise the subdivision previously numbered as (a)(4)(D) to now read, "Living or extended travel outside of the United States."

Adopt subdivision (a)(6)(F). The Department has added "or living in the same dwelling, including a multi-unit dwelling, as defined in the California Code of Regulations, title 4, section 8078.3, with an individual or individuals with a blood lead level equal to or greater than 3.5 mcg/dL" to the originally noticed language for this subdivision (previously numbered as (a)(4)(e)). This change was made in response to comments received from the California Center for Environmental Health and Children Now that children living in the same building or multi-unit building may be exposed to the same housing-related lead hazards, such as soil around the building or dust on landings and shared walkways, regardless of if the children interact with each other directly. The Department selected the definition of a multi-unit dwelling already in the California Code of Regulations at title 4, section 8078.3 for the clarity of the regulated public. Since this definition uses "dwelling" instead of building, the Department also used "dwelling" in this subdivision for consistency of language.

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Adopt subdivision (a)(6)H). In response to feedback received from Children Now and Western Center on Law and Poverty, the Department added spices made outside the United States to the list of items specified in this risk factor. Children Now pointed to a <u>Food and Drug Administration alert dated March 6, 2024</u>, that all consumers and retailers should throw away and not buy certain ground cinnamon products.

Amend subdivision (c) to add language to this subdivision specifying that, if consent to screening is refused, the health care provider shall provide oral or written guidance, or both, to the person refusing consent, including, at a minimum, the information contained in "Getting Your Child Tested for Lead" (May 2019), available at the Department's website

(www.cdph.ca.gov/Programs/CCDPHP/DEODC/CLPPB/CDPH%20Document%20Librar y/CLPPB-TestingCard.pdf), incorporated by reference. The Department recognizes that not all families will consent to screening, and have included this language to ensure these families are provided information on the risks of childhood lead poisoning.

Universal changes

Subdivisions were re-numbered or re-lettered as necessary to reflect the movement, deletion, or addition of regulatory text. In addition, typographical errors were corrected.

Documents Relied Upon

The Department added the following documents relied upon to the rulemaking file:

- 168. Klemick, H., Mason, H., & Sullivan, K. (2020). Superfund cleanups and children's lead exposure. Journal of Environmental Economics and Management, 100.
- 169. Ettinger, A. S. and M. J. Brown (2018). "Re: Errata for Prevention of Childhood Lead Toxicity." Pediatrics 141(4). Screening Young Children for Lead Poisoning: Guidance for State and Local Public Health Officials. Atlanta, GA: Centers for Disease Control and Prevention; 1997.
- 170. Cantor, A. G., et al. (2019). "Screening for Elevated Blood Lead Levels in Childhood and Pregnancy: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force." JAMA 321(15): 1510-1526.
- 171. Ruckart, Perri Z., Rebecca Schondelmeyer, Ashley Allen, and Paul Allwood.
 2024. "State-Level Childhood Lead Poisoning Prevention Policies and Practices in the United States: 2022–2023." Pediatrics 154 (Suppl 2): e2024067808N. <doi.org/10.1542/peds.2024-067808N>.
- 172. Abbasi, Ali B., Francis J. DiTraglia, Ludovica Gazze, and Bridget Pals. 2023. "Hidden Hazards and Screening Policy: Predicting Undetected Lead Exposure in Illinois." Journal of Health Economics 90: 102783. <doi.org/10.1016/j.jhealeco.2023.102783>.
- 173. Illinois Department of Public Health. 2025. "IDPH Expands Mandatory Childhood Lead Testing to More ZIP Codes." <dph.illinois.gov/resource-center/news/2025/july/release-20250701.html>.
- 174. Michigan Compiled Laws § 333.5474d. MCL 333.5474d lead testing

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- 175. Wisconsin Statutes ch. 254, subch. II, § 156. ">docs.legis.wisconsin.gov/statutes/statutes/254/ii/156>.
- 176. McMenamin, Shannon B., Susan P. Hiller, Emily Shigekawa, Tyler Melander, and Riti Shimkhada. 2018. "Universal Lead Screening Requirement: A California Case Study." American Journal of Public Health 108 (3): 355–357. <doi.org/10.2105/AJPH.2017.304239>.
- 177. U.S. Food and Drug Administration. (2024, March 6). FDA Alert concerning certain cinnamon products due to presence of elevated levels of lead. U.S. Department of Health and Human Services. https://www.fda.gov/food/alerts-advisories-safety-information/fda-alert-concerning-certain-cinnamon-products-due-presence-elevated-levels-lead.