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Analysis of California Assembly Bill 1316: Childhood Lead Poisoning Prevention

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Publication Date

2017

Data Availability

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California Health Benefits Review Program

Analysis of California Assembly Bill 1316
Childhood Lead Poisoning: Prevention

A Report to the 2017-2018 California State Legislature April 13, 2017

Key Findings:

Analysis of California Assembly Bill 1316
Childhood Lead Poisoning: Prevention

Summary to the 2017-2018 California State Legislature, April 13, 2017

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

AT A GLANCE

California Assembly Bill (AB) 1316 would amend Section 1367.3 of the Health and Safety Code to specify that group health care service plans shall provide coverage for blood lead tests to measure blood lead levels in all children (rather than only in children deemed "at risk" for lead poisoning). AB 1316 proposes changing the standard of care to indicate that all children, not just those deemed to be at risk, should receive a blood lead test unless a parent/guardian refuses. The bill would also require medically necessary follow-up services and appropriate case management if lead poisoning is identified.

1. CHBRP estimates that, in 2018, of the 24.0 million Californians enrolled in state-regulated health insurance, 13.2 million will have insurance subject to AB 1316.
2. **Benefit coverage.** At baseline, CHBRP estimates that 100% of enrollees impacted by this bill have coverage for blood lead tests, but in private plans subject to the bill, they are only routinely provided when a child is deemed at risk. AB 1316 would not appear to exceed the essential health benefits.
3. **Utilization.** In the first year of implementation, CHBRP estimates that for enrollees aged 0 to 72 months in DMHC- and CDI-regulated plans, there is an increase of 252,754 blood lead level tests, which is a utilization increase of 15.6 tests per 1,000, or a 273% utilization increase. Broken down by age group, this increase is comprised of:
    a. **0–24 months:** additional 249,853 enrollees in DMHC- and CDI-regulated plans tested for blood lead levels, an increase of 393%
    b. **24–72 months:** additional 2,901 blood level tests, an increase of 10%.
4. **Expenditures.** Total net expenditures are estimated to increase by $6,221,000 or 0.004% for the year following implementation of the mandate.
5. **Medical effectiveness.** CHBRP concludes that there is insufficient evidence that a universal screening approach for childhood lead exposure is more effective than a targeted approach of screening high-risk children. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.
6. **Public health.** In the first year, CHBRP estimates that an additional 4,777 California children may be accurately detected with blood lead levels (BLLs) ≥4.5 µg/dL due to increased testing, 13.8% of whom may have BLLs ≥9.5 µg/dL.
7. **Long-term impacts.** It stands to reason that changes in childhood lead exposure detection due to AB 1316 could mediate socioeconomic determinants of health at a population level by increasing surveillance and subsequently prevention and large-scale abatement interventions in a more comprehensive population of California children.

CONTEXT

Events on a national scale related to lead exposure have brought increased attention to lead exposure and lead poisoning. Lead exposure and poisoning are associated with cognitive and other health harms that appear to be irreversible. [1] According to the California Department of Public Health (CDPH), common sources of lead include:

- Lead-based paint (pre-1978) in homes and on furniture, including paint chips;
- Lead contaminated soil;
- Dust contaminated with lead from paint or soil;
- Imported cosmetics and metal jewelry;
- Imported pottery and dishware with leaded glaze;
- Some imported foods.

Lead can also be found in water due to lead piping, soldering and industrial lead contamination and in soil. Over the last several years, the Centers for Disease Control and Prevention (CDC) has altered its guidelines related to lead exposure, recognizing that there is no "safe" level of exposure. In 2012, the CDC released a report called "Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention." The CDC made this recommendation based on the growing body of evidence that lead exposure resulting in low blood lead levels can have lifelong health impacts. The report recommended a renewed focus on primary prevention for lead exposure and the CDC asserts that a lower blood lead level threshold could lead to the identification of more children with lead exposure, allowing parents, health care providers and public health professionals to address a child's lead exposure and address community-level exposures to lead.

BILL SUMMARY

Existing code (Section 1367.3 of the Health and Safety Code) requires that every group health care service plan that covers hospital, medical, or surgical expenses offer benefits for the comprehensive preventive care of children. Assembly Bill 1316 would amend Section 1367.3 to specify that group health care service plans shall

[1] Refer to CHBRP's full report for full citations and references.

provide coverage for blood lead tests to measure blood lead levels in all children (rather than only in children deemed "at risk" for lead poisoning as current code states). It would also require appropriate case managing if lead poisoning is identified.

Current code states that preventive care for children shall be consistent with the Recommendations for Preventive Pediatric Health Care, as adopted by the American Academy of Pediatrics. Current code also states that the CDPH shall adopt regulations establishing a standard of care for lead screening, at least as stringent as the most recent United States Centers for Disease Control and Prevention (CDC) screening guidelines, whereby all children shall be evaluated for risk of lead poisoning by health care providers during each child's periodic health assessment. Existing guidelines, such as the Early Periodic Screening Diagnostic and Treatment (EPSDT) guidelines, and the American Academy of Pediatrics guidelines, focus lead-related periodicity schedules on children ages 6 months to 72 months (6 years).

AB 1316 proposes changing the standard of care to indicate that all children should receive a blood lead test unless a parent or guardian refuses. Blood lead tests shall be administered in accordance with the periodicity schedule from the Recommendations for Preventive Pediatric Health Care, as adopted by the American Academy of Pediatrics or the CDC guidelines. AB 1316 does not allow for the Childhood Lead Poisoning Prevention Fund to fund these tests. Based on the bill language, it is unclear what, if any, mechanism for enforcement exists for this standard of care.

AB 1316 would also require that if a child with lead poisoning is identified, the CDPH "shall ensure appropriate case management."[2] CHBRP considered this to be under the purview of CDPH, rather than health plans and health insurers. Therefore, CHBRP does not project anticipated costs for case management following identification of a child with lead poisoning in this report.

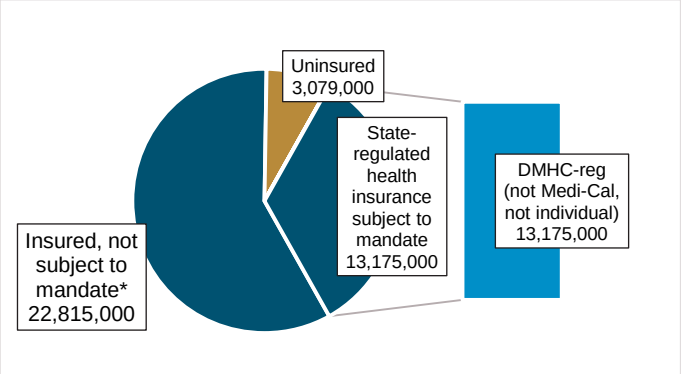
[2] AB 1316 defines "appropriate case management" as health care referrals, environmental assessments, and educational activities, performed by the appropriate person, professional, or entity, necessary to reduce a child's exposure to lead and the consequences of the exposure, as determined by the United States Centers for Disease Control, Control and Prevention, or as determined by the department pursuant to Section 105300.

IMPACTS

Benefit Coverage, Utilization and Cost

As written, AB 1316 only affects DMHC-regulated group plans. However, CHBRP assumes AB 1316 would similarly affect individual DMHC-regulated plans and all CDI-regulated policies because providers who administer the blood lead test would do so for all children under their care as they would not be able to discern the regulating body of the commercial carriers for each of their patients. For an overview of which insurance plans and policies are subject to AB 1316, see Figure 1.

Figure 1. Health Insurance in CA and AB 1316



*Such as enrollees in Medicare or self-insured products.
Source: California Health Benefit Review Program, 2017

Benefit Coverage

Currently, 100% of enrollees with DMHC-regulated group health insurance subject to AB 1316 have coverage for blood lead testing, as do 100% of enrollees with individual coverage and CDI-regulated group coverage who are not subject to the mandate. However, commercial plan enrollees currently receive blood lead testing only after a risk assessment (e.g., questionnaire) has been conducted and a child is deemed at-risk for lead exposure. Thus, CHBRP assumes 0% of commercial enrollees are tested for blood lead without a prior risk assessment.

Current coverage of blood lead testing was determined by a survey of the largest (by enrollment) providers of health insurance in California. Postmandate, 100% of enrollees with private health insurance will continue to have coverage for blood lead testing, but the standard of care will shift to testing all children for lead exposure without a prior risk assessment.

Utilization

Postmandate, CHBRP assumes utilization of blood lead tests would increase per AB 1316's mandate that all children be tested for lead at the 12- and 24-month preventive visit.

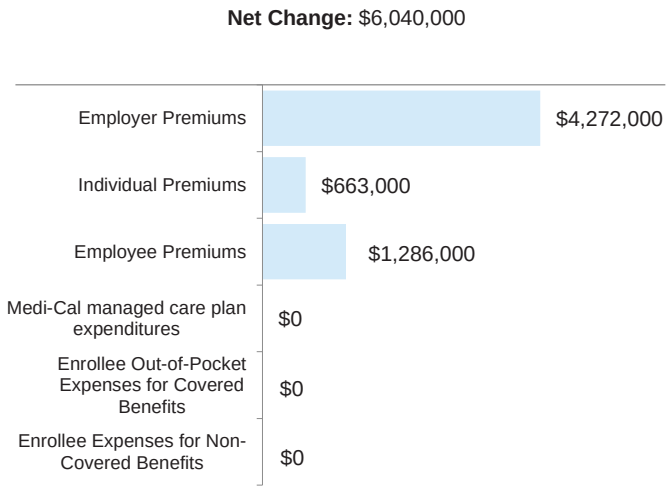
Based on the literature for compliance with blood lead testing, CHBRP assumes postmandate compliance would be 80%. CHBRP assumes this postmandate utilization increase represents a steady state scenario where providers will modify clinical practice in the first year postmandate and will continue this practice in subsequent years. This postmandate utilization increase will result in an additional 252,754 enrollees (aged 0 to 72 months) tested for blood lead: an increase of 273% (see Table 1).

Consistent with the rate of retesting observed in the MarketScan® database as well as CDPH data, CHBRP assumed that of the additional postmandate lead tests, 1.8% would lead to a retest.

Expenditures

AB 1316 would increase total net annual expenditures by $6,221,000 or 0.0043% for enrollees with DMHC-regulated plans and CDI-regulated policies. This comes from the increase in premiums paid by payers for increased utilization of lead testing, which is already a covered benefit at the preventive visit.

Figure 2. Expenditure Impacts of AB 1316, Postmandate, by Category



Source: California Health Benefits Review Program, 2017.

Medi-Cal

In California, all children in publicly supported programs (such as Medi-Cal and WIC) are covered for blood lead level testing. Children are tested at both 12 and 24 months. Children who were not tested at those scheduled ages in publicly supported programs are covered for testing between 24 to 72 months. Therefore, there would be no measurable impact projected on the Medi-Cal population.

CalPERS

CHBRP estimates that total employer premium expenditures for CalPERS HMOs are estimated to increase by $291,000, or 0.0060%. Of the amount CalPERS would pay in additional total premium, about $165,000 would be the cost borne by the General Fund for CalPERS HMO members who are state employees or their dependents.[3]

Number of Uninsured in California

This bill would have no measureable projected impact on the number of uninsured in the state.

Medical Effectiveness

CHBRP concludes that there is insufficient evidence that a universal screening approach for childhood lead exposure is more effective than a targeted approach of screening high-risk children. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

Public Health

In the first year postmandate, CHBRP estimates that an additional 4,777 California children may be accurately detected with blood lead levels (BLLs) ≥4.5 µg/dL due to increased testing, 13.8% of whom may have BLLs ≥9.5 µg/dL. This increased surveillance may lead to the discovery of new "hot spots" of lead exposure risk around the state, with the potential for longer term abatement activities to prevent further exposure. This impact would

[3] It should be noted, however, that should CalPERS choose to make similar adjustments for consistency to the benefit coverage of enrollees associated with CalPERS' self-insured products, the fiscal impact on CalPERS could be greater.

extend past the first year of implementation. CHBRP estimates no further public health impact in the first 12 months due to clear and convincing evidence that the majority of counseling and education interventions to reduce child blood lead levels are ineffective and the minimal proportion of cases which would have BLLs high enough to receive chelation therapy.

Long-term Impacts

It is likely there will continue to be a steady state of enrollees receiving blood lead tests after the first year of implementation as blood lead testing for 12- and 24-month-old children is conducted. As with utilization impacts, it is not likely that expenditures will change if a steady state of testing is assumed.

The long-term public health impacts will include increased childhood lead exposure surveillance and potentially the identification of previously unknown areas where lead exposure is a problem, which could lead to public health environmental abatement efforts and reduced prevalence of elevated childhood lead exposures. Environmental interventions undertaken by public health agencies or at the policy level to remove lead paint from homes or to reduce lead in soil have been found to be effective in lowering blood lead levels within affected communities.

Essential Health Benefits and the Affordable Care Act

AB 1316 would not require coverage for a new state benefit. Preventive care, screening, and immunizations are a covered benefit in California's benchmark plan, Kaiser Foundation Health Plan Small Group HMO 30. AB 1316 appears not to exceed the definition of EHBs in California.

A Report to the California State Legislature

Analysis of California Assembly Bill 1316
Childhood Lead Poisoning: Prevention

April 13, 2017

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ABOUT CHBRP

The California Health Benefits Review Program (CHBRP) was established in 2002. As per its authorizing statute, CHBRP provides the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit bills. The state funds CHBRP through an annual assessment on health plans and insurers in California.

An analytic staff in the University of California's Office of the President supports a task force of faculty and research staff from several campuses of the University of California to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact, and content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications are available at www.chbrp.org.

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Table 1. AB 1316 Impacts on Benefit Coverage, Utilization, and Cost, 2018

	Baseline	Postmandate	Increase/ Decrease	Percentage Change
Benefit coverage				
Total enrollees with health insurance subject to state benefit mandates [a]	24,048,000	24,048,000	0	0%
Total enrollees with health insurance subject to AB 1316 [b]	13,175,000	13,175,000	0	0%
Total children enrollees (0–72 months) with health insurance subject to AB 1316 [c]	1,016,435	1,016,435	0	0%
Total children enrollees (0–24 months) with health insurance subject to AB 1316	326,711	326,711	0	0%
Total children enrollees (25–72 months) with health insurance subject to AB 1316	689,724	689,724	0	0%
Percentage of enrollees with coverage for the mandated benefit, aged 0–72 months	100%	100%	0%	0%
Utilization and unit cost				
Number of enrollees 0–24 and 24–72 months receiving lead tests				
0–24 months	63,651	313,504	249,853	393%
24–72 months	29,014	31,915	2,901	10%
Total Enrollees 0–72 months Receiving Lead Tests [d]	92,665	345,419	252,754	273%
Utilization (Units per 1,000 Covered Enrollees)				
0–24 months	3.9	19.3	15.4	393%
24–72 months	1.8	2.0	0.2	10%
Total Utilization (Units per 1,000 Covered Enrollees) [e]	5.7	21.3	15.6	273%
Average Cost per Unit				
0–24 months	$22	$21	-$1	-4.5%
24–72 months	$23	$23	$0	0.0%
Total Average Cost per Unit	$21	$21	$0	0.0%
Expenditures				
Premium expenditures by payer				
Private employers for group insurance	$64,820,615,000	$64,824,596,000	$3,981,000	0.0061%
CalPERS HMO employer expenditures [f]	$4,884,262,000	$4,884,553,000	$291,000	0.0060%
Medi-Cal Managed Care Plan expenditures [g]	$27,983,856,000	$27,983,856,000	$0	0.0000%
Enrollees for individually purchased insurance	$14,608,214,000	$14,608,877,000	$663,000	0.0045%
Enrollees with group insurance, CalPERS HMOs, Covered California [a] [h]	$20,387,090,000	$20,388,376,000	$1,286,000	0.0063%
Enrollee expenses				
for covered benefits (deductibles, copayments, etc.)	$13,565,623,000	$13,565,623,000	$0	0.0000%
for noncovered benefits [i]	$0	$0	$0	0.00%
Total expenditures	$146,249,660,000	$146,255,881,000	$6,221,000	0.0043%

Source: California Health Benefits Review Program, 2017.
Notes: (a) This population includes persons with privately funded and publicly funded (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans) health insurance products regulated by DMHC or CDI. Population includes enrollees aged 0 to 64 years and enrollees 65 years or older covered by employment-sponsored insurance.
(b) Total enrollees reported in this table include enrollees in all DMHC- and CDI-regulated plans (13,175,000 in DMHC- and CDI-regulated plans of 24,048,000 in all plans subject to state benefit mandates is equivalent to 55%)
(c) Total enrollees aged 0 to 72 months reported in this table include enrollees in all DMHC- and CDI-regulated plans; 0 to 72 months is the recommended age group for blood lead testing per American Academy of Pediatrics guidelines.
(d) Total enrollees counts reported in the table include enrollees in all DMHC- and CDI-regulated plans. The total impact of mandate 252,754 is the sum of: 205,610 enrollees in DMHC group, 21,597 in DMHC individual, 10,764 in CDI-regulated, and 14,784 in CalPERS HMO
(e) Utilization change reported in the table includes aggregated estimates for DMHC- and CDI-regulated plans. The utilization change for DMHC-group alone is 16.73 per 1,000; DMHC-individual is 9.08 per 1,000; CDI-regulated is 16.36; and CalPERS HMO is 16.72 per 1,000
(f) Of the increase in CalPERS employer expenditures, about 56.7% or $165,000 would be state expenditures for CalPERS members who are state employees or their dependents. It should be noted, however, that should CalPERS choose to make similar adjustments for consistency to the benefit coverage of enrollees associated with CalPERS' self-insured products, the fiscal impact on CalPERS could be greater.
(g) Does not include enrollees in County Organized Health System (COHS).
(h) Premium expenditures by enrollees include employee contributions to employer-sponsored health insurance and enrollee contributions for publicly purchased insurance.
(i) Includes only those expenses that are paid directly by enrollees to providers for services related to the mandated benefit that are not currently covered by insurance. In addition, this only includes those expenses that will be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

Key: CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health; COHS=County Organized Health Systems

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[4] conduct an evidence-based assessment of the medical, financial, and public health impacts of AB 1316, Childhood Lead Poisoning Prevention.

If enacted, AB 1316 would affect the health insurance of approximately 13,175,000 enrollees (33.7 percent of all Californians). This represents 55 percent of the 24 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law. If enacted, the law would affect the health insurance of group enrollees in Department of Managed Health Care (DMHC)-regulated plans, exempting individual DMHC-regulated plans, all California Department of Insurance (CDI)-regulated policies, and Medi-Cal (including Medi-Cal managed care). In California, children in state assistance programs, including Medi-Cal, are already covered for universal screening, as all children in California's state assistance programs are assumed to be at-risk for lead exposure (CDPH, 2017a).

According to the California Department of Public Health (CDPH), common sources of lead include:

- Lead-based paint (pre-1978) in homes and on furniture, including paint chips;
- Lead contaminated soil;
- Dust contaminated with lead from paint or soil;
- Imported cosmetics;
- Imported pottery and dishware with leaded glaze;
- Some imported foods; and
- Metal jewelry.

Lead can also be found in water due to lead piping, soldering and industrial lead contamination and in soil (Craft-Blacksheare, 2017, CDC, 2015).

Bill-Specific Analysis of AB 1316, Childhood Lead Poisoning Prevention

Bill Language

Existing code (Section 1367.3 of the Health and Safety Code) requires that every group health care service plan that covers hospital, medical, or surgical expenses shall offer benefits for the comprehensive preventive care of children.

Assembly Bill 1316 would amend Section 1367.3 to specify that group health care service plans shall provide coverage for blood lead tests to measure blood lead levels in all children (rather than only in children deemed "at risk" for lead poisoning as current code states). AB 1316 also states that health care providers shall be responsible for medically necessary follow-up services. The bill would also require that CDPH ensures appropriate case management when a child is identified with lead poisoning. Per the bill language, CDPH may contract with public or private entities, including local agencies, to conduct case management. The bill defines case management as "health care referrals, environmental assessments, and educational activities, performed by the appropriate person, professional, or entity, necessary to reduce a child's exposure to lead and the consequences of the exposure, as determined by the United States Centers for Disease Control and Prevention (CDC) or CDPH pursuant to Section 105300 of the Health and Safety Code.

[4] CHBRP's authorizing statute is available at http://chbrp.org/faqs.php.

Current code states that preventive care for children shall be consistent with the Recommendations for Preventive Pediatric Health Care, as adopted by the American Academy of Pediatrics. Current code also states that the CDPH shall adopt regulations establishing a standard of care for lead screening, at least as stringent as the most recent CDC screening guidelines, whereby all children shall be evaluated for risk of lead poisoning by health care providers during each child's periodic health assessment.

AB 1316 proposes changing the standard of care to indicate that all children should receive a blood lead test unless a parent or guardian refuses. Blood lead tests shall be administered in accordance with the periodicity schedule from the Recommendations for Preventive Pediatric Health Care, as adopted by the American Academy of Pediatrics or the CDC guidelines.

Existing law has established the Childhood Lead Poisoning Prevention Fund wherein fees are imposed on manufacturers formerly and/or presently engaged in commerce of lead or products containing lead, or responsible for identifiable sources of lead. AB 1316 does not allow for the Childhood Lead Poisoning Prevention Fund to finance these blood lead tests.

The bill language uses "screen" as the medical procedure by which the concentration of lead in whole venous blood is measured. For the purpose of this analysis, CHBRP will use the following phrasing and definitions:

- Risk assessment: a questionnaire or question from a health care provider that determines whether a child is at a higher risk for lead exposure and/or an elevated blood lead level.

- Blood lead test: a capillary or venous blood draw test to measure lead levels in blood. A capillary test requires a finger prick and a few drops of blood. A venous test requires a venous blood draw.

While AB 1316 bill language states blood lead is to be determined via the measurement of lead in venous blood, blood lead tests are also performed via capillary tests during preventive visits to providers. CHBRP assumes providers would continue their standard clinical practice — whether it is to use capillary and/or venous testing — to obtain blood samples of their patients, and thus providers who currently routinely use capillary blood specimen collection as part of their preventive visit would not switch to using venous blood collection due to AB 1316 postmandate. For the full bill language, see Appendix A.

Analytic Approach and Key Assumptions

While as written AB 1316 only affects DMHC-regulated group plans, CHBRP assumes AB 1316 would similarly affect individual DMHC-regulated plans and all CDI-regulated policies because it would alter the provider standard of care for blood lead testing. Providers who administer the blood lead test would do so for all children of a certain age under their care as they would not be able to discern the regulating body of the commercial carriers for each of their patients prior to administering the blood test. CHBRP presumes that the new standard of care would be the main driver of change from this bill.

CHBRP does not assume that compliance with this bill would reach 100% among providers and parents or guardians of child enrollees. Based on the literature for compliance with blood lead testing, CHBRP assumes postmandate compliance would be 80% (Vivier et al., 2001; Wilken et al., 2004). CHBRP assumes this postmandate utilization increase represents a steady state scenario such where providers would modify clinical practice in the first year postmandate and continue this practice in subsequent years. This postmandate utilization increase would result in an additional 252,754 enrollees (aged 0–72 months) tested for blood lead at which translates into an increase of 273 percent overall among children in this age group (see Table 1).

Consistent with the rate of retesting observed in the MarketScan® database as well as CDPH data, CHBRP assumed that of the additional postmandate lead tests associated with preventive visits, 1.8% would lead to a retest (e.g., as a result of a false positive test).

It is important to note that CHBRP's analysis of proposal benefit mandate bills address the incremental effects — how the proposed legislation would impact benefit coverage, utilization, costs, and public health. CHBRP's estimates of these incremental effects are presented in this report.

Interaction with Existing Requirements

Health benefit mandates may interact and align with the following federal and state mandates or provisions.

Changing CDC Requirements

Blood lead level guidelines

Over the last several years, the Centers for Disease Control and Prevention (CDC) have altered their guidelines related to lead exposure. Previously, the CDC defined 10 micrograms per deciliter (µg/dL) of lead in the blood as a "level of concern." However, in 2012, the CDC's Advisory Committee on Childhood Lead Poisoning Prevention released a report called "Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention." The report recommended elimination of the term "blood lead level of concern" because evidence representing a diverse group of children found that low blood lead levels were associated with IQ deficits; attention-related behaviors; decreased academic achievement; and cardiovascular, immunological, and endocrine effects. Furthermore, these impacts appeared to be irreversible. The report also declared that these negative impacts are not confined to children of lower socioeconomic status groups. The report recommended a renewed focus on primary prevention (CDC, 2012).

In place of a "blood lead level of concern" of 10 µg/dL, the report recommended a reference value based on the 97.5th percentile of the National Health and Nutrition Examination Survey (NHANES) blood lead level distribution for children aged 1 to 5 years, which is currently 5 µg/dL. The committee recommended that 5 µg/dL of lead in the blood be used to identify an elevated blood lead level in children. At the time of the 2012 report, the committee estimated that about 450,000 children in the U.S. had blood lead levels above the 5 µg/dL cut off and should subsequently receive lead education, medical monitoring, and environmental assessments (CDC, 2012).

Universal versus targeted screening

In 2009, the CDC Advisory Committee on Childhood Lead Poisoning updated its recommendations for targeted versus universal screening. The CDC recommended that in states where existing data demonstrates that universal screening is not the most effective way to identify lead exposure, states should target lead screening toward groups of children that are at higher risk for elevated blood lead levels. The CDC noted that "a new blood lead screening strategy is needed that accounts for local variations in risk and disparities at the local level" (Wengrovitz and Brown, 2009). The CDC update noted that state lead poisoning prevention programs should work with state Medicaid programs to analyze existing data on lead exposure and lead screening patterns.

In 2012, the Centers for Medicare & Medicaid Services (CMS) aligned with the CDC's recommendations on lead screening for Medicaid eligible children. Together, the CDC and CMS developed a protocol for states that wished to apply to move from a universal screening program for Medicaid-eligible children to a

targeted approach. In order to switch to a targeted approach, state Medicaid programs and health departments must demonstrate with data that universal screening is not needed. State Medicaid programs and health departments in states that switch to a targeted approach must also create new lead screening guidelines for providers. States that do not have this type of data must continue to universally screen Medicaid-eligible children for lead exposure (CMS, 2012). At the time of this report, only one state had switched to a targeted Medicaid screening program: Arizona in 2014 (CMS, 2017). The Arizona Department of Health Service's three-year goal is to increase the utility of their targeted screening plan by 1) increasing screening rates to 85% in targeted ZIP codes; 2) assessing the indicators used to develop the targeted high-risk ZIP codes, and; 3) reducing the number of targeted high-risk ZIP codes (ADHS, 2014).

Medicaid and Early Periodic Screening Diagnostic and Treatment

All children in Medicaid (both funded through title XIX or XXI) are required to receive blood lead tests at 12 and 24 months (CMS, 2017). Any child enrolled in Medicaid between 24 and 72 months who did not receive a test at the scheduled times must receive a blood lead test. Administering the risk assessment questionnaire without a blood lead test does not meet requirements for children enrolled in Medicaid (CMS, 2017).

Through the Early and Periodic Screening Diagnostic and Treatment (EPSDT) benefit, Medicaid provides coverage for any medically necessary service to address conditions identified by screening, regardless of whether a necessary service is covered through the state plan (CMS, 2017). Additionally, Medicaid reimburses for "lead investigations" in the primary residence or home of a child with an elevated blood lead level to identify source(s) of lead exposure (CMS, 2017). Health care providers who meet the specific state's qualifications may provide the home or residence lead investigation.[5]

Periodicity Schedules

CHBRP has considered the following two blood lead risk assessment and testing schedules to be the most relevant for this bill: the Early Periodic Screening Diagnostic and Treatment guidelines and the American Academy of Pediatrics' Bright Futures guidelines.

As stated above EPSDT requires a blood lead test for children enrolled in Medicaid at 12 months and 24 months. If any child enrolled in Medicaid between 24 and 72 months does not have a record of a previous blood lead test, they must receive one (CMS, 2017).

The Recommendations for Preventive Pediatric Health Care, also known as Bright Futures, published by the American Academy of Pediatric recommends a risk assessment for lead exposure and subsequent blood lead test if the risk assessment is positive. The Bright Futures periodicity schedule recommends a risk assessment at well-child visits for the following ages: 6, 9, 12, 18, 24 months and at 3, 4, 5 and 6 years of age (AAP, 2016, 2017).

State Requirements

California law and regulations

In 1986, the California Legislature declared that childhood lead exposure was the state's most significant childhood environmental health problem (CDPH, 2017a).[6] The Childhood Lead Poisoning Prevention Acts

[5] Medicaid Manual section 5123.2.D.1.a

[6] California Health & Safety Code § 124125 to 124165

of 1986 and 1989 established the Childhood Lead Poisoning prevention Program within the CDPH and directed the program to reduce childhood lead exposure in the state.[7] Subsequently, the Childhood Lead Poisoning Act of 1991 gave the CDPH authority to define blood lead testing protocols, and to identify and ensure follow up services for children exposed to lead.[8] The state also requires that laboratories that analyze human blood for lead levels to report all results (not limited to children) to the state.

Current statute related to blood lead testing for California children

All children who are enrolled in state assistance programs in California, including but not limited to Medi-Cal, are automatically considered at-risk for lead exposure and are tested for blood lead levels (CDPH, 2017a; CDPH, 2016c; DHS, 2002).

Relevant to DMHC-regulated plans, Section 1367.3 of the California Health and Safety code requires health care service plans covering hospital, medical, or surgical expenses on a group basis to offer benefits that include testing for blood lead levels in at-risk children.

Relevant to CDI-regulated policies, Section 10119.9 of the California Insurance Code requires insurers offering individual or group disability insurance policies covering hospital, medical, or surgical expenses to offer coverage for blood lead testing for covered children.

Similar requirements in other states

Currently, 11 states and Washington, D.C., require blood lead tests for all children: including AL, CT, DE, IA, LA, MA, MD, NJ, NY, RI, and VT (Schneyer and Pell, 2016).

Federal Requirements

Affordable Care Act

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how AB 1316 may interact with requirements of the ACA as it presently exists in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[9]

Any changes at the federal level may impact the analysis or implementation of this bill, were it to pass into law. However, CHBRP analyzes bills in the current environment given current law.

Essential Health Benefits

State health insurance marketplaces, such as Covered California, are responsible for certifying and selling qualified health plans (QHPs) in the small-group and individual markets. QHPs are required to meet a minimum standard of benefits as defined by the ACA as EHBs. In California, EHBs are related to

[7] California Health & Safety Code § 124125 to 124165
[8] California Health & Safety Code § 105275 to 105310
[9] The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs sold in Covered California — to cover 10 specified categories of EHBs. Resources on EHBs and other ACA impacts are available on the CHBRP website: http://www.chbrp.org/other_publications/index.php.

the benefit coverage available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.[10,11]

States may require QHPs to offer benefits that exceed EHBs.[12] However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the QHP.[13,14] State rules related to provider types, cost sharing, or reimbursement methods would *not meet* the definition of state benefit mandates that could exceed EHBs.[15]

AB 1316 would not require coverage for a new state benefit. Preventive care, screening, and immunizations are a covered benefit in California's benchmark plan, Kaiser Foundation Health Plan Small Group HMO 30. AB 1316 appears not to exceed the definition of EHBs in California.

Federally selected preventive services

The ACA requires that nongrandfathered group and individual health insurance plans and policies cover certain preventive services without cost sharing when delivered by in-network providers and as soon as 12 months after a recommendation appears in any of the following:[16]

- The United States Preventive Services Task Force (USPSTF) A and B recommendations;
- The Health Resources and Services Administration (HRSA)-supported health plan coverage guidelines for women's preventive services;
- The HRSA-supported comprehensive guidelines for infants, children, and adolescents, which include:
    - The Bright Futures Recommendations for Pediatric Preventive Health Care; and
    - The recommendations of the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children; and

The Advisory Committee on Immunization Practices (ACIP) recommendations that have been adopted by the Director of the Centers for Disease Control and Prevention (CDC).

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[10] The U.S. Department of Health and Human Services (HHS) has allowed each state to define its own EHBs for 2014 and 2015 by selecting one of a set of specified benchmark plan options. CCIIO, Essential Health Benefits Bulletin. Available at: cciio.cms.gov/resources/files/Files2/12162011/essential_health_benefits_bulletin.pdf.
[11] H&SC Section 1367.005; IC Section 10112.27.
[12] ACA Section 1311(d)(3).
[13] State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: www.gpo.gov\fdsys\pkg\FR-2013-02-25\pdf\2013-04084.pdf.
[14] However, as laid out in the Final Rule on EHBs HHS released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the state's EHBs and there would be no requirement that the state defray the costs of those state mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.
[15] Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.
[16] A resource on this ACA requirement is available on the CHBRP website: www.chbrp.org/other_publications/index.php.

As stated previously, the Bright Futures Recommendations for Pediatric Preventive Health Care include a schedule for lead risk assessment to be performed with appropriate action to follow, if positive. The guidelines recommend a risk assessment at well-child visits for the following ages: 6, 9, 12, 18, 24 months and at 3, 4, 5 and 6 years of age (AAP, 2016, 2017).

BACKGROUND ON CHILDHOOD LEAD EXPOSURE

This section provides context for the consideration of the impacts of AB 1316 by defining childhood lead exposure and poisoning, sources of exposure, symptoms and short- and long-term health and non-health effects (e.g., educational attainment), risk assessment and testing procedures, and methods for preventing and abating lead exposure, or in more severe cases, medical treatment to remove lead from the body.

Childhood Lead Exposure: Sources, Symptoms and Effects, Risk Assessment & Testing, and Prevention, Abatement, & Treatment

Sources of Lead Exposure

The toxic effects of lead (Pb) on human health are well known, and young children face the most serious effects from prolonged exposure, even at low levels (Flora et al., 2012; Needleman, 2004). Childhood lead exposure and poisoning in the U.S. can occur through multiple pathways; the most common source of high-dose exposure is through lead paint used in homes prior to 1978. Lead can also be found in water, soil, and household products such as imported traditional cookware, jewelry, candy, food, and folk remedies, particularly coming from developing countries in South Asia, Southeast Asia, East Asia, Africa, and Latin America and the Caribbean (CDC, 2015). Babies may also be exposed to lead in utero or through their mother's breastmilk (CDC, 2010). Lead piping and soldering or industrial lead contamination can leach into public water sources, as has been highlighted in recent coverage of lead exposure in Flint, Michigan (Craft-Blacksheare, 2017). Although lead service pipes in California water systems are thought to be rare, recent analyses suggest that approximately 100 water systems across California exceed regulations, with more than 10% of water samples taken between 2012 and 2015 showing elevated lead levels (Newkirk, 2016; Young and Nichols, 2016). In addition, a federal law passed in 1986 prohibits the use of lead pipes in residential and non-residential facilities that provide water for human consumption, but home plumbing installed prior to this law may still contain lead.[17] Although laws to remove lead from gasoline in the 1970s reduced exposure, dust and soil near roadways and industrial zones may still contain high levels of lead deposited over time from car exhaust and smoke (Miracle, 2017; Tong et al., 2000). Some forms of industry, such as battery recycling plants, may also be a source of lead exposure. For example, a battery recycling plant in Vernon, CA released harmful levels of lead and arsenic into the environment and surrounding communities (County of Los Angeles, Public Health, 2017). While stringent U.S. regulations have reduced the risk of exposures from other household products, imports from the regions mentioned above may contain lead either within the products themselves or from the preparation or packaging process CDC, 2015).

Symptoms and Effects of Lead Toxicity

The symptoms and long-term health effects of lead toxicity in children vary with the duration and intensity of the exposure (Miracle, 2017). Acute lead toxicity is brought on by exposure to a large dose of lead over a short period of time, and is relatively rare in the U.S., generally occurring due to occupational exposures in adults; acute lead poisoning can result in severe neurological symptoms, organ failure, and death (Flora et al., 2012). Acute toxicity is not a focus of this analysis due to its relative rarity, higher prevalence among adults, and rapid onset and severity of symptoms. This analysis focuses on chronic lead toxicity, caused by smaller doses of lead over a longer period of time, for which most children are asymptomatic

[17] California Department of Toxic Substances Control. Lead in Plumbing Legislation. Available at: http://www.dtsc.ca.gov/PollutionPrevention/LeadInPlumbing_Legislation.cfm. Accessed on April 6, 2017.

and require risk assessment and testing to detect any elevated blood lead level.[18] In children, who do show symptoms, low levels of lead exposure may manifest first as irritability, a lack of focus, headache, and memory loss (Flora et al., 2012). Greater exposure to lead may result in early signs of encephalopathy (i.e., progressive degeneration of brain tissue) such as abdominal pain, anemia, a lack of coordination, and behavioral changes, leading to episodes of confusion or disorientation and seizures (Ahamed et al., 2011; Flora et al., 2012; Needleman, 2004).

In the longer term, even low levels of childhood lead exposure have been linked to slower cognitive development and physical growth, autism, attention deficit hyperactivity disorder (ADHD), learning disabilities and lower educational attainment, and anti-social behavioral issues (Adams et al., 2013; Needleman et al., 1990; Nigg et al., 2010; Reyes, 2015). On a societal level, reductions in lead exposure after regulations such as the prohibition of lead paint and the removal of leaded gasoline from the U.S. market in the 1970s have been linked to reductions in crime years later as children who matured in lower-lead environments became adults (Boutwell et al., 2016; Nevin, 2007; Taylor et al., 2016).

Lead Exposure Risk Assessments and Blood Testing Recommendations

Current American Academy of Pediatrics (AAP) preventive health recommendations call for pediatricians to ask parents a set of risk assessment questions and, if deemed "at risk," to conduct initial finger prick blood-lead level (BLL) testing and confirmatory venous blood testing at 6, 9, 12, 18, and 24 months, and at ages three through six years (Richerson et al., 2017). California Department of Public Heath (CDPH) guidelines are similar, directing pediatricians to ensure that a child[19] is screened for risk status at least once by 12 months and again by 24 months, or if no prior risk assessment has been done, between the ages of three and six years; during these risk assessments, lead tests should be ordered for children if their parents answer "yes" or "don't know" to the question: "Does your child live in, or spend a lot of time in, a place built before 1978 that has peeling or chipped paint or that has been recently remodeled?" (CDPH, 2012). Lead tests are also indicated if a parent requests it, if there is a suspected exposure, or if the child has lived in or traveled to a country with environmental lead issues (CDPH, 2012). California Code of Regulations Title 17, Division 1, Chapter 9: Screening for Childhood Lead Poisoning mandates that all children in publicly funded programs such as Medi-Cal, WIC, or the Targeted Low Income Children's Program (TLICP), formerly known as Healthy Families, should receive a blood lead test as these children are automatically considered "high risk" (CDPH, 2012).

There is no known "safe" detected BLL; a low exposure may be less than 5 µg/dL (micrograms per deciliter), while values equal to or greater than 70 µg/dL would be a very high dose with severe health effects (Raymond and Brown, 2017). Nationally, experts recommend using a BLL that reflects the top 2.5% of a nationally representative sample of U.S. children aged 1 to 5 for reporting cases of lead exposure to public health authorities, which is currently approximately 5 µg/dL (CDC, 2017). The state of California requires *all* lead testing results be reported to the Childhood Lead Poisoning Prevention Branch of the CDPH, and defines a case of lead poisoning as "any child (under age 21) who is found with a single BLL of ≥14.5 µg/dL (venous) or persistent BLLs ≥9.5 µg/dL, taken at least 30 days apart and with the second test being venous" (CDPH, 2016a; CDPH, 2016b).

Lead Exposure Prevention, Abatement, and Treatment

In California, children with at least two elevated blood lead level tests above 15 µg/dL taken at least 30 days apart are referred by their physician to the local public health department Childhood Lead Poisoning

[18] Personal communication with content expert, Dr. Alex Kemper, Duke University, Durham, NC; March 2017.
[19] Only for children who are not already in a publicly funded program that mandates universal lead testing, per EPSDT requirements (see *Policy Context* section).

Prevention Branch for case management, including evaluation and follow-up by a public health nurse, environmental inspections/investigation, and recommendations or referrals for remediating any sources of lead exposure (CDPH, 2008). It is important to note the effectiveness of any intervention to reduce blood lead levels is limited because most of the damage done by lead exposure is permanent, and cannot be reversed, but can only avert further damage through prolonged exposure (Lanphear et al., 2016).[20] Prevention and abatement through the elimination of environmental sources of lead is the main strategy to reduce the prevalence and incidence of lead poisoning, such as removing or sealing lead paint; wiping shoes clean of soil when entering the home and dusting frequently; avoiding candy, traditional remedies, and cookware brought by friends and relatives from developing countries; and ensuring that their child has a balanced and nutritious diet (foods rich in iron, calcium and vitamin C can reduce the absorption of any ingested lead) (CDPH, 2013; USDA, 2016). If lead in tap water is an issue, preventive measures include using a filter that is certified to remove lead, to only use cold water for drinking and cooking, and running the water for at least 30 seconds before using any if the faucet has not been turned on for a few hours (EPA, 2013).

Large-scale soil abatement and lead paint removal interventions to improve public health outcomes have been shown to be costly but effective in reducing children's blood lead levels in high-prevalence areas around the U.S., including in Butte, Montana, with a history of mining and Syracuse, New York, with a history of industrial activity (Schoof et al., 2016; Shao et al., 2017). Studies on the effectiveness of case management, residential/environmental inspection, and abatement activities on reducing child blood lead levels have mixed results; some have found significant reductions in child BLLs attributable to these policies or interventions (Aizer et al., 2015; Billings and Schnepel, 2015; Kennedy et al., 2014), but others, especially those which included or focused more on educational interventions to reduce lead exposures in the household, have found no significant differences (Campbell et al., 2012; Yeoh et al., 2014).

Medical treatments for lead toxicity (e.g., chelation therapy, calcium and iron supplements) have limited effectiveness and cannot reverse systemic damage caused by lead (Flora et al., 2012; Lanphear et al., 2016; Miracle, 2017). According to CDPH Guidelines, medical interventions for lead poisoning are not typically recommended for BLLs below 45 µg/dL (CDPH, 2008). Medical treatments for lead exposure are described in greater depth in the *Medical Effectiveness* section of this analysis.

Prevalence of Blood Lead Testing and Child Exposure to Lead in California

Approximately 20% of California children under 72 months of age were tested for lead in 2012 (i.e., 603,357 out of 3,016,000), and the proportion of children with elevated blood lead levels ≥4.5 µg/dL[21] in California (1.9%) is lower than the national average (4.3%) (CDPH, 2015a; Shah et al., 2017). Table 2 describes the prevalence of lead exposure in California by child age groups and location in 2012; overall, 1.9% of children under 72 months of age had elevated BLLs (CDPH, 2015a).[22] Among an additional 47,045 older children and young adults aged 6 to 21 years, a total of 2.3% had elevated BLLs.[23] False positive test results were removed from the data to derive these estimates, but the number of false positives is not reported. It is important to note that in general, regulations imposed over the last four decades have reduced the prevalence of lead exposure across the U.S. by 84%, with the proportion of children with BLLs ≥10 µg/dL falling from 8.6% in the late 1980s to 1.4% in the early 2000s (Jones et al., 2009).

[20] Personal communication with content expert, Dr. Alex Kemper, Duke University, Durham, NC; March 2017.
[21] The California elevated blood lead level threshold is reported as 4.5 µg/dL, differing from the 5 µg/dL reported nationally; CDPH indicates that 4.5 µg/dL may be rounded up to 5 µg/dL for comparison purposes.
[22] 1.6% of children under 72 months of age had BLLs ≥4.5 to <9.5 µg/dL, and 0.3% with BLLs ≥9.5 µg/dL.
[23] 1.9% age six to 21 had BLLs ≥4.5 to <9.5 µg/dL, and 0.4% had BLLs ≥9.5 µg/dL.

Table 2. Proportion of California Children with Blood-Lead Levels <4.5 µg/dL and ≥4.5 µg/dL by Age Group and Geographical Location in 2012

	Proportion of CA Children with Elevated BLLs (≥4.5 µg/dL)	Total Number of Children Tested
Child Age in CA		
California children age <72 months	1.9%	603,357
California children age 6 to 21 years	2.3%	47,045
CA Counties with Highest Percent of Children Exposed to Lead (a)		
Trinity	20.0%	35
Sierra	12.5%	8
Siskiyou	6.1%	163
Humboldt	7.0%	1,626
Nevada	5.3%	557
CA ZIP Codes with Highest Percent of Children Exposed to Lead (a)		
Fresno: 93706, 93702, 93703 (Fresno County)	5.4-13.6%	3,114
Eureka: 95501 (Humboldt County)	10.9%	303
Oakland/Fruitvale: 94601 (Alameda County)	7.6%	502
Seaside: 93955 (Monterrey County)	7.4%	672
Selma: 93662 (Fresno County)	6.6%	515
Los Angeles: 90011, 90037, 91770 (LA County)	5.2-5.3%	6,118

Sources: CDPH, 2015b; CDPH 2015a; Pell and Schneyer, 2016; Schneyer and Pell, 2017.

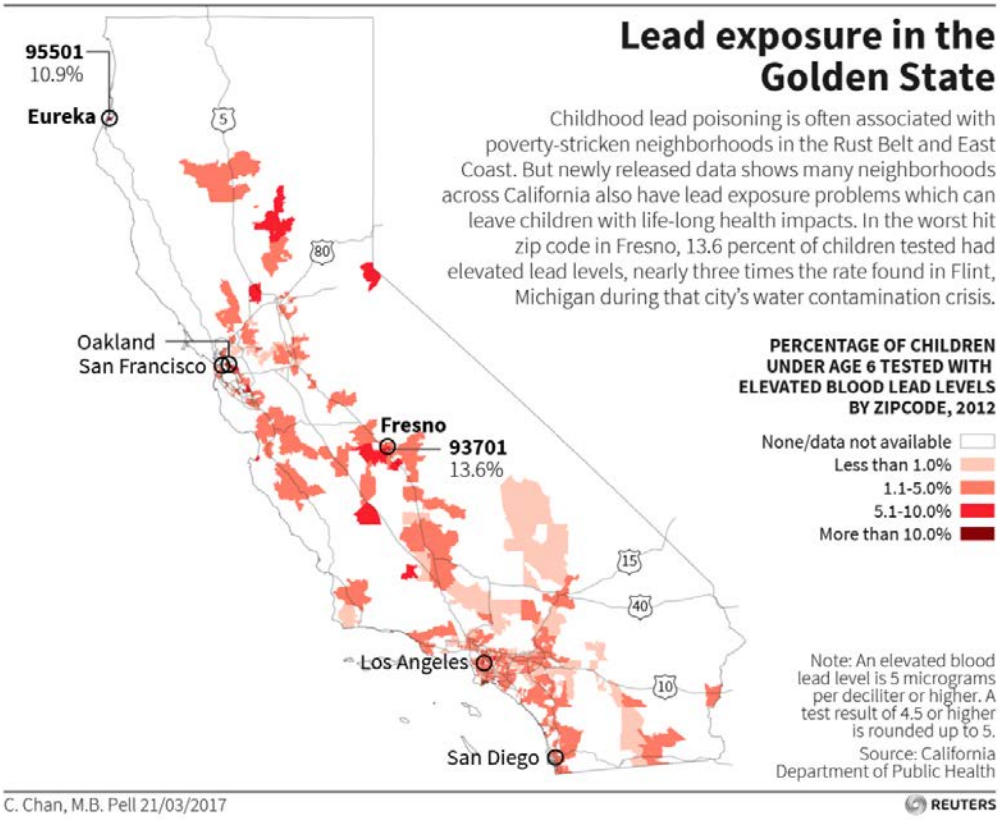
Note: CDPH includes blood lead levels reported from the analyzing laboratory as "<5µg/dL" in the category "BLL <4.5"

(a) Children aged <72 months only

Key: CA=California, BLL=Blood Lead Level

In 2012, rural Northern California counties of Trinity, Sierra, Siskiyou, Humboldt, and Nevada had between 5% and 20% of children who were tested show BLLs ≥4.5 µg/dL (CDPH, 2015a). Several ZIP codes within urban or semi-urban areas also showed elevated prevalence of lead exposure, with between 5.0% and 13.6% of children tested in parts of the cities of Oakland, Fresno, Selma (near Fresno), and Los Angeles having blood-lead levels ≥4.5 µg/dL (CDPH, 2015b; Schneyer and Pell, 2017). Figure 1 demonstrates how exposure to lead varies geographically across California, with some communities facing higher risks than others (Ibarra, 2017; Pell and Schneyer, 2016; Schneyer and Pell, 2017). Recent news reports suggest that contaminated water systems may play a larger role than previously thought in this geographic distribution of lead exposures in California (Newkirk, 2016; Young and Nichols, 2016).

Figure 1. Proportions of Children with Elevated Blood Lead Levels (≥4.5 µg/dL) across California using 2012 CDPH data



Source: Image from Schneyer and Pell, 2017.

Health Disparities[24] in Childhood Lead Exposure and Access to Risk Assessment and Testing

"'Health disparity' denotes differences, whether unjust or not. 'Health inequity' on the other hand, denotes differences in health [status or] outcomes that are systematic, avoidable, and unjust." (Wyatt et al., 2016). CHBRP found literature identifying differences by age, gender, and race/ethnicity. No disparities were found by gender identity or sexual orientation.

Age

Young children are more vulnerable to environmental toxins in general compared to older children and adults due to their propensity for putting objects in their mouth (i.e., increased risk of exposure), how their digestive system absorbs more than adults (i.e., receiving a higher dose if exposed), and because the systems within their bodies, especially the central nervous system, are still developing (i.e., more severe health effects if exposed) (Needleman, 2004). Consequently, lead poisoning in children is more likely to affect their central nervous system (i.e., brain functioning), whereas in adults the peripheral nervous system is more affected (Finkelstein et al., 1998).

Gender

Findings are mixed regarding gender disparities in childhood exposure to lead; a case-control study set in Cleveland, Ohio, of children aged 3 to 4 years found that boys were 3.1 times more likely than girls to present with elevated BLLs (Raymond et al., 2009). However, a study of national data (i.e., NHANES survey) found no significant differences in BLLs for boys and girls aged 5 and younger between 1988 and 2004 (Jones et al., 2009). Outcomes of lead exposure may differ by gender; limited data from Krakow, Poland, and Omaha, Nebraska, suggest that boys exposed to lead either prenatally or as young children, even at very low doses, show significant cognitive delays compared to unexposed boys, while lead-exposed girls perform as well or nearly as well as unexposed girls (Jedrychowski et al., 2009; Khanna, 2015). It has been suggested that estrogen, estradiol, and other hormones more present in females may have protective effects against neurotoxins, preventing the loss of brain matter (Brubaker et al., 2010; Chetty et al., 2007; Khanna, 2015).

Race/Ethnicity

At the national level, a review of multiple studies found that among children aged 5 and younger, African American children were more likely to have higher rates of lead in their blood than non-Hispanic white or Hispanic children; however, the most recent data from the studies included in the review was from 2004 (White et al., 2016). The previously mentioned case-control study set in Cleveland, Ohio, found that African American children were 1.5 times more likely to have a high BLL compared to non-Hispanic white children. Furthermore, African American children's BLLs tended to increase if a child had a second test, compared to decreases in BLLs for white children (Raymond et al., 2009).

Children in immigrant and refugee families from diverse racial and ethnic backgrounds may also be at greater risk for exposure to lead, either through recently living in a foreign country or being exposed to products from a foreign country that contain lead (Cleveland et al., 2008; Eisenberg and Van

[24] Several competing definitions of "health disparities" exist. CHBRP relies on the following definition:
Health disparity is defined as the difference in health outcomes between groups within a population. While the terms may seem interchangeable, "health disparity" is different from "health inequity." "Health disparity" denotes differences, whether unjust or not. "Health inequity," on the other hand, denotes differences in health [status or] outcomes that are systematic, avoidable, and unjust." Wyatt et al., 2016.

Wijngaarden, 2008; Ling et al., 2002; Salehi et al., 2015; Tehranifar et al., 2008). One case-control study in New York City found that adjusting for other housing and behavioral risk factors, immigrant children (primarily from Haiti, Pakistan, Mexico, and the Dominican Republic) who had lived in another country within the last six months prior to their blood test were 11 times more likely to qualify as lead-poisoned (i.e., >20 µg/dL in a single test or 15-19 µg/dL in two tests at least three months apart) than U.S. born children who had never traveled to or lived in another country (Tehranifar et al., 2008).

Social Determinants of Health[25] in Childhood Lead Exposure

Per statute, CHBRP includes discussion of social determinants of health (SDoH) that may contribute to the prevalence and/or outcomes of exposure to lead. SDoH include factors outside of the traditional medical care system that influence health status and health outcomes (e.g., income, education, geography). In the case of AB 1316, evidence shows that geographical location and socioeconomic status (SES) may contribute to childhood lead exposure, access to risk assessment/testing, compliance with prevention or treatment, and lead-related health outcomes. In particular, lead exposure is linked to lower cognitive and educational attainment, which impacts SES later in life (Aizer et al., 2015; Billings and Schnepel, 2015; Reuben et al., 2017). Evidence indicates that the aforementioned SDOH may contribute in part to the racial/ethnic disparities described in this analysis due to systemic inequalities in SES.

Geographic Location

There are both rural and urban areas within California that are known to have higher prevalence of childhood lead exposure. Rural California areas are believed to be at risk for child lead exposures due to a combination of older housing with lead paint and fixtures, general infrastructure issues, and local levels of poverty, but not due to surface water lead, which is sometimes an issue in areas with defunct mining industries (Houston, 2016). Urban areas with persistent air pollution issues have elevated levels of lead in the soil due to the legacy of leaded gasoline and other industrial contaminants (Mielke et al., 2010). Older housing in impoverished urban neighborhoods may also be partially to blame for higher rates of lead exposure in specific areas and linked to socioeconomic status (SES) and racial/ethnic disparities, as low SES families may not have the resources or permission if they rent their homes to renovate or take measures to seal lead paint if present within the home (Macey et al., 2001; Vivier et al., 2011; White et al., 2016). The location of impoverished neighborhoods in relation to industrial areas within cities may also play a role in exposure to lead and other toxins (Fisher et al., 2006). Furthermore, public health agencies responsible for low SES neighborhoods may be overburdened or lack the resources to effectively carry out lead abatement activities (Rechtschaffen, 1997).

Socioeconomic Status

Socioeconomic status and health literacy issues may partially explain racial/ethnic disparities in lead exposure and treatment due to systemic inequities in the distribution of income and educational attainment. While being in a publicly funded program facilitates access to blood lead testing due to national and California regulations, children from low SES families still tend to have higher BLLs (Dilworth-Bart and Moore, 2006; Jones et al., 2009; Tehranifar et al., 2008). This may be due in part to health literacy and awareness issues; a review of studies found that parents of low SES families, such as

[25] CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from Healthy People 2020, 2015; CDC, 2014). See CHBRP's SDoH white paper for further information: http://www.chbrp.org/analysis_methodology/docs/Incorporating Relevant Social_Determinants of Health in CHBRP Analyses Final to WEBSITE 033016.pdf.

those receiving WIC benefits, may not be aware of risks from lead paint or protective actions such as feeding their children nutritious foods or wiping down windowsills often (Dilworth-Bart and Moore, 2006). One study noted that their findings regarding having an incomplete immunization record as a risk factor for elevated blood-lead levels in young children in Cleveland, Ohio, especially among African American children, could be an indicator of a lack of access to care or education about the importance of preventive health care (Raymond et al., 2009). The same study noted that of the cases it detected that warranted intervention by the local health department, 31% of families refused environmental inspections, which may indicate a lack of compliance with preventive or abatement measures although the reason for refusal (e.g., lack of trust, perceived ineffectiveness of interventions) was not provided (Raymond et al., 2009).

Emerging research is strengthening the link between childhood lead exposure, educational and cognitive attainment, and adult SES; a recent cohort study of children born in the early 1970s in New Zealand found that childhood lead exposure was independently associated with lower IQ, memory issues, and lower socioeconomic status (Bellinger, 2017; Reuben et al., 2017). Another study set in Rhode Island attributed lead abatement policies and falling BLLs to reduced disparities in educational testing scores between African-American and white 4th to 8th graders between 1997 and 2010 (Aizer et al., 2015).

Societal Burden of Lead Exposure in the U.S.

The following presents an estimated cost of lead exposure/poisoning in the U.S. as no data specific to California was found. These costs include direct (medical care, etc.) and indirect costs (lost wages, etc.) and differ from the incremental cost estimates associated with AB 1316 that are discussed in the *Benefit Coverage, Utilization, and Cost Impacts* section.

Direct Costs

Estimated prevention costs for lead exposure vary greatly depending on the degree to which lead is removed from or controlled within the environment. The cost of removing lead paint entirely from a home can be costly (>$200,000), while sealing lead paint has been estimated to cost homeowners between $1200 and $10,800 per home (Gould, 2009). Similarly, measures to control exposure to lead in water or soil could vary greatly in cost, ranging from using a certified water filter and dusting the home frequently which are relatively inexpensive but require continued effort and maintenance to more costly but permanent replacement of water lines and removing or covering affected soil from around the exterior of the home (CDPH, 2013; EPA, 2013). Direct medical costs of child lead poisoning hospitalizations were estimated at between $35 and $48 million from 1988 to 1992 (Vergara et al., 1996). A more recent analysis estimated direct medical costs for lead poisoning to be lower, at $5.9 million per year (Trasande and Liu, 2011), which is reasonable due to falling rates of lead poisoning across the country (Jones et al., 2009).

Indirect Costs

In the longer term, childhood lead exposure may have significant costs in terms of productivity loss due to lower cognitive attainment in afflicted children. A 2011 update to an analysis which was conducted under the assumption that no level of lead in a child's blood is safe, and using estimates of a loss of 0.25 IQ points per 1 µg/dL of lead in a child's blood and 2.39% lower lifetime income per one IQ point lost, estimated $44.8 to $60.6 billion in economic loss due to lead exposure (Landrigan et al., 2002; Trasande and Liu, 2011). Another study estimated that a 5 µg/dL blood lead level translates to a six-point loss in educational testing scores among 4th to 8th grade students in Rhode Island (Aizer et al., 2015).

Lead paint remains the primary cause of childhood lead exposure in the U.S., and it has been estimated that effectively controlling lead paint exposure in all U.S. homes would cost between $1.2 and $11.0 billion, but would ultimately save between $192 and $270 billion in “medical treatment ($11–$53 billion), lost earnings ($165–$233 billion), tax revenue ($25–$35 billion), special education ($30–$146 billion), lead-linked ADHD cases ($267 million), and criminal activity ($1.7 billion)” (Gould, 2009). Another study, taking into account the direct and indirect societal costs of lead exposure including crime, welfare use, earnings loss, and health issues estimated that the total savings of ensuring that all U.S. children under 72 months (6 years) of age had BLLs of <1 µg/dL at $1.2 trillion and would add 4.8 million quality adjusted life years (QALYs) over the course of the children’s lifetime (Muennig, 2009). The cost effectiveness of reducing childhood lead exposure through large-scale prevention efforts is notable given estimates that only 20% of preventive interventions across a broad range of chronic health issues yield quantifiable improvements and cost savings in health outcomes (Russell, 2009).

MEDICAL EFFECTIVENESS

At present, California Department of Public Health (CDPH) standard of care guidelines require that children at "high risk" of lead exposure (i.e., children enrolled in publically supported programs including Medi-Cal, Child Health and Disability Prevention [CHDP], and WIC) receive a blood test (capillary or venous) at their 12- and 24-month pediatric visits to measure their blood lead levels. For children who are not considered at high risk, CDPH guidelines state that providers should assess children for their risk of lead exposure based on a risk assessment tool; children who are found at higher risk based on this tool should receive a blood test to measure blood lead levels. As discussed in the *Policy Context* section, AB 1316 would require all DMHC-regulated group health care service plans test all children for elevated blood lead levels, regardless of risk, omitting the use of the assessment tool. The bill language also states that health care providers should be responsible for medically necessary follow-up services and that CDPH should be responsible for case management when a child is identified with lead poisoning.

Research Approach and Methods

The medical effectiveness review searched the literature from 1990 to present to answer the following **key questions:**

1. What is the evidence of the effectiveness of universal screening (i.e., screening all children, regardless of risk) for lead poisoning compared with a targeted screening approach?

2. What is the evidence that risk screening questionnaires can accurately identify children with elevated blood lead levels?

3. What is the evidence that blood lead tests can accurately identify children with elevated blood lead levels?

4. What is the evidence that medically necessary follow-up treatment for elevated blood lead levels improves health outcomes or reduces blood lead levels?

Studies of lead screening and related health outcomes were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, Business Source Complete, the Cumulative Index of Nursing and Allied Health Literature, and PsycINFO. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network. The search was limited to abstracts of studies published in English.

The search was originally limited to studies published from 2012 to present. As discussed in the *Policy Context* section, the CDC revised its guidelines on lead screening in 2012, recommending a blood lead reference level of 5.0 µg/dL (the previous recommended level was 10.0 µg/dL). As such, the medical effectiveness review attempted to identify studies of universal screening, risk assessment accuracy, and blood test accuracy using the current recommended blood lead reference value.

Where studies using a reference level of 5.0 µg/dL were unavailable, the medical effectiveness review expanded its search to include studies published prior to 2012 using the previously recommended reference level of 10.0 µg/dL. While these studies do not directly answer the questions of lead screening effectiveness against a threshold of 5.0 µg/dL, they can provide an upper bound for measures of

effectiveness (i.e., if a test performs a certain way at 10.0 µg/dL, it can be expected to perform worse at a lower threshold).

Of the 3,720 unique articles found in the literature review, 112 were reviewed for potential inclusion in this report on AB 1316, and a total of eight studies were included in the medical effectiveness review for this report. The other articles were eliminated because they did not focus on blood lead screening or assessment questionnaires or related health outcomes, were conducted in adults, were of poor quality, or did not report findings from clinical research studies. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B

Methodological Considerations

The medical effectiveness review defines *universal screening* as testing all children, regardless of lead exposure risk, with a blood lead test (capillary of venous). A *targeted screening approach* is defined as testing children who are deemed at elevated risk for lead exposure (in California, these are children in publically funded programs) and assessing other children for their risk of lead exposure. As discussed previously, CDPH regulations require that physicians use the following risk assessment question to determine the lead exposure risk for all children who are not in a publically funded program: *"Does your child live in, or spend a lot of time in, a place built before 1978 that has peeling or chipped paint or that has been recently remodeled?"* (CDPH, 2017b). This question is based on more expansive risk assessment questionnaires recommended by the CDC, which (in addition to asking about exposure to older buildings) ask parents or guardians about whether their child lives near a likely source of lead exposure (e.g., active smelter, battery recycling plant), lives with an adult whose job or hobby involves lead exposure, or if they have a sibling or playmate who has been treated for lead poisoning (Roper et al., 1991; Satcher et al., 1997).

CHBRP excluded literature on the impacts of interventions of elevated lead exposure in children from low- or middle-income countries, because the effectiveness of lead screening and management interventions is directly related to the prevalence of lead exposure, and children in low- and middle-income countries are likely to have more frequent exposures to higher lead levels compared to U.S. children (WHO, 2009). Where possible, CHBRP highlighted the results of studies set in California, as the prevalence of lead in California is likely to be different than other states (CDC, 2016).

Outcomes Assessed

To address key question #1, CHBRP included studies reporting clinical and neurocognitive outcomes among children who were tested through a universal program (i.e., in the absence of any risk assessment) compared with children who were tested after being deemed at high risk. In the absence of literature comparing the effectiveness of universal versus targeted approaches, CHBRP included studies assessing the accuracy of risk assessment questionnaires and blood lead tests compared with a blood lead reference level (key questions #2 and #3). These studies can provide an estimate of how many children had an elevated BLL but were screened out by the risk assessment questionnaire and how many children received false positive blood lead tests. Relevant outcomes include test performance characteristics:

- Sensitivity, which is the proportion of children with an elevated BLL who screen positive with a risk assessment questionnaire;

- Specificity, which is the proportion of children who do not have an elevated BLL who screen negative with a risk assessment questionnaire;

- Positive predictive value (PPV), which measures how well the risk assessment questionnaire correctly identifies children with an elevated BLL (i.e., the proportion of children who screen positive with a risk assessment questionnaire who have an elevated BLL); and

- Negative predictive value (NPV), which measures how well the risk assessment questionnaire correctly identifies children who do not have an elevated BLL (i.e., the proportion of children who screen negative who do not have an elevated BLL).

To address key question #4, CHBRP included studies reporting clinical and cognitive outcomes among children who were treated with chelation (the primary pharmacologic therapy for elevated blood lead levels) or who received an intervention aimed to reduce or eliminate future lead exposure (i.e., environmental, counseling, educational, or nutritional interventions). The medical effectiveness review included studies of interventions that would involve a healthcare provider, such as in-office counseling or education about sources of lead exposure, nutritional supplementation, and chelation therapy. In-home or large-scale environmental interventions, such as residential lead paint removal and soil abatement, were excluded from the medical effectiveness review but are discussed in more detail in the *Public Health Impacts* section.

Study Findings

Findings Related to the Effectiveness of Universal Screening for Lead Poisoning

CHBRP identified a systematic review published in December 2006 by the United States Preventive Services Task Force (USPSTF) that reviewed the peer-reviewed literature to determine the effectiveness of universal versus targeted screening on clinical or neurocognitive outcomes. This review found that there was no direct evidence of the effectiveness of universal testing for elevated blood lead levels on these outcomes compared with a targeted approach. In CHBRP's review of the literature published since 2006, CHBRP did not identify any studies comparing the effectiveness of a universal versus targeted approach.

CHBRP concludes that there is insufficient evidence that a universal testing approach for childhood lead exposure is more effective than a targeted approach of testing high-risk children. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

It should also be noted in order for a screening program approach to be effective, the prevalence of the disease or condition in question must be high among the population being screened or the screening test will result in a high false-positive rate. Data over the past two decades shows that the prevalence of children with moderate or high blood lead levels in the U.S. has been decreasing, which contributed to the CDC moving away from a universal screening recommendation in 1997 (CDC, 1997). Between 1997 and 2015, the percentage of children tested and found to have BLL $\geq$10 µg/dL decreased from 7.6% to 0.5%; between 2010 and 2015, the percentage of children found to have BLL $\geq$5 µg/dL decreased from 6.6% to 3.3% (Child Trends Databank, 2017).

Findings Related to the Accuracy of Risk Assessment Questionnaires

As CHBRP did not identify any studies directly comparing the effectiveness of a universal versus targeted approach on clinical or neurocognitive outcomes, CHBRP reviewed studies assessing the ability of risk

assessment questionnaires to accurately identify children with elevated BLLs. Since AB 1316 would remove the requirement that some children undergo a risk assessment in order to determine their risk level for elevated BLL, the performance of these tools can be used to estimate how many children with elevated BLLs are potentially being missed by these questionnaires or how many children receive a false-positive result.

Blood lead reference level of 5.0 µg/dL

As previously mentioned, in 2012 the CDC changed the blood lead reference threshold from 10.0 µg/dL to 5.0 µg/dL (CDC, 2017). The medical effectiveness review identified a single study assessing the performance of risk assessment questionnaire against a reference blood lead level of 5.0 µg/dL or less (Nicholson and Cleeton, 2016).

In a retrospective cohort study, Nicholson and Cleeton (2016) assessed the performance of a set of lead exposure risk questions, including two questions that asked about exposure to a building built before 1978 with or without recent renovations. For a sample of 172 children aged 3 to 5 years enrolled in Head Start in Florida, the study matched parental questionnaire responses to children's BLLs on file with the program (collected by pediatricians or by a school nurse) and assessed how accurately the questionnaire identified children with a BLL exceeding 2.0 µg/dL. The authors found that an affirmative response to either question regarding exposure to a home built before 1978 had a sensitivity of 16.7%, specificity of 80.0%, PPV of 8.8%, and NVP of 89.2% (Nicholson and Cleeton, 2016).

There is limited evidence that risk assessment questionnaires using a blood lead threshold at or below µg/dL do not accurately identify children with elevated blood lead levels; an estimated 83% of children with an elevated BLL would not be identified by the questionnaire (i.e., false-negatives) and 20% of children would receive a false-positive result.

Blood lead reference level of 10.0 µg/dL

While the medical effectiveness review only identified a single study relevant to the current blood lead threshold level of 5.0 µg/dL, there is a larger body of literature studying the effectiveness of risk assessment questionnaires against the blood lead threshold previously recommended by the CDC (10.0 µg/dL). These studies cannot directly address the question of whether risk assessment questionnaires can accurately identify children with BLLs exceeding 5.0 µg/dL, but they can provide an upper bound for the accuracy of the questionnaires.

In addition to the 2006 USPSTF systematic review, CHBRP identified a 2013 meta-analysis of the accuracy of risk assessment questionnaires (Ossiander, 2013). These two reviews identified 22 unique studies on the test performance of risk assessment questionnaires against a blood lead reference level of 10.0 µg/dL. Both reported studies using CDC-recommended tools or state-developed questionnaires (often based on the CDC tool, but with additional questions). The USPSTF review of 12 studies (10 of which are included in the meta-analysis discussed below) reported that the questionnaires had sensitivities ranging from 64% to 87% and specificities ranging from 32% to 75%. This means that anywhere from 13% to 36% of children with an elevated BLL would not be identified by the questionnaire (i.e., false negatives) and that 25% to 68% received a false-positive result. The review notes that the performance of the risk assessment tools improved when detecting BLLs at higher levels (i.e., exceeding 15.0 to 20.0 µg/dL) (Rischitelli et al., 2006)

The meta-analysis included 20 studies, and conducted separate analyses depending on whether the study used a CDC-recommended tool or whether it used a state-developed questionnaire. For the CDC questionnaire, the meta-analysis reported a pooled sensitivity of 61% (95% CI, 53% to 68%) and a

specificity of 52% (95% CI, 45% to 60%). For studies using other questionnaires, the pooled sensitivity was 76% (95% CI, 68% to 85%) and specificity was 41% (95% CI, 33% to 49%). Depending on the questionnaire used, this means that anywhere from 24% to 39% of children with an elevated BLL would not be identified by the questionnaire (i.e., false negatives) and that 48% to 59% received a false-positive result (Ossiander, 2013).

Based on one systematic review and one meta-analysis, CHBRP concludes that there is clear and convincing evidence that risk assessment questionnaires are inaccurate; using a blood lead threshold of 10 µg/dL, 13% to 39% of children with an elevated blood lead level would not be identified and 25% to 68% of children would receive a false-positive test result. At a threshold of 5.0 µg/dL, risk assessment questionnaires may be even less accurate.

Findings Related to the Accuracy of Blood Lead Level Testing

Blood lead reference level of 5.0 µg/dL

The medical effectiveness review did not identify any trials or other comparative studies assessing the accuracy of blood lead testing (either capillary or venous) against the current threshold of 5.0 µg/dL. CHBRP identified one modeling study that predicted the impact of varying thresholds on test sensitivity.

A modeling study by McCloskey et al. (2013) assessed the impact on test sensitivity as a function of blood lead thresholds (≥10 µg/dL vs. ≥5µg/dL); their model predicts that test sensitivity (i.e., the ability of the test to correctly identify children with elevated BLLs) will decrease as the threshold is lowered. This study found that as the threshold is lowered, a larger proportion of positive tests will result in false-positive results, as the readings fall within a range where misclassification can occur due to measurement imprecision (McCloskey et al., 2013).

There is insufficient evidence of assess the accuracy of blood lead testing at the current threshold. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown. It should also be noted as the blood lead threshold is lowered, the accuracy of the blood test may decrease due to measurement imprecision.

Blood lead reference level of 10.0 µg/dL

As with CHBRP's review of the accuracy of risk assessment questionnaires, since CHBRP identified a single study on the accuracy of blood lead testing at 5.0 µg/dL, CHBRP has summarized the evidence of accuracy against a reference level of 10.0 µg/dL to provide an upper bound estimate of accuracy.

The 2006 USPSTF systematic review found that the false-positive rates for blood lead testing are low, but that contamination can impact the accuracy of the tests. The review reports that studies using BLL thresholds of 10 or 20 µg/dL reported false-positive rates between 3.0% and 9.0% for capillary testing as compared to simultaneously collected venous blood samples (Rischitelli et al., 2006). Anderson et al. (2007) retrospectively reviewed blood lead test results for children less than 5 years of age in Maine during 2002–2003 to determine the percentage of false-positive blood tests, defined as an elevated (>10 µg/dL) capillary test but with a venous test lower than the threshold. They found that that 73% of children with elevated capillary tests and venous confirmatory tests had a false-positive capillary result, and that false-positive results were more likely when the capillary blood test results were slightly above the reference level (Anderson et al., 2007).

The 2006 USPTF review notes that contamination — either from the testing equipment or skin — can positively bias capillary testing results by up to an average of 1.0 µg/dL. Variability in the blood from day-

to-day and trends over time can also contribute to the higher false-positive rate for initial capillary testing when compared to venous testing completed at a later date and variability in the accuracy of laboratory testing may also contribute to the accuracy of the blood lead tests (Rischitelli et al., 2006).

It should also be noted that testing for lead in populations with lower prevalence of lead will result in a larger number of false-positive results as a proportion of all positive results (Rainey and Schonfeld, 1994).

Based on findings from a well-conducted systematic review, CHBRP concludes that there is a preponderance of evidence blood lead tests yield false positive rates ranging from 3.0% to 9.0% against a blood lead reference level of 10.0 µg/dL, but that contamination can impact the accuracy of blood lead tests.

Findings Related to the Effectiveness of Medically Necessary Follow-up Services for Lead Poisoning

In order for a screening program to be effective and result in improved health outcomes, there must be effective treatments or follow-up services for the disease or condition identified. The type of medically necessary follow-up services varies depending on the level of lead detected in the blood. Between levels of 5.0 µg/dL and 20.0 to 44.0 µg/dL, the primary approach for managing asymptomatic children outlined by the CDC and CDPH guidelines is to reduce or eliminate the lead exposure through environmental, counseling, educational, or nutritional interventions. When blood lead levels reach or exceed 45 µg/dL, chelation therapy is the recommended treatment, along with the previously mentioned interventions to reduce lead exposure (CDPH, 2008; Koplan et al., 2002).

This section focuses primarily on interventions that would involve a healthcare provider, such as in-office counseling or education about sources of lead exposure, nutritional supplementation, and chelation therapy. Environmental interventions, such as soil abatement residential lead paint removal interventions, would not involve a health care provider and are considered beyond the scope of the medical effectiveness review; these interventions will be discussed in more detail in the *Public Health Impacts* section.

Educational interventions

The goal of counseling and educational interventions is to help parents or guardians reduce their child's exposure to residential and nonresidential sources of lead (Koplan et al., 2002); however, studies have not demonstrated that these interventions are effective for reducing blood lead levels in children. A 2016 Cochrane Review of household interventions for lead exposure did not identify any studies (published prior to May 2016) that assessed the impact of educational interventions on cognitive or neurobehavioral outcomes. This review meta-analyzed blood lead level data from five trials on the effect of education interventions compared to either standard education or no intervention and did not find any significant difference in blood lead level (Nussbaumer-Streit et al., 2016). The 2006 USPSTF review identified four studies (two of which were included in the Cochrane review) of counseling or educational interventions for children with elevated lead levels and found insufficient evidence to determine whether these interventions result in lowered BLLs (Rischitelli et al., 2006). While the 2002 CDC guidelines for management of lead exposure recommend educating caregivers on personal hygiene practices, such as handwashing and washing toys, the guidelines note that there is no direct evidence that handwashing is associated with a decrease in BLL (but recommend regardless due to minimal risk) (Koplan et al., 2002). CHBRP did not identify any studies assessing the impact of educational interventions on cognitive outcomes associated with lead exposure.

There is clear and convincing evidence from a well-conducted systematic review and meta-analysis that educational interventions are not effective strategies for reducing blood lead levels in children. CHBRP found insufficient evidence of the effectiveness of educational interventions on cognitive outcomes. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

Nutritional interventions

None of the three randomized trials included in the 2006 USPSTF review found that altering nutrient intake resulted in decreased BLLs; the review did identify six cohort studies and four cross-sectional studies which found significant associations between intake of some nutrients (e.g., calories, carbohydrates, fat, folate, iron, vitamins C and D) and blood lead levels. (Rischitelli et al., 2006). CHBRP did not identify any studies published since 2006 on nutritional interventions for treating elevated blood lead levels.

CHBRP finds that there is conflicting evidence on the effectiveness of nutritional interventions to reduce blood lead levels in children. While some cohort and cross-sectional studies have found significant associations between the intake of some nutrients and blood lead levels, randomized controlled trials have not demonstrated a significant relationship.

Medical interventions

Chelation therapy, recommended for children with BLL $\geq$45 µg/dL, can decrease lead levels in the blood and reverse or alleviate some of the resulting symptoms of lead poisoning, such as encephalopathy, vomiting, abdominal pain, anemia, and renal insufficiency (Flora and Pachauri, 2010; Lowry, 2017); however, chelation therapy has not been found to reduce chronic neurocognitive effects due to lead exposure (Lowry, 2017). While chelation therapy can decrease BLL, ongoing exposure to environmental lead (in the absence of environmental abatement interventions) will lead to a subsequent increase in BLL.

Among children with initial BLL between 20 and 70 µg/dL, the 2006 USPSTF systematic review identified eight studies that found that chelation reduced BLL in the short term; however, these studies often combined chelation with environmental interventions and found that the BLL reductions were not sustained in the absence of additional chelation or environmental interventions. Uncontrolled studies of asymptomatic children with initial BLL between 40 and 471 µg/dL included in the systematic review found that chelation resulted in large BLL reductions (to levels ranging from less than 40 to 70 µg/dL) and that these reductions did persist in the long term; however, these studies also included environmental intervention components but the effect of these interventions was not evaluated (Rischitelli et al., 2006).

As previously mentioned, the prevalence of blood lead levels $\geq$10 µg/dL in the U.S. children decreased from 7.6% in 1997 to 0.5% in 2015 (Child Trends Databank, 2017); it stands to reason that only few of the 0.5% of children with elevated blood lead levels would have a BLL high enough to warrant chelation therapy.

It should be noted that chelation therapy is not without harm; it carries the risks of toxic metal redistribution, essential metal loss, hepatotoxicity, nephrotoxity, pro-oxidant effects, headaches, nausea, and increased blood pressure (Flora and Pachauri, 2010).

There is clear and convincing evidence that for children with BLL exceeding 44 µg/dL, chelation therapy reduces blood lead levels in the short term; therefore, it stands to reason that it would be expected to reduce associated acute toxicity and potentially prevent progression of lead poisoning. However, its use is also not without harm. It is also important to note that sustained reductions in blood lead levels as a

result of chelation need to be accompanied by environmental interventions to reduce or eliminate ongoing lead exposure.

Summary of Findings

The charts in this section summarize CHBRP's findings regarding the strength of the evidence for the effects of specific tests, treatments, and services addressed by AB 1316. Separate charts are presented for each test, treatment, or service for which the bill would mandate coverage and for each outcome for which evidence of the effectiveness of a treatment is available. The title of the chart indicates the test, treatment, or service for which evidence is summarized. The statement under the heading "Conclusion" presents CHBRP's conclusion regarding the strength of evidence about the effect of a particular test, treatment, or service on a specific relevant outcome and the number of studies on which CHBRP's conclusion is based. For test, treatments, and services for which CHBRP concludes that there is clear and convincing, preponderance, limited, or conflicting evidence, the placement of the vertical bar indicates the strength of the evidence. If CHBRP concludes that evidence is insufficient, a graph that states "Insufficient Evidence" will be presented.

Figure 2. Findings Related to the Effectiveness of Universal Testing for Lead Poisoning

Conclusion

CHBRP concludes that there is insufficient evidence that a universal testing approach for childhood lead exposure is more effective than a targeted approach of testing high-risk children. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

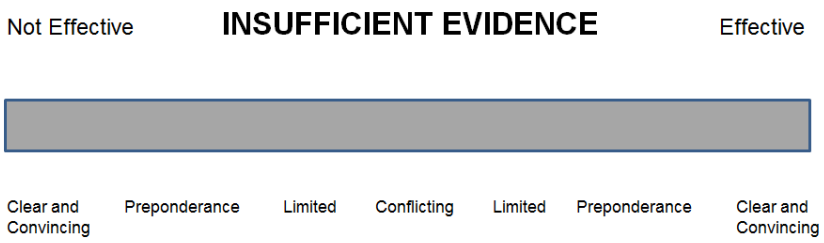


Figure 3. Findings Related to the Accuracy of Risk Assessment Questionnaires using a reference level, of 5.0 µg/dL

Conclusion

There is limited evidence that risk assessment questionnaires using a blood lead threshold at or below µg/dL do not accurately identify children with elevated blood lead levels; an estimated 83% of children with an elevated BLL would not be identified by the questionnaire (i.e., false-negatives) and 20% of children would receive a false-positive result.

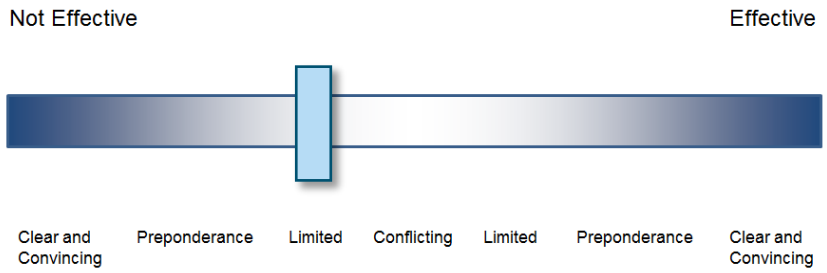


Figure 4. Findings Related to the Accuracy of Risk Assessment Questionnaires using a reference level, of 10.0 µg/dL

Conclusion

Based on one systematic review and one meta-analysis, CHBRP concludes that there is clear and convincing evidence that risk assessment questionnaires are inaccurate; using a blood lead threshold of 10 µg/dL, 13% to 39% of children with an elevated blood lead level would not be identified and 25% to 68% of children would receive a false-positive test result. At a threshold of 5.0 µg/dL, risk assessment questionnaires may be less accurate.

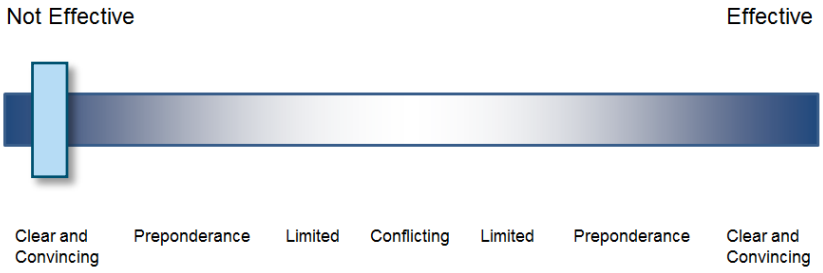


Figure 5. Findings Related to the Accuracy of Blood Lead Level Testing using a reference level of 5.0 µg/dL

Conclusion

There is insufficient evidence of assess the accuracy of blood lead testing at the current threshold. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown. It should also be noted as the blood lead threshold is lowered, the accuracy of the blood test may decrease due to measurement imprecision

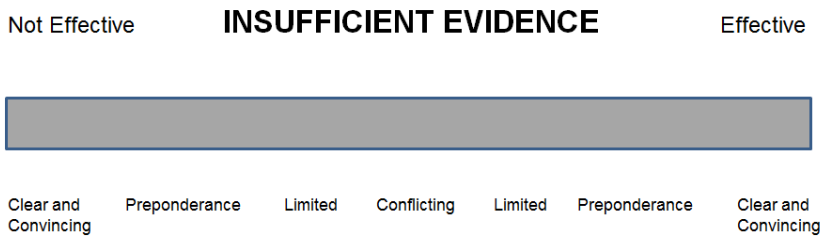


Figure 6. Findings Related to the Accuracy of Blood Lead Level Testing using a reference level of10.0 µg/dL

Conclusion

CHBRP concludes that there is a preponderance of evidence that blood lead tests are accurate, with false positive rates ranging from 3.0% to 9.0% against a blood lead reference level of 10.0 µg/dL, but that contamination can impact the accuracy of blood lead tests.

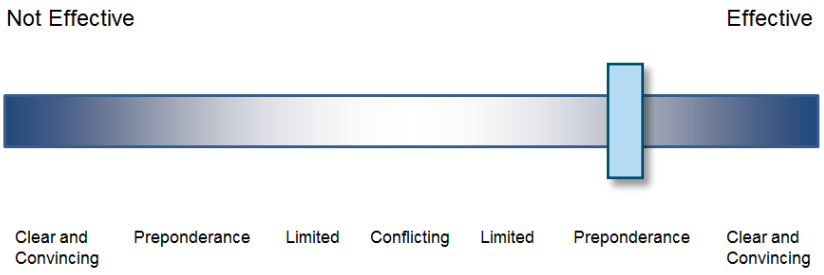


Figure 7. Findings Related to the Effectiveness of Medically Necessary Followup Services for Lead Poisoning : Educational Interventions and Blood Lead Levels

Conclusion

There is clear and convincing evidence from a well-conducted systematic review and meta-analysis that educational interventions are not effective strategies for reducing blood lead levels in children.

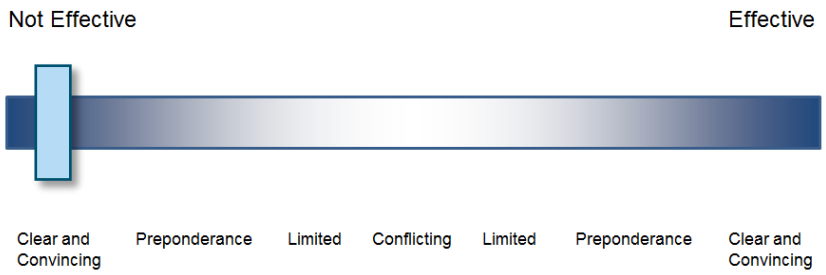


Figure 8. Findings Related to the Effectiveness of Medically Necessary Followup Services for Lead Poisoning : Educational Interventions and Cognitive Outcomes

Conclusion

CHBRP found insufficient evidence of the effectiveness of educational interventions on cognitive outcomes. CHBRP notes that the absence of evidence does not mean there is no effect; it means that the effect is unknown.

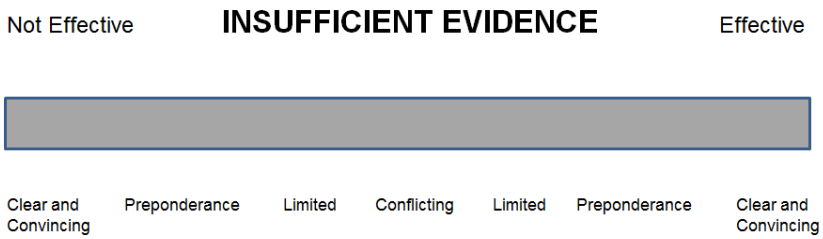


Figure 9. Findings Related to the Effectiveness of Medically Necessary Follow-up Services for Lead Poisoning : Nutritional Interventions

Conclusion

CHBRP finds that there is conflicting evidence on the effectiveness of nutritional interventions to reduce blood lead levels in children based on results from a well-conducted systematic review. While some cohort and cross-sectional studies have found significant associations between the intake of some nutrients and blood lead levels, randomized controlled trials have not demonstrated a significant relationship.

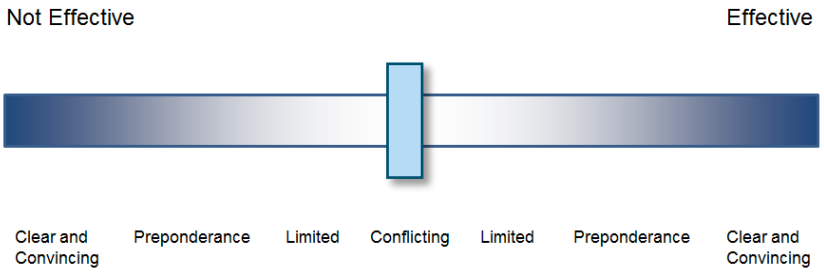
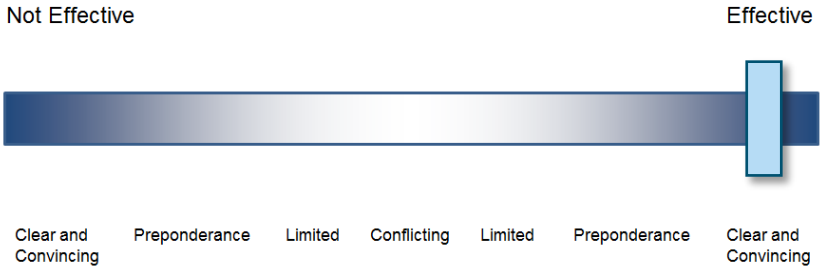


Figure 10. Findings Related to the Effectiveness of Medically Necessary Followup Services for Lead Poisoning : Medical Interventions

Conclusion

There is clear and convincing evidence that chelation therapy in children with BLL >45 µg/dL reduces blood lead levels in the short-term based on one well-conducted systematic review; therefore, it stands to reason that it would be expected to reduce associated acute toxicity and potentially prevent progression of lead poisoning. However, its use is also not without harm and only a small proportion of children will be found with BLL warranting chelation. It is also important to note that sustained reductions in blood lead levels as a result of chelation need to be accompanied by environmental interventions to reduce or eliminate ongoing lead exposure.



BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

AB 1316 would amend state code (Section 1367.3 of the Health and Safety Code) such that it would require all DMHC-regulated group health care service plans to provide coverage for the testing of blood lead levels in all children, regardless of risk. This section reports the potential incremental impacts of AB 1316 on estimated baseline benefit coverage, utilization, and overall cost.

While as written AB 1316 only affects DMHC-regulated group plans, CHBRP projects AB 1316 would similarly affect individual DMHC-regulated plans and all CDI-regulated plans because providers who administer the blood lead test would do so for all children under their care. They would not be able to discern the regulating body of the commercial carriers for each of their patients prior to administering the blood test.

All children under Medi-Cal plans are already required to receive blood lead tests regardless of risk (0–72 months of age), and receive blood lead tests at 12 and 24 months; any child between 24 and 72 months who did not receive a test by 24 months must receive a blood lead test. This Medi-Cal lead blood test schedule is in line with screening guidelines published by the Early and Periodic Screening Diagnostic and Treatment (EPSDT). EPSDT is the child health component of Medicaid under which federal statutes and regulations state that children under age 21 who are enrolled in Medicaid are entitled to EPSDT benefits and that states must cover a number of preventive and treatment services (see the *Policy Context* section).

CHBRP assumes AB 1316's requirement to test all children regardless of risk would result in a change in the standard of practice such that all children regardless of insurance carrier type would receive blood lead tests and the blood lead tests would be conducted per the EPSDT screening guidelines. CHBRP assumes utilization of blood lead testing at ages outside of the preventive screening guidelines bracket would not change due to the mandate, except for follow-up testing if abnormal results are found. Clinical treatment of elevated blood lead, or chelation, occurs at concentrations beyond those that would be symptomless and uncovered through routine preventive testing (see *Medical Effectiveness*) and is thus not included as part of costs of treatment for elevated blood lead levels in this analysis. While clinicians are responsible to notify parents and health departments and may provide patient education and counseling in cases where blood lead is well below the levels requiring clinical treatment, these costs are not retrievable from claims database. Health departments play a particularly important role in providing education and abatement strategies for children who are determined by blood tests to have elevated lead levels and this is discussed in *Background on Childhood Lead* Exposure.

While AB 1316 states blood lead is to be determined via the measurement of lead in venous blood, blood lead tests are also performed via capillary tests during preventive visits to providers, as evidenced by CHBRP's examination of MarketScan® claims data as well as from consultation provided by CHBRP's clinical content expert. CHBRP assumes providers would continue their standard clinical practice — whether it is to use capillary and venous testing — to obtain blood samples of their patients and thus providers who currently routinely use capillary blood specimen collection as part of their preventive visit would not switch to using venous blood collection due to AB 1316 postmandate. The costs of both capillary and venous testing include the collection of the blood specimen (i.e., blood draw) and the laboratory exam that determines lead levels. CHBRP estimates baseline cost and utilization of blood lead tests (both capillary and venous) using 2014 and 2015 MarketScan® data. CHBRP included in estimates of utilization and costs of lead testing those tests associated with preventive visits and those associated with nonpreventive visits, which includes follow-up testing.

For further details on the underlying data sources and methods, please see Appendix C

Baseline and Postmandate Benefit Coverage

Currently, 100% of enrollees with DMHC-regulated group health insurance that would be subject to AB 1316 have coverage for blood lead testing, as do 100% of enrollees with individual coverage and CDI-regulated group coverage who are not subject to the mandate. However, commercial plan enrollees currently receive blood lead testing only after risk assessment for lead exposure has been conducted and yields a positive result.

Current coverage of blood lead testing was determined by a survey of the largest (by enrollment) providers of health insurance in California. Responses to this survey represent 85% of enrollees with private market health insurance that can be subject to state mandates.

Postmandate, 100% of enrollees with private health insurance would continue to have coverage for blood lead testing. Utilization of blood lead testing is what is affected by AB 1316 and discussed in the section below.

Baseline and Postmandate Utilization

To determine baseline utilization of blood lead tests, CHBRP analyzed blood lead test claims from the 2014 and 2015 MarketScan® database (see Appendix C for a description of the capillary and venous test CPT codes). Blood lead testing associated with a preventive visit and nonpreventive visit (which includes follow-up testing) were included in the utilization and cost estimates presented in this section.

The total number of enrollees 0 to 72 months in DMHC- and CDI-regulated plans with health insurance subject to AB 1316 receiving blood lead tests at baseline is 92,665 (63,651 for 0- to 24-month-olds; 29,014 for 24- to 72-month-olds). This is equivalent to 5.7 blood tests per 1,000 covered enrollees 0 to 72 months (3.9 per 1,000 for 0- to 24-month-olds; 1.8 per 1,000 for 24- to 72-month-olds) (Table 1).

Postmandate, CHBRP assumed utilization of blood lead tests would increase per AB 1316's mandate that all children be tested for lead at the 12- and 24-month preventive visit. If there were perfect provider and patient compliance, 100% of all children at the 12-month and 24-month visit would receive a blood lead test (either capillary or venous and a subsequent follow-up test if the initial test returns blood lead levels >4.5 µg/dL). However, in review of the literature on compliance with blood lead testing, there is a degree of noncompliance from both the provider and patient sides that dampen compliance rates. In settings where universal testing is part of the clinical guidelines, as for Medicaid, reports suggest compliance is around 70% to 80% (Vivier et al., 2001; Wilken et al., 2004). CHBRP assumes postmandate compliance would be 80% for DMHC- and CDI-regulated group and individual markets, as the uniformity of guidelines stemming from AB 1316 for all children across all insurance types would no longer be a barrier to compliance (Cabana et al., 1999; A. Haboush-Deloye et al., 2017). Thus, CHBRP assumes postmandate, 80% of children who should be tested at the 12- and 24-month preventive visits would be tested, consistent with the EPDST guidelines for blood lead testing for enrollees in Medi-Cal. Children who fall in the 24- to 72-month-old age group in 2018 postmandate would also receive some degree of blood lead testing. CHBRP assumes parental demand for blood lead tests among this group of children is the primary driver of increased utilization. CHBRP assumes 10% of children in this age cohort (24–72 months) in 2018 would be tested. This cohort of children would finally age out of the 24- to 72-month age range in 4 years and at that point blood lead test utilization would largely be only among the 12- and 24-month-olds if providers and parents comply with blood testing guidelines.

Using the above assumptions on utilization increases postmandate, CHBRP estimates AB 1316 would lead to an additional 249,853 enrollees aged 0 to 24 months in DMHC- and CDI-regulated plans tested

for blood lead levels, which translates into an increase of 393%. Among the 24- to 72-month-old enrollees in DMHC- and CDI-regulated plans, if AB 1316 were enacted there would be an increase in 2,901 tests in 2018. Thus, for the entire group of 0- to 72-month-old enrollees in DMHC- and CDI-regulated plans, there is an increase in 252,754 tests, which is equivalent to a utilization increase of 15.6 tests per 1,000, or an increase of 273% in utilization (see Table 1).

CHBRP assumes that there would be no increase in the utilization of clinical treatment as a result of preventive blood lead tests required by AB 1316. Clinical treatment of elevated blood lead occurs at high blood lead levels (e.g., ≥45 µg/dL); a child is less likely to be asymptomatic at this level and lead exposure of such a level is unlikely to be discovered through a preventive blood lead test. This assumption is based on CHBRP's examination of 2014-2015 Marketscan data, which found clinical treatment for elevated blood lead, such as chelation (recommended when BLL ≥45 µg/dL), is rare; CHBRP's content expert corroborated this finding and agreed with the aforementioned assumption.

Baseline and Postmandate Per-Unit Cost

Using the MarketScan® dataset and projecting to 2018, baseline unit costs of blood lead testing (both capillary and venous) were determined to be $16.77 on average for the lead test and $5.91 for the blood specimen collection ($21 total). The unit cost reflects the average cost of blood lead tests conducted at preventive and nonpreventive visits.

For lead tests performed during a 12-month-old preventive visit, CHBRP assumed that there was no additional cost for a blood draw because blood was likely being drawn already for anemia blood test screening, which is routinely done at this visit, confirmed by CHBRP's content expert. For lead tests not associated with the 12-month-old preventive visit, MarketScan® data indicated that only 66% of lead tests were accompanied by a claim for a blood specimen collection. The costs of blood specimen collection were included in the analysis for the 24-month-old blood tests as well as tests occurring in the 24- to 72-month-old children.

CHBRP estimates a $1 decrease in average cost per blood test for the 0- to 24-month-olds,stemming from the assumption that postmandate blood lead tests would occur at the preventive visit (where blood specimen collection is not an additional cost) and postmandate there would be more tests done during preventive visits than at baseline.

Baseline and Postmandate Expenditures

Table 2 and Table 3 present baseline and postmandate expenditures by market segment for DMHC-regulated plans and CDI-regulated policies. The tables present per member per month (PMPM) premiums, enrollee expenses for both covered and noncovered benefits, and total expenditures (premiums as well as enrollee expenses).

AB 1316 would increase total net annual expenditures by $6,221,000 or 0.0043% for enrollees with DMHC-regulated plans and CDI-regulated policies. This comes from the increase in premiums paid by payers for increased utilization of lead testing, which is already a covered benefit at the preventive visit.

Premiums

Changes in premiums as a result of AB 1316 would vary by market segment. Note that such changes are related to the number of enrollees with health insurance that would be subject to AB 1316. Increases in

premiums in the private market range from a high of 0.008% in the CDI-regulated individual market to a low of 0.0042% for the DHMC-regulated individual market.

As blood lead testing is already conducted among Medi-Cal enrollees per the EPDST, there is no change among publicly funded DMHC-regulated health plans Medi-Cal managed care (MCMC) premiums and expenditures. The increase in premiums among CalPERs HMOs, which are DMHC-regulated, is 0.0060%.

Enrollee Expenses

There would not be any AB 1316-related changes in enrollee expenses for covered benefits (deductibles, copays, etc.) since blood lead tests are considered preventive and covered with no cost share.

Potential Cost Offsets or Savings in the First 12 Months After Enactment

CHBRP does not anticipate any cost offsets or savings in the first year postmandate, as blood lead testing does not correspond to any reduction in use of clinical services during the first year (refer to the *Medical Effectiveness* section). There are likely significant cost offsets in the longer term, largely associated with improved cognitive development, and these are addressed qualitatively in the *Public Health Impacts* section.

Postmandate Administrative Expenses and Other Expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies would remain proportional to the 0.0043% increase in premiums. CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs, which are passed on to consumers in the form of increased premiums. CHBRP assumes that the administrative cost proportion of premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums.

Other Considerations for Policymakers

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, related considerations for policymakers are discussed below.

Potential Cost of Exceeding Essential Health Benefits

As explained in the *Policy Context* section, AB 1316 would not require coverage for a new state benefit and thus does not exceed the definition of EHBs in California.

Postmandate Changes in the number of uninsured persons[26]

As the change in average premiums does not exceed 1% for any market segment (see Table 3), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of AB 1316.

[26] See also CHBRP's *Criteria and Methods for Estimating the Impact of Mandates on the Number of Uninsured*, available at www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of AB 1316.

How Lack of Benefit Coverage Results in Cost Shifts to Other Payers

Because blood lead testing is a covered benefit for all children under 72 months of age, CHBRP assumes there is no cost shifting to other payers. There are likely little or no instances where blood lead testing is denied reimbursement by carriers when ordered by a provider, would be paid for directly by enrollees and whereby enrollees would seek payment help from other entities. Other governmental bodies, such as county departments of health or school districts, may provide blood lead testing when environmental lead exposure has been identified in the community and thus these tests are done outside of the screening that AB 1316 addresses.

Table 3. Baseline Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2018

	DMHC-Regulated						CDI-Regulated			
	Privately Funded Plans (by Market) [a]			Publicly Funded Plans			Privately Funded Plans (by Market) [a]			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs* [b]	*MCMC (Under 65)* [c]	*MCMC (65+)* [c]	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates [d]	9,128,000	3,163,000	2,379,000	884,000	7,192,000	644,000	276,000	145,000	237,000	24,048,000
Total enrollees in plans/policies subject to AB 1316 [e]	9,128,000	3,163,000	2,379,000	884,000	0	0	276,000	145,000	237,000	13,175,000
Premiums										
Average portion of premium paid by employer	$456.42	$324.76	$0.00	$460.43	$257.00	$751.00	$527.06	$433.40	$0.00	$97,688,732,000
Average portion of premium paid by employee	$115.59	$149.62	$469.56	$115.11	$0.00	$0.00	$166.32	$157.88	$423.05	$34,995,304,000
Total premium	**$572.01**	**$474.38**	**$469.56**	**$575.54**	**$257.00**	**$751.00**	**$693.38**	**$591.28**	**$423.05**	**$132,684,037,000**
Enrollee expenses										
For covered benefits (deductibles, copays, etc.)	$44.11	$103.11	$126.07	$31.49	$0.00	$0.00	$115.39	$166.25	$75.74	$13,565,623,000
For noncovered benefits [f]	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0
Total expenditures	**$616.12**	**$577.49**	**$595.64**	**$607.03**	**$257.00**	**$751.00**	**$808.77**	**$757.53**	**$498.79**	**$146,249,660,000**

Source: California Health Benefits Review Program, 2017.

Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, both on Covered California and outside the exchange.

(b) As of September 2016, 57% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2018.

(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who also have Medicare coverage. This population does not include enrollees in COHS.

(d) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.
(e) DMHC-group is only listed as being affected in the bill language of AB 1316, but CHBRP assumes the all DMHC- and CDI-regulated plans would incur changes due to AB 1316.
(f) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. In addition, this only includes those expenses that would be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.
Key: CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; COHS=County Operated Health Systems; MCMC = Managed Care Medi-Cal

Table 4. Postmandate Per Member Per Month Premiums and Total Expenditures by Market Segment, California, 2018

	DMHC-Regulated						CDI-Regulated			
	Privately Funded Plans (by Market) [a]			Publicly Funded Plans			Privately Funded Plans (by Market) [a]			
	Large Group	*Small Group*	*Individual*	*CalPERS HMOs* [b]	*MCMC (Under 65)* [c]	*MCMC (65+)* [c]	*Large Group*	*Small Group*	*Individual*	**Total**
Enrollee counts										
Total enrollees in plans/policies subject to state mandates [d]	9,128,000	3,163,000	2,379,000	884,000	7,192,000	644,000	276,000	145,000	237,000	24,048,000
Total enrollees in plans/policies subject to AB 1316 [e]	9,128,000	3,163,000	2,379,000	884,000	0	0	276,000	145,000	237,000	13,175,000
Premiums										
Average portion of premium paid by employer	$0.0266	$0.0247	$0.0000	$0.0274	$0.0000	$0.0000	$0.0262	$0.0263	$0.0000	$4,273,000
Average portion of premium paid by employee	$0.0067	$0.0114	$0.0198	$0.0069	$0.0000	$0.0000	$0.0083	$0.0096	$0.0345	$1,949,000
Total premium	$0.0333	$0.0360	$0.0198	$0.0343	$0.0000	$0.0000	$0.0344	$0.0358	$0.0345	**$6,221,000**
Enrollee expenses										
For covered benefits (deductibles, copays, etc.)	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0
For noncovered benefits [f]	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0.0000	$0
Total expenditures	$0.0333	$0.0360	$0.0198	$0.0343	$0.0000	$0.0000	$0.0344	$0.0358	$0.0345	$6,221,000
Percent Change										
Premiums	0.0058%	0.0076%	0.0042%	0.0060%	0.0000%	0.0000%	0.0050%	0.0061%	0.0081%	0.0047%
Total expenditures	0.0054%	0.0062%	0.0033%	0.0057%	0.0000%	0.0000%	0.0043%	0.0047%	0.0069%	0.0043%

Source: California Health Benefits Review Program, 2017.
Notes: (a) Includes enrollees with grandfathered and nongrandfathered health insurance, both on Covered California and outside the exchange.
(b) As of September 2016, 57% of CalPERS HMO members were state retirees under age 65, state employees or their dependents. CHBRP assumes the same ratio for 2018.
(c) Medi-Cal Managed Care Plan expenditures for members over 65 include those who also have Medicare coverage. This population does not include enrollees in COHS.
(d) This population includes both persons who obtain health insurance using private funds (group and individual) and through public funds (e.g., CalPERS HMOs, Medi-Cal Managed Care Plans). Only those enrolled in health plans or policies regulated by the DMHC or CDI are included. Population includes all enrollees in state-regulated plans or policies aged 0 to 64 years, and enrollees 65 years or older covered by employer-sponsored health insurance.
(e) DMHC-group is only listed as being affected in the bill language of AB 1316, but CHBRP assumes the all DMHC- and CDI- regulated plans would incur changes due to AB 1316.
(f) Includes only those expenses that are paid directly by enrollees or other sources to providers for services related to the mandated benefit that are not currently covered by insurance. In addition, this only includes those expenses that would be newly covered, postmandate. Other components of expenditures in this table include all health care services covered by insurance.
Key: CalPERS HMOs=California Public Employees' Retirement System Health Maintenance Organizations; CDI=California Department of Insurance; DMHC=Department of Managed Health Care; COHS=County Operated Health Systems; MCMC = Managed Care Medi-Cal

PUBLIC HEALTH IMPACTS

AB 1316 would mandate that DMHC-regulated insurers conduct blood lead tests for all children in California, regardless of assessed risk level.

The public health impact analysis includes estimated impacts in the short term (within 12 months of implementation) and in the long term (beyond the first 12 months postmandate). This section estimates the short-term impact[27] of AB 1316 on describe mandate-relevant health outcomes, potential treatment harms, potential disparities, and financial burden. See the *Long-Term Impacts* section for discussion of population-level public health outcomes, social determinants of health, premature death, and economic loss.

Estimated Public Health Outcomes

Measurable health outcomes relevant to AB 1316 include accurate detection of elevated blood lead levels through risk assessments and/or blood lead testing, the prevalence of elevated blood lead levels across a population or a reduction in blood lead level on a case-by-case basis, and short/long term health and non-health outcomes of lead exposure, such as nausea, abdominal pain, neurological issues, and cognitive and educational attainment.

As presented in the *Medical Effectiveness* section, there was insufficient evidence to determine whether universal lead testing was more effective than targeted lead testing in high-risk populations in identifying the prevalence of elevated BLLs. There was limited evidence using a reference level 5.0 µg/dL and clear and convincing evidence using a reference level, of 10.0 µg/dL that suggested that risk assessment questionnaires administered by physicians were only marginally effective or ineffective at identifying children with elevated BLLs. There was clear and convincing evidence that educational/counseling interventions delivered by medical professionals to parents and caregivers to reduce blood lead levels in children are *ineffective* and conflicting evidence as to whether nutritional interventions could actually reduce blood lead levels. Clear and convincing evidence was found for the effectiveness of chelation therapy in reducing blood lead levels in severe cases of lead poisoning, but it was noted that chelation therapy can be harmful in the short term. In cases where the benefit outweighed the risk, chelation is effective in removing lead from the body. As presented in the *Background on Childhood Lead* Exposure section, large-scale policies and interventions for environmental lead abatement, such as lead paint removal and the unleading of gasoline to reduce atmospheric lead, have been more effective in reducing blood lead levels across the country over the past several decades.

As presented in the *Benefit Coverage, Utilization, and Cost Impacts* section, an additional 252,754 enrollees age 0 to 72 months would be tested for lead at a preventive care visit each year, a 273% increase in utilization from baseline in the first 12 months postmandate.

Generally speaking, the public health impact of this bill in the first 12 months postmandate would be increased surveillance of child blood lead levels in a larger population through increased blood lead testing. This increase in testing could change the prevalence of *known* cases of elevated blood lead levels in California children.[28] Assuming 2012 prevalence estimates for California children who exceed the threshold for blood lead (i.e., 1.9% of children age 0 to 72 months with BLLs ≥4.5 µg/dL) accurately represent the true population prevalence, CHBRP estimates that approximately 4,777 additional children

[27] CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

[28] For example, prevalence could decrease if more low-risk children are tested and found to not have been exposed to lead, but prevalence could also increase if there are unknown sources of lead affecting groups of children who are not currently thought to be at risk.

may be detected with BLLs ≥4.5 µg/dL in the first 12 months postmandate as a result of AB 1316. Of these, 657 (13.8%) may have BLLs ≥9.5 µg/dL. See Appendix C for calculations. Despite this increased identification of exposures, CHBRP estimate no public health effect on BLLs or short-term health effects of lead exposure for the children who will be screened and found to have elevated BLLs as a result of AB 1316 in the first 12 months postmandate due to the low proportion of these children who would have BLLs high enough to experience symptoms or receive chelation therapy,[29] the clear and convincing evidence that counseling and education interventions to reduce children's blood lead levels are ineffective, and the time it would take for any potential public health environmental interventions (e.g., lead paint removal, soil abatement) to be initiated and have any effects.

In the first year postmandate, CHBRP estimates that increased surveillance would lead to a change in the known prevalence of elevated child blood lead levels in California leading to an additional 4,777 California children may be accurately detected with BLLs ≥4.5 µg/dL due to increased testing, 13.8% of whom may have BLLs ≥9.5 µg/dL. This increased surveillance may lead to the discovery of new "hot spots" of lead exposure risk around the state, with the potential for longer term abatement activities to prevent further exposure, although this may extend past the short-term timeframe. However, CHBRP estimates no further public health impact in the first 12 months due to clear and convincing evidence that the majority of counseling and education interventions to reduce child blood lead levels are ineffective and the minimal proportion of cases which would have BLLs high enough to receive chelation therapy. CHBRP also estimates AB 1316 would have impacts beyond the first 12 months of implementation; see the *Long-Term Impacts* section for a description.

Potential Harms from AB 1316

A potential for harm occurs with screening tests, in general, in that there is the potential for patients to have false-positive test results. Estimates of false positive testing rates described in the *Medical Effectiveness* section varied between 3% and 9% at a blood lead threshold of 10 µg/dL. A lower threshold of 5 µg/dL is likely to have a higher rate of false positives due to increased precision of measurement required. Therefore, it stands to reason that at least 3% to 9% or more of the additional tests conducted as a result of AB 1316 would yield more false positive results. The negative impacts of false-positive test results include increased anxiety and reduced quality of life as well as the receipt of unnecessary follow-up medical care.

Impact on Disparities[30]

Insurance benefit mandates that bring all state-regulated plans and policies to parity may change an existing disparity.[24] As described in the *Background on Childhood Lead* Exposure section, disparities in lead exposure exist by race/ethnicity, age, gender, and geographic location. Within the first 12 months postmandate, CHBRP estimates that no change in disparities in blood lead levels or health outcomes of lead exposure due to AB 1316. Increased testing may provide more data to improve understanding of or reinforce known lead exposure disparities in California and identify more communities with elevated lead exposure, but given the evidence for the ineffectiveness of educational interventions and the lack of a significant number of children who would receive chelation, CHBRP cannot assess the impact on

[29] CHBRP was unable to identify data regarding the prevalence of BLLs greater than 45 µg/dL at which level chelation therapy may be initiated, but it stands to reason that it would be a very small proportion of all children with elevated BLLs in California.

[30]. For details about CHBRP's methodological approach to analyzing disparities, see http://www.chbrp.org/analysis_methodology/docs/Estimating Impacts on Racial and Ethnic Disparities FINAL.pdf.

disparities in the short term. (For discussion of potential impacts beyond the first 12 months of implementation, see the *Long-Term Impacts* section.)

In the first year postmandate, despite an increase in detected cases of elevated blood lead levels resulting from AB 1316, CHBRP estimates that no change in age, racial/ethnic, or geographical disparities in blood lead levels or health outcomes of lead exposure due to the documented ineffectiveness of educational interventions and the lack of a significant number of children who would receive chelation.

Estimated Impact on Financial Burden

When possible, CHBRP estimates the marginal impact of mandates on financial burden, defined as uncovered medical expenses paid by the enrollee as well as out-of-pocket expenses (e.g., deductibles, copayments, and co-insurance). Because blood lead testing is a covered benefit for all children ages 6 to 72 months, CHBRP estimates that there are currently no enrollees who would be affected by AB1316 with uncovered blood lead testing expenses at baseline, and thus no subsequent change in their financial burden associated with uncovered expenses (Table 1). CHBRP also estimates that total out-of-pocket expenses for the 13.2 million enrollees affected by AB 1316 would not change under the new mandate. However, it should be noted that the cost model does not include potential costs that may be incurred by families whose children are tested and found to have elevated blood lead levels such as the cost of taking measures to remove environmental lead from a home.

CHBRP estimates that AB 1316 would not modify coverage and the net financial burden would remain unchanged in the first year postmandate for enrollees using blood lead testing services. However, it should be noted that the cost model does not include potential costs that may be incurred by families whose children are tested and found to have elevated blood lead levels such as the cost of taking measures to remove environmental lead from a home.

LONG-TERM IMPACTS

Long-Term Utilization and Cost Impacts

In this section, CHBRP estimates the long-term cost impact[31] of AB 1316, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. There are likely long-term impacts stemming from prevention of prolonged exposure to blood lead and these are described qualitatively in the *Public Health Impacts* section. Other notable impacts not examined here, but important nonetheless include the potential harm from labeling children as having elevated blood lead levels and over diagnosis of elevated blood lead levels (see Public Health Impacts section). CHBRP does not provide quantitative estimates of long-term cost impacts.

Utilization Impacts

Postmandate, CHBRP estimates that in the first year of implementation of AB 1316 there would be 252,754 more 0- to 72-month-old enrollees in DMHC- and CDI-regulated plans who would receive blood lead tests, which is equivalent to a utilization increase of 15.6 tests per 1,000, or an increase of 273% in utilization. It is likely there would continue to be a steady state of enrollees receiving blood lead tests post–1 year as blood lead testing for 12- and 24-month-old children is conducted according to guidelines, assuming no major fluctuations in the number of children in this age group. For the children who fall in the 24- to 72-month age group in 2018, CHBRP assumed they are also likely to receive some degree of testing postmandate as lead testing becomes broadly used for children under 24 months old. After this entire cohort of children ages out of the 24- to 72-month-old bracket (the youngest age group who are just over 24 months would fall over the 72-month cut-off in 4 years), then a state of equilibrium may be reached whereby all children at 12 and 24 months are tested before hitting the 24- to 72-month age bracket.

Cost Impacts

As with utilization impacts, it is not likely that expenditures would change if a steady state of testing is assumed (CHBRP estimates in the first year AB 1316 would increase health care expenditures by 0.0043%). Enrollee expenses for blood lead testing would not change in the first year of the mandate and not likely to change post–1 year.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments) while other interventions may take years to make a measurable impact (e.g., coverage for tobacco cessation or vaccinations). When possible, CHBRP estimates the long-term effects (beyond 12 months postmandate) to the public's health that would be attributable to the mandate, including impacts on social determinants of health, premature death, and economic loss.

In the case of AB 1316, CHBRP estimates the change in utilization would be an additional 252,754 enrollees aged 0 to 72 months in DMHC- and CDI-regulated plans who would be tested for lead at a preventive care visit each year, a 273% increase; although this rate may not be sustained at this level after the first 12 months postmandate, it is reasonable to expect that child lead blood testing rates would

[31] See also CHBRP's *Criteria and Guidelines for the Analysis of Long-Term Impacts on Healthcare Costs and Public Health*, available at http://www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

continue to be higher than baseline. Therefore, the long-term public health impacts of AB 1316 include increased childhood lead exposure surveillance and potentially the identification of previously unknown hot spots, or areas in which lead exposure is a problem, which could lead to public health environmental abatement efforts and reduced prevalence of elevated childhood lead exposures. Unlike counseling and education interventions implemented at the individual level, environmental interventions undertaken by public health agencies that affect entire communities or at the policy level to remove lead paint from homes or to reduce lead in soil have been found to be more effective in lowering blood lead levels within affected communities. Large-scale soil abatement and lead paint removal interventions to improve public health outcomes have been shown to be costly but effective in reducing children's blood lead levels in high-prevalence areas around the U.S., including in Butte, Montana, with a history of mining and Syracuse, New York, with a history of industrial activity (Schoof et al., 2016; Shao et al., 2017). Studies on the effectiveness of residential inspection and abatement policies on reducing child blood lead levels have mixed results; some have found significant reductions in BLLs attributable to these policies or interventions (Aizer et al., 2015; Billings and Schnepel, 2015; Kennedy et al., 2014), but others have found no significant differences (Campbell et al., 2012; Yeoh et al., 2014). On a societal level, reductions in lead exposure after regulations such as the prohibition of lead paint and the removal of leaded gasoline from the U.S. market in the 1970s have been linked to reductions in crime years later as children who matured in lower-lead environments became adults (Boutwell et al., 2016; Nevin, 2007; Taylor et al., 2016).

Impacts on the Social Determinants of Health[32] and Disparities

Periodically, health insurance mandates can influence SDoH, which can mediate health inequities. Evidence presented in the *Background on Childhood Lead* Exposure section indicates that disparities exist in childhood lead exposure by age and race/ethnicity, and that geographic location and socioeconomic status, specifically educational attainment, is correlated with childhood exposure to lead. AB 1316 would result in increased blood lead testing and the identification of more cases of elevated blood lead levels. This information can be used to more comprehensively identify populations at risk and implement measures to prevent ongoing or new exposures.

Emerging research is strengthening the link between childhood lead exposure, educational and cognitive attainment, and adult SES; a recent cohort study of children born in the early 1970s in New Zealand found that childhood lead exposure was independently associated with lower IQ, memory issues, and lower socioeconomic status (Bellinger, 2017; Reuben et al., 2017). Another study set in Rhode Island attributed lead abatement policies and falling BLLs to reduced disparities in educational testing scores between African American and white 4th to 8th graders between 1997 and 2010 (Aizer et al., 2015). Studies have also estimated a loss of 0.25 IQ points per 1 µg/dL of lead in a child's blood and 2.39% lower lifetime income per one IQ point lost (Landrigan et al., 2002; Trasande and Liu, 2011).

Although CHBRP estimates that an additional 4,777 children with elevated blood lead levels above 4.5 µg/dL would be identified per year, it is unclear if and to what extent resulting abatement and treatment strategies would reduce blood-lead levels either in affected children or children who avoid exposure through these activities. However, it stands to reason if lead exposure is seen as a factor that inhibits maximum educational attainment and earning potential in disproportionately exposed African American children, children in families with lower socioeconomic status, and children living in specific regions with environmental lead issues, treatment and abatement strategies triggered by increased testing can potentially reduce future exposure in these groups, and potentially ameliorate disparities in educational attainment, and consequently socioeconomic status, related to lead exposure.

[32] For more information about SDoH, see CHBRP's publication *Incorporating Relevant Social Determinants of Health into CHBRP Benefit Mandate Analyses* at http://www.chbrp.org/analysis_methodology/docs/Incorporating Relevant Social_Determinants of Health in CHBRP Analyses Final to WEBSITE 033016.pdf.

It stands to reason that changes in childhood lead exposure detection due to AB 1316 could mediate socioeconomic determinants of health at a population level by increasing surveillance and subsequently triggering large scale public health prevention and abatement interventions in a more comprehensive population of California children. This would increase the likelihood that more children disproportionately affected by lead exposure would experience lower BLLs and fewer health and non-health effects of lead exposure, reaching a higher level of educational and cognitive attainment.

Impacts on Premature Death and Economic Loss

Premature death

Premature death is often defined as death occurring before the age of 75 years[33] (Cox, 2006). In California, it is estimated that there are nearly 102,000 premature deaths each year, accounting for about 1.9 million years of potential life lost (YPLL) (CDPH, 2011).

Elevated blood lead levels, particularly those above 20 µg/dL, have been associated with increased mortality due to all causes (49%), cardiovascular disease (36%), and cancer (68%) (Lustberg and Silbergeld, 2002). Research on associations between premature death and lower blood lead levels is limited, although a systematic review found some studies that identified similar mortality effects at BLLs as low as 5 µg/dL (Navas-Acien et al., 2007). It stands to reason that a small proportion of premature deaths in California may be attributable either directly or indirectly to childhood lead exposure, but the impact of increased blood lead testing through AB 1316 on premature death is unknown.

Economic loss

Economic loss associated with disease is generally presented in the literature as an estimation of the value of the YPLL in dollar amounts (i.e., valuation of a population's lost years of work over a lifetime). In addition, morbidity associated with the disease or condition of interest can also result in lost productivity by causing a worker to miss days of work due to illness or acting as a caregiver for someone else who is ill.

As previously stated, studies have estimated a loss of 0.25 IQ points per 1 µg/dL of lead in a child's blood and 2.39% lower lifetime income per one IQ point lost (Landrigan et al., 2002; Trasande and Liu, 2011). Although CHBRP estimates that an additional 4,777 children with elevated blood lead levels above 4.5 µg/dL would be identified per year, it is unclear if and to what extent resulting abatement and treatment strategies would reduce child blood-lead levels either in affected children or children who avoid exposure through these activities. However, it stands to reason that increased detection of elevated blood lead levels in children as a result of AB 1316 would reduce blood lead levels to some unknown extent, creating a commensurate reduction in economic loss over time.

[33] The overall impact of premature death due to a particular disease can be measured in years of potential life lost prior to age 75 and summed for the population (generally referred to as "YPLL") (Cox, 2006). For more information about CHBRP's public health methodology, see: http://www.chbrp.org/analysis_methodology/docs/Public%20Health%20Approach%20Final%20091216.pdf.

APPENDIX A TEXT OF BILL ANALYZED

On February 21, 2017, the California Assembly Committee on Health requested that CHBRP analyze AB 1316.

CORRECTED MARCH 06, 2017

CALIFORNIA LEGISLATURE— 2017–2018 REGULAR SESSION

ASSEMBLY BILL **No. 1316**

Introduced by Assembly Members Quirk and Cristina Garcia

February 17, 2017

An act to amend Sections 1367.3, 105280, 105285, 105290, and 105310 of the Health and Safety Code, relating to childhood lead poisoning.

LEGISLATIVE COUNSEL'S DIGEST

AB 1316, as introduced, Quirk. Public health: childhood lead poisoning: prevention.

Existing law, the Childhood Lead Poisoning Prevention Act of 1991, required the State Department of Public Health (formerly the State Department of Health Services) between July 1, 1992, and July 1, 1993, to adopt regulations establishing a standard of care, at least as stringent as the most recent United States Centers for Disease Control and Prevention screening guidelines, whereby all children are evaluated for risk of lead poisoning by health care providers during each child's periodic health assessment. The standard of care, among others, is required to be that, upon evaluation, those children determined to be at risk for lead poisoning, according to the regulations, are required to be screened. Existing law creates the Childhood Lead Poisoning Prevention Fund consisting of fees imposed on manufacturers and other persons formerly, presently, or both formerly and presently engaged in the stream of commerce of lead or products containing lead, or who are otherwise responsible for identifiable sources of lead that have significantly contributed historically, currently contribute, or both have significantly contributed historically and contribute currently to environmental lead contamination. The moneys in the

fund are required to be expended, upon appropriation by the Legislature, for the purposes of the act.

This bill would instead require the standard of care to be that all children be screened for blood lead levels and would clarify that the lead screening would not be paid for by funds from the Childhood Lead Poisoning Prevention Fund. The bill would also make conforming changes and delete obsolete provisions.

DIGEST KEY

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: no

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BILL TEXT

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1.

Section 1367.3 of the Health and Safety Code is amended to read:

1367.3.

(a) ~~On and after January 1, 1993, every~~ *Every* health care service plan that covers hospital, medical, or surgical expenses on a group basis shall offer benefits for the comprehensive preventive care of children. This section shall apply to children 17 and 18 years of age, except as provided in ~~paragraph (4)~~ *subparagraph (D) of paragraph (2)* of subdivision (b). Every plan shall communicate the availability of these benefits to all group contractholders and to all prospective group contractholders with whom they are negotiating. This section shall apply to a plan ~~which,~~ *that,* by rule or order of the director, has been exempted from subdivision (i) of Section 1367, insofar as that section and the rules thereunder relate to the provision of the preventive health care services described herein.

(b) For purposes of this section, benefits for the comprehensive preventive care of children shall comply with both of the following:

(1) Be consistent with both of the following:

(A) The Recommendations for Preventive Pediatric Health Care, as adopted by the American Academy of Pediatrics in September of 1987.

(B) The most current version of the Recommended Childhood Immunization Schedule/United States, jointly adopted by the American Academy of Pediatrics, the Advisory Committee on Immunization Practices, and the American Academy of Family Physicians, unless the State Department of ~~Health Services~~ *Public Health* determines, within 45 days of the published date of the schedule, that the schedule is not consistent with the purposes of this section.

(2) Provide for the following:

(A) Periodic health evaluations.

(B) Immunizations.

(C) Laboratory services in connection with periodic health evaluations.

(D) For health care service plan contracts within the scope of this ~~section that are issued, amended, or renewed on and after January 1, 1993, screening for blood lead levels in children at risk for lead poisoning, as determined by a physician and surgeon affiliated with the plan,~~ *section, screening for blood lead levels in all children* when the screening is prescribed by

a physician and surgeon affiliated with the plan. This subparagraph shall be applicable to all children and shall not be limited to children 17 and 18 years of age.

SEC. 2.

Section 105280 of the Health and Safety Code is amended to read:

105280.

For purposes of this chapter, the following definitions apply:

(a) "Appropriate case management" means health care referrals, environmental assessments, and educational activities, performed by the appropriate person, professional, or entity, necessary to reduce a child's exposure to lead and the consequences of the exposure, as determined by the United States Centers for Disease ~~Control,~~ *Control and Prevention,* or as determined by the department pursuant to Section 105300.

(b) "Lead poisoning" means the disease present when the concentration of lead in whole venous blood reaches or exceeds levels constituting a health risk, as specified in the most recent United States Centers for Disease Control *and Prevention* guidelines for lead poisoning as determined by the department, or when the concentration of lead in whole venous blood reaches or exceeds levels constituting a health risk as determined by the department pursuant to Section 105300.

(c) "Department" means the State Department of ~~Health Services.~~ *Public Health.*

(d) "Health assessment" has the same meaning as prescribed in Section 6800 of Title 17 of the California Code of Regulations.

(e) "Screen" means the medical procedure by which the concentration of lead in whole venous blood is measured.

(f) "Health care" means the identification, through evaluation and screening, if indicated, of lead poisoning, as well as any followup medical treatment necessary to reduce the elevated blood lead levels.

(g) "Environmental lead contamination" means the persistent presence of lead in the environment, in quantifiable amounts, that results in ongoing and chronic exposure to children.

SEC. 3.

Section 105285 of the Health and Safety Code is amended to read:

105285.

(a) ~~After July 1, 1992, but on or before July 1, 1993, the~~ *The* department shall adopt regulations establishing a standard of care, at least as stringent as the most recent United States Centers for Disease Control *and Prevention* screening guidelines, whereby all children ~~shall be~~ *are* evaluated for risk of lead poisoning by health care providers during each child's periodic health assessment. The regulations shall be developed in consultation with medical experts, environmental experts, appropriate professional organizations, and the public, as determined by the department.

(b) The standard of care shall provide ~~that, upon evaluation, those children determined to be "at risk" for lead poisoning, according to the regulations adopted pursuant to subdivision (a),~~ *that all children* shall be screened.

(c) The standard of care shall provide that ~~no~~ *a* child shall *not* be screened pursuant to this ~~article~~ *chapter* if the parent or guardian of the child refuses to consent to the screening.

(d) The standard of care shall provide that health care providers ~~shall be~~ *are* responsible only for evaluation of all ~~children, for screening of children determined to be at risk,~~ *children* and for medically necessary followup services.

~~(e)The standard of care established pursuant to this section shall not become operative before April 1, 1993.~~

SEC. 4.

Section 105290 of the Health and Safety Code is amended to read:

105290.

~~On or after April 1, 1993, in those instances in which~~ *When* a child is identified with lead poisoning, the department shall ensure appropriate case management. The department may contract with any public or private entity, including local agencies, to conduct the case management.

SEC. 5.

Section 105310 of the Health and Safety Code is amended to read:

105310.

(a) There is hereby imposed a fee on manufacturers and other persons formerly, presently, or both formerly and presently engaged in the stream of commerce of lead or products containing lead, or who are otherwise responsible for identifiable sources of ~~lead, which~~ *lead that* have significantly contributed historically, currently contribute, or both have significantly contributed historically and contribute currently to environmental lead contamination.

(b) After July 1, 1992, but on or before January 1, 1993, the department shall, by regulation, establish specific fees to be assessed on manufacturers and other parties formerly, presently, or both formerly and presently engaged in the stream of commerce of lead or products containing lead, or who are otherwise responsible for identifiable sources of lead ~~which,~~ *that,* as determined by the department, have significantly contributed historically, currently contribute, or both have significantly contributed historically and contribute currently to environmental lead contamination.

To the maximum extent practicable, the fees shall be assessed on the basis of the following criteria:

(1) A person's past and present responsibility for environmental lead contamination.

(2) A person's "market share" responsibility for environmental lead contamination.

This section shall not apply to, and no fee shall be assessed upon, any retailer of lead or products containing lead.

(c) The fee shall be assessed and collected annually by the State Board of Equalization. The first payment of these fees shall be due on or before April 1, 1993. The annual fee assessment in subdivision (a) shall be adjusted by the department to reflect both of the following:

(1) The increase in the annual average of the California ~~Consumers~~ *Consumer* Price Index, as recorded by the California Department of Industrial Relations, for the most recent year available.

(2) The increase or decrease in the number of children in California who are receiving ~~services~~ *services, excluding screening for blood lead levels as described in Section 105285,* pursuant to this ~~article.~~ *chapter.*

This adjustment of fees shall not be subject to the requirements of Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code.

(d) (1) ~~No~~ *A* fee shall *not* be assessed upon a person if that person can demonstrate, as determined by the department, that his or her industry did not contribute in any manner, as described in this section, to environmental lead contamination.

(2) ~~No~~ *A* fee shall *not* be assessed upon a party if that party demonstrates, as determined by the department, that the lead, or the product containing lead, with which it is currently, or was historically, associated does not currently, or did not historically, result in quantifiably persistent environmental lead contamination.

(e) The fee imposed pursuant to this section shall be administered and collected by the ~~board~~ *State Board* of Equalization in accordance with Part 22 (commencing with Section 43001) of Division 2 of the Revenue and Taxation Code. The fees shall be deposited in the Childhood Lead Poisoning Prevention Fund, which is hereby created in the State Treasury. Moneys in the fund shall be expended for the purposes of this chapter, including the State Board of Equalization's costs of collection and administration of fees, upon appropriation by the Legislature. All interest earned on the moneys ~~which~~ *that* have been deposited into the Childhood Lead Poisoning Prevention Fund shall be retained in that fund.

(f) The fees collected pursuant to this section and the earnings therefrom shall be used solely for the purposes of implementing this chapter. The department shall not collect fees pursuant to this section in excess of the amount reasonably anticipated by the department to fully implement this chapter. The department shall not spend more than it collects from the fees and the earnings in implementing this chapter. In no fiscal year shall the department collect more than sixteen million dollars ($16,000,000) in fees, as adjusted for inflation pursuant to subdivision (b).

(g) It is the intent of the Legislature, in subsequent legislation, to appropriate and deposit into the Childhood Lead Poisoning Prevention Fund the sum of one hundred twenty-eight thousand dollars ($128,000) from the General Fund on July 1, 1992, to the Controller for allocation as loans as follows:

(1) Seventy-eight thousand dollars ($78,000) to the department, for the purposes of adopting regulations to establish the fee schedule authorized by this section. The State Board of Equalization shall repay the amount of this appropriation, on or before June 30, 1993, with interest at the pooled money investment rate, from fees collected pursuant to this section.

(2) Fifty thousand dollars ($50,000) to the State Board of Equalization, for the purposes of implementing this section. The State Board of Equalization shall repay the amount of this appropriation on or before June 30, 1993, with interest at the pooled money investment rate, from fees collected pursuant to this section.

(h) Regulations adopted for fee assessment and collection pursuant to this section shall be exempt from review by the Office of Administrative Law.

APPENDIX B LITERATURE REVIEW METHODS

Appendix B describes methods used in the medical effectiveness literature review conducted for this report. A discussion of CHBRP's system for grading evidence, as well as lists of MeSH terms, publication types, and keywords, follows.

Studies of lead screening and related health outcomes were identified through searches of PubMed, the Cochrane Library, Web of Science, EconLit, Business Source Complete, the Cumulative Index of Nursing and Allied Health Literature, and PsycINFO. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network.

The search was limited to abstracts of studies published in English, published from 2000 to present. As there were few studies published assessing the effectiveness of the current CDC lead screening threshold (5.0 µg/dL, revised in 2012), CHBRP relied on a systematic review published in 2013 for findings from studies on the accuracy of risk assessment questionnaires against the previous threshold (10.0 µg/dL).

Reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

Of the 3,720 unique articles found in the literature review, 112 were reviewed for potential inclusion in this report on AB 1316, and a total of eight studies were included in the medical effectiveness review for this report. The other articles were eliminated because they did not focus on blood lead screening or assessment questionnaires or related health outcomes, were conducted in adults, were of poor quality, or did not report findings from clinical research studies.

Evidence Grading System

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well as the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach.*[34] To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance
- Direction of effect
- Size of effect; and
- Generalizability of findings

[34] Available at: http://www.chbrp.org/analysis_methodology/medical_effectiveness_analysis.php.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- Clear and convincing evidence;
- Preponderance of evidence;
- Limited evidence
- Conflicting evidence; and
- Insufficient evidence

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently finds that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

A grade of *conflicting evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

The search terms used to locate studies relevant to AB 1316 were as follows:

Major MeSH terms used to search PubMed

Lead Poisoning

Subheadings used with above heading

/blood

/complications

/diagnosis

/diet therapy

/drug Therapy

/economics

/epidemiology

/mortality

/prevention and control

/statistics and numerical data

Keywords used to search PubMed, Embase, Cochrane Library, Web of Science, and relevant websites:

Blood lead/Pb levels

Blood lead test

Age factors

Cognitive achievement

Comorbidities

Cost or Costs

Cost Effectiveness

Demand

Economics

Educational attainment

Environmental Health

Epidemiologic Factors or Epidemiology

Ethnicity

Lead Exposure

Lead Poisoning

Morbidity

Mortality

Outcome*

Prevalence

Quality of Life

Racial Disparities

Savings

Social Determinants of Health

Statistics

Supply

Utilization

* = Truncation

APPENDIX C COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firm PricewaterhouseCoopers (PwC).[35]

Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impacts analyses are available at CHBRP's website.[36]

This appendix describes analysis-specific data sources, estimation methods, caveats and assumptions used in preparing this cost impact analysis.

Analysis Specific Caveats and Assumptions

This subsection discusses the caveats and assumptions relevant to analysis of AB 1316. Baseline lead testing rates and associated costs were developed based on 2014 and 2015 MarketScan® commercial claims and enrollment data. The analysis was limited to enrollees aged 0 to 72 months since that is the demographic targeted by AB 1316 for universal testing.

- CHBRP assumes AB 1316 would also similarly affect individual DMHC-regulated plans and all CDI-regulated plans because providers who administer the blood lead test would do so for all children under their care as they would not be able to discern the regulating body of the commercial carriers for each of their patients prior to administering the blood test.
- CHBRP expects that lead testing in the absence of specific risk factors, as intended by AB 1316, would occur in conjunction with the child's regular preventive visits at ages 12 months and 24 months. The marginal cost for lead testing during a preventive visit is assumed to be limited to the cost of the test itself since a blood draw is likely being performed for other services. CHBRP assumes costs would incur for both the collection of blood and laboratory testing for children at the 24-month visit and for children between 24 and 72 months.

The following tables list the Current Procedural Terminology (CPT) and diagnosis codes used to identify lead testing related claims.

Table 5. Lead Lab Test and Blood Draws

CPT Code	Description
83655	Lead lab test
36415	Collection of venous blood specimen
36416	Collection of capillary blood specimen

[35] CHBRP's authorizing statute, available at www.chbrp.org/docs/authorizing_statute.pdf, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
[36] See *2017 Cost Impact Analyses: Data Sources, Caveats, and Assumptions*, available at www.chbrp.org/analysis_methodology/cost_impact_analysis.php.

Table 6. Lead Diagnosis Codes

Diagnosis Codes (ICD 9 and 10)	Description
9840	Toxic effect of lead and its compounds (including fumes)
9841	Toxic effect of lead and its compounds (including fumes)
9842	Toxic effect of lead and its compounds (including fumes)
9843	Toxic effect of lead and its compounds (including fumes)
9844	Toxic effect of lead and its compounds (including fumes)
9845	Toxic effect of lead and its compounds (including fumes)
9846	Toxic effect of lead and its compounds (including fumes)
9847	Toxic effect of lead and its compounds (including fumes)
9848	Toxic effect of lead and its compounds (including fumes)
9849	Toxic effect of lead and its compounds (including fumes)
E8615	Accidental poisoning by lead paints
E8660	Accidental poisoning by lead and its compounds and fumes
T560X1A	Toxic effect of lead and its compounds (including fumes)
T560X1D	Toxic effect of lead and its compounds (including fumes)
T560X1S	Toxic effect of lead and its compounds (including fumes)
T560X2A	Toxic effect of lead and its compounds (including fumes)
T560X2D	Toxic effect of lead and its compounds (including fumes)
T560X2S	Toxic effect of lead and its compounds (including fumes)
T560X3A	Toxic effect of lead and its compounds (including fumes)
T560X3D	Toxic effect of lead and its compounds (including fumes)
T560X3S	Toxic effect of lead and its compounds (including fumes)
T560X4A	Toxic effect of lead and its compounds (including fumes)
T560X4D	Toxic effect of lead and its compounds (including fumes)
T560X4S	Toxic effect of lead and its compounds (including fumes)
V825	Lead poisoning screening
Z1388	Lead poisoning screening
Z77011	Accidental poisoning by lead paints

Table 7. Preventive and Office Visits

Type of Visit	CPT Codes
Preventive Visit	99381
	99382
	99383
	99384
	99391
	99392
	99393
	99394
Office Visit	99201
	99202
	99203
	99204
	99205
	99211
	99212
	99213
	99214
	99215

- The following lead testing rates were determined from the MarketScan® data and were used as the baseline utilization assumptions.

Table 8. Baseline Average Rate of Lead Testing per Year

	Baseline	
Age	In Conjunction with Preventive Visit	In Conjunction with Nonpreventive Visit
0	1.2%	0.4%
1	13.5%	8.0%
2	7.2%	4.7%
3	2.4%	2.2%
4	1.7%	1.8%
5	2.7%	2.0%
6	0.9%	0.7%
Average	4.2%	2.9%

- About 1.8% of children who went in for an initial lead test associated with a preventive visit had a follow-up lead test within 180 days after the initial lead test. Among those children who went in for an additional lead test, approximately 50% had an office visit on the same day, though the cost of the office visit was not included in the cost analysis.
- Postmandate lead testing rates are assumed to reflect the lead testing schedule recommended by Bright Futures/American Academy of Pediatrics and required under EPSDT for children enrolled in Medicaid, which call for testing at 12 and 24 months of age.
- CHBRP assumed 80% testing compliance at those ages, which would occur in conjunction with regular preventive visits. In review of the literature on compliance with blood lead testing, there is a degree of noncompliance from both the provider and patient sides that dampen compliance rates. In settings where universal testing is part of the clinical guidelines, as for Medicaid, reports suggest compliance is around 70% to 80% (Vivier et al., 2001; Wilken et al., 2004). CHBRP assumes postmandate compliance would be 80%, as the uniformity of guidelines stemming from AB 1316 for all children across all insurance types would no longer be a barrier to compliance (Cabana et al., 1999; A. Haboush-Deloye et al., 2017).
- The children who fall in the 24- to 72-month age group in 2018 are also likely to receive some degree of testing postmandate as lead testing becomes broadly used for children under 24 months old. CHBRP assumes a 10% increase in postmandate blood lead testing among this group drawing from the literature that suggests a utilization increase of 0-20% in use of vaccinations among children when cost-sharing is lifted (CHBRP, 2006 citing Lurie et al, 1987; , Cherkin et al, 1990; Valdez et al, 1989). CHBRP used the midpoint, 10%, of the 0% to 20% range for the utilization increase in blood lead tests postmandate. Increase in blood lead testing postmandate among this age group would likely be due to increased parental and provider awareness of blood lead testing and change in preventive testing among the younger 0- to 24-month age group. After this entire cohort of children ages out of the 24- to 72-month-old bracket (the youngest age group who are just over 24 months would fall over the 72-month cut-off in 4 years) then a state of equilibrium may be reached whereby all children at 12 and 24 months are tested before hitting the 24- to 72-month age bracket.

- CHBRP assumed 1.8% of the additional children receiving lead tests would also receive follow-up tests consistent with the baseline utilization.

Table 9. Postmandate Average Rate of Lead Testing per Year

	Postmandate	
Age	In Conjunction with Preventive Visit	In Conjunction with Nonpreventive Visit
0	1.2%	0.4%
1	80.0%	8.0%
2	80.0%	4.7%
3	2.4%	2.2%
4	1.7%	1.8%
5	2.7%	2.0%
6	0.9%	0.7%
Average	24.0%	2.9%

- The marginal cost for lead testing performed outside a preventive visit is assumed to have a slightly higher cost to account for the capillary or venous blood draws, though the MarketScan® data showed that 70% of such lead tests were billed in conjunction with a blood draw. The average cost for a lead test in 2018 is estimated at $16.77, and the average cost of a blood draw is estimated at $5.91. The analysis assumed that the unit cost per tests do not change postmandate.

APPENDIX D PUBLIC HEALTH CALCULATIONS

Short Term

A. 252,754 additional children <72 months old screened each year under AB 1316 (Cost Section)
Multiplied by (x)
1.89% of prevalence of BLLs ≥4.5 µg/dL among children <72 months old (CDPH, 2015a)
Equals (=)
4,777.0506 additional children <72 months old detected with BLLs ≥4.5 µg/dL

B. 252,754 additional children <72 months old screened each year under AB 1316 (Cost Section)
Multiplied by (x)
0.26% of prevalence of BLLs ≥9.5 µg/dL among children <72 months old (CDPH, 2015a)
Equals (=)
657.1604 additional children <72 months old detected with BLLs ≥9.5 µg/dL

C. 657.1604 additional children <72 months old detected with BLLs ≥9.5 µg/dl (Calculation B)
Divided by (/)
4,777.0506 additional children <72 months old detected with BLLs ≥4.5 µg/dL (Calculation A)
Convert to %, Equals (=)
13.8% of all children <72 months old with BLLs ≥ 4.5 µg/dL will have BLLs ≥9.5 µg/dL

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CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM COMMITTEES AND STAFF

A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing contributors to CHBRP from UC that conduct much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, PricewaterhouseCoopers, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

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**A small percentage of AJ Scheitler's time is available to serve as a backup CHBRP staff resource.*

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ACKNOWLEDGEMENTS

Ronald Fong, MD and Meghan Soulsby Weyrich, MPH, of the University of California, Davis, prepared the medical effectiveness analysis. Bruce Abbott, MLS, of the University of California, Davis, conducted the literature search. Sarah Hiller, MA, Sara McMenamin, PhD, and Sara Yoeun, all of the University of California, San Diego, prepared the public health impact analysis. Riti Shimkhada, PhD, of the University of California, Los Angeles, prepared the cost impact analysis. Peter Davidson, FSA, MAAA., and supporting actuarial staff, provided actuarial analysis. Content expert, Alex Kemper, MD, of Duke University provided technical assistance with the literature review and expert input on the analytic approach. Erin Shigekawa, MPH, of CHBRP staff prepared the Policy Context and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see final pages of this report) and a member of the CHBRP Faculty Task Force, Sylvia Guendelman, PhD, LCSW, of the University of California, Berkeley, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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A group of faculty and staff undertakes most of the analysis that informs reports by the California Health Benefits Review Program (CHBRP). The CHBRP Faculty Task Force comprises rotating representatives from multiple University of California (UC) campuses. In addition to these representatives, there are other ongoing contributors to CHBRP from UC. This larger group provides advice to the CHBRP staff on the overall administration of the program and conducts much of the analysis.

CHBRP staff coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and coordinates all external communications, including those with the California Legislature.

CHBRP is also grateful for the valuable assistance of its National Advisory Council, who provide expert reviews of draft analyses and offer general guidance on the program. CHBRP is administered by UC Health at the University of California, Office of the President, led by John D. Stobo, MD, Executive Vice President.

CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

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