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For Medicaid-Enrolled Children Diagnosed With Lead Toxicity in Five States, Documentation Reviewed for Diagnoses and Treatment Services Raises Concerns

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Why OIG Did This Review

Lead toxicity is an environmental health concern that can have lasting effects on the lives of children. Although there is no safe level of lead exposure for young children, exposure is preventable. Children's exposure to lead can be minimized through actions such as regular cleaning of the home; washing of hands and toys; and preventive care to support early detection of lead toxicity and timely followup testing and treatment services.

An Office of Inspector General (OIG) report issued in October 2021 found that more than one-third of Medicaid-enrolled children in five States (California, New York, Ohio, Pennsylvania, and Texas) did not receive required blood lead screening tests during fiscal years (FYs) 2015–2018, which potentially left children vulnerable to the toxic effects of lead exposure. This study expands on that work.

How OIG Did This Review

For the same States noted above, we reviewed Medicaid claims data for FYs 2015–2018. From this data, we selected a sample of 625 enrolled children with a diagnosis indicating lead toxicity, and reviewed children's medical records from the date of diagnosis through 6 months later. The review examined whether children received followup testing and treatment services for their identified blood lead levels (FYs 2015–2019), as recommended by the Centers for Medicare & Medicaid Services (CMS) and the Centers for Disease Control and Prevention (CDC). We also collected public health data from four States to account for services provided exclusive of Medicaid payment and received outside clinical settings, and we asked medical reviewers to consider the respective State medical management guidance. Finally, we interviewed stakeholders regarding followup testing and treatment services for children exposed to lead.

Medicaid offers comprehensive, preventive medical screening services for millions of children annually through the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit. This benefit also includes treatment services to correct issues (e.g., lead toxicity) identified through screenings such as blood lead testing. When young children with confirmed blood lead levels do not receive timely followup testing and treatment services, they could be left vulnerable to continuing lead exposure and permanent developmental effects.

Key Takeaway

In five States, most of the medical records that our study reviewed for children with a lead toxicity diagnosis in their Medicaid claims lacked adequate information to confirm a diagnosis of lead toxicity, highlighting potential implications for oversight of the Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program. Among children for whom there was sufficient medical record documentation to confirm their diagnosis, many did not receive comprehensive followup testing and treatment services, as recommended, for their identified blood lead level.

What OIG Found

In this evaluation of medical records for Medicaid-enrolled children with a diagnosis of lead toxicity in Medicaid claims, medical reviewers could not identify adequate information to confirm that diagnosis in the majority of records (415 out of 581 children).

It is unclear why this many medical records, across five States, lacked information to confirm the diagnosis of lead toxicity identified in the Medicaid claims. According to the American Academy of Pediatrics, it could be a matter of confusion about appropriate diagnosis codes. Nonetheless, the lack of documentation in the medical records to confirm children's lead toxicity diagnoses raises concerns regarding the accuracy of using Medicaid claims data to identify children being treated for lead toxicity. This may have potential implications for State and Federal oversight, including States' annual EPSDT reporting

to CMS regarding blood lead testing and treatment services, which are calculated using claims data.

Because there is no safe lead level for children, even very low blood lead levels may indicate, in some instances, a need for treatment, based on individual factors (e.g., age, environment, increasing blood lead level trend). However, without adequate information in the medical record of a blood lead level at or above 5 µg/dL, or signs, symptoms, and/or notes regarding an elevated blood lead level, medical reviewers could not objectively distinguish children whose medical records indicated a need for followup testing and treatment services during the 6-month review period. Similarly, without accurate data, CMS may be unable to accurately measure EPSDT performance and ensure that Medicaid-enrolled children with lead toxicity are given the best possible health care.

Among the 166 children with sufficient medical record documentation to confirm their diagnoses, medical reviewers determined that half of the children did not receive comprehensive followup testing and treatment services (e.g., environmental assessments to determine the source of exposure), as recommended. Medical reviewers determined appropriate services for lead toxicity based on each child's medical record, using their professional judgment, with reference to followup testing and treatment services recommended by CMS and CDC, and in consideration of State medical management guidance for children's identified blood lead levels.

What OIG Recommends

We recommend that—to address concerns related to the accuracy of claims data for Medicaid-enrolled children diagnosed with lead toxicity, and related to the treatment component of EPSDT for these children—CMS:

1. explore the discrepancy between Medicaid claims data and medical documentation for lead toxicity and implement solutions to ensure better oversight of the EPSDT program; and

2. issue guidance to reiterate State obligations under the EPSDT benefit to ensure access to services to correct or ameliorate confirmed blood lead levels identified during screenings.

CMS concurred with both of the recommendations.

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BACKGROUND

OBJECTIVE

To determine the extent to which Medicaid-enrolled children diagnosed with lead toxicity received followup testing and treatment services as recommended by the Centers for Medicare & Medicaid Services and the Centers for Disease Control and Prevention during fiscal years (FYs) 2015–2019.

Lead toxicity is an environmental health concern that can have lasting effects on the lives of children. Although there is no safe level of lead exposure for young children, exposure is preventable.[1] Children's exposure to lead can be minimized through actions such as regular cleaning of the home; washing of hands and toys; a healthy diet; and preventive care to support early detection of lead toxicity and timely followup.[2, 3]

Millions of children receive comprehensive, preventive medical screening services annually as part of Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit.[4] Under this benefit, States must provide or arrange for screening services including blood lead screening tests and treatment for issues identified via screenings.[5] When young children are screened and found to have developmental delays, they can also become eligible for State early intervention services.[6, 7]

When children with lead toxicity do not receive timely followup testing and treatment services, they could be left vulnerable to continuing exposure and serious, permanent developmental impacts of toxic lead exposure. Children exposed to lead may suffer stunted cognitive development (e.g., reduced academic performance and increased impulsivity), slowed growth, and hearing and speech problems.[8, 9, 10] Longer term, childhood lead exposure has been linked to increased incidence of hypertension and coronary heart disease, and higher rates of crime and arrests in adulthood.[11, 12]

Lasting behavioral and educational benefits have been identified for young children exposed to lead who receive treatment services in the form of public health and early intervention services (e.g., lead remediation, speech therapy). Specifically, early interventions for lead exposure are associated with a decline in antisocial behaviors such as absences and school crimes, and consequences such as suspensions and arrests.[13] Research also yields broader academic and economic impacts associated with these types of interventions. Children exposed to lead who received such services scored higher on third-grade standardized tests.[14] Similarly, each $1 invested in early interventions for children with confirmed blood lead levels could yield a return of nearly $1.40 associated with test score improvements and crime reduction.[15]

Early and Periodic Screening, Diagnostic, and Treatment services for children with lead toxicity

Every State Medicaid program must offer the EPSDT benefit. States share responsibility for implementing the benefit, along with CMS. States have an affirmative obligation to make sure that Medicaid-enrolled children and their families are aware of EPSDT and have access to required screenings and necessary treatment services.[16] States also have flexibility in determining how to best ensure that EPSDT services are provided, and may administer the benefit outright via fee for service arrangements or contract with managed care entitities for service provision. States must establish periodicity schedules for EPSDT screening services (e.g., blood lead screening tests) and must consult with medical organizations involved in child health care to assist in the development of State periodicity schedules.

The Centers for Medicare and Medicaid Services (CMS) considers all Medicaid-enrolled children to be at risk of lead toxicity; therefore, blood lead screening tests are a required service under EPSDT.[17, 18] When screening services indicate a need for further evaluation, CMS suggests that children should receive a complete diagnostic evaluation and diagnostic services to evaluate any conditions discovered by a screening (e.g., a blood lead level).[19] States are required to cover necessary health care and treatment services for children's conditions identified during EPSDT screenings, including services not otherwise covered under State plans.[20] Treatment services for children with lead toxicity may include referrals to other Federal programs or State health agencies and community-based programs.[21]

Diagnosis of elevated blood lead levels

In its guidance, CMS references two distinct blood lead levels related to confirmatory testing, followup and treatment services for lead toxicity. First, the CMS State Medicaid Manual cites to a blood lead level of 10 µg/dL (micrograms per deciliter). The Manual notes that if a blood lead screening test result obtained by capillary specimen (fingerstick) identifies a blood lead level equal to or greater than 10 µg/dL, the result must be confirmed using a venous blood sample. Further, the Manual states that children with confirmed levels at or above 10 µg/dL must be diagnosed with an elevated blood lead level in order for practitioners to receive reimbursement for some activities to determine the source of lead exposure.[22] Second, a 2016 CMS informational bulletin cites to the Centers for Disease Control and Prevention (CDC) blood lead reference value as the threshold level at which the CDC recommended public health actions should be initiated.[23] During our review period, the CDC blood reference level was 5 µg/dL. Following our review period, in October 2021, CDC lowered the CDC blood lead reference value to 3.5 µg/dL, CMS updated the lead screening web page on Medicaid.gov to reflect CDC's updated reference value, and CMS highlighted the updated reference value during a call with Medicaid medical directors.[24, 25] The updated reference value was not reflected in the CMS State Medicaid Manual as of December 2022.

Followup testing and treatment services for children diagnosed with elevated blood lead levels

EPSDT provides for necessary health care, diagnostic services, and treatment to correct or ameliorate any physical and mental illnesses or conditions discovered by a screening (e.g., a blood lead level identified via a blood lead screening test).[26] The CMS State Medicaid Manual offers additional guidance for treating children with blood lead levels at or above 10 µg/dL. The Manual notes that practitioners should use professional judgment and refer to CDC guidelines for patient management and treatment, including followup blood lead tests and investigations to determine the source of lead, where indicated.[27] Practitioners are also advised to coordinate with other Federal partners such as the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and Head Start, as well as private and public resources, to help ensure comprehensive diagnosis and treatment for children diagnosed with lead toxicity. In some cases, this coordination could include States' public health departments; the Manual indicates that public health departments' childhood lead poisoning prevention programs may be available.

Other guidance related to followup testing and treatment services for lead toxicity

In the State Medicaid Manual, CMS suggests that States reference or adopt clinical practice guidelines such as guidance published by the CDC, or the American Academy of Pediatrics' (AAP's) Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents.[28] State public health departments also establish State-specific guidance for practitioners related to medical management of children's blood lead levels. See Appendix A for Federal guidance and recommendations related to followup testing and treatment services for lead toxicity, and a summary table of CDC-recommended actions based on blood lead level. See Appendix B for a table of guidance from States included in this review related to medical management of children's identified blood lead levels.

CDC

CDC publishes recommendations for followup and case management of children with confirmed blood lead levels (i.e., a capillary blood lead test confirmed with blood drawn by venipuncture). CDC also makes recommendations regarding the blood lead reference value, which can help identify children with higher levels of lead in their blood compared to most children.[29] CDC notes that the blood lead reference value serves as a guide to empower public health partners to determine whether medical or environmental followup actions should be initiated for individual children, and to prioritize community prevention efforts.[30] CDC has also developed recommended timelines for (1) obtaining a confirmatory venous blood sample, (2) early followup testing, and (3) later followup testing after a child's blood lead level begins to decline

(see Exhibit 1 on the next page for recommended timelines during our review period).[31]

CDC-recommended case management services vary depending on a child's identified blood lead level. Although CDC updated the blood lead reference value to 3.5 µg/dL in October 2021, CDC used a blood lead reference value of 5 µg/dL prior to October 2021, and during our review period.[32] Therefore, for children with blood lead levels below 5 µg/dL during our review period, services recommended by CDC included routine assessments of nutritional and developmental milestones, anticipatory guidance about lead exposure sources, and followup testing at age-based intervals. As blood lead levels increase above the reference value, CDC recommended more frequent testing, public health actions such as environmental assessments and investigations, nutritional counseling, lab work to identify nutritional deficiencies, abdominal X-rays, neurological exams, and chelation therapy (see Appendix A).[33]

Exhibit 1: During our review period, CDC recommendations for followup and case management of children with confirmed blood lead levels included timeframes for when children should receive followup blood lead testing.

Venous blood lead levels (µg/dL)	Early followup testing (2-4 tests after identification)	Later followup testing after blood lead level declining
≥5*–9	3 months	6–9 months
10–19	1–3 months	3–6 months
20–24	1–3 months	1–3 months
25–44	2 weeks–1 month	1 month
≥45	As soon as possible	As soon as possible

*In October 2021, following our review period, CDC lowered the blood lead reference value from 5 µg/dL to 3.5 µg/dL.

Source: OIG review of CDC documentation, 2022.

AAP

AAP guidance regarding screening children for lead exposure and followup for children's blood lead levels emphasizes prevention and risk assessment as key factors in reducing childhood lead exposure. One prevention effort is AAP's anticipatory guidance, which outlines discussion points to educate parents about lead exposure, minimize risks, and develop a plan to create a lead-safe environment for children.[34] During our review period, AAP recommended that when practitioners identify blood lead levels of 5 µg/dL or greater in a child, they should initiate services such as finding and removing environmental sources of lead, and optimizing the child's diet and nutritional status.[35, 36]

State medical management guidance

State health departments issue State-specific guidance related to medical management of children exposed to lead. During our review period, all five States in

this review (California, New York, Ohio, Pennsylvania, and Texas) offered recommendations for children based on identified blood lead level; these recommendations did not always align with guidance from CMS and CDC (see Detailed Methodology). Although these State recommendations varied, for children with levels below 5 µg/dL, State-recommended services typically included followup testing at specified intervals, anticipatory guidance, or parent education, depending on the State. For children with blood lead levels above 5 µg/dL, State recommendations included services such as more frequent blood lead testing; nutritional counseling; developmental monitoring; and environmental assessments and investigations, among others. State guidance on early intervention services for children exposed to lead also varied. California recommended that practitioners consider referrals to WIC and encourage participation in early enrichment activities for children with identified blood lead levels below 5 µg/dL. Ohio recommended that children with blood lead levels at or above 5 µg/dL receive referrals to WIC and State early intervention services if developmental delays were identified. See Appendix B for additional details on State medical management guidance.[i]

CMS oversight of State reporting on Early and Periodic Screening, Diagnostic, and Treatment services

Each year, CMS requires States to submit data on the annual EPSDT report Form CMS-416, which tracks the expected and actual number of EPSDT screening services provided to Medicaid-enrolled children in different age groups.[37, 38] The report demonstrates State EPSDT participation ratios and screening goals. Additionally, the report is used to identify trends and patterns that CMS notes can inform decisions and recommendations to ensure that Medicaid-enrolled children are given the best possible health care.

Form CMS-416 instructs States to report annually, based on Medicaid claims data, certain medical screening procedures including blood lead screening tests. Form CMS-416 notes that States may count as blood lead screening tests instances of a blood lead test procedure in Medicaid claims when accompanied by a diagnosis code to indicate that the test was a blood lead screening test (e.g., a well-child check or exposure to lead diagnosis code), among other methods.[39] The instructions also note that Medicaid claims with a blood lead test procedure and a lead toxicity diagnosis code generally indicate that a child has already been diagnosed with, or is being treated for, lead toxicity; followup tests for children who are being treated for lead toxicity should not be counted toward the total number of blood lead screening tests.

In addition to tracking screening services, CMS instructs States to count the total number of children referred for corrective and/or treatment services after an initial or

[i] Although some States have incorporated elements of their guidance into regulation, the objective of this review was not to assess compliance with legal requirements, but to assess the extent to which children diagnosed with lead toxicity received recommended followup testing and treatment services for their identified blood lead level.

periodic screening (e.g., referred for treatment services for a blood lead level identified during a screening office visit).

Related work

This study follows earlier OIG work on EPSDT services. One report, issued in October 2021, found that in FYs 2015–2018, more than one-third of 1 million children enrolled in Medicaid did not receive a blood lead screening test at ages 12 months and 24 months, as required by Medicaid's schedule.[40] OIG made three recommendations to CMS related to monitoring of national EPSDT performance data for blood lead screening tests to increase tests according to Medicaid's schedule, ensuring consistency across CMS guidance, and coordinating with partners to develop and disseminate educational materials on requirements and schedules for blood lead screening tests. An earlier OIG report on the completeness of EPSDT medical screenings for Medicaid-enrolled children also identified deficiencies in blood lead screening tests for children ages 12 and 24 months.[41] In response to this work, CMS convened a National EPSDT Improvement Workgroup to identify the most critical areas for improvement in EPSDT, discuss steps to increase the number of children who access EPSDT services, and improve data reporting.[42]

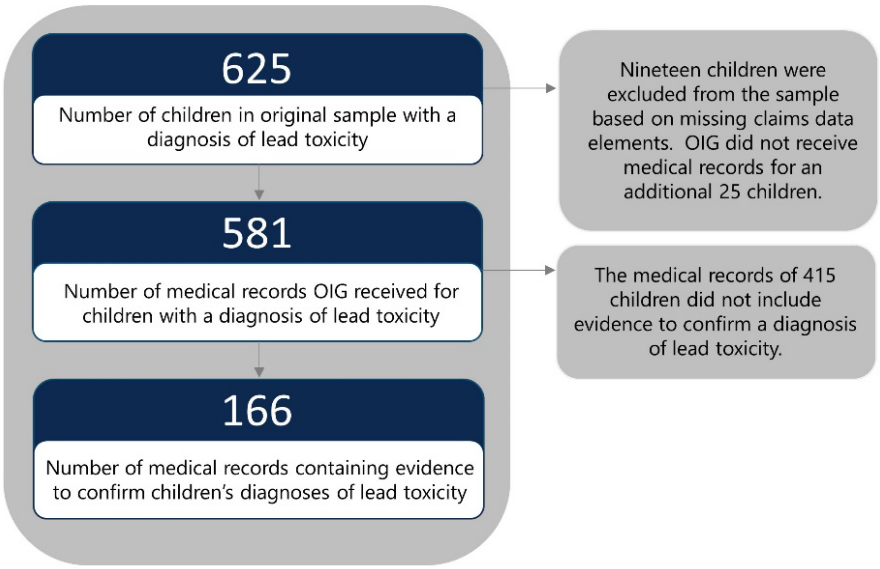
Methodology

This study includes a medical record review for Medicaid-enrolled children with a diagnosis of lead toxicity in Medicaid claims, in five States—California, New York, Ohio, Pennsylvania, and Texas—and stakeholder interviews. These States had among the greatest numbers of children with confirmed high blood lead levels based on National Childhood Blood Lead Surveillance Data from CDC and were selected to ensure that we had a large enough population to sample from for medical record review.[43]

Data collection. To examine followup testing and treatment services for children diagnosed with lead toxicity, we first collected Medicaid Management Information System data for FYs 2015–2018 from the five selected States. Specifically, we collected all incurred fee-for-service claims and managed care encounters, and eligibility data. We used the Medicaid data to identify a population of children with (1) a diagnosis in Medicaid claims indicating lead toxicity, as described in the Form-CMS 416 State reporting instructions, and (2) at least 6 months of continuous Medicaid enrollment following that diagnosis. From this population, we selected a simple random sample of 625 children—125 children per State. Of the 625 children in our sample who had a diagnosis of lead toxicity in their respective Medicaid claims, we received medical records for 581 children, a 93-percent overall weighted response rate (see Exhibit 2 on next page).

The medical record review included records that we collected for each child, from the date of diagnosis in Medicaid claims through the 6 months following their diagnosis, including FYs 2015–2019. We selected this period in consideration of recommended

Exhibit 2: Flowchart of Medicaid-enrolled children with a diagnosis of lead toxicity in Medicaid claims who were included in our medical record review



Source: OIG analysis of medical record documentation, 2022.

timelines for followup blood lead testing from CDC, and from the States selected for this review. See the Detailed Methodology for more information on medical record collection timelines. See Appendices A and B for details on recommended followup testing timelines from CDC and the selected States.

We developed a medical record review instrument using the guidance noted above, and in collaboration with physician toxicologist reviewers (medical reviewers) with experience in followup testing and treatment services for children exposed to lead. The instrument was not designed to test for compliance with payment, coverage, or other legal requirements, but was designed to assess the extent to which recommended treatment services were provided to children diagnosed with lead toxicity.

All 581 medical records were reviewed first by contracted nurse abstractors, who flagged in the records documentation related to followup testing or treatment services for children's identified blood lead levels. Medical reviewers then reviewed each abstracted record for evidence to confirm the diagnosis of lead toxicity in the Medicaid claims, and, for confirmed records, evidence of followup testing and treatment services in the 6 months following a child's diagnosis. Of the 581 records received, medical reviewers deemed 166 records to include sufficient evidence to confirm the diagnosis of lead toxicity. These confirmed records had either evidence of a blood lead level at or above 5 µg/dL—the CDC's blood lead reference value in use during our review period—or evidence of a blood lead level below 5 µg/dL, accompanied by documentation of signs, symptoms, or practitioner notes regarding an elevated blood lead level. The instrument incorporated the CDC's 5 µg/dL blood lead reference value for confirming a diagnosis of lead toxicity so that medical

reviewers could objectively distinguish children whose medical records indicated a need for followup testing and treatment services during the 6-month review period, irrespective of variances among State medical management guidance.

To account for public health and case management services that children diagnosed with lead toxicity may have received outside of clinical settings—services that may not show up in medical records—we requested data and documentation from State health departments for the 625 children selected for the medical record review. State health departments in 4 States—California, New York, Ohio, and Texas—returned data and/or case file documentation for 144 children, 75 of whom were among the 166 children whose lead toxicity diagnoses our medical reviewers confirmed.

To collect information regarding barriers and challenges in the provision of followup testing and treatment services for children with lead toxicity, we identified medical reviewer notes from the medical record review and conducted stakeholder interviews. We interviewed stakeholders from government agencies and professional organizations regarding followup testing and treatment services for Medicaid-enrolled children exposed to lead.

Data analysis. For the 166 medical records with a lead toxicity diagnosis our medical reviewers were able to confirm, we analyzed results of the review to assess whether children received treatment services for their identified blood lead levels. Per the CMS State Medicaid Manual, we asked medical reviewers to use their professional judgment, with reference to followup testing and treatment services recommended by CMS and CDC. The Manual also suggests that treatment for children diagnosed with lead toxicity may include coordination with health departments; therefore, we asked reviewers to consider respective State medical management guidance for children's identified blood lead levels. Using these criteria, medical reviewers determined whether children received appropriate services for lead toxicity. Additionally, medical reviewers examined the records to determine whether children with blood lead levels at or above 5 µg/dL received early followup blood lead testing as recommended by the CDC schedule during the review period, or whether there was evidence of any followup blood tests during children's respective periods of review.

For this review, medical reviewers determined **appropriate services** for lead toxicity using their professional judgment, with reference to:

- followup testing and treatment services recommended by CMS and CDC; and
- respective State medical management guidance for children's identified blood lead levels.

We reviewed data and case file documentation from State health departments to identify other services that children with a confirmed diagnosis of lead toxicity may have received outside of clinical settings. Specifically, we looked for dates of services

and types of case management and/or public health services that children received to provide a sense of other possible followup care.

Finally, we analyzed medical reviewer notes and interview data to identify common themes related to the provision of followup testing and treatment services for children exposed to lead. See the Detailed Methodology for more information on data analysis.

Limitations

We identified diagnoses of lead toxicity for this work using incurred (i.e., paid and unpaid) Medicaid claims; we did not assess payment associated with this diagnosis, nor compliance with coverage requirements. Our medical reviewers found that 415 of the 581 reviewed medical records contained insufficient information to determine whether these children had the blood lead levels and symptoms to warrant further followup services. Although the medical reviewers conducted a thorough examination of the remaining 166 medical records, the results of these medical record reviews are not projectable.

Data obtained from State health departments were limited and, as such, were not used by our medical reviewers to make their determinations as to whether appropriate services were provided. That assessment was based solely on medical records. The limited data obtained from State health departments only provide some awareness of the types of case management or public health services that children may receive outside of clinical settings.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

In 5 States, more than two-thirds of 581 medical records for Medicaid-enrolled children lacked adequate information to confirm the diagnosis of lead toxicity in the Medicaid claims

In this evaluation of medical records for 581 Medicaid-enrolled children with a diagnosis of lead toxicity in their Medicaid claims, medical reviewers could not find adequate information to confirm a diagnosis of lead toxicity in 415 children's records (see Exhibit 3 below). For these 415 children, medical reviewers could not identify (1) evidence that a child had a blood lead level at or above 5 µg/dL, or (2) evidence of a blood lead level below 5 µg/dL, accompanied by (A) signs and symptoms of an elevated blood lead level, and/or (B) notes from a practitioner regarding an elevated blood lead level. Because there is no safe lead level for children, even very low blood lead levels may indicate in some instances a need for treatment, based on individual factors (e.g., age, environment, increasing blood lead level trend). However, without adequate information in the medical records, medical reviewers were unable to determine the applicability of recommended followup testing and treatment services for these children.[44]

Exhibit 3: Medical records for the majority of the children (415 of 581) did not contain adequate information to confirm the diagnosis of lead toxicity in the Medicaid claims.

Source: OIG analysis of medical record documentation, 2022.

It is unclear why this many medical records, across five States, lacked information to confirm the diagnosis of lead toxicity identified in the Medicaid claims. One possible explanation provided by AAP is that there may be confusion regarding different diagnosis codes. There are several diagnosis codes that a practitioner could apply when screening a child for a potential lead exposure; when testing and confirming a blood lead level; and when treating a child for lead toxicity. Stakeholders from AAP shared with OIG that a diagnosis of lead toxicity would typically be associated with serious cases, such as when a child is hospitalized for acute lead toxicity. Otherwise, if a patient does not demonstrate toxic effects, AAP suggested, a code that indicates signs and symptoms, such as a diagnosis of abnormal lead levels in the blood, would more often be used. One clinical stakeholder suggested that it is possible that some practitioners may use the lead toxicity code as a means to order a blood lead screening test during an EPSDT preventive care office visit. Regardless of the reason, AAP shared that the number of cases that lacked adequate information to confirm a diagnosis of lead toxicity was concerning.

There are possible implications for Federal oversight of the EPSDT benefit if an initial or periodic blood lead screening test during an EPSDT office visit is mistakenly coded as lead toxicity, instead of a well-child check. Specifically, the Medicaid claim could be incorrectly excluded from State reporting of blood lead screening tests to CMS, as CMS presumes this diagnosis to be a flag of ongoing treatment and not an initial screening. This could result in an undercount of the total number of blood lead screening tests reported by the States. Further, this could result in an overcount of the number of children referred for corrective and/or treatment services that a State reports to CMS. Without reliable claims data on blood lead testing and treatment services for children with lead toxicity, CMS lacks sufficient information to oversee States' blood lead screening and remediation efforts for Medicaid-enrolled children exposed to lead.

Among children whose medical records lacked information to confirm a diagnosis of lead toxicity, 340 children had blood lead levels below the reference value, and the remaining 75 children had no recorded blood lead levels

For 340 of the 415 children with a diagnosis of lead toxicity in their Medicaid claims, medical reviewers frequently identified blood lead levels below the blood lead reference value of 5 µg/dL that was in use during our review period. As such, they could not establish a justification for followup testing and treatment services for lead toxicity (see Exhibit 4).

Further, blood lead levels in the medical records for more than three quarters of these children (305 out of 340) had levels that fell below CDC's updated blood lead reference value of 3.5 µg/dL—the value currently used to identify children with higher levels of lead in their blood compared to most other children. Most of the remaining 35 children had a blood lead level between 3.5 and 4.9 µg/dL.[45] Medical reviewers often indicated in case notes for these children that a child (1) appeared to be a normal infant or toddler; (2) had a low blood lead level and no related signs or symptoms; or (3) had a low blood lead level associated with a routine preventive care office visit.

Exhibit 4: Among the 415 children with medical records that lacked adequate information to confirm a diagnosis of lead toxicity, 340 children had blood lead levels below 5 µg/dL, and records for the remaining 75 children did not include evidence of any blood lead level.

Source: OIG analysis of medical record documentation, 2022.

For the remaining 75 of the 415 children with a diagnosis of lead toxicity in their Medicaid claims, medical reviewers could not find evidence in the medical record of any documented blood lead level during a child's period of review (see Exhibit 4,

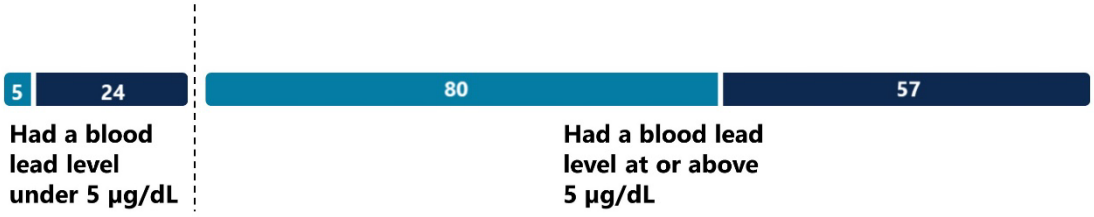
above). For 32 of these children for whom medical reviewers included case notes, medical reviewers indicated that the record contained minimal documentation to review (e.g., orders for blood lead tests but no lab results recorded in the record; minimal practitioner notes or documentation of visits).

In 5 States, half of the 166 medical records for children with a confirmed diagnosis of lead toxicity did not include evidence of comprehensive followup testing and treatment services, as recommended

Among the 166 Medicaid-enrolled children with sufficient documentation to confirm a diagnosis of lead toxicity in their Medicaid claims, medical reviewers determined whether children received appropriate followup testing and treatment services. For the purposes of this review, medical reviewers determined appropriate services for lead toxicity using their professional judgment, with reference to followup testing and treatment services recommended by CMS and CDC, and in consideration of respective State medical management guidance for children's identified blood lead levels (see Appendices A and B). Therefore, recommended services that reviewers looked for in the records varied according to a child's blood lead level and State. These recommended services ranged from routine developmental and nutritional assessments for children with low levels to neurological examinations for children with high levels.

Medical reviewers determined that 85 of the 166 children with a confirmed diagnosis did not receive appropriate followup testing and treatment services for children's identified blood lead levels while 81 children received appropriate followup testing and treatment services. A greater proportion of children with blood lead levels less than 5 µg/dL, for whom medical reviewers also identified signs, symptoms, and/or notes in the medical record, received appropriate services than did children with blood lead levels at or above 5 µg/dL. See Exhibit 5 below for the blood lead level ranges of the 166 children and whether each received appropriate services. See Appendix C for results of the medical record review.

Exhibit 5: Of the 166 children, 85 children did not receive services as recommended for their identified blood lead level, and 81 children received appropriate services, as recommended.



Source: OIG analysis of medical record documentation, 2022.

Among the 85 children who did not receive appropriate services, medical reviewers found documentation demonstrating that nearly two-thirds of the 85 children received some services; however, they determined that the services did not meet recommendations for followup testing or treatment services from CMS, CDC, and medical management guidance from children's respective States. Specifically, medical reviewers found that 51 children had no medical record documentation of early followup blood lead testing as recommended by the CDC schedule for their identified blood lead levels.[46] Further, 32 of these children had no medical record documentation of followup tests at all during their respective periods of review. Medical reviewers also found that more than three-quarters of the 85 children did not receive environmental services (e.g., assessments or investigations to identify potential sources of exposure) or referrals for services, as recommended by CDC. In nearly half of the records for children with blood lead levels at or above 10 µg/dL, medical reviewers identified a lack of services such as nutritional counseling and/or lab work to assess iron status, as recommended by CDC. Medical reviewers determined that nearly a quarter of the 85 children did not receive any services or treatment recommended by CMS, CDC, and medical management guidance from the children's respective States. In the absence of recommended services for their identified blood lead levels, children could miss out on critical early interventions to help mitigate ongoing exposure and to identify nutritional and developmental issues related to lead exposures.

In the medical record for one child with a blood lead level of 10 µg/dL, the reviewer **did not identify recommended followup tests and treatment services in the record.** The reviewer indicated that the child did not receive any followup testing to see if their blood lead level was declining until 6 months later. Further, the child did not receive recommended assessments to identify nutritional deficiencies, developmental delays, or environmental sources of lead exposure. Instead, the child received an abdominal X-ray and a bone lead survey; **the reviewer noted that these tests were done unnecessarily.**

For 81 of the 166 children with a confirmed diagnosis, medical reviewers determined that children received appropriate services to treat their identified blood lead levels that met recommendations from CMS, CDC, and medical management guidance from children's respective States. In contrast to the 85 children who did not receive appropriate followup testing and treatment services, these 81 children received a variety of services and treatments. Two-thirds of the children for whom the CDC schedule recommended early followup testing within 3 months received testing as recommended.[47] Moreover, nearly all of these children received a followup blood lead test during their respective periods of review. Almost all of the 81 children

received assessments of nutrition and developmental milestones. These children also more frequently received environmental services to identify potential sources of lead exposure and were more often referred for recommended services than were children who did not receive appropriate services. Reviewer notes for these children indicated referrals for services such as speech therapy; developmental assessment; neurology; dietary counseling; and health department or environmental health clinic involvement. These types of recommended public health interventions and services are associated with long-term behavioral and educational benefits for young children with identified blood lead levels.

In the medical record of another child with a blood lead level of 10 µg/dL, a reviewer identified **followup tests and treatment services, as recommended.** In this case, the reviewer found that the child received subsequent tests to monitor blood lead levels throughout the review period. The record also noted involvement of the health department to identify the source of lead exposure in the child's home, and nutritional and developmental services.

In four of the five States, State health department data demonstrated that children diagnosed with lead toxicity may receive public health services outside of clinical settings

For children with confirmed blood lead levels, public health resources can help facilitate important services such as lead remediation efforts in the home. Because health department data were only obtained from four of the five States in this review and were not comparable to the medical record review data (see Detailed Methodology), medical reviewers did not review and assess this data to help make their determinations as to whether children received appropriate services for their identified blood lead levels from payors other than Medicaid. Still, the identification of these public health services demonstrates that case management and coordination of care for blood lead levels can, at times, occur outside clinical settings. These data may have complemented the medical care that children received in clinical settings.

For example, among the 166 children with a confirmed diagnosis, we found evidence of at least 1 public health service for just under half of the children during their respective periods of review. For the previously mentioned 85 children who did not receive appropriate followup testing and treatment services according to the medical record review, we identified in State health department data that 33 children in California, New York, and Ohio had 1 or 2 documented services during their respective review periods; 11 children had 3 or more services (e.g., blood lead testing, environmental, nutritional, or parent education services) documented in health

department data. For the 81 children who medical reviewers determined had received appropriate followup testing and treatment services, we also identified at least 1 public health service for more than one-third of these children in New York, Ohio, and Texas. Specifically, 26 of these 81 children had 1 or 2 documented services during their review period, and 5 children had 3 or more services documented in health department data.

These public health data included additional services for children diagnosed with lead toxicity; however, a lack of corresponding medical record documentation could present a challenge to coordination of care. A child with lead toxicity may benefit from public health services such as followup blood lead testing or an environmental investigation conducted by a local health department, but if such services are not documented in the medical record, future case management and followup care for identified blood lead levels could suffer.

CONCLUSION AND RECOMMENDATIONS

Our review underscores the importance for CMS to focus its attention on two aspects of EPSDT: State reporting of Medicaid claims data that CMS uses to measure EPSDT program participation each year, and the treatment component of EPSDT for children diagnosed with lead toxicity. For the majority of children in this evaluation, medical reviewers could not find adequate information to confirm a diagnosis of lead toxicity in the Medicaid claims. It is unclear why this many medical records, across five States, lacked information to confirm the diagnosis of lead toxicity in children's Medicaid claims. Regardless of the reason, this raises concerns about the accuracy of the Medicaid claims data and annual State EPSDT reporting to CMS. Without accurate claims data, CMS may be unable to accurately measure States' EPSDT performance and ensure that Medicaid-enrolled children with lead toxicity are given the best possible health care.

Among the children for whom medical records confirmed the diagnosis, medical reviewers determined that half of the children did not receive comprehensive followup blood lead testing and treatment services (e.g., environmental assessments to determine the source of exposure), as recommended by CMS, CDC, and respective State medical management guidance for a child's identified blood lead level. In a few cases, children had no followup testing or treatment services for their identified blood lead levels documented in their medical record. However, half of the 85 children who did not receive appropriate followup testing and treatment according to the medical record review did receive at least 1 public health service for lead toxicity during their respective period of review. This suggests that treatment for blood lead levels can occur outside of clinical settings. Nonetheless, the fact that public health services may not be not captured in medical documentation could present challenges for case management and coordination of care.

We recommend that CMS:

Explore the discrepancy between Medicaid claims data and medical documentation for lead toxicity and implement solutions to ensure better oversight of the EPSDT program

Given that the majority of medical records in our review lacked adequate information to confirm the diagnoses of lead toxicity in children's Medicaid claims, CMS should explore this discrepancy to identify root causes, examine potential impacts, and identify solutions to address the issue. CMS could accomplish this by convening a workgroup similar to the National EPSDT Improvement Workgroup that includes State Medicaid agency representatives, children's health providers, and other experts in Medicaid, data analysis, and environmental health issues such as lead toxicity. CMS

could also accomplish this by using an existing workgroup or standing meeting structure to hold a webinar or information sharing session with similar experts. CMS could share the findings from OIG's report with this group and engage the group to determine the root causes for the discrepancy between the Medicaid claims data and the medical records. CMS could also engage the group to examine potential impacts on oversight of the EPSDT program and identify solutions to address the issue. CMS could then work to implement solutions based on the group's determinations.

Issue guidance to reiterate State obligations under the EPSDT benefit to ensure access to services to correct or ameliorate confirmed blood lead levels identified during screenings

To ensure that Medicaid-enrolled children with illnesses and conditions identified during EPSDT screenings (e.g., a confirmed blood lead level following a blood lead screening test) receive necessary treatment services, CMS should issue guidance to States. The guidance should remind States of EPSDT service requirements related to treatment and corrective services for illnesses and conditions identified during screenings. The guidance should also reaffirm Medicaid coverage for services such as followup blood lead testing or investigations to determine the source of lead exposure for children with confirmed blood lead levels. The guidance could promote case management and coordination of care among the practitioner community, health departments, and other local resources when treating children for conditions including lead toxicity.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with both of OIG's recommendations.

In response to our first recommendation—that CMS explore the discrepancy between Medicaid claims data and medical documentation for lead toxicity and implement solutions to ensure better oversight of the EPSDT program—CMS stated that it would collaborate with other Federal partners and AAP to share the findings from OIG's report with State Medicaid agency medical directors. Additionally, CMS stated that it would remind States of their obligations to provide clinical and coding guidance to their providers.

Although OIG views CMS's planned response to the first recommendation as positive, we do not consider these activities sufficient to close this recommendation. Because CMS lacks complete information to determine the cause of the discrepancy that OIG identified, we urge CMS to engage the appropriate experts and State Medicaid agencies in determining the root causes of the discrepancy between the claims and the medical records; examining potential impacts; and identifying and implementing solutions. We look forward to updates in CMS's Final Management Decision on any activities related to this collaborative effort, and any conclusions that the group reaches regarding root causes for the discrepancy between Medicaid claims data and medical documentation for lead toxicity. If, after CMS engages in this effort, CMS comes to the conclusion that the root cause is a coding issue, then CMS's planned action to remind States of their obligations to provide clinical and coding guidance may help demonstrate movement toward meeting the intent of the recommendation.

In response to our second recommendation—that CMS issue guidance to reiterate State obligations under the EPSDT benefit to ensure access to services to correct or ameliorate confirmed blood lead levels identified during screenings—CMS stated that it would issue guidance to States reminding them of their obligations under the EPSDT benefit to provide comprehensive and preventive health care services for children under age 21. Further, CMS stated that it will remind States that they are required to furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions.

We appreciate CMS's proposed actions for the second recommendation to remind States of EPSDT service requirements related to treatment and corrective services for illnesses and conditions identified during screenings. In this report, we recommend that CMS include in its guidance to States a discussion of Medicaid coverage for services such as followup blood lead testing and investigations to determine the source of lead exposure for children with confirmed blood lead levels. We also encourage CMS to promote case management and coordination of care when treating children for conditions including lead toxicity. After CMS takes these actions, we look forward to updates in CMS's Final Management Decision regarding CMS's

guidance to States on EPSDT service requirements for treatment and corrective services for lead toxicity.

For the full text of CMS's comments, see Appendix D.

DETAILED METHODOLOGY

State selection

For this medical record review of followup testing and treatment services and treatment for children diagnosed with lead toxicity, we selected five States: California, New York, Ohio, Pennsylvania, and Texas. These States had among the highest number of children with confirmed elevated blood lead levels based on National Childhood Blood Lead Surveillance Data from CDC. We selected these States to ensure that we had a large enough population of children diagnosed with lead toxicity to sample from for our medical record review.

Medicaid claims analysis

Population selection

This study included Medicaid-enrolled children from California, New York, Ohio, Pennsylvania, and Texas. These States had a total of 21,353 children under 3 years of age who had a diagnosis that indicated lead toxicity in their Medicaid claims and 6 months of continuous Medicaid eligibility following diagnosis. See Exhibit 7 for the number of children in our population from each State. We examined the population of children, born between January 1, 2013, and December 31, 2016, with at least 6 months of continuous Medicaid enrollment after receiving a diagnosis indicating lead toxicity.

Data collection

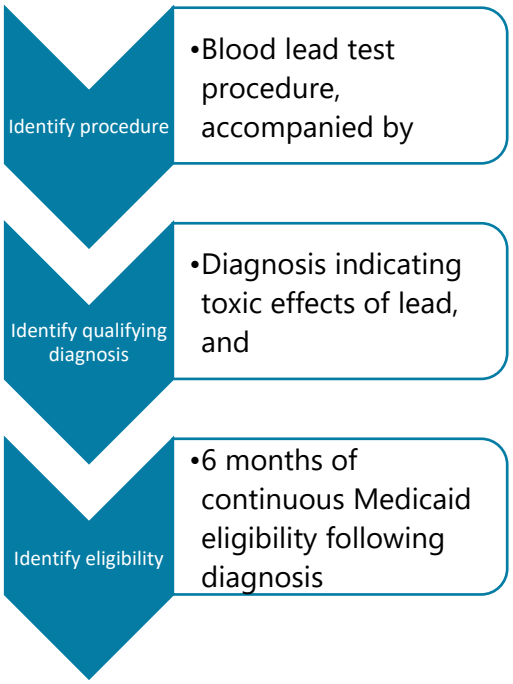
We collected from each State Medicaid Management Information System fee-for-service claims and managed care encounters from FYs 2015–2018, as well as all dates of Medicaid eligibility for the defined population in the selected States. The data included eligibility information and all incurred outpatient claims (i.e., all claims that practitioners submitted) for our population of children.

Claims analysis

Eligibility. From the Medicaid claims, we identified children who had at least 6 months of continuous enrollment in Medicaid after receiving a diagnosis that indicated lead toxicity. For instance, a child diagnosed with lead toxicity at 24 months of age had to have been continuously enrolled in Medicaid until reaching 30 months of age. This approach provided a reasonable buffer for children to receive some recommended services, such as early followup blood lead testing for confirmed blood lead levels (see Appendices A and B for criteria that we used to develop the review instrument for this study). Children with a populated date of death variable were excluded from all analyses.

Data analysis. To identify children in the Medicaid claims data with lead toxicity diagnoses, we referenced the Form CMS-416 annual EPSDT reporting instructions for States. The Form CMS-416 instructions note that claims in which a blood lead test procedure is accompanied by a lead toxicity diagnosis generally indicate that a child receiving the test has been diagnosed with or is being treated for lead poisoning. The instructions also reference a series of diagnosis codes that are used to describe toxic effects of lead.[48] Using this series of codes, we conducted pilot testing and limited the series to only those diagnoses that we determined would aid in the identification of initial occurrences for children diagnosed with lead toxicity. We then applied these criteria to select a simple random sample of 125 Medicaid-enrolled children in each of the selected States (625 children total) for our medical record review. Of the 625 children initially selected, 19 children were excluded from review because we were unable to identify in claims data referring practitioners for blood lead test orders. This resulted in a final sample of 606 unique children. Our review included records from FYs 2015–2019 that we collected for each child for the 6 months following their diagnosis.

Exhibit 6: Criteria used to identify in Medicaid claims a sample of children with a lead toxicity diagnosis for inclusion in the medical record review



Source: OIG review of *2700.4 Instructions for Completing Form CMS-416: Annual Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Participation Report*, 2022.

Data validation and quality assurance

We performed data validation and quality assurance checks, including:

- null analysis of selected variables compared to Medicaid Statistical Information System (MSIS) threshold tolerances;[49] and
- independent, peer review, and quality assurance checks of analyses.

Through this validation process, we concluded that the data were usable for the analyses conducted for this study.

Medical record review

Collection of medical records from the date of diagnosis through 6 months later (including FYs 2015–2019)

We developed a letter that our medical review contractor used to request medical records from the practitioners identified in the Medicaid claims data for FYs 2015–2018. The contractor sent the initial mailing for the records request in June 2019 and ceased collection efforts in December 2020; therefore, practitioners had from 8 months to more than 72 months to finalize documentation in the medical records related to children's diagnoses of lead toxicity. If a practitioner did not respond to this initial request letter, the contractor sent up to two additional letters, and followed up by telephone. Practitioners who did not respond to three letters and followup phone calls were marked as non-responders. See Exhibit 7 for the final response rates.

Exhibit 7: Population, sample sizes, and response rates

State	Population	Sample size	Excluded cases	Respondents	Response rate
California	11,776	125	7	112	95%
New York	4,284	125	1	116	94%
Ohio	1,988	125	1	124	100%
Pennsylvania	1,618	125	10	107	93%
Texas	1,687	125	0	122	98%
Total	**21,353**	**625**	**19**	**581**	**95%***

*The weighted response rate, based on responses within each State, was 93 percent.
Source: OIG analysis of medical record request respondents, 2022.

Review of medical records

Development of medical record review criteria. We collaborated with contracted physician toxicologists (medical reviewers) to develop the medical record review instrument. The review instrument criteria included recommendations from CMS, CDC, and State-specific medical management guidance for followup testing and treatment services for identified blood lead levels. Because these recommendations did not always align, the medical reviewers were instructed to review records using their professional judgment, in consideration of the criteria noted above. See Appendices A and B for these criteria.

Pretest of medical review instrument. To test and refine the medical review instrument, we pretested it using five cases selected by the medical review contractor. We asked contracted nurse abstractors and medical reviewers to complete the medical review instrument and used reviewers' feedback to improve the instrument before initiating the medical review.

Record review and quality assurance activities. To ensure consistent interpretation of the medical review criteria, we developed training materials and guidance documents for contracted nurse abstractors and medical reviewers. All medical records were reviewed first by the contracted nurse abstractors, who identified for further review any documentation related to followup testing or treatment services for children's identified blood lead levels. Medical reviewers then reviewed the abstracted records for evidence to confirm the diagnosis of lead toxicity in the Medicaid claims, and evidence of followup testing and treatment services for the 6 months following a child's diagnosis. Throughout the medical review, we engaged the medical reviewers in quality assurance activities to ensure consistent reviews of the records. Per the CMS State Medicaid Manual, we asked medical reviewers to use their professional judgment and to refer to followup testing and treatment services recommended by CMS and CDC. The Manual also suggests that treatment for children diagnosed with lead toxicity may include coordination with health departments; therefore, we asked reviewers to consider respective State medical management guidance for children's identified blood lead levels. In some cases, State guidance may have included more stringent recommendations for followup services than CDC recommendations (e.g., for children with blood lead levels less than 5 µg/dL, California recommended that practitioners consider a referral to the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC). Using these criteria, medical reviewers determined whether children received appropriate followup testing and treatment services for their identified blood lead levels.

Analysis of medical record review data. We examined the data collected during the medical record review to identify the proportion of children that medical reviewers determined received appropriate followup testing and treatment services for their identified blood lead level, as recommended by CMS and CDC, and in consideration of State medical management guidance. During the study period, CDC recommendations included a published schedule for early followup testing of children with blood lead levels at or above 5 µg/dL.

Additionally, we examined reviewer notes to identify potential themes, as well as any challenges and barriers in the provision of followup testing and treatment services for children exposed to lead.

State health department data analysis

Data collection. Medicaid-enrolled children may receive public health and case management services for lead toxicity that are not documented in medical records. To account for these types of services, we requested additional data and documentation from State health departments. Specifically, we sent unique identifiers for the 625 children selected for this medical record review to their respective State health departments. We received data on public health and case management services for our sample from State health departments in four States—California, New York, Ohio, and Texas. From the Ohio health department, we also received case file documentation. The State health department in Pennsylvania shared that lead-related case management services were not recorded in the State's public health

data system, and that it was unable to meet our request. From the 4 responding States, we received data for 144 of the selected children.

Data analysis. For the 166 children who were eligible for the medical record review analysis, we looked for evidence of public health and case management services in the State health department data. Specifically, we looked for evidence of dates of service and types of services received. The data we received from the State health departments were not comparable to the medical record review data or to the data from other States; therefore, we were not able to use the health department data to determine whether children diagnosed with lead toxicity received appropriate followup testing and treatment services. Instead, we were only able to determine whether a public health service occurred.

Interviews with subject matter experts and stakeholder groups

To gather information regarding followup testing, treatment services, and public health services for children exposed to lead, and to gain insights related to our medical record review for children diagnosed with lead toxicity, we conducted structured interviews with subject matter experts and stakeholder groups. Specifically, we interviewed specialists from the Pediatric Environmental Health Specialty Unit Network and Agency for Toxic Substances and Disease Registry, and officials from the American Academy of Pediatrics, selected State health departments, and the Children's Environmental Health Network.

APPENDICES

Appendix A: Federal Guidance and Recommendations Related to Followup Testing and Treatment Services Based on Identified Blood Lead Levels

Table A-1: Overview of guidance from CMS and CDC related to blood lead levels, followup testing, and treatment services for children's identified blood lead levels

	Blood lead reference value	Followup test	Treatment service
CMS State Medicaid Manual[I]	10 µg/dL.		If a child is found to have blood lead levels equal to or greater than 10 µg/dL, providers are to use their professional judgment, with reference to CDC guidelines covering patient management and treatment, including followup blood tests and initiating investigations to determine the source of lead, where indicated. Coordination with the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC); Head Start; and other private and public resources enables elimination of duplicate testing and ensures comprehensive diagnosis and treatment. Public health agencies' childhood lead poisoning prevention programs may be available. These agencies may have the authority and ability to investigate a lead-poisoned child's environment and to require remediation.
CMS 2016 Informational Bulletin[II]	The bulletin references the CDC blood lead reference value of 5 µg/dL as the threshold level at which CDC recommended that public health actions be initiated, at the time of our review.		
CMS Lead Screening web page[III]	Following our review period, CMS updated the Lead Screening web page on Medicaid.gov to reference CDC's updated blood lead reference value of 3.5 µg/dL as the threshold level at which		

	CDC recommends that public health actions be initiated.		
CDC[IV]	During our review period, CDC used a blood lead reference value of 5 µg/dL. In October 2021, following our review period, CDC lowered the blood lead reference value from 5 µg/dL to 3.5 µg/dL. The current blood lead reference value is based on the 97.5th percentile of the blood lead values among U.S. children ages 1–5 years from the 2015–2016 and 2017–2018 National Health and Nutrition Examination Survey (NHANES) cycles.	During our review period, CDC provided a schedule with recommended timelines for followup blood lead testing for blood lead levels ranging from ≥5 µg/dL to ≥45 µg/dL.[V] In October 2021, following our review period, CDC provided an updated schedule with recommended timelines for followup blood lead testing for blood lead levels ranging from ≥3.5 µg/dL to ≥45 µg/dL.[VI]	During our review period, CDC provided recommendations for followup and case management of children based on confirmed blood lead levels ranging from <5 µg/dL to ≥70 µg/dL (see summary of recommendations from CDC, Table A-2).[V] In October 2021, following our review period, CDC provided updated recommendations for followup and case management of children based on confirmed blood lead levels ranging from <3.5 µg/dL to ≥45µg/dL.[VI]

Sources:

I) CMS, "Chapter 5: Early and Periodic Screening, Diagnostic and Treatment Services," *The State Medicaid Manual*, 5123.2, D, 09-98. Accessed at https://go.usa.gov/xU2VG on February 28, 2022.

II) CMS, "Coverage of Blood Lead Testing for Children Enrolled in Medicaid and the Children's Health Insurance Program," *CMCS Informational Bulletin*. Accessed at https://go.usa.gov/xHF8p on February 28, 2022.

III) CMS, *Lead Screening*. Accessed at https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/lead-screening/index.html on August 17, 2022.

IV) CDC, "Update of the Blood Lead Reference Value—United States, 2021," *Morbidity and Mortality Weekly Report*, October 2021. Accessed at https://www.cdc.gov/mmwr/volumes/70/wr/mm7043a4.htm?s_cid=mm7043a4_w on June 29, 2022.

V) CDC, *Recommended Actions Based on Blood Lead Level*, December 2017. Accessed at http://web.archive.org/web/20200713205506/https://www.cdc.gov/nceh/lead/advisory/acclpp/actions-blls.htm on August 17, 2022.

VI) CDC, *Recommended Actions Based on Blood Lead Level*, October 2021. Accessed at https://go.usa.gov/xz4ab on February 28, 2022.

Table A-2: Summary of CDC recommendations for followup and case management of children based on confirmed blood lead levels, during our review period

µg/dL	CDC recommended actions[I]
<5	Routine assessment of nutritional and developmental milestones, anticipatory guidance about common sources of lead exposure, followup blood lead testing at recommended intervals based on child's age.
5-9	Routine assessment of nutritional and developmental milestones, environmental exposure history to identify potential sources of lead and environmental investigation of the home to identify potential sources of lead (as required according to local conditions based on jurisdictional requirements and available resources), nutritional counseling related to calcium and iron intake, early followup blood lead monitoring (2-4 tests after identification) within 3 months, later followup testing after blood lead level declining within 6-9 months.
10-19	Routine assessment of nutritional and developmental milestones, environmental exposure history to identify potential sources of lead and environmental investigation of the home to identify potential sources of lead (as required according to local conditions based on jurisdictional requirements and available resources), nutritional counseling related to calcium and iron intake, consider lab work to assess iron status, early followup blood lead monitoring (2-4 tests after identification) within 1-3 months, later followup testing after blood lead level declining within 3-6 months.
20-24	Complete history and physical exam with neurodevelopmental assessment, environmental investigation of the home and lead hazard reduction, lab work including iron status and hemoglobin or hematocrit, abdominal X-ray (with bowel decontamination if indicated), early followup blood lead monitoring (2-4 tests after identification) within 1-3 months, later followup testing after blood lead level declining within 1-3 months.
25-44	Complete history and physical exam with neurodevelopmental assessment, environmental investigation of the home and lead hazard reduction, lab work including iron status and hemoglobin or hematocrit, abdominal X-ray (with bowel decontamination if indicated), early followup blood lead monitoring (2-4 tests after identification) within 2 weeks to 1 month, later followup testing after blood lead level declining within 1 month.
45-69	Complete history and physical exam with neurodevelopmental assessment and complete neurological exam, environmental investigation of the home and lead hazard reduction, lab work including iron status and hemoglobin or hematocrit, abdominal X-ray (with bowel decontamination if indicated), oral chelation therapy may be considered in consultation with a medical toxicologist or a pediatric environmental health specialty unit (consider hospitalization, if lead-safe home environment cannot be assured), early followup blood lead monitoring (2-4 tests after identification) as soon as possible, later followup testing after blood lead level declining as soon as possible.
≥70	Hospitalize and commence chelation therapy in consultation with a medical toxicologist or a pediatric environmental health specialty unit, complete history and physical exam with neurodevelopmental assessment and complete neurological exam, environmental investigation and lead hazard reduction, lab work including iron status and hemoglobin or hematocrit, abdominal X-ray (with bowel decontamination if indicated), early followup blood lead monitoring (2-4 tests after identification) as soon as possible, later followup testing after blood lead level declining as soon as possible.

Source:
I) CDC, Recommended Actions Based on Blood Lead Level, December 2017. Accessed at http://web.archive.org/web/20200713205506/https://www.cdc.gov/nceh/lead/advisory/acclpp/actions-blls.htm on August 17, 2022.

Appendix B: State Guidance on Medical Management of Children's Identified Blood Lead Levels

Table B-1 : General overview of guidance from the five States that medical reviewers considered when reviewing followup testing and treatment services for children's identified blood lead levels during the review period

µg/dL	CA[I]	NY[II]	OH[III]	PA[IV]	TX[V]
<5	Testing: Routine test at 12 and 24 months of age based on certain factors. Followup test in 6-12 months, if indicated. Retest for indicated risk must be venous. Case Management: Provide anticipatory guidance, encourage good nutrition and early enrichment activities, consider referral to Special Supplemental Nutrition Program for Women, Infants, and Children (WIC).	Testing: Routine test at 12 and 24 months of age. Followup test not required. Case Management: Provide parent education.	Testing: Retest at 24 months if first test is at 12 months. Consider retest if child moves to a home, daycare, etc., built before 1978. Case Management: Discuss exposure risks, monitor neurological, psychosocial, and language development.	Testing: If test result is <10 µg/dL, followup test every 6 months. After 2 subsequent consecutive measurements are <10 µg/dL or 3 are ≤15 µg/dL, decrease testing to 1 time per year. Case Management: N/A	Testing: Routine test at 12 and 24 months of age. Case Management: May screen for risk of lead exposure and provide anticipatory guidance.
5-9	Testing: Venous followup test in 1-3 months; retest in 3 months and thereafter based on venous blood lead level trend. Case Management: Manage as for <5 and counsel on nutrition, refer to WIC, treat iron insufficiency, note elevated blood lead level in medical record, refer to early enrichment, consider medical referral and testing for other children and pregnant and lactating women in the home, and coordinate with local Childhood Lead Poisoning Prevention Program (CLPPP) or state Childhood Lead Poisoning Prevention Branch (CLPPB).	Testing: If blood lead level is approaching 10 µg/dL, more frequent testing might be appropriate (i.e., in 3-6 months). Case Management: Manage as for <5 and monitor development, consider child at risk for developmental delays and behavior problems.	Testing: Venous followup test every 3 months for first 2-4 tests, then after 4 tests, every 6-9 months until blood lead level drops below 5 µg/dL. Case Management: Manage as for <5 and provide lead education, monitor blood lead level until it remains <5 for at least 6 months, complete history and physical exam, assess iron status, obtain abdominal X-ray if lead ingestion suspected and bowel decontamination if lead ingestion indicated, refer to WIC, refer to Help Me Grow for developmental delay, refer to Children with Medical Handicaps program.	Testing: If test result is <10 µg/dL, followup test every 6 months. After 2 subsequent consecutive measurements are <10 µg/dL or 3 are ≤15 µg/dL, decrease testing to 1 time per year. Case management: N/A	Testing: Venous followup test in 3-6 months. Case Management: Dietary and environmental lead education, continued blood lead level monitoring.

µg/dL	CA	NY	OH	PA	TX
10-14	Testing: Venous followup test in 1-3 months to be sure blood lead level is not rising; if blood lead levels are stable or decreasing, retest in 3 months and thereafter based on venous blood lead level trend. Case Management: Manage as for 5-9 and If blood lead level persists for 30 days or more, contact local CLPPP for full case management services.	Testing: Venous followup test every 3 months until blood lead level is declining; retest every 6 months thereafter until blood lead level is <10. Case Management: Conduct lead exposure assessment, provide education and nutritional counseling.	Testing: Venous followup test within 1 month. Case Management: Manage as for 5-9.	Testing: Followup test in 3-4 months or more often if indicated. Case Management: Provide education and nutritional counseling, take a detailed environmental history.	Testing: Venous followup test in 3 months. Case Management: Manage as for 5-9 and environmental lead investigation if blood lead level persists at least 12 weeks following diagnostic venous test.
15-19	Testing: Venous followup test within 1-4 weeks to be sure blood lead level is not rising; retest 1-3 months and thereafter based on venous blood lead level trend. Case Management: Manage as for 10-14 and consider gut decontamination if foreign bodies consistent with lead are found on X-ray, contact local CLPPP for full case management services for a single blood lead level in this range.	Testing: Venous followup test every 1-3 months until blood lead level is declining; retest every 3 months thereafter until blood lead level is <15. Case Management: Confirm that local health department is conducting environmental investigation and followup services, conduct lead exposure assessment, provide education, nutritional assessment including iron status, developmental screening, consult Regional Lead Resource Center (RLRC).	Testing: Venous followup test within 1 month. Case Management: Manage as for 5-9.	Testing: Followup test in 3-4 months or more often if indicated. Case Management: Manage as for 10-14 and discuss interventions to reduce lead levels. If blood lead level persists, conduct environmental investigation and abatement.	Testing: Venous followup test in 1-3 months. Case Management: Manage as for 10-14 and if blood lead level persists at least 12 weeks following diagnostic venous test, conduct complete history and physical exam, lab work, environmental lead investigation, lead hazard reduction, neurodevelopmental monitoring, abdominal X-ray if lead ingestion suspected and bowel decontamination if lead ingestion indicated.
20-44	Testing: Venous followup test in 1-4 weeks to be sure blood lead level is not rising; then, if stable or decreasing, retest every 2-4 weeks and thereafter based on venous blood lead level trend. Case Management: Manage as for 15-19 and consider referral to California Children's Services, consider referral for medical nutrition therapy.	Testing: For blood lead levels 20-24, venous followup test every 1-3 months until blood lead level is declining, then retest every 3 months thereafter until blood lead level is <15. For blood lead levels 25-44, venous followup test every 2-4 weeks until blood lead level is declining, then every month thereafter until blood lead level is <25. Case Management: Manage as for 15-19.	Testing: Venous followup test within 1 month. Case Management: Manage as for 5-9.	Testing: Venous confirmation, then followup test every 3-4 months or more often if indicated. Case Management: Manage as for 15-19 and medical evaluation, and followup.	Testing: Venous followup test in 1-3 months. Case Management: Manage as for 15-19 and conduct complete history and physical exam, lab work, environmental lead investigation, lead hazard reduction, neurodevelopmental monitoring, abdominal X-ray if lead ingestion suspected and bowel decontamination if lead ingestion indicated.

µg/dL	CA	NY	OH	PA	TX
45-69	Testing: For blood lead levels 45-59, venous followup test in 48 hours; for blood lead levels 60-69, venous followup test in 24 hours, venous retest every 2-4 weeks thereafter based on venous blood lead level trend. Case Management: Manage as for 20-44 and obtain abdominal X-ray, perform gut decontamination, if indicated, before chelation, consider hospitalization, immediately contact local CLPPP or state CLPPB.	Testing: For blood lead levels 45-59, venous followup test within 48 hours; for blood lead levels 60-69, venous followup test within 24 hours, further followup testing as per RLRC instruction. Case Management: Notify local health department within 24 hours for environmental investigation and followup services, consult RLRC within 24 hours, conduct lead exposure assessment, provide education, nutritional assessment, developmental screening, hospital discharge to lead-safe housing.	Testing: For blood lead levels > 45, followup testing as soon as possible. Case Management: Manage as for 5-9 and confirm results by venous sample immediately, conduct lab work, immediately remove child from exposure source, consider hospitalization and chelation therapy.	Testing: Venous confirmation, then every 3-4 months or more often if indicated. Case Management: Manage as for 20-44 and urgent medical and environmental followup.	Testing: Venous followup test as soon as possible. Case Management: Manage as for 20-44 and chelation therapy.
≥70	Testing: Immediately confirm initial BLL with venous test, venous retest every 2-4 weeks thereafter based on venous blood lead level trend. Case Management: Manage as for 45-69 and hospitalize to stabilize, chelate, reduce exposure and monitor, immediately contact CLPPP or state CLPPB.	Testing: Immediately confirm with a venous test, followup testing as per RLRC instruction. Case Management: Manage as for 45-69 and consult RLRC immediately and immediately admit to a hospital for chelation.	Testing: For blood lead levels > 45, followup testing as soon as possible. Case Management: Manage as for 5-9 and confirm results by venous sample immediately, conduct lab work, immediately remove child from exposure source, consider hospitalization and chelation therapy.	Testing: Venous followup test immediately. Case Management: Manage as for 45-69 and immediate inpatient chelation therapy.	Testing: Venous followup test as soon as possible. Case Management: Manage as for 45-69 and hospitalize and commence chelation therapy.

Sources:
I) California Department of Public Health, *California Management Guidelines on Childhood Lead Poisoning for Health Care Providers*, September 2017. Accessed at https://www.cdph.ca.gov/Programs/CCDPHP/DEODC/CLPPB/CDPH%20Document%20Library/Lead_HAGs_Table.pdf on October 12, 2018.
II) New York State Department of Health, *New York State Department of Health Guidelines for the Identification and Management of Lead Exposure in Children,* October 2011. Accessed at https://www.health.ny.gov/publications/2501/ on October 12, 2018.
III) Ohio Department of Health, *Medical Management Recommendations for Ohio Children Receiving Blood Lead Tests*, February 2018. Accessed at https://odh.ohio.gov/wps/wcm/connect/gov/718d4ebf-c78a-4f64-b250-cd7190c3bfbe/Medical-Management-Guidelines.pdf?MOD=AJPERES&CONVERT_TO=url&CACHEID=ROOTWORKSPACE.Z18_M1HGGIK0N0JO00QO9DDDDM3000-718d4ebf-c78a-4f64-b250-cd7190c3bfbe-mstQ9jD on October 12, 2018.
IV) 55 Pa. Code Part III, Chapter 1241, Appendix E, *Guidelines on Childhood Lead Poisoning Prevention*. Accessed at https://www.pacode.com/secure/data/055/chapter1241/chap1241toc.html on September 10, 2018.
V) Texas Department of State Health Services, *Reference for Blood Lead Retesting and Medical Case Management*. Accessed at https://www.dshs.texas.gov/lead/pdf_files/pb_109_physician_reference.pdf on August 17, 2018.

Appendix C: Results of the Medical Record Review for 166 Children With a Confirmed Diagnosis of Lead Toxicity

Table C-1: Blood lead level ranges for 166 children in the medical record review with a confirmed diagnosis of lead toxicity, and the number of children in the medical record review who received or did not receive appropriate followup testing and treatment services for their identified blood lead level, as recommended by CMS, CDC, and medical management guidance from children's respective States

State	Less than 5 µg/dL	5–9 µg/dL	10–19 µg/dL	20–44 µg/dL	Total cases reviewed
Did not receive appropriate followup testing and treatment services for their identified blood lead level*					
CA	0	2	0	0	2
NY	0	11	9	1	21
OH	3	17	12	4	36
PA	1	6	9	1	17
TX	1	5	2	1	9
Subtotal	**5**	**41**	**32**	**7**	**85**
Received appropriate followup testing and treatment services for their identified blood lead level					
CA	0	0	0	0	0
NY	6	12	7	1	26
OH	9	8	4	4	25
PA	1	9	2	2	14
TX	8	4	3	1	16
Subtotal	**24**	**33**	**16**	**8**	**81**
Total	**29**	**74**	**48**	**15**	**166**

*Among the 85 children who did not receive appropriate followup testing and treatment services, reviewers identified that 56 children received some services, but services were not appropriate to treat children's identified blood lead levels. Reviewers found that 20 children did not receive any followup testing and treatment services during their period of review, and reviewers were unable to determine whether identified services were appropriate for the remaining 9 children.

Source: OIG analysis of medical record review data, 2022.

The following tables display information on the treatment services provided to each of the 166 children based on blood lead levels and State of residence. The recommended services differ based on blood lead levels. Each table contains a compilation of services for children's identified blood lead levels recommended by CDC and State medical management guidance.

Table C-2: Identified recommended services among the 29 children in the medical record review with blood lead levels less than 5 µg/dL

	Routine assessment of nutritional and developmental milestones	Anticipatory guidance about common sources of lead exposure	Referrals for public health services and programs	Total cases reviewed
CA	0	0	0	0
NY	6	4	2	6
OH	10	9	4	12
PA	2	0	0	2
TX	7	7	0	9
Total	**25**	**20**	**6**	**29**

Source: OIG analysis of medical record review data, 2022.

Table C-3: Identified recommended services among the 74 children in the medical record review with blood lead levels between 5-9 µg/dL

	Routine assessment of nutritional and developmental milestones	Environmental assessment/ environmental investigation to identify potential sources of lead exposure	Nutritional counseling related to calcium and iron intake	Referrals for public health services and programs	Total cases reviewed
CA	1	0	1	2	2
NY	17	8	12	6	23
OH	22	8	18	3	25
PA	9	3	5	0	15
TX	9	6	6	1	9
Total	**58**	**25**	**42**	**12**	**74**

Source: OIG analysis of medical record review data, 2022.

Table C-4: Identified recommended services among the 48 children in the medical record review with blood lead levels between 10-19 µg/dL

	Routine assessment of nutritional and developmental milestones	Environmental assessment/ environmental investigation to identify potential sources of lead exposure	Nutritional counseling related to calcium and iron intake/ lab work to assess iron	Referrals for public health services and programs	Total cases reviewed
CA	0	0	0	0	0
NY	16	6	12	7	16
OH	11	8	10	3	16
PA	8	4	6	2	11
TX	4	2	2	2	5
Total	**39**	**20**	**30**	**14**	**48**

Source: OIG analysis of medical record review data, 2022.

Table C-5: Identified recommended services among the 15 children in the medical record review with blood lead levels between 20-44 µg/dL

	Complete history and physical exam	Neuro-developmental assessment	Investigation of home environment /lead hazard reduction	Lab work	X ray	Referrals for public health services and programs	Total cases reviewed
CA	0	0	0	0	0	0	0
NY	2	2	1	2	0	0	2
OH	8	6	6	7	0	5	8
PA	3	2	2	2	0	0	3
TX	2	1	1	1	1	0	2
Total	**15**	**11**	**10**	**12**	**1**	**5**	**15**

Source: OIG analysis of medical record review data, 2022.

Of the 166 children, there were 137 children for whom followup blood lead testing was recommended during their review period based on their identified blood lead level at or above 5 µg/dL. The tables below display information as to whether children received followup testing as recommended by the CDC schedule and at any time during the 6 months following a diagnosis indicating lead toxicity within our review period.

Table C-6: Among the 137 children in the medical record review with blood lead levels at or above 5 µg/dL, those who received early followup blood lead testing as recommended by the CDC schedule*

	Followup testing received as recommended	Followup testing not received as recommended	Total number of cases reviewed
CA	0	2	2
NY	21	19	40
OH	25	22	47
PA	11	17	28
TX	6	10	16
Total	**63**	**70**	**133***

*Records for four children in the medical record review from New York, Ohio, and Pennsylvania indicated blood lead levels at or above 5 µg/dL but did not identify in the record a numeric blood lead value associated with the diagnosis of lead toxicity. These records were excluded from the followup testing analysis.
Source: OIG analysis of medical record review data, 2022.

Table C-7: Among the 137 children in the medical record review with blood lead levels at or above 5 µg/dL, those who received a followup blood lead test during the 6 months following a diagnosis indicating lead toxicity*

	Followup testing received during review period	Followup testing not received during review period	Total number of cases reviewed
CA	1	1	2
NY	28	12	40
OH	35	12	47
PA	18	10	28
TX	12	4	16
Total	**94**	**39**	**133***

*Records for four children in the medical record review from New York, Ohio, and Pennsylvania indicated blood lead levels at or above 5 µg/dL but did not identify in the record a numeric blood lead value associated with the diagnosis of lead toxicity. These records were excluded from the followup testing analysis.
Source: OIG analysis of medical record review data, 2022.

Table C-8: For 75 children in 4 States, identified types of public health services that children received during their respective periods of review*

	Blood lead test	Parent education /guidance	Environmental service	Case management	Developmental service	Nutritional service	Total cases reviewed
CA	2	0	0	0	0	0	2
NY	6	12	7	1	0	4	18
OH	53	18	22	9	5	5	53
TX	0	2	2	0	0	0	2
Total	**61**	**32**	**31**	**10**	**5**	**9**	**75**

*The State health department in Pennsylvania shared that lead-related case management services were not recorded in the State's public health data system, and that it was unable to meet our request.
Source: OIG analysis of medical record review data, 2022.

Appendix D: Agency Comments

Following this page are the official comments from CMS.

DATE: November 21, 2022

TO: Ann Maxwell
Deputy Inspector for Evaluation and Inspections
Office of Inspector General

FROM: Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: For Medicaid-Enrolled Children Diagnosed with Lead Toxicity in Five States, Documentation Reviewed for Diagnoses and Treatment Services Raises Concerns (OEI-07-18-00370)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS is committed to working with federal and state partners to ensure that children with elevated blood lead levels (EBLLs) enrolled in Medicaid and the Children's Health Insurance Program (CHIP) receive necessary medical and environmental follow-up services.

The amount of lead in blood is referred to as the blood lead level, which is measured in micrograms of lead per deciliter of blood (µg/dL). Currently the Centers for Disease Control and Prevention (CDC) recommends a blood lead reference value of 3.5 µg/dL to identify children with EBLLs.[1] Lead exposure can affect nearly every system in the body and often goes undetected because, at low levels of exposure, it may display no obvious symptoms. Comprehensive screening and surveillance ensures that lead-poisoned infants and children receive necessary medical and environmental follow-up as soon as possible, and also allows for the development of neighborhood-based efforts to prevent lead poisoning. While the CDC recommends certain follow-up and case management activities for children with EBLLs, it is the responsibility of state health departments to set a blood lead reference value and establish clinical treatment standards for providers. Further, CMS has not established a blood lead reference value, does not establish clinical guidelines for children with EBLLs, and does not have the authority to require state Medicaid agencies to adopt CDC's recommendations.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit provides comprehensive and preventive health care services for children under age 21 who are enrolled in Medicaid. Under the EPSDT benefit states are required to provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions, based on certain federal guidelines. This means that in addition to covering blood lead screening tests, the EPSDT benefit also ensures that children with EBLLs

[1] CDC, Recommended Actions Based on Blood Lead Level. 2022. Accessed at: https://www.cdc.gov/nceh/lead/advisory/acclpp/actions-blls.htm

receive medically necessary follow-up and treatment services. While states have broad flexibility when administering the EPSDT benefit, they have an affirmative obligation to ensure that children and their families are aware of the services that are a part of the benefit, and that they have access to required screenings and necessary treatment services. In addition, Medicaid can provide reimbursement for lead investigations in the home or primary residence of a child with an EBLL, if the investigation is conducted by a credentialed health practitioner who meets the qualifications established by the state, and is undertaken to identify the source of lead exposure.

As noted in the OIG's report, state Medicaid agencies are required to submit EPSDT data annually to CMS using the Form CMS-416, which includes reporting for the number of blood lead screening tests for children enrolled in Medicaid from birth to age six. According to data reported on the Form CMS-416, the number of children enrolled in Medicaid who receive blood lead screening tests varies considerably from state to state. Further, because the Form CMS-416 only captures Medicaid claims and encounter based data, it underrepresents the actual number of children who received blood lead screening tests. For example, it does not capture screenings that are not paid for by Medicaid, such as screenings performed by clinics using CDC funding or funded by state health departments. While CMS appreciates the OIG's efforts to collect data from the state health departments in their selected states under review, by ultimately excluding blood lead screening and follow-up services administered by state health departments, the report does not provide an accurate representation of the services the selected children received.

In support of state efforts to improve blood lead screening rates for children, CMS issued an informational bulletin[2] in November 2016 to remind states of the screening and treatment requirements for children enrolled in Medicaid and CHIP. The informational bulletin included information on steps that states could take to improve lead screening efforts, while also noting that states need to think beyond screening, and ensure that guidance and resources are available to support providers, families and other stakeholders who work to obtain appropriate services for children with EBLLs. In addition to reminding states of the requirement to furnish all medically necessary services needed to correct and ameliorate health conditions under the EPSDT benefit, CMS also informed states that case management can be used to provide services to children with EBLLs. Case management benefits include services that assist eligible individuals to gain access to needed medical, social, and educational services, and must include a comprehensive assessment of an eligible individual, the development of a specific care plan, referrals to needed services, and monitoring activities. In addition, in May 2022, CMS and CDC held a call with state Medicaid Medical Directors and State Health Officials to remind them of Medicaid's blood lead screening requirements and of the EPSDT requirement to furnish all medically necessary services needed to correct and ameliorate health conditions.

OIG's recommendations and CMS's responses are below.

[2] CMS, Coverage of Blood Lead Testing for Children Enrolled in Medicaid and the Children's Health Insurance Program. 2016. Accessed at:https://www.medicaid.gov/federal-policy-guidance/downloads/cib113016.pdf

OIG Recommendation

Explore the discrepancy between Medicaid claims data and medical documentation for lead toxicity and implement solutions to ensure better oversight of the EPSDT program.

CMS Response

CMS concurs with this recommendation. In collaboration with other federal partners and the American Academy of Pediatrics (AAP), CMS will share the findings from the OIG's report with State Medicaid Agency medical directors, and will remind states of their obligations to provide clinical and coding guidance to their providers.

OIG Recommendation

Issue guidance to reiterate State obligations under the EPSDT benefit to ensure access to services to correct or ameliorate confirmed blood lead levels identified during screenings.

CMS Response

CMS concurs with this recommendation. CMS will issue guidance to states reminding them of their obligations under the EPSDT benefit to provide comprehensive and preventive health care services for children under age 21. Specifically, CMS will remind states that they are required to furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions.

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

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This report was prepared under the direction of Brian Whitley, Regional Inspector General for Evaluation and Inspections in the Kansas City regional office, and Abbi Warmker, Deputy Regional Inspector General.

Contact

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ENDNOTES

[1] Centers for Disease Control and Prevention (CDC), *Childhood Lead Poisoning Prevention*, January 2022. Accessed at https://go.usa.gov/xU2VH on February 28, 2022.

[2] CDC, National Lead Poisoning Prevention Week, *Lead Poisoning Prevention Week 2020 Partner Kit*, October 2020.

[3] U.S. Environmental Protection Agency, *Fight Lead Poisoning with a Healthy Diet*, October 2019. Accessed at https://go.usa.gov/xzvRv on March 22, 2022.

[4] In fiscal year (FY) 2019, over 41 million children were eligible to receive Medicaid's Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) benefit, almost 4.5 million of which children were ages 12 to 24 months. Centers for Medicare & Medicaid Services (CMS), "Early and Periodic Screening, Diagnostic & Treatment," *2019 Annual Reporting Data Files*. Accessed at https://go.usa.gov/xzvQU on February 28, 2022.

[5] Screening services covered under the EPSDT benefit include a blood lead level assessment appropriate for age and risk factors, as well as other necessary health care, diagnostic services, and treatment to correct or ameliorate issues discovered by a screening. The Social Security Act (the Act) § 1905(r)(1)(B); the Act § 1905(r)(5); the Act § 1902(a)(43).

[6] Under the Individuals with Disabilities Education Act (IDEA), the U.S. Department of Education awards grants annually to States to support early intervention (EI) services for infants and toddlers with disabilities or developmental delays. 20 USC §§ 1431 and 1432(5); U.S. Department of Education, *State Formula Grants*. Accessed at https://go.usa.gov/xSaxp on May 23, 2022.

[7] A survey of State requirements found that in 18 States, exposure to lead meets the medical criteria for automatic eligibility in an Early Intervention Program; 4 other States include a blood lead level as a risk factor that may contribute to potential delays in development. Nicole Hamp, MD, et al., "Advocating for Automatic Eligibility for Early Intervention Services for Children Exposed to Lead," *Pediatric Annals*, Vol. 47, No. 10, 2018. Accessed at https://doi:10.3928/19382359-20180924-01 on March 21, 2022.

[8] The first signs of lead toxicity in children are often subtle neurobehavioral problems that may affect classroom behavior and social interaction. Hearing, speech, and other developmental milestones should be carefully evaluated and documented. Agency for Toxic Substances and Disease Registry, *Lead Toxicity: Clinical Assessment—Signs and Symptoms*, July 2019. Accessed at https://go.usa.gov/xzFjK on March 29, 2022.

[9] U.S. Environmental Protection Agency, *Integrated Science Assessment (ISA) for Lead*, June 2022. Accessed at https://go.usa.gov/xUgUs on April 22, 2021.

[10] CDC, *Health Effects of Lead Exposure*, January 2022. Accessed at https://go.usa.gov/xz4Cq on February 28, 2022.

[11] Brian Boutwell, et al., "Aggregate-Level Lead Exposure, Gun Violence, Homicide, and Rape," *PLoS One*, Vol. 12, No. 11, 2017. Accessed at https://doi.org/10.1371/journal.pone.0187953 on April 22, 2021.

[12] John Wright, et al., "Association of Prenatal and Childhood Blood Lead Concentrations with Criminal Arrests in Early Adulthood." *PLoS Med*, Vol. 5, No. 5, 2008. Accessed at https://doi.org/10.1371/journal.pmed.0050101 on April 22, 2021.

[13] Stephen Billings and Kevin Schnepel, "Life after Lead: Effects of Early Interventions for Children Exposed to Lead," *American Economic Journal: Applied Economics*, Vol. 10, No. 3, July 2018. Accessed at https://doi.org/10.1257/app.20160056 on April 22, 2021.

[14] In a New York City study of longitudinal development, young children with blood lead levels of 4 µg/dL or greater who received at least one early intervention (EI) service before age 3 were 16 percent more likely to meet test-based standards in English language arts on third-grade standardized testing. Children with blood lead levels of 10 µg/dL or greater who received EI services before age 3 were 38 percent more likely to meet test-based standards in English language arts than were children who did not receive services. Jeanette Stingone, et al., "Receipt of Early Intervention Services Before Age 3 Years and Performance on Third-Grade Standardized Tests Among Children Exposed to Lead," *Journal of the American*

Medical Association Pediatrics, published online March 7, 2022. Accessed at https://doi.org/10.1001/jamapediatrics.2022.0008 on March 21, 2022.

[15] Stephen Billings and Kevin Schnepel, "Life after Lead: Effects of Early Interventions for Children Exposed to Lead," *American Economic Journal: Applied Economics*, Vol. 10, No. 3, July 2018. Accessed at https://doi.org/10.1257/app.20160056 on April 22, 2021.

[16] CMS, *EPSDT – A Guide for States: Coverage in the Medicaid Benefit for Children and Adolescents*. Accessed at https://www.medicaid.gov/sites/default/files/2019-12/epsdt_coverage_guide.pdf on November 29, 2022.

[17] The Act § 1905(r)(1)(B)(iv).

[18] The CMS State Medicaid Manual schedule requires enrolled children to receive blood lead screening tests at 12 and 24 months of age. Children between the ages of 36 months and 72 months should also receive a blood lead test if they have not been previously screened for lead poisoning. CMS, "Chapter 5: Early and Periodic Screening, Diagnostic and Treatment Services," *The State Medicaid Manual*, 5123.2, D1, 09-98. Accessed at https://go.usa.gov/xU2VG on February 28, 2022.

[19] CMS, "Chapter 5: Early and Periodic Screening, Diagnostic and Treatment Services," *The State Medicaid Manual*, 5124, A, 04-90. Accessed at https://go.usa.gov/xU2VG on February 28, 2022.

[20] The Act § 1905(r)(5).

[21] 42 CFR § 441.61. Accessed at https://www.law.cornell.edu/cfr/text/42/441.61 on September 24, 2020.

[22] CMS, "Chapter 5: Early and Periodic Screening, Diagnostic and Treatment Services," *The State Medicaid Manual*, 5123.2, D.1a, 09-98. Accessed at https://go.usa.gov/xU2VG on February 28, 2022.

[23] Center for Medicaid & Children's Health Insurance Program (CHIP) Services, *Coverage of Blood Lead Testing for Children Enrolled in Medicaid and the Children's Health Insurance Program*, November 2016. Accessed at https://go.usa.gov/xzwQX on February 28, 2022.

[24] CDC, *CDC Updates Blood Lead Reference Value to 3.5 µg/dL*, January 2022. Accessed at https://go.usa.gov/xz4Cv on February 28, 2022.

[25] CMS, *Lead Screening*. Accessed at https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/lead-screening/index.html on August 17, 2022.

[26] The Act § 1905(r)(5).

[27] CMS, "Chapter 5: Early and Periodic Screening, Diagnostic and Treatment Services," *The State Medicaid Manual*, 5123.2, D.1a, 09-98. Accessed at https://go.usa.gov/xU2VG on February 28, 2022.

[28] CMS, "Chapter 5: Early and Periodic Screening, Diagnostic and Treatment Services," *The State Medicaid Manual*, 5123.2, D, 09-98. Accessed at https://go.usa.gov/xU2VG on February 28, 2022.

[29] The blood lead reference value is based on the 97.5th percentile of blood lead values among the U.S. population of children, 1 to 5 years of age, obtained from the National Health and Nutrition Examination Survey cycles. Children with blood lead levels at or above the blood lead reference value are among the top 2.5 percent of U.S. children with the highest blood lead levels. CDC, *Blood Lead Levels in Children*, December 2022. Accessed at https://go.usa.gov/xz4a2 on December 1, 2022.

[30] CDC, "Update of the Blood Lead Reference Value—United States, 2021," *Morbidity and Mortality Weekly Report*, October 2021. Accessed at https://www.cdc.gov/mmwr/volumes/70/wr/mm7043a4.htm?s_cid=mm7043a4_w on June 29, 2022.

[31] CDC, *Recommended Actions Based on Blood Lead Level*, October 2021. Accessed at https://go.usa.gov/xz4ab on February 28, 2022.

[32] CDC, *CDC Updates Blood Lead Reference Value to 3.5 µg/dL*, January 2022. Accessed at https://go.usa.gov/xz4Cv on February 28, 2022.

[33] CDC, *Recommended Actions Based on Blood Lead Level*, December 2017. Accessed at http://web.archive.org/web/20200713205506/https://www.cdc.gov/nceh/lead/advisory/acclpp/actions-blls.htm on August 17, 2022.

[34] Joseph F. Hagan, Jr., M.D., FAAP, et al., AAP, *Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents (Fourth Edition)*, 2017.

[35] AAP, *Treatment of Lead Poisoning*, July 2021. Accessed at https://www.aap.org/en/patient-care/lead-exposure/treatment-of-lead-poisoning/ on February 28, 2022.

[36] Following our review period, in October 2021, AAP acknowledged the updated CDC blood lead reference value of 3.5 µg/dL. For children with levels below the updated reference value, AAP suggested that clinicians may need to retest children depending on age and other factors and reassess the child's environment in the future. For children with levels above the updated reference value, AAP suggested that clinicians should retest to establish a trend, discuss possible sources of lead exposure, consider an environmental assessment, and follow health department guidelines for public health intervention. AAP, "Revised Blood Lead Reference Value: Pprogress, but More Work to Be Done," *AAP News*, October 2021. Accessed at https://publications.aap.org/aapnews/news/17767 on June 15, 2022.

[37] The Act § 1902(a)(43)(D); CMS, "Chapter 5: Early and Periodic Screening, Diagnostic and Treatment Services," *The State Medicaid Manual*, 5320.2.C. Accessed at https://go.usa.gov/xU2VG on February 28, 2022.

[38] CMS, *2700.4 Instructions for Completing Form CMS-416: Annual Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Participation Report*, effective for the reporting period federal fiscal year 2020. Accessed at https://go.usa.gov/xHF9x on June 4, 2021.

[39] CMS, *2700.4 Instructions for Completing Form CMS-416: Annual Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Participation Report*, effective for the reporting period federal fiscal year 2020, section E, Line14a-14b. Accessed at https://go.usa.gov/xHF9x on June 4, 2021.

[40] OIG, *More Than One-Third of Medicaid-Enrolled Children in Five States Did Not Receive Required Blood Lead Screening Tests*, October 2021. Accessed at https://oig.hhs.gov/oei/reports/OEI-07-18-00371.pdf on May 16, 2022.

[41] OIG, *Most Medicaid Children in Nine States Are Not Receiving All Required Preventive Screening Services*, May 2010. Accessed at https://go.usa.gov/xU4gG on July 6, 2022.

[42] The National EPSDT Improvement Workgroup included State representatives, children's health providers, consumer representatives, and other experts in the areas of maternal and child health, Medicaid, and data analysis. OIG, *Recommendation Followup Memorandum Report: CMS Needs To Do More To Improve Medicaid Children's Utilization of Preventive Screening Services*, November 2014. Accessed at https://go.usa.gov/xSacU on July 8, 2022.

[43] The population included 21,353 children across the 5 States.

[44] For 21 of the 415 children for whom medical records lacked adequate information for medical reviewers to confirm the diagnosis of lead toxicity, we identified a service in State health department data during children's respective periods of review. Specifically, for 19 of the 21 children, we identified in State health department data a blood lead test associated with the child's date of diagnosis that was also identified in Medicaid claims data. For the remaining children, we identified in State health department data a parent education service during the child's respective review period.

[45] Reviewer notes identified that 29 children had a blood lead level between 3.5 and 4.9 µg/dL; reviewers indicated "low," "normal," or "negative" levels for the remaining 6 children.

[46] Of the 85 children who did not receive services as recommended, 5 children had a blood lead level below 5 µg/dL and reviewer notes for 3 additional children indicated blood lead levels at or above 5 µg/dL, but did not identify in the records numeric blood lead values associated with the diagnosis of lead toxicity. These eight cases were excluded from the followup testing analysis.

[47] Of the 81 children who received services as recommended, 24 children had a blood lead level below 5 µg/dL and reviewer notes for 1 additional child indicated blood lead levels at or above 5 µg/dL, but did not identify in the record a numeric blood lead value associated with the diagnosis of lead toxicity. These 25 cases were excluded from the followup testing analysis.

[48] CMS, *2700.4 Instructions for Completing Form CMS-416: Annual Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) Participation Report*, 2020. Accessed at https://go.usa.gov/xHF9x on June 4, 2021.

[49] Medicaid Statistical Information System (MSIS) threshold error tolerances allow between 0.1 and 5.0 percent missing, unknown, or invalid codes for the variables used in this analysis. CMS, *MSIS File Specifications and Data Dictionary*, 2012.