

Supporting Statement Part A
Annual Early and Periodic Screening, Diagnostic and
Treatment (EPSDT) Participation Report
CMS-416, OMB 0938-0354

Background

Section 1902(a)(43)(D) of the Social Security Act (the Act) requires States to report annually by age group and basis of Medicaid eligibility for medical assistance, information relating to Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services provided under the State Plan. The Centers for Medicare & Medicaid Services (CMS) is responsible for administering the EPSDT benefit, in partnership with states, and uses the annual reports to evaluate the benefit's effectiveness in meeting the health care needs of Medicaid-eligible children. The report also is used to provide data to Congress and the public on the use of health care services by children enrolled in Medicaid.

States, the District of Columbia, and territories—collectively referred to here as respondents—meet this reporting requirement by submitting a completed Form CMS-416 report to CMS by April 1st of each calendar year, or by electing to have CMS generate the form on their behalf using data they submit to CMS from the Transformed Medicaid Statistical Information System (T-MSIS), provided they meet certain data quality criteria. In FFY 2024, the most recent reporting year, 63 percent of respondents opted to have CMS generate Form CMS-416 on their behalf.

This 2026 collection of information request is a Revision that proposes changes to the CMS-416 form and the form's instructions. We are also proposing to reduce our burden estimates by 384 hours and \$25,834. See section 15 of this Supporting Statement for details.

A. Justification

1. Need and Legal Basis

The authority for requiring respondents to submit the annual EPSDT report is section 1902(a)(43)(D) of the Act. The report is submitted to CMS on Form CMS-416 (attached). CMS then makes the compiled state and national data publicly available. The data are used to assess the effectiveness of state Medicaid programs in reaching EPSDT eligible children.

2. Information Users

Respondents submit Form CMS-416 to CMS's Center for Medicaid and CHIP Services (CMCS). The data collected are used to assess the effectiveness of state Medicaid programs in reaching EPSDT eligible children, by age group and basis of Medicaid eligibility, who are provided initial and periodic child health screening services, referred for corrective treatment, and receiving dental, and lead screening services.

3. Information Technology

CMS developed a uniform electronic form by which respondents must report the required data. All respondents use a Medicaid Management Information System (MMIS) from which the data are extracted, based on programming according to the CMS-416 instructions. The state extracts the data and inputs it into the electronic CMS form and then submits the report via email to the CMS EPSDT Technical Assistance mailbox.

The form provides respondents with the option of allowing CMS to calculate EPSDT data on their behalf using information they submit to CMS via T-MSIS, provided that the quality of the state's T-MSIS data meets internal data quality standards. All respondents are required to submit T-MSIS data to CMS monthly.

4. Duplicate Information

CMCS is the only CMS component collecting EPSDT data. Therefore, there is no duplication.

5. Small Business

Respondents are limited to states, territories, and the District of Columbia. In that regard this collection of information request does not involve small businesses or other small entities.

6. Less Frequent Collection

Section 1902(a)(43)(D) of the Act requires annual reporting of the EPSDT data by respondents. Less frequent collection does not provide adequate/current data necessary for response to Congressional and public inquiries. Respondents that do not provide Form CMS-416 by the annual deadline are considered out of compliance with the authorizing statute.

7. Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

- Submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultations

The 60-day notice published in the Federal Register on January 22, 2026 (91 FR 2778). Comments must be received on/by March 23, 2026.

9. Payments or Gifts

There is no provision for any payment or gift to respondents associated with this reporting requirement.

10. Confidentiality

Because no personal identifying information is collected in the report, there is no issue of confidentiality with respect to the data submitted by the state. The data collected on the report are available for public review.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Respondent Requirements and Burden Estimates

12.1 Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2024 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

Occupation Title	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Hourly Wage (\$/hr)
Computer and Information Analysts	15-1210	55.83	55.83	111.66

We are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from

employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate method.

12.2 *Burden Estimates*

CMS receives Form CMS-416 submissions annually from 56 respondents. Respondents who are current on their T-MSIS data submissions and whose T-MSIS data meet internal data quality standards are eligible for this option. It is estimated that approximately 20 respondents will choose to complete and submit the Form CMS-416 themselves and that approximately 36 respondents will choose to have CMS generate the form. This estimate is based on the number of respondents that are expected to meet the internal T-MSIS data quality standards and the proportion that typically choose to have CMS generate the form.

Burden for respondents that complete the Form CMS-416:

- **Reporting**

385 hours = 20 Respondents x 1 report annually x 19.25 hours

\$42,989 per year = \$111.66/hr x 385 hours

\$10,747 = Adjusted cost, 25% of the total cost to account for the state portion of the costs

- **Recordkeeping**

185 hours = 20 Respondents x 1 report annually x 9.25 hours

\$20,657 per year = \$111.66/hr x 185 hours

\$5,164 = Adjusted cost, 25% of the total cost to account for the state portion of the costs

Requirement	Respondents	Total Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost (\$/hr)	Adjusted Cost (\$)
CMS-416 (Reporting)	20	20	19.25	385	111.66	10,747
CMS-416 (Recordkeeping)			9.25	185		5,164
Total	20	20	varies	570	111.66	15,911

Burden for respondents that opt to have CMS generate the Form CMS-416:

- **Reporting**

288 hours = 36 Respondents x 1 report annually x 8.0 hours

\$32,158 per year = \$111.66/hr x 288 hours

\$8,040 = Adjusted cost, 25% of the total cost to account for the state portion of the costs

- **Recordkeeping**

270 hours = 36 Respondents x 1 report annually x 7.5 hours

\$30,148 per year = \$111.66/hr x 270 hours

\$7,537 = Adjusted costs, 25% of the total cost to account for the state portion of the costs

Requirement	Respondents	Total Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost (\$/hr)	Adjusted Cost (\$)
CMS-416 (Reporting)	36	36	8	288	111.66	8,040
CMS-416 (Recordkeeping)			7.5	270		7,537
Total	36	36	varies	558	111.66	15,577

12.3. Summary of Annual Burden Estimates

Requirement	Respondents	Total Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost (\$/hr)	Adjusted Cost (\$)
Respondents that complete the Form CMS-416	20	20	19.25	385	111.66	10,747
Respondents that opt to have CMS generate the Form CMS-416	36	36	8.0	288	111.66	8,040
<i>Subtotal: Reporting</i>	<i>56</i>	<i>56</i>	<i>27.25</i>	<i>673</i>	<i>111.66</i>	<i>18,787</i>
Respondents that complete the Form CMS-416	20	20	9.25	185	111.66	5,164
Respondents that opt to have CMS generate the Form CMS-416	36	36	7.5	270	111.66	7,537
<i>Subtotal: Recordkeeping</i>	<i>56</i>	<i>56</i>	<i>16.75</i>	<i>455</i>	<i>111.66</i>	<i>12,701</i>
TOTAL	56	56	varies	1,128	111.66	31,488

12.4. Information Collection Instruments and Supporting Documents

- Form CMS-416, “Annual EPSDT Participation Report.” (Revised)

Respondents submit the Form CMS-416 to CMS’s Center for Medicaid and CHIP Services (CMCS). The data are used to assess the effectiveness of state Medicaid programs in reaching EPSDT eligible children, by age group and basis of Medicaid eligibility, who are provided initial and periodic child health screening services; referred for corrective treatment; and receiving dental and lead screening services.

- Form CMS-416, “Instructions for Completing Form CMS-416: Annual Early and Periodic

Screening, Diagnostic, and Treatment (EPSDT) Participation Report.” (Revised)

Section 2700.4 of the State Medicaid Manual (SMM) contains the Form CMS-416 as well as instructions for completing the form.

13. Capital Costs

There are no start-up costs associated with this information collection because the Medicaid EPSDT benefit has been in existence since 1967.

All respondents use the Medicaid Management Information System to capture claims data, from which CMS-416 data can be derived. However, CMS does not mandate state data system types or data collection methodologies. Some respondents may use a different data system and/or a hybrid approach of claims data and managed care encounter data to collect the CMS-416 data. Therefore, it is necessary to estimate a range of operating and maintenance costs for EPSDT data. These costs are estimated to range from \$3,000 to \$15,000 annually.

14. Federal Costs

The annualized cost to the Federal Government when the state generates the CMS Form-416 is \$70,042 (\$47,735 + \$22,307) which is computed as follows:

75 percent (Federal share) of the respondents’ total costs	$\$47,735 = \$63,646 \times 0.75$
Data entry, analysis, and inquiry responses (GS-13/8)	$\$22,307 = \$148,716 \times 0.15 \text{ FTE}$

The annualized cost to the Federal Government when CMS generates the CMS Form-416 is \$69,037 (\$46,730 + \$22,307) which is computed as follows:

75 percent (Federal share) of the respondents’ total costs	$\$46,730 = \$62,306 \times 0.75$
Data entry, analysis, and inquiry responses (GS-13/8)	$\$22,307 = \$148,716 \times 0.15 \text{ FTE}$

Note: \$148,716 @ GS-13 step 8 for the Washington-Baltimore-Arlington locality (effective January 2025). See <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2025/DCB.pdf>.

The total annualized cost to the Federal Government is \$139,079 (\$70,042 + \$69,037).

15. Burden/Program Changes

This 2026 collection of information request proposes changes to the CMS-416 form and the form’s instructions. A discussion of the changes follow and are presented in the attached crosswalk and redline versions of the revised documents.

As indicated below, we are also proposing to reduce our active time estimate by 384 hours and \$25,834.

Form CMS-416

The primary change is to respecify the instructions for Line 14, Blood Lead Screenings, to count the number of eligible individuals who received a blood lead screening rather than the number of screening blood lead tests provided to eligible individuals. This change will allow CMS to more easily calculate the rate of individuals with blood lead screenings; will better align with the HEDIS version of the measure (Lead Screening in Children [LSC]), which CMS allows respondents to report on Line 14a, and relies on counts of individuals rather than tests; and will yield more accurate counts. This change is accompanied by the removal of examples of inclusionary and exclusionary diagnosis codes that can be used to indicate a screening versus follow-up blood lead test; use of these examples may result in inconsistent reporting across respondents and potential undercounting of the number of screenings conducted since the list is incomplete.

Another change is the addition of a HCPCS code (T1015) to Line 6, Total Screens Received, to enable state reporting of children's well-child visit screenings rendered at Federally Qualified Health Centers (FQHCs) and community health centers (CHCs).

CMS also is providing additional guidance to support state reporting of the dental and oral health lines of Form CMS-416, Lines 12a-12g. First, CMS added a reference to a resource that respondents can use to classify providers of dental services. Second, CMS added language to the instructions for Line 12f, Total Eligibles Receiving Oral Health Services Provided by a Non-Dentist Provider, and 12g, Total Eligibles Receiving any Preventive Dental or Oral Health Service. This language will help respondents use CPT codes to report dental or oral health services by specifically referencing CPT code 99188 or other codes identified by the respondent. Third, CMS added guidance to the instructions for Line 12f to acknowledge that some respondents allow oral health assessments to be conducted by primary care medical providers as part of office visits and specify that these visits can be included on this line.

CMS also added language under Important Reporting Requirements to clarify that respondents should count the number of unique screens that occurred using unique dates of service (rather than counting the number of claims that indicate a screen) to avoid the potential for duplicate counting of services with multiple claims.

Finally, CMS updated the expiration date in the PRA disclaimer, made several minor text edits to improve the consistency of language across the instructions, and corrected a few minor grammatical errors.

We note that these changes are expected to have the biggest impact on burden in the first year of reporting after these changes have been implemented. We also note that these changes primarily impact those respondents submitting Form CMS-416 to CMS versus those that opt to have CMS generate the form on their behalf.

The new burden estimate for respondents is 1,128 hours (see section 12 of this Supporting Statement). This reflects the completion and submission of the Form CMS-416 by respondents as well as CMS generation and state review and verification of the Form CMS-416 for respondents that opt to have CMS generate the form for them.

This is a reduction of 384 hours (1,512 active hours - 1,128 proposed hours) from our active burden estimate for reporting and recordkeeping. The 384-hour reduction reflects relatively small decreases to state reporting and recordkeeping burden due to the proposed changes, balanced against an approximate estimated 46 percent difference (as explained below) in the reporting burden for respondents who select to have CMS generate Form CMS-416 on their behalf, and an increased in the estimated number of respondents that will opt in to have CMS generate the Form CMS-416 based on current reporting experience.

Because respondents have the option to either complete the Form CMS-416 themselves or have CMS generate the form, we have provided two burden estimates. We estimate a reporting and recordkeeping burden of 570 total hours for the estimated 20 respondents that will choose to complete the form. This is a reduction of 329 hours from the active burden estimate (899 active reporting hours – 570 proposed reporting hours), reflecting a decrease in the number of respondents choosing to submit the form themselves (28 respondents in the active estimate – 20 respondents in the proposed estimate) and a small (0.25) expected decrease in reporting and recordkeeping burden due to the proposed changes. For respondents that choose to have CMS generate the Form CMS-416 and then review and verify the data, the burden is estimated to be 558 total hours reflecting submissions from 36 respondents. This represents a decrease of 55 hours from the active burden (613 active recordkeeping hours - 558 proposed recordkeeping hours), due to an increase in the number of respondents choosing to have CMS generate the form (25 respondents in the active estimate – 36 respondents in the proposed estimate based on the current reporting experience), and our determination that the active burden overestimates the burden associated with this option. The revised burden estimate represents a 46 percent reduction in the per response reporting burden (15.5 hours) as compared to a state-generated submission (28.5 hours).

Changes to the reporting form include:

- Updated the titles of Lines 14a and 14b to reflect 1) the methodology to report Lines 14a and 14b to capture the total number of eligibles who received blood lead screenings versus a count of screenings blood lead tests; and 2) reflect the removal of the inclusionary and exclusionary codes in the instructions to report blood lead screenings.
 - 14a. Total Eligibles Receiving Blood Lead Screenings
 - 14b. Methodology Used to Calculate the Total Eligibles Receiving Blood Lead Screenings
- Updated Method I under Line 14b to reflect the removal of inclusionary and exclusionary codes in the instructions for reporting data on the number of eligible who received blood lead screening vs. screening blood lead tests.
 - CPT Code 83655 (Method I)
- Updated the disclosure statement to reflect proposed new expiration date and the estimated average number of hours for completion.
 - Disclosure Statement - Annual completion of the Form CMS-416 is mandatory for states pursuant to section 1902(a)(43)(D) of the Social Security Act which requires states to annually report on the provision of Early and Periodic

Screening, Diagnostic and Treatment (EPSDT) services. Under the Privacy Act of 1974 any personally identifying information obtained will be kept private to the extent of the law. According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0354 (expiration date July 31, 2029). The time required to complete this information collection is estimated to average 28.5 hours per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop: C4-26-05, Baltimore, Maryland 21244-1850.

Form CMS-416 (Instructions)

Changes to the instructions for completing the form include:

- Updated the federal fiscal year (FFY) in the header.
- Updated the expiration date and estimated average number of hours for completion in the PRA Disclosure Statement.
- Updated “the state lead in their CMS state office” to “their CMS state lead.”
- Updated the effective date of these revised instructions in Section C.
- Updated the example provided under Federal Fiscal Year in Section E, Detailed Instructions, specifying the time period of FFY 2026:
 - For example, FFY 2026 is October 1, 2025 through September 30, 2026.
- Made minor grammatical edits under Important Reporting Requirements and added language to clarify how respondents should report screening services:
 - Count the number of unique screens that occurred using unique dates of service (rather than counting claims that indicate a screen). This will avoid the potential for duplicate counting of services with multiple claims.
- Updated the date accompanying the table that identifies how to report the periodicity schedule on Line 2a to the most current version of the Bright Futures guidelines:
 - If your state follows the 2025 American Academy of Pediatrics’ Bright Futures™ guidelines, the periodicity schedule should be reported on the form as follows:
- Added HCPCS code, T1015 All-Inclusive Clinic Visit/Encounter, to the instructions for Line 6, which respondents can use to report children’s initial or periodic screenings.
- Removes language in the instructions for Lines 9, 12a, 12b, 12c, 12d, 12e, 12f, 12g, 14a to

ensure a parallel structure to the language throughout the instructions for each line:

- Line 9, 12a, c, e, f, g: under the age of 21 with at least 90 continuous days of enrollment during the federal fiscal year
 - Line 12d: with at least 90 continuous days of enrollment during the federal fiscal year
 - Line 14a: (that is, with at least 90 continuous days of enrollment during the federal fiscal year) under fee-for service, prospective payment, managed care, or any other payment arrangements, based on an unduplicated paid, unpaid, or denied claim.
- Added language to NOTE B pertaining to the Dental and Oral Health Lines 12a-12g to provide a resource that respondents can use to classify dental service providers.
 - The Dental Quality Alliance maintains a value set of taxonomy codes to identify dental services that the state may use as a resource for classifying providers.
- Added language the instructions for Lines 12f and 12g to provide respondents with additional coding guidance about how to report dental or oral health services using CPT codes:
 - These services are defined by HCPCS codes D1000 - D1999 (or equivalent CDT codes D1000 – D1999), or CPT code 99188 (or other equivalent CPT codes specifically identified by the state) that are for preventive dental or oral health services, based on an unduplicated paid, unpaid, or denied claim
- Added language to the NOTE accompanying Line 12f to acknowledge that some respondents allow oral health assessments to be conducted by physicians as part of office visits, and that these visits can be included on Line 12f:
 - CMS recognizes that some states allow oral health assessments to be conducted by physicians as part of office visits and documented with the modifier ‘DA’. These oral health assessments are appropriate for inclusion in Line 12f but should not be counted for any other Line 12 measures.
- Revised the methodology to report Lines 14a and 14b to capture the total number of eligibles who received blood lead screenings versus a count of screenings to allow CMS to more easily calculate the rate of individuals with blood lead screenings and to better align with the HEDIS version of the measure (LSC), which CMS allows respondents to report on Line 14a, and relies on counts of individuals rather than tests. Additionally, analysis data indicates that nationally there are 10% more tests than distinct beneficiaries tested, this method may result in more accurate counts:
 - **Line 14a -- Total Eligibles Receiving Blood Lead Screenings** -- Enter the unduplicated number of individuals under the age of six from Line 1b who received at least one blood lead screening. You may use one of two methods, or a combination of these methods, to calculate the number of blood lead screenings provided:
 - 1) Count the unduplicated number of eligibles for whom CPT code 83655 (“lead”) for a blood lead screening was reported; or
 - 2) You may include data collected from use of the HEDIS®¹ measure developed by the National Committee for Quality Assurance to report

blood lead screenings if your state has elected to use this performance measure.

- **Line 14b -- Methodology Used to Calculate the Total Eligibles Receiving Blood Lead Screenings** -- Identify the methodology used by your state to calculate the unduplicated number of individuals reported on Line 14a who received at least one blood lead screening by entering an “X” on the form next to the methodology used:

- 1) CPT Code 83655 (Method I)
- 2) HEDIS (Method II)
- 3) Combination Methodology (Method III)

¹ Health Effectiveness Data and Information Set

- Removed the NOTE beneath Line 14 that provided examples of inclusionary and exclusionary diagnosis codes that could be used to indicate a blood lead screening rather than a follow-up blood lead test. This note is being removed because this list of examples is incomplete and may result in inconsistency in reporting across respondents and potential undercounting of the number of screenings conducted. Since this line now captures individuals receiving blood lead screenings, the titles of Lines 14a and 14b have been updated accordingly.

16. Publication and Tabulation Data

Data from state submissions of the form may be posted on the CMS website, Medicaid.gov. Some of the data may be published in tables and charts to show reporting progress across FFYs.

17. Display of Expiration Date

The CMS-416 form and instruction display the expiration date.

18. Exception to Certification Statement

Not applicable. There are no exceptions.

B. Collections of Information Employing Statistical Methods

CMS does not intend to collect information employing statistical methods.