

**Supporting Statement Part A**  
**Annual Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Participation**  
**Report and Supporting Statutory Language**  
**Contained in 1902(a)(43)(D) of the Social Security Act**  
**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 the Congress and the public on the use of health care services by children enrolled in Medicaid.

In this 2019/2020 iteration, we propose to revise the EPSDT reporting requirements on Form CMS-416: Annual EPSDT Participation Report (EPSDT Report). We are making two changes to the Form CMS-416. A line has been added to the top of the form to give states the option to allow CMS to generate the Form CMS-416 on behalf of states using data from the CMS Transformed Medicaid Statistical Information System (T-MSIS). This option is available to states who are both current on their T-MSIS submissions to CMS and whose T-MSIS data meets internal data quality standards. In addition, CMS is modifying line 12g to capture preventive dental or oral health services. Corresponding changes have been made to the instructions.

We are also proposing to revise the instructions to provide and simplify examples; clarify which lines states do not need to complete as they will be auto-calculated; clarify lines 12a-12g and coding guidance for lines 12f and 12g; and revise the instructions for line 14 to reflect lines 14a and 14b on the Form CMS-416.

The new burden estimate for states is 1,512 hours. This reflects the completion and submission of the Form CMS-416 by states as well as CMS generation and state review and verification of the Form CMS-416 for states that opt to have CMS generate the form for them.

This is a reduction of 112 hours (1,512 proposed hr - 1,624 active hr) from our active burden estimate for the recordkeeping and reporting. The 112 hour reduction reflects the estimated 20 percent reduction (as explained below) in the reporting burden for states who select to have CMS generate Form CMS-416 on their behalf.

Section 2700.4 of the State Medicaid Manual (SMM) contains Form CMS-416, instructions for completion of the form.

The reference to the six YouTube training module videos in the instructions has been removed. These videos were available as supplements to the instructions and have been removed as there was not significant state utilization.

**A. Justification**

1. Need and Legal Basis

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

2. Information Users

States submit the CMS Form-416 to CMS' 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 states must report the required data. All states and territories use a Medicaid Management Information Systems (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 revised Form CMS-416 provides states 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 states are required to submit T-MSIS data to CMS on a monthly basis.

4. Duplicate Information

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

5. Small Business

This collection of information does not involve small businesses or other small entities.

6. Less Frequent Collection

Section 1902 (a)(43)(D) of the Act requires the annual reporting by states of the EPSDT data. Less frequent collection does not provide adequate/current data necessary for response to Congressional and public inquiries. States 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 secret, 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 October 31, 2019 (84 FR 58390). We received three public comments. The comments and our response are attached to this package.

Subsequent to the publication of the notice and the posting of the package we have updated our federal cost estimates based on updated OPM wage tables. We have also revised the CMS contact information in section B of the instructions.

The 30-day notice published in the Federal Register on January 28, 2020 (85 FR 4992).

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 is 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. Estimate of Hour Burden and Cost to Respondents

12.1 *Wage Estimates*

The following costs are based on the U.S. Bureau of Labor Statistics’ May 2018 National Occupational Employment and Wage Estimates United States for all salary estimates ([http://www.bls.gov/oes/current/oes\\_nat.htm](http://www.bls.gov/oes/current/oes_nat.htm)).

Occupation Title	Occupation Code	Mean Hourly Wage	Fringe Benefits and Overhead	Adjusted Hourly Wage
Computer and Information Analysts	15-1120	\$45.67/hr	\$45.67/hr	\$91.34/hr

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 overhead 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 estimation method.

12.2 *Burden Estimates*

CMS receives Form CMS-416 submissions annually from 56 state entities. States 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 31 state entities will choose to complete and submit the Form CMS-416 themselves and that approximately 25 state entities will choose to have CMS generate the form. This estimate is based on the number of states who are expected to meet the internal T-MSIS data quality standards.

Burden for states that complete the Form CMS-416:

- Reporting

**604.5 hours** = 31 State entities x 1 report annually x 19.5 hours  
 \$ 55,215 per year = \$91.34/hr x 604.5 hours  
 \$13,803 = Adjusted cost, 25% of the total cost to account for the state portion of the costs

- Recordkeeping

**294.5 hours** = 31 State entities x 1 report annually x 9.5 hours  
 \$26,900 per year = \$91.34/hr x 294.5 hours  
 \$6,725 = Adjusted cost, 25% of the total cost to account for the state portion of the costs

Requirement	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting	Total Cost (\$)	Adjusted Cost*
CMS-416 (Reporting)	31	31	19.5	604.5	\$91.34/hr	55,215	13,803
CMS-416 (Recordkeeping)			9.5	294.5		26,900	6,725
<b>Total</b>	31	31	varies	899	\$91.34/hr	82,115	20,528

\*The cost is adjusted by 25 percent to account for the state share.

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

- Reporting

**375 hours** = 25 State entities x 1 report annually x 15 hours  
 \$34,253 per year = \$91.34/hr x 375 hours  
 \$8,563 = Adjusted cost, 25% of the total cost to account for the state portion of the costs

- Recordkeeping

**237.5 hours** = 25 State entities x 1 report annually x 9.5 hours  
 \$21,693 per year = \$91.34/hr x 237.5 hours  
 \$5,423 = Adjusted costs, 25% of the total cost to account for the state portion of the costs

Requirement	Respondents	Responses	Burden per Response (hours)	Total Annual Burden (hours)	Labor Cost of Reporting	Total Cost (\$)	Adjusted Cost*
CMS-416 (Reporting)	25	25	15	375	\$91.34/hr	34,253	8,563
CMS-416 (Recordkeeping)			9.5	237.5		21,693	5,423

<b>Requirement</b>	<b>Respondents</b>	<b>Responses</b>	<b>Burden per Response (hours)</b>	<b>Total Annual Burden (hours)</b>	<b>Labor Cost of Reporting</b>	<b>Total Cost (\$)</b>	<b>Adjusted Cost*</b>
<b>Total</b>	25	25	varies	612.5	\$91.34/hr	55,946	13,986

\*The cost is adjusted by 25 percent to account for the state share.

### 12.3. Summary of Annual Burden Estimates

<b>Requirement</b>	<b>Respondents</b>	<b>Responses</b>	<b>Burden per Response (hours)</b>	<b>Total Annual Burden (hours)</b>	<b>Labor Cost of Reporting</b>	<b>Total Cost (\$)</b>	<b>Adjusted Cost*</b>
States that complete the Form CMS-416	31	31	19.5	604.5	\$91.34/hr	55,215	13,803
States that opt to have CMS generate the Form CMS-416	25	25	15	375	\$91.34/hr	34,253	8,563
<i>Subtotal: Reporting</i>	<i>56</i>	<i>56</i>	<i>34.5</i>	<i>979.5</i>	<i>\$91.34/hr</i>	<i>89,468</i>	<i>22,366</i>
States that complete the Form CMS-416	31	31	9.5	294.5	\$91.34/hr	26,900	6,725
States that opt to have CMS generate the Form CMS-416	25	25	9.5	237.5	\$91.34/hr	21,693	5,423
<i>Subtotal: Recordkeeping</i>	<i>56</i>	<i>56</i>	<i>19</i>	<i>532</i>	<i>\$91.34/hr</i>	<i>48,593</i>	<i>12,148</i>
<b>TOTAL</b>	<b>56</b>	<b>56</b>	<b>varies</b>	<b>1,512</b>	<b>\$91.34/hr</b>	<b>138,061</b>	<b>34,514</b>

### 12.4. Information Collection Instruments and Supporting Documents

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

States submit the Form CMS-416 (which is titled “Annual EPSDT Participation Report”) to CMS’ 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.”

Section 2700.4 of the State Medicaid Manual (SMM) contains the CMS-416 form 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 states 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 states 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 in a range of \$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 \$80,579 (\$61,586 + \$18,993) which is computed as follows:

75 percent (Federal share) of the states' total costs	\$61,586 = \$82,115 x 0.75
Data entry, analysis, and inquiry responses (GS-13/8)	\$18,993 = \$126,620 x 0.15 FTE

The annualized cost to the Federal Government when CMS generates the CMS Form-416 is \$67,283 (\$41,959 + \$25,324) which is computed as follows:

75 percent (Federal share) of the states' total costs	\$41,959 = \$55,946 x 0.75
Data entry, analysis, and inquiry responses (GS-13/8)	\$25,324 = \$126,620 x 0.2 FTE

*Note: \$126,620 @ GS-13 step 8 for the Washington-Baltimore-Arlington locality (effective January 2020). See <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/DCB.pdf>.*

The total annualized cost to the Federal Government is \$147,862 (\$80,579 + \$67,283).

15. Changes in Burden and/Program Changes

The currently approved (active) burden is 1,778 hours, consisting of 1,624 hours for state submission of the Form CMS-416 and 154 hours for a series of YouTube training videos.

*Training Videos*

In this 2020 iteration we propose to remove the training videos, which were developed to support states and their contractors more accurately report the dental data included in the Form CMS-416, and were voluntary for states and their contractors. We are removing the training videos since there was not significant state use. Therefore, the corresponding 154 hours of burden has

been removed from our active burden estimate.

### *Form CMS-416*

The revised CMS-416 Form would provide states with the option to complete the Form themselves or have CMS generate the form and submit it to states for verification.

CMS receives Form CMS-416 submissions annually from 56 state entities. States 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 31 state entities will choose to complete and submit the Form CMS-416 themselves and that approximately 25 state entities will choose to have CMS generate the form. This estimate is based on the number of states who are expected to meet the internal T-MSIS data quality standards.

The new burden estimate for states is 1,512 hours (see section 12 of this Supporting Statement). This reflects the completion and submission of the Form CMS-416 by states as well as CMS generation and state review and verification of the Form CMS-416 for states that opt to have CMS generate the form for them.

This is a reduction of 112 hours (1,512 proposed hr - 1,624 active hr) from our active burden estimate for the recordkeeping and reporting. The 112 hour reduction reflects the estimated 20 percent reduction (as explained below) in the reporting burden for states who select to have CMS generate Form CMS-416 on their behalf.

There are two changes to the reporting lines on the Form CMS-416. The first is to add a checkbox for states to indicate their permission for CMS to generate the data for the form on their behalf using information reported in the Transformed Medicaid Statistical Information System (T-MSIS). This option will be provided to states whose T-MSIS data have been deemed to meet CMS data quality standards. The second is to change the definition of line 12g from a count of beneficiaries receiving any dental oral health services to a count of beneficiaries receiving preventive dental or preventive oral health services. This small definitional change will allow CMS to more fully capture the providers and settings where preventive oral health services are being delivered. In addition, the expiration date in the PRA disclaimer; has been updated and a few minor typos and formatting errors have been corrected.

Because states now have the option to either complete the Form CMS-416 themselves or have CMS generate the form and provide it to the state for review, we have provided two reporting burdens.

For states that choose to complete the form, we have reduced the number of states entities from 56 to 31, reflecting a burden of 899 total hours. For states that choose to have CMS generate the Form CMS-416 and then submit it to the state for verification, the burden is estimated to be 613 total hours reflecting submissions from 25 state entities. This reflects a 20 percent reduction in the per response burden as compared to a state-generated submission.

### *Form CMS-416 (Instructions)*

Changes to the instructions for completing the form include:

- Update to the federal fiscal year (FFY) in the header.
- Update to the URL where the instructions and reporting form can be found on the CMS Medicaid.gov website - <https://www.medicaid.gov/medicaid/benefits/epsdt/index.html>.
- Revision to CMS contact information in section B.
- Revision of section E. Detailed Instructions to reflect addition of new instructions corresponding to the new CMS Generated Reporting of State Form CMS-416 Using T-MSIS option for states. These instructions clarify the new option available to states to allow CMS to generate state-specific Form CMS-416 reports using T-MSIS. Section E (page 2) will now appear as follows:

- **E. Detailed Instructions – Enter your state name and the federal fiscal year as directed below.**

**State** – Enter the name of your state using the two character state code in upper case format.

**Fiscal Year** – Enter the federal fiscal year (FFY) being reported in YYYY format.

**Note:** The federal fiscal year is from October 1 through September 30. For example, FFY 2020 is October 1, 2019 through September 30, 2020.

**CMS Generated Reporting of State Form CMS-416 Using T-MSIS** -- In an effort to reduce state reporting burden, CMS has developed the capacity to generate state-specific Form CMS-416 reports using state-reported data to CMS via the Transformed Statistical Information System (T-MSIS). This option is available only to states that are current with T-MSIS data submissions and pass T-MSIS benchmarks for data quality and completeness. If your state gives CMS permission to generate Form CMS-416 data using T-MSIS, please enter an “X” in the space provided on the form, along with the two digit state code and the federal fiscal year. The rest of the form should remain blank. The form and copies of the state’s current medical and dental periodicity schedules should be submitted to CMS by April 1<sup>st</sup> via the EPSDT technical assistance mailbox. States who select this option will be given an opportunity to review and validate the T-MSIS generated report before it is finalized and made publically available.

States that choose not to have CMS generate the state-specific Form CMS-416 or who do not meet the criteria to have CMS generate the Form CMS-416 should follow the detailed instructions for the completion of the Form CMS-416.

- Modifications to the Important Reporting Requirements (page 2). These modifications include simplification of the example in the second bullet in order to clarify that it applies across the age spans in the report and addition of language clarifying that states should not report in grayed out cells. Revised language:

- Revision to second bullet - For example, if a child turned age 3 on September 1<sup>st</sup>, but received EPSDT services at age 2, these services would be counted in the age 3-5 category.
- Addition of fifth bullet - Do not enter any data into the grayed out cells.
- Change the placement of language about reporting by basis of eligibility from the instructions for Line 1a to the instructions for reporting the categorically and medically needy groups (page 3). Revised language:
  - States should determine the basis of eligibility consistent with the instructions from the Transformed Medicaid Statistical Information System (T-MSIS) Data Dictionary, in consultation with state Medicaid eligibility officials, if needed.
- Addition of language to Line 1a, Total Individuals Eligible for EPSDT, to clarify that eligible individuals terminated prior to September 30<sup>th</sup> should be included (page 3). Revised language:
  - If a child was not enrolled in Medicaid on September 30<sup>th</sup> because their eligibility was terminated prior to this date, the child should still be included on this line. Their age should be reported as of September 30<sup>th</sup> of the reporting year, while their basis of eligibility should be reported as of the date they were terminated.
- Addition of a table that identifies how to report the periodicity schedule on Line 2a (page 5) for states that follow the 2019 American Academy of Pediatrics Bright Futures™ guidelines.
- Updated instructions for lines 2c, 3b, 4, 5, 7, 8, and 10 to clarify that states should not input any information into these lines because they are auto-calculated. This corresponds to the previous addition of new language to the Important Reporting Requirements section on page 2 stating that states should not enter data in the greyed out cells (Lines 2c, 3b, 4, 5, 7, 8, 10; pages 6-8).
- Revisions to instructions to the Dental and Oral Health Lines (12a – 12g) to make minor clarifications to the instructions and to provide coding guidance for Lines 12f and 12g (page 8). In addition, rename the section entitled “Important” to NOTE C, updating it to reflect the revised instructions for Line 12g, and including reference to this note in the instructions for all dental and oral health lines (page 8).
- Revision to the instructions to line 12g to capture unduplicated preventive dental and oral health services, with corresponding HCPCS and CPT codes.
- Revision of instructions for line 14 to reflect lines 14a and 14b on the Form CMS-416. Instructions regarding the methodology used by states to calculate the total number of screening blood lead tests have become the instructions for line 14b.

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.