

SUPPORTING STATEMENT A
Generic Clearance for Medicaid and CHIP State Plan,
Waiver, and Program Submissions
CMS-10398, OMB 0938-1148

BACKGROUND

The Centers for Medicare & Medicaid work in partnership with States to implement Medicaid and the Children’s Health Insurance Program (CHIP). Together these programs provide health coverage to millions of Americans. Medicaid and CHIP are based in Federal statute, associated regulations and policy guidance, and the approved State plan documents that serve as a contract between CMS and States about how Medicaid and CHIP will be operated in that State. When modifications or enhancements to the program are prescribed by Congress through legislation, each State’s programs must be amended to comply. For example, in March 2010, Congress passed (and the President signed into law) the Affordable Care Act, which enacted comprehensive reform of the Medicaid program. CMS works collaboratively with States in the ongoing management of programs and policies, and CMS continues to develop implementing guidance and templates for States to use to elect new options available as a result of the Affordable Care Act or to comply with new statutory provisions. CMS also continues to work with States through other methods to further the goals of health reform, including program waivers and demonstrations, and other technical assistance initiatives.

In this July 2024 iteration we propose to reinstate our burden ceiling without change. Similarly, we also propose to reinstate 49 (see section 12 of this Supporting Statement) of the generic collection of information requests that had been active prior to the April 30, 2024, expiration. The associated generic collection of information requirements, burden estimates, and reporting instruments and instructions would be reinstated without change.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act (PRA), the Centers for Medicare & Medicaid Services (CMS) has submitted the following for emergency review to the Office of Management and Budget (OMB). We are requesting emergency review and approval of the information collection request related to the reinstatement of our burden ceiling and the 49 of the generic collection of information requests. In accordance with 5 CFR 1320.13(a)(2)(i), we believe that public harm will result if the standard, non-emergency clearance procedures are followed.

A. JUSTIFICATION

1. Need and Legal Basis

Section 1901 of the Social Security Act (42 U.S.C. 1936) requires that States must establish a State plan for medical assistance that is approved by the Secretary to carry out the purpose of Title XIX. CHIP has a corresponding statutory requirement for a State plan outlined in Section 2101 to carry out the purpose of Title XXI. The State plan functions as a contract between the State and Federal government describing how the State will implement its program in accordance with Federal laws and regulations in order to secure Federal funding.

The Act also provides the Secretary some discretion in waiving program requirements when it does not have a negative financial impact (cost effectiveness, cost neutrality, and budget neutrality) and promotes the objectives of the program. For instance, Section 1915(b) allows for the waiver of Medicaid provisions to allow for the implementation of managed care programs. Additionally, Section 1115 of the Act provides the Secretary flexibility to waive program requirements in Section 1902 and provide Federal funding for costs that are otherwise unmatchable. Written applications from States are required for these programs that outline what the State proposes to do and the financial impact it will have.

2. Information Users

State Medicaid and CHIP agencies are responsible for developing submissions to CMS, including State plan amendments and requests for waivers and program demonstrations. States use templates when they are available and submit the forms to CMS to review for consistency with statutory and regulatory requirements (or in the case of waivers and demonstrations whether the proposal is likely to promote the objectives of the Medicaid program). If the requirements are met, CMS approves the State's submission giving the State the authority to implement the flexibilities. For a State to receive Medicaid Title XIX funding, there must be an approved Title XIX State plan.

The development of streamlined submission forms enhances the collaboration and partnership between States and CMS by documenting CMS policy for States to use as they are developing program changes. Streamlined forms improve efficiency of administration by creating a common and user-friendly understanding of the information needed by CMS to quickly process requests for State plan amendments, waivers, and demonstration, as well as ongoing reporting.

3. Improved Information Technology

The forms for the States to use are available in electronic format. We expect every submittal to be forwarded to CMS using the electronic format. The forms create streamlined and structured data, decreasing the time required by States to develop their submissions to CMS.

4. Duplication

There is no duplication of similar information.

5. Small Business

There is no burden on small businesses.

6. Less Frequent Collection

Under Medicaid and CHIP State plans, there is no need to resubmit information once it is approved, unless the State elects to change its program. For waiver and demonstration programs, renewals of the programs are required on cycles that vary across statutory authority from 2 – 5

years. However, within the approved waiver cycle, States are not asked to resubmit information once it is approved unless the State elects to change its program.

7. Special Circumstances

The implementation of these templates is often time sensitive and must be coordinated with the release of guidance documents such as regulations and policy letters. Additionally, some of the templates that would be approved under this collection must be available to States to implement the changes timely.

8. Federal Register Notice/Prior Consultation

Emergency Reinstatement

Our 5-day notice published in the Federal Register on July 11, 2024 (89 FR 56878). Comments must be received by July 16, 2024.

The notice solicits comment and provides the public with general instructions for obtaining documents that are associated with this iteration's emergency reinstatement request. Details such as the collection's requirements and burden estimates can be found in each collection's supporting statement and associated materials.

Given the limitations of OMB's approval timeframe, we are also using the standard 60-/30-day PRA process to extend OMB's approval past the emergency reinstatement's anticipated expiration timeframe of five months. The 60-day notice for extending the expiration timeframe past five months published in the Federal Register on June 13, 2024 (89 FR 50333). Comments must be received by August 12, 2024.

Generic Information Collections (GenICs)

While the generic umbrella lays the groundwork for the content of the GenICs that fall under the aforementioned umbrella, the GenICs specify the collection of information requirements and burden that are associated with those requirements. It also sets forth the collection's reporting instruments (if any) and instructions.

For new and revised GenICs we will continue to publish 14-day Federal Register notices that will provide interested parties with an opportunity to review and comment on the generic information collection request. Instructions for obtaining the GenIC's documents and for submitting comments will be set out in each Federal Register notice.

However, new or revised GenICs that are affiliated with SMD or SHO letters may publish the 14-day Federal Register notice before, on, or after the issuance of the OMB's approval of the generic collection of information request. Requests that are not tied to such letters must publish the 14-day Federal Register notice a minimum of 14-days prior to OMB's approval.

For SMD and SHO letter-related GenICs, when the 14-day Federal Register notice's comment

period closes after OMB’s approval of the GenIC, CMS shall submit a subsequent GenIC that includes all public comments as well as CMS’ response to those comments. If the collection of information requirements and/or burden need to be revised, the subsequent GenIC must address the proposed changes.

9. Payment/Gift to Respondents

There is no payment or gift to respondents.

10. Confidentiality

Program submissions to CMS from States are public information, and there is no personal identifying information collected in the documents. No assurance of confidentiality is provided to respondents.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimates

As of the April 30, 2024, expiration, we had used 360,281 of the 450,000 hours for the GenICs that are set out in the most recent Notice of Action (see attached NOA, dated April 26, 2024). In this July 2024 iteration, we propose to reinstate all of the previously approved GenICs with the exception of CMS-10398 #72 (Expressions of Interest in the Infant Well-Child Visit Affinity Group) which does not meet the emergency processing criteria. Consequently, we are removing such burden (145 hours) from this request, resulting in a burden of 360,136 hours (360,281 hr – 145 hr).

Cost estimates are dependent on our requirements and the respondent’s BLS Occupation Title and wage. Since this information will not be known until upcoming GenICs are developed, our cost estimates will be set out when each GenIC package is submitted to OMB for approval.

Our previously approved burden ceiling of 450,000 hours is unchanged.

A list of the reinstated GenICs follows.

| | GenIC Title | CMS ID Number |
|----|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------|
| 1. | Generic Clearance for Medicaid and CHIP State Plan, Waiver, and Program Submissions | CMS-10398 (Reinstates the 450,000 hr burden ceiling) |
| 2. | CHIP Annual Report Template System (CARTs) | CMS-10398 #1 |
| 3. | Medicaid Managed Care Data Collection | CMS-10398 #2 |
| 4. | Medicaid Payment Suspensions | CMS-10398 #5 |
| 5. | Cycle IV (AI/AN Round II Outreach & Enrollment Grant Final Report Addendum) and Cycle V (Connecting Kids to Coverage Outreach and Enrollment Semi-Annual and Final | CMS-10398 #7 |

| | | |
|-----|---------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| 6. | Application for Section 1915(b)(4) Waiver - Fee For Service Selective Contracting Program | CMS-10398 #9 |
| 7. | Section 1115 Demonstration and Waiver Application | CMS-10398 #10 |
| 8. | MAGI- Based Eligibility Verification Plan | CMS-10398 #11 |
| 9. | Medicaid Accountability – Nursing Facility, Outpatient Hospital and Inpatient Hospital Upper Payment Limits | CMS-10398 #13 |
| 10. | Federally-Facilitated Marketplace (FFM) Integration Data Collection Tool | CMS-10398 #16 |
| 11. | CHIP State Plan Eligibility | CMS-10398 #17 |
| 12. | FMAP Claiming State Plan Amendment | CMS-10398 #21 |
| 13. | Medicaid Accountability – UPL ICF/IID, Clinic Services, Medicaid Qualified Practitioner Services and Other Inpatient & Outpatient Facility Providers | CMS-10398 #24 |
| 14. | MAGI Conversion Plan Part 2 | CMS-10398 #27 |
| 15. | MMIS APD Template NCCI Coding Initiative | CMS-10398 #28 |
| 16. | Medicaid Cost Sharing | CMS-10398 #29 |
| 17. | State Reporting Medicaid Payment Suspension | CMS-10398 #30 |
| 18. | Statewide HCBS Transition Plans | CMS-10398 #31 |
| 19. | Provider- Preventable Conditions under 42 CFR 438.6 and 447.26 and Title 2702 Non-Payment Preprint (Attachment 4.19) | CMS-10398 #32 |
| 20. | Opportunity for families of Disabled Children to Purchase Medicaid Coverage for Such Children (DRA 6062) | CMS-10398 #33 |
| 21. | Model Application Template and Instructions for State Child Health Plan Under Title XXI of the Social Security Act, State Children's Health Insurance Program | CMS-10398 #34 |
| 22. | Eligibility and Enrollment Performance Indicators | CMS-10398 #35 |
| 23. | Managed Care Rate Setting Guidance | CMS-10398 #37 |
| 24. | Section 223 Demonstration Programs to Improve Community Mental Health Services | CMS-10398 #43 |
| 25. | 1915(i) State Plan Home and Community Based Services | CMS-10398 #46 |
| 26. | Section 223 Demonstration Programs to Improve Community Mental Health Services | CMS-10398 #48 |
| 27. | Community First Choice State Plan | CMS-10398 #50 |
| 28. | Fast Track Federal Review Process for Section 1115 Medicaid and CHIP Demonstration Extensions | CMS-10398 #51 |
| 29. | Delivery System and Provider Payment Initiatives Under Medicaid Managed Care Products | CMS-10398 #52 |
| 30. | Section 1115 Substance Use Disorder (SUD) Demonstration: Guide for Developing Implementation Plan Protocols | CMS-10398 #53 |
| 31. | Electronic Visit Verification (EVV) Good Faith Effort Exemption Requests | CMS-10398 #54 |
| 32. | Limit on Federal Financial Participation for Durable Medical Equipment in Medicaid | CMS-10398 #55 |
| 33. | Section 1115 Demonstration: Budget Neutrality Workbook | CMS-10398 #56 |
| 34. | Section 1115 Substance Use Disorder (SUD) Demonstration: Monitoring Reports Documents and Templates | CMS-10398 #57 |
| 35. | Medicaid Section 1115 Eligibility and Coverage Demonstration Implementation Plan and Monitoring Reports Documents and Templates | CMS-10398 #58 |

| | | |
|-----|-----------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| 36. | Medicaid Section 1115 Severe Mental Illness and Children with Serious Emotional Disturbance Demonstrations | CMS-10398 #59 |
| 37. | Medicaid Disaster Relief for the COVID-19 National Emergency State Plan Amendment Template and Instructions | CMS-10398 #61 |
| 38. | Data Collection for Section 1003 of the SUPPORT Act | CMS-10398 #62 |
| 39. | 1932(a) State Plan Amendment Template | CMS-10398 #63 |
| 40. | Federal Meta-Analysis Support: Section 1115 Substance Use Disorder Demonstrations | CMS-10398 #64 |
| 41. | Medicaid and CHIP COVID 19 Public Health Emergency Unwinding Reports | CMS-10398 #66 |
| 42. | Section 1006(b) of the SUPPORT Act: Medicaid Assisted Treatment (MAT) | CMS-10398 #68 |
| 43. | Reporting Requirements for Additional Funding for Medicaid HCBS During the COVID-19 Emergency | CMS-10398 #69 |
| 44. | Reporting Requirements for State Planning Grants for Qualifying Community Based Mobile Crisis Intervention Services During the COVID-19 Emergency | CMS-10398 #71 |
| 45. | Supplemental Payment Reporting under the Consolidated Appropriations Act, 2021 | CMS-10398 #73 |
| 46. | Coverage of Routine Patient Cost for Items & Services in Qualifying Clinical Trials | CMS-10398 #74 |
| 47. | ARP 1135 State Plan Amendment | CMS-10398 #75 |
| 48. | Expressions of Interest in the Improving Maternal Health by Reducing Low-Risk Cesarean Delivery Affinity Group | CMS-10398 #76 |
| 49. | COVID-19 Risk Corridor Reconciliation Reporting Template | CMS-10398 #79 |
| 50. | Improving Quality of Care and Outcomes Data for Pregnant Medicaid Beneficiaries and Newborn Infants through Linkage and Evaluation of VR, BC, DC, and TAF | CMS-10398 #81 |

13. Capital Costs

There are no capital costs associated with this information collection.

14. Costs to Federal Government

There is no cost to the Federal government.

15. Program/Burden Changes

In this July 2024 iteration we propose to reinstate our burden ceiling (450,000 hours) without change. Similarly, we also propose to reinstate 49 (see section 12 of this Supporting Statement) of the generic collection of information requests that had been active prior to the April 30, 2024, expiration. The associated generic collection of information requirements, burden estimates, and reporting instruments and instructions would be reinstated without change via our emergency processing request which is attached to this collection of information request. The 49 GenICs account for 360,136 hours of burden.

16. Publication and Tabulation Dates

There are no plans to publish the information for statistical use.

17. Expiration Date

CMS seeks to continue our exemption from displaying the expiration date on our generic instruments. The exemption would reduce work on replacing the expiration date every 3 years with the renewal of the Generic Umbrella package. We currently have more than 50 approved GenICs. Most of these may have multiple templates associated with them.

Moreover, in certain cases displaying the expiration date causes unnecessary burden and confusion, especially in instances where the expiration date is near the approval date. In one real example, a GenIC was approved on October 29, 2014, while the expiration date was a few days later, on October 31, 2014. It would be confusing to respondents to forward templates on Oct 29th with an expiration date of Oct 31st of the same year. It would also be burdensome to produce and revise the expiration dates in such a short period of time.

18. Certification Statement

There are no exceptions.

B. COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS

The use of statistical methods does not apply for purposes of this collection.