SUPPORTING STATEMENT
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.

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 2101to 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 submissions 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**

The 60-day Federal Register notice published on July 11, 2014 (79 FR 40105). No comments were received.

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 Estimate**

The newly proposed annual burden estimate (see Total, below) considers the currently approved collections (see the October 29, 2014, Notice of Action) that we seek to continue along with the collections projected (see attached) over the upcoming 3-year approval period.

Currently Approved GenICs

Currently, OMB has approved 67,864 hours of burden for the GenICs that are set out in OMB's October 29, 2014, Notice of Action. We seek to carry over all of the approved GenICs along with the 67,864 burden hours into the upcoming 3-year approval period.

Projected

For the upcoming 3-year (2014 – 2017/2018) approval period, we estimate the time involved for completing a template is 20 hours for shorter/less complex templates and 40 hours for templates that are more comprehensive/complex. Under the above scenario, each State could spend 1,540 hours to produce 60 responses including 17 complex templates requiring 40 hours and 43 shorter templates requiring 20 hours (1,540 hours = [17 templates * 40 hours] + [43 templates * 20 hours]). If all 56 respondents spent 1,540 hours over the 3-year period, the total 3-year burden would be 86,240 hours (1,540 hours * 56 States).

The 86,240 hr burden estimate is the same estimate proposed under this collection's initial 2011 umbrella package. A list of the projected GenICs has been added to this

package.

Total

The requested burden for this 3-year (2014 – 2017/2018) renewal equates to 67,864 hours from (2011 – 2014) plus 86,240 projected hours for a total of 154,104 hr.

To complete and return the templates, we estimate an average cost of $41 per hour, which is equivalent to the 2014 base salary of a GS-14 Step 1 Federal employee and a comparable position to State employees likely responsible for completing and returning the templates. Under the above scenario, the total cost to respondents is $6,318,264 ($41 per hour * 154,104 hours) or $2,106,088 (annually).

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**

We are adding 67,864 hours that have been approved as of October 29, 2014 to the 86,240 hours estimated in 2011.

16. **Publication and Tabulation Dates**

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

17. **Expiration Date**

CMS is asking for an exception 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 36 approved Gen-ICs. 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 recent example, our last GenIC bundle was approved on October 29, 2014, while the expiration date is a few days later, on October 31, 2014. It would be confusing to respondents to forward templates on Oct 29 with an expiration date of Oct 31 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.