Generic Supporting Statement
Clearance for Medicaid and CHIP State Plan, Waiver, and Program Submissions
(CMS-10398, OMB 0938-1148)

Generic Information Collection # 74 (Revised)
Coverage of Routine Patient Cost for Items & Services in Qualifying Clinical Trials

Center for Medicaid and CHIP Services (CMCS)
Centers for Medicare & Medicaid Services (CMS)

A. Background

The Centers for Medicare & Medicaid Services (CMS) 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. 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.

Section 210 of the Consolidated Appropriations Act of 2021 amended section 1905(a) of the Social Security Act (the Act) to add a new mandatory benefit at 1905(a)(30). The new benefit mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials. Routine costs for services provided in connection with participation in a qualifying clinical trial generally include any item or service provided to the individual under the qualifying clinical trial, including any item or service provided to prevent, diagnose, monitor, or treat complications resulting from participation in the qualified clinical trial, to the extent that the provision of such items or services to the individual would otherwise be covered under the state plan or waiver.

We propose that States and territories review the preprints completed for a Medicaid beneficiary to receive coverage of routine patient services and costs furnished in connection with participation in qualifying clinical trials. Completion of the preprint pages verifies in the Medicaid state plan that the mandatory clinical trials benefit is being furnished by a state. Completion of the preprint verifies that the requirements of a federally sponsored clinical trial is appropriate for the Medicaid beneficiary.

B. Description of Information Collection

Section 210 of the Consolidated Appropriations Act of 2021 amended section 1905(a) of the Social Security Act (the Act) to add a new mandatory benefit at 1905(a)(30) that mandates coverage of routine patient services and costs furnished in connection with participation by Medicaid beneficiaries in qualifying clinical trials.

Section 210 allows states to request an exception for compliance with the requirements of this provision based on the need for state legislation to authorize a state plan amendment when that legislation cannot be secured by January 1, 2022, and the only reason the state cannot come into compliance by January 1, 2022, is due to lack of state legislation that is needed to meet the requirement. States that require legislative changes to implement coverage of routine patient costs as specified in section 1905(a)(30) of the Act will not be regarded as failing to comply with the requirements newly added by section 210, solely on the basis of their failure to meet these requirements before the first day of the first calendar quarter beginning after the close of the first

regular session of the state legislature that begins after December 27, 2020, the date of enactment of the Consolidated Appropriations Act, 2021.

The state submission to add this coverage in the state plan consists of SPA preprints for item 1905(a)(30). The SPA preprint forms indicate if the clinical trial benefit is provided that the state attest to coverage for routine patient cost associated with a qualifying clinical trial as defined in Section 210 of the Consolidated Appropriations Act. Additionally, the Secretary is directed by the statute to develop a form for state use that ensures appropriate implementation for qualifying clinical trials. Per Section 210 of the Consolidated Appropriations Act subsection (gg)(3), coverage determination for routine patient cost for qualifying clinical trials is contingent on the completion of the attestation form developed by the Secretary. Failure to utilize the attestation developed by the Secretary shall be regarded as failure to comply with the requirements set forth in Section 210 of the Consolidated Appropriations Act.

Since Section 210 of the Consolidated Appropriations Act makes Qualifying Clinical Trial a mandatory state plan benefit under section 1905(a)(30) of the Act for the period beginning January 1, 2022, states will react favorably to the availability of the preprint pages that outline what states need to provide in their SPA submissions. The preprint pages and attestation should facilitate prompt review and approval of states' SPAs.

While states/territories/D.C. (hereinafter, "states") are not required to submit both preprint pages, they are required to submit the categorically needy population preprint page to cover services for the mandatory categorically needy Medicaid population. States have the discretion to cover the optional medically needy population by submitting Preprint Attachment 3.1-B. We anticipate that most if not all states will submit the categorically needy population preprint.

In this March 2022 iteration, preprints for Attachment 3.1-A and preprint Attachment 3.1-B are unchanged. We are, however, revising the qualifying clinical trial attestation form (see the attached Crosswalk for details). We are not making any changes to our burden estimates.

C. Deviations from Generic Request

No deviations are requested.

D. Burden Hour Deduction

Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2020 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 overhead (calculated at 100 percent of salary), and our adjusted hourly wage.

The wage is a comparable position to State employees likely responsible for reviewing the attestation completed by the principal investigator and healthcare provider on behalf of the

Medicaid beneficiary.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead (at 100%) ($/hr)	Adjusted Hourly Wage ($/hr)
Business Operations Specialist	13-1000	37.66	37.66	75.32

As indicated, 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.

Burden Estimates

In this March 2022 iteration, preprints for Attachment 3.1-A and preprint Attachment 3.1-B are unchanged. We are, however, revising the qualifying clinical trial attestation form (see the attached Crosswalk for details). We are not making any changes to our burden estimates.

There will be a total of 56 States and territories as possible respondents for this request, all of whom made the required entry when the election of Medicaid in its State was made.

Preprint Attachment 3.1-A attest to routine patient cost as defined in section 1905(gg)(1), the definition of a qualifying clinical trial and coverage determination requirements. Preprint Attachment 3.1B also attest to routine patient cost as defined in section 1905(gg)(1), the definition of a qualifying clinical trial and coverage determination requirements. The qualifying clinical attestation form is formally owned by HHS and will be for state's use and posted on an HHS-owned website.

For Preprint Attachment 3.1-A we estimate it would take 1 hour at $75.32/hr for a business operations specialist to review and complete the preprint pages. Considering all 56 respondents, we estimate a one-time burden of 56 hours (56 responses x 1 hr/response and a cost of $4,217 (56 hr x $75.32/hr). Although we estimate a one-time requirement and burden, states have the option to submit updates as with any state plan. We are not setting out burden for such subsequent updates since we have no reliable way of knowing when or how many times a state will update their plan.

For the medically needy population (Preprint Attachment 3.1-B) we anticipate minimal state burden (30 min) since states can copy and paste their responses from their Preprint Attachment 3.1-A submission into their Attachment 3.1-B submission. In that regard we estimate it would take 0.5 hours at $75.32/hr for a business operations specialist to copy/paste, review, and submit Preprint Attachment 3.1-B to CMS.

While we estimate 56 respondents for Preprint Attachment 3.1-A, we have no means of reliably estimating the number of respondents that will be submitting Preprint Attachment 3.1-B. To help ensure that we are in compliance with the PRA, we are proposing an estimate of 10 respondents which we believe reasonably overestimates the actual figure.

When accounting for 10 respondents, we estimate a one-time burden of 5 hours (10 responses x 0.5 hr/response at a cost of $377 (5 hr x $75.32/hr). Although we estimate a one-time requirement and burden, states have the option to submit updates as with any state plan. We are not setting out burden for such subsequent updates since we have no reliable way of knowing when or how many times a state will update their plan.

Burden Summary

Document	No. Respondents	Total Responses	Time per Response (hours)	Total Time (hours)	Labor Cost ($/hr)	Total Labor Cost ($)
Preprint to Attachment 3.1-A	56	56	1.0	56	75.32	4,217
Preprint to Attachment 3.1-B	10	10	0.5	5	75.32	377
TOTAL	56	66	Varies	61	75.32	4,594

Collection of Information Instruments and Instruction/Guidance Documents

- Qualifying Clinical Trial Attestation Form (Revised)

This is not a CMS form. Instead, it is owned by HHS.

- Qualifying Clinical Trial Draft Preprint Att. 3.1-A (No changes)

This is a CMS-owned preprint.

- Qualifying Clinical Trial Draft Preprint Att. 3.1.-B (No changes)

This is a CMS-owned preprint.

E. Timeline

Our 14-day notice published in the Federal Register on March 29, 2022 (87 FR 18022). Comments s must be received by April 12, 2022.

We are requesting approval of this collection of information request under this generic collection of information request until we can appropriately obtain approval via the standard PRA process under its proper place (CMS-179, OMB 0938-0193).