DEPARTM

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10398 #74 and #76]

Medicaid and Children's Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance related to the "generic" clearance process. Generally, this is an expedited process by which agencies may obtain OMB's approval of collection of information requests that are "usually voluntary, low-burden, and uncontroversial collections," do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that would fall under its umbrella. On October 23, 2011, OMB approved our initial request to use the generic clearance process under control number 0938–1148 (CMS-10398). It was last approved on April 26, 2021, via the standard PRA process which included the publication of 60- and 30-day **Federal Register** notices. The scope of the April 2021 umbrella accounts for Medicaid and CHIP State plan amendments, waivers, demonstrations, and reporting. This **Federal Register** notice seeks public comment on one or more of our collection of information requests that we believe are generic and fall within the scope of the umbrella. Interested persons are invited to submit comments regarding our burden estimates or any other aspect of this collection of information, including: the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by **[INSERT DATE 14 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: When commenting, please reference the applicable form number (see below) and the OMB control number (0938-1148). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to http://www.regulations.gov. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs

Division of Regulations Development

Attention: CMS-10398 (#___)/OMB control number: 0938-1148

Room C4-26-05

7500 Security Boulevard

Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may access CMS' Web Site at https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Following is a summary of the use and burden associated with the subject information collection(s). More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

Generic Information Collections

1. *Title of Information Collection:* Coverage of Routine Patient Cost for Items &

Services in Qualifying Clinical Trials; *Type of Information Collection Request:* Revised; *Use:* 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. *Form Number:* CMS-10398 (#74) (OMB control number: 0938–1148); *Frequency:* Once and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 66; *Total Annual Hours: 61*. (For policy questions regarding this collection contact Myla Adams at 410-786-8107.)

2. *Title of Information Collection:* Expressions of interest in the Improving Maternal Health by Reducing Low-Risk Cesarean Delivery Affinity Group; *Type of Information Collection Request:* New collection of information request; *Use:* State Medicaid and CHIP agencies are given the opportunity to submit the attached Expression of Interest Form regarding participation in the Improving Maternal Health by Reducing Low-Risk Cesarean Delivery Affinity Group. Information requested will be used to see if each state meets the criteria for participation in the Affinity Group. Criteria for affinity group participation include:

- Well-articulated goals for improving low-risk cesarean delivery rates,
- An understanding of the state's challenges and opportunities related to low-risk cesarean deliveries,
- Access to low-risk cesarean delivery data, including the ability to report the Core Set measure Low-Risk Cesarean Delivery (LRCD-CH),
- Identification of a well-rounded state team willing to work about 10 to 15 hours each month (depending on role, project, and team size) on the state quality improvement (QI) project, and
- Commitment to action, with support from Medicaid and/or CHIP leadership.

Once participating in the Affinity Group, a states will meet monthly virtually for workshops and one-on-one state coaching calls, learning from QI advisors, subject matter experts, and peers in order to test, implement, and assess their data-driven QI change idea.

Form Number: CMS-10398 (#76) (OMB control number: 0938–1148); *Frequency:* Once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 20; *Total Annual Responses:* 20; *Total Annual Hours: 140*. (For policy questions regarding this collection contact Kristen Zycherman at 410-786-6974.)

Dated: March 24, 2022.

William N. Parham, III,

Director,

Paperwork Reduction Staff,

Office of Strategic Operations and Regulatory Affairs.

4120-01-U-P

[FR Doc. 2022-06593 Filed: 3/28/2022 8:45 am; Publication Date: 3/29/2022]