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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10280, CMS-1557 and CMS-3070G-I]

Agency Information Collection Activities: Proposed Collection; Comment Request

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

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send 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 October 19, 2021.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. 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: Document Identifier/OMB Control Number: _____, 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 make your request using one of following:

1. Access CMS' website address at website address 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:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10280 Home Health Change of Care Notice

CMS-1557 Survey Report Form for Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations

CMS-3070G-I ICF/IID Survey Report Form and Supporting Regulations

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of the Information Collection:* Home Health Change of Care Notice; *Use:* The

purpose of the Home Health Change of Care Notice (HHCCN) is to notify original Medicare beneficiaries receiving home health care benefits of plan of care changes. Home health agencies (HHAs) are required to provide written notice to Original Medicare beneficiaries under various circumstances involving the reduction or termination of items and/or services consistent with Home Health Agencies Conditions of Participation (COPs).

The home health COP requirements are set forth in § 1891[42 U.S.C. 1395bbb] of the Social Security Act (the Act). The implementing regulations under 42 CFR 484.10(c) specify that Medicare patients receiving HHA services have rights. The patient has the right to be informed, in advance about the care to be furnished, and of any changes in the care to be furnished. The HHA must advise the patient in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished. The HHA must advise the patient in advance of any change in the plan of care before the change is made."

Notification is required for covered and non-covered services listed in the plan of care (POC). The beneficiary will use the information provided to decide whether or not to pursue alternative options to continue receiving the care noted on the HHCCN. *Form Number:* CMS-10280 (OMB control number: 0938-1196); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 11,157; *Total Annual Responses:* 12,385,108; *Total Annual Hours:* 824,848. (For policy questions regarding this collection contact Jennifer McCormick at 410-786-2852.)

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Survey Report Form for Clinical Laboratory Improvement Amendments (CLIA) and Supporting Regulations; *Use:* The form is used to report surveyor findings during a CLIA survey. For each type of survey conducted (*i.e.*, initial certification, recertification, validation, complaint, addition/deletion of specialty/subspecialty, transfusion fatality investigation, or revisit inspections) the Survey Report Form incorporates the requirements specified in the CLIA regulations. *Form Number:* CMS-1557 (OMB control number: 0938-0544); *Frequency:* Biennially; *Affected Public:* Private sector (Business or other for-profit and Not-for-profit institutions, State, Local or Tribal Governments and Federal Government); *Number of Respondents:* 15,975; *Total*

Annual Responses: 7,988; *Total Annual Hours:* 3,994. (For policy questions regarding this collection contact Kathleen Todd at 410-786-3385).

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* ICF/IID Survey Report Form and Supporting Regulations; *Use:* The information collected with forms 3070G, CMS-3070H and CMS-3070I is used by the surveyors from the State Survey Agencies (SAs) to determine the level of compliance with the ICF/IID Conditions of Participation (CoPs) necessary to participate in the Medicare/Medicaid program and to report any non-compliance with the ICF/IID CoPs to the Federal government. These forms summarize the survey team characteristics, facility characteristics, client population, and the special needs of clients. These forms are used in conjunction with the CMS regulation text and additional surveyor aids such as the CMS interpretive guidelines and probes. The CMS-3070G-I forms serves as coding worksheets, designed to facilitate data entry and retrieval into the Automated Survey Processing Environment Suite (ASPEN) in the State and at the CMS regional offices. *Form Number:* CMS-3070G-I (OMB control number: 0938-0062); *Frequency:* Reporting—Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 5,758; *Total Annual Responses:* 5,758; *Total Annual Hours:* 17,274. (For policy questions regarding this collection contact Caroline Gallaher at 410-786-8705.)

Dated: August 17, 2021.

William N. Parham, III

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Updates to Uniform Standard for Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement, OMB No. 0906-XXXX-NEW

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, this notice announces that the Information Collection Request (ICR) is being forwarded by HRSA to the Office of Management and Budget (OMB) for review and approval. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this Notice has closed.

DATES: Comments on this ICR should be received no later than September 20, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at paperwork@hrsa.gov or call (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Updates to Uniform Standard for Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement, OMB No. 0906-XXXX-NEW.

Abstract: In accordance with sections 2604(c), 2612(b), and 2651(c) of the Public Health Service Act, Ryan White HIV/AIDS Program (RWHAP) recipients

are required to spend not less than 75 percent of grant funds on core medical services for individuals with HIV identified and eligible under the statute, after reserving statutory permissible amounts for administrative and clinical quality management costs. The RWHAP statute also grants the Secretary authority to waive this requirement for RWHAP Parts A, B, or C recipients if a number of requirements are met and a waiver request is submitted to HRSA for approval. RWHAP Part A, B, and C core medical services waiver requests—if approved—are effective for a 1-year budget period, and apply to funds awarded under the Minority AIDS Initiative.

Currently, for a core medical services waiver request to be approved, (1) core medical services must be available and accessible to all individuals identified and eligible for the RWHAP in the recipient's service area within 30 days, without regard to payer source; (2) there cannot be any AIDS Drug Assistance Program waiting lists in the recipient's service area; and (3) a public process to obtain input on the waiver request from impacted communities, including clients and RWHAP-funded core medical services providers, on the availability of core medical services and the decision to request the waiver must have occurred. The public process may be a part of the same one used to seek input on community needs as part of the annual priority setting and resource allocation, comprehensive planning, statewide coordinated statement of need, public planning, and/or needs assessment processes.

HRSA is proposing to simplify the waiver request process for RWHAP Parts A, B, and C recipients by revising Policy Number 13-07: Uniform Standard for Waiver of Core Medical Services Requirement for Grantees Under Part, A, B, and C. The proposed changes would reduce the administrative burden for recipients by lessening the documentation they must submit to HRSA when requesting a waiver. Under the proposed policy, recipients would be required to submit a one-page "HRSA RWHAP Core Medical Services Waiver Request Attestation Form" to HRSA in lieu of the multiple documents, including but not limited to a narrative of up to 10 pages currently required to submit a waiver request. Waiver request submission deadlines would also be revised. When finalized, the policy would replace HAB Policy Number 13-07 effective October 1, 2021, and would be named "Waiver of the Ryan White HIV/AIDS Program Core Medical Services Expenditure Requirement."