

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 <https://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 (#64)/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, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>

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 Collection

1. *Title of Information Collection:* CHIP State Plan Eligibility; *Type of Information Collection Request:* Revision of a currently approved collection; *Use:* This iteration proposes to revise CHIP State Plan template CS27 to make continuous eligibility mandatory for separate CHIPs. Additional revisions would: (1) revise language in the template to reflect that CE for children is mandatory, (2) remove age selection for optional CE and the drop-down menu for the number of months for the CE eligibility period, (3) add assurances for a state that elects to provide coverage for the from-conception-to-end-of-pregnancy (FCEP) population (otherwise known as the “unborn”), and (4) change the authority of continuous eligibility from section 2105(a)(4)(A) to 2107(e)(1)(K). *Form Number:* CMS–10398 (#17) (OMB control number: 0938–1148); *Frequency:*

Once and on occasion; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 2,800. For policy questions regarding this collection contact: Joyce Jordan at (410) 786–3413.

Dated: October 24, 2023.

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

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10393, CMS–10861 and CMS–10146]

Agency Information Collection Activities: Submission for OMB Review; 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 (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 a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate 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 on the collection(s) of information must be received by the OMB desk officer by November 27, 2023.

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 30-day Review—Open for Public Comments” or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

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

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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 (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-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 that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a previously approved collection; *Title of Information Collection:* Beneficiary and Family Centered Data Collection; *Use:* To ensure the QIOs are effectively meeting their goals, CMS collects information about beneficiary experience receiving support from the QIOs. This is a request to revise the information collection. The revisions to this information collection include the deletion of the previously approved Direct Feedback Survey and associated instructions and the General Feedback Web Survey and associated instructions. The information collection uses both qualitative and quantitative strategies to ensure CMS and the QIOs understand beneficiary experiences through all interactions with the QIO including initial contact, interim interactions, and case closure. Information collection

instruments are tailored to reflect the steps in each type of process, as well as the average time it takes to complete each process. The information collection will:

- Allow beneficiaries to directly provide feedback about the services they receive under the QIO program;
- Provide quality improvement data for QIOs to improve the quality of service delivered to Medicare beneficiaries; and
- Provide evaluation metrics for CMS to use in assessing performance of QIO contractors.

To achieve the above goals, information collection will include: Experience Survey: The Experience Survey will be administered via telephone and mail to beneficiaries/representatives after the Quality of Care (Medical Record Review) complaint/Immediate Advocacy/appeal case has been closed. The goal of the Experience Survey is to assess beneficiary overall and specific experiences with the BFCC QIOs. *Form Number:* CMS–10393 (OMB control number: 0938–1177); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 9,000; *Number of Responses:* 9,000; *Total Annual Hours:* 2,250. (For policy questions regarding this collection, contact Renee Graves-Dorsey at 410–786–7142.)

2. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Medicare Health Outcomes Survey Field Test; *Use:* CMS is required to collect and report quality and performance of Medicare health plans under provisions of the Social Security Act. Specifically, Section 1851(d) of the Act (Providing Information to Promote Informed Choice) requires CMS to collect data for MA plan comparison, including data on enrollee satisfaction and health outcomes, and report this information and other plan quality and performance indicators to Medicare beneficiaries prior to the annual enrollment period. The HOS meets the requirement for collecting and publicly reporting quality and other performance indicators, as HOS survey measures are incorporated into the Medicare Part C Star Ratings that are published each fall for consumers on the Medicare website.

This request is to conduct a field test with the goal of evaluating the measurement properties of new survey items, and the effects of new content and a web-based mode on response patterns and measure scores as compared to existing HOS survey items and protocols. Within each of the proposed field test protocol arms, there

will be two versions of the questionnaire (see Attachments A and B) that will be identical except for slight differences in selected items where empirical data are needed to ascertain which of the two versions produces the best results (see Attachment C). The two versions of the questionnaire will test alternatives for selected new survey content that will potentially enhance and refine existing measures, allow CMS to develop new and methodologically simpler cross-sectional and longitudinal measures, expand on CMS's measurement of physical functioning and mental health, and add to CMS's efforts to measure and address health equity.

The data collected in this field test will be used by CMS to inform decisions on possible changes to HOS content and survey administration procedures. The items in the questionnaire reflect current health priorities and would provide CMS with data to study new longitudinal PROMs, cross-sectional measures, and enhancements to existing HOS measures for MA plans to use as a focus of their quality improvement efforts. Potential new measures derived from new HOS items will go through the Measures Under Consideration (MUC) process and rule-making before they are added to Star Ratings. *Form Number:* CMS–10861 (OMB Control Number: 0938–New); *Frequency:* Once; *Affected Public:* Individuals and Households; *Number of Respondents:* 136; *Number of Responses:* 6,800; *Total Annual Hours:* 2,267. (For policy questions regarding this collection contact Kimberly DeMichele at 410–786–4286.)

3. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Notice of Denial of Medicare Prescription Drug Coverage; *Use:* Part D plan sponsors are required to issue the Notice of Denial of Medicare Prescription Drug Coverage notice when a request for a prescription drug or payment is denied, in whole or in part. The written notice must include a statement, in understandable language, the reasons for the denial and a description of the appeals process.

The purpose of this notice is to provide information to enrollees when prescription drug coverage has been denied, in whole or in part, by their Part D plans. The notice must be readable, understandable, and state the specific reasons for the denial. The notice must also remind enrollees about their rights and protections related to requests for prescription drug coverage and include an explanation of both the standard and expedited redetermination processes and the rest of the appeal process. *Form*

Number: CMS–10146 (OMB control number 0938–0976); *Frequency:* Daily; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 743; *Total Annual Responses:* 2,631,728; *Total Annual Hours:* 657,932. (For policy questions regarding this collection contact: Coretta Edmondson at 410–786–0512.)

Dated: October 24, 2023.

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

Registration Requirements in the 340B Drug Pricing Program

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

ACTION: Notice.

SUMMARY: HRSA is issuing this Notice to inform and remind stakeholders of the registration requirements for off-site, outpatient hospital facilities to participate in the 340B Drug Pricing Program (340B Program). This Notice applies to all hospital types that participate in the 340B Program.

FOR FURTHER INFORMATION CONTACT:

Questions should be directed to Michelle Herzog, Deputy Director, Office of Pharmacy Affairs, Office of Special Health Initiatives, HRSA, 5600 Fishers Lane, Room 8W12, Rockville, MD 20857, or by telephone at 301–594–4353.

SUPPLEMENTARY INFORMATION: Section 340B(a)(4) of the Public Health Service Act (PHS) Act (42 U.S.C. 256b) lists the various types of organizations (“covered entities”) eligible to participate in and benefit from the 340B Program. Section 340B(d)(2)(B)(i and ii) of the PHS Act requires the development of a system by which covered entities can attest to, and HRSA can verify, continued accuracy of information in the 340B database and compliance with 340B Program requirements. Section 340B(a)(9) of the PHS Act requires the Secretary to notify participating manufacturers of the identity of those organizations that meet the definition of covered entity under 340B(a)(4). Section 340B(d)(2)(B)(iv) of the PHS Act includes requirements for the establishment of a standardized