

amount of available operating reserves would be phased in over the first 3 years of BsUFA III (33 weeks in fiscal year 2023, 27 weeks in fiscal year 2024, and 21 weeks in fiscal year 2025). BsUFA III also proposes to add a strategic hiring and retention adjustment to ensure FDA has the funding necessary to provide for the costs of retaining and hiring highly qualified scientific and technical staff for the process for the review of biosimilar biological product applications under BsUFA. This strategic hiring and retention adjustment would add \$150,000 to the base revenue amount each fiscal year during BsUFA III.

#### *K. Impact of BsUFA III Enhancements on User Fee Revenue*

To implement the proposed enhancements for BsUFA III, funding for a cumulative total of 15 FTE staff is proposed to be phased in over the course of BsUFA III. The new funding would be phased in as follows:

- \$4,428,886 for fiscal year 2023
- \$320,569 for fiscal year 2024

#### **IV. Public Meeting Information**

##### *A. Purpose and Scope of the Meeting*

The virtual public meeting will include a presentation by FDA and an industry panel. For members of the public who would like to make verbal comments on the proposed enhancements, there will be a public comment period at the end of the meeting (see instructions below). We will also provide an opportunity for individuals to submit written comments to the docket before and after the meeting.

##### *B. Participating in the Public Meeting*

*Registration:* Registration is optional and not required to attend this virtual public meeting. However, registering will allow FDA to provide you with email updates if any meeting details change. If you wish to register, you can do so at <https://bsufaiii-finalpublicmeeting.eventbrite.com>.

*Opportunity for Verbal Public Comment:* Those who register online will receive a confirmation email that includes a link to a request form to make a verbal public comment at the meeting. If you wish to speak during the public comment session, follow the instructions in the notification and identify which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and request time jointly. All

requests to make a public comment during the meeting must be received by October 19, 2021, 11:59 p.m. Eastern Time. Depending on the number of requests, we will determine the amount of time allotted to each commenter, the approximate time each comment is to begin, and will select and notify participants by October 26, 2021. No commercial or promotional material will be permitted to be presented at the public meeting.

*Streaming Webcast of the Public Meeting:* The Zoom Webinar ID for this public meeting is 161 047 8285. The webcast link for this public meeting can be found here: <https://fda.zoomgov.com/j/1610478285?pwd=MG1N2hrYzBVTGhsd1F2eVhwZG1DQT09>. The link above should allow you to enter the webinar directly. If Zoom asks for a passcode, please use the case-sensitive passcode below.

Case-Sensitive Passcode for Zoom Webinar: S9d&fx

*Transcripts:* Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see **ADDRESSES**). Transcripts of the meeting will be available on the FDA web page <https://www.fda.gov/industry/biosimilar-user-fee-amendments/bsufaiii-fiscal-years-2023-2027> approximately 30 days after the meeting.

Dated: September 16, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–20432 Filed 9–21–21; 8:45 am]

**BILLING CODE 4164–01–P**

#### **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

##### **Health Resources and Services Administration**

##### **Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Information Collection Request Title: Bureau of Primary Health Care—Program Management Resource Compendium, 0906–XXXX, New**

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

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of

Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. 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 October 22, 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](http://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 Samantha Miller, the HRSA Information Collection Clearance Officer, at [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call (301) 443–9094.

##### **SUPPLEMENTARY INFORMATION:**

*Information Collection Request Title:* Bureau of Primary Health Care—Program Management Resource Compendium, OMB No. 0906–XXXX, New.

*Abstract:* The Program Management Resource Compendium project will encompass a historical analysis of HRSA's Bureau of Primary Health Care (BPHC), as well as a historical analysis of the Health Center Program, performed by federal contractors. Dating from the founding of the initial community health centers in the mid-1960s up to the present time, the analysis will consider the evolution and critical milestones of BPHC and the Health Center Program based on documentary research and interviews with individuals with historical knowledge of the Health Center Program and the health center movement.

A 60-day notice published in the **Federal Register** (86 FR 30962 (June 10, 2021)). There were no public comments.

*Need and Proposed Use of the Information:* The information gathered through interviews will be combined with information drawn from documentary research to inform the historical analysis. The results of the analysis will be presented in communication products for an internal audience, as well as products for an external audience. The goals of the project are to increase awareness of the Health Center Program management

within the government and among the general public, as well as to inform BPHC's future development by analyzing and drawing lessons from its earlier administration of the Health Center Program.

*Likely Respondents:* Interviews are expected with current and former BPHC employees, as well as representatives of the National Association of Community Health Centers, other national organizations, state and regional Primary Care Associations, and HRSA-funded health centers. A list of possible interviewees has been compiled with input by current and former HRSA leadership and staff. A total of 35–50 interviews are expected.

Interviews will be conducted virtually by a trained moderator and note taker, using a structured in-depth interview guide. Each interview is expected to last approximately one hour. It is also anticipated that interviewees may spend up to 15 minutes preparing for their interviews, for example by reviewing historical files. Signed consent forms regarding participation and the use of recording devices during the interview will be obtained from each participant prior to their participation in the interviews. The in-depth interview guide is available upon request.

*Burden Statement:* Burden in this context means the time expended by persons to generate, maintain, retain,

disclose or provide the information requested. This includes the time needed to: Review instructions; develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; train personnel and to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Historical interview .....	50	1	50	1.25	62.5
Total .....	50	.....	50	.....	62.5

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**Maria G. Button,**

*Director, Executive Secretariat.*

[FR Doc. 2021-20524 Filed 9-21-21; 8:45 am]

BILLING CODE 4165-15-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Announcement of Opportunity To Become an Office on Women's Health (OWH) Self-Measured Blood Pressure (SMBP) Program Partner; Notice by the U.S. Department of Health and Human Services**

**AGENCY:** Office on Women's Health, Office of the Assistant Secretary for Health, Office of the Secretary, U.S. Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** The U.S. Department of Health and Human Services' (HHS) Office on Women's Health (OWH) invites public and private sector

organizations to apply to become an OWH Self-Measured Blood Pressure (SMBP) Partner. This ongoing partnership opportunity engages support from partner organizations to promote SMBP and encourages women to maintain healthy blood pressure levels at every age and stage of their lives. Through the OWH SMBP Partnership Program ("SMBP Program"), OWH seeks to increase knowledge and access to SMBP information and resources, as well as encourage organizations to address heart health disparities, prevent hypertension, promote self-measured blood pressure, and improve health equity on a community level. The SMBP Program will launch during the 2nd annual observance of National Women's Blood Pressure Awareness Week (NWBPAW), October 17–23, 2021. The SMBP Program will build on momentum generated by NWBPAW, which emphasizes the importance of blood pressure control and empowers women to improve their heart health through simple, everyday actions.

*Eligibility:* Any organization may apply to be a SMBP Program partner. The selected SMBP Program partners may be recognized for their commitment and their work toward achieving the goals of the program.

SMBP Program partners can be public and private organizations such as those at the state, local, county, and tribal levels, non-governmental organizations, non-profit organizations, businesses,

academic organizations, organizations that impact health outcomes, philanthropic organizations, and tribal organizations that identify themselves as being aligned with or promoting the goals of the program.

Organizations that work in areas such as fitness, nutrition, housing, health education, and those working to improve health outcomes in women may apply. Social organizations that work with, or have access to large populations of women, organizations promoting women in sports, and child-care facilities may apply. Organizations that have a defibrillator accessible onsite and are willing to make a self-measured blood pressure cuff accessible onsite, and organizations that identify themselves as being aligned with, or promoting blood pressure control are encouraged to apply.

All organizations may apply.

Individuals are not eligible to become an SMBP Program partner.

Applicants shall submit a letter of interest and identify how they support or plan to support the SMBP Program goals. Applicants will be considered according to the organization's commitment to support those goals.

SMBP Program partners may receive recognition from OWH on *womenshealth.gov*, *girlshealth.gov*, or OWH Social Media platforms. They may also receive SMBP information and resources for dissemination.

The following activities may be considered as an organization's