modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: During the morning session, the committee will discuss new drug application 212578 for padeliporfin dipotassium powder for solution for injection, submitted by STEBA Biotech, S.A. The proposed indication (use) for this product is for the treatment of patients with localized prostate cancer, meeting the following criteria: Stage T1–T2a and prostate specific antigen less than or equal to 10 ng/mL and Gleason Grade Group 1 based on transrectal ultrasound guided biopsy or unilateral Gleason Grade Group 2 based on multiparametric magnetic resonance imaging-targeted biopsy with less than 50 percent of cores positive.

During the afternoon session, the committee will discuss supplemental biologics license application 125477/S–034, for CYRAMZA (ramucirumab) injection for intravenous use, submitted by Eli Lilly and Company. The proposed indication (use) for this product is in combination with erlotinib, for first-line treatment of patients with metastatic non-small cell lung cancer whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 (L858R) substitution mutations.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before February 19, 2020, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 11 a.m. to 11:30 a.m. and 3:30 p.m. to 4 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 13, 2020. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 14, 2020.

Persons attending FDA's advisory committee meetings are advised that FDA is not responsible for providing access to electrical outlets.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Lauren Tesh Hotaki (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 17, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–01150 Filed 1–23–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Bureau of Health Workforce (BHW) Substance Use Disorder (SUD) Evaluation, OMB No. 0906–xxxx—New

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than March 24, 2020.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N136B, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

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

Information Collection Request Title: Bureau of Health Workforce (BHW) Substance Use Disorder (SUD) Evaluation.

OMB No.: 0906–xxxx—New.

Abstract: In September 2017, HRSA launched a multi-part effort to increase the workforce capacity of the U.S. health care system to prevent and treat the opioid crisis. As a part of this effort, HRSA developed or expanded activities under five programs to help combat the crisis: (1) The National Health Service Corps (NHSC) Loan Repayment Program offers loan repayment to providers focused on Substance Use Disorder treatment (NHSC SUD Workforce LRP), (2) the National Health Service Corps Rural Communities Loan Repayment

Program (NHSC Rural Communities LRP), (3) the Opioid Workforce Expansion Program (OWEP), (4) the Behavioral Health Workforce Education and Training Program (BHWET), and (5) the Graduate Psychology Education (GPE) Program. These programs provide either loan repayment to providers (NHSC SUD Workforce LRP, NHSC Rural Communities LRP) or funding for training programs for behavioral health professionals and paraprofessionals to increase integrated behavioral health into primary care treatment and interprofessional team-based care to high-need areas (OWEP, BHWET, GPE).

The purpose of the planned evaluation is to assess these five programs with respect to their stated goals of increasing access to the number of clinicians delivering evidence-based SUD treatment, enhancing education and training in substance use prevention and treatment for current and future health care professionals and paraprofessionals in rural and underserved communities, and integrating behavioral health into primary care to improve the capacity of the health care delivery system to provide SUD prevention and treatment services.

The evaluation will include data collection through web-based surveys to trainees, recipients of loan repayments, grantee organizations, and training sites participating in BHW's SUD prevention and treatment programs. At the trainee/participant level, questions will focus on educational and professional background, motivation and incentives to join or leave the program, training experiences, perceived readiness to deliver SUD treatment services (where applicable), capacity to engage in prevention strategies, and post-graduation employment (where applicable). At the recipient grantee organization level *(note: This level is not relevant to the NHSC programs),* questions will focus on recruitment and retention of students, how their SUD prevention and treatment training program curriculum was developed, as applicable, collaboration with SUD prevention and treatment training sites, plans for sustainability of SUD prevention and treatment activities, as well as any other benefits that resulted from the program. At the site level, questions will focus on SUD prevention and treatment training such as addressing motivation for the site to participate, whether and what type of integrated care delivery is available, and other organizational factors of the site. At all three levels, and for all programs, we will collect survey SUD prevention and treatment training data on satisfaction with the program and recommendations for improving it.

In total, six survey instruments will be used in this evaluation: (1) NHSC SUD Workforce Loan Repayment Program/NHSC Rural Communities Loan Repayment Program/NHSC Loan Repayment Program—Participant Survey, (2) NHSC Loan Repayment Program—Site Survey, (3) Grantee Training and Educational Programs—Trainee Survey, (4) Grantee Training and Educational Programs—Alumni Survey, (5) Grantee Training and Educational Programs—Site Survey, and (6) Grantee Training and Educational Programs—Grantee Organization Survey. As part of a comprehensive questionnaire design process, questions will be limited and refined to collect information not available through secondary sources. Any data collected will not be duplicative of that collected under progress reports or other BHW grant monitoring. NHSC site and participant survey questions will be drawn from prior NHSC Satisfaction Surveys, which were fielded in 2017 and 2018 but were discontinued. Skip patterns will allow respondents to answer only relevant questions for each of their programs. Participation in all surveys is voluntary, and all surveys will be fielded annually for three years beginning in 2020 and concluding in 2022 to include each annual cohort of trainees and participants. Each trainee, participant, or site will complete their respective surveys one time.

Need and Proposed Use of the Information: The purpose of this effort is to evaluate BHW's SUD prevention and treatment expansion program investments with respect to the following objectives:

- *Objective 1:* What is the impact of the NHSC SUD Workforce LRP and the NHSC Rural Communities LRP on the provision of SUD, services in underserved areas compared to those who participate in the non-SUD NHSC LRP?
- *Objective 2:* How are the activities in the BHWET, GPE, and OWEP programs contributing to the expansion of service delivery for SUD prevention and treatment, at the individual, educational, and service-delivery system level?
- *Objective 3:* To what extent are the BHW's programs successful at increasing access to treatment for SUD, including opioid treatment services? The survey data will be critical to understanding the factors related to the success of current BHW programs, and assist in the development of future programs and ongoing SUD prevention and treatment workforce policy development.

Likely Respondents: Data will be collected from trainees, grantee organizations, and sites participating in BHW's SUD prevention and treatment expansion programs as described below.

NHSC SUD Workforce Loan Repayment Program/NHSC Rural Communities LRP/NHSC LRP—Participants Survey: All NHSC SUD Workforce LRP participants, NHSC Rural Communities LRP participants, and NHSC traditional LRP participants who have served at an NHSC site for at least nine months will be invited to respond. Respondents will also include those whom have exited a program early to understand reasons for termination.

NHSC Loan Repayment Program—Site Survey: All sites that were approved to receive NHSC resources, regardless if they currently have a participant on staff will be invited to respond.

Grantee Training and Educational Programs—Trainee Survey: All individuals identified by a grantee as currently receiving training as part of one of the grantee training and educational programs will be invited to respond. Respondents will also include those who have exited a program early, to understand reasons for termination.

Grantee Training and Educational Programs—Alumni Survey: All individuals who completed the Grantee Training and Educational Program Trainee Survey but had not completed their training at the time of the participant survey, will be invited to respond to this short survey which will ask about employment since graduation.

Grantee Training and Educational Programs—Site Survey: All sites that were approved to receive BHWET, OWEP, or GPE trainees, regardless of whether they currently have trainees, will be invited to respond.

Grantee Training and Educational Programs—Grantee Organization Survey: All grantee organizations that received awards in fiscal year 2018 for the BHWET program, and received fiscal year 2019 awards for the GPE and OWEP programs will be invited to respond.

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; to 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; to train personnel and to be able to respond to

a collection of information; to search data sources; to complete and review the collection of information; and to 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
NHSC Loan Repayment Programs—Participant Survey	8,000	1	8,000	0.33	2,640
NHSC Loan Repayment Programs—Site Survey	18,000	1	18,000	0.33	5,940
Grantee Programs—Trainee Survey	8,000	1	8,000	0.33	2,640
Grantee Programs—Alumni Survey	2,000	1	2,000	0.16	320
Grantee Programs—Site Survey	5,000	1	5,000	0.33	1,650
Grantee Programs—Grantee Organization Survey	300	1	300	0.33	99
Total	41,300	.....	41,300	.....	13,289

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. 2020–01119 Filed 1–23–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Solicitation of Nominations for Membership To Serve on the Advisory Committee on Infant Mortality

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

ACTION: Request for nominations.

SUMMARY: HRSA is seeking nominations of qualified candidates for consideration for appointment as members of the Advisory Committee on Infant Mortality (ACIM). The ACIM provides advice to the Secretary of HHS on Department activities and programs directed at reducing infant mortality and improving the health status of pregnant women and infants. With a focus on life course, ACIM addresses disparities in maternal health to improve maternal health outcomes, including preventing and reducing maternal mortality and severe maternal morbidity. HRSA is seeking nominations of qualified candidates to fill positions on the ACIM.

DATES: Written nominations for membership on the ACIM must be received on or before February 24, 2020.

ADDRESSES: Nomination packages must be submitted electronically as email attachments to David de la Cruz, the ACIM's Designated Federal Official, at: *dcruz@hrsa.gov*.

FOR FURTHER INFORMATION CONTACT: David de la Cruz, Ph.D., MPH. Address: Maternal and Child Health Bureau, HRSA 5600 Fishers Lane, Room 18N25, Rockville, MD 20857; phone number: 301–443–0543; email: *dcruz@hrsa.gov*. A copy of the ACIM charter and list of the current membership can be obtained by accessing the ACIM website at *https://www.hrsa.gov/advisory-committees/Infant-Mortality/index.html*.

SUPPLEMENTARY INFORMATION: The ACIM was established in 1991 and advises the Secretary of HHS on Department activities and programs directed at reducing infant mortality and improving the health status of pregnant women and infants. The ACIM represents a public-private partnership at the highest level to provide guidance and focus attention on the policies and resources required to address the reduction of infant mortality and the improvement of the health status of pregnant women and infants. Women who experience conditions such as hypertension, malnutrition, substance use disorder, and/or diabetes during pregnancy are at an elevated risk of delivering a baby who is low birth weight or premature. These are two of the leading causes of infant mortality. The ACIM provides advice on how best to coordinate a myriad of federal, state, local, and private programs and efforts that are designed to deal with the health and social problems affecting infant mortality and maternal health including implementation of the Healthy Start program and the maternal and infant health objectives from the National Health Promotion and Disease Prevention Objectives.

Nominations: HRSA is requesting nominations for voting members to serve as Special Government Employees (SGEs) on the ACIM. The Secretary appoints up to 21 members for a term of up to 4 years. Nominees should include medical, technical, or scientific professionals with special expertise in the field of maternal and child health, in particular infant mortality and related health disparities; members of the public having special expertise about or concern with infant mortality; and/or representatives from such public health constituencies, consumers, and medical professional societies. Interested applicants may self-nominate or be nominated by another individual or organization.

Members appointed as SGEs receive a stipend and reimbursement for per diem and travel expenses incurred for attending the ACIM meetings and/or conducting other business on behalf of the ACIM, as authorized by 5 U.S.C. 5703 for persons employed intermittently in government service. The ACIM meets approximately twice per year.

The following information must be included in the package of materials submitted for each individual being nominated for consideration: (1) A statement that includes the name and affiliation of the nominee and a clear statement regarding the basis for the nomination, including the area(s) of expertise that may qualify a nominee for service on the ACIM, as described above; (2) confirmation the nominee is willing to serve as a member of the ACIM; (3) the nominee's contact information (please include home address, work address, daytime