On October 19, 2023, FDA met with Takeda to discuss the voluntary withdrawal of EXKIVITY (mobocertinib succinate) capsule, EQ 40 mg base, according to § 314.150(d) (21 CFR 314.150(d)). On October 25, 2023, FDA recommended the applicant voluntarily request withdrawal of approval of EXKIVITY (mobocertinib succinate) capsule, EQ 40 mg base, for EGFR exon 20 insertion-mutated NSCLC according to § 314.150(d) because the postmarketing trial did not verify clinical benefit. FDA also requested Takeda waive its opportunity for a hearing.

On March 15, 2024, Takeda submitted a letter asking FDA to withdraw approval of NDA 215310 for EXKIVITY (mobocertinib succinate) capsule, EQ 40 mg base, according to § 314.150(d) and waiving its opportunity for a hearing.

For the reasons discussed above, and in accordance with the applicant's request, approval of NDA 215310 for EXKIVITY (mobocertinib succinate) capsule, EQ 40 mg base, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of EXKIVITY (mobocertinib succinate) capsule, EQ 40 mg base, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: July 9, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15371 Filed 7–12–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Council on Blood Stem Cell Transplantation (ACBSCT or Advisory Council) has scheduled public meetings. Information about the Advisory Council and the agenda for these meetings can be found on the ACBSCT website at *https://bloodstemcell.hrsa.gov/about/advisory-council.*

DATES: Thursday, August 22, 2024, 2:00 p.m.–6:00 p.m. Eastern Standard Time; and Thursday, October 24, 2024, 2:00 p.m.–6:00 p.m. Eastern Standard Time.

ADDRESSES: Both meetings will be held virtually by webinar. A link to register and join each meeting will be posted at least 10 days prior to the meeting date at: *https://bloodstemcell.hrsa.gov/about/advisory-council.*

FOR FURTHER INFORMATION CONTACT: Shelley Tims Grant, Designated Federal Official, HRSA Health Systems Bureau, Division of Transplantation, 5600 Fishers Lane, 8W–67, Rockville, Maryland 20857; 301–443–8036; or *ACBSCTHRSA@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACBSCT provides advice and recommendations to the Secretary of Health and Human Services on policy, program development, and other matters of significance concerning the activities under the authority of 42 U.S.C. 274k (Section 379 of the Public Health Service Act), as amended, and Public Law 109–129, as amended. The Advisory Council may transmit its recommendations through the HRSA Administrator on matters related to the activities of the C.W. Bill Young Cell Transplantation Program and National Cord Blood Inventory.

The agenda for the August 22, 2024, meeting is being finalized and may include the following topics: criteria for defining a high-quality cord blood unit for banking specifications; the unmet needs in blood stem cell transplantation and cellular therapy; updates on transplant outcomes by different donor sources; strategies to improve rates of donation for adult blood stem cell donors; and other areas to increase blood stem cell donation and transplantation. The agenda for the October 24, 2024, meeting will be determined based on discussion, priorities, and/or action items from the August 22, 2024, meeting. All agenda items will be posted on the Advisory Council's website no later than 10 days prior to the respective meeting dates. Agenda items are subject to change as priorities dictate. Interested individuals are encouraged to monitor the Advisory Council's website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meetings; oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to ACBSCT should be sent to Shelley Tims Grant, using the contact information above, at least 3 business days prior to the meeting.

Individuals who plan to attend and need special assistance or other reasonable accommodations should notify Advisory Council at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–15391 Filed 7–12–24; 8:45 am]

BILLING CODE 4165–15–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; Rural Communities Opioid Response Program Performance Measures, OMB No 0906–0044, Revision

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 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 August 14, 2024.

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 Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Rural Communities Opioid Response Program (RCORP) Performance Measures, OMB No. 0906–0044–Revision

Abstract: HRSA administers RCORP, which is authorized by Section 711(b)(5) of the Social Security Act (42 U.S.C. 912(b)(5)) and is a multi-initiative program that aims to: (1) support treatment for and prevention of substance use disorder (SUD), including opioid use disorder (OUD); and (2) reduce morbidity and mortality associated with SUD, including OUD, by improving access to and delivering prevention, treatment, and recovery support services to high-risk rural communities. To support this purpose, RCORP grant initiatives include:

- RCORP—Implementation grants fund established networks and consortia to deliver SUD/OUD prevention, treatment, and recovery activities in high-risk rural communities;
- RCORP—Psychostimulant Support grants aim to strengthen and expand access to prevention, treatment, and recovery services for individuals in rural areas who misuse psychostimulants, to enhance their ability to access treatment and move toward recovery;
- RCORP—Medication Assisted Treatment Access grants aim to establish new access points in rural facilities where none currently exist;
- RCORP—Behavioral Health Care support grants aim to expand access to and quality of behavioral health care services at the individual-, provider-, and community-levels;
- RCORP—Overdose Response recipients address immediate needs in rural areas through improving access to, capacity for, and sustainability of prevention, treatment, and recovery services for SUD;
- RCORP—Child and Adolescent Behavioral Health grants aim to establish and expand sustainable behavioral health care services for children and adolescents aged 5–17 years who live in rural communities; and
- RCORP—Neonatal Abstinence Syndrome grants aim to reduce the incidence and impact of Neonatal Abstinence Syndrome in rural communities by improving systems of care, family supports, and social determinants of health.

Note that additional grant initiatives may be added pending fiscal year 2025 and future fiscal year appropriations.

HRSA currently collects information about RCORP grants using approved performance measures. HRSA developed separate performance measures for RCORP's new Overdose Response, Behavioral Health, and Neonatal Abstinence Syndrome grants and seeks OMB approval for the new performance measures.

A 60-day notice published in the **Federal Register** on May 7, 2024, vol. 89, No. 89; pp. 38163–64. There were no public comments.

Need and Proposed Use of the Information: Due to the growth in the number of grant initiatives included within RCORP, as well as emerging SUD and other behavioral health trends in rural communities, HRSA is submitting a revised ICR that includes measures for RCORP's new Overdose Response, Child and Adolescent Behavioral Health, and Neonatal Abstinence Syndrome grants.

For this program, performance measures were developed to provide data on each RCORP initiative and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act of 1993. These measures cover the principal topic areas of interest to HRSA's Federal Office of Rural Health Policy, including: (a) provision of, and referral to, rural behavioral health care services, including SUD prevention, treatment and recovery support services; (b) behavioral health care, including SUD prevention, treatment, and recovery, process and outcomes; (c) education of health care providers and community members; (d) emerging trends in rural behavioral health care needs and areas of concern; and (e) consortium strength and sustainability. All measures will speak to the progress on meeting the set goals of the Federal Office of Rural Health Policy.

Likely Respondents: The respondents will be the recipients of the RCORP grants.

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
RCORP—Implementation	290	2	580	1.24	719.20
RCORP—Psychostimulant Support	15	1	15	1.30	19.50
RCORP—Medication Assisted Treatment Access	11	1	11	1.95	21.45
RCORP—Behavioral Health Care Support	58	1	58	2.02	117.16
Rural Communities Opioid Response—Overdose Response (NEW)	47	3	141	0.56	78.96
RCORP—Child and Adolescent Behavioral Health (NEW)	9	2	18	0.48	8.64
RCORP—Neonatal Abstinence Syndrome (NEW)	41	4	164	2.31	378.84
Total	471		987		1,343.75

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–15441 Filed 7–12–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–new]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before August 14, 2024.

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.

FOR FURTHER INFORMATION CONTACT: Sherrette Funn, *Sherrette.Funn@hhs.gov* or (202) 264–0041, or *PRA@HHS.GOV*. When submitting comments or requesting information, please include the document identifier 0990-New-30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (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.

Title of the Collection: OASH Performance Project Report for Grants and Cooperative Agreements.

Type of Collection: New.

OMB No. 0990–NEW—Office of the Assistant Secretary for Health.

Abstract: The Office of the Assistant Secretary for Health (OASH) is seeking OMB approval on a new information collection, the OASH Periodic Performance Project Report for Grants and Cooperative Agreements (hereafter the OASH PPR). The purpose of this data collection is to gather quantitative and qualitative information common to the assessment of recipient performance on individual grants and cooperative agreements (collectively, grants) managed in OASH. OASH will collect common data elements measuring the performance of each recipient against the approved grant project plan, including progress toward goals and outcomes as required by 45 CFR 75.342(b)(2).

OASH oversees a broad range of grant programs within the Office of the Secretary (OS), Department of Health and Human Services (HHS). The current active OASH programs with discretionary grants (with assistance listing number) include: Public Awareness Campaigns on Embryo Adoption (93.007); Research on Research Integrity (93.085); Advancing System Improvements for Key Issues in Women's Health (93.088); Community Programs to Improve Minority Health Grant Programs (93.137); Family Planning Services (93.217); Family Planning Personnel Training (93.260); Teenage Pregnancy Prevention Program (93.297); Public Health Service Evaluation Funds (93.343); Research, Monitoring and Outcomes Definitions for Vaccine Safety (93.344); Minority HIV/AIDS Fund (93.899); Family Planning Service Delivery Improvement Research Grants (93.974); and National Health Promotion (93.990). OASH grants span a wide range of project types, including service, demonstration project, evaluation, research, training, and conference projects. Within each program, the awards are subdivided into cohorts aligned with the notices of funding opportunity under which OASH competed the awards. Currently, there are 47 cohorts of active awards across OASH. In any given year, OASH programs collectively monitor 450–550 active awards with another 200–300 inactive awards awaiting final reports as a prerequisite to closing the grant.

The collection is needed to enhance project performance information and simplify reporting under 45 CFR 75.301. Each recipient currently must submit a quarterly Federal Financial Report (FFR or SF–425)(45 CFR 75.341) and a periodic Performance Progress Report (PPR) for each grant (45 CFR 75.342(b)(2). PPR reporting periods in OASH are scheduled quarterly, semi-annually, or annually, depending on the need determined by the program office using a narrative format that can vary by cohort. The PPR schedule is specifically aligned with the quarterly FFRs whenever possible to create a complete snapshot of the project's progress at the end of the reporting period.

The common elements identified in the new collection for OASH programs will standardize the collection of the required information (45 CFR 75.342(b)(2)) including: (1) a comparison of the actual accomplishments to the objectives of the award for the period; (2) the reasons why established goals were not met; and (3) pertinent information, analysis and explanation of cost overruns or high unit costs. The common elements include reporting on publications, including data sets and other work products, to facilitate implementation of OSTP Memorandum Ensuring Free, Immediate, and Equitable Access Federally Funded Research (August 25, 2022). The new information collection will limit the content of the report to those activities taking place during the reporting period (*i.e.,* quarterly, semiannually, or annually). The information collection is structured to facilitate program review across reporting periods. This will allow OASH to identify and improve program outcomes, share lessons learned, and spread the adoption of promising practices among its grant recipients and other HHS awarding agencies.

The content of the new collection is structured for web-based data collection under 7 headings: Report Header; Project Progress; Significant Project Accomplishments; Broader Program Impacts; Products and Dissemination; Collaboration and Partnering Activities; and Project Evaluation Activities. Information will be prepopulated based on the login credentials for the user submitting the report and the specific grant being reported. Not all grants will have reportable activities under all headings (*e.g.,* not all grants have an evaluation component embedded in the project). However, most OASH grants will have reportable information under most headings. Program offices with additional reporting programmatic information collections will eventually transition collection of any overlapping data elements to this OASH PPR. During the transition, OASH will not require grant recipients to provide the same information twice.

Likely Respondents: Members and staff from academia, community organizations, local/state/federal government, private sector, and tribal government and services organizations including those who serve American Indian and Alaska Native and/or racial and ethnic minorities.