TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CDER					
Priority Review Designation Requests (Expedited Programs for Serious Conditions Guidance (EPSC) Section VIII)	81	1.53	124	30	3,720
Breakthrough Therapy Designation Requests (EPSC Section VI)	71	1.08	77	70	5,390
Fast Track Designation Requests (EPSC Section V)	235	1.18	277	60	16,620
Accelerated Approval Designation (EPSC Section VII)	26	1.27	33	100	3,300
Premeeting Packages (21 CFR 312.82)	163	1.01	165	100	16,500
CDER Subtotal			676		45,530
CBER					
Priority Review Designation Request (EPSC Section VIII)	8	1	8	30	240
Breakthrough Therapy Designation Request (EPSC Section VI)	15	1.1	17	70	1,190
Fast Track Designation Requests (EPSC Section VII)	64	1.2	77	60	4,620
RMAT Designation Requests (Regenerative Medicine Therapies for Serious Conditions Guidance (RMAT) Section III)					
Guidance p 6)	33	1.1	36	60	2,160
Premeeting Packages (RMAT Section V)	146	1.9	277	100	27,700
CBER Subtotal			415		35,910
Total			1,091		81,440

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on FY 2022 receipts, we estimate that for Center for Drug Evaluation and Research (CDER) products, 81 respondents will submit 124 requests for priority review designation annually, and we assume 30 hours are needed to prepare such a request. We estimate 71 respondents will submit 77 requests for breakthrough designation annually, and we assume 70 hours are needed to prepare such a request. We estimate that 235 respondents will submit 277 requests for fast-track designation requests annually, and we assume 60 hours are required to prepare such a request. We estimate 26 respondents will submit 33 accelerated approval designation requests annually and we assume 100 hours are required to prepare such a request. Finally, CDER received 165 pre-meeting package submissions from 163 respondents. We assume 100 hours are needed to prepare a pre-meeting package.

Similarly, also based on FY 2022 receipts, we estimate that for CBER products, 8 applicants will submit 8 requests for priority review designation annually, and we assume 30 hours are required to prepare such a request. We estimate 15 respondents will submit 17 requests for breakthrough designation annually, and we assume 70 hours are needed to prepare such a request. We estimate that 64 respondents will submit 78 requests for fast-track designation annually, and we assume 60 hours is required to prepare such a request. We also estimate 33 respondents will submit 35 requests for RMAT designation annually and assume that 60 hours are needed to prepare each RMAT designation request. Finally, CBER received 283 pre-meeting package submissions from 146 respondents. We assume 100 hours are needed to prepare a pre-meeting package.

Based on a review of the information collection since our last request for OMB approval, we have increased our burden estimate by 143 responses and 10,350 hours to reflect actual submissions we have received. We attribute these changes to increased interest in the expedited programs, new expedited programs, and an increase in the number of submissions we received over the last few years.

Dated: January 4, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–00217 Filed 1–8–24; 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 Performance Data Collection, OMB No. 0915–0061—Revision

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 February 8, 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: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Bureau of Health Workforce Performance Data Collection, OMB No. 0915–0061—Revision.

Abstract: Over 50 Bureau of Health Workforce (BHW) programs award grants to health professions schools and training programs across the United States to develop, expand, and enhance training, and to strengthen the distribution of the health workforce. These programs are governed by titles III, VII, and VIII of the Public Health Service Act. Performance information is collected in the HRSA Performance Report for Grants and Cooperative Agreements. Data collection activities consisting of an annual progress report and an annual performance report satisfy statutory and programmatic requirements for performance measurement and evaluation (including specific title III, VII and VIII requirements), as well as Government Performance and Results Act of 1993, the Government Performance and Results Act Modernization Act of 2010, and the Foundations for Evidence-Based Policymaking Act of 2018 requirements. The performance measures were last revised in 2022 to ensure they addressed programmatic changes, met evolving program management needs, and responded to emerging workforce concerns. As these changes were successful, BHW will continue with its current performance management strategy and make additional changes that reduce burden, simplify reporting, reflect new Department of Health and Human Services and HRSA priorities, and enable longitudinal analysis of program performance. Specifically, an Excel upload feature was implemented for all programs to reduce burden. Questions on partnerships were revised and standardized across forms to understand the type and purposes of partnerships associated with grant funding. Employment-related questions were standardized across programs and forms to provide consistent outcomes on employment location, type of employment, and hiring organization. New questions were added for programs using apprenticeships. Specifically, questions were added to measure additional employment outcomes including role at the employment site and vulnerable populations served and to measure program satisfaction and types of competencies graduates were ready to perform.

A 60-day notice published in the **Federal Register** on October 19, 2023, 88 FR 72086–87. There was one public comment. The commenter was complementary of BHW's efforts to consolidate performance data into one collection and raised questions related to collaborating with other departments on the data collection, defining apprenticeships, and making individual-level data publicly available. Specifically, the commenter asked how HRSA collaborates on data collection with agencies outside of the Department of Health and Human services. Our response to the commenter explained the data collected via this OMB package are performance metrics specific to HRSA grant programs and the data are used to meet obligations for performance budgeting. This is in alignment with the Government's authorization to collect data to meet reporting requirements. The commenter also asked how HRSA defines apprenticeships and how it aligns with definitions from other agencies. HRSA responded that it uses the Department of Labor's definition of apprentices and that it included questions from the Department of Labor's Employment and Training Administration instrument to reduce reporting burden and made data comparable across the agencies. Lastly, the commenter requested that HRSA make more individual-level data available, but statute prohibits HRSA from doing so (see 42 U.S.C. 292 *et seq.*). There was a follow-up comment from the same commenter regarding HRSA working with external researchers to analyze data on workforce program participants. HRSA's response was that HRSA does not work with external researchers to analyze data collected on workforce programs. Aggregated data is publicly available to external researchers via HRSA's data warehouse.

Need and Proposed Use of the Information: The purpose of the proposed data collection is to continue analysis and reporting of grantee training activities and education, identify details about the practice locations where trainees work (or plan to work) after program completion, and report outcomes of funded initiatives. Data collected from these grant programs will also provide a description of the program activities of approximately 1,828 reporting grantees to inform policymakers on the barriers, opportunities, and outcomes involved in health care workforce development. The proposed measures focus on four key outcomes:

(1) increasing the workforce supply of well-educated practitioners in needed professions,

(2) increasing the number of practitioners that practice in underserved and rural areas,

(3) enhancing the quality of education, and

(4) supporting educational infrastructure to increase the capacity to train more health professionals in high demand areas.

Likely Respondents: Respondents are awardees of BHW health professions grant programs.

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
Direct Financial Support Program	619	1	619	2.7	1,671.3
Infrastructure Program	219	1	219	4.8	1,051.2
Multipurpose or Hybrid Program	1,044	1	1,044	3.1	3,236.4
Total	1,882		1,882		5,958.9

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. 2024–00210 Filed 1–8–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Notice.

SUMMARY: In accordance with section 1111(g) of the Public Health Service Act, and the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC or Committee) has scheduled a public meeting. Information about the ACHDNC and the agenda for this meeting can be found on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.*

DATES: Monday, January 29, 2024, from 10 a.m. to 5 p.m. Eastern Time (ET) and Tuesday, January 30, 2024, from 10 a.m. to 3 p.m. ET.

ADDRESSES: This meeting will be held in person with webcast options. While this meeting is open to the public, advance registration is required. Please visit the ACHDNC website for information on registration, *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html,* by the deadline of 12 p.m. ET on Friday, January 26, 2024. Instructions on how to access the meeting via webcast will be provided upon registration. If you are a non-United States citizen who would like to attend the January meeting in-person, please contact *ACHDNC@hrsa.gov* by January 11, 2024.

FOR FURTHER INFORMATION CONTACT: Kim Morrison, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room, Rockville, Maryland 20857; 301–822–4978; or *ACHDNC@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of Health and Human Services (Secretary) on the development of newborn screening activities, technologies, policies, guidelines, and programs for effectively reducing morbidity and mortality in newborns and children having, or at risk for, heritable disorders. ACHDNC reviews and reports regularly on newborn and childhood screening practices, recommends improvements in the national newborn and childhood screening programs, and fulfills requirements stated in the authorizing legislation. In addition, ACHDNC's recommendations regarding inclusion of additional conditions for screening on the Recommended Uniform Screening Panel (RUSP), following adoption by the Secretary, are evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA pursuant to section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering non-grandfathered group or individual health insurance are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for preventive services for plan years (*i.e.,* policy years) beginning on or after the date that is one year from the Secretary's adoption of the condition for screening.

During the January 29–30, 2024, meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items include the following topics:

(1) A possible presentation on qualitative research that focuses on family perspectives;

(2) Updates from Committee ad hoc topic groups. Potential topics include: the nomination process and revisions to the decision matrix;

(3) An update on the evidence review of Duchenne muscular dystrophy nomination; and

(4) Presentation of the final evidence-based review report on the Krabbe disease condition nomination for possible inclusion on the RUSP. Following this report presentation, the ACHDNC expects to vote on the second meeting day, on January 30, 2024, whether to recommend to the Secretary adding Krabbe disease to the RUSP (with potential implications under section 2713 of the Public Health Service Act, as noted above).

The agenda for this meeting includes a potential vote to recommend a nominated condition (Krabbe disease) be added by the Secretary to the RUSP. Agenda items are subject to change as priorities dictate. Information about the ACHDNC, including a roster of members and past meeting summaries, is also available on the ACHDNC website.

Members of the public also will have the opportunity to provide comments on any or all of the above agenda items. Public participants may request to provide general oral comments and may submit written statements in advance of the scheduled meeting. Oral comments will be honored in the order they are requested and may be limited as time allows. Subject to change: members of the public registered to submit oral public comments on Krabbe disease are tentatively scheduled to provide their statements on Tuesday, January 30, 2024. Members of the public registered to provide oral public comments on all other newborn screening related topics are tentatively scheduled to provide