The burden estimates are based on FDA's experience with voluntary recalls under 21 CFR part 7. FDA expects no more than two mandatory recalls per year, as most recalls are done voluntarily.

Section 810.10(d)—Collections Specified in the Order—(Reporting)—FDA may require the person named in the cease distribution and notification order to submit certain information to the Agency, *e.g.,* distribution information, progress reports.

Section 810.11(a)—Request for Regulatory Hearing—(Reporting)—A request for regulatory hearing regarding the cease distribution and notification order must be submitted in writing to FDA.

Section 810.12(a) and (b)—Written Request for Review—(Reporting)—In lieu of requesting a regulatory hearing under § 810.11, the person named in the cease distribution and notification order may submit a written request to FDA asking that the order be modified or vacated. A written request for review of a cease distribution and notification order shall identify each ground upon which the requestor relies in asking that the order be modified or vacated, address an appropriate cease distribution and notification strategy, and address whether the order should be amended to require a recall of the device that was the subject of the order and the actions required by such a recall order.

Section 810.14—Mandatory Recall Strategy—(Reporting)—The person named in the cease distribution and notification order or a mandatory recall order must develop and submit a strategy to FDA for complying with the order that is appropriate for the individual circumstances.

Section 810.15(a) through (c)—Notifications to Recipients—(Third-Party Disclosure)—The person named in a cease distribution and notification order or a mandatory recall order must promptly notify each health professional, user facility, consignee, or individual of the order.

Section 810.15(b)—Documentation of Notifications to Recipients—(Recordkeeping)—Telephone calls or other personal contacts may be made in addition to, but not as a substitute for, the verified written communication, and shall be documented in an appropriate manner.

Section 810.15(d)—Notification to Recipients; Followup—(Third-Party Disclosure)—The person named in the cease distribution and notification order or mandatory recall order shall ensure that followup communications are sent to all who fail to respond to the initial communication.

Section 810.15(e)—Notification of Consignees by Recipients—(Third-Party Disclosure)—Health professionals, device user facilities, and consignees should immediately notify their consignees of the order.

Section 810.16(a) and (b)—Periodic Status Reports—(Reporting)—The person named in a cease distribution and notification order or a mandatory recall order must submit periodic status reports to FDA to enable the Agency to assess the person's progress in complying with the order. The frequency of such reports and the Agency official to whom such reports must be submitted will be specified in the order.

Section 810.17(a)—Termination Request—(Reporting)—The person named in a cease distribution and notification order or a mandatory recall order may request termination of the order by submitting a written request to FDA. The person submitting a request must certify that he or she has complied in full with all the requirements of the order and shall include a copy of the most current status report submitted to the Agency.

Based on a review of the information collection since our last request for OMB approval, we have made no changes to the burden estimate.

Dated: July 26, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16635 Filed 8–3–21; 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: Health Center Program: COVID–19 Data Collection Tools, OMB No. 0906–0062—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 September 3, 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.* 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 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:

Information Collection Request Title: Health Center Program: COVID–19 Data Collection Tools, OMB No. 0906–0062—Revision.

Abstract: This information collection request was previously approved by OMB on June 11, 2020, as an emergency clearance (OMB No.: 0906–0062). HRSA is currently undertaking the standard Paperwork Reduction Act process for normal OMB approval.

During the COVID–19 public health emergency, HRSA-supported health centers and Federally Qualified Health Center Look-Alikes (look-alikes) have played a key role in providing testing and care for those affected by the virus. HRSA has awarded billions of dollars in new funding to support health center awardees and look-alikes in the detection, prevention, diagnosis, and treatment of COVID–19. This funding has enabled health centers to maintain or increase their staffing levels, conduct training, provide COVID–19 treatment, and administer millions of tests for both existing and new patients. In addition, HRSA, in collaboration with the Centers for Disease Control and Prevention, launched the Health Center COVID–19 Vaccine program as part of an Administration initiative focused on health equity. This occurred in February 2021 to directly allocate COVID–19 vaccines to HRSA-supported health centers.

This ICR to support the implementation of COVID–19 relief funding and response activities includes forms previously submitted in the emergency information collection

request clearance: (1) Health Center COVID–19 Data Collection Survey Tool, (2) Addendum to COVID–19 Data Collection Survey Tool, and (3) the Health Center COVID–19 Vaccine Program Readiness Assessment Tool. This revised information collection request also includes two newly added forms: (1) Primary Care Association (PCA) COVID–19 Data Collection Survey Tool [1] and (2) the Health Center COVID–19 Vaccine Program Conditions of Participation Agreement.

A 60-day notice published in the **Federal Register** on April 23, 2021, vol. 86, No. 77; pp. 21756–57. There were no public comments.

Need and Proposed Use of the Information: HRSA uses the data collected to optimize COVID–19 testing and vaccination; track health center capacity and the impact of COVID–19 on operations, patients, and staff; and better understand training and technical assistance, funding, and other health center resource needs. The data allow HRSA to assess health center capacity prior to program enrollment, supporting successful vaccine allocation strategies, while providing HRSA with information on the effectiveness of vaccine distribution through this program. In addition, the data inform HRSA in resource allocation and technical assistance to health centers.

The readiness assessment supports HRSA's analysis of health center ability to successfully participate in the Health Center COVID–19 Vaccine Program. These data are critical to determine health center capacity to implement the vaccination program as well as comply with program requirements. These data are used to assess program readiness including:

- Ability to safely store the vaccine
- Availability of trained and credentialed staff and other staff capacity
- Reporting capacity
- Sufficient PPE
- Plan for vaccine transport

The health center weekly survey and addendum support HRSA's ability to monitor progress towards the development and delivery of COVID–19 prevention, preparedness, and/or response activities; and ensure appropriate vaccine administration as well as better understand training and technical assistance, funding, and other health center resource needs.

The Conditions of Participation Agreement governs all COVID–19 vaccination activities at all health center sites that receive COVID–19 vaccine through the HRSA Health Center COVID–19 Vaccine Program. Health Centers that sign the agreement agree to adhere to each of the stated requirements.

The PCA weekly survey increases information sharing between health centers, PCAs, and HRSA in order to better support COVID–19 emergency response efforts inclusive of testing and vaccination activities. Data collected from the survey tool is used to track and monitor issues/challenges to program implementation and assess the need for the delivery/dissemination of targeted training and technical assistance.

Likely Respondents: HRSA-supported health centers, look-alikes, and PCAs.

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 to form per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Condition of Participation Agreement (one-time completion for vaccine program participants only).	1,467 (Total health centers, including look-alikes, in 2019).	1	1,467	.25	366.75
Readiness Assessment Tool (one-time completion for vaccine program participants only).	1,467 (Total health centers, including look-alikes, in 2019).	1	1,467	.50	733.50
Health Center COVID–19 Data Collection Survey Tool (weekly completion of existing 20 questions).	1,389 (Total health centers in 2019)	48	66,672	1.00	66,672.00
Addendum to COVID–19 Data Collection Survey Tool (weekly completion for vaccine program participants only).	1,389 (Total health centers in 2019)	48	66,672	.50	33,336.00
PCA COVID–19 Data Collection Survey Tool (bi-weekly completion of existing six questions).	52	6	312	.75	234.00
Total	5,764		136,590		101,342.25

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

[1] The bi-weekly COVID–19 PCA Survey Tool (comprised of six questions) is currently approved under the HHS Secretary's Public Health Emergency Authority to waive the requirements of the Paperwork Reduction Act during the Public Health Emergency for reporting on a voluntary basis.

technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–16591 Filed 8–3–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Charter Amendment for the Advisory Committee on Heritable Disorders in Newborns and Children

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA) and section 1111 of the Public Health Service (PHS) Act, HHS is hereby giving notice that the charter for the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) has been amended to set the time period for appointment of members to a term of up to 4 years. The effective date of the amendment is July 30, 2021.

FOR FURTHER INFORMATION CONTACT: Mia Morrison (DFO), Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–2521; or *mmorrison@hrsa.gov.*

SUPPLEMENTARY INFORMATON: The ACHDNC provides advice and recommendations to the Secretary of HHS on policy, program development, and other matters of significance concerning certain activities described in section 1111 of the PHS Act (42 U.S.C. 300b–10), as further described below. The ACHDNC is also governed by the provisions of the FACA, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of advisory committees. The ACHDNC advises the Secretary of HHS about aspects of newborn and childhood screening and technical information for the development of policies and priorities that will enhance the ability of the state and local health agencies to provide for newborn and child screening, counseling and health care services for newborns and children having, or at risk for, heritable disorders. The ACHDNC will review and report regularly on newborn and childhood screening practices, recommend improvements in the national newborn and childhood screening programs, and fulfill responsibilities described in section 1111 of the PHS Act. In addition, the ACHDNC's recommendations regarding inclusion of additional conditions for screening, following adoption by the Secretary, are considered evidence-informed preventive health services provided for in the comprehensive guidelines supported by HRSA through the Recommended Uniform Screening Panel (RUSP) pursuant to section 2713 of the PHS Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered group health plans and health insurance issuers offering 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.

The filing date of the ACHDNC charter remains November 10, 2020. A copy of the ACHDNC charter is available on the ACHDNC website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* A copy of the charter also can be obtained by accessing the FACA database that is maintained by the Committee Management Secretariat under the General Services Administration. The website address for the FACA database is *http://www.facadatabase.gov/.*

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–16618 Filed 8–3–21; 8:45 am]

BILLING CODE 4165–15–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: National Health Service Corps Scholar/Students To Service Travel Worksheet, OMB No. 0915–0278—Extension

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 October 4, 2021.

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 information request collection title for reference.

Information Collection Request Title: National Health Service Corps Scholar/Students to Service Travel Worksheet, OMB No. 0915–0278—Extension.

Abstract: Clinicians participating in the HRSA National Health Service Corps (NHSC) Scholarship Program (SP) and the Students to Service (S2S) Loan Repayment Program (LRP) use the online Travel Request Worksheet to request and receive travel funds from the federal government to visit eligible NHSC sites to which they may be assigned in accordance with the Public Health Service Act, section 331(c)(1).

The travel approval process is initiated when an NHSC scholar or S2S participant notifies the NHSC of an impending interview at one or more NHSC-approved practice sites. The Travel Request Worksheet is also used to initiate the relocation process after a NHSC scholar or S2S participant has successfully been matched to an approved practice site in accordance with the Public Health Service Act, section 331(c)(3). Upon receipt of a completed Travel Request Worksheet, the NHSC will review and approve or disapprove the request and promptly notify the scholar or S2S participant and the NHSC logistics contractor regarding travel arrangements and authorization of the funding for the site visit or relocation.

Need and Proposed Use of the Information: This information will facilitate NHSC scholar and S2S participants' receipt of federal travel funds that are used to visit high-need NHSC-approved practice sites. The Travel Request Worksheet is also used to initiate the relocation process after a NHSC scholar or S2S participant has