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 810.16(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 device 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.

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

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.
not processed yet
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 INFORMATION: 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