21 CFR 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.

21 CFR 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.

21 CFR 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.

21 CFR 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.

21 CFR 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.

21 CFR 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.

21 CFR 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.

21 CFR 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.

21 CFR 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.

21 CFR 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: March 30, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–06960 Filed 4–2–21; 8:45 am]

BILLING CODE 4164–01–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 Health Network Development Program, OMB No. 0906–0010—Revision

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

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA has 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 May 5, 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 a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Rural Health Network Development Program OMB No. 0906–0010—Revision

Abstract: The Rural Health Network Development Program (RHND) is authorized under Section 330A(e) of the Public Health Service Act (42 U.S.C. 254(e)). The purpose of this program is to support integrated rural health care networks that have combined the functions of the entities participating in the network to address the health care needs of the targeted rural community. Recipients will combine the functions of the entities participating in the network to address the following legislative aims: (i) Achieve efficiencies; (ii) expand access, coordinate, and improve the quality of essential health care services; and (iii) strengthen the rural health care system as a whole.

RHND-funded programs promote population health management and the transition towards value-based care through diverse network membership that includes traditional and non-traditional network partners. Evidence of program impacted demonstrated by outcome data and program sustainability are integral components of the program. This is a 3-year competitive program for networks composed of at least three members that are separate existing health care providers or entities.

A 60-day Notice published in the **Federal Register** on November 19, 2020, vol. 85, No. 224, pages 73728–73729. There were no public comments.

Need and Proposed Use of the Information: This program needs measures that will 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 the Federal Office of Rural Health Policy, including: (a) Access to care; (b) population demographics; (c) staffing; (d) consortium/network; (e) sustainability; and (f) project specific domains. All measures will evaluate HRSA's progress toward achieving its goals.

The proposed changes of RHND measures are a result of the accumulation of grantee feedback, peer-reviewed research, and information gathered from the previously approved RHND program measures. The proposed changes include additional questions surrounding the network's components of sustainability. Questions surrounding Health Information Technology and Telehealth have been modified to reflect updated knowledge on the use of both and to improve understanding of how these important technologies are affecting HRSA grantees. Additional National Quality Forum measures were also included in an effort to allow uniform collection efforts throughout the Federal Office of Rural Health Policy.

Likely Respondents: Respondents will be awardees of the Rural Health Network Development Program.

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
Performance Improvement and Measurement System Database	44	1	44	6	264
Total	44		44		264

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. 2021–06880 Filed 4–2–21; 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 (HHS).

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 to be held on Thursday, May 13, 2021, and Friday, May 14, 2021. 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: Thursday, May 13, 2021, from 10:00 a.m. to 3:00 p.m. Eastern Time (ET) and Friday, May 14, 2021, from 10:00 a.m. to 3:00 p.m. ET.

ADDRESSES: This meeting will be held via webinar. While this meeting is open to the public, advance registration is required.

Please register online at *https://www.achdncmeetings.org/registration/* by 12:00 p.m. ET on May 12, 2021. Instructions on how to access the meeting via webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Alaina Harris, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Rockville, Maryland 20857; 301–443–0721; or *ACHDNC@hrsa.gov*.

SUPPLEMENTARY INFORMATION: ACHDNC provides advice and recommendations to the Secretary of HHS (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. The 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, following adoption by the Secretary, are 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 Public Health Service 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 1 year from the Secretary's adoption of the condition for screening.

During the May 13–14, 2021, 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:

(1) Mucopolysaccharidosis type II (MPS II) nomination summary;

(2) Possible Committee vote on whether to move MPS II forward to a full evidence review;