highlighting further the interrelationship between a clinical protocol and an imaging charter.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on clinical trial imaging endpoint process standards. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *https://www.regulations.gov.*

Dated: April 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–08903 Filed 4–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

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 of Meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Committee on Heritable Disorders in Newborns and Children (ACHDNC) will hold a public meeting.

DATES: Wednesday, May 9, 2018, from 9:30 a.m. to 5:00 p.m. Eastern Time (ET) and Thursday, May 10, 2018, from 9:30 a.m. to 1:00 p.m. ET.

ADDRESSES: The public may attend this meeting in person or via Webcast. While this meeting will be open to the public, advance registration is required. Please register online at *http://www.achdncmeetings.org/* by 12:00 p.m. ET on May 7, 2018.

The address for the meeting is 5600 Fishers Lane, Rockville, MD 20857. Non-U.S. citizens planning to attend in person will need to provide additional information to HRSA by Monday, April 30, 2018, 12 p.m. ET. To facilitate access to the building, please contact Ann Ferrero at the contact information listed below. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify Ms. Ferrero at least 10 days prior to the meeting.

The meeting will also be accessible via Webcast. Instructions on how to access the meeting via Webcast will be provided upon registration.

FOR FURTHER INFORMATION CONTACT: Anyone requesting information regarding the ACHDNC should contact Ann Ferrero, Maternal and Child Health Bureau (MCHB), HRSA, in one of three ways: (1) Send a request to the following address: Ann Ferrero, MCHB, HRSA 5600 Fishers Lane, Room 18N100C, Rockville, MD 20857; (2) call 301–443–3999; or (3) send an email to *AFerrero@hrsa.gov.*

SUPPLEMENTARY INFORMATION:

Background: The ACHDNC provides advice and recommendations to the Secretary of HHS 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. In addition, ACHDNC's recommendations regarding inclusion of additional conditions and inherited disorders for screening are included in the Recommended Uniform Screening Panel (RUSP) following adoption by the Secretary. Conditions listed on the RUSP constitute part of the comprehensive preventive health guidelines supported by HRSA for infants and children under section 2713 of the Public Health Service Act (42 U.S.C. 300gg–13). Under this provision, non-grandfathered health plans and health insurance issuers are required to provide insurance coverage without cost-sharing (a co-payment, co-insurance, or deductible) for screenings included in the HRSA-supported comprehensive guidelines 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.

Agenda: The meeting agenda will include: (1) Presentations and discussion on risk assessment in newborn screening; (2) presentation of educational tools for communicating newborn screening results; (3) presentations from states working toward timeliness goals in newborn screening; (4) an update on the status of newborn screening pilot studies for Guanidinoacetate Methyltransferase (GAMT) deficiency; (5) updates from the Laboratory Standards and Procedures workgroup; (6) updates from the Follow-up and Treatment workgroup; (7) updates from the Education and Training workgroup; and (8) reviewing the process for assessing the public health impact of adding conditions to the RUSP.

There are no votes scheduled for this meeting. The final meeting agenda will be available two (2) days prior to the meeting on the Committee's website at *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html.* Please note that agenda items and meeting times are subject to change as priorities dictate.

Public Participation: Members of the public will have the opportunity to provide comments, which are part of the official Committee record. To submit written comments or request time for an oral comment at the meeting, please register online by 12:00 p.m. ET on May 3, 2018, at *http://www.achdncmeetings.org/.* Oral comments will be honored in the order they are requested and may be limited as time allows. Individuals associated with groups or who plan to provide comments on similar topics may be asked to combine their comments and present them through a single representative. No audiovisual presentations are permitted. Written comments should identify the individual's name, address, email, telephone number, professional or organization affiliation, background or area of expertise (*i.e.,* parent, family member, researcher, clinician, public health, etc.) and the topic/subject matter.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2018–08853 Filed 4–26–18; 8:45 am]

BILLING CODE 4165–15–P