selected by the Commissioner or designee from among authorities knowledgeable in the fields of digital health, such as AI/ML, augmented reality, virtual reality, digital therapeutics, wearables, remote patient monitoring, software development, user experience, real-world data, real-world evidence, patient-generated health data, interoperability, personalized medicine/genetics, decentralized clinical trials, cybersecurity, and implementation in clinical practice of and patient experience with digital health, as well as other relevant areas. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve either as special government employees or non-voting representatives. Federal members will serve as regular government employees. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who serves as an individual, but who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons.

The Commissioner or designee shall also have the authority to select from a group of individuals nominated by industry to serve temporarily as non-voting members who are identified with and represent industry interests. The number of temporary members selected for a particular meeting will depend on the meeting topic.

In announcing the establishment of this Advisory Committee under the Federal Advisory Committee Act (5 U.S.C. 1001 *et seq.*), FDA is also soliciting public feedback on potential topics for this committee to discuss and upon which to advise the Agency. The following topics may include, but are not limited to:

- Transparency and bias management considerations, including promoting health equity in DHTs
- Augmented reality and virtual reality technical and clinical questions
- Transparency and labeling considerations for ''opaque box'' algorithms
- Digital therapeutics
- AI/ML
- Input on regulation of AI/ML-enabled devices
- Real-world data and real-world evidence
- Patient-generated health data
- Postmarket monitoring considerations for a total product lifecycle approach to DHTs
- Interoperability
- Personalized medicine/genetics
- Wearables, remote patient monitoring, and internet of things
- Postmarket monitoring of DHTs
- Technologies to enable decentralized clinical trials
- Cybersecurity best practices in software development for cloud-based software

Elsewhere in this issue of the **Federal Register**, FDA is publishing separate documents regarding: (1) Digital Health Advisory Committee: Request for Nominations for Voting Members on a Public Advisory Committee: Digital Health Advisory Committee; (2) Request for Nomination of Individuals and Consumer Organizations for the Digital Health Advisory Committee; and (3) Request for Nomination of Individuals and Industry Organizations for the Digital Health Advisory Committee.

FDA intends to publish in the **Federal Register** a final rule adding the Digital Health Advisory Committee to 21 CFR 14.100.

Dated: October 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–22566 Filed 10–11–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Commission on Childhood Vaccines

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, this notice announces that the Advisory Commission on Childhood Vaccines (ACCV) will hold public meetings for the 2024 calendar year (CY). Information about ACCV, agendas, and materials for these meetings can be found on the ACCV website at *https://www.hrsa.gov/advisory-committees/vaccines/index.html.*

DATES: ACCV meetings will be held on March 7, 2024, 10:00 a.m.–4:00 p.m. Eastern Time (ET); March 8, 2024, 10:00 a.m.–4:00 p.m. ET; September 5, 2024, 10:00 a.m.–4:00 p.m. ET; September 6, 2024, 10:00 a.m.–4:00 p.m. ET.

ADDRESSES: Meetings may be held in-person or by Zoom webinar. For updates on how the meeting will be held, visit the ACCV website meeting page included below 30 business days before the date of the meeting, where instructions for joining meetings either in-person or remotely will be posted. In-person ACCV meetings will be held at 5600 Fishers Lane, Rockville, MD 20857. For meeting information updates, go to the ACCV website meeting page at *https://www.hrsa.gov/advisory-committees/vaccines/meetings.html.*

FOR FURTHER INFORMATION CONTACT: Pita Gomez, Principal Staff Liaison, Division of Injury Compensation Programs, HRSA, 5600 Fishers Lane, 8W–25A, Rockville, MD 20857; 800–338–2382; or *ACCV@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACCV provides advice and recommendations to the Secretary of HHS (Secretary) on policy, program development, and other issues related to implementation of the National Vaccine Injury Compensation Program and concerning other matters as described under section 2119 of the Public Health Service Act (42 U.S.C. 300aa–19).

Since priorities dictate meeting times, be advised that start times, end times, and agenda items are subject to change. For CY 2024 meetings, agenda items may include, but are not limited to: updates from the Division of Injury Compensation Programs, Department of Justice, Office of Infectious Disease and HIV/AIDS Policy (HHS), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health) and Center for Biologics Evaluation and Research (Food and Drug Administration). Refer to the ACCV website listed above for all current and updated information concerning the CY 2024 ACCV meetings, including draft agendas and meeting materials that will be posted 5 calendar days before the meeting.

These meetings are open to the public. Meetings held by Zoom webinar will require registration. Registration details will be provided on our ACCV website at *https://www.hrsa.gov/advisory-committees/vaccines/meetings.html.* All registrants will be asked to provide their name, affiliation, and email address. After registration, individuals will receive personalized Zoom information via email.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meeting(s). Oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to ACCV should

be sent to Pita Gomez using the contact information listed above at least 5 business days before the meeting date(s).

Individuals who need special assistance or another reasonable accommodation should notify Pita Gomez using the contact information listed above at least 10 business days before the meeting(s) they wish to attend. Since all in-person meetings will occur in a federal government building, attendees must go through a security check to enter the building. Non-U.S. Citizen attendees must notify HRSA of their planned attendance at least 20 business days prior to the meeting to facilitate their entry into the building. All attendees are required to present government-issued identification prior to entry.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–22584 Filed 10–11–23; 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 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, November 2, 2023, and Friday, November 3, 2023. 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, November 2, 2023, from 10:00 a.m. to 4:00 p.m. Eastern Time (ET) and Friday, November 3, 2023, from 10:00 a.m. to 2:00 p.m. ET.

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

Please visit the ACHDNC website for information on registration: *https://www.hrsa.gov/advisory-committees/heritable-disorders/index.html* by the deadline of 12:00 p.m. ET on November 1, 2023. 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, Room 18W66, Rockville, Maryland 20857; 301–443–0721; 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, 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 1 year from the Secretary's adoption of the condition for screening.

During the November 2–3, 2023, 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) An update on the Krabbe disease expedited evidence review update;

(2) An update on the Duchenne Muscular Dystrophy evidence review update;

(3) An update by the ACHDNC Decision Matrix ad hoc topic group and potential vote on revisions to the ACHDNC Decision Matrix;

(4) A presentation and discussion on the ACHDNC's conflict of interest procedures;

(5) Ad hoc topic group updates; and

(6) A possible presentation on the National Academies of Sciences, Engineering, and Medicine Workshop on Next Generation Screening.

ACHDNC will not vote on recommending conditions for inclusion in the Recommended Uniform Screening Panel during this meeting; however, Krabbe disease and Duchenne Muscular Dystrophy evidence review updates along with a discussion and a potential vote on revisions to the ACHDNC Decision Matrix may inform such potential future recommendations. Agenda items are subject to change as priorities dictate. Information about ACHDNC, including a roster of members and past meeting summaries, is available on the ACHDNC website.

Members of the public 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. Members of the public registered to provide oral public comments on all other newborn screening related topics are tentatively scheduled to provide their statements on Thursday, November 2, 2023. Requests to provide a written statement or make oral comments to ACHDNC must be submitted via the registration website by 12:00 p.m. ET on Friday, October 20, 2023. Written comments will be shared with the Committee, so that they have an opportunity to consider them prior to the meeting.

Individuals who need special assistance or another reasonable accommodation should notify Alaina Harris at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–22493 Filed 10–11–23; 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 Infant and Maternal Mortality

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory