

21 CFR part or guidance	Topic	OMB control No.
"Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program". 58	Q-submissions and Early Payor Feedback Request Programs for Medical Devices. Good Laboratory Practice (GLP) Regulations for Nonclinical Laboratory Studies.	0910-0756 0910-0119

Dated: March 26, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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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. Information about 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 9, 2024, from 10 a.m. to 5 p.m. eastern time (ET) and Friday, May 10, 2024, from 10 a.m. to 3 p.m. ET.

ADDRESSES: This meeting will be held in person with webcast options. 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 p.m. ET on Wednesday, May 8, 2024. Instructions on how to access the meeting via webcast will be provided upon registration.

If you are a non-U.S. citizen who would like to attend the May meeting in-person, please contact ACHDNC@hrsa.gov by April 19, 2024.

FOR FURTHER INFORMATION CONTACT: Kim Morrison, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room, Rockville, Maryland 20857; 301-443-6672; 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. 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 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 May 9-10, 2024, meeting, ACHDNC will hear from experts in the fields of public health, medicine, heritable disorders, rare disorders, and newborn screening. Agenda items may include the following topics:

- (1) A possible presentation on drug trials for rare diseases;
- (2) A possible presentation on assessing evidence from qualitative research using the GRADE-CERQUAL approach;
- (3) Updates from Committee ad hoc topic groups. Potential topics include: the nomination process and revisions to the decision matrix, counting conditions, and naming conditions;
- (4) An update on the evidence review of Duchenne Muscular Dystrophy (DMD), which was previously

nominated for Committee consideration; and

(5) Following the DMD evidence review presentation, a potential vote on whether to recommend to the Secretary the addition of DMD to the Recommended Uniform Screening Panel at this time or to take other Committee action regarding this nominated condition. Agenda items are subject to change as priorities dictate. Information about ACHDNC, including a roster of members and past meeting summaries, is also available on the ACHDNC website.

Members of the public also 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. Requests to provide a written statement or make oral comments to ACHDNC must be submitted via the registration website by 12 p.m. ET on Friday, April 26, 2024. Written comments will be shared with the Committee prior to the meeting so that they have an opportunity to consider them in advance of the meeting.

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

Since this meeting occurs 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 15 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.

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