made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: George Greeley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6406, Silver Spring, MD 20993–002, 301–796–4025; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Measuring Growth and Evaluating Pubertal Development in Pediatric Clinical Trials.'' The purpose of this draft guidance is to assist sponsors in monitoring growth and pubertal development in clinical trials that enroll pediatric patients with both rare and common diseases. This draft guidance is focused on the most appropriate methods for measuring and recording growth and evaluating pubertal development for evaluation of safety.

If an investigational drug or biological product may affect growth or pubertal development, then accurate, serial measurement and recording of growth parameters are essential for data interpretation in pediatric clinical trials. In general, growth is assessed using measurements of weight, linear growth (length and height), and when appropriate, head circumference. Additional measurements and calculations may be needed in certain pediatric age groups and disease populations. In general, pubertal development is assessed using clinical phenotyping. Identifying the onset and progression of puberty are essential for accurate interpretation of growth data.

This draft guidance addresses measurement of growth, evaluation of pubertal development, and other measurements. The discussion of growth measurements consists of general considerations to ensure accurate, reproducible measurements followed by specific suggestions about how to measure weight, linear growth (length and height), and head circumference in the entire pediatric population starting at birth. The recommendations for pubertal development focus on use of the sexual maturity rating. The draft guidance also provides recommendations on other measurements, specifically use of skeletal age and dual-energy X-ray absorptiometry.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Measuring Growth and Evaluating Pubertal Development in Pediatric Clinical Trials.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014. The collection of information in 21 CFR part 314 has been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: October 27, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–23730 Filed 10–31–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics; Meeting and RFC

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of meeting. notice of request for comment (RFC).

SUMMARY: Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee meeting and related Request for Comment (RFC). The meeting is open to the public. The public is welcome to obtain the link to attend this meeting by following the instructions posted on the Committee website: *https://ncvhs.hhs.gov/*

meetings/standards-subcommittee-hearing/.

Name: National Committee on Vital and Health Statistics (NCVHS) Standards Subcommittee Meeting.

DATES: The meeting will be held Wednesday, January 18, 2023: 10:00 a.m.–5:30 p.m. EST and Thursday, January 19, 2023: 10:00 a.m.–5:30 p.m. EST.

To submit comments in response to the RFC, please send by close of business December 15, 2022, to *NCVHSmail@cdc.gov,* and include on the subject line: RFC on X12 and CAQH CORE Proposals.

ADDRESSES: Virtual open meeting.

FOR FURTHER INFORMATION CONTACT: Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, via electronic mail to *vgh4@cdc.gov;* or by telephone (301) 458–4715. Summaries of meetings and a roster of Committee members are available on the home page of the NCVHS website *https://ncvhs.hhs.gov/,* where further information including an agenda and instructions to access the broadcast of the meeting will be posted.

Should you require reasonable accommodation, please telephone the CDC Office of Equal Employment Opportunity at (770) 488–3210 as soon as possible.

SUPPLEMENTARY INFORMATION: As outlined in its Charter, the National Committee on Vital and Health Statistics assists and advises the Secretary of HHS on health data, data standards, statistics, privacy, national health information policy, and the Department's strategy to best address those issues. This includes the adoption and implementation of transaction standards, unique identifiers, and code sets adopted under the Health Insurance Portability and Accountability Act of 1996 (HIPAA),[1] and operating rules adopted under the Patient Protection and Affordable Care Act (ACA).[2]

Purpose: The purpose of this hearing is to inform the Committee as it develops recommendations to HHS. During the hearing, the Committee will receive input from representatives of standards development organizations (SDOs), Operating Rule Authoring Entities (ORAEs) and industry stakeholders in response to requests received from two organizations: X12[3] and the Council for Affordable Quality Healthcare's (CAQH) Committee on Operating Rules for Information Exchange (CORE) Board.[4] Together, these requests ask NCVHS to consider and develop recommendations to HHS regarding proposed mandatory updates to four HIPAA-adopted transactions, mandatory updates to four adopted operating rules, and six new operating rules described below.

The agenda for the hearing dedicates one day to the X12 proposed standards updates and one day to the proposed updated and new operating rules. The agenda on both days will include time for public comment. Meeting times and topics are subject to change.

Request for comment: This Notice also serves as a Request for Comment (RFC) to solicit input from industry stakeholders, patients, any interested individuals and organizations, or any members of the public to the Subcommittee in advance of the January 18–19, 2023, hearing. The Committee is seeking input about the value of the proposed transactions and operating rules, including costs, benefits, test results, and overall impact of updating and adopting (or not adopting) these transaction standards and operating rules. The comments will inform the Committee's deliberations about the value, benefits, and costs of the proposed updates to the standard transactions and operating rules. The Committee will compile the responses in advance of the January 18–19, 2023, hearing and consider them together with the live testimony of subject matter experts provided at the meeting. In addition, NCVHS is collaborating with the Workgroup for Electronic Data Interchange (WEDI) that is also gathering and providing information as described below.

The RFC includes suggested topics and questions to guide commenters. However, comments are welcome on any subject relevant to the Committee's inquiry and any aspect of the agenda. The suggested topics and questions are available on the Committee's website at: *https://ncvhs.hhs.gov/January-2023-Standards-Subcommittee-Hearing-Public-Comment-Guidelines.* To submit comments in response to the RFC, please send by December 15, 2022, to *NCVHSmail@cdc.gov, and* include on the subject line: RFC on X12 and CAQH CORE Proposals.

Requests From X12 and CAQH CORE

On June 7, 2022, X12 submitted a letter to NCVHS to recommend an update of adopted transactions: from version 5010 to version 8020 for the adopted administrative standard for the health care claims (professional, institutional, and dental) and the remittance advice transactions.[5]

HIPAA requires the Secretary of HHS to promulgate regulations adopting standards, code sets, and identifiers to support the exchange of electronic health information between covered entities, including standards for retail pharmacy and medical transactions. Standards setting organizations or the Designated Standards Maintenance Organization (DSMO) bring forward new versions of the adopted standards to NCVHS after completion of a consensus-based review and evaluation process. Under section 1173(3)(B), the organizations with whom a DSMO should consult for input include the National Uniform Billing Committee, the National Uniform Claim Committee, the Workgroup for Electronic Data Interchange, and the American Dental Association.

On May 23, 2022, the CAQH CORE submitted a letter to NCVHS to consider a package of CAQH CORE Operating Rules for federal adoption as follows:[6]

Updates to Adopted Operating Rules

- Updated Eligibility & Benefits Data Content Rule;
- Updated Claim Status Infrastructure Rule (updates + reference to new Connectivity rule);
- Updated Payment & Remittance Advice Infrastructure Rule (reference to new Connectivity rule);
- Updated Eligibility & Benefits Infrastructure Rule (updates + reference to new Connectivity rule).

Proposed New Operating Rules

- CAQH CORE Connectivity Rule vC4.0.0—replaces existing connectivity requirements in infrastructure components of adopted operating rules; adds new requirements to all operating rules;
- New CAQH CORE Eligibility & Benefits (270/271) Single Patient Attribution Data Content Rule;

[1] Public Law 104–191, 110 Stat. 1936 (Aug 21, 1996), available at: *https://www.congress.gov/104/plaws/publ191/PLAW-104publ191.pdf.*

[2] Public Law 111–148, 124 Stat. 119 (Mar 23, 2010), available at: *https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf.*

[3] Letter from X12 to NCVHS, June 7, 2022: *https://ncvhs.hhs.gov/wp-content/uploads/2022/09/X12-Request-for-review-of-8020-transactions-060822-to-NCVHS-508.pdf.*

[4] Letter from CAQH CORE to NCVHS, May 23, 2022: *https://ncvhs.hhs.gov/wp-content/uploads/2022/09/CAQH-CORE-Board-Letter-to-NCVHS-re-New-Updated-OR-052322-508.pdf.*

[5] Letter from X12 to NCVHS, June 7, 2022: *https://ncvhs.hhs.gov/wp-content/uploads/2022/09/X12-Request-for-review-of-8020-transactions-060822-to-NCVHS-508.pdf.*

[6] Letter from CAQH CORE to NCVHS dated May 23, 2022: *https://ncvhs.hhs.gov/wp-content/uploads/2022/09/CAQH-CORE-Board-Letter-to-NCVHS-re-New-Updated-OR-052322-508.pdf.*

- New Attachments Prior Authorization Infrastructure Rule;
- New Attachments Prior Authorization Data Content Rule;
- New Attachments Health Care Claims Infrastructure Rule;
- New Attachments Health Care Claims Data Content Rule.

Section 1104 of ACA amended HIPAA by introducing the requirement to adopt operating rules to support the business function of each HIPAA-adopted standard transaction. HHS has adopted operating rules for the eligibility, claim status, electronic remittance advice, and electronic funds transfer transactions. HHS has not yet adopted operating rules for health care claims, enrollment/disenrollment, premium payments, prior authorization for referrals, or health care claim attachments transactions.

Additional Opportunity To Provide Comment

In addition to the January 18–19, 2023, hearing and RFC, the Committee is collaborating with the Workgroup for Electronic Data Interchange (WEDI) in its role as advisor to the Secretary of Health and Human Services (HHS). WEDI is considered an authority on the use of health information technology (HIT) to improve health information exchange. Its membership includes a cross-section of HIPAA covered entities that implement the HIPAA standards and operating rules, as well as vendors and other subject matter experts who support those implementations. WEDI is supporting NCVHS' efforts to obtain input from a diverse group of stakeholders through educational programs, its annual conference October 25–27, 2022, and other organized information gathering activities. WEDI will compile and analyze this information and share the results with NCVHS by early December 2022. Additional information regarding the WEDI conference and its upcoming outreach efforts is available at: *https://www.wedi.org/about-us/* and *https://members.wedi.org/event-calendar.* The results of WEDI's upcoming information-gathering activities will be presented during NCVHS's January 18–19, 2023, hearing.

Sharon Arnold,

Associate Deputy Assistant Secretary, Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2022–23678 Filed 10–31–22; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Clinical Trials SEP (UG3, U24, R34).

Date: November 30, 2022.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Zhihong Shan, Ph.D., MD, Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 205–J, Bethesda, MD 20892, (301) 827–7085, *zhihong.shan@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 26, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–23686 Filed 10–31–22; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel R13 Conference Grant Review.

Date: December 1, 2022.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Tony L Creazzo, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 207–Q, Bethesda, MD 20892–7924, (301) 827–7913, *creazzotl@mail.nih.gov*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Diversity Training Grants.

Date: December 6, 2022.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Sun Saret, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–S, Bethesda, MD 20892, (301) 435–0270, *sun.saret@nih.gov.*

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel Catalyze: Enabling Technologies.

Date: December 14, 2022.

Time: 9:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Kristin Goltry, Ph.D.,Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 209–B, Bethesda, MD 20892, (301) 435–0297, *goltrykl@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood 2 Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 26, 2022.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2022–23692 Filed 10–31–22; 8:45 am]

BILLING CODE 4140–01–P