

part 606 have been approved under OMB control number 0910-116.

Dated: October 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Hearing

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee hearing.

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

Date and Times: Wednesday, December 12, 2018: 9 a.m.–5 p.m. (EST); Thursday, December 13, 2018: 9 a.m.–1 p.m. (EST).

Place: Omni Shoreham Hotel, 2500 Calvert Street NW, Washington, DC 20008.

Status: Open. There will be a public comment period during the final 15 minutes of both days of the meeting.

Purpose: Health Insurance Portability and Accountability Act (HIPAA) legislation from 1996, as amended,¹ directed the Secretary of Health and Human Services (HHS) to publish regulations adopting standards, code sets and identifiers to support the exchange of electronic health information between covered entities. The standards are for retail pharmacy and medical transactions.

In its capacity to advise the HHS Secretary on health data, statistics, privacy, national health information policy, and HIPAA, NCVHS is in the final stages of the development of a standards update and adoption roadmap, referred to as the Predictability Roadmap. The development of the Predictability Roadmap has been a year and a half long process, achieved in collaboration with industry stakeholders and the standards development organizations (SDOs). The overall vision for the Predictability Roadmap is that:

- HIPAA covered entities and their business associates use the adopted standards and operating rules in a consistent way to exchange health information and conduct business; and
- Standards are reliably updated and adopted so that covered entities know

when they will need to, and/or be able to update systems and business processes.

To accomplish this goal, NCVHS conducted several information gathering activities and stakeholder engagement meetings and workshops: In June 2017 the Subcommittee on Standards met with each of the standards development organizations (SDOs) to learn about their individual maintenance processes; in August 2017 the Subcommittee held a visioning exercise with the SDOs and Designated Standards Maintenance Organization (DSMO); and in May 2018, the Subcommittee conducted a CIO Forum with 21 health care technology experts and senior corporate officers representing a cross-section of organizations that were end-users of the HIPAA and ACA administrative standards. The goal of this Forum was to elicit input for improving the standards development, update and adoption process, and address barriers to use of those standards. Based on this work, the Subcommittee on Standards developed a draft Predictability Roadmap comprised of 23 recommendations organized under three major focus areas. The draft recommendations were presented at the September 13–14 NCVHS meeting and are posted on the website at: <https://ncvhs.hhs.gov/wp-content/uploads/2018/09/Presentation-NCVHS-Draft-Predictability-Roadmap-Recs-Coussoule-and-Goss.pdf>.

The purpose of this Subcommittee hearing is to obtain input from stakeholders on the draft recommendations designed to improve the processes for updating, adopting and using standards and operating rules, and developing a formal Predictability Roadmap. The Subcommittee will use the feedback received at this hearing to finalize recommendations to the Secretary of HHS.

Individuals and representatives of organizations interested in submitting written testimony are invited to respond to the following questions:

In general,

1. Would these recommendations as a whole improve the predictability of the adoption of administrative standards and operating rules?
2. What additional recommendations are critical to achieve predictability? And specifically,
3. What is the value proposition of each recommendation and what improvements to the current state do you believe will arise from each recommendation/group of similar recommendations?
4. Are there potential unintended consequences? What are those and how

can they be mitigated with modifications to the recommendations?

The questions outlined above can be used to guide written submissions to the Subcommittee. Written submissions should be sent electronically to NCVHSmal@cdc.gov with “Predictability Roadmap” in the subject line no later than November 20, 2018.

The times and topics for this meeting are subject to change. Please refer to the posted agenda at www.ncvhs.hhs.gov for any updates.

Contact Persons for More Information:

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, telephone (301) 458-4715. Information pertaining to meeting content may be obtained from Lorraine Doo, MSW, MPH, (410) 786-6597; and/or Geanelle G. Herring, MSW, (410) 786-4466; Centers for Medicare & Medicaid Services, Office of Information Technology, Division of National Standards, 7500 Security Boulevard, Baltimore, Maryland, 21244. Summaries of meetings and a roster of Committee members are available on the NCVHS website: www.ncvhs.hhs.gov where further information including an agenda and instructions to access the live audio broadcast of the meeting will be posted.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (770) 488-3210 as soon as possible.

Sharon Arnold,

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

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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

¹ Along with Section 1104(c) of the Patient Protection and Affordable Care Act (ACA) of 2010.

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; Review of NHLBI Cardiac Surgery Network Clinical Centers.

Date: November 14, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton BWI (Baltimore), 1100 Old Elkridge Landing Road, Baltimore, MD 21090.

Contact Person: Shelley S. Sehnert, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7206, Bethesda, MD 20892-7924, 301-435-0303, ssehnert@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Clinical Ancillary Studies (R01).

Date: November 16, 2018.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: YingYing Li-Smerin, MD, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7184, Bethesda, MD 20892-7924, 301-827-7942, lismerein@nhlbi.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Early Phase Clinical Trials (R61/R33).

Date: November 16, 2018.

Time: 1:30 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892 (Telephone Conference Call).

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, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892-7924, 301-827-7913, creazzotl@mail.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Early Phase Clinical Trials (R33).

Date: November 16, 2018.

Time: 2:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892 (Telephone Conference Call).

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, 6701 Rockledge Drive, Room 7180, Bethesda, MD 20892-7924, 301-827-7913, creazzotl@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 Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 16, 2018.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Complementary and Integrative Health; Notice of Meeting

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

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 Center for Complementary and Integrative Health Special Emphasis Panel, Early Phase Clinical Trials of Natural Products (NP).

Date: November 29, 2018.

Time: 12:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Martina Schmidt, Ph.D., Chief, Office of Scientific Review, National Center for Complementary and Integrative Health, NIH, 6707 Democracy Blvd., Suite 401, Bethesda, MD 20892, 301-594-3456, schmidma@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.213, Research and Training in Complementary and Integrative Health, National Institutes of Health, HHS)

Dated: October 16, 2018.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Center for Scientific Review Special Emphasis Panel; Fellowships: Physiology and Pathobiology of Cardiovascular and Respiratory Systems.

Date: November 6-7, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Richard D. Schneiderman, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4138, Bethesda, MD 20817, 301-402-3995, richard.schneiderman@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Biological Chemistry, Biophysics and Assay Development.

Date: November 8-9, 2018.

Time: 8:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: JW Marriott New Orleans, 614 Canal Street, New Orleans, LA 70130.

Contact Person: Vonda K. Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6188, MSC 7892, Bethesda, MD 20892, 301-435-1789, smithvo@csr.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Developmental Brain Disorders and Alzheimer's Disease Applications.

Date: November 8, 2018.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Seetha Bhagavan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194,