December 29, 2015 (80 FR 81335). Specific questions were posed to solicit input into the content of the draft guidance and comments were collected through Docket No. FDA–2012–N–1021. FDA also considered comments received on the draft guidance that appeared in the **Federal Register** of September 15, 2017 (82 FR 43390). FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

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 ''Utilizing Animal Studies to Evaluate Organ Preservation Devices.'' 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.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all CDRH guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Utilizing Animal Studies to Evaluate Organ Preservation Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500083 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information 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 the following FDA regulations and guidance and the Federal Food, Drug, and Cosmetic Act (FD&C Act) have been approved by OMB as listed in the following table:

21 CFR Part; guidance; or FD&C act section	Topic	OMB Control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''	De Novo classification process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756

Dated: May 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09402 Filed 5–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Council on Blood Stem Cell Transplantation

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice; correction.

SUMMARY: The Advisory Council on Blood Stem Cell Transplantation (ACBSCT) meeting has been rescheduled due to unforeseen circumstances and will now be held on Tuesday, July 2, 2019, from 10:00 a.m.–4:00 p.m. Eastern Time. The meeting will be held by webinar and conference call. The webinar link, conference call-in number, agenda, and instructions for registration will be posted 15 business days before the meeting on the ACBSCT website at *https://bloodcell.transplant.hrsa.gov/about/advisory_council/meetings/index.html.*

FOR FURTHER INFORMATION CONTACT: Robert Walsh, Designated Federal Officer, at the Healthcare Systems Bureau, Division of Transplantation, HRSA, 5600 Fishers Lane, 8W60, Rockville, Maryland 20857; 301–443–6839; or *RWalsh@hrsa.gov.*

New meeting date: Tuesday, July 2, 2019, rather than May 7, 2019, as previously announced.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2019–09434 Filed 5–7–19; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Visioning Session

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

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

Date and Times: Wednesday, July 10, 2019: 9:00 a.m.–5:00 p.m. (EDT), Thursday, July 11, 2019: 8:30 a.m.–5:00 p.m. (EDT).

Place: U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue SW, Rm. 505–A, Washington, DC 20201.

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

Purpose: Health Insurance Portability and Accountability Act (HIPAA) legislation from 1996, as amended,[1] established a regulatory framework to support the exchange of electronic information between covered entities, and directed the Secretary of Health and Human Services (HHS) to publish regulations adopting standards, code sets, and unique identifiers. The administrative simplification provisions of HIPAA pertain to retail pharmacy and medical transactions, such as eligibility, claims, payment, enrollment, and authorizations.

NCVHS advises the HHS Secretary on health data, statistics, privacy, national health information policy, and is mandated to report to Congress on the implementation status of HIPAA. Since mid-2017, the Subcommittee on Standards has been focused on developing a ''predictability roadmap'' through collaboration with industry to identify and evaluate barriers to the efficient and timely update and

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

adoption of standards and operating rules. NCVHS sought to identify and understand the challenges under the current standards development and regulatory processes. Based on feedback the Committee obtained from stakeholders over an eighteen-month period, in February 2019 the Committee delivered five recommendations to the HHS Secretary supporting the industry's need for trusted cadence to improve the updates, adoption and implementation of transaction standards and operating rules to keep pace with innovative business needs and technology changes. The five recommendations represented actionable steps for adopting, implementing, and enforcing the administrative simplification provisions of HIPAA.

One recommendation was specific to certain entities and processes related to the maintenance, modification, and recommendations to the Secretary for updated and new standards or transactions. Regarding this process, NCVHS urged HHS ''to re-evaluate the function and purpose of the Designated Standards Maintenance Organizations (DSMO).''

In the HIPAA Transaction and Code Sets final rule of August 2000 (65 FR 50312), the Secretary named the six DSMOs. After the publication of the final rule, the six organizations and the Secretary of HHS signed a Memorandum of Understanding (MOU) establishing a steering committee and formalizing the processes for reviewing updated or new standards in advance of a recommendation to NCVHS and the Secretary.

Between 2001 and 2004, the DSMO steering committee received more than 150 change requests. Today, the DSMO receives fewer than 10 change requests per year. The DSMO appears to have accomplished the purposes for which it was established.

To support future work the HHS Secretary may undertake regarding the NCVHS recommendation to re-evaluate the DSMO, the Subcommittee will conduct a facilitated visioning session with a group of industry stakeholders. The goal of this session is to develop a set of viable options for a next-generation DSMO.

Following the meeting, the Subcommittee plans to draft additional recommendations for the full Committee to consider for submission to the HHS Secretary. These recommendations will take into account the input received during the facilitated visioning session.

The times and topic for this meeting are subject to change. Participation in the visioning session will be by invitation in order to maximize effectiveness. Members of the public are welcome to submit comments and suggestions through August 20, 2019, to *ncvhsmail@cdc.gov.* Please refer to the posted agenda at *www.ncvhs.hhs.gov* for 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. To obtain information pertaining to meeting content, contact 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 and/or Lorraine Doo, MSWA, MPH, (410) 786–6597. Summaries of past 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 also be posted.

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

Dated: May 2, 2019.

Sharon Arnold,

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

[FR Doc. 2019–09460 Filed 5–7–19; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Statement of Organization, Functions, and Delegations of Authority: Office of the Assistant Secretary for Financial Resources

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) is updating a portion of one office, the Office of the Assistant Secretary for Financial Resources (ASFR), which is located within the Office of the Secretary (OS). ASFR is modifying its structure to streamline and improve operational functionality by replacing the Office of Grants and Acquisition Policy and Accountability (AMT) and establishing in its place the Office of Acquisitions (AMV), and the Office of Grants (AMU).

FOR FURTHER INFORMATION CONTACT: Jen Moughalian, Acting Assistant Secretary for Financial Resources, 200 Independence Ave. SW, Washington, DC 20201, (202) 690–6061. Part A, Office of the Secretary, Statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services (HHS) is being amended at Chapter AM, Office of Financial Resources, as last amended at 76 FR 69741–42, dated November 9, 2011, 74 FR 57679–82, dated November 9, 2009, and 74 FR 18238–39, dated April 21, 2009. This reorganization will eliminate the Office of Grants and Acquisition Policy and Accountability (AMT) within the Office of Financial Resources (ASFR) and establish the Office of Grants (AMU) and Office of Acquisitions (AMV). This reorganization will make the following changes under Chapter AM, Office of Financial Resources:

I. Under Section AM.10 Organization, delete in its entirety and replace with the following:

Section AM.10 Organization: The Office of Financial Resources is headed by the Assistant Secretary for Financial Resources (ASFR). The Assistant Secretary for Financial Resources is the Departmental Chief Financial Officer (CFO), Chief Acquisition Officer (CAO) and Performance Improvement Officer (PIO), and reports to the Secretary. The office consists of the following components:

- Immediate Office of the Assistant Secretary (AM).
- Office of Budget (AML).
- Office of Finance (AMS).
- Office of Grants (AMU).
- Office of Acquisitions (AMV).

II. Under Chapter AM, ''Office of the Assistant Secretary for Financial Resources,'' delete Chapter AMT, ''Office of Grants and Acquisition Policy and Accountability,'' in its entirety and replace with the following:

Chapter AMU, Office of Grants (AMU)
Section AMU.00 Mission

The Office of Grants (OG) provides Department-wide leadership, guidance, and oversight to constituent organizations, and coordinates long and short-range planning for HHS' grants management policies, practices, systems and workforce. OG provides technical assistance to the Department's OPDIVs and STAFFDIVs, evaluates effectiveness of the grants programs and processes; develops pertinent HHS-wide regulatory guidance, policies, and performance standards; maintains and reports