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 Specific questions were posed to solicit input into the content of the draft guidance and comments were collected through Docket No. FDA–2012–N–1021. FDA also considered comments received on the draft guidance that appeared in the **Federal Register** of September 15, 2017 (82 FR 43390).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

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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.