major health agencies within HHS—CDC, Centers for Medicare & Medicaid Services, FDA, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, National Library of Medicine, Office of the National Coordinator for Health Information Technology, Office of Public Health and Science, and Substance Abuse and Mental Health Services Administration—as well as the DoD and VA.

When developing Common Formats, AHRQ first reviews existing patient safety practices and event reporting systems. In collaboration with the PSWG and Federal subject matter experts, AHRQ drafts and releases beta versions of the Common Formats for public review and comment. The PSWG assists AHRQ with assuring the consistency of definitions/formats with those of relevant government agencies as refinement of the Common Formats continues.

Since the initial release of the Common Formats in August 2008, AHRQ has regularly revised the formats based upon public comment. AHRQ solicits feedback on beta (and subsequent) versions of Common Formats from private sector organizations and individuals. Based upon the feedback received, AHRQ further revises the Common Formats. To the extent practicable, the Common Formats are also aligned with World Health Organization (WHO) concepts, frameworks, and definitions.

Participation by the private sector in the development and subsequent revision of the Common Formats is achieved through working with the NQF. The Agency engages the NQF, a non-profit organization focused on health care quality, to solicit comments and advice regarding proposed versions of the Common Formats. AHRQ began this process with the NQF in 2008, receiving feedback on AHRQ's 0.1 Beta release of the Common Formats for Event Reporting—Hospital. After receiving public comment, the NQF solicits the review and advice of its Common Formats Expert Panel and subsequently provides feedback to AHRQ. The Agency then revises and refines the Common Formats and issues them as a production version. AHRQ has continued to employ this process for all subsequent versions of the Common Formats.

The technical specifications promote standardization of collected patient safety event information by specifying rules for data collection and submission, as well as by providing guidance for how and when to create data elements, their valid values, conditional and go-to logic, and reports. These specifications will ensure that data collected by PSOs and other entities have comparable clinical meaning.

The technical specifications also provide direction to software developers, so that the Common Formats can be implemented electronically, and to PSOs, so that the Common Formats can be submitted electronically to the Patient Safety Organization Privacy Protection Center (PSOPPC) for data de-identification and transmission to the NPSD.

Common Formats technical specifications consist of the following:

- Data dictionary—defines data elements and their attributes (data element name, answer values, field length, guide for use, etc.) included in Common Formats;
- Clinical document architecture (CDA) implementation guide—provides instructions for developing a file to transmit the Common Formats Patient Safety data from the PSO to the PSOPPC using the Common Formats;
- Validation rules and errors document—specifies and defines the validation rules that will be applied to the Common Formats data elements submitted to the PSOPPC;
- Common Formats flow charts—diagrams the valid paths to complete generic and event specific formats (a complete event report);
- Local specifications—provides specifications for processing, linking and reporting on events and details specifications for reports; and
- Metadata registry—includes descriptive facts about information contained in the data dictionary to illustrate how such data corresponds with similar data elements used by other Federal agencies and standards development organizations [*e.g.,* HL—7, International Standards Organization (ISO)].

Agenda, Registration, and Other Information about the Meeting

The 2016 meeting will be an interactive forum designed to allow meeting participants not only to provide input but also to respond to the input provided by others. The meeting agenda will include: an update of Federal efforts related to the Common Formats, including development of formats for new settings; Common Formats software products demonstrations; a discussion of data integrity related to submission of patient safety adverse events; and a question and answer session.

AHRQ requests that interested persons send an email to the PSOPPC at *support@psoppc.org* for registration information. Before the meeting, a detailed agenda and logistical information will be provided to registrants. Prior to the meeting, AHRQ invites review of the technical specifications for Common Formats which can be accessed through AHRQ's PSO Web site at *https://www.psoppc.org/psoppc_web/publicpages/commonFormatsOverview.*

Sharon B. Arnold,

AHRQ Deputy Director.

[FR Doc. 2016–01353 Filed 1–25–16; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Request for Nominations of Candidates To Serve on the Advisory Committee on Immunization Practices (ACIP)

The Centers for Disease Control and Prevention (CDC) is soliciting nominations for membership on ACIP. The ACIP consists of 15 experts in fields associated with immunization, who are selected by the Secretary of the U.S. Department of Health and Human Services (HHS) to provide advice and guidance to the Secretary, the Assistant Secretary for Health, and the CDC on the control of vaccine-preventable diseases. The role of the ACIP is to provide advice that will lead to a reduction in the incidence of vaccine preventable diseases in the United States, and an increase in the safe use of vaccines and related biological products. The committee also establishes, reviews, and as appropriate, revises the list of vaccines for administration to children eligible to receive vaccines through the Vaccines for Children (VFC) Program.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the committee's objectives. Nominees will be selected based on expertise in the field of immunization practices; multi-disciplinary expertise in public health; expertise in the use of vaccines and immunologic agents in both clinical and preventive medicine; knowledge of vaccine development, evaluation, and vaccine delivery; or knowledge about consumer perspectives and/or social and community aspects of immunization programs. Federal employees will not be considered for membership. Members may be invited to serve for four-year terms.

The next cycle of selection of candidates will begin in the fall of 2016,

for selection of potential nominees to replace members whose terms will end on June 30, 2017. Selection of members is based on candidates' qualifications to contribute to the accomplishment of ACIP objectives (*http://www.cdc.gov/vaccines/acip/index.html*). The U.S. Department of Health and Human Services policy stipulates that committee membership be balanced in terms of professional training and background, points of view represented, and the committee's function. Consideration is given to a broad representation of geographic areas within the U.S., with equitable representation of the sexes, ethnic and racial minorities, and persons with disabilities. Nominees must be U.S. citizens, and cannot be full-time employees of the U.S. Government. Candidates should submit the following items:

- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address)
- At least one letter of recommendation from person(s) not employed by HHS *

The deadline for receipt of all application materials (for consideration for term beginning July 1, 2017) is November 4, 2016. All files must be submitted electronically as email attachments to: Ms. Stephanie Thomas, ACIP Secretariat, Email: *SThomas5@cdc.gov.*

Nominations may be submitted by the candidate him- or herself, or by the person/organization recommending the candidate.

* Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by HHS (*e.g.,* CDC, NIH, FDA, etc.).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–01443 Filed 1–25–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Health Statistics (BSC, NCHS)

Notice of Cancellation: This notice was published in the **Federal Register** on December 23, 2015, Volume 80, Number 246, pages 79899–79900. The meeting previously scheduled to convene on January 21–22, 2016, has been cancelled.

Contact Person for More Information: Virginia S. Cain, Ph.D., Director of Extramural Research, NCHS/CDC, 3311 Toledo Road, Room 7208, Hyattsville, Maryland 20782, Telephone (301) 458–4395, Fax (301) 458–4020, Email: *vcain@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–01442 Filed 1–25–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4852]

Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled ''Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices''. FDA is issuing this draft guidance to assist industry and FDA staff in identifying specific considerations related to the ability of electronic medical devices to safely and effectively exchange and use exchanged information. This document highlights considerations that should be included in the development and design of interoperable medical devices and provides recommendations for the content of premarket submissions and labeling for such devices. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 28, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions''.