application form and rank applications by reported hypertension control rate.

In the second phase of assessment, applicants with the highest preliminary scores are asked to participate in a two-hour data verification and validation process. The applicant reviews the application form with a reviewer, describes how information was obtained from the providers', practices', or healthcare systems' electronic records, chart reviews, or other sources, and reviews the methodology used to calculate the reported hypertension control rate. Data verification and validation is conducted to ensure that all applicants meet eligibility criteria and assure accuracy of their reported hypertension control rate according to a standardized method. Applicants must have achieved a hypertension control rate of at least 80% among their adult patients aged 18–85 years with hypertension.

Finalists who pass the data verification and validation process and background check will be reviewed by a CDC panel of judges to determine the Champion status. Several Champions will be asked to participate in a one-hour, semi-structured interview and provide detailed information about the patient population served, the geographic region served, and the strategies employed by the practice or health system to achieve exemplary rates of hypertension control, including barriers and facilitators for those strategies. Based on the information collected for Challenges in 2013 through 2017, CDC recognized a total of 83 public and private health care practices and systems as Million Hearts® Hypertension Control Champions. The Champions are announced roughly annually, approximately six months after the Challenge application period ends. The current OMB approval for information collection expires December 31, 2019.

CDC plans to continue the Million Hearts® Hypertension Control Challenge through 2022 with revisions. The 2020 Challenge is planned to launch in February 2020, coinciding with American Heart Month. The application period will be open for approximately 45–60 days, with recognition of the 2020 Champions in the fall of 2020. A similar calendar year schedule is planned for 2021 and 2022. Revision for 2020, 2021, and 2022 includes a reduction in the estimated number of respondents. During the period of this Renewal request, on an annual basis, CDC estimates that information will be collected from up to 200 applicants using the application form, at most 40 data verifications, and at most 35 semi-structured interviews. There is an overall reduction in estimated annualized burden hours.

The overall goal of the Million Hearts® initiative is to prevent one million heart attacks and strokes, and controlling hypertension is one focus of the initiative. CDC will use the information collected through the Million Hearts® Hypertension Control Challenge to increase widespread attention to hypertension at the clinical practice level, improve understanding of successful and sustainable implementation strategies at the practice or health system level, bring visibility to organizations that invest in hypertension control, and motivate individual practices to strengthen their hypertension control efforts. Information collected through the

Million Hearts® Hypertension Control Challenge will link success in clinical outcomes of hypertension control with information about strategies that can be used to achieve similar favorable outcomes so that the strategies can be replicated by other providers and health care systems.

OMB approval for a revision is requested for three years. CDC estimates that up to 200 applicants will submit an application covered by this information collection each year. It is estimated that information collection activities will total 215 burden hours per year. This represents a decrease in the estimated annualized burden hours from 370 hours to 215 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Physicians, Practices, and healthcare systems.	Million Hearts® Hypertension Control Champion Application form.	200	1	30/60	100
Finalists	Data Verification Form	40	1	2	80
Champions	Semi-structured interview guide	35	1	1	35
Total					215

Jeffrey M. Zirger,

Acting Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2018–26876 Filed 12–11–18; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Administration on Intellectual and Developmental Disabilities, President's Committee for People With Intellectual Disabilities

AGENCY: Administration for Community Living, HHS.

ACTION: Notice of rescheduled meeting due to the closure of federal offices on December 5, 2018.

SUMMARY: The President's Committee for People with Intellectual Disabilities (PCPID) will host a webinar/conference call for its members to discuss the potential topics of the Committee's 2019 Report to the President. All the PCPID meetings, in any format, are open to the public. This virtual meeting will be conducted in a discussion format.

DATES: *Webinar/Conference Call:* Wednesday, December 12, 2018 from 9:00 a.m. to 10:00 a.m. (EST).

FOR FURTHER INFORMATION CONTACT: For further information and accommodations needs, please contact Ms. Allison Cruz, Director, Office of Innovation, 330 C Street SW, Switzer Building, Room 1114, Washington, DC

20201. Telephone: 202–795–7334. Fax: 202–795–7334. Email: *allison.cruz@acl.hhs.gov.*

SUPPLEMENTARY INFORMATION: The purpose of this virtual meeting is to discuss the Committee's preparation of the 2019 Report to the President, including its content and format, and related data collection and analysis required to complete the writing of the Report. This meeting was originally scheduled for December 5 from 9:00–10:00 a.m. (EST). This meeting is rescheduled to December 12 from 9:00–10:00 a.m. (EST) due to the closure of Federal offices on December 5 and to allow for the call to occur before the end of year.

Agenda: The Committee will discuss the preparation of the PCPID 2019 Report to the President, including its content and format, and related data collection and analysis required to complete the writing of the Report.

Webinar/Conference Call: The webinar/conference call is scheduled for Wednesday, December 12, 2018, 9:00 a.m. to 10:00 a.m. (EST) and may end early if discussions are finished.

Instructions to Participate in the Webinar/Conference Call on Wednesday, December 12, 2018: Please dial: (888) 949–2790; Pass Code: 1989852.

Background Information on the Committee: The PCPID acts in an advisory capacity to the President and the Secretary of Health and Human Services on a broad range of topics relating to programs, services and support for individuals with intellectual disabilities. The PCPID executive order stipulates that the Committee shall: (1) Provide such advice concerning intellectual disabilities as the President or the Secretary of Health and Human Services may request; and (2) provide advice to the President concerning the following for people with intellectual disabilities: (A) Expanding employment opportunities; (B) connecting people to services; (C) supporting families and caregivers; (D) strengthening the networks; and (E) protecting rights and preventing abuse.

Dated: December 6, 2018.

Julie Hocker,

Commissioner, Administration on Disabilities (AoD).

[FR Doc. 2018–26857 Filed 12–11–18; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4267]

Biomarker Qualification: Evidentiary Framework; 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 a draft guidance for industry and FDA staff entitled ''Biomarker Qualification: Evidentiary Framework.'' This draft guidance provides recommendations on general considerations to address when developing a biomarker for qualification under the 21st Century Cures Act (Cures Act), enacted on December 13, 2016, that added a new section to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Qualification of a biomarker is a determination that within the stated context of use, the biomarker can be relied on to have a specific interpretation and application in drug development and regulatory review.

DATES: Submit either electronic or written comments on the draft guidance by February 11, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–4267 for ''Biomarker Qualification: Evidentiary Framework; Draft Guidance for Industry and FDA Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be 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.gpo.gov/*