protections requirements should be applied to research studying one or more interventions which are used as standard of care treatment in the non-research context. HHS specifically is requesting input regarding how an IRB should assess the risks of research involving randomization to one of more standard of care interventions, and what reasonably foreseeable risks of the research should be disclosed to research subjects in the informed consent process. This meeting and the written comments are intended to assist HHS, through the OHRP, OASH, in developing guidance regarding what constitutes reasonably foreseeable risk in research involving standard of care interventions such that the risk is required to be disclosed to research subjects.

While HHS is considering whether other processes should be incorporated into OHRP's compliance oversight procedures and guidance, including, but not limited to, consultation with subject matter experts during the course of a compliance oversight investigation, and an administrative process for appealing OHRP determinations of noncompliance, this meeting is not intended to specifically address possible revisions to OHRP's compliance oversight procedures.

B. Format of the Meeting

The meeting will be conducted by a panel of HHS officials, including the Director of OHRP. The majority of the meeting will be reserved for presentations of comments, recommendations, and data from registered presenters. The time for each presenter's comments will be determined by HHS and will be based on the number of registered presenters. Presenters will be scheduled to speak in the order in which they register. Only the HHS panel members may question any presenter during or at the conclusion of each presentation. The meeting will be recorded and transcribed.

In addition, written comments will also be accepted and presented at the meeting, time permitting, if they are received by the date specified in the **DATES** section of this notice.

C. Security and Building Guidelines

Because the public meeting will be located on federal property, for security reasons any persons wishing to attend this meeting must register by the date specified in the **DATES** section of this notice. Attendees should allow sufficient time to go through the security checkpoints. Attendees should arrive at the Hubert H. Humphrey Building no later than 8:30 a.m.

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Guard Service personnel.
- Passing through a metal detector and inspection of items brought into the building; note that all items brought to HHS are subject to inspection.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting in person. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting(s). All visitors must be escorted while in the building.

D. Live Streaming Information

For participants who cannot attend the public meeting in person there will be an option to view the public meeting via live streaming technology. Information on the option to view the meeting via live streaming technology will be posted at a later time on the OHRP Web site at *http://www.hhs.gov/ohrp.* Any other updates to information on the meeting will be posted on the OHRP Web site.

III. Issues for Discussion

HHS invites comment at the public meeting about how an IRB should assess the risks of research involving randomization to one or more standard of care interventions, and what risks of the research should be disclosed to research subjects in the informed consent process. HHS is specifically interested in public input on the following questions:

1. How should an IRB assess the risks of standard of care interventions provided to subjects in the research context?

a. Under what circumstances should an IRB consider those to be risks that may result from the research?

b. Under what circumstances should an IRB refrain from considering those risks as unrelated to the research?

c. What type of evidence should an IRB evaluate in identifying these risks?

2. What factors should an IRB consider in determining that the research-related risks of standard of care interventions, provided to research subjects in the research context, are reasonably foreseeable and therefore required to be disclosed to subjects?

a. What criteria should be used by the IRB to evaluate whether the risks to subjects are reasonably foreseeable?

3. How should randomization be considered in research studying one or more interventions within the standards of care? Should the randomization procedure itself be considered to present a risk to the subjects? Why or why not? If so, is the risk presented by randomization more than minimal risk? Should an IRB be allowed to waive informed consent for research involving randomization of subjects to one or more standard of care interventions? Why or why not?

4. How, and to what extent, does uncertainty about risk within the standard of care affect the answers to these questions? What if the risk significantly varies within the standard of care?

5. Under what circumstances do potential risks qualify as reasonably foreseeable risks? For example, is it sufficient that there be a documented belief in the medical community that a particular intervention within the standard of care increases the risk of harm, or is it necessary that there be published studies identifying the risk?

IV. Transcripts

As soon as a transcript of the public meeting is available, it will be accessible on the OHRP Web site, *http://www.hhs.gov/ohrp.* A transcript also will be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the PHS FOIA Office, 7700 Wisconsin Avenue, Suite #920, Bethesda, MD 20857; telephone (301) 492–4800; fax (301) 492–4848; email *FOIARequest@psc.hhs.gov*.

Dated: June 19, 2013.

Howard K. Koh,

Assistant Secretary for Health.

[FR Doc. 2013–15160 Filed 6–25–13; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health

AGENCY: Office of the Surgeon General of the United States Public Health Service, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In accordance with Section 10(a) of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App.), notice is hereby given that a meeting is scheduled to be held for the Advisory Group on Prevention, Health Promotion, and Integrative and Public Health (the ''Advisory Group''). The meeting will be open to the public.

Information about the Advisory Group and the agenda for this meeting can be obtained by accessing the following Web site: *http://www.surgeongeneral.gov/initiatives/prevention/advisorygrp/index.html.*

DATES: The meeting will be held on July 15, 2013 from 12–2 p.m.

ADDRESSES: The meeting will be held via teleconference. For conference information and to register for the meeting, please send an email to *prevention.council@hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Office of the Surgeon General, 200 Independence Ave. SW.; Hubert H. Humphrey Building, Room 701H; Washington, DC 20201; 202–205–9517; *prevention.council@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Advisory Group is a non-discretionary Federal advisory committee that was initially established under Executive Order 13544, dated June 1, 2012, to comply with the statutes under Section 4001 of the Patient Protection and Affordable Care Act, Public Law 111–148. The Advisory Group was established to assist in carrying out the mission of the National Prevention, Health Promotion, and Public Health Council (the Council). The Advisory Group provides recommendations and advice to the Council. Under Executive Order 13591, dated November 23, 2011, operation of the Advisory Group was terminated on September 30, 2012. On December 7, 2012, President Obama issued Executive Order 13631 to re-establish the Advisory Group. The Advisory Group is authorized to operate until September 30, 2013.

It is authorized for the Advisory Group to consist of not more than 25 non-federal members. The Advisory Group currently has 22 members who were appointed by the President. The membership includes a diverse group of licensed health professionals, including integrative health practitioners who have expertise in (1) worksite health promotion; (2) community services, including community health centers; (3) preventive medicine; (4) health coaching; (5) public health education; (6) geriatrics; and (7) rehabilitation medicine.

This will be the eighth meeting of the Advisory Group. Topics for discussion during this meeting include the status of the Advisory Group's third set of recommendations, updates from the working groups, and the draft agenda for the next Advisory Group meeting, which is planned to be held on September 26–27, 2013.

Members of the public who wish to attend must register by 12:00 p.m. EST on July 10, 2013. Individuals should register for public attendance at *prevention.council@hhs.gov* by providing your full name and affiliation. The public will have the opportunity to provide comments to the Advisory Group during this meeting; public comment will be limited to 3 minutes per speaker. Registration through the designated contact for the public comment session is also required.

Dated: June 20, 2013.

Corinne M. Graffunder,

Designated Federal Officer, Advisory Group on Prevention, Health Promotion, and Integrative and Public Health Office of the Surgeon General.

[FR Doc. 2013–15324 Filed 6–25–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Advisory Council on Alzheimer's Research, Care, and Services; Meeting

AGENCY: Assistant Secretary for Planning and Evaluation, HHS.

ACTION: Notice of meeting.

SUMMARY: This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer's Research, Care, and Services provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. During the July meeting, the Advisory Council will discuss the *National Plan to Address Alzheimer's Disease: 2013 Update,* and the 2013 recommendations. The Advisory Council will discuss international activities related to Alzheimer's disease since the April meeting. The Advisory Council will discuss issues related to long-term care financing.

DATES: The meeting will be held on July 19, 2013 from 9:00 a.m. to 5:00 p.m. EDT.

ADDRESSES: The meeting will be held at the U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 800, Washington, DC 20201.

Comments: Time is allocated on the agenda to hear public comments. In lieu of oral comments, formal written comments may be submitted for the record to Helen Lamont, Ph.D., OASPE, 200 Independence Avenue SW., Room 424E, Washington, DC 20201. Comments may also be sent to *napa@hhs.gov.* Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Helen Lamont, Ph.D. (202) 690–7996, *helen.lamont@hhs.gov.* Note: Seating may be limited. Those wishing to attend the meeting must send an email to *napa@hhs.gov* and put ''July 19 meeting attendance'' in the Subject line by Friday, July 5, 2013, so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

SUPPLEMENTARY INFORMATION: Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: The Advisory Council will discuss the *National Plan to Address Alzheimer's Disease: 2013 Update,* and the 2013 recommendations. The Advisory Council will discuss international activities related to Alzheimer's disease since the April meeting. The Advisory Council will discuss issues related to long-term care financing.

Procedure and Agenda: This meeting is open to the public.

Authority: 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92–463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: June 25, 2013.

Donald Moulds,

Acting Assistant Secretary for Planning and Evaluation.

[FR Doc. 2013–15326 Filed 6–25–13; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Subcommittee on Procedures Review, Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act