responsibilities regarding the maintenance and availability of inventory records of assets. Without this information or ability to access the information, after an ownership change, the Government would be unable to ascertain whether contractor assets were properly valuated. The cost principles at FAR 31.205–52 address the allowability of certain costs resulting from asset valuations following business combinations. In order to administer the cost principles adequately, the information required by FAR 52.215–19 is necessary.

Comment: The respondent commented that the agency did not accurately estimate the public burden challenging that the agency's methodology for calculating it is insufficient and inadequate and does not reflect the total burden.

Response: Serious consideration is given, during the open comment period, to all comments received and adjustments are made to the paperwork burden estimate based on reasonable considerations provided by the public. This is evidenced, as the respondent notes, in FAR Case 2007–006 where an adjustment was made from the total preparation hours from three to 60. This change was made considering particularly the hours that would be required for review within the company, prior to release to the Government.

The burden is prepared taking into consideration the necessary criteria in OMB guidance for estimating the paperwork burden put on the entity submitting the information. For example, consideration is given to an entity reviewing instructions; using technology to collect, process, and disclose information; adjusting existing practices to comply with requirements; searching data sources; completing and reviewing the response; and transmitting or disclosing information. The estimated burden hours for a collection are based on an average between the hours that a simple disclosure by a very small business might require and the much higher numbers that might be required for a very complex disclosure by a major corporation. Also, the estimated burden hours should only include projected hours for those actions which a company would not undertake in the normal course of business.

Upon consideration of the respondent's comments and review of Fiscal Year 2012 (FY12) Federal Procurement Data System (FPDS) information an adjustment is being made to the estimated annual burden. Based on FPDS information approximately 1200 novations and non-novated mergers and acquisitions were recorded in FY12 as descriptions for modifications. However, it is estimated that 50 percent or 600 of such actions will require the contractor to meet the requirements specified at FAR 52.215–19. The clause is only required to be inserted in solicitations and contracts for which it is contemplated that certified cost or pricing data will be required or for which any pre-award or post-award cost determination will be subject to *Subpart 31.2.* The estimate of hours per response is adjusted upwards to partly allow for the internal coordination and analysis before submitting the information to the Government as stated by the respondent. However the significant adjustment suggested was not made because, apart from a notification to the ACO, the requirements of the clause are passive, requiring contractors to maintain rather than to create records to meet the specific requirements for Government submission, and should be part of the normal course of doing business. At any point, members of the public may submit comments for further consideration, and are encouraged to provide data to support their request for an adjustment.

C. Annual Reporting Burden

Respondents: 600.

Responses per Respondent: 1.

Total Responses: 600.

Hours per Response: 5.

Total Burden Hours: 3000.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat (MVCB), 1275 First Street NE., Washington, DC 20417, telephone (202) 501–4755. Please cite OMB Control No. 9000–0115, Notification of Ownership Changes, in all correspondence.

Dated: June 21, 2013.

William Clark,

Acting Director, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2013–15300 Filed 6–25–13; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of a Department of Health and Human Services Public Meeting and Request for Comments on Matters Related to the Protection of Human Subjects and Research Studying Standard of Care Interventions

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of meeting and request for comments.

SUMMARY: The Department of Health and Human Services (HHS) is announcing a public meeting to seek public input and comment on how certain provisions of the HHS requirements related to the protection of human subjects 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 institutional review board (IRB) should assess the risks of research involving randomization to one or more treatments within the standard of care for particular interventions, and what reasonably foreseeable risks of the research should be disclosed to research subjects in the informed consent process. HHS is seeking participation in the meeting and written comments from all interested parties, including, but not limited to, IRB members, IRB staff, institutional officials, research institutions, investigators, research subject advocacy groups, ethicists, and the regulated community at large. This meeting and the written comments are intended to assist HHS, through the Office for Human Research Protections (OHRP), Office of the Assistant Secretary for Health (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. HHS is seeking input on a number of specific questions but is interested in any other pertinent information participants in the public meeting would like to share.

DATES: *Meeting:* The public meeting will be held on August 28, 2013, from 9 a.m. to 5 p.m.

Deadline for Registration for Participants (not Presenting) at the Public Meeting and Submitting Requests for Special Accommodations: Registration to attend the public meeting and requests for special accommodations must be received no later than 5 p.m. on August 14, 2013.

Deadline for Registration of Presenters at the Public Meeting: Registration to present at the public meeting must be received no later than 5 p.m. on August 7, 2013.

Deadline for Submission of Written Comments for the Public Meeting: Written comments for discussion at the public meeting must be received no later than 5 p.m. on August 7, 2013. In addition to materials submitted for discussion at the public meeting, individuals may submit other written comments after the public meeting, as specified in the **ADDRESSES** section of this notice. These comments must be received no later than 5 p.m. on September 9, 2013, for consideration by HHS.

ADDRESSES: The Public Meeting will be held at the Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Ave. SW., Great Hall, Washington, DC 20201; Metro: Federal Center SW station.

In addition, we are providing an alternative to attending the meeting in person; participants may view the public meeting via live streaming technology. Information on that option is provided in section II.D. of this notice.

Registration and Special Accommodations: While there is no registration fee, individuals planning to attend the public meeting in person must register to attend. Registration may be completed by sending an email to *OHRP@hhs.gov*, with the subject line ''Registration for HHS Public Meeting''; or a request to register may be sent to: Registration for HHS Public Meeting, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852. Please include your name, address, telephone number, email address, and fax number. If you would like to present at the public meeting, please state this in the registration submission.

Registration to attend the public meeting will be accepted on a first-come, first-served basis. If seating capacity has been reached, you will be notified that the meeting has reached capacity.

Registration to present at the public meeting will be accepted on a first-come, first-served basis. HHS has included questions for comment in section III of this document. Please identify by number each question you wish to address in your presentation and the approximate time requested. HHS will do its best to accommodate requests to speak. HHS will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin. Once HHS notifies registered presenters of their scheduled times, presenters should submit a copy of each presentation, identified with docket number HHS–OPHS–2013–0004, to *http://www.regulations.gov.*

Individuals who need special accommodations should contact staff listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Submission of Comments for the Public Meeting

Submit electronic comments, identified with docket number HHS–OPHS–2013–0004, to *http://www.regulations.gov.*

Submit written comments to Comments for HHS Public Meeting, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Dr. Jerry Menikoff, Director, Office for Human Research Protections, Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, MD 20852; phone 240–453–6900; email *Jerry.Menikoff@hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. HHS Protection of Human Subjects Regulations

HHS, through OHRP, regulates research involving human subjects conducted or supported by HHS in regulations. The HHS human subjects protection requirements pertain to several different entities, including the IRB charged with reviewing non-exempt human subjects research.

The IRB is an administrative body that takes the form of a board, committee, or group, and is responsible for conducting the initial and continuing review of research involving human subjects. The IRB must have authority to approve, require modification in (in order to secure approval), or disapprove all research activities regulated by HHS. An IRB's primary purpose in reviewing research is to ensure the protection of the rights and welfare of human research subjects. In order to approve research, an IRB is required to make certain determinations, including that the following criterion is met:

> Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

The HHS human subjects protections further require that, unless this requirement is waived by the IRB, an investigator must obtain informed consent from research subjects prior to the subjects' participation in the research, and that, in this informed consent process, the subjects must be provided ''a description of any reasonably foreseeable risks or discomforts to the subject.''

B. OHRP's Compliance Oversight Investigation of SUPPORT

On March 7, 2013, OHRP issued a compliance oversight determination letter regarding its investigation into ''The Surfactant, Positive Pressure, and Oxygenation Randomized Trial'' (SUPPORT) clinical trial (*http://www.hhs.gov/ohrp/detrm_letrs/YR13/mar13a.pdf*), in which OHRP determined that certain risks related to the interventions being studied in the SUPPORT trial were required by the HHS protection of human subjects regulations to be disclosed to the research subjects, and the subjects were not informed of these risks. OHRP's view of the SUPPORT trial, as described in this determination letter, triggered extensive public discussions regarding (1) what risks to subjects are presented by clinical trials studying interventions that are standard of care in the clinical treatment context, such that an IRB must evaluate those risks in relation to the anticipated benefits of the research; and (2) how an IRB should assess whether those risks are reasonably foreseeable such that the risks must be described to subjects in informed consent. Through the public reaction to OHRP's determination letter, HHS has become aware of differing perspectives in the scientific, research, and ethics communities about these issues and how the relevant requirements of the HHS protection of human subjects regulations should apply to research studying standard of care interventions.

II. Public Meeting

A. Purpose and Scope of the Meeting

The public meeting is intended to provide an opportunity for broad public participation and comment concerning how the HHS human subjects

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.