### TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS—Continued

[New burdens associated with the final rule]

<table>
<thead>
<tr>
<th>Section</th>
<th>Type of respondent</th>
<th>Number of respondents</th>
<th>Average number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>164.520</td>
<td>Dissemination of Notice of Privacy Practices for Protected Health Information (health plans).</td>
<td>20,000,000</td>
<td>1</td>
<td>.00333335</td>
<td>66,667</td>
</tr>
<tr>
<td>164.520</td>
<td>Revision of Notice of Privacy Practices (providers).</td>
<td>697,000</td>
<td>1</td>
<td>.11111</td>
<td>77,444</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>619,278</td>
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</tbody>
</table>

### ONGOING ANNUAL BURDENS OF COMPLIANCE WITH THE RULES

<table>
<thead>
<tr>
<th>Section</th>
<th>Type of respondent</th>
<th>Number of respondents</th>
<th>Average number of responses per respondent</th>
<th>Average burden hours per response</th>
<th>Total burden hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>160.204</td>
<td>Process for Requesting Exception Determinations (states or persons).</td>
<td></td>
<td>1</td>
<td>16</td>
<td>16</td>
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<tr>
<td>164.504</td>
<td>Uses and Disclosures—Organizational Requirements ....</td>
<td>700,000</td>
<td>1</td>
<td>5/60</td>
<td>58,333</td>
</tr>
<tr>
<td>164.508</td>
<td>Uses and Disclosures for Which Individual authorization is required.</td>
<td>700,000</td>
<td>1</td>
<td>1</td>
<td>700,000</td>
</tr>
<tr>
<td>164.512</td>
<td>Uses and Disclosures for Research Purposes ...............</td>
<td>113,524</td>
<td>1</td>
<td>5/60</td>
<td>9,460</td>
</tr>
<tr>
<td>164.520</td>
<td>Notice of Privacy Practices for Protected Health Information (health plans—periodic distribution of NPPs by paper mail).</td>
<td>100,000,000</td>
<td>1</td>
<td>0.25</td>
<td>416667</td>
</tr>
<tr>
<td>164.520</td>
<td>Notice of Privacy Practices for Protected Health Information (health care providers—dissemination and acknowledgement).</td>
<td>100,000,000</td>
<td>1</td>
<td>0.167</td>
<td>278333</td>
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<tr>
<td>164.520</td>
<td>Notice of Privacy Practices for Protected Health Information (health plans—periodic distribution of NPPs by electronic mail).</td>
<td>613,000,000</td>
<td>1</td>
<td>3/60</td>
<td>30,650,000</td>
</tr>
<tr>
<td>164.522</td>
<td>Rights to Request Privacy Protection for Protected Health Information.</td>
<td>150,000</td>
<td>1</td>
<td>3/60</td>
<td>7,500</td>
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<tr>
<td>164.524</td>
<td>Access of Individuals to Protected Health Information (disclosures).</td>
<td>150,000</td>
<td>1</td>
<td>3/60</td>
<td>7,500</td>
</tr>
<tr>
<td>164.526</td>
<td>Amendment of Protected Health Information (requests)</td>
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<td>1</td>
<td>3/60</td>
<td>7,500</td>
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<tr>
<td>164.528</td>
<td>Amendment of Protected Health Information (denials) ....</td>
<td>50,000</td>
<td>1</td>
<td>3/60</td>
<td>2,500</td>
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<tr>
<td>164.528</td>
<td>Accounting for Disclosures of Protected Health Information.</td>
<td>70,000</td>
<td>1</td>
<td>3/60</td>
<td>5,833</td>
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<td>Total</td>
<td></td>
<td></td>
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<td></td>
<td>32,143,642</td>
</tr>
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</table>

Total Hours: 32,762,920.

Darius Taylor,
Deputy Information Collection Clearance Officer.
[FR Doc. 2013–22148 Filed 9–11–13; 8:45 am] BILLING CODE 4153–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

National Foundation on Fitness, Sports, and Nutrition Establishment Act; Delegation of Authority; Office of the Assistant Secretary for Health

Notice is hereby given that I have delegated to the Assistant Secretary for Health authority under Section 5 of the National Foundation on Fitness, Sports, and Nutrition Establishment Act, Public Law 111–332 (Dec. 22, 2010). The delegation excludes the authorities to issue regulations and to submit reports to the Congress. This authority may be re-delegated.

I hereby affirm and ratify any actions taken by the Assistant Secretary for Health, or his subordinates, which involved the exercise of this authority delegated herein prior to the effective date of this delegation of authority.

This delegation is effective upon date of signature.

Dated: September 6, 2013.
Kathleen Sebelius,
Secretary.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary’s Advisory Committee on Human Research Protections

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

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary’s Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the

DATES: The meeting will be held on Thursday, October 3, 2013 from 8:30 a.m. until 5:00 p.m. and Friday, October 4, 2013 from 8:30 a.m. until 4:30 p.m.


FOR FURTHER INFORMATION CONTACT: Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP), or Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; 240–453–8141; fax: 240–453–6909; email address: Julia.Gorey@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services and the Assistant Secretary for Health on issues and topics pertaining to or associated with the protection of human research subjects.

The meeting will open to the public at 8:30 a.m., Thursday, October 3. Following opening remarks from Dr. Jerry Menikoff, OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair, the Subcommittee on Harmonization (SOH) will give their report.

SOH was established by SACHRP at its July 2009 meeting and is charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

Following opening remarks on the morning of October 4, the Subpart A Subcommittee (SAS) will give their report. SAS is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment; this subcommittee was established by SACHRP in October 2006.

Public attendance at the meeting is limited to space available. Individuals who plan to attend the meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the designated contact persons. Members of the public will have the opportunity to provide comments on both days of the meeting. Public comment will be limited to five minutes per speaker. Any members of the public who wish to have printed materials distributed to SACHRP members for this scheduled meeting should submit materials to the Executive Director, SACHRP, prior to the close of business September 30, 2013.


Jerry Menikoff,
Director, Office for Human Research Protections,
Executive Secretary, Secretary’s Advisory Committee on Human Research Protections.

[FR Doc. 2013–22236 Filed 9–11–13; 8:45 am]
BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Multi-Agency Informational Meeting Concerning Compliance with the Select Agent Regulations; Public Webcast

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of public webcast.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) announces a public webcast for all interested parties, including individuals and entities possessing, using, or transferring biological agents and toxins. The purpose of the webcast is to provide guidance related to the select agent regulations established under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

The webcast is being organized by the U.S. Department of Agriculture (USDA)’s Animal and Plant Health Inspection Service (APHIS), HHS/CDC, and the Department of Justice’s Federal Bureau of Investigation (FBI), Criminal Justice Information Services. Changes to Section 11(Security) of the select agent regulations including information security, physical security, and personnel suitability will be discussed. Topics will focus on additional requirements for entities possessing select agents and toxins designated as Tier 1 agents.

DATES: The webcast will be held on Friday, November 15, 2013 from 10 a.m. to 4 p.m. EST. All who wish to join the webcast must register by October 18, 2013. Registration instructions can be found on the Web site http://www.selectagents.gov.

ADDRESSES: The webcast will be broadcast from the APHIS facility, 4700 River Road, Unit 2, Riverdale, MD 20737.

FOR FURTHER INFORMATION CONTACT: APHIS: Dr. Keith Wiggins, APHIS Select Agent Program, 4700 River Road, Unit 2, Riverdale, MD 20737; 301–851–3300 option 1 (voice only); ASAP@aphis.usda.gov.

CDC: Diane Martin, Division of Select Agents and Toxins, Office of Public Health Preparedness and Response, CDC, 1600 Clifton Road, NE., MS A–46, Atlanta, GA 30333; (404) 718–2000; lrsat@cdc.gov.

SUPPLEMENTARY INFORMATION: Title II of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, “Enhancing Controls on Dangerous Biological Agents and Toxins” (sections 201 through 221), provides for the regulation of certain biological agents and toxins by HHS (subtitle A, sections 201–204) and USDA (subtitle B, sections 211–213), and provides for interagency coordination between the two departments regarding overlap agents and toxins (subtitle C, section 221). HHS/CDC regulates the possession, use or transfer biological agents and toxins that have the potential to pose a severe threat to public health and safety. The HHS/CDC select agent regulations can be found at 42 CFR part 73.

USDA/APHIS has a parallel program that regulates the possession, use or transfer biological agents that have the potential to pose a severe threat to animal or plant health, or to animal or plant products. The USDA/APHIS select agent regulations can be found at 7 CFR part 311 and 9 CFR part 121.

The Criminal Justice Information Service (CJIS) in the Federal Bureau of Investigation (FBI) conducts security risk assessments of all individuals and nongovernmental entities that require access to select agents and toxins. The webcast announced here is an opportunity for the regulated community (i.e., registered entity responsible officials, alternate responsible officials, and entity owners) and other interested individuals to obtain specific regulatory guidance and information on standards concerning security issues related to the select agent regulations. Representatives from HHS/CDC, USDA/APHIS, and the FBI will be present during the webcast to address questions from and concerns of the web participants.

Changes to Section 11 (Security) of the select agent regulations including