FHCs to document any routine management or operation of a portfolio company and to make this documentation available to the Federal Reserve on request.[10] Examiners use this information to assess whether the FHC is conducting its merchant banking activities in a safe and sound manner and whether the FHC is in compliance with applicable regulatory requirements for engaging in merchant banking activities.

There are no formal reporting forms for these collections of information, which are event generated, though in each case the type of information required to be filed is described in the Board's regulations. These collections of information are required pursuant to amendments made by the GLB Act to the BHC Act or the Federal Reserve Act, or Board regulations issued to carry out the GLB Act.

Current Actions: The Federal Reserve proposes to revise FR 4012 to include SLHCs, consistent with interim final Regulation LL (CFR 238.66(b)).[11]

Board of Governors of the Federal Reserve System, May 23, 2013.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2013–12715 Filed 5–29–13; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–19129–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before July 1, 2013.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS–OS–19129–30D for reference.

Information Collection Request Title: HIPAA Audit Review Survey.

Abstract: This information collection consists of an online survey of 115 covered entities (health plans, health care clearinghouses, and health care providers) that were audited in 2012 through the Office for Civil Rights HIPAA Audit Program. The survey will gather information on the effect of the audits on the audited entities and the entities' opinions about the audit process.

Need and Proposed Use of the Information: The Office for Civil Rights is currently conducting a review of the HIPAA Audit program to determine its efficacy in assessing the HIPAA compliance efforts of covered entities. As part of that review, the online survey will be used to:

- Measure the effect of the HIPAA Audit program on covered entities;
- Gauge their attitudes towards the audit overall and in regards to major audit program features, such as the document request, communications received, the on-site visit, the audit-report findings and recommendations;
- Obtain estimates of costs incurred by covered entities, in time and money, spent responding to audit-related requests;
- Seek feedback on the effect of the HIPAA Audit program on the day-to-day business operations; and
- Assess whether improvements in HIPAA compliance were achieved as a result of the Audit program.

The information, opinions, and comments collected using the online survey will be used to produce recommendations for improving the HIPAA Audit program.

Likely Respondents: The 115 audit points-of-contact for each covered entity audited as part of the 2012 HIPAA Compliance Audit Program.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Covered Entity Privacy and Security Officer(s).	OCR HIPAA Audit Evaluation Survey.	115	1	27	52
Total					52

[10] 12 CFR 225.171(e)(4).

[11] (76 FR 56508) September 13, 2011.

Darius Taylor,

Deputy, Information Collection Clearance Officer.

[FR Doc. 2013–12828 Filed 5–29–13; 8:45 am]

BILLING CODE 4153–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Food and Drug Administration Safety and Innovation Act (FDASIA): Request for Comments on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology

AGENCY: Office of the National Coordinator for Health Information Technology, Department of Health and Human Services.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The Food and Drug Administration (FDA), Office of the National Coordinator for Health Information Technology (ONC), and Federal Communication Commission (FCC) seek broad input from stakeholders and experts on the elements we should consider as we develop a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework for health IT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication. To that end, we are requesting comments on the topics identified in Section III.

DATES: This Docket on *regulations.gov* will remain open for public comments until 11:59pm Eastern Time, August 31, 2013.

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Director, Federal Policy Division, Office of Policy and Planning, Office of the National Coordinator for Health IT, 202–690–7151.

SUPPLEMENTARY INFORMATION:

I. The Food and Drug Administration Safety and Innovation Act Workgroup Under ONC's HIT Policy Committee

Section 618(a) of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 (Pub. L. 112–144) directs the Secretary of the Department of Health and Human Services (HHS), acting through the Commissioner of the Food and Drug Administration (FDA), and in consultation with the HHS Office of the National Coordinator for Health Information Technology (ONC) and the Chairman of the Federal Communications Commission (FCC), to publish a report that will offer a proposed strategy and recommendations for an appropriate risk-based Health IT regulatory framework that would include mobile medical applications and promotes innovation, protects patient safety, and avoids regulatory duplication.

To assist the agencies' efforts in developing this report, the FDA in collaboration with ONC and FCC formed a new workgroup, referred to as the FDASIA Workgroup, under ONC's HIT Policy Committee to help the HIT Policy Committee provide appropriate input and recommendations to FDA, ONC, and FCC as suggested by section 618(b) of FDASIA. Accordingly, the FDASIA Workgroup is charged with providing input on issues relevant to the report FDA, ONC, and FCC will develop, which include:

- Types of risk that may be posed by health IT that impact patient safety, the likelihood that these risks will be realized, and the impact of these considerations on a risk-based approach;
- Factors or approaches that could be included in a risk-based regulatory approach for health IT that also promote innovation and protect patient safety; and
- Approaches to avoid duplicative or overlapping regulatory requirements.

The workgroup's membership includes agency officials and representatives from a wide range of stakeholders, including patients, consumers, health care providers, startup companies, health plans and other third-party payers, venture capital investors, information technology vendors, health information technology vendors, small businesses, purchasers, and employers.

Through this request for comments, FDA, ONC, and FCC would like to provide an opportunity for broad public input on section 618 of FDASIA. Timely submitted written comments will inform the new FDASIA Workgroup's deliberations on the input it will provide to the HIT Policy Committee regarding the report required by section 618 of FDASIA. We seek input on a number of specific topics identified in Section III, but welcome any other pertinent information stakeholders wish to share. *For commenters that wish to have their comments considered by the FDASIA Workgroup, we encourage you to submit your comments as early as possible and preferably before June 30, 2013.*

FDASIA Workgroup In-Person Meeting

On May 30 and 31, 2013, in Washington, DC, the FDASIA Workgroup will hold an in-person meeting which will also be Webcast. Persons interested in attending the in-person meeting or viewing the Webcast can access information about doing so at this URL: *http://www.healthit.gov/policy-researchers-implementers/policy-fdasia-1.*

Interested parties may submit electronic comments to *http://www.regulations.gov*. Submit written comments to Office of the National Coordinator for Health Information Technology, Attention: FDASIA Report Hubert H. Humphrey Building, Suite 729D, 200 Independence Ave. SW., Washington, DC 20201.

II. Background

Health IT is being rapidly adopted by the health care industry and there is a growing need for the Federal government to develop a coordinated approach to its oversight of health IT that promotes innovation, protects patient safety, and avoids regulatory duplication. FDA, FCC, and ONC each have important roles with respect to the development and use of health IT that significantly impacts public health and welfare. Congress recognized the importance of a coordinated regulatory approach and through FDASIA, specifically tasked the FDA, ONC, and FCC with creating a report that includes a proposed strategy and recommendations for an appropriate, risk-based regulatory framework for health IT. To inform the report required by FDASIA, FDA, ONC, and FCC, in addition to receiving input from the HIT Policy Committee, intend to provide multiple opportunities, as appropriate, for input from other stakeholders at different stages throughout the report's development, including, if feasible, feedback on the draft framework prior to finalizing the report.

III. Topics for Discussion

Public comment is sought on any or all of the following topics below.

1. Taxonomy

a. What types of health IT should be addressed by the report developed by FDA, ONC, and FCC?

2. Risk and Innovation

a. What are the risks to patient safety posed by health IT and what is the likelihood of these risks?

b. What factors or approaches could be included in a risk-based regulatory approach for health IT to promote innovation and protect patient safety?