

FHCs to document any routine management or operation of a portfolio company and to make this documentation available to the Federal Reserve on request.<sup>10</sup> 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)).<sup>11</sup>

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

<sup>10</sup> 12 CFR 225.171(e)(4).

<sup>11</sup> (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](http://www.healthit.gov/policy-researchers-implementers/policy-fdasia-1).

Interested parties may submit  
electronic comments to [http://  
www.regulations.gov](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?