

PRA Clearance Package

The Blue Button Connector

Part A. Justification

Version: September 4, 2014

Simone Myrie, Office of Consumer eHealth,
Office of the National Coordinator for Health IT, HHS
Department of Health and Human Services
Office of the Chief Information Officer
Office of Resources Management
200 Independence Avenue, S.W. 537-H
Washington, DC 20201

Table of Contents:

1. Background.....	3
2. Justification.....	3-4
3. Purpose & Use of Information Collection.....	5
4. Use of Improved Information Technology and Burden Reduction.....	5
5. Efforts to Identify Duplication and Use of Similar Information.....	5-6
6. Impact on Small Businesses or Other Small Entities.....	6
7. Consequences of Collecting the Information Less Frequent Collection.....	6
8. Special Circumstances Relating to the Guidelines of 5 CFR 1320.6.....	6
9. Comments in Response to the Federal Register Notice/Outside Consultation.....	7
10. Explanation of any Payment/Gift to Respondents.....	7
11. Assurance of Confidentiality Provided to Respondents.....	7
12. Justification for Sensitive Questions.....	7
13. Estimates of Annualized Hour and Cost Burden.....	7-8
14. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs.....	8
15. Annualized Cost to Federal Government.....	8-9
16. Explanation for Program Changes or Adjustments.....	9
17. Plans for Tabulation and Publication and Project Time Schedule.....	9
18. Reason(s) Display of OMB Expiration Date is Inappropriate.....	9
19. Exceptions to Certification for Paperwork Reduction Act Submissions.....	9

Background:

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule requires covered entities to provide individuals with an electronic copy of their health information if that information is both requested in that format and readily producible. (See 45 C.F.R § 164.524(c)(2)(i)). As of October 6, 2014, this provision will also apply to HIPAA-covered lab entities. 42 C.F.R. §493.1291(f), 45 C.F.R. § 164.524, 79 FR 7316. Regulations governing the implementation of the Centers for Medicare and Medicaid Services (CMS) Standards for the Electronic Health Record Technology Incentive Program require participating providers to give their patients the ability to “view online, download and transmit” their health information electronically in order to meet meaningful electronic health record (EHR) use criteria (See 45 CFR § 495.6(j)(10)(i)). Criteria for complete EHR modules also require that they provide patients with the ability to view, download and transmit their electronic health data. 45 CFR §170.314 (e)(1).

In spite of these recent regulatory and statutory reforms promoting availability of electronic copies of patients’ health records, millions of Americans remain unaware of their ability to request health information in an electronic format. This problem is exacerbated by the fact that there is currently no one location where patients can go to learn which entities offer electronic access to personal health information. Increasingly, consumers have access to their health information electronically from multiple sources and it may be difficult for consumers to keep track of or understand how to manage all that information. It may therefore be difficult for patients to gather all of their health information in one location for easy access. It is often hard for patients to know how to start gathering their electronic health information and what tools might be available to help them manage that information once they have access to it.

The application developer community is very active in this space, and is increasingly developing tools to meet the above-mentioned patient needs. In order aid developers in enabling effective use of electronic health data by patients, it is necessary to make available information on which health care entities are providing access to electronic health information and how that information is being provided. The development of the Blue Button Connector is one way in which this information need can be met.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Blue Button Connector is a web site, created by ONC as part of its efforts to promote access to electronic health care information, that helps consumers find out which health care entities have the capability to provide electronic access to patient health information and where that information can be accessed online. This online survey tool will collect that information through voluntary responses from health care entities including provider clinics (doctors, dentists, nurse practitioners, nurse-midwives, physician assistants) hospitals, pharmacies, state health information exchanges (HIEs), insurers, state immunization registries

and from application developers. The responses will help to provide transparency about which entities are providing electronic access to health information and what tools are available to help consumers use and maintain their health data. The Connector facilitates the process of consumers retrieving their electronic health care information by including a direct link to a site where consumers can go online to access that information. It also empowers consumers with knowledge about what types of things they can do with their health information by featuring a list of applications and services that can help consumers organize and make use of their electronic health information.

In order to provide these services, the Blue Button Connector will collect voluntarily reported information from health care entities including: the organization's name, type of health data holding entity (i.e pharmacy, lab, hospital), phone contact, link to where consumers can access their health information digitally, the state in which the organization resides, the services they provide, download formats and other available features. This collection is necessary in order to obtain the information that will be included on the Blue Button Connector website. In particular, it is necessary to survey all health care entities in order to determine whether they provide patients with electronic access to their medical records, what type of access is provided, and whether there is a link that can be provided to consumers to facilitate access to electronic copies of their medical records. The information collected will be used to provide patients with a single online location where they can easily obtain access to their electronic health records.

In order for the Blue Button Connector to perform its coordinating function, it is also necessary to collect information from app developers. The information collected from app developers will include the name of the app, the name of the developer, and a brief description of the app's functionality. This will enable patients to use the Blue Button Connector to select apps that will help them manage their electronic health records.

Information will be collected from both health care entities and app developers on an ongoing basis through the creation of a profile for each respondent entity. Respondents can update their information if there is a change that they would like to convey to consumers. Providers and developers who were not previously listed on the connector may also create new profiles at any time. This is designed to be a living tool that can be populated with content at any time by the organizations that choose to be listed on the connector website.

2. Purpose and Use of Information Collection

The Blue Button Connector is an electronic survey that will collect information at the BlueButtonconnector.healthit.gov website from health care entities (including providers, labs, pharmacies, hospitals and health information exchanges) and application developers to help consumers locate their health information electronically and find out how they can manage it once they receive it so that it is useful and actionable. The information collected will be used to populate the content of the Blue Button Connector website. The answers provided to the survey questions will be included in an online directory where patients can easily identify which health care entities provide access to electronic health information, and, where possible, it will provide

links to the relevant web-pages where patients may access their electronic health information. The Blue Button Connector will also provide a living tool where providers and app developers can update their information in order to allow consumers greater access both to their electronic health information and to tools to manage that information. Information in the Connector will be able to be updated by survey respondents at any time and will be maintained indefinitely for use as a directory for patients attempting to find electronic copies of their health care information.

This information will be used only for the purposes listed above. It is not intended for quantitative or qualitative analysis, or for use in informing future policy decisions. For this reason, no statistical analysis has been provided as part of this information collection request.

3. Use of Improved Information Technology and Burden Reduction

The Blue Button Connector is an electronic survey of health care providers and app developers that will collect information about the access capabilities they provide to patients and use that information to directly populate an online directory. We expect only one respondent per organization to complete the survey. The survey will be provided online for ease of access, and can be saved or updated at the respondent's convenience. The electronic survey was also designed with quick clickable multiple choice responses to avoid being burdensome on the daily workflow of respondent organizations.

4. Efforts to Identify Duplication and Use of Similar Information

ONC has used various environmental scan initiatives to establish that the information being gathered by the Blue Button Connector is not duplicative of other collection efforts. Actions taken by ONC have included online searches, solicitation of feedback from conferences and speaking events, public inquiries, and the convening of stakeholder meetings. There is currently no comprehensive available list of which health care providers allow patients to access their health data electronically. The Blue Button Connector provides a valuable service by collecting information from all providers in one central location for easy patient access. It is possible that the information contained in the surveys could be obtained by searching the internet to find the policies of the relevant institutions and the information on the relevant applications. That process, however, is time consuming and inefficient. The Blue Button Connector is designed to function as a living directory that enables providers and app developers to provide current, up to date, information about their services and products. The burden on providers to provide and update this information is minimal, and incidental duplication of information that may be available elsewhere on the internet is outweighed by the efficiencies gained in having the Connector create a living directory.

5. Impact on Small Businesses or Other Small Entities

The collection of this information will have minimal burden on small businesses as the collection of this information may be completed by anyone with general understanding of their

organization's offerings and the time needed to complete the survey will not exceed 3 minutes. The electronic survey was also designed with quick clickable multiple choice responses to avoid undue burden upon survey respondents. Additionally, the transparency that the Blue Button Connector offers stands to benefit small business health care practices and entities that ordinarily would not have the resources to publicize their electronic offerings on a national-scale.

6. Consequences of Collecting the Information Less Frequent Collection

The Blue Button Connector is designed to be a living directory. It is necessary that providers and application developers be able to update their information whenever there is a change in that information that would be relevant to consumers. Without both the initial collection and the ability of providers and developers to provide timely updates, the Connector would not be able to serve its core purpose of providing a complete directory for patients to locate places where they can access their electronic health information and tools to help them manage that information.

We suspect that entities responding to the survey for the purposes of having their affiliated organizations listed on the Connector may want to update their profile information on an annual basis. Technology is ever-evolving and as such, health data holders continue to update their access offerings as they make upgrades to their technologies. The access continuum ranges from view capabilities all the way to integration with third party applications and tools that allow for automatic updates to patients' health records. Access offerings are also dependent on strategic goals and available financial resources. Therefore, when a given entity initially completes their page profile on the Blue Button Connector to note their current offerings, the information may be out of date after a year if it is not updated. For this reason, we would like to provide flexibility to the entities featured on the Connector to allow them to make appropriate updates on an as-needed basis.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.6

There are no special circumstances that would cause the collection of information to be inconsistent with 5 C.F.R. 1320.6.

8. Comments in Response to the Federal Register Notice/Outside Consultation

A 60-day Federal Register Notice was published in the *Federal Register* on April 2, 2014, vol. 79, No. 63; pp. 18552-1855384. No public comments were received. The 30-Day Federal Register Notice was published on June 17, 2014.

9. Explanation of any Payment/Gift to Respondents

There will be no payment of gifts of any kind given to respondents.

10. Assurance of Confidentiality Provided to Respondents

Because the information collected for the Blue Button Connector will be used to form an online directory for patient access to electronic health information, no assurances of confidentiality are given to respondents. Information being collected is not of a sensitive or proprietary nature.

11. Justification for Sensitive Questions

The survey for which we are requesting PRA clearance will not have any sensitive or personal questions.

12. Estimates of Annualized Hour and Cost Burden

The following types of entities are expected to respond to the Blue Button Connector survey in order to populate the website: providers, hospitals, labs, state immunization registries, pharmacies and State Health Information Exchanges as well as application developers. From these specific data holder sources, we expect a single respondent from each organization to complete the online Blue Button Connector survey approximately once on an annual basis. The total time it will take each respondent to complete the online survey will not exceed three minutes.

The provider numbers are estimated based on ONC's understanding of providers who will likely meet Meaningful Use Stage 2 patient engagement requirements under the CMS Electronic Health Records Incentive Program over the course of next year (See 45 CFR§ 495.6(j)(10)(i). Thus far in 2014, only 972 physicians and 10 hospitals have attested to Meaningful Use Stage 2 which has electronic patient engagement requirements. The app developer numbers are based on ONC's ongoing interaction and communication with the developer community. The Connector allows entities of both types to self-report information that will populate the website. There is a possibility, therefore, that response rates might be higher or lower than initially anticipated.

12A. Total Estimated Annualized Burden - Hours

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Providers (doctors, dentists, nurse practitioners, certified nurse midwives, dentists, Physician Assistants)	2,000	1	3/60	100
Hospitals	500	1	3/60	25

Labs	10	1	3/60	30
State Immunization Registries	7	1	3/60	21
Pharmacies	10	1	3/60	30
State HIEs	15	1	3/60	45
Application developers	200	1	3/60	10
Total				261

12B. Total Estimated Annualized Cost

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Providers (doctors, dentists, nurse practitioners, certified nurse midwives, dentists, Physician Assistants)	100	\$43.72	\$ 4372.00
Hospitals	25	\$47.34	\$1183.50
Labs	30	\$32.15	\$ 964.50
State Immunization Registries	21	\$ 42.59	\$894.39
Pharmacies	30	\$59.41	\$1782.30
State HIEs	45	\$42.49	\$1912.05
Application developers	10	\$44.88	\$448.8
Total			\$11,557.54

The US Department of Labor 2013 median wage estimates for these respondent types were used to determine annualized cost.

13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

There will be no other annual cost burden to respondents or recordkeepers/capital costs.

14. Annualized Cost to Federal Government

The annualized cost to the government is \$40,000 in 2014, \$20,000 in the 2015, and \$10,000 in 2016-17, for a total cost of \$80,000. This is due to initial cost for building the website and contract support associated with improving and updating the website over three years. ONC currently has one contractor supporting the effort whose billable rate is \$232.88 per hour. In 2014, he will devote 170 hours to the project and we project the existing contractor or a future contractor will devote 90 hours to the project in 2015 and 45 hours in 2016 and 2017.

	2014	2015	2016	2017
--	------	------	------	------

Development of website	\$40,000			
Maintenance of website & version update		\$20,000		
Maintenance of website			\$10,000	
Maintenance of website				\$10,00

15. Explanation for Program Changes or Adjustments

There are currently no changes or adjustments. This is a new collection. Any changes to burden will be reported on an annual basis.

16. Plans for Tabulation and Publication and Project Time Schedule

Beginning September 2014 and through September 2017, the information that is submitted by respondents via the Blue Button Connector website “supporters” page will be made public immediately upon completion. The general public will then be able to view the respondent’s information at any point. All organizations who submit information about their company’s access capabilities to patients within the 3 year clearance will be made public for the duration of the webpages’ lifetime on bluebuttonconnector.healthit.gov.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We are not seeking approval to not show expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.