SUPPORTING STATEMENT

Collections of Information under the
Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology

The Office of the National Coordinator for Health Information Technology

A. Justification

1. Circumstances Making the Collection of Information Necessary

a. Need and Legal Basis for the Information Collection

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created "Title XXX – Health Information Technology and Quality" (Title XXX) to improve health care quality, safety, and efficiency through the promotion of health information technology (HIT) and electronic health information exchange.

Section 3001(c)(5) of the PHSA requires the National Coordinator for Health Information Technology ("the National Coordinator"), in consultation with the Director of the National Institute of Standards and Technology (NIST), to "keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria" adopted by the Secretary under section 3004. In a notice of proposed rulemaking implementing section 3001(c)(5), ONC proposed to establish two certification programs, a temporary certification program and a permanent certification program. On June 24, 2010, a final rule (75 FR 36158) was published that established the temporary certification program. On January 7, 2011, a final rule (76 FR 1262) was published that established the permanent certification program which is scheduled to be renamed "ONC HIT Certification Program" upon publication of the *Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology* final rule.

Under the permanent certification program, accreditation organizations that wish to become the ONC-Approved Accreditor (ONC-AA) must submit certain information, organizations that wish to become an ONC-Authorized Certification Bodies (ONC-ACBs) must submit the information specified by the application requirements, and ONC-ACBs must comply with collection and reporting requirements, records retention requirements, and submit annual surveillance plans and annually report surveillance results.

b. Revisions to Previously Approved Collection of Information (OMB control #: 0990-0378)

OMB previously approved the collections of information under the permanent certification program (OMB control number 0990-0378). Under 45 CFR 170.523(f), ONC-ACBs are required to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified which includes, at a minimum, the vendor name (if applicable), the date certified, the product version, the unique certification number or other specific product identification, and where applicable, the certification criterion or certification criteria to which each EHR Module has been certified. We proposed to revise section 170.523(f) and, correspondingly, seek to amend the approved collection of information by requiring ONC-ACBs to include one additional data element in the list of information about Complete EHRs and

EHR Modules they must provide ONC. This data element is discussed in further detail in s*ection c.iii below ("Collection and Reporting Requirements").*

c. Specific Collections of Information

i. Request for ONC-AA Status

Organizations that wish to become ONC-ACBs must comply with certain application requirements, including providing documentation that the applicant has been accredited by the ONC-AA. ONC will select the best qualified accreditation organization as the ONC-AA based on the information that must be submitted to be considered for ONC-AA status. The required information will be used to assess an accreditation organization's qualifications and abilities to be the ONC-AA. In order to be considered for ONC-AA status, an accreditation organization must submit a request in writing to the National Coordinator during the 30-day period provided for submitting requests along with the following information to demonstrate its ability to serve as the ONC-AA: (1) A detailed description of the accreditation organization's conformance to ISO/IEC 17011:2004 (ISO 17011) and experience evaluating the conformance of certification bodies to ISO/IEC Guide 65:1996 (Guide 65); (2) A detailed description of the accreditation organization's accreditation requirements as well as how those requirements would complement the Principles of Proper Conduct for ONC-ACBs and ensure the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods; (3) Detailed information on the accreditation organization's procedures that would be used to monitor ONC-ACBs; (4) Detailed information, including education and experience, about the key personnel who review organizations for accreditation; and (5) Procedures for responding to, and investigating, complaints against ONC-ACBs.

ii. Application for ONC-ACB Status

The application process for ONC-ACB status requires applicants to: (1) Identify the type of authorization they seek (for only EHR Module authorization, the type(s) of EHR Modules must be specified); (2) Provide general identifying information; (3) Provide documentation that confirms that the applicant has been accredited by the ONC-AA (copy of the accreditation record created by the ONC-AA); (4) Execute an agreement to adhere to the Principles of Proper Conduct for ONC-ACBs; and (5) Submit all of the information either electronically, via email (or web submission if available), or by regular or express mail.

iii. Collection and Reporting Requirements (with additional reporting element*)

An ONC-ACB must provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified, which includes, at a minimum: (1) The Complete EHR or EHR Module developer name (if applicable); (2) The date certified; (3) The product version; (4) The unique certification number or other specific product identification; (5) The clinical quality measures to which a Complete EHR or EHR Module has been certified; (6) Where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or criteria adopted by the Secretary; and

(7) Where applicable, the certification criterion or criteria to which each EHR Module has been certified.

We seek to amend this collection of information by requiring ONC-ACBs to include one additional data element in the set of data they are required to provide to ONC in accordance with § 170.523(f). Specifically, an ONC-ACB would be required to provide ONC a hyperlink with each Complete EHR and EHR Module it certifies that provides the public with the ability to access the test results used to certify the Complete EHR or EHR Module. Similar to all the other data an ONC-ACB reports to ONC, we would subsequently make such a hyperlink available on the Certified HIT Products List (CHPL) with the respective certified Complete EHR or certified EHR Module. This requirement would be added at § 170.523(f)(8).

Compliance with this collection of information (§ 170.523(f)) is a requirement for ONC-ACBs to maintain good standing under the permanent certification program.

iv. Records Retention

An ONC-ACB must retain all records related to the certification of Complete EHRs and/or EHR Modules for a minimum of 5 years.

Compliance with this collection of information is a requirement for ONC-ACBs to maintain good standing under the permanent certification program.

v. Submission of Surveillance Plan and Surveillance Results

An ONC-ACB must submit an annual surveillance plan to the National Coordinator and annually report to the National Coordinator its surveillance results.

Compliance with this collection of information is a requirement for ONC-ACBs to maintain good standing under the permanent certification program.

2. Purpose and Use of Information Collection

a. Request for ONC-AA Status

The information collected will be used to assess the qualifications and abilities of accreditation organizations to become the ONC-AA under the permanent certification program.

b. Application for ONC-ACB Status

The information collected through the application process will be used to assess the qualifications and abilities of applicants for ONC-ACB status under the permanent certification program. ONC will use the contact information provided for an applicant's authorized representative to communicate and correspond with the applicant about the application. ONC will continue to use the authorized representative's contact information to communicate and correspond with the applicant if the applicant becomes an ONC-ACB.

If an applicant is granted ONC-ACB status, ONC intends to post its name and the fact that it has been granted ONC-ACB status on ONC's website.

c. Collection and Reporting Requirements (with additional reporting element*)

The information collected will be used to provide the public and the Centers for Medicare & Medicaid Services (CMS) with an aggregate list of certified Complete EHRs and EHR Modules. The hyperlink to the testing results of certified Complete EHRs and EHR Modules will increase transparency in the testing and certification processes and will serve to make more information available to prospective purchasers of EHR technology as well as other stakeholders.

d. Records Retention

The purpose of the records retention requirement is twofold. An ONC-ACB's records will be directly relevant to a determination by the National Coordinator that the ONC-ACB committed a Type-2 violation and/or to revoke the ONC-ACB's status. Second, ONC-ACBs' certification records will likely be necessary for ONC-ACBs to conduct surveillance under the permanent certification program.

e. Submission of Surveillance Plan and Surveillance Results

ONC will use surveillance plans and surveillance results as a feedback mechanism to assess the permanent certification program, particularly the performance of certified Complete EHRs and EHR Modules in relation to their certifications.

3. Use of Improved Information Technology and Burden Reduction

a. Request for ONC-AA Status

Accreditation organizations interested in becoming the ONC-AA are encouraged to submit the required information by email to ONC and to communicate with ONC via email. ONC also intends to conduct most of its communications by email and issue correspondence by email.

b. Application for ONC-ACB Status

The application process includes provisions that permit the use of electronic media for communication and correspondence. Applicants are permitted and encouraged to submit applications by email to ONC and to communicate with ONC via email. ONC also intends to conduct most of its communications related to the application process by email. These communications may include identifying any deficiencies in the application, requesting clarifications and requesting additional information.

c. Collection and Reporting Requirements (with additional reporting element*)

ONC anticipates that ONC-ACBs will electronically collect and store the requested information about certified Complete EHRs and EHR Modules. Additionally, ONC anticipates that the information would be electronically transmitted to ONC.

d. Records Retention

ONC anticipates that ONC-ACBs will electronically collect and store certification records of Complete EHRs and/or EHR Modules.

e. Submission of Surveillance Plan and Surveillance Results

ONC anticipates that the information would be electronically transmitted to ONC.

4. Efforts to Identify Duplication and use of Similar Information

a. Request for ONC-AA Status

The collection of information is not duplicative of any other collection of information.

b. Application for ONC-ACB Status

The collection of information for the application process is not duplicative of any other information collection. In addition, through the temporary certification program final rule (75 FR 36160), ONC has subsumed within the ONC-ACB application process the Department of Health and Human Services' application process for "recognized certification bodies" (RCB) that was specified in guidance issued by ONC in August 2006 (entitled "Interim Guidance Regarding the Recognition of Certification Bodies"). This guidance specified how ONC would evaluate applications for "recognized certification body" status and specified the information a body would need to provide to apply for and obtain such status. By including the RCB application process in the ONC-ACB application process, ONC has created efficiencies and eliminated potential duplication of application processes.

c. Collection and Reporting Requirements (with additional reporting element*)

The collection of information is not duplicative of any other collection of information.

d. Records Retention

This requirement is based on standard industry practice and is not duplicative of any other requirement.

e. Submission of Surveillance Plan and Surveillance Results

The collection of information is not duplicative of any other collection of information.

5. Impact on Small Businesses or Other Small Entities

All of the collections of information (including the records retention requirement), as applicable, require the same collection of information from any accreditation organization requesting ONC-AA status, any applicant that applies for ONC-ACB status, or any ONC-ACB, regardless of the accreditation organization's, applicant's, or ONC-ACB's size. ONC believes that it has established the minimum amount of information collection requirements (and records retention requirement) that are necessary for the proper functioning of the permanent certification program. In this regard, if some accreditation organizations requesting ONC-AA status, applicants for ONC-ACB status, or ONC-ACBs could be classified as small entities, ONC does not believe that any appropriate alternatives exist to lessen the information collection (or records retention) burden for these entities.

6. Consequences of Collecting the Information Less Frequently

a. Request for ONC-AA Status

An accreditation organization will only need to submit the required information once under the permanent certification program to be considered for ONC-AA status. ONC will accept requests for ONC-AA status approximately every three years after selecting the first ONC-AA for the permanent certification program. At the time ONC begins to accept requests again, an accreditation organization may again submit the required information to be considered for ONC-AA status.

b. Application for ONC-ACB Status

An applicant will only need to apply once under ONC's permanent certification program. If an applicant is denied ONC-ACB status, it may reapply six months after receiving a notice denying it ONC-ACB status. An ONC-ACB will be required to seek renewal of its status every three years and will have to submit a renewal application that is substantively the same as the initial application for ONC-ACB status.

c. Collection and Reporting Requirements (with additional reporting element*)

If the information was collected less frequently, ONC believes that eligible professionals and eligible hospitals who seek to become meaningful users under CMS' Medicare and Medicaid EHR Incentive Programs may have difficulty determining what Complete EHRs and/or EHR Modules have been certified and are available for them to adopt. ONC's weekly collection of information will ensure that information about certified Complete EHRs and EHR Modules is available to the public in a timely manner.

d. Records Retention

The records retention requirement is no longer than is the industry standard for such organizations based on ONC' consultations with NIST. Absent a records retention policy, ONC-ACBs would still maintain their certification records as part of their normal day-to-day operations and course of business.

e. Submission of Surveillance Plan and Surveillance Results

Annual surveillance plans and the annual reporting of surveillance results are consistent with the time needed to conduct and report surveillance results and the proper performance of the permanent certification program.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

a. Request for ONC-AA Status

Accreditation organizations that seek ONC-AA status may potentially submit information they identify or consider to be proprietary, a trade secret, or other confidential information. ONC will protect the information to the extent permitted by law.

b. Application for ONC-ACB Status

Organizations that apply for ONC-ACB status may potentially submit information they identify or consider to be proprietary, a trade secret, or other confidential information. ONC will protect the information to the extent permitted by law.

c. Collection and Reporting Requirements (with additional reporting element*)

This information will be made public. As previously specified, ONC will require that the information be provided on a weekly basis so that appropriate parties and entities are fully aware of the Complete EHRs and/or EHR Modules that have been certified as soon as practical. This will require the information to be prepared in less than 30 days each time it is reported. However, as previously noted, ONC anticipates that the information will be collected, stored and transmitted electronically. The use of electronic media will substantially reduce the burden on ONC-ACBs and will allow them to readily meet the weekly reporting requirements. The collection of information is otherwise fully compliant with 5 CFR 1320.5.

d. Records Retention

Not applicable.

e. Submission of Surveillance Plan and Surveillance Results

ONC may choose to make some of this information public (undetermined format), but will otherwise protect the information to the extent permitted by law.

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

A 60-day Federal Register Notice was published in the **Federal Register** on March 7, 2012, vol. 77, No. 45; pp. 13832-88 (see attachment *Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology; Proposed Rule*). No public comments were received.

a. Request for ONC-AA Status

The requirements are codified at § 170.503(b).

b. Application for ONC-ACB Status

The requirements are codified at § 170.520.

c. Collection and Reporting Requirements (with additional reporting element*)

The requirements are codified at § 170.523(f)(1)-(7). The reporting of a hyperlink is proposed to be codified at § 170.523(f)(8)

d. Records Retention

The requirements are codified at § 170.523(g).

e. Submission of Surveillance Plan and Surveillance Results

The requirements are codified at § 170.523(i).

9. Explanation of any Payment/Gift to Respondents

a. Request for ONC-AA Status

Accreditation organizations requesting ONC-AA status will not receive any payments or gifts for submitting the required information.

b. Application for ONC-ACB Status

Applicants for ONC-ACB status will not receive any payments or gifts for applying.

c. Collection and Reporting Requirements (with additional reporting element*)

ONC-ACBs will not receive any payments or gifts for collecting and reporting information on certified Complete EHRs and/or EHR Modules. Compliance with this collection of information is a requirement for maintaining good standing under the permanent certification program.

d. Records Retention

ONC-ACBs will not receive any payments or gifts for retaining records of certifications issued for Complete EHRs and/or EHR Modules. Compliance with this collection of information is a requirement for maintaining good standing under the permanent certification program.

e. Submission of Surveillance Plan and Surveillance Results

ONC-ACBs will not receive any payments or gifts for submitting annual surveillance plans and annually reporting surveillance results. Compliance with this collection of information is a requirement for maintaining good standing under the permanent certification program.

10. Assurance of Confidentiality Provided to Respondents

As appropriate, ONC will protect the information to the extent permitted by law. In some instances the information will be made available to the public, such as the information collected weekly from ONC-ACBs ("*Collection and Reporting Requirements*") and potentially surveillance results submitted by ONC-ACBs to ONC.

11. Justification for Sensitive Questions

These collections of information do not require the disclosure of any sensitive information.

12A. Estimated Annualized Burden Hours

a. Request for ONC-AA Status

ONC requires an accreditation organization to submit specific information to the National Coordinator to be considered for ONC-AA status under the permanent certification program. ONC estimates that there will only be two accreditation organizations that will prepare and submit the information sought by the National Coordinator to be considered for ONC-AA status. To provide the requested information, ONC believes that for an accreditation organization to meet the requirements for requesting ONC-AA status, it will take approximately:

- 20 minutes for an accreditation organization to provide a detailed description of the accreditation organization's conformance to ISO 17011 and experience evaluating the conformance of certification bodies to Guide 65;
- 20 minutes for an accreditation organization to provide a detailed description of the accreditation organization's accreditation requirements and how the requirements complement the Principles of Proper Conduct for ONC-ACBs and ensure the surveillance approaches used by ONC-ACBs include the use of consistent, objective, valid, and reliable methods;
- 5 minutes for an accreditation organization to provide a copy of the procedures that would be used to monitor ONC-ACBs;
- 10 minutes for an accreditation organization to provide detailed information, including education and experience, about the key personnel who review certification bodies for accreditation; and
- 5 minutes for an accreditation organization to provide a copy of the procedures for responding to, and investigating, complaints against ONC-ACBs.

These estimates are expressed in the table below.

Estimated Annualized Burden Hours

Type of	Number of	Number of Responses per	Burden Hours per Response	Total Burden

Respondent	Respondents	Respondent		Hours
Accreditation Organization	2	1	1	2

b. Application for ONC-ACB Status

ONC requires an organization to submit specific information to the National Coordinator to be considered for ONC-ACB status under the permanent certification program. ONC estimates that there will be no more than 6 applicants for ONC-ACB status under the permanent certification program. In the proposed rule, ONC did not specifically attribute an amount of time (i.e., burden) to identifying the type of authorization sought by a potential applicant. Although identifying the type of authorization sought is a requirement to apply for ONC-ACB status, ONC believes any time utilized to provide this information can be accounted for within the 10 minutes that have been allotted for providing the requested general identifying information. Accordingly, ONC's estimates of the burden for an applicant to collect and submit the information necessary to apply for ONC-ACB status remains the same as previously specified in the proposed rule. Specifically, ONC believes that for an applicant to apply for ONC-ACB status, it will take approximately:

- 10 minutes to provide the general identifying information requested in the application;
- 30 minutes to assemble the information necessary to provide documentation of accreditation by an ONC-AA; and
- 20 minutes to review and agree to the "Principles of Proper Conduct for ONC-ACBs."

These estimates are expressed in the table below.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Burden Hours per Response	Total Burden Hours
Applicant	N/A	6	1	1	6

c. Collection and Reporting Requirements (with additional reporting element*)

The collections of information in § 170.523(f)(1)-(7), approved under OMB control number 0990-0378, require an ONC-ACB to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been certified as well as certain minimum information about each certified Complete EHR and/or EHR Module.

ONC seeks to require ONC-ACBs to additionally report to ONC a hyperlink with each Complete EHR and EHR Module it certifies that provides the public with the ability to access the test results used to certify the Complete EHR or EHR Module. ONC-ACBs will be capturing this additional reporting element in conjunction with the other information ONC requested that they report on a weekly basis. Consequently, ONC believes that the reporting of this additional element will have minimal effect on the reporting burden previously placed on ONC-ACBs.

For the purposes of estimating the potential burden, we have used the following assumptions. We assume that all of the estimated applicants will apply and become ONC-ACBs (i.e., 6 applicants) and that they will report weekly (i.e., respondents will respond 52 times per year). We assume an equal distribution among ONC-ACBs in certifying EHR technology on a weekly basis. As such, based on the number of Complete EHRs and EHR Modules listed on the CHPL at the end of September of 2011 (approximately one year since the CHPL's inception), we estimate that, on average, each ONC-ACB will report 4 test results hyperlinks to ONC on a weekly basis. We believe it will take approximately 5 minutes to report the hyperlink to ONC. Therefore, as reflected in the table below, we estimate an additional 20 minutes of work per ONC-ACB each week. With this new proposed collection of information, we believe a total of 103 burden hours will be added to our burden estimate in OMB control number 0990-0378.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Burden Hours per Response	Total Burden Hours
45 CFR 170.523(f)	N/A	6	52	1.33	415

d. Records Retention

Not applicable. See section 13 below.

e. Submission of Surveillance Plan and Surveillance Results

ONC requires an ONC-ACB to submit an annual surveillance plan to the National Coordinator and annually report to the National Coordinator its surveillance results. For the purposes of estimating the potential burden, ONC assumes that all of the estimated number of applicants for the permanent certification program (i.e., six) will become ONC-ACBs. ONC anticipates that the burden for each ONC-ACB will be the same based on the following assumptions. ONC assumes that all surveillance plans will be fairly comparable. ONC assumes that all ONC-ACBs will conduct surveillance on an equal number of Complete EHRs and EHR Modules and thus have a similar burden in submitting results. Finally, ONC assumes that an ONC-ACB will submit a copy of their annual surveillance plan and annually report surveillance results by either electronic transmission or paper submission. In either instance, ONC believes that an ONC-ACB will spend a similar amount of time and effort in organizing, categorizing and submitting the requested information. Therefore, ONC estimates that an ONC-ACB will annually allocate 1

hour to submit the plan (response # 1) and 1 hour to report the results (response # 2). Our estimates are expressed in the table below.

Estimated Annualized Burden Hours

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
ONC-ACB Surveillance Plan and Results	6	2	1	12

12B. Estimated Annualized Respondent Costs

a. Requesting ONC-AA Status

ONC believes that an employee equivalent to the Federal Salary Classification of GS-15 Step 1 would be responsible for preparing and submitting the required information. ONC has taken this employee assumption and utilized the corresponding employee hourly rate for the locality pay area of Washington, D.C., as published by the U.S. Office of Personnel Management, to calculate the cost estimates. ONC has also calculated the costs of the employee's benefits while preparing and submitting the required information to be considered for ONC-AA status. ONC has calculated these costs by assuming that an accreditation organization expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. ONC has concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. Based on the estimate of two accreditation organizations submitting the required documentation to be considered for ONC-AA status, ONC estimates the total cost at $161.30. This cost estimate is expressed in the table below.

Estimated Annualized Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate with Benefits	Annual Costs
Accreditation Organization	2	$80.65	$161

b. Application for ONC-ACB Status

Based on consultations with NIST and ONC's own calculations, ONC believes that an employee equivalent to the Federal Salary Classification of GS-9 Step 1 could provide the general information requested in the application and documentation of accreditation status. ONC also believes that an employee equivalent to the Federal Salary Classification of GS-15 step 1 would be responsible for reviewing and agreeing to the "Principles of Proper Conduct for ONC-ACBs." ONC has taken these employee assumptions and utilized the corresponding employee hourly rates for the locality pay area of Washington, D.C., as published by the U.S. Office of Personnel Management, to calculate the cost estimates. ONC has also calculated the costs of an employee's benefits while completing the application. ONC has calculated these costs by assuming that an applicant expends thirty-six percent (36%) of an employee's hourly wage on

benefits for the employee. ONC has concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. ONC's "Hourly Wage Rate with Benefits" is an average of a GS-9 Step 1 hourly wage with benefits ($30.45) attributed to the specified tasks for the specified time and a GS-15 Step 1 hourly wage with benefits ($80.65) attributed to the specified task for the specified time. ONC's cost estimates are expressed in table below. To estimate the highest possible cost, ONC assumes that all of the estimated applicants will apply and become ONC-ACBs (i.e., 6 applicants). The total cost for all applicants to apply for ONC-ACB status would be $283.08. This cost estimate is expressed in the table below.

Estimated Annualized Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate with Benefits	Annual Costs
Applicant	6	$47.18	$283

c. Collection and Reporting Requirements (with additional reporting element)*

ONC believes that an employee equivalent to the Federal Classification of GS-9 Step 1 could report the hyperlink to ONC. We have utilized the corresponding employee hourly rate for the locality pay area of Washington, D.C., as published by OPM, to calculate our cost estimates. We have also calculated the costs of the employee's benefits while completing the specified tasks. We have calculated these costs by assuming that an ONC-ACB expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. We have concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. ONC's calculations are expressed in the table below. To estimate the highest possible cost, ONC assumes that all of the estimated applicants will apply and become ONC-ACBs (i.e., 6 applicants). Under the previously approved information collection, ONC estimated that the total annual costs for weekly reporting of certified Complete EHRs and EHR Modules to be $9,500 (rounded). The cost of the additional reporting element (i.e., the hyperlink) is estimated to be $3,136 (rounded). Therefore, the new total annual cost estimate for weekly reporting of certified Complete EHRs and EHR Modules is $12,636.

This cost estimate is expressed in the table below.

Estimated Annualized Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate with Benefits	Annual Costs
45 CFR 170.523(f)	415	$30.45	$12,636

d. Records Retention

Not applicable. See section 13 below.

e. Submission of Surveillance Plan and Surveillance Results

ONC believes that an employee equivalent to the Federal Classification of GS-9 Step 1 could complete the transmissions of the surveillance plan and surveillance results to ONC. ONC has utilized the corresponding employee hourly rate for the locality pay area of Washington, D.C., as published by OPM, to calculate the cost estimates. ONC has also calculated the costs of the employee's benefits while completing the transmissions of the surveillance plan and surveillance results. ONC has calculated these costs by assuming that an ONC-ACB expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. ONC has concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. To estimate the highest possible cost, ONC assumes that all of the estimated applicants will apply and become ONC-ACBs (i.e., 6 applicants). Therefore, ONC estimates that the total annual costs for submitting surveillance plans and surveillance results will be $365. This cost estimate is expressed in the table below.

Estimated Annualized Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate with Benefits	Annual Costs
ONC-ACB Surveillance Plan and Results	12	$30.45	$365

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

a. Request for ONC-AA Status

There are no capital costs associated with this collection of information.

b. Application for ONC-ACB Status

There are no capital costs associated with this collection of information.

c. Collection and Reporting Requirements (with additional reporting element*)

ONC does not believe that there are any specific recordkeeping or capital costs associated with this collection of information. ONC-ACBs would need to maintain databases that collect and store the information ONC is requiring that they report as part of the normal course of business for such entities. ONC understands from its consultations with NIST that it is standard industry practice to maintain such information related to certifications. Therefore, ONC believes that the only costs attributable to this collection of information are those associated with the electronic transmission of the information to ONC, which ONC has accounted for in the estimated annualized burden costs.

d. Records Retention

ONC-ACBs will need to retain certification records as part of the normal course of business for such entities when they certify developers' Complete EHRs and/or EHR Modules. As noted in the proposed rule, based on consultations with NIST, ONC understands that it is standard industry practice to maintain such information related to certification for a period of 5 years. Therefore, as noted in the proposed and final rules, ONC believes that there are no costs specifically attributable to the records retention requirement. Further, no public comments were received to the contrary.

e. Submission of Surveillance Plan and Surveillance Results

ONC-ACBs will be required to conduct surveillance and gather surveillance results in accordance with the surveillance plans that are approved by the ONC-AA. ONC requires ONC-ACBs to submit a copy of their annual surveillance plans and to annually report their surveillance results. Therefore, ONC believes that the only costs attributable to this collection of information are those associated with the transmission of the information to ONC, which ONC has accounted for in the estimated annualized burden costs. ONC did not receive any public comments related to the burden of conducting surveillance or, more specifically, to submitting annual copies of surveillance plans and annually reporting surveillance results.

14. Annualized Cost to Federal Government

a. Request for ONC-AA Status

ONC anticipates that there will be some costs associated with reviewing applications for ONC-AA status under the permanent certification program. ONC believes that a GS-15 Step 1 employee will review the submissions and that the National Coordinator (or designated representative) will issue final decisions on all submissions. ONC anticipates that it will take 40 hours to review all submissions and reach a final decision on the best qualified accreditation organization. This estimate includes the time necessary to review the documentation that is required to be submitted and to prepare a briefing for the National Coordinator on approving the best qualified ONC-AA. This estimate also includes the time of the National Coordinator and other senior executive officials devoted to reaching a decision on the best qualified ONC-AA. Their time has been included in the 40 hour estimate at the GS-15 cost level. ONC estimates the Federal government's overall cost to review the submissions and approve an ONC-AA to be $3,226. Based on ONC's estimate of two accreditation organizations submitting the required documentation to be considered for ONC-AA status and on the requirement that an ONC-AA be selected every three years, the annualized cost to the Federal government for reviewing the submissions for ONC-AA status will be $1,075. If ONC notifies the public of the selection of the ONC-AA by posting the information on its website and/or by issuing a press release, ONC believes that it will incur negligible costs from these actions.

b. Application for ONC-ACB Status

ONC estimates the cost to develop the ONC-ACB application to be $350 based on the 5 hours of work ONC believes it will take a Federal Salary Classification GS-14 Step 1 employee located in Washington, D.C. to develop an application form. ONC also anticipates that there will be costs associated with reviewing applications under the permanent certification program. ONC expects

that a GS-15 Step 1 employee will review the applications and the National Coordinator (or designated representative) will issue final decisions on all applications. ONC anticipates that it will take approximately 20 hours to review and reach a final decision on each application. This estimate assumes a satisfactory application (i.e., no formal deficiency notifications) and includes the time necessary to verify the information in each application and prepare a briefing for the National Coordinator. ONC estimates the cost for the application review process to be $10,392. As a result, ONC estimates the Federal government's overall cost for administering the entire application process at approximately $10,742. ONC has averaged this cost over a timeframe of 5 years (2012 through 2016) to correspond with the proposed meaningful use stages (Stages 2 and 3) of CMS' Medicare and Medicaid EHR Incentive Programs. Based on a timeframe of 5 years, the annualized cost to the Federal government will be $2,148.

As previously noted, ONC will also post the names of applicants granted ONC-ACB status on its website. ONC believes that there will be minimal cost associated with this action and has calculated the potential cost to be approximately $312 on an annual basis for posting and maintaining the information on its website (a maximum of 6 hours of work for a Federal Salary Classification GS-12 Step 1 employee located in Washington, D.C.).

c. Collection and Reporting Requirements (with additional reporting element*)

We do not believe that we will incur any additional costs to post test results hyperlinks than the costs we estimated for posting a list of all certified Complete EHRs and EHR Modules (with the specified information) on our website (i.e., the CHPL), which was $10,784 on an annualized basis (76 FR 1323).

d. Records Retention

There are no associated Federal government costs.

e. Submission of Surveillance Plan and Surveillance Results

ONC believes that it will incur negligible costs in receiving ONC-ACBs' annual transmissions of surveillance plans and surveillance results.

Overall Annual Costs

Estimated annual costs for the Federal government have been averaged over the appropriate timeframe. For example, costs for reviewing and selecting an ONC-AA are averaged over a 3-year period. ONC estimates that the annual Federal government cost to be $14,320 for these collections of information.

15. Explanation for Program Changes or Adjustments

This is a revision to a collection of information previously approved by OMB under control number 0990-0378. We propose to revise the approved collection of information by requiring ONC-ACBs to include one additional data element in the set of data they are required to provide on the Complete EHRs and EHR Modules they report as certified to ONC under § 170.523(f). We believe this additional element is important to increase transparency in the testing and

certification processes and would serve to make more information available to prospective purchasers of CEHRT as well as other stakeholders. We do not believe that this proposed requirement will cause ONC-ACBs to incur any more costs than the costs we originally estimated for posting a list of all certified Complete EHRs and EHR Modules (with the requested information) on our website (i.e., the CHPL). We estimated those costs at $10,784 on an annualized basis (76 FR 1323). Regarding the potential burden of this proposed new requirement, we estimate that ONC-ACBs will incur an additional 20 minutes of work per week. Accordingly, this new proposed new collection of information will add a total of 103 burden hours to our burden estimate under OMB control number 0990-0378.

16. Plans for Tabulation and Publication and Project Time Schedule

a. Request for ONC-AA Status

For the purposes of public notification, ONC will publish on its website the name of the accreditation organization that is selected to be the ONC-AA.

A sunset date for the permanent certification program does not exist. Therefore, ONC intends to maintain an ONC-AA as long as the permanent certification program remains in existence. As previously mentioned, ONC will accept requests for ONC-AA status approximately every three years after selecting the first ONC-AA for the permanent certification program.

b. Application for ONC-ACB Status

For the purposes of public notification, ONC will publish on its website the names of those applicants that are granted ONC-ACB status and their associated authorization to certify Complete EHRs and/or EHR Modules.

Neither a finite application period nor a sunset date exist for the permanent certification program. Therefore, ONC anticipates that it will continue to accept applications, including renewal applications, and collect information as long as the permanent certification program remains in existence.

c. Collection and Reporting Requirements (with additional reporting element*)

ONC will publish all reported certified Complete EHRs and certified EHR Modules on its CHPL website and maintain the information on its website consistent with the specifications of the permanent certification program.

d. Records Retention

Not applicable.

e. Submission of Surveillance Plan and Surveillance Results

Although we have not yet determined whether or in what form, there is the possibility that surveillance results may be made available to the public.

17. Reason Display of OMB Expiration Date is Inappropriate

ONC does not seek this exception. The OMB expiration date may be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

B. Collection of Information Employing Statistical Methods

Not applicable. The collections of information required above in part A do not require the application of statistical methods.