Supporting Statement For Paperwork Reduction Act Submissions

A. Background

The American Recovery and Reinvestment Act of 2009 (Recovery Act) (P. L. 111-5) was enacted on February 17, 2009. The Recovery Act includes many measures to modernize our nation's infrastructure, and improve affordable health care. Expanded use of health information technology (HIT) and certified electronic health record (EHR) technology will improve the quality and value of America's health care. Title IV of Division B of the Recovery Act amends Titles XVIII and XIX of the Social Security Act (the Act) by establishing incentive payments to eligible professionals (EPs), eligible hospitals and critical access hospitals (CAHs), and Medicare Advantage (MA) organizations participating in the Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of certified EHR technology. These Recovery Act provisions, together with Title XIII of Division A of the Recovery Act, may be cited as the "Health Information Technology for Economic and Clinical Health Act" or the "HITECH Act."

The HITECH Act creates incentive programs for EPs and eligible hospitals, including CAHs, in the Medicare Fee-for-Service (FFS), MA, and Medicaid programs that successfully demonstrate meaningful use of certified EHR technology. In their first payment year, Medicaid EPs and eligible hospitals may adopt, implement or upgrade to certified EHR technology. It also, provides for payment adjustments in the Medicare FFS and MA programs starting in FY 2015 for EPs and eligible hospitals participating in Medicare that are not meaningful users of certified EHR technology. These payment adjustments do not pertain to Medicaid providers.

The first final rule for the Medicare and Medicaid EHR Incentive Program, which was published in the Federal Register on July 28, 2010 (CMS-0033-F), specified the initial criteria EPs, eligible hospitals and CAHs, and MA organizations must meet in order to qualify for incentive payments; calculation of incentive payment amounts; payment adjustments under Medicare for covered professional services and inpatient hospital services provided by EPs, eligible hospitals and CAHs failing to demonstrate meaningful use of certified EHR technology beginning in 2015; and other program participation requirements. On the same date, the Office of the National Coordinator of Health Information Technology (ONC) issued a closely related final rule (45 CFR Part 170, RIN 0991-AB58) that specified the initial set of standards, implementation specifications, and certification criteria for certified EHR technology. ONC has also issued a separate final rule on the establishment of certification programs for health information technology (HIT) (45 CFR Part 170, RIN 0991-AB59). The functionality of certified EHR technology should facilitate the implementation of meaningful use. Subsequently, final rules have been issued by CMS (77 FR 53968) and ONC (77 FR 72985) to create a Stage 2 of meaningful use criteria and other changes to the CMS EHR Incentive Programs and the 2014 Edition Certification Criteria for EHR technology.

B. Justification

1. Need and Legal Basis

Authority for the collection of this information is provided under sections1848(o), 1886(m), 1848(l), and 1853 (l) and (m) of the Social Security Act which were added or amended by the HITECH Act, and respectively authorize incentive payments for EPs, eligible hospitals, CAHs and MA organizations that successfully demonstrate meaningful use of certified EHR technology. Sections 1903(a)(3) and 1903(t) of the Social Security Act provide authority for the Medicaid EHR Incentive Program. These provisions are implemented by 75 FR 44314, 77 FR 53968 and 42 CFR Parts 412, 413, 422, 495 collectively known as the Medicare and Medicaid Programs; Electronic Health Record Incentive Program. Final Rule and the Medicare and Medicaid Programs; Electronic Health Record Incentive Program.

§495.10 Participation requirements for EPs, eligible hospitals, or CAHs

Section 1848(o)(1)(A) of the Act, as amended by section 4101(a) of the HITECH Act, provides for an incentive payment to Medicare EPs, beginning in CY 2011, who demonstrate meaningful use of certified EHR technology during the relevant EHR reporting period.

Section 1886(n) of the Act, as amended by section 4102(a)(1) of the HITECH Act, provides for Medicare incentive payments, beginning in FY 2011, for eligible hospitals that demonstrate meaningful use of certified EHR technology during the EHR reporting period for the payment year. Section 4102(b)(2) of the HITECH Act amends section 1814(l) of the Act to provide an incentive payment to CAHs that demonstrate meaningful use of certified EHR technology based on the hospitals' reasonable costs beginning in FY 2011.

Section 1903(t)(2) of the Act prohibits an EP from receiving incentive payments under the Medicaid program unless the EP has waived any rights to incentive payments under the Medicare FFS or MA programs. This non-duplication requirement applies only to EPs meeting both the Medicare FFS/MA and Medicaid EHR incentive programs eligibility criteria, and does not apply to those hospitals which may be eligible to receive incentive payments from both Medicare and Medicaid simultaneously. Section 495.10 of the proposed regulations would allow an EP meeting the eligibility criteria for both the Medicare and Medicaid programs to participate in either program, but not both. Further, the dually eligible Medicare and Medicaid EP would be permitted to change his or her program election one time after receiving the first payment, prior to 2015.

To ensure accurate and timely incentive payments and avoid duplication of incentive payments as required by the statute, CMS collects administrative (registration) data, in a manner specified by CMS, from EPs, eligible hospitals, CAHs, and MA organizations participating in the Medicare and Medicaid EHR Incentive Program. EPs, eligible hospitals and CAHs must update CMS of any subsequent changes in the administrative data. MA organizations may register and update information on behalf of their affiliated EPs and hospitals. The administrative registration data collections for EPs, eligible hospitals and CAHs are:

- Name of the EP, eligible hospital or CAH;
- National Provider Identifier (NPI)
- Taxpayer Identification Number (TIN) to which the incentive payment should be made

- Payee NPI
- Business address, email address and phone number;
- For eligible hospitals and CAHs, CMS Certification Number (CCN)
- For EPs, whether they elect to participate in the Medicare programs or the Medicaid program;
- •
- State selection for Medicaid providers.

CMS collects additional information that is pertinent to the successful implementation of this program, including:

- For MA organizations, contract number;
- E-mail address (optional);
- EHR Certification Number;
- For EPs, specialty.

§495.8 Demonstration of Meaningful Use Criteria

Section 1848(o)(3)(C) of the Act, as added by section 4101(a) of the HITECH Act, requires that as a condition of eligibility for the Medicare incentive payment, an EP must demonstrate meaningful use of certified EHR technology, which may include the following: an attestation, the submission of claims with appropriate coding, a survey response, reporting of clinical quality or other measures, or other means. Similarly, section 1886(n)(3)(c) of the Act, as added by section 4102(a) of the HITECH Act, requires that eligible hospitals and CAHs seeking an EHR incentive payment to demonstrate meaningful use of certified EHR technology in the manner specified by the Secretary. Under both Medicare and Medicaid, the program year for EPs is aligned with the calendar year (CY) while the program year for eligible hospitals and CAHs is aligned with the Federal fiscal year (FY). For CY 2011 and FY 2011, we are requiring Medicare EPs, eligible hospitals and CAHs to attest, through a secure (electronic) mechanism and in a manner specified by CMS, that they used certified EHR technology, the technology used, and that they have satisfied each of the applicable meaningful use objectives and associated measures during a ninety-day EHR reporting period. Similarly, for CY 2012, FY 2012, and subsequent years, in order to receive a Medicare incentive, we require EPs, eligible hospitals and CAHs to attest, through a secure (electronic) mechanism and in a manner specified by CMS, that during the EHR reporting period, they used certified EHR technology, specify the technology used, and they have satisfied each of the applicable meaningful use objectives and associated measures and the results for each applicable measure.

In accordance with sections 1848(o)(2)(A)(iii) and 1886(n)(3)(A)(iii) of the Act, an EP, eligible hospital or CAH must submit, using certified EHR technology, information on the clinical quality measures selected by the Secretary in order to demonstrate they are meaningful users of certified EHR technology for an EHR reporting period for a payment year. For CY 2012, FY 2012 and subsequent years, we require Medicare EPs, eligible hospitals and CAHs to report electronically ambulatory quality measures or hospital quality measures to CMS, in the form and manner specified by CMS.

Section 1903(t)(6)(B)-(C) allows for States to have flexibility in defining meaningful use for Medicaid EPs and eligible hospitals. Since CMS made a policy decision to align the Medicare and Medicaid EHR incentive programs when possible, the final rule allows States to add up to four of the public health-related measures to the meaningful use core set of measures for their individual programs. However, CMS will review and approve the policies prior to implementation.

§495.202 Identification of Qualifying MA EPs and Qualifying MA-affiliated Eligible Hospitals

Section 1853(l) of the Act, as added by section 4101(c) of the HITECH Act, requires that Medicare incentive payments be applicable to EPs for certain MA organizations for meaningful use of certified EHR technology. Section 1853(m) of the Act, as added by section 4102(c) of the HITECH Act, requires that incentive payments be applicable to MA-affiliated hospitals for meaningful use of certified EHR technology.

Specifically, we require that qualifying MA organizations, as part of their initial bids starting for plan year 2012, must identify themselves to CMS in a form and manner specified by CMS. Also, as part of their initial bids starting in June 2011, we require qualifying MA organizations to identify potentially qualifying MA EPs and potentially qualifying MA-affiliated eligible hospitals seeking EHR incentive payments, along with an attestation that these EPs and hospitals meet the eligibility criteria.

In addition, we require that qualifying MA organizations to identify the name, practice address or location, and NPI or CCN (as appropriate) for all potential qualifying EPs and hospitals for which the qualifying MA organization requests payment under the MA EHR incentive payment program.

§495.204 Incentive Payments to Qualifying MA Organizations for MA-EPs and Hospitals

Section 1853(l)(1) of the Act, as added by section 4101(c) of the HITECH Act, provides for incentive payments to qualifying MA organizations for their affiliated EPs who are meaningful users of certified EHR technology during the relevant EHR reporting period for a payment year. Section 4102(c) of the HITECH Act adds a new subsection (m) to section 1853 of the Act to provide incentive payments to MA organizations for their affiliated hospitals that meaningfully use certified EHR technology.

To address avoidance of duplicate payments, section 1853(l)(3)(A) of the Act provides that in applying section 1848(o), instead of the additional payment amount specified under section 1848(o)(1)(A) of the Act, the Secretary may substitute an amount determined by the Secretary, to the extent feasible and practical, to be similar to the estimated amount in the aggregate that would be payable if payment for services furnished by such professionals was payable under Part B instead of Part C. Under this approach, we require that the qualifying MA organization must report to us the aggregate annual amount of revenue received by each salaried qualifying MA EP for MA plan enrollees of the MA organization. The revenue received by the qualifying MA EP for services provided to enrollees of the qualifying MA organization is used to calculate the incentive payments for MA EPs. We also require that qualifying MA organizations must develop

a methodology to estimate the portion of each qualifying MA EP's salary attributable to providing services that would otherwise be covered under Part B to MA plan enrollees of the MA organization in the payment year.

For qualifying MA EPs who are not salaried, (that is, who are paid on a capitated or fee-forservice basis, or are employed by third party entities), we require that qualifying MA organizations must provide, or have others provide, and submit to CMS, attestations as to the amount of compensation paid to each MA EP for Part B services provided to MA plan enrollees of the MA organization.

§495.210 Meaningful Use Attestation

As required by sections 1853(1)(6) and 1853(m)(1) of the Act, we establish Medicare meaningful user attestation requirements. For each MA EP and MA-affiliated hospital for which a qualified MA organization seeks an incentive payment, we require that the MA organization must attest, in a form and manner specified by us, that its MA EPs and MA-affiliated eligible hospitals are meaningful EHR users. We adopt the definitions of meaningful user proposed under the Medicare FFS program related to EPs and hospitals. We require qualifying MA organizations to attest each payment year whether each of their MA EPs, and MA-affiliated eligible hospitals for which t an incentive payment is sought was a meaningful EHR user for the EHR reporting period for a payment year.

§495.306 Establishing patient volume

Section 1903of the Social Security Act (the Act), as amended by Section 4201 of HITECH Act by the addition of 1903(t)(2), requires that in establishing eligibility Medicaid providers must meet certain criteria and must provide services to a minimum threshold of Medicaid patients or needy individuals in order to receive an incentive payment. To ensure that Medicaid providers are eligible to receive an incentive payment, providers will be required to annually attest to States that they have reached the minimum threshold of the requisite patient volume.

<u>§495.316</u> State monitoring and reporting regarding activities required to receive an incentive payment; <u>§495.350</u> State Medicaid agency attestations; <u>§495.352</u> Reporting Requirements; <u>§495.366</u> Financial oversight and monitoring of expenditures

As noted above, Medicaid providers will be required to attest annually to States that they have met the minimum threshold of the requisite patient volume in order to be eligible to receive an incentive payment. Consistent with the requirements outlined in Section 1903(t)(9) of the Act, as amended by Section 4201 of HITECH, States are required to conduct adequate oversight of the program including routine tracking of meaningful use attestations and reporting mechanisms. Thus, States will be required to monitor and verify patient volume attestations as well as other information related to receiving incentive payments. States will be required to submit to CMS a State Medicaid HIT Plan which will provide a detailed outlined of how States plan to implement this program, including how they plan to ensure accurate payments, provider eligibility, providers' having adopted, implemented upgraded or meaningfully used certified EHR technology and how they plan to identify and recoup improper payments. CMS will review and approve these plans. States will be required to report to CMS on an annual basis details regarding incentive payments made for provider adoption, implementation, upgrade or meaningful use of certified EHR technology, State activities to promote EHR adoption and meaningful use; and activities for tracking and verifying expenditures related to Medicaid provider incentive payments. States will also be required to submit quarterly progress reports documenting specific implementation and oversight activities performed during the quarter including progress in implementing the State's Medicaid HIT Plan. Reporting on the number of incentive payments by provider NPI and for adopting, implementing, upgrading or meaningfully using certified EHR technology will be provided by States to CMS through an interface with the NLR.

§495.330 Termination of FFP for failure to provide access to information

Similarly, consistent with the requirements outlined in Section 1903(t)(9) of the Act, States are responsible for maintaining records of, among other things, provider eligibility, patient volume, the level of provider adoption, implementation or upgrade and meaningful use of certified EHR technology and CMS is authorized to review these records at any time. States risk termination of FFP for failure to provide access to any information related to Medicaid provider incentive payments for meaningful use of certified EHR technology. CMS is proposing that States collect and provide access to all information/data required to implement this program.

§495.348 Procurement Standards

Consistent with the requirements outlined in Section 1903(t)(9) of the Act, we believe States will procure contractors for many aspects of implementation. Contractors, as agents of the State, will be required to maintain compliance with all aspects of the award and administration of the contract including maintaining written standards of conduct, procurement procedures, and a system for contract administration. CMS proposes that this information be collected and be made accessible to the Departmental awarding agency, the U.S. Comptroller General, or any of their duly authorized representatives.

2. Information Users

The information collection requirements described herein are needed to implement the HITECH Act. In order to avoid duplicate payments, all EPs are enumerated through their NPI, while all eligible hospitals and CAHs are enumerated through their CCN. State Medicaid agencies and CMS uses the provider's TIN and NPI or CCN combination in order to make payment, validate payment eligibility and detect and prevent duplicate payments for EPs, eligible hospitals and CAHs.

3. <u>Use of Information Technology</u>

All the proposed information collection described in this form is be done electronically. EPs, eligible hospitals and CAHs use the existing CMS (electronic) National Plan and Provider Enumeration System (NPPES) to register, through a secure mechanism in a manner specified by CMS, for participating in the EHR Incentive Program. CMS uses the existing (electronic) Provider

Enrollment and Chain Ownership System (PECOS) to validate Medicare EP, eligible hospital and CAH eligibility and attestation data and also Medicaid hospital enumeration and national eligibility. The data collected feeds into a NLR to process payments, track/avoid duplicate payments, and exchange payment information with the States.

Respondents are required to attest that the information provided and captured by the NLR is not false. Identify is verified by using the NPPES log-in credentials of the provider or an individual designated by a provider to act on their behalf.

4. Duplication of Efforts

This is not a duplicative collection of information because this is a new EHR Incentive Program. No other collections can substitute for this. Where possible, we leverage existing systems, including PECOS and NPPES.

5. <u>Small Businesses</u>

Since the vast majority of Medicare providers (well over 90 percent) are small entities within the definition in the Regulatory Flexibility Act (RFA), it is the normal practice of HHS simply to assume that all affected providers are "small" under the RFA. In this case, most Medicare and Medicaid EPs, eligible hospitals and CAHs are either non-profit entities or meet the SBA's size standard for small business. We also believe that the effects of the incentive program on many of these affected entities is economically significant. We believe that the adoption of EHRs will have an impact on virtually every EP, eligible hospital and CAHs, as well as some physicians and hospitals affiliated with MA plans. While the program is voluntary, in the first five years for Medicare participation, it carries substantial positive incentives that will make it attractive to virtually all eligible entities. Medicaid participation carries positive incentives through the life of the program.

6. Less Frequent Collection

With respect to Medicare, registration information collection is voluntary for the first five years from the effective date of the final rule. After the initial registration, the subsequent registration frequency depends on the EPs, eligible hospitals and CAHs' changing business needs, such as changes in their business practices, eligibility, or EHR incentive program they elect to participate. EPs, eligible hospitals and CAHs would then communicate such changes to CMS electronically. To implement the meaningful use provisions of the HITECH Act and receive incentives, (registered) EPs, eligible hospitals and CAHs are required to attest to the identification of the certified EHR technology used, satisfaction of the applicable objectives and measures, and reporting of quality measures annually. Less frequent information collection would impede efforts to establish compliance with the HITECH Act.

With respect to Medicaid, registration information collection is voluntary for the first six years from the time the State initiates the program. After the initial registration, the State must also verify annual eligibility, but subsequent registration frequency depends on the EPs and eligible

hospitals' changing business needs, such as changes in their business practices, eligibility, or EHR incentive program they elect to participate (e.g., they may switch States or to the Medicare program). EPs and eligible hospitals would then communicate such changes to CMS or the State electronically. To implement the meaningful use provisions of the HITECH Act and receive incentives, (registered) EPs and eligible hospitals are required to attest to the State the identification of the certified EHR technology used, satisfaction of the applicable objectives and measures, and reporting of quality measures annually. Less frequent information collection would impede efforts to establish compliance with the HITECH Act.

7. Special Circumstances

Without legislative amendments, we are unable to anticipate any circumstances that would change the requirements of this package.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice for the reinstatement of this information collection request published on June 7, 2013.

The proposed rule published on January 13, 2010 (75 FR 1844). The final rule published on July 23, 2010 (75 FR 44314). We subsequently published another 30-day FR notice on October 22, 2010 (75 FR 65354). The subsequent program rule "Stage 2" was proposed on March 7, 2012 (77 FR 13698) with corrections published on April 18, 2012 (77 FR 23193). The final rule for Stage 2 was published on September 4, 2012 (77 FR 53968) with corrections published on October 23, 2012 (77 FR 64755).

9. Payments/Gifts to Respondents

There will be no payments/gifts to respondents.

10. Confidentiality

Respondent information is kept in a physically secured area (electronic). The computer system is password protected for electronic information. Files containing the actual forms or information from these forms is safeguarded.

11. <u>Sensitive Questions</u>

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimates (Hours & Wages)

Burden requirements for registration and attesting to Stage 1 of meaningful use are in Table 34 of the "Stage 1" final rule. Burden requirements for attesting to Stage 2 of meaningful use are in

Table 21 in the Stage 2 final rule. We are re-stating the burden here as they appeared in the rule. Salary data is based on the U.S. Department of Labor Bureau of Labor Statistics (BLS), May 2008 National Occupational Employment and Wage Estimates found at <u>www.bls.gov</u>.

Table 34 Stage 1	Final	Rule
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	ОМВ			Burden per	Total Annual	Hourly Labor Cost	Total Cost of	Total Capital/	Total Conto
Reg Section	Control No.	Respondents	Responses	Response (in hours)	Burden (in hours)	of Reporting (in \$)	Reporting (in \$)	Maintenance Costs (in \$)	Total Costs (in \$)
§495.8 (a)(1)- EHR	140.	Respondents	Responses	(in nours)	(in nours)	(11.4)	(11 \$	(Π Ψ)	(11.4)
Technology Used, Core Set									
Objectives/Measures &									
Quality Measures (EPs)	0938-								
(2011)	1158	521,600	521,600	9.367	4,885,827	79.33	387,592,672	0	387,592,672
§495.8 (a)(1)- Menu Set			- ,		, , -		, ,-		, ,-
Objectives/Measures high	0938-								
(EPs) (2011)	1158	521,600	521,600	2.666	1,390,586	79.33	110,315,156	0	21,810,315,156
§495.8 (a)(1)- Menu Set									
Objectives/Measures low	0938-								
(EPs) (2011)	1158	521,600	521,600	0.700	365,120	79.33	28,964,970	0	21,728,964,970
§495.8 (a)(1)- Menu Set									
Objectives/Measures average	0938-								
(EPs) (2011)	1158	521,600	521,600	1.683	877,853	79.33	69,640,063	0	21,769,640,063
§495.8(a)(2) - EHR									
Technology Used & Core Set									
Objectives/Measures (EPs)	0938-								
(2012)	1158	527,254	527,254	8.867	4,675,161	79.33	370,880,539	0	370,880,539
§495.8 (a)(2)- Menu Set									
Objectives/ Measures high	0938-							_	
(EPs) (2012)	1158	527,254	527,254	2.666	1,405,659	79.33	111,510,941	0	4,611,510,941
§495.8 (a)(2)- Menu Set									
Objectives/ Measures low	0938-	507.054	507.054	0.700	000 070	70.00	00 070 0 40		4 500 070 040
(EPs) (2012)	1158	527,254	527,254	0.700	369,078	79.33	29,278,942	0	4,529,278,942
§495.8 (a)(2)- Menu Set									
Objectives/ Measures	0938-	E07.0E4		1 000	007.000	70.00	70 204 042	0	4 570 204 042
average (EPs) (2012)	1158	527,254	527,254	1.683	887,368	79.33	70,394,942	0	4,570,394,942
§495.8 (a)(2)- Ambulatory	0938-								
Quality Measures (EPs) (2012)	1158	527,254	527,254	0.500	263,627	14.81	3,904,316	0	3,904,316
§495.8 (b)(1) EHR	1130	521,254	527,254	0.500	203,027	14.01	3,904,310	0	3,904,310
Technology Used, Core Set									
Objectives/Measures &									
Quality Measures	0938-								
(hospitals/CAHs) (2011)	1158	5,011	5,011	9.200	46,101	59.98	2,765,150	0	2,765,150

Den Continu	OMB Control	Descusion	Deserves	Burden per Response	Total Annual Burden	Hourly Labor Cost of Reporting	Total Cost of Reporting	Total Capital/ Maintenance Costs	Total Costs
Reg Section	No.	Respondents	Responses	(in hours)	(in hours)	(in \$)	(in \$)	(in \$)	(in \$)
§495.8(b)(1) - Menu Set	0000								
Objectives/ Measures low	0938-	F 011	F 011	0.700	0 500	50.00	010 000		00 000 010 000
(hospitals/CAHs) (2011)	1158	5,011	5,011	0.700	3,508	59.98	210,392	0	20,600,210,392
§495.8(b)(1) - Menu Set	0000								
Objectives/ Measures high	0938-	F 011	F 011	0.500	17 500	50.00	1 051 050		00 001 051 050
(hospitals/CAHs) (2011)	1158	5,011	5,011	3.500	17,539	59.98	1,051,959	0	20,601,051,959
§495.8(b)(1) - Menu Set									
Objectives/ Measures									
average (hospitals/CAHs)	0938-								
(2011)	1158	5,011	5,011	2.100	10,523	59.98	631,176	0	20,600,631,176
§495.8 (b)(2) EHR									
Technology Used & Core Set									
Objectives/Measures	0938-								
(hospitals/CAHs) (2012)	1158	5,011	5,011	8.700	43,596	59.98	2,614,870	0	2,614,870
§495.8 (b)(2)- Menu Set									
Objectives/ Measures low	0938-								
(hospitals/CAHs) (2012)	1158	5,011	5,011	0.700	3,508	59.98	210,392	0	5,000,210,392
§495.8 (b)(2)- Menu Set									
Objectives/ Measures high	0938-								
(hospitals/CAHs) (2012)	1158	5,011	5,011	3.500	17,539	59.98	1,051,959	0	5,001,051,959
§495.8 (b)(2)- Menu Set									
Objectives/ Measures									
average (hospitals/CAHs)	0938-								
(2012)	1158	5,011	5,011	2.100	10,523	59.98	631,176	0	5,000,631,176
§495.8 (b)(2)- Hospital									
Quality Measures	0938-								
(hospitals/CAHs) (2012)	1158	5,011	5,011	0.500	2,506	14.81	37,106	0	37,106
§495.10(a)-(c) (EPs)	0938-								
(2011) low	1158	521,600	521,600	0.500	260,800	14.81	3,862,448	0	3,862,448
§495.10(a)-(c) (EPs)	0938-								
(2011) high	1158	521,600	521,600	0.500	260,800	79.33	20,689,264	0	20,689,264
§495.10(a)-(c) (EPs)	0938-								
(2011) average	1158	521,600	521,600	0.500	260,800	47	12,275,856	0	12,275,856
· · · · · ·	0938-								
§495.10(d) - (EPs) (2012) low	1158	57,998	57,998	0.500	28,999	14.81	429,475	0	429,475
§495.10(d) - (EPs) (2012)	0938-		,						· -
high	1158	57,998	57,998	0.500	28,999	79.33	2,300,491	0	2,300,491

	OMB Control			Burden per Response	Total Annual Burden	Hourly Labor Cost of Reporting	Total Cost of Reporting	Total Capital/ Maintenance Costs	Total Costs
Reg Section	No.	Respondents	Responses	(in hours)	(in hours)	(in \$)	(in \$)	(in \$)	(in \$)
§495.10(d) - (EPs) (2012)	0938-								
average	1158	57,998	57,998	0.500	28,999	47	1,364,983	0	1,364,983
§495.10(e)(1) - (EPs) (2011)	0938-	05 500	05 500	0.500	47 750	14.01	707 170	0	707 170
low	1158	95,500	95,500	0.500	47,750	14.81	707,178	0	707,178
§495.10(e)(1) - (EPs) (2011)	0938-	05 500	05 500	0.500	47 750	70.00	0 700 000		0 700 000
high	1158	95,500	95,500	0.500	47,750	79.33	3,788,008	0	3,788,008
§495.10(e)(1) - (EPs) (2011)	0938-	05 500	05 500	0.500	47 750		0.047.500		
average	1158	95,500	95,500	0.500	47,750	47	2,247,593	0	2,247,593
§495.10(e)(2) - (EPs) (2012)	0938-								
low	1158	96,500	96,500	0.500	48,250	14.81	714,583	0	714,583
§495.10(e)(2) - (EPs) (2012)	0938-							_	
high	1158	96,500	96,500	0.500	48,250	79.33	3,827,673	0	3,827,673
§495.10(e)(2) - (EPs) (2012)	0938-							_	
average	1158	96,500	96,500	0.500	48,250	47	2,271,128	0	2,271,128
§495.10(a) (b) (hospital)	0938-								
(2011)	1158	5,011	5,011	0.500	2,506	14.81	37,106	0	37,106
	0938-								
§495.10(d) - (hospital) (2012)	1158	401	401	0.500	201	14.81	2,969	0	2,969
§495.202(b)(2) (2012)	0938-								
EPs-preliminary ID	1158	12	12	0.500	6	59.98	360	0	360
§495.202(b)(2) (2012)									
MA-affiliated hospitals-	0938-								
preliminary ID	1158	12	12	0.250	3	15.44	46	0	46
§495.202(b)(2) (2012) EPs-	0938-								
final ID	1158	12	12	0.500	6	59.98	360	0	360
§495.202(b)(2) (2012) MA-	0938-								
affiliated hospitals-final ID	1158	12	12	0.250	3	15.44	46	0	46
§495.204(b)(2) (2012)	0938-								
Revenue reporting	1158	12	12	40.000	480	15.44	7,411	0	7,411
§495.204(b)(4) (2012) EPs-	0938-								
method	1158	2	2	1.500	3	31.65	95	0	95
§495.204(b)(5) or (b)(6)	0938-								
(2012) EPs-salary	1158	12	12	58.300	700	15.44	10,802	0	10,802
§495.210(b) (2012) EPs-	0938-								
attestation	1158	12	12	40.000	480	59.98	28,790	0	28,790
	0938-								
§495.306(a)(1)(i)	1158	139,600	139,600	0.500	69,800	79.33	5,537,234	0	5,537,234

Reg Section	OMB Control No.	Respondents	Responses	Burden per Response (in hours)	Total Annual Burden (in hours)	Hourly Labor Cost of Reporting (in \$)	Total Cost of Reporting (in \$)	Total Capital/ Maintenance Costs (in \$)	Total Costs (in \$)
Reg Section	0938-	Respondents	Responses	(in nours)	(in nours)	(11.5)	(11 \$)	(111 \$)	(111 \$)
§495.306(a)(1)(ii)(A)	1158	139,600	139,600	0.500	69,800	79.33	5,537,234	0	5,537,234
	0938-	100,000	100,000	0.000	00,000	10.00	0,001,204		0,001,204
§495.306(a)(1)(ii)(B)	1158	139,600	139,600	0.500	69,800	79.33	5,537,234	0	5,537,234
	0938-			0.000			0,001,201	_	0,001,201
§495.306(a)(2)	1158	4,933	4,933	0.500	2,467	14.11	34,802	0	34,802
	0938-								
§495.316	1158	56	56	5.000	280	100	28,000	0	28,000
	0938-								
§495.330(a) - high	1158	56	56	5.000	280	35.37	9,904	0	9,904
	0938-								
§495.330(a) - low	1158	56	56	5.000	280	14.11	3,951	0	3,951
	0938-								
§495.330(a) - average	1158	56	56	5.000	280	24.74	6,927	0	6,927
	0938-								
§495.348(c)	1158	28	56	0.500	28	35.37	990	0	990
	0938-								
§495.348(e)	1158	28	56	0.500	28	35.37	990	0	990
	0938-								
§495.348(f)	1158	28	56	5.000	280	35.37	9,904	0	9,904
	0938-							_	
§495.350high	1158	56	56	1.000	56	35.37	1,981	0	1,981
S 405 050 1	0938-		50	1 000	50		700		700
§495.350low	1158	56	56	1.000	56	14.11	790	0	790
S405 250 average	0938-	56	56	1.000	56	04.74	1 205		1 205
§495.350average	<u> 1158</u> 0938-	50	50	1.000	50	24.74	1,385	0	1,385
§495.352high	1158	56	56	5.000	280	35.37	9,904	0	9,904
9495.352nign	0938-	50	50	5.000	200	30.37	9,904	0	9,904
§495.352low	1158	56	56	5.000	280	14.11	3,951	0	3,951
3433.332-1010	0938-	50	50	5.000	200	14.11	3,331	0	5,951
§495.352average	1158	56	56	5.000	280	24.74	6,927	0	6,927
	0938-			0.000		<u> </u>	0,021		0,021
§495.366high	1158	56	56	5.000	280	35.37	9,904	0	9,904
	0938-			0.000		00.01	0,001		0,001
§495.366low	1158	56	56	5.000	280	14.11	3,951	0	3,951

Reg Section	OMB Control No.	Respondents	Responses	Burden per Response (in hours)	Total Annual Burden (in hours)	Hourly Labor Cost of Reporting (in \$)	Total Cost of Reporting (in \$)	Total Capital/ Maintenance Costs (in \$)	Total Costs (in \$)
	0938-								
§495.366average	1158	56	56	5.000	280	24.74	6,927	0	6,927
Total 2011*					6,344,458		481,944,348		42,781,944,348
Total 2012*					6,175,290		466,366,443		9,966,366,443

Table 21 Stage 2 Final Rule

	OMB Control	Number of	Number of	Burden per Respons	Total Annual Burden	Hourly Labor Cost of Reporting	Total Cost (Å)
Reg Section §495.6 - EHR Technology Used, Core	No.	Respondents	Responses	e (hours)	(hours)	(\$)	Total Cost (\$)
Set Objectives/Measures (EPs)	0938-1158	198,912	198,912	8.22	1,635,057	\$89.96	\$147,089,695.33
§495.6 - Menu Set Objectives/Measures (EPs) HIGH	0938-1158	198,912	198,912	0.50	99,456	\$89.96	\$8,947,061.76
§495.6 - Menu Set Objectives/Measures (EPs) LOW	0938-1158	198,912	198,912	0.05	9,946	\$89.96	\$894,706.18
§495.6 - Menu Set Objectives/Measures (EPs) AVERAGE	0938-1158	198,912	198,912	0.28	54,701	\$89.96	\$4,920,883.97
§495.8 - CQMs for EPs	0938-1158	198,912	198,912	1.50	298,368	\$89.96	\$26,841,185.28
§495.6 - EHR Technology Used, Core Set Objectives/Measures (hospitals/CAHs)	0938-1158	2,696	2,696	7.75	20,894	\$62.23	\$1,300,233.62
§495.6 - Menu Set Objectives/Measures (hospitals/CAHs)	0938-1158	2,696	2,696	0.50	1,348	\$89.96	\$121,266.08
§495.8 - CQMs for hospitals/CAHs	0938-1158	2,696	2,696	2.67	7,198	\$89.96	\$647,560.87
§495.210 - Gather information for attestation (MA EPs)	0938-1158	13,000	13,000	0.75	9,750	\$25.00	\$243,750.00
§495.210 - Attesting on behalf of MA EPs	0938-1158	13,000	13,000	0.25	3,250	\$59.00	\$191,750.00
§495.210 - Total cost of attestation for Stage 2 (MA EPs)	0938-1158	13,000	13,000	1.00	13,000	n/a	\$435,500.00

Reg Section	OMB Control No.	Number of Respondents	Number of Responses	Burden per Respons e (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$)	Total Cost (\$)
§495.210 - Gather information for attestation (MA-affiliated hospitals)	0938-1158	30	30	7.00	210	\$25.00	\$5,250.00
§495.210 - Attesting on behalf of MA-affiliated hospitals	0938-1158	30	30	1.48	44	\$59.00	\$2,619.60
§495.210 - Total cost of attestation for Stage 2 (MA-affiliated hospitals)	0938-1158	30	30	8.48	254	n/a	\$7,869.60
§495.342 - 1. Frequency of Health Information Technology (HIT) Implementation Advanced Planning		56	56	70.00	3,920	\$56.24	\$220,460.80
Document (IAPD) Updates Burden Total for 2014	0938-1158				2,034,740.16		\$181,584,656

13. <u>Capital Costs</u>

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

14. Cost to Federal Government

To collect the required information, the Federal Government (CMS) will build the IT infrastructure in 3 phases. The projected IT infrastructure cost for Phase 1 is \$40 million. The projected IT infrastructure cost for Phase 2 is \$65 million.

<u>"Phase 1 (10/2009 – 12/2011)"</u> – Establish a National Level Repository (NLR) that will be available in January 2011 and will support registering EPs and hospitals for the program, attestation, calculating incentive payments and assuring no duplicate payments are issued. An oversight (program integrity) strategy will also be developed and implemented during this Phase.

<u>"Phase 2 (1/2012 – 12/2014)"</u> - Implement coding to the NLR that will support the next stage of the Electronic Health Record Incentive program in preparing for Stage 2 of this program. In August 2012, CMS published a final rule that specifies the Stage 2 criteria that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet in order to continue to participate in the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs.

The costs estimates for Phase 3 are not available at this time since planning for procurement has not yet occurred."

15. Changes to Burden

Burden has been updated to include the Stage 2 meaningful use criteria.

16. <u>Publication/Tabulation Dates</u>

The publication date associated with this collection is December XX, 20XX.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. <u>Certification Statement</u>

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

This collection of information does not employ statistical methods.