Supporting Statement for Paperwork Reduction Act for Implementation of Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 (CMS-3310-FC)

Background

The Centers for Medicare & Medicaid Services (CMS) is requesting approval to collect information from eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) in order to implement requirements under Stage 3 of the Medicare and Medicaid EHR Incentive Programs, as discussed in the final rule that published on October 16, 2016 (80 FR 62762)[1].

The American Recovery and Reinvestment Act of 2009 (Recovery Act) (Pub. 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 (CEHRT). In their first payment year, Medicaid EPs and eligible hospitals may adopt, implement or upgrade to certified EHR technology. It also, provides for negative payment adjustments in the Medicare FFS and MA programs starting in 2015 for EPs, eligible hospitals, and CAHs participating in Medicare that are not meaningful users of CEHRT. The Medicaid EHR Incentive Program does not authorize payment adjustments.

The Medicare and Medicaid EHR Incentive Programs consist of 3 stages of meaningful use. Stage 1 of meaningful use began in 2011 and encouraged the adoption of EHR technology. Stage 2 of meaningful use began in 2014 and incorporated requirements based on supporting advanced clinical processes and health information exchange through certified EHR technology. Stage 3 of meaningful use focuses on advanced use of EHRs to support health information exchange, interoperability, advanced quality measurement, and maximizing clinical effectiveness and efficiencies.

[1] https://www.federalregister.gov/documents/2015/10/16/2015-25595/medicare-and-medicaid-programs-electronic-health-record-incentive-program-stage-3-and-modifications

The Stage 1 final rule for the Medicare and Medicaid EHR Incentive Program, which was published in the Federal Register on July 28, 2010 (75 FR 44314)[2], 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) (75 FR 44590)[3] 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) (76 FR 1262)[4]. The functionality of Certified EHR Technology should facilitate the implementation of meaningful use.

Subsequently, final rules have been issued by CMS (77 FR 53968)[5] that specified the Stage 2 criteria EPs, eligible hospitals and CAHs must meet to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs; and by ONC (77 FR 72985)[6] to create the 2014 Edition Certification Criteria for EHR technology that new and revised certification criteria would establish the technical capabilities and specify the related standards and implementation specifications that Certified EHR Technology would need to include to, at a minimum, support the achievement of meaningful use by EPs, eligible hospitals, and CAHs beginning with the EHR reporting periods in fiscal year and calendar year 2014. The CMS' Stage 2 final rule (77 FR 53968) was published on September 4, 2012. ONC's companion final rule (77 FR 72985) was published on September 4, 2012.

In the March 30, 2015 **Federal Register**, we published a proposed rule titled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program Stage 3" (80 FR 16731 through 16804) and the and the ONC 2015 Edition Certification Criteria proposed rule (80 FR 16804 through 16921). In the Stage 3 proposed rule, we specified the proposed meaningful use criteria that EPs, eligible hospitals, and critical access hospitals must meet in order to demonstrate meaningful use of CEHRT for Stage 3 of the Medicare and Medicaid EHR Incentive Programs.

Starting in program year 2017, we will only be collecting data from eligible hospitals and CAHs to determine the application of the Medicare payment adjustments. Medicare eligible professionals will not report to the EHR Incentive Program as they will report under the Merit-based Incentive Payment

[2] https://www.gpo.gov/fdsys/pkg/FR-2010-07-28/pdf/2010-17207.pdf
[3] https://www.gpo.gov/fdsys/pkg/FR-2010-07-28/pdf/2010-17210.pdf
[4] https://www.gpo.gov/fdsys/pkg/FR-2011-01-07/pdf/2010-33174.pdf
[5] https://www.federalregister.gov/documents/2012/09/04
[6] https://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29607.pdf

System. The information collected will also be used to make incentive payments to eligible hospitals in Puerto Rico.

A. Justification

1. Need and Legal Basis

This information collection serves to implement the HITECH Act. Eligible providers submit information to successfully demonstrate meaningful use and thus avoid the negative Medicare payment adjustment. Information on 8 objectives and their associated measures and on clinical quality measures must be submitted.

2. Information Users

The collection of information under data collection is to be used to validate compliance with the requirements for being a successful meaningful user under the Medicare and Medicaid EHR Incentive Programs. Providers attest to the required objectives and measures and meet the required thresholds. They must also submit clinical quality measure data. If it is determined that the provider is a not a meaningful user, the provider would be subject to a Medicare negative payment adjustment.

3. Improved Information Technology

The attestation is completed using online submission. The document is completed in a 508 compliant format.

4. Duplication of Similar Information

There is no duplication of effort on information associated with this collection.

5. Small Businesses

The only small businesses affected by this effort will be those small or medium-sized physician practices, eligible hospitals, and CAHs (<= 20 providers) that participate in the Medicare and Medicaid EHR Incentive Programs. Ninety-nine percent of all hospitals have adopted EHRs, whereas about 77% of all of EPs have adopted EHRs.

6. Less Frequent Collection

With respect to Medicare, participation in the EHR Incentive program was voluntary for the first five years from the effective date of the July 28, 2010 final rule. Providers had to register and then attest on an annual basis to demonstrate meaningful use. 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 and avoid Medicare payment adjustments, 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.

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 Notice/Outside Consultation

The 60-day Federal Register notice published as part of the notice of proposed rulemaking on March 30, 2015 (80 FR 16732). The final rule published on October 16, 2015 (80 FR 62762). No comments were received.

9. Payment/Gift To Respondent

There are no payments of gifts associated with this collection.

10. Confidentiality

We pledge privacy to the extent provided by law. As a matter of policy, CMS will prevent the disclosure of personally identifiable information contained in the data submitted. The data collected will be for CMS internal use only and will not be published.

11. Sensitive Questions

There are no questions of a sensitive nature associated with these forms.

12. Burden Estimate (Total Hours and Wages)

The information collection requirements and associated burden are discussed in detail in the final rule that was published October 16,2015 (80 FR 62916-62928).We estimate the burden will be virtually identical for the 627,635 EPs, eligible hospitals, and CAHs participating and represents a cost of $388,408,189. Below is the burden table (Table 25) on page 62928. Please note that the information collection requirements are not being submitted under 0938-1158. These requirements are being submitted as part of a new information request. We are requesting a new OMB control number for the information collection requirements contained in this information collection request.

TABLE J5: ESTIMATED ANNUAL INFORMATION COLLECTION BURDEN

Burden and Cost Estimates Associated with Information Collection							
Reg Section	**OMB Control No.**	**Number of Respondents**	**Number of Responses**	**Burden per Response (hours)**	**Total Annual Burden (hours)**	**Hourly Labor Cost of Reporting ($)**	**Total Cost ($)**
§495.x - Objectives/Measures (EPs)	0938-1158	609,100	609,100	6.86	4,178,426	92.25	385,834,395
§495.6 Objectives/Measures (hospitals/CAHs)	0938-1158	4,900	4,900	6.86	33,614	63.46	2,135,204
§495.210 - Gather information for attestation (MA EPs)	0938-1158	13,635	13,635	0.75	10,226	25.00	255,650
§495.210 –Attestation on behalf of MA EPs	0938-1158	13,635	13,635	0.25	3408.75	50.00	170,400
§495.316 – Quarterly Reporting	0938-1158	56	224	20	4480	3.00	13,440
Totals		**627,635**	**627,635**		**4,225,674**		**388,408,189**

Notes: All non-whole numbers in this table are rounded to 2 decimal places.

**There are no capital/maintenance costs associated with the information collection requirements contained in this rule. Therefore, we removed the associated column from Table J2.

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs.

14. Cost to the Federal Government

To collect the required information, the Federal Government (CMS) will modify the IT infrastructure at an estimated cost of $10 million.

15. Program or Burden Changes

This is a new request related to the final rule that establishes Stage 3 of the EHR Incentive Program which, as noted, builds on the requirements for the program in the Stage 2 final rule. However, there is an overall reduction in the burden per response from the Stage 2 final rule burden estimate and the Stage 3 final rule burden estimate. The burden under Stage 3 is estimated to be 6 hours, 52 minutes for each EP, eligible hospital. and CAH while the estimated burden under Stage 2 was 10 hours, 10 minutes for EPs and 10 hours and 55 minutes for eligible hospitals and CAHs. The reduction in burden is due to a reduction in the number of measures required under Stage 3.

16. Publication and Tabulation Dates

Information will begin to be collected in 2017. The information will be on viewable on the EHR Incentive Program website[7]. We believe that very few providers will attest to Stage 3 in 2017 due to the lack of products certified to the 2015 Edition. Most will attest to the existing Modified Stage 2

17. Expiration Date

There are no forms associated with this information collection request. However, upon receiving OMB approval, CMS will publish a notice in the Federal Register to inform the public of both the approval as well as the expiration date. In addition, the public will always be able access the expiration date on OMB's web site by performing a search on the OMB control number.[8] .

18. Certification Statement

There are no exceptions to the certification statement.

B. Collection of Information Employing Statistical Methods

[7] https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?gclid=CK3miejv3dACFUhWDQodC6oCQw

[8] http://www.reginfo.gov/public/do/PRAMain

The use of statistical methods does not apply to this form.