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

## 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.

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 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.

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), 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.

On March 7, 2012, CMS published a proposed rule (77 FR 13693) that specifies the Stage 2 criteria EPs, eligible hospitals and CAHs must meet to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs. In addition, it specifies payment adjustments for Medicare EPs, eligible hospitals and CAHs who fail to demonstrate meaningful use, revises certain Stage 1 criteria, and the proposed one year delay for Stage 2. Again, ONC has issued a separate proposed rule (77 FR 13832) to revise the initial set of standards, implementation specifications, and certification criteria. The proposed 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. 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.
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.

## A. Justification

### 1. Need and Legal Basis

This information collection serves to implement the HITECH Act. To avoid duplicate payments, all EPs are enumerated through their individual National Provider Identifier (NPI), and all eligible hospitals and CAHs are enumerated through their CMS Certification Number (CCN). State Medicaid agencies and CMS use the provider tax identification number and NPI or CCN combination

to make payments; validate payment eligibility; and detect and prevent duplicate payments for EPs, eligible hospitals, and CAHs.

2. Information Users

The collection of information under this extension is to be used to validate compliance with the requirements for being a successful meaningful user under the Medicare and Medicaid EHR Incentive Programs. If it is determined that the provider is a not a meaningful user, the provider would be subject to a Medicare payment adjustment.

3. Improved Information Technology

The forms will be available in electronic format. We expect attestations to be forwarded to our agency using the electronic format. The document is completed in a user friendly 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.

6. Less Frequent Collection

With respect to Medicare, registration information collection is voluntary for the first five years from the effective date of the July 28, 2010 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 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.

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 (for example, EPs may change States or switch 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. The information is to be collected on an annual basis. Eligible professionals will submit for their exemption once during the reporting period. States are only required to provide this information if they are specifically seeking FFP for efforts related to the Medicaid EHR Incentive Program, including health information exchange. States that are not seeking FFP for this purpose do not need to submit this additional APD documentation. With the exception of the annual update, once any documents are approved, there is no need to resubmit additional documents, unless the State initiates a change. This process is a longstanding process to implement States Medicaid IT systems and has been used for years. States must submit annual SMHP updates under the final rule.

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).

9. Payment/Gift To Respondent

There are no payments of gifts associated with this collection.

10. Confidentiality

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 notice of proposed rulemaking that published on March 30, 2015 (80 FR 16732). The collection of information section of the rule begins on page 16781. Below is the burden table (Table 7) on page 16787. Please note that the information collection requirements are not being submitted under 0938-1158. The burden table in this document has been revised to reflect the error in the notice of proposed rulemaking. 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.

| Regulation Section(s) | 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-New | 609,100 | 609,100 | 6.86 | 4,178,426 | 92.25 | 385,459,798 |
| §495.6 Objectives/Measures (hospitals/CAHs) | 0938-New | 4,900 | 4,900 | 6.86 | 33,614 | 63.46 | 2,133,144 |
| §495.210 - Gather information for attestation (MA EPs) | 0938-New | 13,635 | 13,635 | 0.75 | 10,226 | 25.00 | 255,650 |
| §495.210 – Attestation on behalf of MA EPs | 0938-New | 13,635 | 13,635 | 0.25 | 3409 | 50.00 | 170,450 |
| §495.316 – Quarterly Reporting | 0938-New | 56 | 224 | 20 | 4480 | 3.00 | 13,440 |
| **Totals** | | **627,635** | **627,635** | | **4,230,155** | | **388,032,482** |

**There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 7.

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 modification to an existing information collection.

16. Publication and Tabulation Dates

Information will begin to be collected in 2017.

17. Expiration Date

CMS does not oppose the display of the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

**B. Collection of Information Employing Statistical Methods**

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