Supporting Statement
Medicare and Medicaid Programs; Promoting Interoperability Program (Formerly known as the Medicare and Medicaid EHR Incentive Program) (CMS-10336)

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 Promoting Interoperability Programs (formerly known as the Medicare and Medicaid EHR Incentive Programs), 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 Medicare and Medicaid Promoting Interoperability Programs (formerly known as the EHR Incentive Program) and the 2014 Edition Certification Criteria for EHR technology. This ICR previously consisted of stage 1 and stage 2 however stage 1 has been completed. The requirements were revised in 80 FR 62762, Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule and the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 through 2017. With the passage of the Medicare Access and CHIP Reauthorization Act of 2015 and implemented through 81 FR 77008-77831 the Medicare EHR Incentive Program for eligible professionals was replaced by the Quality Payment Program starting in 2017.

B. Justification

1 . Need and Legal Basis

This information collection serves to implement the HITECH Act. Eligible professionals, eligible hospitals and CAHs submit information to successfully demonstrate meaningful use in order receive an incentive payment in the Medicaid Promoting Interoperability Program (formerly the Medicaid EHR Incentive Program) or avoid a downward payment adjustment in the Medicare Promoting Interoperability Program (formerly the Medicare EHR Incentive Program). They must submit information on 8 objectives and their associated measures and on clinical quality measures.

As noted above eligible professionals no longer participate in the Medicare Promoting Interoperability Program and the program was sunset back in CY 2017. In the 2018 Inpatient Prospective Payment System (IPPS) final rule we enabled eligible hospitals and CAHs in Medicare or an eligible hospital, or EP in Medicaid to attest to Modified Stage 2 or Stage 3 in CY 2018 to allow for greater flexibility.

According to the HITECH Act of 2009 we have to have some means to collect data from these participants and we have used attestation as the way to do so. As a result we have developed objectives and measures as the tool to collect data and have the healthcare providers attest that they have met the requirements of the Medicare and Medicaid Promoting Interoperability Programs.

2. Information Users

The information collection requirements described herein are needed to implement the HITECH Act. In order to avoid duplicate payments, all Medicaid EPs are enumerated through their NPI, while all eligible hospitals and CAHs are enumerated through their CCN. State Medicaid agencies and CMS uses the health care 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. We are using this the information collected in order to make payments for

EPs in the Medicaid Promoting Interoperability Program (formerly known as the Medicaid EHR Incentive Program)as well as provide incentive payments to eligible hospitals in Puerto Rico as well as payment adjust eligible hospitals and CAHs in the Medicare Promoting Interoperability Program (formerly known as the Medicare EHR Incentive Program) who are not considered to be a meaningful user of EHR technology.

3. Use of Information Technology

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 Promoting Interoperability Program (formerly known as the EHR Incentive Program). CMS uses the existing (electronic) Provider Enrollment and Chain Ownership System (PECOS) to validate eligible hospital and CAH eligibility and attestation data and also Medicaid hospital enumeration and national eligibility. The data collected feeds into quality net (QNET) 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 (QNET) 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 and no other collections can substitute for this. Where possible, we leverage existing systems, including PECOS and NPPES. We are also utilizing Quality Net (QNET) to collect data but this data is unique to the Medicare Promoting Interoperability Program. The National Level Repository (NLR) collects data for the Medicaid Promoting Interoperability Program.

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 PI Programs (formerly known as the Medicare and Medicaid EHR Incentive Program). Ninety-nine percent of all hospitals have adopted EHRs, whereas about 77% of all of EPs have adopted EHRs. We have minimized the impact on these entities by allowing all healthcare providers to apply for a significant hardship exception by meeting certain requirements. This will help to minimize the impact on healthcare providers who are unable to meet the requirements. Please note each hardship is reviewed on a case by case basis.

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. Updates to registration depends on the eligible hospitals and CAHs' changing business needs, such as changes in their business practices, eligibility, or the PI Program (formerly known as the EHR Incentive Program) they elect to participate. Eligible hospitals and CAHs would then communicate such changes to CMS electronically. To implement the meaningful use provisions of the HITECH Act and avoid a negative payment adjustment 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 PI Program (formerly known as the 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 published on March 27, 2018 (83 FR 13030). There were no public comments received.

The 30-day Federal Register notice published on June 8, 2018 (83 FR 26691)

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. Sensitive Questions

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

12. Burden Estimates (Hours & Wages)

The Table below provides the burden estimates. These are based on the National Occupational Employment and Wage Estimates found at www.bls.gov . Please note in the table below we used the BLS statistics and doubled the amount to take into account fringe benefits and overhead.

We are updating the burden estimates below to take into account the removal of the Stage 1 requirements from the Medicare and Medicaid Promoting Interoperability Programs. Additionally, we are taking into account the streamlined Modified Stage 2 objectives and measures that were finalized in previous rulemaking. We believe the burden will be different for Medicaid healthcare providers compared to Medicare eligible hospitals and CAHs as we now have different requirements for the two programs. As a result we are modifying the burden estimates. We note that the Medicare PI Program (formerly known as the Medicare EHR Incentive Program) was sunset for EPs in 2017 and now these EPs report to the Quality Payment Program (QPP). We estimate that approximately 198,000 EPs now participate in QPP based on the participation requirements. Currently the burden is estimated at $388,408,189 annually. We estimate the burden for all participants in the Medicare and Medicaid Promoting Interoperability Programs represent a total cost of $113,194,129.70 which is a reduction of $275,214,059 annually. This burden reduction will occur as a result of the reduced numbers of EPs, the conclusion of Stage 1, and the removal of the menu objectives and measures. We are requesting an update to the existing OMB control number 0938-1158 for the information collection requirements contained in this information collection request.

ESTIMATED ANNUAL INFORMATION COLLECTION BURDEN

Reg Section	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($)	Total Cost ($)
§495.22(b)-Medicaid EPs	0938-1158	80,000	80,000	6.86	548,800	$200.00	$109,760,000
§495.2(e)-Medicaid eligible hospitals/ CAHs	0938-1158	133	133	7.43	988	$134.50	$132,912
§495.22(c)-Medicare eligible hospitals/CAHs	0938-1158	3,300	3,300	7.43	24519	$134.50	$3,297,806
§495.342 - 1. Frequency of Health Information Technology (HIT) Implementation Advanced Planning Document (IAPD) Updates	0938-1158	56	56	20	1,120	$3.05	$3,413
Burden Total for 2018					575,427		$113,194,130

Position	**Salary**[1]	**Bureau of Labor Statistics/Federal Salary Database**

1 Please note that the salary presented in this table does note take into account fringe benefits and overheard. However, we have taken this into account in the collection burden table as provided above.

Physician	$100.00	https://www.bls.gov/ooh/healthcare/physicians-and-surgeons.htm
Lawyer	$67.25	https://www.bls.gov/oes/current/oes231011.htm
State employee equivalent to a GS 12	$3.047[2]	https://www.federalpay.org/gs/2018/GS-12

2 This number is based on the salary rate of a GS 12 step 1 (2018 unadjusted for locality rate), with an hourly rate of approximately $30.47. This amount is reduced by the 90 percent federal contribution for administration services under the Medicaid PI Program (formerly known as the Medicaid EHR Incentive Program).

13. Capital Costs

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. The average cost of Phase 2 is $21.6 million over three years. We note that Phase 3 has no additional costs associated with included Promoting Interoperability Program (formerly known as the EHR Incentive Program) data in Quality Net (QNET).

"Phase 1 (10/2009 – 12/2011)" – 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.

"Phase 2 (1/2012 – 11/2017)" - Implement coding to the NLR that will support the next stage of the Promoting Interoperability Program (formerly known as the EHR 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, eligible hospitals, and CAHs must meet in order to continue to participate in the Medicare and Medicaid Promoting Interoperability Programs (formerly known as the Medicare and Medicaid EHR Incentive Program).

"Phase 3 (12/2017- 12/2022)- At the end of 2017 we note that the data that was previously included in the NLR is now being transferred and collected in the Quality Net (QNET) system. We began using this platform to collect EHR data and for attestation purposes as we note most of the other hospital quality reporting programs already use this platform and we note that there would be reduced burden in hospitals using just one system to submit their data. As a result there was no additional cost to the Medicare and Medicaid Promoting Interoperability Programs (formerly known as the Medicare and Medicaid EHR Incentive Program) as the system already had the capability to ingest our data without any additional burdens.

15. Changes to Burden

The previous package included burden for both Stage 1 and Stage 2. Stage 1 is no longer applicable and has caused for us to reduce the number of hours required, this change also takes into account the streamlined objectives and measures in Modified Stage 2. Additionally, we note that this burden reduction would occur as a result of the reduced numbers of eligible professionals, as they have transitioned to the Quality Payment Program. We previously estimated that there

were 198,912 Medicare and Medicaid EPs in the Medicare and Medicaid PI Program (formerly known as the Medicare and Medicaid EHR Incentive Program). We have since updated this to only include the remaining Medicaid EPs which we estimate to be 80,000 Medicaid EPs. We also wanted to note that many of the Medicare EPs are also Medicaid EPs. These remaining 80,000 Medicaid EPs are those we assume can still receive an incentive payment. We estimate the burden for all participants in the Medicare and Medicaid Promoting Interoperability Programs (formerly the Medicare and Medicaid EHR Incentive Program) represents a total cost of $113,194,130**,** which is a reduction of $275,214,059 annually. We also note that the currently approved burden in hours are 4,792,112 and as a result of the changes discussed above those hours are reduced to 575,427 hours.

16. Publication/Tabulation Dates

N/A

17. Expiration Date

The expiration date will be displayed on the following website:
https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

This collection of information does not employ statistical methods.