Supporting Statement

Implementation of Medicare and Medicaid Programs; - Promoting Interoperability Programs Stage 3 (CMS-10552)

Background

As discussed in the final rule that published on October 16, 2016 (80 FR 62762)[1], 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. We are making further changes to this program as finalized in the 2019 IPPS Final Rule[2]. Please note beginning in 2018 the Medicare and Medicaid EHR Incentive Programs has been changed to the Medicare and Medicaid Promoting Interoperability 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 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

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

[2] https://www.federalregister.gov/documents/2018/08/17/2018-16766/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-and-the

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)[3], 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)[4] 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)[5]. The functionality of Certified EHR Technology should facilitate the implementation of meaningful use.

Subsequently, final rules have been issued by CMS (77 FR 53968)[6] 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)[7] 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 CY 2017, we began collecting data from eligible hospitals and CAHs to determine the application of the Medicare payment adjustments. Medicare eligible professionals no longer report to the EHR Incentive Program, as they report under the Merit-based Incentive Payment System. The information collected will also be used to make incentive payments to eligible hospitals in Puerto Rico.

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

In the 2019 inpatient prospective payment system (IPPS) final rule we are finalizing several changes that we believe will reduce burden on eligible hospitals and CAHs in the Medicare Promoting Interoperability Program. We are finalizing a new scoring methodology for eligible hospitals and CAHs that removes the requirement that eligible hospitals and CAHs must report on and meet the threshold for all objectives and measure. Our new propsed approach requires an eligible hospital and CAH to meet six measures and are scored based on the performance. This new scoring approach reduces burden and also reduces the amount of time needed to report on measures. Additionally, we note that we are finalizing two new optional opioid measures and one new care coordination measure that we believe are helping to combat the opioid epidemic and improve interoperability. These new measures all fit within the new hospital scoring approach and reduce burden tremendously.

A. Justification

1. Need and Legal Basis

This information collection serves to implement the HITECH Act. Eligible providers, eligible hospitals and CAHs submit information to successfully demonstrate meaningful use and receive an incentive payment in the Medicaid Promoting Interoperability Program.

As noted above, eligible providers no longer participate in the Medicare Promoting Interoperability Program. We are finalizing a new scoring methodology for eligible hospitals and CAHs in the Medicare Promoting Interoperability Program. In the new scoring methodology, these healthcare providers will be required to submit data on six required measures and two optional measures. In addition, they must also report on clinical quality measures.

According to the HITECH Act of 2009, we have to have some mean to collect data from these participants and we have used attestation. 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 collection of information under data collection is used to validate compliance with the requirements for being a successful meaningful user under the Medicare and Medicaid Promoting Interoperability 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.

CMS will use this information to getting a better understanding of how eligible hospitals and CAHs are using certified electronic health record technology (CEHRT). This data is then used to determine the impact of CEHRT on care for Medicare beneficiaries. Our goal is to continue to advance health information technology with the goal of having improved interoperability with various health systems.

3. Improved Information Technology

The attestation is completed using online submission, 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 Promoting Interoperability Programs. 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, participation in the Promoting Interoperability 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 Promoting Interoperability 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/or avoid Medicare payment adjustments, EPs, eligible hospitals and CAHs are required to attest to the identification of the CEHRT 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 CEHRT 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 May 7, 2018 (83 FR 20164). The final rule was published in the Federal Register on August 17, 218 (83 FR 41144).

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 2019 Inpatient Prospective Payment System final rule). We updated the burden estimate to take into account the reduced burden associated with the new requirements for Medicare eligible hospital and CAHs for Stage 3 of the Promoting Interoperability Program. 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 EHR Incentive Program was sunset for EPs in 2017 and now these EPs report to the Quality Payment Program (QPP). 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 $61,113,527.8, which is a reduction of $327,294,661 annually. This burden reduction will occur as a result of the reduced numbers of EPs participating in the program and the new scoring methodology finalized in the rule (83 FR 41698). Below is the burden table in the 2019 Inpatient Prospective Payment System final rule. Please note that the information collection requirements are being submitted under 0938-1278 as part of the existing information request. We are requesting an update to the existing OMB control number 0938-1278 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	**Number of Respondents**	**Number of Responses**	**Burden per Response (hours)**	**Total Annual Burden (hours)**	**Hourly Labor Cost of Reporting ($)**	**Total Cost ($)**
§495.24(d) - Objectives/Measures (Medicaid EPs)	80,000	80,000	7.43	594,400	100	$59,440,000
§495.24(d) Objectives/Measures Medicaid (eligible hospitals/CAHs)	133	133	7.43	988	67.25	$66,455.78
§495.24(e) Objectives/Measures Medicare (eligible hospitals/CAHs)	3300	3300	7.18	23,694	67.25	$1,593,421.5
§495.316 – Quarterly Reporting (Medicaid)	56	224	20	4,480	3.047	$13,650.56
Totals	83,489	83,657	……	623,562		**$61,113,528**

Notes: All non-whole numbers in this table are rounded to two 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.

Position	Salary	Bureau of Labor Statistics/Federal Salary Database
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[8]	https://www.federalpay.org/gs/2018/GS-12

[8] 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 EHR Incentive Program.

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 not have any additional cost, as this data will be collected in a system that is currently operating under different programs. We note that we are currently collecting this data with the quality net (QNET) system. QNET is currently operating with all of the hospital quality reporting programs and the addition of this data beginning in 2018 does not add any additional cost.

15. Program or Burden Changes

The total burden under Stage 3 is estimated to be $61,113,528 in the Medicare and Medicaid Promoting Interoperability Programs. We also note that the total burden under Stage 3 in the Medicare Promoting Interoperability Program is estimated to be $1,593,4216.

We note that the number of respondents in the approved burden is 641,494. As a result of program changes, we note that this will be reduced to 83,489 respondents. The burden hours have decreased from 4,230,155 to 623,562. Additionally, we note that we are reducing total burden from $388,408,189 to $61,113,527.8 as discussed in the chart in section 12. Please note that our burden estimates have changed.

16. Publication and Tabulation Dates

Information will begin to be collected in 2019. The information will be on viewable on the Promoting Interoperability Program website[9].

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. We plan to post the PRA disclosure statement including the expiration date on the cms.gov website, https://www.cms.gov/Regulations-and-

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

Guidance/Legislation/EHRIncentivePrograms/index.html. 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.[10]

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.

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