

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 Rule². 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 CEHRT 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 (MIPS). 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 finalized several changes that we believe will reduce burden on eligible hospitals and CAHs in the Medicare Promoting Interoperability Program. We finalized 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 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 finalized 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.

In the 2020 IPPS Final Rule (84 FR 42591 through 42602), for purposes of an increased level of stability, reducing the burden on eligible hospitals and CAHs, and clarifying certain existing policies, we finalized several changes to the Promoting Interoperability Program. Specifically, we are: establishing an EHR reporting period of a minimum of any continuous 90-day period in CY 2021 for new and returning participants (eligible hospitals and CAHs) in the Medicare Promoting Interoperability Program attesting to CMS; requiring that the Medicare Promoting Interoperability Program measure actions must occur within the EHR reporting period, beginning with the EHR reporting period in CY 2020; revising the Query of PDMP measure to make it an optional measure worth 5 bonus points in CY 2020, removing the exclusions associated with this measure in CY 2020, requiring a yes/no response instead of a numerator and denominator for CY 2019 and CY 2020, and clearly stating our intended policy that the measure is worth a full 5 bonus points in CY 2019 and CY 2020; and removing the Verify Opioid Treatment Agreement measure beginning in CY 2020 and clearly stating our intended policy that this measure is worth a full 5 bonus points in CY 2019.

A. 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 and receive an incentive payment in the Medicare Promoting Interoperability Program.

As noted above, eligible professionals no longer participate in the Medicare Promoting Interoperability Program. We are finalizing several changes for eligible hospitals and CAHs in the Medicare Promoting Interoperability Program that do not have an impact to burden estimates. We anticipate that the burden will decrease for the Electronic Prescribing objective due to the finalized change requiring a “yes/no” response instead of a numerator/denominator manual calculation for the Query of PDMP measure.

According to the HITECH Act of 2009, we have to have a mean to collect data from these

participants, and we have used attestation. We have developed objectives and measures as the tools to collect data, in addition to having 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 not a meaningful user, the provider would be subject to a Medicare negative payment adjustment. The collection of information burden analysis in this finalized rule focuses on eligible hospitals and CAHs that attest to the objectives and measures, and report CQMs, under the Medicare Promoting Interoperability Program for the reporting period in CY 2021.

CMS will use this information to get a better understanding of how eligible hospitals and CAHs are using 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 via an online submission form (508 compliant). Outside of this online attestation, there are no physical nor additional forms used. Developers and CMS commonly refer to this program-specific format as the Attestation Screens, which are only open for completion by eligible hospitals and CAHs between January and March (exact dates may vary due to calendar).

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 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

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

The 30-day Federal Register notice of the FY 2020 IPPS/LTCH final rule published on August 16, 2019 (84 FR 42044).

9. Payment/Gift to Respondent

While no gifts will be given to respondents for participation, the program has historically utilized incentive payments to Medicare and Medicaid providers who successfully demonstrated meaningful use. However, the vast majority of these positive/upward incentive adjustments have ended or provider participation will be completed by the end of CY 2021 (excluding specific exemptions for Puerto Rico who began the program late), therefore, Medicare is currently the one remaining program with only a downward/negative payment adjustment.

The HITECH Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified electronic health record technology (CEHRT). Incentive payments under Medicare were available to eligible hospitals and CAHs for certain payment years (as authorized under sections 1886(n) and 1814(l) of the Act, respectively) if they successfully demonstrated meaningful use of CEHRT, which

included reporting on eCQMs using CEHRT. Incentive payments were available to MA organizations under section 1853(m)(3) of the Act for certain affiliated hospitals that successfully demonstrate meaningful use of CEHRT. In accordance with the timeframe set forth in the statute, these incentive payments under Medicare generally are no longer available, except for Puerto Rico eligible hospitals. For more information on the Medicare incentive payments available to Puerto Rico eligible hospitals, please refer to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41672 through 41675).

Sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act also establish downward payment adjustments under Medicare, beginning with FY 2015, for eligible hospitals and CAHs that do not successfully demonstrate meaningful use of CEHRT for certain associated EHR reporting periods. Section 1853(m)(4) of the Act establishes a negative payment adjustment to the monthly prospective payments of a qualifying MA organization if its affiliated eligible hospitals are not meaningful users of CEHRT, beginning in 2015. Section 1903(a)(3)(F)(i) of the Act establishes 100 percent Federal financial participation (FFP) to States for providing incentive payments to eligible Medicaid providers (described in section 1903(t)(2) of the Act) to adopt, implement, upgrade, and meaningfully use CEHRT.

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 2020 IPPS 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 the 2020 EHR reporting period 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 MIPS. We estimate the burden for all participants in the Medicare and Medicaid Promoting Interoperability Programs represent a total cost of \$60,983,413, which is a reduction of \$130,115 annually. This burden reduction will occur as a result of the reduced number of EPs participating in the program and the new scoring methodology finalized in the 2019 IPPS final rule (83 FR 41698). Below is the burden table that takes into account the 2020 IPPS final rule changes to “§495.24(e) Objectives/Measures Medicare (eligible hospitals/CAHs)” (84 FR 42610) and “§495.24(d) Objectives/Measures (Medicaid EPs),” “§495.24(d) Objectives/Measures (Medicaid eligible hospitals/CAHs),” and “§495.316 – Quarterly Reporting (Medicaid)” of the 2019 IPPS final rule for the Medicaid Promoting Interoperability Program (83 FR 41698). 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	\$66,443
§495.24(e) Objectives/Measures Medicare (eligible hospitals/CAHs)	3300	3300	6.5	21,450	68.22	\$1,463,319
§495.316 – Quarterly Reporting (Medicaid)	56	224	20	4,480	3.047	\$13,651

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 (\$)
Totals	83,489	83,657	621,318		\$60,983,413

Notes: All non-whole numbers in this table are rounded to two decimal places, with the exception of "Total Cost (\$)," which is rounded to the nearest dollar.

**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 is estimated to be \$60,983,413 in the Medicare and Medicaid Promoting Interoperability Programs. We also note that the total burden in the Medicare Promoting Interoperability Program is estimated to be \$1,463,319. The burden hours have decreased from 623,562 to 621,318. The reduction in hours is due to a finalized proposal regarding the Electronic Prescribing Objective Query of PDMP measure's reporting requirement which was converted from a numerator/denominator manual calculation to a "yes/no" attestation response (previously taking an estimated 40 minutes per respondent).

16. Publication and Tabulation Dates

Information will begin to be collected in 2019. The information will be viewable on the Promoting Interoperability Program website⁹. The sort of information for public viewing on this site include Data and Program Reports which overview topics such as active registrations (current and program-to-date), provider counts by stage number, and annual payment summaries (per program and field/specialty). Additional information provided is geared toward educational and contextual assistance for those learning about the program including but not limited to: latest news, dates to remember, program requirements, contact information, as well as useful links to the Federal Register, FAQ, and measure specification sheets.

17. Expiration Date

There are no additional forms associated with this information collection request besides the online form used for submitting attestations. We plan to post the **PRA disclosure statement including the expiration date** on the cms.gov website, <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html>.

18. Certification Statement

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

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.