

**Supporting Statement Part A**  
**Implementation of Medicare and Medicaid Programs; - Promoting Interoperability**  
**Programs Stage 3 (CMS-10552)**

**Background**

As discussed in the Final Rule published on October 16, 2016 (80 FR 62762)<sup>1</sup>, 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 proposed in the FY 2021 Inpatient Prospective Payment System (IPPS)/Long-term Care Hospital Prospective Payment System (LTCH PPS) Proposed Rule. Please note beginning in 2018 the names of the Medicare and Medicaid EHR Incentive Programs were 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 amended 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 created 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 could adopt, implement, or upgrade to certified EHR technology. It also provided 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 Promoting Interoperability Program did not authorize negative payment adjustments, but participants were eligible for positive incentive payments.

The Medicare and Medicaid Promoting Interoperability 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 the use of certified EHR technology. Stage 3 of meaningful use focuses on advanced use of certified

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

EHR technology to support health information exchange, interoperability, advanced quality measurement, and maximizing clinical effectiveness and efficiencies. The CMS 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)<sup>2</sup>, 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 CEHRT 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)<sup>3</sup> that specified the initial set of standards, implementation specifications, and certification criteria for CEHRT. ONC 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)<sup>4</sup>. The functionality of CEHRT should facilitate the implementation of meaningful use.

Subsequently, final rules have been issued by CMS ([77 FR 53968](#))<sup>5</sup> 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](#))<sup>6</sup> 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 ONC 2015 Edition Certification Criteria Proposed Rule (80 FR 16804 through 16921). In the CMS 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. Both the CMS Stage 3 Final Rule (80 FR 62762) and ONC's companion Final Rule (80 FR 62602) were published on October 16, 2015.

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.

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<sup>2</sup><https://www.gpo.gov/fdsys/pkg/FR-2010-07-28/pdf/2010-17207.pdf>

<sup>3</sup><https://www.gpo.gov/fdsys/pkg/FR-2010-07-28/pdf/2010-17210.pdf>

<sup>4</sup><https://www.gpo.gov/fdsys/pkg/FR-2011-01-07/pdf/2010-33174.pdf>

<sup>5</sup><https://www.federalregister.gov/documents/2012/09/04>

<sup>6</sup><https://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29607.pdf>

In the FY 2019 IPPS/LTCH PPS Final Rule (83 FR 41634 through 41667), we finalized several changes to 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 their performance. This new scoring approach reduces burden and also reduces the amount of time needed to report on measures. Additionally, we finalized two new optional opioid measures and one new care coordination measure to help address the opioid epidemic and improve interoperability.

In the FY 2020 IPPS/LTCH Final Rule (84 FR 42591 through 42602), we finalized the conversion of the Electronic Prescribing Objective's Query of Prescription Drug Monitoring Program (PDMP) measure to a yes/no attestation response (removing the numerator-denominator calculation) as well as finalizing that the measure should continue as optional and eligible for 5 bonus points in CY 2020. The Final Rule established the EHR Reporting Period to be 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, as well as finalizing the removal of the Electronic Prescribing Objective's Verify Opioid Treatment Agreement measure beginning with the EHR reporting period in CY 2020. These changes were made with the consideration of extensive stakeholder feedback in amending the program's existing policies to enhance consistency, clarity, and to reduce undue provider reporting burden.

In the FY 2021 IPPS/LTCH PPS Final Rule ([85 FR 58966 through 58977](#)), we are finalizing as proposed a few changes that we believe will continue to be a low reporting burden on eligible hospitals and CAHs in the Medicare Promoting Interoperability Program while incentivizing the advanced use of CEHRT to support health information exchange, interoperability, advanced quality measurement, and maximizing clinical effectiveness and efficiencies. These finalized changes include continuing an EHR reporting period of a minimum of any continuous 90-day period in CY 2022, and maintaining the Query of PDMP measure as optional and worth 5 bonus points in CY 2021.

## **A. Justification**

### **1. Need and Legal Basis**

This information collection serves to implement the HITECH Act. We have developed objectives and measures to collect data and have the healthcare providers attest that they have met the requirements of the Medicare and Medicaid Promoting Interoperability Programs. Eligible professionals and eligible hospitals submit information to successfully demonstrate meaningful use and receive an incentive payment in the Medicaid Promoting Interoperability Program through CY 2021, after which this Medicaid program will no longer continue. Eligible hospitals and CAHs must successfully demonstrate meaningful use under the Medicare Promoting Interoperability Program to avoid a negative payment adjustment.

As noted above, eligible professionals no longer participate in the Medicare Promoting

Interoperability Program. In the FY 2021 IPPS/LTCH PPS Final Rule, we finalized several updates for eligible hospitals and CAHs in the Medicare Promoting Interoperability Program that do not have an impact to burden estimates.

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 this 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 electronically 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 proposed rule focuses on eligible hospitals and CAHs that attest to the objectives and measures, and report CQMs, under the Medicare Promoting Interoperability Program.

We use this information to get a better understanding of how eligible hospitals and CAHs are using CEHRT. These data are then used to determine the impact of CEHRT on care for Medicare beneficiaries. Our goal is to continue to advance the meaningful use of health information technology with one of our main priorities to improve interoperability and health information exchange among various health systems' EHRs and with their patients.

## 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 ( $\leq 20$  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

We have designed the collection of information under the Medicare and Medicaid Promoting Interoperability Programs to be the minimum necessary for eligible professionals, eligible hospitals, or CAHs to demonstrate the meaningful use of CEHRT. To implement the meaningful use provisions of the HITECH Act and receive incentives and/or avoid negative payment adjustments under the Medicare Promoting Interoperability Program, 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 payment incentives under the Medicaid Promoting Interoperability Program, (registered) EPs and eligible hospitals are required to attest to their respective States 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 published as part of the notice of proposed rulemaking of the FY 2021 IPPS/LTCH final rule on September 18, 2020 (85 FR 58432).

CMS is supported in this initiative by the Office of the National Coordinator for Health Information Technology (ONC). ONC collaborates with CMS on an ongoing basis, providing technical assistance with regard to health IT certification requirements and in developing and/or identifying measures and objectives, as well as by assisting in making the information accessible, understandable, and relevant to the public.

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. In addition, the tools used for transmission of data are considered confidential forms of communication, and there are safeguards in place in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules to protect the submission of patient information, at 45 CFR Part 160 and 164, Subparts A, C and E. The data collected will be for CMS internal use only and will not be published, except as finalized for public display under section 1886(n)(4)(B) of the Social Security Act, which requires the Secretary to post on the CMS website, in an easily understandable format, a list of the names of the eligible hospitals and CAHs that are meaningful EHR users, and other relevant data as determined appropriate by the Secretary.

#### 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 due to the updates for the

Medicare Promoting Interoperability Program are discussed in detail in the FY 2021 IPPS/LTCH PPS final rule. In addition, 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 modified the burden estimates. We note that the Medicare EHR Incentive Program was sunset for EPs in 2017 (remaining participants report to MIPS) and, as discussed in the FY 2020 IPPS/LTCH PPS Final Rule (84 FR 42592), 2021 will be the last year for including Medicaid eligible hospitals and CAHs in the burden estimate for this information collection as the Medicaid Promoting Interoperability Program concludes December 31<sup>st</sup>, 2021.

We estimated the annual burden for all participants in the Medicare and Medicaid Promoting Interoperability Programs represent a total of 249,818 hours and a total cost of \$23,985,802, which is a decrease of 371,500 hours and \$36,997,611 from the previously estimated total burden. This burden decrease will largely occur as a result of significantly fewer participating Medicaid EPs. CMS's Center for Medicaid and CHIP Services indicated that the number of objective and measure respondents has dropped from 80,000 EPs to 30,000 EPs, subsequently reducing Table J5's total hours and cost. We note that the total burden in the Medicare Promoting Interoperability Program by itself is estimated to be \$1,487,343. While our changes in the FY 2021 IPPS/LTCH PPS final rule were to continue the same reporting requirements as for the 2020 EHR reporting period, and thus would not change the estimated burden hours, we utilized the Bureau of Labor Statistics' updated labor cost for Medicare eligible hospitals and CAHs (from \$68.22 per hour to \$69.34 per hour), which increased the total burden cost by \$24,024. In addition, we corrected a previous numerical error in Medicaid's Quarterly Reporting labor cost (we inadvertently used \$3.047 per hour when it should have been \$30.47 per hour), as well as utilized the updated 2020 federal General Schedule (GS) pay scale (from \$30.47 per hour to \$31.70 per hour), which increased the total burden cost by \$128,365. While these revised calculations resulted in an isolated cost increase, the total annual burden change still resulted in a net reduction.

Below is the estimated burden table which takes into account the FY 2021 IPPS/LTCH PPS Proposed Rule changes to “§495.24(e) Objectives/Measures (Medicare eligible hospitals/CAHs)”, as well as the FY 2020 IPPS/LTCH PPS Final Rule changes to “§495.24(e) Objectives/Measures (Medicare eligible hospitals/CAHs)” (84 FR 42610), “§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 OMB control number 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 (currently pending approval). These burden estimates exclude burden associated with the reporting of electronic clinical quality measures under OMB control number 0938-1022, as Medicare hospitals report the data to CMS once per year for credit under both the Hospital Inpatient Quality Reporting Program and the Medicare Promoting Interoperability Program for eligible hospitals and CAHs.

**TABLE J5: ESTIMATED ANNUAL INFORMATION COLLECTION BURDEN**

<b>Burden and Cost Estimates Associated with Information Collection</b>						
<b>Regulatory Section</b>	<b>Number of Respondents</b>	<b>Number of Responses</b>	<b>Burden per Response (hours)</b>	<b>Total Annual Burden (hours)</b>	<b>Hourly Labor Cost of Reporting (\$)</b>	<b>Total Cost (\$)</b>
§495.24(d) - Objectives/Measures (Medicaid EPs)	30,000	30,000	7.43	222,900	\$100	\$22,290,000
§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)	3,300	3,300	6.5	21,450	\$69.34	\$1,487,343
§495.316 – Quarterly Reporting (Medicaid)	56	224	20	4,480	\$31.70	\$142,016
<b>Totals</b>	<b>33,489</b>	<b>33,657</b>		<b>249,818</b>		<b>\$23,985,802</b>

<b>Position</b>	<b>Salary</b>	<b>Bureau of Labor Statistics/Federal Salary Database</b>
Physician	\$100.00	<a href="https://www.bls.gov/ooh/healthcare/physicians-and-surgeons.htm">https://www.bls.gov/ooh/healthcare/physicians-and-surgeons.htm</a>
Lawyer	\$69.34	<a href="https://www.bls.gov/oes/2018/may/oes231011.htm">https://www.bls.gov/oes/2018/may/oes231011.htm</a>
State employee equivalent to a GS 12	\$31.70 <sup>7</sup>	<a href="https://www.federalpay.org/gs/2020/GS-12">https://www.federalpay.org/gs/2020/GS-12</a>

<sup>7</sup> This number is based on the salary rate of a GS 12 step 1 (2020 unadjusted for locality rate), with an hourly rate of approximately \$31.70. This amount is reduced by the 90 percent federal contribution for administration services under the Medicaid Promoting Interoperability 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 cost to the Federal Government (CMS) is minimal, as these data will be collected in a system that is currently operating to support different hospital quality reporting programs. We note that we are currently collecting these data with the Hospital Quality Reporting system, which eligible hospitals and CAHs access via the QualityNet secure portal.

15. Program or Burden Changes

The total burden for 2021 reporting is estimated to be 249,818 hours and \$23,985,802 in the Medicare and Medicaid Promoting Interoperability Programs, which is a decrease of \$36,997,611 from our previous burden estimate for 2020 reporting. The large decrease in total cost, in tandem with last year's total annual burden hours (621,318), is due to the drop-off of Medicaid EPs reporting from 80,000 to 30,000. We also note that the total burden specifically for the Medicare Promoting Interoperability Program is estimated to be a total of 21,450 hours and \$1,487,343. While finalized proposals in the FY 2021 IPPS/LTCH PPS final rule would not directly impact the estimated burden hours, we are utilizing the Bureau of Labor Statistics' updated labor costs which do contribute a negligible but slight additional cost.

16. Publication and Tabulation Dates

The information will be viewable on the Promoting Interoperability Program website<sup>8</sup>. 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 objective-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,

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<sup>8</sup> <https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?gclid=CK3miejv3dACFUhWDQodC6oCQw>

<https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html>.

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.