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)[1], the Centers for Medicare & Medicaid Services (CMS) is requesting approval to collect information from eligible hospitals and critical access hospitals (CAHs). We are making further changes to this program as proposed in the FY 2022 Inpatient Prospective Payment System (IPPS)/Long-term Care Hospital Prospective Payment System (LTCH PPS) Proposed Rule (86 FR 25628), and as finalized in the FY 2022 Inpatient Prospective Payment System (IPPS)/Long-term Care Hospital Prospective Payment System (LTCH PPS) Final Rule (86 FR 45460).

The American Recovery and Reinvestment Act of 2009 (Recovery Act) (Pub. L. 111-5) was enacted on February 17, 2009. 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 (CEHRT). 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. In their first payment year, Medicaid EPs and eligible hospitals could adopt, implement, or upgrade to certified EHR technology. It also allowed 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 its participants were eligible for positive incentive payments.

In CY 2017, we began collecting data from eligible hospitals and CAHs to determine the application of the Medicare payment adjustments. At this time, Medicare eligible professionals no longer reported to the EHR Incentive Program, as they began reporting under the Merit-based Incentive Payment System (MIPS). This information collected was also used to make incentive payments to eligible hospitals and critical access hospitals in Puerto Rico.

In the FY 2019 IPPS/LTCH PPS Final Rule (83 FR 41634 through 41667), we focused on reducing burden on eligible hospitals and CAHs. We finalized a new scoring methodology for eligible hospitals and CAHs, removing the requirement to report on and meet the threshold for all objectives and measures. This approach required an eligible

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

hospital or CAH to meet the requirements on six measures, with scoring based on performance. This approach reduced burden by decreasing 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 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.

In the FY 2021 IPPS/LTCH PPS Final Rule (85 FR 58966 through 58977), we are finalizing as proposed 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.

In the FY 2022 IPPS/LTCH PPS Proposed Rule (86 FR 25628 through 25654), we proposed 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, advance quality measurement, and maximize clinical effectiveness and efficiencies. The proposals include continuing an EHR reporting period of a minimum of any continuous 90-day period in CY 2023, maintaining the Query of PDMP measure as optional but worth 10 bonus points in CY 2022, the addition of a new Health Information Exchange Bi-Directional Exchange measure beginning in CY 2022 as an optional alternative to the two existing measures, a requirement of reporting 4 specific Public Health and Clinical Data Exchange Objective measures, the inclusion of a new SAFER Guides measure attestation response, and to adopt two new eCQMs to the Medicare Promoting Interoperability Program's eCQM measure set beginning with the reporting period in CY 2023 (in addition to removing three eCQMs from the measure set beginning with the reporting period in CY 2024, in alignment with the finalized changes to the Hospital IQR Program. In the FY 2022 IPPS/LTCH PPS Final Rule (86 FR 45460 through 45498), we finalized these proposals. We did not finalize a proposal to update the Provide Patients Electronic Access to their Health Information measure to include a data retention requirement; however, this proposal would not have affected our information collection burden estimate.

We note the previously approved PRA package under OMB control number 0938-1278 reflecting updates to information collection burden estimates based on policies finalized in the FY 2021 IPPS/LTCH PPS Final Rule include information collection burden estimates for 2021, which is the last year for including Medicaid eligible providers, eligible hospitals, and CAHs in the burden estimate as the Medicaid Promoting

Interoperability Program concludes December 31, 2021. Therefore, this PRA request for information collection burden in 2022 does not include any burden under the Medicaid Promoting Interoperability Program.

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 Promoting Interoperability Program. Eligible professionals and eligible hospitals submit information to successfully demonstrate meaningful use and receive an incentive payment under 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 downward payment adjustment.

According to the HITECH Act of 2009, we must have a means to collect data from participants, and we have used attestation as that means. 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.

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.

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. Participants attest to the required objectives and measures to meet the required thresholds for being considered a Meaningful User. They must also electronically submit clinical quality measure data (eCQMs). If it is determined that the participant is a not a Meaningful User, they would be subject to a downward payment adjustment. The collection of information burden analysis in the FY 2022 IPPS/LTCH PPS proposed rule and FY 2022 IPPS/LTCH PPS final rule focus on eligible hospitals and CAHs that attest to the objectives and measures, and report eCQMs, under the Medicare Promoting Interoperability Program.

We use the information collected from measure submissions to gain a better understanding of how eligible hospitals and CAHs are utilizing CEHRT and its functionality. We use the information collected from clinical quality measure data to determine its impact on care delivery for Medicare beneficiaries. Our goal is to continue

to advance the meaningful use of health information technology with our priority to continue promoting interoperability through health information exchange among various health systems' EHRs.

3. Improved Information Technology

The attestation is completed on an annual basis 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 eligible hospitals and CAHs (we define a "small hospital" as one with 1-99 inpatient beds) that participate in the Medicare Promoting Interoperability Program. Ninety-nine percent of all hospitals have adopted EHRs. We have minimized the impact on these entities by allowing all healthcare providers to apply for a significant hardship exception if they meet certain hardship criteria. This will help to minimize the impact on healthcare providers that are unable to meet the program requirements. Eligible hospitals and CAHs would need to submit a new application for subsequent years and no eligible hospital or CAH can be granted an exception for more than five years (Section 1886(b)(3)(B)(ix)(II) of the Social Security Act). 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 Promoting Interoperability Program to be the minimum necessary for eligible hospitals and CAHs to demonstrate the meaningful use of CEHRT. To implement the meaningful use provisions of the HITECH Act and receive incentives and/or avoid downward payment adjustments under the Medicare Promoting Interoperability Program, eligible hospitals and CAHs are required to attest to the identification of the CEHRT used, satisfaction of the applicable objectives and measures, and electronic 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 60-day Federal Register notice published October 14, 2021 (86 FR 57149). There were no public comments received.

The 30-day Federal Register notice published December 21, 2021 (86 FR 72242).

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, these positive incentive adjustments have ended by the end of CY 2021, therefore, Medicare is currently the one remaining program with only a downward payment adjustment.

The HITECH Act authorized 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 are no longer available. The last reporting year that Puerto Rico eligible hospitals could receive an incentive payment was in 2020 (FY 2021 payment year), and reporting year 2021 (FY 2022 payment year) is the first year where they would be subject to a downward/negative payment adjustment for failing to demonstrate meaningful use of CEHRT. 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.

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 2022 IPPS/LTCH PPS Proposed Rule and the FY 2022 IPPS/LTCH PPS Final Rule. As a result, we are modifying the burden estimates. We note that the Medicare EHR Incentive Program sunset for EPs in 2017 (remaining participants report to MIPS).

The Medicare Promoting Interoperability Program has previously utilized a lawyer's hourly wage rate; however, we have determined that it is no longer the most accurate profession among the hospital staff members who are most likely to complete the program's required electronic responses and attestations. Rather, we believe hospital staff similar to the staff who report for the Hospital Inpatient Quality Reporting Program are utilized to report for the Medicare Promoting Interoperability Program, specifically, a Medical Records and Health Information Technician staff role. We believe that both current and anticipated labor performed by participating hospitals in order to successfully complete the program's reporting requirements is accomplished by this technical role and not the position of a lawyer. Therefore, in calculating our estimated burden, we have replaced the existing lawyer's hourly wage rate of $69.34 with that of a Medical Records and Health Information Technician's median wage rate ($20.50 according to the 2019 U.S. Bureau of Labor Statistics[2]).

We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with the Hospital Inpatient Quality Reporting Program. This is a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($20.50 × 2 = $41) to estimate total cost is a reasonably accurate estimation method (as reflected on Table J5's Hourly Labor Cost of Reporting column). Utilizing the Bureau of Labor Statistics' role of a Medical Records and Health Information Technician instead of a Lawyer is what contributed to the total cost reduction (from $69.34 per hour to $41 per hour). Given the proposals in the FY 2022 IPPS/LTCH PPS proposed rule and the proposals finalized in the FY 2022 IPPS/LTCH PPS final rule, we estimate a total burden estimate of 6 hours 33 minutes per respondent (roughly 6.5 hours), which is a slight increase of 2 minutes per hospital from the FY 2021 IPPS/LTCH PPS Final Rule that similarly utilized a rounded total of 6.5 hours.

We estimate the total annual burden for all participants in the Medicare Promoting Interoperability Program represents a total of 21,450 hours and a total cost of $879,450.

[2] Bureau of Labor Statistics. https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm#tab-1. Accessed on [02/10/21].

This is a decrease of $607,893 from the previously estimated total burden ($1,487,343 for CY 2021), due to an administrative adjustment as discussed above made to the hourly wage role for hospital staff who would report attestation responses for purposes of satisfying requirements under the Medicare Promoting Interoperability Program (resulting in the subsequent reduction to Table J5's total cost).

Below is the estimated burden table which takes into account the FY 2022 IPPS/LTCH PPS Proposed Rule and FY 2022 IPPS/LTCH Final Rule changes to 42 CFR 495.24(e) Objectives/Measures (Medicare eligible hospitals/CAHs) (86 FR 25628 through 25654) as well as the FY 2021 IPPS/LTCH PPS Final Rule changes to 42 CFR 495.24(e) Objectives/Measures (Medicare eligible hospitals/CAHs) (85 FR 58966 through 58977).

We are revising the information collectin request under OMB control number 0938-1278. 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

Burden and Cost Estimates Associated with Information Collection						
Regulatory Section	**Number of Respondents**	**Number of Responses**	**Burden per Response (hours)**	**Total Annual Burden (hours)**	**Hourly Labor Cost of Reporting ($)**	**Total Cost ($)**
42 CFR 495.24(e) Objectives/Measures (Medicare eligible hospitals/CAHs)	3,300	3,300	6.5	21,450	$41	$879,450
Totals	3,300	3,300		21,450		**$879,450**

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 CY 2022 reporting is estimated to be 21,450 hours and $879,450 for the Medicare Promoting Interoperability Program across 3,300 participation eligible hospitals and CAHs, which is a decrease of $607,893 from our previous burden estimate for CY 2021 reporting. The decrease in cost is due to an administrative adjustment made to the hourly wage role for hospital staff who would report attestation responses for purposes of satisfying requirements under the Medicare Promoting Interoperability Program.

Utilizing the Bureau of Labor Statistics' role of a Medical Records and Health Information Technician instead of a Lawyer is what contributed to the reduction (from $69.34 per hour to $41.00 per hour). Given the proposals in the FY 2022 IPPS/LTCH PPS proposed rule and the proposals finalized in the FY 2022 IPPS/LTCH PPS final rule, we estimate a total burden estimate of 6 hours 33 minutes per respondent (roughly 6.5 hours), which is a slight increase of 2 minutes per hospital from the FY 2021 IPPS/LTCH PPS Final Rule which likewise utilized a rounded total of 6.5 hours per respondent.

As discussed, 2021 is the last year for including Medicaid in the burden estimate for this information collection given the Medicaid Promoting Interoperability Program concludes December 31, 2021; therefore, these estimates for 2022 do not include any burden under the Medicaid Promoting Interoperability Program. This programmatic sunset of the Medicaid components is what accounted for the estimated burden hours to reduce from 249,818 to 21,450 hours.

16. Publication and Tabulation Dates

Information will be viewable on the Medicare Promoting Interoperability Program website[3]. The information for public viewing available on this site 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, https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html.

18. Certification Statement

[3] https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html

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.