#### **Supporting Statement - Part A**

Submission of Information for the Medicare Promoting Interoperability Program: FY 2025 IPPS/LTCH PPS Final Rule (OMB# 0938-1278, CMS-10552)

### A. Background

This is a revision of the currently approved information collection request. This information collection serves to implement the Health Information Technology for Economic and Clinical Health (HITECH) Act. We have developed objectives and measures to collect data and have the healthcare providers attest or report data as applicable to determine that they have met the requirements of the Medicare Promoting Interoperability Program. Eligible hospitals and Critical Access Hospitals (CAHs) must successfully demonstrate meaningful use under the Medicare Promoting Interoperability Program to avoid a downward payment adjustment.

In CY 2017, we began collecting data from eligible hospitals and CAHs to determine the application of the Medicare payment adjustments. This information collection was also used to make incentive payments to eligible hospitals in Puerto Rico from 2016 through 2021. At this time, Medicare eligible professionals no longer reported to the Electronic Health Record (EHR) Incentive Program, as they began reporting under the Merit-based Incentive Payment System (MIPS) Promoting Interoperability Performance Category. In 2019, the EHR Incentive Program for eligible hospitals and CAHs was subsequently renamed the Medicare Promoting Interoperability Program. In subsequent years, we have focused on balancing reporting burden for eligible hospitals and CAHs while also implementing changes designed to incentivize the advanced use of certified EHR technology (CEHRT) to support health information exchange, interoperability, advanced quality measurement, and maximizing clinical effectiveness and efficiency.

The information collection requirements through the CY 2026 EHR reporting period are currently approved under OMB control number 0938-1278 (expiration date April 30, 2027). This request covers data collection requirements for the EHR reporting period in CY 2025 and subsequent years. The revised information collection request includes burden for the modification to the Antimicrobial Use and Antimicrobial Resistance (AUR) measure, the Actions to Limit or Restrict the Compatibility or Interoperability of CEHRT measure, the Office of the National Coordinator for Health IT (ONC) Direct Review measure, the submission of hardship applications, as well as updated data and wage rates impacting previously approved burden calculations. It also includes the Electronic Prior Authorization measure which was previously finalized in the Advancing Interoperability and Improving Prior Authorization Processes for MA Organizations and Medicaid Managed Care Plans, State Medicaid Agencies, State CHIP Agencies, CHIP Managed Care Entities, and Issuers of QHPs in the Federally-Facilitated Exchanges Final Rule published on February 8, 2024 (89 FR 8758).

#### B. Justification

### 1. Need and Legal Basis

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 by establishing incentive payments to eligible professionals (EPs), eligible hospitals and CAHs, and Medicare Advantage (MA) organizations participating in the Medicare and Medicaid programs that adopt and successfully demonstrate meaningful use of CEHRT. These Recovery Act provisions, together with Title XIII of Division A of the Recovery Act, may be cited as the HITECH Act.

The HITECH Act created incentive programs for EPs, eligible hospitals and CAHs (under sections 1886(n) and 1814(l) of the Social Security Act), and MA organizations in the Medicare and Medicaid programs (under section 1853(m)(3) of the Social Security Act) that successfully demonstrated meaningful use of CEHRT, which included reporting on electronic clinical quality measures (eCOMs). In accordance with the timeframe set forth in the statute, these incentive payments under Medicare are no longer available. The Act also allowed for negative payment adjustments in the Medicare FFS and MA programs starting in 2015 for EPs, eligible hospitals, CAHs, and MA organizations participating in Medicare that are not meaningful users of CEHRT. The last EHR reporting period that eligible hospitals in Puerto Rico could receive an incentive payment was in CY 2019 (FY 2021 payment year), and the EHR reporting period in CY 2020 (FY 2022 payment year) was the first year where they would be subject to a downward payment adjustment for failing to demonstrate meaningful use of CEHRT. The Medicaid Promoting Interoperability Program did not authorize downward payment adjustments, but its participants were eligible for incentive payments until December 31, 2021, when the program ended.

## (a) Medicare Promoting Interoperability Program Measures

For the EHR reporting period in CY 2025 and subsequent years, eligible hospitals and CAHs are required to report data for or attest to the measures shown in Table 1, as applicable, annually via an online submission form.

Table 1: Currently Approved Medicare Promoting Interoperability Program Measures for the EHR Reporting Period in CY 2025 and Subsequent Years

Objective	Measure			
Protect Patient Health Information	Security Risk Analysis			
	Safety Assurance Factors for EHR Resilience (SAFER) Guides			
	Actions to Limit or Restrict the Compatibility or Interoperability of CEHRT			
	ONC Direct Review			
	e-Prescribing			
Electronic Prescribing	Query of Prescription Drug Monitoring Program (PDMP)			

Objective	Measure				
	Support Electronic Referral Loops by Sending Health Information				
	Support Electronic Referral Loops by Receiving and Reconciling Health Information				
	OR				
Health Information Exchange	Health Information Exchange (HIE) Bi- Directional Exchange				
	OR				
	Enabling Information Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) measure				
	AND				
	Electronic Prior Authorization measure*				
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information				
	Report the following 5 measures:				
	Syndromic Surveillance Reporting				
	Immunization Registry Reporting				
	Electronic Case Reporting				
	<ul> <li>Electronic Reportable Laboratory Result Reporting</li> </ul>				
Public Health and Clinical Data Exchange	<ul> <li>Antimicrobial Use and         Antimicrobial Resistance (AUR)         Surveillance Measure**     </li> </ul>				
	Submit Level of Active Engagement				
	Report one of the following measures (BONUS):				
	Public Heath Registry Reporting				
	Clinical Data Registry Reporting				

<sup>\*</sup> Required beginning with the EHR reporting period in CY 2027

In addition, eligible hospitals and CAHs are required to report data for eCQMs annually. For eCQMs, information is electronically extracted from EHRs and/or health information technology (HIT) systems. Because patient data are already entered into EHRs and HITs as part of clinical practice, only the time associated with electronically submitting data to CMS is accounted for in our burden estimates as part of the Hospital Inpatient Quality Reporting (IQR) Program under OMB control number 0938-1022 (expiration date January 31, 2026). The currently approved eCQMs for the CY 2025 reporting period are shown in Table 2.

<sup>\*\*</sup> We finalized in the FY 2025 IPPS/LTCH PPS final rule that the AUR Surveillance measure will be separated into the Antimicrobial Use Surveillance measure and Antimicrobial Resistance Surveillance measure beginning with the EHR reporting period in CY 2025.

Table 2. Currently Approved Medicare Promoting Interoperability Program eCQMs for the CY 2025 Reporting Period and Subsequent Years

Short Name	Measure Name	CBE#
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
PC-02	Cesarean Birth	0471e
PC-07	Severe Obstetric Complications	3687e
STK-2	Discharged on Antithrombotic Therapy	0435e
STK-3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436e
STK-5	Antithrombotic Therapy by End of Hospital Day Two	0438e
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
НН-НҮРО	Hospital Harm - Severe Hypoglycemia	3503e
HH-HYPER	Hospital Harm - Severe Hyperglycemia	3533e
HH-OREA	Hospital Harm - Opioid-Related Adverse Events	3501e
HH-PI	Hospital Harm - Pressure Injury	3498e
HH-AKI	Hospital Harm - Acute Kidney Injury	3713e
GMCS	Global Malnutrition Composite Score	3592e
IP-ExRad	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient)	3663e

# (b) Summary of Finalized Medicare Promoting Interoperability Program Changes

In the FY 2025 IPPS/LTCH PPS final rule, we are separating the previously finalized AUR Surveillance measure into two separate measures, beginning with the EHR reporting period in CY 2025: (1) the Antimicrobial Use (AU) Surveillance measure, and (2) the Antimicrobial Resistance (AR) Surveillance measure. We are also increasing the total number of eCQMs eligible hospitals and CAHs report from six to eight eCQMs for the CY 2026 reporting period, from eight to nine eCQMs for the CY 2027 reporting period, and then from nine to eleven eCQMs beginning with the CY 2028 reporting period.

We are also finalizing several policies in the FY 2025 IPPS/LTCH PPS final rule which will not affect information collection burden. We are adopting two new eCQMs and modifying one eCQM beginning with the CY 2026 reporting period: (1) the new Hospital Harm - Falls with Injury eCQM; (2) the new Hospital Harm - Postoperative Respiratory Failure eCQM; and (3) the modified GMCS eCQM. Lastly, we are increasing the minimum scoring threshold from 60 points to 70 points for the EHR reporting period in CY 2025 and then from 70 points to 80 points beginning with the EHR reporting period in CY 2026. Because we are not requiring eligible hospitals or CAHs to collect or submit any additional data, we do not estimate any change in information collection burden associated with this policy.

#### (c) Medicare Promoting Interoperability Program Forms

The Medicare Promoting Interoperability Program allows eligible hospitals and CAHs to apply for a Hardship Exception and avoid a downward payment adjustment in circumstances out of the hospital's control that make it difficult to meet program requirements. To be considered for an exception, eligible hospitals and CAHs must complete and submit a Hardship Exception application. If approved, the Hardship Exception is valid for only one payment adjustment year. Eligible hospitals and CAHs would need to submit a new application for subsequent years and no eligible hospital or CAH can be granted more than five exceptions, per section 1886(b)(3)(B)(ix)(II) of the Social Security Act. Hospitals may cite one of the following specified reasons for review and approval: (1) using decertified EHR technology, (2) insufficient internet connectivity; or (3) extreme and uncontrollable circumstances. The Hardship Exception form is only available electronically at <a href="https://cmsqualitysupport.servicenowservices.com/cms/mh.">https://cmsqualitysupport.servicenowservices.com/cms/mh.</a>

#### 2. Information Users

The data collected under this information collection request is used to validate compliance with the requirements for being a successful Meaningful User under the Medicare Promoting Interoperability Program. Participants attest or report data as applicable to the required objectives and measures to meet the required threshold for being considered a Meaningful User. They must also electronically submit measure data for 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 2025 IPPS/LTCH PPS final rule focuses on eligible hospitals and CAHs that report on the objectives, measures, and 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 eCQM 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.

This information is also available to Medicare beneficiaries, as well as to the general public, by providing hospital information on the *Care Compare* website and to assist them in making decisions about their healthcare. CMS sometimes conducts focus groups or market testing prior to publicly reporting hospital quality data on the Compare tool hosted by HHS or its successor website(s) to get feedback on ways to make the website more user-friendly. Feedback from these focus groups has helped CMS understand how beneficiaries and consumers use the Compare tool hosted by HHS or its successor website(s).

Under section 3014 of the Patient Protection and Affordable Care Act of 2010 (ACA), CMS is required to evaluate the impact and efficiency of CMS measures in quality reporting programs and to post the report every three years. Following the compilation of eCQM data from the Medicare Promoting Interoperability Program and other CMS programs, CMS' findings were formally written into the latest triennial National Impact Assessment

Report, which was released in CY 2024.1

#### 3. Use of Information Technology

To assist eligible hospitals and CAHs in participating in standardized data collection initiatives across the industry, CMS continues to improve data collection tools with the goal of making data submission easier (e.g., the automated collection of electronic patient data in EHRs for eCQMs), and to increase the utility of the data provided by participants. CMS also provides a secure data warehouse via CMS' Hospital Quality Reporting (HQR) system for storage and transmittal of data. Participants have the option of using vendors to transmit the data. CMS has engaged a national support contractor to provide technical assistance with program requirements and to provide education to support program participants.

Attestation and data reporting are completed on an annual basis via an online submission form. 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 slightly year to year).

### 4. **Duplication of Efforts**

The information to be collected is not duplicative of similar information collected by CMS or other efforts to collect data from eligible hospitals or CAHs. We prioritize efforts to reduce reporting burden for the collection of information by utilizing electronic data to the extent possible, as well as aligning eCQMs and related reporting requirements with the Hospital IQR Program for eligible hospitals and CAHs.

#### 5. Small Businesses

Information collection requirements are designed to allow maximum flexibility specifically to small hospitals wishing to participate in hospital reporting. This effort will assist small hospitals in gathering information for their own quality improvement efforts. We define a "small hospital" as one with 1-99 inpatient beds. The Medicare Promoting Interoperability Program included approximately 931 eligible hospitals for the EHR reporting period in CY 2022. In addition, as defined under 42 CFR Part 485 subpart F, a CAH may have no more than 25 inpatient beds and therefore, we assume all 1,400 CAHs would qualify as small hospitals. As a result, we estimate a total of 2,331 small hospitals (931 eligible hospitals + 1,400 CAHs) will submit data for the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2025.

#### 6. Less Frequent Collection

The Health Services & Resources Administration's Medicare Rural Hospital Flexibility Program (Flex) and Medicare Beneficiary Quality Improvement Project, as well as CMS'

<sup>&</sup>lt;sup>1</sup> The latest 2024 Impact Assessment Report, as well as earlier reports from 2012, 2015, 2018, and 2021 may be found at: <a href="https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/">https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/</a> QualityMeasures/National-Impact-Assessment-of-the-Centers-for-Medicare-and-Medicaid-Services-CMS-Quality-Measures-Reports.

Quality Improvement Organizations, provide technical assistance to small hospitals to reduce burden and improve healthcare quality. We also provide a help-desk hotline for troubleshooting purposes and 24/7 free information available on the QualityNet website through a Questions and Answers function.

CMS has 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 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 clinical 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 for the FY 2025 IPPS/LTCH PPS proposed rule (RIN 0938-AV34, CMS-1808-P) was published on May 2, 2024 (89 FR 35934). No comments were received regarding the burden estimates included in this PRA package. The FY 2025 IPPS/LTCH PPS final rule (RIN 0938-AV34, CMS-1808-F) was published on August 28, 2024 (89 FR 68986).

### 9. Payment/Gift to Respondent

No gifts will be given to respondents for participation. The program had previously utilized incentive payments to Medicare and Medicaid providers who successfully demonstrated meaningful use, however, these positive incentive adjustments ended in CY 2021.

#### 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. All information collected under the Medicare Promoting Interoperability Program will be maintained in strict accordance with statutes and regulations governing confidentiality requirements for CMS data, including the Privacy Act of 1974 (5 U.S.C. 552a), the Health Insurance Portability and Accountability Act (HIPAA), and the Quality Improvement Organizations confidentiality requirements, which can be found at 42 C.F.R. Part 480. In addition, the tools used for transmission of data are considered confidential forms of communication, and there are safeguards in place in accordance with HIPAA Privacy and Security Rules to protect the submission of patient information, at 45 CFR Part 160 and 164, Subparts A, C and E. Only hospital-specific data will be made publicly available as mandated by statute. 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 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.

Data related to the Medicare Promoting Interoperability Program is housed in the HQR application group. CMS' HQR is a General Support System (GSS) housing protected health information (PHI). Users who access CMS' HQR system are identity-managed to permit access to the system and have role-based restrictions (including log-in and password) to the data they can see. The System of Records Notice (SORN) in use for the quality programs including the Medicare Promoting Interoperability Program is MBD 09-70-0536, as modified on February 14, 2018 (83 FR 6591).

#### 11. Sensitive Questions

There are no questions of a sensitive nature associated with these forms.

### 12. Burden Estimate (Total Hours and Wages)

#### (a) Background

In the FY 2025 IPPS/LTCH PPS final rule, we are finalizing two policies which will affect information collection burden. We are separating the previously finalized AUR Surveillance measure into two separate measures, beginning with the EHR reporting period in CY 2025: (1) the AU Surveillance measure, and (2) the AR Surveillance measure. We are also increasing the total number of eCQMs eligible hospitals and CAHs report from six to eight eCQMs for the CY 2026 reporting period, from eight to nine eCQMs for the CY 2027 reporting period, and then from nine to eleven beginning with the CY 2028 reporting period.

We discuss other policies promulgated in the FY 2025 IPPS/LTCH PPS final rule which will not affect information collection burden under OMB control number 0938-1278 in section B.1.a.

#### (b) Burden for the EHR Reporting Period in FY 2025

Our currently approved burden estimates are based on an assumption of 3,150 eligible hospitals and 1,350 CAHs, for a total number of 4,500 respondents. Based on data from the EHR reporting period in CY 2022, we are updating our assumption and estimate approximately 3,150 eligible hospitals and 1,400 CAHs will report data to the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2025 and subsequent years, for a total number of 4,550 respondents. In the FY 2024 IPPS/LTCH PPS final rule, the Medicare Promoting Interoperability Program and Hospital IQR Program used the same estimate for the number of eligible hospitals and IPPS hospitals for both programs (88 FR 59325). In the FY 2025 IPPS/LTCH PPS final rule, we updated our estimate of hospitals for the Hospital IQR Program to 3,050 IPPS hospitals and 1,500 non-IPPS hospitals for the CY 2025 reporting period. Upon further analysis, we believe it is no longer appropriate to use the same estimate for both the Hospital IQR and Medicare Promoting Interoperability programs as the approximately 100 eligible hospitals located in Maryland and Puerto Rico which were previously excluded from our

estimate of IPPS hospitals and included in our estimate of non-IPPS hospitals should be included as eligible hospitals for the Medicare Promoting Interoperability Program.

OMB has currently approved burden of 29,625 hours at a cost of \$1,328,978 under OMB control number 0938-1278, accounting for information collection burden experienced by approximately 3,150 IPPS hospitals and 1,350 Non-IPPS hospitals for the EHR reporting period in CY 2024. As shown in Table 3, using our updated assumption of 3,150 eligible hospitals and 1,400 CAHs and updated wage rates, we estimate a revised baseline burden of 29,954 hours at a cost of \$1,561,211 for the EHR reporting period in CY 2024, an increase of 329 hours and \$17,156. As previously stated, our burden estimates exclude burden associated with eCQM reporting for CAHs which is accounted for in our burden estimates as part of the Hospital IQR Program under OMB control number 0938-1022 (expiration date January 31, 2026).

Table 3: Currently Approved Burden Estimates for the Medicare Promoting Interoperability Program for the EHR Reporting Period in CY 2024

Objective/Measure	Estimated Time per Eligible Hospital/CAH (minutes)	Number reporting quarters per year	Number of eligible hospitals/ CAHs	Number records per hospital per quarter	Total Burden Hours for EHR Reporting Period in CY 2024
PROTECT PATIENT HEALTH INFOR	MATION				
Security Risk Analysis Measure	360	1	4,550	1	27,300
SAFER Guides Measure	1	1	4,550	1	76
ELECTRONIC PRESCRIBING					
e-Prescribing Measure	10	1	4,550	1	758
Query of PDMP Measure	0.5	1	4,550	1	38
HEALTH INFORMATION EXCHANGE	Ξ				
Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information Measures OR	10	1	4,550	1	758
HIE Bi-Directional Exchange Measure					
OR					
Enabling Information Exchange Under the TEFCA Measure					
PROVIDER TO PATIENT EXCHANGE	L .				
Provide Patients Electronic Access to	10	1	4,550	1	758

PUBLIC HEALTH AND CLINICAL DA	ATA EXCHANGE	2			
Syndromic Surveillance Reporting Measure	0.5	1	4,550	1	38
Immunization Registry Reporting Measure	0.5	1	4,550	1	38
Electronic Case Reporting Measure	0.5	1	4,550	1	38
Electronic Reportable Laboratory Result Reporting Measure	0.5	1	4,550	1	38
AUR Surveillance Measure	0.5	1	4,550	1	38
Submit Level of Active Engagement	0.5	1	4,550	1	38
Bonus Measures:	0.5	1	4,550	1	38
Public Heath Registry Reporting Measure					
OR					
Clinical Data Registry Reporting Measure					
Total Burden Hours					29,954
Total Burden @ Medical Records Specialist labor rate (\$52.12/hr)					\$1,561,211

#### (c) Updated Hourly Wage Rate

While the most recent data from the Bureau of Labor Statistics (BLS) reflects a median hourly wage of \$22.69 per hour for all medical records specialists, \$26.06 is the mean hourly wage for "general medical and surgical hospitals," which is an industry within medical records specialists (we note that BLS does not provide median occupation wage rates for individual industries).<sup>2</sup> We believe the industry of "general medical and surgical hospitals" is more specific to our settings for use in our calculations than other industries that fall under medical records specialists, such as "office of physicians" or "nursing care facilities." We calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, consistent with previous years. This is necessarily 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 ( $$26.06 \times 2 = $52.12$ ) to estimate total cost is a reasonably accurate estimation method. Accordingly, we will calculate cost burden to hospitals using a wage plus benefits estimate of \$52.12 per hour throughout the discussion in this section of this rule for the Medicare Promoting Interoperability Program.

# (d) Protect Patient Health Information Objective Reporting and Submission Burden

As shown in Table 3, under the Protect Patient Health Information Objective, eligible hospitals and CAHs are required to conduct or review a security risk analysis including addressing the security (to include encryption) of data created or maintained by CEHRT, implement security updates as necessary, and correct identified security deficiencies as

<sup>&</sup>lt;sup>2</sup> Bureau of Labor Statistics, Occupational Employment and Wages. Accessed on March 7, 2024: https://www.bls.gov/oes/current/oes292072.htm.

part of the provider's risk management process. Eligible hospitals and CAHs are also required to complete an annual self-assessment on each of the nine SAFER Guides at any point during the calendar year in which their EHR reporting period occurs. Eligible hospitals and CAHs must then submit "yes" attestations for both the Security Risk Analysis and SAFER Guides Reporting measures. We continue to estimate it will require eligible hospitals and CAHs approximately 6 hours to fulfill the requirements of the Security Risk Analysis measure and 1 minute to attest to the SAFER Guides Reporting measure annually.

In the Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-facilitated Exchanges and Health Care Provider Final Rule published on May 1, 2020 (85 FR 25580), we finalized the Actions to Limit or Restrict the Compatibility or Interoperability of CEHRT measure. In the CY 2017 Medicare Program; Merit-Based Incentive Payment System and Alternative Payment Model Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models final rule published on November 4, 2016, we finalized the ONC Direct Review measure (81 FR 77027 and 77028). As attestation measures, eligible hospitals and CAHs are required to report a "yes" or "no" response for each measure. Similar to the SAFER Guides measure, we estimate an information collection burden for each eligible hospital and CAH of 1 minute to report each measure.

We estimate a total burden for this Objective of 363 minutes (6.05 hours) to successfully meet the requirements of this Objective. We estimate a total burden for this Objective of 27,528 hours (6.05 hours  $\times$  4,550 eligible hospitals and CAHs) annually at a cost of \$1,434,759 (27,528 hours x \$52.12).

#### (e) Electronic Prescribing Objective Reporting and Submission Burden

As shown in Table 3, for the Electronic Prescribing Objective, eligible hospitals and CAHs are required to report both the Electronic Prescribing and Query of PDMP measures. We continue to estimate that eligible hospitals and CAHs will require 10 minutes to report the Electronic Prescribing measure and 0.5 minutes to report the Query of PDMP measure for a total of 10.5 minutes (0.175 hours) to report both measures. We estimate a total burden for this Objective of 796 hours across all eligible hospitals and CAHs (0.175 hours  $\times$  4,550 eligible hospitals and CAHs) annually at a cost of \$41,488 (796 hours x \$52.12).

# (f) Health Information Exchange Objective Reporting and Submission Burden

As shown in Table 3, for the Health Information Exchange Objective, eligible hospitals and CAHs are required to report one of three alternatives: (1) the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures; (2) the HIE Bi-Directional Exchange measure; or (3) the Enabling Exchange Under the TEFCA measure. We

continue to estimate eligible hospitals and CAHs will require 10 minutes (0.167 hours) to report one of the three alternatives.

In the Advancing Interoperability and Improving Prior Authorization Processes for MA Organizations and Medicaid Managed Care Plans, State Medicaid Agencies, State CHIP Agencies, CHIP Managed Care Entities, and Issuers of QHPs in the Federally-Facilitated Exchanges Final Rule published on February 8, 2024 (89 FR 8758), we finalized the Electronic Prior Authorization measure beginning with the EHR reporting period in CY 2027. As an attestation measure, eligible hospitals and CAHs are required to report a "yes" or "no" response. As finalized in the aforementioned final rule, we estimate an information collection burden for each eligible hospital and CAH of 0.5 minutes to report this measure (89 FR 8955).

In aggregate, for the EHR reporting periods in CY 2025 and CY 2026, we estimate a total burden for this Objective across all eligible hospitals and CAHs of 758 hours (0.167 hours  $\times$  4,550 hospitals) at a cost of \$39,507 (758 hours  $\times$  \$52.12). Beginning with the EHR reporting period in CY 2027, we estimate a total burden for this Objective across all eligible hospitals and CAHs of 796 hours (0.175 hours  $\times$  4,550 hospitals) at a cost of \$41,488 (796 hours  $\times$  \$52.12).

# (g) Provider to Patient Exchange Objective Reporting and Submission Burden

As shown in Table 3, we continue to estimate eligible hospitals and CAHs will require 10 minutes (0.167 hours) to report the Provide Patients Electronic Access to Their Health Information measure. Therefore, we estimate a total information collection burden for this Objective of 758 hours (0.167 hours x 4,550 hospitals) at a cost of \$39,507 (758 hours x \$52.12).

# (h) Public Health and Clinical Data Exchange Objective Reporting and Submission Burden

As shown in Table 3, for the Public Health and Clinical Data Exchange Objective, eligible hospitals and CAHs are required to attest to their level of active engagement for the measures under this Objective, either Pre-production and Validation or Validated Data Production. Eligible hospitals and CAHs must also attest to five measures: (1) the Syndromic Surveillance Reporting Measure, (2) the Immunization Registry Reporting Measure, (3) the Electronic Case Reporting Measure, (4) the Electronic Reportable Laboratory Result Reporting Measure, and (5) the AUR Surveillance Measure. In addition, eligible hospitals and CAHs may attest to one of the optional bonus Public Heath Registry Reporting or Clinical Data Registry Reporting measures. We estimate the burden associated with each of the seven attestations required under this Objective to be 0.5 minutes/measure for a total of 3.5 minutes in aggregate (0.5 minutes x 7 attestations). We note that under the AUR Surveillance Measure, while eligible hospitals are required to attest to active engagement with CDC's National Healthcare Safety Network (NHSN) to submit AUR data and receive a report from NHSN indicating their successful submission of AUR data for the EHR reporting period, the burden associated with the actual submission of AUR data to NHSN is accounted for under OMB control

number 0920-0666.

In the FY 2025 IPPS/LTCH PPS final rule, we are modifying the AUR Surveillance measure by separating the single measure into two measures: (1) AU Surveillance and (2) AR Surveillance, beginning with the EHR reporting period in CY 2025. In the CY 2023 IPPS/LTCH PPS final rule, we finalized a burden estimate of 0.5 minutes per eligible hospital and CAH to attest to the AUR Surveillance Measure (87 FR 49394). In association with this modification, we estimate an annual increase in burden for each eligible hospital and CAH to attest to both measures of 0.5 minutes.

In aggregate, we estimate the total annual burden per eligible hospital and CAH for this Objective to be 4 minutes (0.0667 hours) beginning with the EHR reporting period in CY 2025. Across all eligible hospitals and CAHs, we estimate a total annual burden of 303 hours (0.0667 hours  $\times$  4,550 hospitals) at a cost of \$15,792 (303 hours  $\times$  \$52.12).

### (i) eCQM Measure Reporting and Submission Requirements

We previously finalized in the FY 2023 IPPS/LTCH PPS final rule that, for the CY 2024 reporting period, CAHs are required to submit data quarterly for six eCQMs each year which must consist of the Safe Use of Opioids-Concurrent Prescribing, Cesarean Birth, and Severe Obstetric Complications eCQMs in addition to three self-selected eCQMs (87 FR 49394 through 49395). In the FY 2025 IPPS/LTCH PPS final rule, we are finalizing that, for the CY 2026 reporting period, CAHs will be required to submit data for eight total eCQMs: three self-selected, Safe Use of Opioids, Severe Obstetric Complications, Cesarean Birth Rate, Hospital Harm — Severe Hypoglycemia, and Hospital Harm — Severe Hyperglycemia. We are also finalizing that, for the CY 2027 reporting period, CAHs will be required to submit data for these eight eCQMs in addition to the Hospital Harm — Opioid-Related Adverse Events eCQM. Lastly, we are also finalizing that, beginning with the CY 2028 reporting period, CAHs will be required to submit data for these nine eCQMs as well as the Hospital Harm — Pressure Injury and Hospital Harm — Acute Kidney Injury eCQMs.

Also in the FY 2025 IPPS/LTCH PPS final rule, we are adopting two new eCQMs to the set of eCQMs from which hospitals may self-select in order to meet their eCQM reporting requirements and modifying one existing eCQM beginning with the CY 2026 reporting period: (1) the Hospital Harm – Falls With Injury eCQM; (2) the Hospital Harm – Postoperative Respiratory Failure eCQM; and (3) the modified GMCS eCQM. While this results in new eCQMs being added to the measure set, eligible hospitals and CAHs will not be required to report more than eight eCQMs for the CY 2026 reporting period, nine eCQMs for the CY 2027 reporting period, and eleven eCQMs for the CY 2028 reporting period.

We continue to estimate the information collection burden associated with the eCQM reporting and submission requirements to be 10 minutes per measure per quarter. The burden associated with the reporting of eCQM measures for eligible hospitals and CAHs as part of the Hospital IQR Program is included under OMB control number 0938-1022.

#### (j) Hardship Exception

As discussed in section B.1.b, eligible hospitals and CAHs may apply electronically for a Hardship Exception and avoid a downward payment adjustment in circumstances out of the hospital's control that make it difficult to meet program requirements. Based on the number of Hardship Exception applications received in prior EHR reporting periods, we estimate approximately 400 eligible hospitals and CAHs will apply annually and estimate the application requires approximately 1 minute (0.0167 hours) to complete. Therefore, we estimate an annual information collection burden of 7 hours (0.0167 hours x 400 applications) at a cost of \$365 (7 hours x \$52.12).

#### (k) Burden Estimate Summary

As shown in Table 4, in summary, under OMB control number 0938-1278, we estimate a total annual information collection burden increase for 4,550 eligible hospitals and CAHs of 564 hours at a cost of \$29,400 associated with our finalized policies and updated burden estimates described above (which also reflects use of updated hourly wage rates as previously discussed), from the EHR reporting period in CY 2025 through the EHR reporting period in CY 2027, compared to our currently approved information collection burden estimates. The table below summarizes the total burden changes for each respective EHR reporting period compared to our currently approved information collection burden estimates (the column for the EHR reporting period in CY 2027 reflects the cumulative burden changes).

Table 4. Summary of Annual Burden Estimates for the EHR Reporting Periods in CY 2024 through CY 2027

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Objective	EHR Reporting Period in CY 2024	Difference From Currently Approved	EHR Reporting Periods in CY 2025- 2026	Difference From Currently Approved	EHR Reporting Period in CY 2027	Difference From Currently Approved
Protecting Patient Health Information	27,376	+301	27,528	+453	27,528	+453
Electronic Prescribing	796	+8	796	+8	796	+8
Health Information Exchange	758	+8	758	+8	796	+46
Provider to Patient Exchange	758	+8	758	+8	758	+8
Public Health and Clinician Data Exchange	265	+3	303	+38	303	+38
Hardship Exception	7	+7	7	+7	7	+7
Total Burden Hour Estimate*	29,961	+336	30,151	+526	30,189	+564
Total Burden Cost Estimate*	\$1,561,576	+\$17,521	\$1,571,47 4	+\$27,419	\$1,573,455	+\$29,400

<sup>\*</sup>Sum of individual Objective estimates may vary from annual totals due to rounding

These burden estimates exclude burden associated with the reporting of eCQMs for eligible hospitals under OMB control number 0938-1022, as Medicare hospitals report the data to CMS once per year for credit under both the Hospital IQR Program and the Medicare Promoting Interoperability Program for eligible hospitals and CAHs.

#### (l) Information Collection Instruments/Instructions

As discussed in section B.3, attestation and data reporting are completed on an annual basis via an online submission form commonly referred to by developers and CMS as the Attestation Screens. Outside of this online attestation, there are no physical nor additional forms used. We will submit screenshots of the revised Attestation Screens with this PRA package.

### 13. Capital Costs (Maintenance of Capital Costs)

In order to attest to the AU Surveillance and AR Surveillance measures successfully, an eligible hospital or CAH must be in active engagement with CDC's NHSN to submit AU and AR data and receive a report from NHSN indicating their successful submission of AU and AR data for the EHR reporting period. We previously discussed in our currently approved PRA application that participation in NHSN's surveillance requires the use of an AUR reporting solution. We estimate the annual cost for commercial software and equipment for use by hospital personnel to range between \$59,100 and \$146,500 annually, with a median of \$70,900.<sup>3</sup> We believe these associated costs are outweighed by the more than \$4.6 billion in health care costs spent annually treating antibiotic resistance threats.<sup>4</sup>

#### 14. Cost to the Federal Government

The cost to the Federal Government for maintaining program activities is for supporting data system architecture, data storage, maintenance and updating of information technology infrastructure on the HQR system secure portal, providing ongoing technical assistance to hospital and data vendors, measure development and maintenance, the provision of hospitals with feedback and preview reports, as well as costs associated with public reporting. These costs are estimated at \$10,050,000 annually for the validation and quality reporting contracts. Additionally, this program takes three CMS staff at a GS-13 Step 5 level with approximate annual salaries of \$133,692 plus benefits (30%) of \$40,108 per staff member to operate for an additional cost of \$521,400. The total annual cost to the Federal Government is \$10,571,400.

#### 15. Program or Burden Changes

We previously requested and received approval for total annual burden estimates under this OMB control number for the EHR reporting period in CY 2025 of 29,625 hours at a total cost of \$1,328,978 as a result of policies finalized in the FY 2024 IPPS/LTCH PPS final rule. Accounting for updated wage rates, the total cost of \$1,328,978 increases to \$1,544,055. For the EHR reporting period in CY 2025, based on the policies in the FY 2025 IPPS/LTCH PPS final rule and addition of burden associated with previously finalized measures, we estimate a total burden of 30,151 hours and \$1,571,474 (an increase of 526 hours and \$27,419 from our currently approved estimate). This burden estimate also represents an increase of 526 hours and \$242,496 from the approved burden estimate of 29,625 hours and \$1,328,978 for the EHR reporting period in CY 2024.

<sup>&</sup>lt;sup>3</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5051263/

<sup>&</sup>lt;sup>4</sup> https://www.cdc.gov/drugresistance/solutions-initiative/stories/partnership-estimates-healthcare-cost.html

The policy in the FY 2025 IPPS/LTCH PPS final rule to modify the AUR Surveillance measure by separating the single measure into two measures beginning with the EHR reporting period in CY 2025 results in an annual burden increase of 38 hours at a cost of \$1,976. The previously finalized Electronic Prior Authorization measure results in an annual burden increase of 38 hours at a cost of \$1,981 (note the difference of \$5 between this measure and the modification of the AUR Surveillance measure is due to rounding). The previously finalized Actions to Limit or Restrict the Compatibility or Interoperability of CEHRT and ONC Direct Review measures result in an annual burden increase of 152 hours at a cost of \$7,922. The inclusion of burden associated with Hardship Applications results in an annual burden increase of 7 hours at a cost of \$365. Accounting for the impact of the policies in the FY 2025 IPPS/LTCH PPS final rule, our updated estimates of the number of eligible hospitals and CAHs results in an annual burden increase of 329 hours at a cost of \$17,156. As shown in Table 4, the aggregate increase due to these policies and adjustments is 564 hours (329 + 38 + 38 + 152 + 7) and \$29,400 (\$17,156 + \$1,976 + \$1,981 + \$7,922 + \$365).

#### 16. Publication/Tabulation Dates

We will continue to display hospital quality information for public viewing as required by Social Security Act sections 1886(b)(3)(B)(viii)(VII) for the Hospital IQR Program, 1886(o)(10) for the Hospital VBP Program, 1886(p)(6) for the HAC Reduction Program, 1886(q)(6) for the Hospital Readmissions Reduction Program, and 1886(n)(4)(B) for the Medicare Promoting Interoperability Program. Hospital data from the Medicare Promoting Interoperability Program is currently used to populate the Compare tool hosted by HHS, available at: https://www.medicare.gov/care-compare/, or its successor website(s). Data are presented on the Compare tool hosted by HHS in a format mainly aimed towards consumers, patients, and the general public, providing access to overall scoring and performance data on eligible hospitals and CAHs. Information for public viewing available on the Medicare Promoting Interoperability Program website 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; and useful links to the Federal Register, FAQ, and objective-measure specification sheets. One of the long-term goals of the Medicare Promoting Interoperability Program is to publicly display data on all measures adopted for the Program.

#### 17. Expiration Date

With the exception of the online form used for submitting attestations and Hardship Exception application which will display the approved expiration date, there are no additional forms associated with the Medicare Promoting Interoperability Program. We will also display the approved expiration date prominently on the Medicare Promoting Interoperability Program pages on <a href="CMS.gov">CMS.gov</a> used to document our measure specifications and reporting guidance.

#### 18. Certification Statement

We are not claiming any exceptions to the Certification for Paperwork Reduction Act Submissions Statement.

# B. Collection of Information Employing Statistical Methods

The use of statistical methods does not apply to this form.