Supporting Statement Part A for Advancing Interoperability and Improving Prior Authorization Processes (0938-1437; CMS-10843)

Background

Health Information Technology is changing the patient experience and the way we do business in health care, including the way we enable patients to have better and more secure access to their own information. In May 2020, the Centers for Medicare & Medicaid Services (CMS) finalized certain policies in the CMS Interoperability and Patient Access final rule (85 FR 25510) that focused on advancing interoperability and improving patient access to their health information. This is a new information collection request for OMB approval.

Subsequently, on January 17, 2024, CMS finalized the CMS Interoperability and Prior Authorization final rule (89 FR 8758) ("final rule") which expands upon federal policies to improve data exchange and reduce administrative burden within the health care system. This final rule enhances the Patient Access API by requiring impacted payers[1] to make additional information available to patients. The final rule also adds new requirements for certain payers to develop three other APIs: (1) an API to enable the exchange of patient information between payers and providers, (2) an API to enable the exchange of patient information between payers, and (3) an API to enable the timely exchange of information to support the prior authorization process. In addition, the policies in the final rule help mitigate the burden of the prior authorization process by finalizing requirements for certain payers to make decisions within defined timeframes and provide specific reasons for denials. The rule will also increase transparency by requiring payers to publicly report certain prior authorization metrics. The final rule includes a new measure, titled Electronic Prior Authorization, for the Merit-based Incentive Payment System (MIPS) Promoting Interoperability Performance Category and Medicare Promoting Interoperability Program.

The final rule includes policies that meet elements of the collection of information provisions under the Paperwork Reduction Act (PRA), which are described below. For additional information about the requirements in the CMS Interoperability and Prior Authorization final rule, see 89 FR 8758.

Provider Access, Payer-to-Payer, and Prior Authorization APIs Data Collections and Related Information Collections

Provider Access API. Impacted payers are required to implement and maintain a Provider Access API that makes patient data available to providers who have a contractual relationship with the payer and a treatment relationship with the patient. The data that must be available includes claims and encounter data (excluding provider remittances and patient cost-sharing information), all data classes and data elements included in a content standard at 45 CFR 170.213 (USCDI), and specified prior authorization information with a date of service on or after January 1, 2016 if the data are maintained by the payer.[2]

[1] Impacted payers include Medicare Advantage (MA) organizations, state Medicaid and Children's Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally Facilitated Exchanges (FFEs).

[2] Information about prior authorization requests and decisions that must be provided via the Provider Access API include prior authorization status; the date the prior authorization was approved or denied; the date or circumstance under which the authorization ends; the items and services approved; if the prior authorization is denied, a specific reason why the request was denied; and related structured administrative and clinical documentation submitted by a provider.

Payer-to-Payer API. Impacted payers are required to implement and maintain a Payer-to-Payer API to make certain data available to other payers. This includes claims and encounter data (excluding provider remittances and patient cost-sharing information), all data classes and data elements included in the content standard at 45 CFR 170.213 (USCDI), and specified prior authorization information the payer maintains with a date of service within five years of the request.[3] If the patient has concurrent coverage with two or more payers, the payers are required to make the patient's data available to other concurrent payer(s) on at least a quarterly basis.

Prior Authorization API. Impacted payers are required to implement and maintain a Prior Authorization API capable of providing information to a provider about whether the payer requires prior authorization for certain items and services, the necessary documentation to accompany the prior authorization request, and the prior authorization request and response exchange between the provider and payer. The decision response from the Prior Authorization API includes the payer's approval (and the date or circumstance under which the authorization ends), the denial (with a specific reason), or requests more information.

Extensions, Exemptions, and Exceptions. The final rule allows state Medicaid and CHIP FFS programs and QHP issuers on the FFEs to apply for an extension, exemption, or exception from implementing the Provider Access, Payer-to-Payer, and Prior Authorization APIs by submitting certain information to CMS.[4] We do not have data on the burden of submitting application documentation with the Advanced Planning Documents (APDs) for extensions or exemptions, as the states do not provide this cost data when submitting APDs for other purposes. Further, the states did not apply for extensions or exemptions for the API provisions for the CMS Interoperability and Patient Access final rule. The Data Services Group (DSG) in the Center for Medicaid and CHIP Services (DSG/CMCS) and the Center for Consumer Information and Insurance Oversight (CCIIO) will evaluate information from the submissions of narratives for other purposes to determine if it can be used as a proxy for estimated burden for those entities that might apply for an extension or exemption. We have been informed that only a few QHP issuers applied for an exemption under the CMS Interoperability and Patient Access final rule, with most indicating that they were compliant or working towards compliance.

Patient Access API Usage and Prior Authorization Decision Metrics Reporting

The final rule requires MA organizations at the contract level; state Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities at the state level; and QHP issuers on the FFEs at the issuer level to report certain Patient Access API use metrics to CMS annually. Impacted payers are required to report the total number of unique patients whose data are transferred via the Patient Access API to a health app designated by the patient and the total number of unique patients whose data are transferred more than once via the Patient Access API to a health app designated by the patient.

---

[3] Information about prior authorization requests and decisions that must be provided via the Payer-to-Payer API include prior authorization status (excluding denied prior authorizations), the date the prior authorization was approved, the date or circumstance under which the authorization ends, the items and services approved, and structured and unstructured related administrative and clinical documentation submitted by a provider.

[4] To apply for an extension, exemption, or exception from implementing the Provider Access and Payer-to-Payer APIs, payers are required to submit documentation identified in 42 CFR 431.61(c)(1) (extension for Medicaid FFS), 42 CFR 457.731(c)(1) (extension for CHIP FFS), 42 CFR 431.61(c)(2) (exemption for Medicaid FFS), 42 CFR 457.731(c)(2) (exemption for CHIP FFS), and 45 CFR 156.222(c) (exception for QHP issuers on the FFEs). To apply for an extension, exemption, or exception from implementing the Prior Authorization API, payers are required to submit documentation identified in 42 CFR 431.80(c)(1) (extension for Medicaid FFS), 42 CFR 457.732(d)(1) (extension for CHIP FFS), 42 CFR 431.80(c)(2) (exemption for Medicaid FFS), 42 CFR 457.732(d)(2) (exemption for CHIP FFS), and 45 CFR 156.223(d) (exception for QHP issuers on the FFEs).

The final rule also requires MA organizations at the contract level, state Medicaid and CHIP FFS programs at the state level, Medicaid managed care plans and CHIP managed care entities at the plan level, and QHP issuers on the FFEs at the issuer level to publicly report certain prior authorization metrics on their websites on an annual basis.

Impacted payers must post a list of all items and services that require prior authorization. In addition, impacted payers must make reports available on all of the following, aggregated for all items and services:

- The percentage of standard prior authorization requests that were approved, aggregated for all items and services.
- The percentage of standard prior authorization requests that were denied, aggregated for all items and services.
- The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a determination by the payer, plan, or issuer, for standard prior authorizations, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a decision by the payer, plan, or issuer, for expedited prior authorizations, aggregated for all items and services.

Electronic Prior Authorization Reporting for Certain Providers

MIPS eligible clinicians participating in the MIPS Promoting Interoperability Performance Category and eligible hospitals and critical access hospitals (CAHs) participating in the Medicare Promoting Interoperability Program are required to report on the Electronic Prior Authorization measure beginning with the calendar year (CY) 2027 performance period/CY 2029 MIPS payment year for MIPS eligible clinicians and the CY 2027 electronic health record (EHR) reporting period for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program. We are finalizing the Electronic Prior Authorization measure as a required attestation (yes/no) measure for the initial year of reporting.

The final rule requires MIPS eligible clinicians and eligible hospitals and CAHs to attest to whether they requested at least one prior authorization electronically from certified electronic health record technology (CEHRT) using a Prior Authorization API (i.e., report yes or no on the measure).[5] They would be required to report a ”yes” for the Electronic Prior Authorization measure or claim an exclusion to satisfy the measure requirements. Specifics for the two exclusions will be provided in a new PRA package to be developed by the Centers for Clinical Standards and Quality.

[5] We are only finalizing this measure as an attestation (yes/no measure) for the initial year of measure reporting, beginning with the CY 2027 performance period and EHR reporting period. We intend to reevaluate the yes/no reporting structure in future years and address it in future rulemaking.

Information Collections Constituting Usual and Customary Business Practices

There are several information collections in the final rule that constitute usual and customary business practices for the payers impacted by the requirements of this rule. Some of these items are also included in Table 2 (Costs) because they are addressed in either the Collection of Information section of the final rule or another PRA package. However, we consider these items to be usual and customary.

- Provide certain information about prior authorization requests and decisions for items and services via the Patient Access API. This API was initially established in the CMS Interoperability and Patient Access final rule.
- Maintain an attribution process to associate patients with their in-network or enrolled providers to inform the payer-to-provider data exchange via the Provider Access API.
- Provide educational resources to providers explaining how they may make a request to the payer for patient data using the Provider Access API and about the mechanism for how patients are attributed to the provider.
- Maintain a process for patients to opt out of having their health information available and shared via the Provider Access API and provide related educational resources to patients.
- Incorporate any information received through the Payer-to-Payer API into a patient's record that the payer maintains.
- Implement and maintain processes to identify a patient's previous payers' information and concurrent payer(s)' information.
- Request a new patient's data from the patient's previous/concurrent payer(s) via the Payer-to-Payer API.
- Impacted payers requesting patient data from a patient's previous payer are required to include an attestation with the request affirming that the patient has enrolled with the requesting payer and has consented to the data exchange through the Payer-to-Payer API.
- Obtain patients' opt in to the payer to payer data exchange.
- Provide educational resources to patients regarding the data exchange for the Payer-to-Payer API.
- Provide the specific reason for denying a prior authorization request in the payer's response to the provider, even when the payer does not provide its prior authorization decision via the Prior Authorization API (shown in Table 2).

We are excluding these information collections from the burden calculation for the final rule pursuant to 5 CFR 1320.3(b)(2).[6]

[6] 5 CFR 1320.3(b)(2) states: The time, effort, and financial resources necessary to comply with a collection of information that would be incurred by persons in the normal course of their activities (e.g., in compiling and maintaining business records) will be excluded from the ''burden'' if the agency demonstrates that the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary.

A. Justification

1. Need and Legal Basis

As described in the **Background** section above, CMS is requiring impacted payers to collect, maintain, and share information with patients, other payers, and providers, and to report certain metrics to CMS and publicly. These actions support CMS and other federal initiatives to advance interoperability and improve patient access to health information, in alignment with goals to improve health care. The established legal bases for the collection of this information are identified below.

- Section 1848(q)(2) of the Social Security Act (the Act)
- Section 1852(h) of the Act
- Section 1852(g)(1) of the Act
- Section 1902(a)(6) of the Act
- 42 CFR 422.112(b)
- 42 CFR 438.208(b)

2. Information Users

Provider Access, Payer-to-Payer, and Prior Authorization APIs and Related Information Collections

Information users of the Provider Access API will be providers that have a contractual relationship with the impacted payer and a treatment relationship with the patient. Providers may use the information received via the Provider Access API to support patient treatment and care coordination.

Information users of the Payer-to-Payer API will be impacted payers and other payers exchanging information via the API.

Information users of the Prior Authorization API will be impacted payers and those providers submitting prior authorization requests for their patients via the API. Payers will respond to the requests from the providers; use the submitted documentation and forms to support decision making; and return responses, as permissible, through the Prior Authorization API. Providers may use the information payers provide via the Prior Authorization API to streamline the prior authorization process by automating certain tasks, determining whether a prior authorization is required for a certain item or service, and identifying documentation requirements.

The information user of the information certain payers (state Medicaid and CHIP FFS programs and QHP issuers on the FFEs) must submit to request an extension, exemption, or exception from implementing the APIs for Provider Access, Payer-to-Payer, and Prior Authorization will be CMS. CMS is in the position of evaluating the requests to grant the extension, exemption, or exception based on the information and eligibility of the entity.

Patient Access API and Prior Authorization Metrics Reporting

CMS will be the information user of Patient Access API use metrics that impacted payers must report under the final rule. CMS will use the information it collects from payers to better understand whether the Patient Access API is supporting the policies of the CMS Interoperability and Patient Access final rule to provide patients access to their health information.

Payers, patients, and providers will be the information users of the prior authorization decision metrics that payers must publicly report under the final rule. Payers may use these reports to learn

about their performance and consider adjustments to prior authorization policies or practices. Patients may review the reports when choosing a new plan, and providers may use the reports when selecting payer networks to join.

Electronic Prior Authorization Reporting

CMS will be the information user of the electronic prior authorization attestation that MIPS eligible clinicians and eligible hospitals and CAHs are required to report to it under the final rule. For additional information, see PRA packages with OMB control numbers 0938-1278 (CMS-10552) and 0938-1314 (CMS-10621).

3. Use of Information Technology

This information collection involves the development of Provider Access, Payer-to-Payer, and Prior Authorization APIs. APIs are automated tools, similar to applications, that enable electronic health information to be exchanged between individuals and entities. As noted throughout this document, CMS is requiring impacted payers to implement standards-based APIs for data exchange between payers and providers. APIs are created by IT software developers and enable other developers to create apps that can interact with that API without needing to know the internal workings of the initial developer's software.

The Provider Access API allows a provider to request patient data from a payer using the API for treatment purposes to support coordination of care for a patient as they move through the health care system. The Payer-to-Payer API allows payers to exchange certain patient data via an API. The Prior Authorization API allows for the exchange of certain prior authorization information between the impacted payer that maintains the API and providers via an API that uses technology that conforms with certain standards and implementation specifications.

This information collection also involves a requirement for payers to report certain Patient Access API and prior authorization decision metrics. CMS will collect Patient Access API use metrics from payers electronically. The information collection associated with the requirement to publicly report prior authorization decision metrics requires payers to post results on their websites.

The use of information technology by QHP issuers on the FFEs that wish to request an exception will be discussed in the next revision to the PRA package approved under OMB control number 0938-1187.[7] QHP issuers will submit their requests for an exception during the QHP certification application process, which is electronic (OMB-0938-1187). Currently, Medicaid and CHIP submit Medicaid Management Information System (MMIS) ADPs to CMS via email. Requirements regarding submission of MMIS ADPs are discussed in the regulation and do not require an associated PRA.

The MIPS Promoting Interoperability Performance Category and Medicare Promoting Interoperability Program will be conducted electronically. For additional information, see PRA packages approved under OMB control numbers 0938-1278[8] (CMS-10552) and 0938-1314[9] (CMS-10621), which is currently pending reapproval.

7 https://www.reginfo.gov/public/do/DownloadNOA?requestID=412919

8 https://www.reginfo.gov/public/do/DownloadNOA?requestID=432949

9 https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202307-0938-005

4. Duplication of Efforts

The information in this information collection document does not duplicate any other effort and the information cannot be obtained from any other source.

For the Provider Access, Payer-to-Payer, and Prior Authorization APIs, payers are the recipients and maintainers of the information on behalf of patients, providers, and other payers, as applicable.

The public (payers, providers, patients, etc.) are the recipients of the information collection associated with the requirement for payers to publicly report prior authorization use metrics. This information is maintained by the payers.

CMS is the recipient and maintainer of the information on behalf of payers for the information collection associated with extensions, exemptions, and exceptions from implementing the Provider Access, Payer-to-Payer, and Prior Authorization APIs. CMS is also the recipient and maintainer of the information for the information collection associated with Patient Access API metrics reporting and on behalf of eligible clinicians and eligible hospitals and CAHs for the information collections associated with the MIPS Promoting Interoperability Performance Category and Medicare Promoting Interoperability Program.

5. Small Businesses

The API requirements in this final rule affect: 1) MA organizations; 2) state Medicaid and CHIP FFS programs; 3) Medicaid managed care plans; 4) CHIP managed care entities; and 5) QHP issuers on the FFEs. These organizations have a minimum threshold for small business size of $41.5 million (https://www.sba.gov/federal-contracting/contracting-guide/size-standards).

The CMS threshold for what constitutes a substantial number of small entities for purposes of the Regulatory Flexibility Act (RFA) is three to five percent.[10]

MA organizations fall below the three to five percent threshold. Thus, this final rule will not have a significant impact on a substantial number of MA organizations that are small businesses. MA organizations that are small businesses are expected to include the costs of compliance in their bids to CMS, thus avoiding additional burden.

Concerning Medicaid managed care plans and CHIP managed care entities, since managed care plans receive 100 percent capitation from the state, we expect that the costs associated with the provisions of this final rule will be included in their capitation rates and may be reasonable costs regardless of whether these entities are a small business. Accordingly, there will not be a significant impact on a significant number of Medicaid managed care plans and CHIP managed care entities.

Few, if any, QHP issuers on the FFEs are small enough to fall below the size threshold for a small business. We estimate that any issuers that would be considered small businesses are likely to be subsidiaries of larger issuers that are not small businesses and do not share the same burdens as an independent small business. There will not be a significant small business burden for these issuers.

For the electronic prior authorization reporting, MIPS eligible clinicians and eligible hospitals and CAHs will be small businesses affected by the final rule. Most Medicare and Medicaid eligible clinicians are either nonprofit entities or meet the Small Business Administration's size standard for

[10] For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions.

small businesses. Small eligible hospitals and CAHs are those with 1-99 inpatient beds. Furthermore, 99% of all hospitals have adopted EHRs, whereas about 77% of all EPs have adopted EHRs. CMS has minimized the impact on these entities by allowing all health care providers to apply for a significant hardship exception by meeting certain requirements. This will help to minimize the impact on health care providers who are unable to meet the requirements. Each hardship is reviewed on a case-by-case basis. A discussion of the anticipated number of small businesses that would be affected by the electronic prior authorization reporting and efforts to minimize burden may be discussed in the next revision to PRA packages approved under OMB control numbers 0938-1278 (CMS-10552) and 0938-1314 (CMS-10621).

6. Less Frequent Collection

Provider Access, Payer-to-Payer, and Prior Authorization APIs Data Collection and Related Information Collections

For the Provider Access API, disclosure of information to the provider will be driven directly by requests made from the provider to the payer, with permission of the patient. The disclosure, once initiated, will establish the data exchange via the provider's EHR, practice management system, or other technology solution, and then be conducted on a regular cadence based on the availability of new data.

For the Payer-to-Payer API, the disclosure of information from a patient's previous payer to the patient's current payer (the impacted payer that has implemented the API) occurs once, with permission of the patient, upon the current payer's request at the time that the patient enrolls with the payer.[11] The disclosure of information from the current payer to other concurrent payer(s) occurs on at least a quarterly basis and will be initiated by the impacted payer.

For the Prior Authorization API, the disclosure of information regarding whether a prior authorization is required and what information is necessary is immediate, based on initiation of the request from the provider. In addition, providers may query the Prior Authorization API for the payer's prior authorization and documentation requirements.

The disclosure of information related to an eligible payer's election to request an extension, exemption, or exception from implementing the Provider Access, Payer-to-Payer, and Prior Authorization APIs will be as needed for payers to whom this provision applies (state Medicaid and CHIP FFS programs and QHP issuers on the FFEs) if these specific payers determine their need to apply for an extension, exemption, or exception.

Patient Access API and Prior Authorization Metrics Reporting

Payers must report Patient Access API use metrics to CMS annually. Payers must publicly report prior authorization decision metrics annually.

Electronic Prior Authorization Reporting

Eligible clinicians and eligible hospitals and CAHs must submit an attestation to CMS indicating whether they requested at least one prior authorization electronically from CEHRT annually. See the

[11] While the impacted payer is required to request information from the patient's previous payer only once, patients may make requests to the impacted payer for additional exchanges.

next revision to PRA packages approved under OMB control numbers 0938-1278 (CMS-10552) and 0938-1314 (CMS-10621) for additional information.

7. Special Circumstances

There are no special circumstances that require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Prepare a written response to a collection of information in fewer than 30 days after receipt of that collection;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include a pledge of confidentiality that is not supported by authority established in statute or regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
- Submit proprietary trade secrets, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

The 60-day notice was published on December 13, 2022 (87 FR 76238) as part of the proposed rule entitled "Interoperability and Prior Authorization for MA Organizations, Medicaid and CHIP Managed Care and State Agencies, QHP issuers on the FFEs, MIPS Eligible Clinicians, Eligible Hospitals and CAHs" (RIN 0938-AU87; CMS-0057-P). A small number of commenters disagreed with CMS calculations for the total burden regarding hours and implementation costs for the APIs described in the information collection requirements. A commenter stated that our estimates were understated. However, that commenter did not provide alternative studies or information we could apply to our calculations. We have included available information in our estimates and noted that we would collaborate with industry during and following implementation to gather cost data to the extent practicable for use in possible future rulemaking.

The final rule entitled "Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the FederallyFacilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program" (RIN 0938-AU87; CMS-0057-F) published on February 8, 2024 (89 FR 8758).

9. Payments/Gifts to Respondents

There will be no payment of gifts of any kind given to participants under this PRA. Payments pertaining to participation in the programs in which the health plans are contracted are not directly connected to this PRA package.

10. Confidentiality

All information collections under this initiative will be maintained in strict accordance with statutes and regulations governing confidentiality requirements. HIPAA covered entities subject to information collection under this final rule, and their business associates, will be responsible for

compliance with the HIPAA Privacy and Security Rules, the Federal Trade Commission Act (FTC Act), regulations protecting sensitive information under Part II, and any state laws applicable to their business activities including, but not limited to, their handling of patients' Protected Health Information (PHI) and other data. CMS will maintain responsibility for the data.

CMS will comply with all Privacy Act and Freedom of Information laws and regulations that apply to the collection of provider information. Privileged or confidential commercial or financial information is protected from public disclosure by Federal law 5 U.S.C. 522(b)(4) and Executive Order 12600.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates (Hours & Wages)

12.1 Wages

To derive average costs, we used data from the U.S. Bureau of Labor (BLS) Statistics' National Occupational Employment and Wage Estimates (https://www.bls.gov/oes/current/oes_nat.htm), and when possible, aligned with other CMS regulatory actions. Table 1 presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 1: HOURLY WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($ / Hour)	Fringe Benefit ($ / Hour)	Adjusted Hourly Wage ($ / Hour)
Business Operations Specialists	13-1000	$37.66	$37.66	$75.32
Clerical (Office and Administrative Support Operations)	43-3000	$20.38	$20.38	$40.76
Computer and Information Analysts	15-1210	$48.40	$48.40	$96.80
Computer and Information Systems Managers	11-3021	$77.76	$77.76	$155.52
Computer Systems Analysts	15-1211	$47.61	$47.61	$95.22
Database Administrators and Architects	15-1245	$48.60	$48.60	$97.20
Designers, All Other	27-1029	$34.30	$34.30	$68.60
Engineers, All Other	17-2199	$51.47	$51.47	$102.94
General and Operations Managers	11-1021	$60.45	$60.45	$120.90
Medical Records Specialists	29-2098	$23.21	$23.21	$46.42
Registered Nurses	29-1141	$38.47	$38.47	$76.94
Operations Research Analysts	15-2031	$44.37	$44.37	$88.74
Physicians, All Other	29-1228	$105.22	$105.22	$210.44
Software and Web Developers	15-1250	$52.86	$52.86	$105.72
Technical Writers	27-3042	$37.78	$37.78	$75.56

In the final rule, we adjusted the employee hourly wage estimates by a factor of 100 percent or double the BLS wage estimates. This is a rough adjustment because fringe benefits and overhead costs vary across employers, based on the age of employees, location, years of employment, education, vocations, and other factors. In addition, methods of estimating these benefits and overhead costs can vary across studies. We chose to use sources in alignment with other CMS regulations after determining that they used similar estimates and formulas.

12.2 Burden Estimates

Implementation and Maintenance of the Provider Access, Payer-to-Payer, and Prior Authorization APIs and Related Collections

CMS calculated burden based on the requirements to implement and maintain Provider Access, Payer-to-Payer,[12] and Prior Authorization APIs. We assumed that to implement the new APIs, the impacted payers will conduct three major work phases: initial design, development and testing, and long-term support and maintenance.[13] A description of tasks included in these work phases was provided in the CMS Interoperability and Patient Access final rule, the PRA package for that rule, and is included in the CMS Interoperability and Prior Authorization final rule. We confirm our assumptions and final estimates in the final rule.

CMS is also calculating burden based on several requirements related to the three new APIs. First, CMS is calculating the additional burden for impacted payers to send a reason for denial of a prior authorization request via the Prior Authorization API, as required by the final rule. Specifically, entities will be required to use the adopted X12 278 standard and remain HIPAA-compliant in order to comply with the requirement in the final rule, unless they are part of a pilot or they choose not to use the standard, as permitted under the HHS enforcement discretion for use of the HIPAA standard. The burden estimate accounts for the multiple skill sets required to comply with this requirement and licensing costs for accessing the X12 standards in developing the burden estimates.

Since we cannot predict the number of state Medicaid and CHIP FFS programs and QHP issuers on the FFEs that might apply for the optional extension, exemption, or exception from implementing the Provider Access, Payer-to-Payer, and Prior Authorization APIs, we do not have an estimate of how many of these organizations would be subject to the information collections. The burden associated with this information collection for QHP issuers on the FFEs will be captured in the next revision to a PRA Package currently approved under OMB control number OMB-0938-1187. As previously discussed, requirements regarding the submission of MMIS ADPs by state Medicaid and CHIP FFS programs do not require a PRA package.

Patient Access API and Prior Authorization Decision Metrics Reporting

CMS calculated burden based on the requirements for impacted payers to report certain metrics to CMS on the use of the Patient Access API annually and to publicly report certain metrics on prior authorization decisions annually.

---

[12] The burden estimates for implementation of the Payer-to-Payer API account for some reduced development costs to implement this API because of efficiencies gained in implementing the same underlying standards and implementation guides (IGs) as for the other APIs. The burden estimates also account for unique costs for implementation of the Payer-to-Payer API to test and integrate the API with payer systems.

[13] See the PRA package associated with the CMS Interoperability and Patient Access final rule (approved under OMB control number 0938-1412) for a detailed discussion of activities associated with these three major work phases.

The burden estimate related to these reporting requirements reflects the time and effort needed to identify, collect, and disclose the information. We estimated an initial set of one-time costs associated with implementing the reporting infrastructure and ongoing annual maintenance costs to report after the reporting infrastructure is established.

Electronic Prior Authorization Reporting

The burden associated with the requirement for MIPS eligible clinicians to report the electronic prior authorization measure for MIPS will be captured in the next revision to the PRA package currently approved under OMB control number 0938-1314 (CMS-10621). The burden associated with the requirement for eligible hospitals and CAHs to report the electronic prior authorization measure for the Medicare Promoting Interoperability Program will be captured in the next revision to the PRA package currently approved under OMB control number 0938-1278 (CMS-10552).

Information Collections that are Usual and Customary Business Practices

As discussed in the **Background** section, information collections we have identified as usual and customary business practices do not require a burden calculation pursuant to 5 CFR 1320.3(b)(2).

Burden Calculation Assumptions

Table 2 summarizes costs for the first and subsequent years of these provisions (reflects the primary estimate) and is based on the following assumptions:

- A modified compliance date for the APIs of 2027. The applicable date for requirements to implement the Provider Access, Payer-to-Payer, and Prior Authorization APIs is January 1, 2027. The applicable date for reporting Patient Access API and prior authorization decision metrics is 2026. Accordingly, Table 2 reflects costs beginning in 2027 for implementation of the APIs and 2026 for Patient Access API and prior authorization decision metrics reporting.
- Maintenance costs for the three APIs, as indicated in Table 2, are assumed to be 25 percent of total costs; we believe these maintenance costs would be incurred in years 2027 and beyond.
- For provisions requiring first-year implementation costs, we believe it is most reasonable that these first-year costs would take place in 2026 and that subsequent year costs, as reflected in the various tables in this section, would take place in years 2027 and beyond.

TABLE 2: COSTS FOR FIRST AND SUBSEQUENT YEARS

Item	Notes	Number of respondents	Time per Respondent (Hour)	Labor Cost ($)	Estimated Annual Burden (Hour)	1st Year Cost (Millions $)	2nd Year Cost (Millions $)	3rd Year Cost (Millions $)	Subsequent Year Costs (Millions $)
Patient Access API Metrics Reporting, 1st year Cost	(1)	365	160	$94.32	58,400			$5.5	
Patient Access API Metrics Reporting, subsequent year costs	(1)	365	40	$75.32	14,600				$1.1
Provider Access API, Development	(2)	365	2,800	$96.44	1,022,000	$32.5	$32.5	$32.5	
Provider Access API, Maintenance	(2)	365	700	96.44	255,500				$24.6
Prior Authorization API, Development	(3)	365	10,880	$105.19	3,971,200	$137.8	$137.8	$137.8	
Prior Authorization API, Maintenance	(3)	365	2,720	$105.19	992,800				$104.4
Update Policies for Communicating Denials for Prior Authorization and Timeframes for Prior Authorization Decisions	(4)	365	8	$120.90	2,920			$0.4	
Public Reporting of Prior Authorization Metrics, 1st Year	(5)	365	320	$92.42	116,800			$10.8	
Public Reporting of Prior Authorization Metrics, subsequent years	(5)	365	120	$75.32	43,800				$3.3
Payer-to-Payer API, Development	(6)	365	916	$104.88	334,340	$11.6	$11.6	$11.6	
Payer-to-Payer API, Maintenance	(6)	365	229	$104.88	83,585				$8.8
Attestation for MIPS Promoting Interoperability, MIPS eligible clinicians		54,770	0.0083	$46.42	456				$0.021
Attestation for Medicare Promoting Interoperability Program, Eligible Hospitals, and CAHs		4,500	0.0083	$46.42	37				$0.002
Total combined cost by year in millions to all 365 Organizations (Payers), all 54,770 MIPS eligible clinicians, and all 4,500 eligible hospitals and CAHs.		59,635		*Varies*	6,896,438	$182	$182	$199	$142

***** The number of responses per respondent is uniformly 1 and therefore omitted.

NOTES:

(1) 42 CFR 422.119, 431.60, 438.242, 457.730, and 457.1233 and 45 CFR 156.221.

(2) 42 CFR 422.121, 431.61, 438.242, 457.731, and 457.1233 and 45 CFR 156.222.

(3) 42 CFR 422.122, 431.80, 438.242, 457.732, 457.1233, 422.122, 431.80, 438.242, 457.732, and 457.1233 and 45 CFR 156.223.

(4) 42 CFR 422.566, 422.568, 422.570, 422.631, 438.210, 440.230, 457.495, and 457.1230.

(5) 42 CFR 422.122, 438.210, 440.230, 457.732, and 457.1233 and 45 CFR 156.223.

(6) 42 CFR 422.121, 431.61, 438.242, 457.731, and 457.1233 and 45 CFR 156.22.

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to Federal Government

The annual cost to the federal government for the information collection that will be required under the final rule varies by year over the next ten years. For example, the total cost to the federal government is $87 million in 2024, $97 million in 2025, and $104 million in 2026. The average annual cost to the federal government over the next ten years is estimated to be $79.3 million.

We provided a detailed discussion regarding how we allocated the percentage of total costs to comply with information collections to the federal government and across the various plans that offered products in MA, Medicaid, CHIP, and the QHPs on the FFEs in the final rule.

15. Changes to Burden

This is a new information collection. We have updated some of our estimates since the publication of the notice of proposed rulemaking. Specifically, we updated the estimates for the first, second, and third year costs to account for the change in the publication date of the final rule from June 2023 in the notice of proposed rulemaking (which would have given payers two and a half years to implement requirements) to December 2023 in the final rule (which will give payers three years to implement requirements). As we explained in the final rule, the updated implementation date of January 2027 for the APIs provides more time for the impacted payers to conduct analysis, development, and testing. This is shown in Table 2. We have also corrected some errors in Table 2 that appeared in the PRA Supporting Statement for the notice of proposed rulemaking.

16. Publication/Tabulation Dates

Impacted payers will manage the additional data required for transmission to the Patient Access API, and through the new Provider Access, Payer-to-Payer, and Prior Authorization APIs, as required by the final rule. CMS will not receive information from these payers about the operations of the new APIs, nor any reports of utilization or uptake. CMS does not intend to publish any performance-based reports about payer implementation of the Provider Access, Payer-to-Payer, or Prior Authorization APIs or their related information collections, including reports to CMS on Patient Access API use and public reports on prior authorization decisions.

CMS also does not intend to publish the interoperability measure attestations that MIPS eligible clinicians and eligible hospitals and CAHs submit in accordance with the electronic prior authorization reporting requirement, or any performance-based reports based on those attestations. See the discussion in the next revision to PRA packages approved under OMB control numbers 0938-1278 (CMS-10552) and 0938-1314 (CMS-10621).

17. Expiration Date

The Office of Burden Reduction & Health Informatics (OBRHI) will provide the expiration date and OMB control number for applicable provisions of the PRA package on the top right of the front page of the OBRHI website when that information is provided by OMB.

18. Certification Statement

There are no exceptions to the certification statement.