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

A. Background

Health information technology (IT) is changing the patient experience and how we do business in health care, including how 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 2020 CMS Interoperability and Patient Access final rule (85 FR 25510) that focused on advancing interoperability and improving patient access to their health information, including requirements for all impacted payers[1] to develop and maintain a Patient Access Application Programming Interface (API) and for certain impacted payers to develop and maintain a Provider Directory API.

In January 2024, CMS published the 2024 CMS Interoperability and Prior Authorization final rule, which expands upon federal policies to improve data exchange and reduce administrative burden within the health care system. This final rule requires impacted payers[2] to develop and maintain Provider Access, Payer-to-Payer, and Prior Authorization APIs. It also requires payers to report metrics on Patient Access API usage to CMS and to publicly report prior authorization metrics for non-drug items and services. For additional information about the requirements in the 2024 CMS Interoperability and Prior Authorization final rule, see 89 FR 8758.

On April 14, 2026 , CMS published the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, which includes proposals that expand upon policies finalized in the previously mentioned interoperability rules, including proposals for impacted payers[3] to report metrics on Provider Access, Payer-to-Payer, and Prior Authorization API usage to CMS,[4] to publicly report additional prior authorization metrics on non-drug items and services, and to publicly report prior authorization metrics on drugs. This proposed rule also proposes to extend certain policies finalized in the previous interoperability rules to small group market Qualified Health Plan (QHP) issuers on the Federally-facilitated Small Business Health Options Programs (FF-SHOPs), including the requirements finalized in the 2024 CMS Interoperability and Prior Authorization final rule to report metrics to CMS on Patient Access API usage and to publicly report non-drug prior authorization metrics. Finally, this proposed rule proposes to require impacted payers to report their API endpoints and API documentation to CMS to streamline access to the Patient Access, Provider Directory, Provider Access, Payer-to-Payer, and Prior Authorization APIs (the "interoperability APIs") finalized in previous rulemaking. For additional information about the proposals in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, see [91 FR 19890].

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1 Payers impacted by the 2020 CMS Interoperability and Patient Access final rule include Medicare Advantage (MA) organizations; state Medicaid and Children's Health Insurance Program (CHIP) fee-for-service (FFS) programs; Medicaid managed care plans; CHIP managed care entities; and issuers that offer individual market QHPs on the Federally-facilitated Exchanges (FFEs) (individual market QHP issuers on the FFEs).

2 The same payers impacted by the 2020 CMS Interoperability and Patient Access final rule are also impacted by the 2024 CMS Interoperability and Prior Authorization final rule.

3 Payers impacted by the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule include MA organizations; state Medicaid and CHIP FFS programs; Medicaid managed care plans; CHIP managed care entities; and QHP issuers on the FFEs, which include both individual market QHP issuers on the FFEs and issuers that offer small group market QHPs on the Federally-facilitated Small Business Health Options Programs (FF-SHOPs) (small group market QHP issuers on the FF-SHOPs).

4 Medicaid managed care plans and CHIP managed care entities would be required to report to states.

The 2024 CMS Interoperability and Prior Authorization final rule included certain provisions that meet elements of the collections of information provisions under the Paperwork Reduction Act (PRA), described below. Certain proposals in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule would also fall under the collection of information provisions described in the PRA, if finalized as proposed. For a description of the information collections in the 2024 CMS Interoperability and Prior Authorization final rule and the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, see Section 13 (Information Collections) in this PRA package.

B. Justification

1. Need and Legal Basis

The collections of information in the 2024 CMS Interoperability and Prior Authorization final rule and the proposed collections of information in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule support CMS' and other federal initiatives to advance interoperability and improve access to health information for patients, providers, and payers, in alignment with goals to improve health care. The established legal bases for these information collections are identified below.

- Section 1852(d)(1)(A) of the Social Security Act (the Act) (requires MA organizations to make covered benefits available and accessible to enrollees in a manner that assures continuity in the provision of benefits as a condition of using a network of providers).
- Section 1852(g)(1)(A) of the Act (requires MA organizations to have a procedure for making determinations about whether an enrollee is entitled to receive a health service, how much the enrollee is required to pay, and to provide an enrollee with a written notice if the plan denies coverage; requires that coverage determinations be made on a timely basis).
- Section 1852(h) of the Act (requires MA organizations to have procedures to maintain accurate and timely medical records and other health information regarding enrollees and to assure enrollees have timely access to those records and information).
- Section 1856(b) of the Act (authorizes the Secretary to establish regulatory standards for MA organizations that are consistent with and carry out Part C of the Medicare statute, including the provisions in section 1852 of the Act).
- Section 1857(e)(1) of the Act (requires that MA organizations add contract terms determined by the Secretary to be "necessary and appropriate").
- Section 1902(a)(4) of the Act (requires state Medicaid plans to provide such methods of administration as are found by the Secretary to be necessary for proper and efficient operation of the state Medicaid plan).
- Section 1902(a)(6) of the Act (requires states to make reports in a form and containing information required by the Secretary).
- Section 1902(a)(8) of the Act (requires states to ensure that Medicaid services are furnished with reasonable promptness to all eligible individuals).
- Section 1902(a)(19) of the Act (requires states to ensure that care and services under a Medicaid state plan are provided in a manner consistent with simplicity of administration and the best interests of the recipients).

- Section 1903(m)(2)(A)(xi) of the Act (requires that contracts with Medicaid managed care organizations [MCOs] include provisions that ensure compliance with applicable requirements).
- Section 1932(a) of the Act (provides authority for states to implement managed care arrangements and includes certain waiver provisions).
- Section 1932(c)(1)(A)(i) of the Act (requires states that contract with Medicaid MCOs to develop and implement a quality assessment and improvement strategy that includes standards for access to care so that covered services are available within reasonable timeframes).
- Section 1932(d)(1) of the Act (establishes that managed care entities must comply with requirements the Secretary determines necessary to carry out the purposes of the Medicaid program).
- Section 2101(a) of the Act (states that the purpose of Title XXI of the Act is to provide funds to states to provide child health assistance to uninsured, low-income children in an effective and efficient manner that is coordinated with other sources of health benefits coverage).
- Section 2107(b)(1) of the Act (requires state CHIP agencies to collect data, maintain records, and furnish reports in order to enable the Secretary to monitor state program administration and compliance and to evaluate and compare the effectiveness of state plans under Title XXI of the Act).
- Section 1311(e)(1)(A) of the Patient Protection and Affordable Care Act (Affordable Care Act) (requires that Exchanges only certify plans as QHPs if they meet the requirements for certification promulgated by the Secretary under section 1311(c)(1) of the Affordable Care Act).
- Section 1311(e)(1)(B) of Affordable Care Act (provides discretion to certify QHPs if the Exchange determines that making such health plans available is in the interests of qualified individuals and qualified employers in the state or states in which such Exchange operates).

2. Information Users

CMS will (or would, for proposals not yet finalized) be the information user of Patient Access, Provider Access, Payer-to-Payer, and Prior Authorization API usage metrics. CMS will use the information it collects about use of the Patient Access API to better understand whether that API is providing patients with access to their health information and would use the information that it would collect from small group market QHP issuers on the FF-SHOPs in the same way. CMS would use the information it would collect about the use of the Provider Access, Payer-to-Payer, and Prior Authorization APIs to better understand whether these APIs support treatment, coordinate patient care, and streamline prior authorization processes.

Payers, patients, and providers will (or would, for proposals not yet finalized) be the information users of the publicly reported prior authorization metrics. Payers could use these reports to learn about their own performance and consider adjustments to prior authorization policies or practices. Patients could review the reports when choosing a new plan. Providers could use the reports when selecting payer networks to join.

Health IT developers (including third-party app developers and electronic health record [EHR] developers), payers, and providers would be the information users of the API endpoints and API documentation. Third-party app developers could use the information to connect to payers' API endpoints to facilitate patients' access to their data via a third-party health app. EHR

developers could use the information to configure providers' EHRs or other systems to query payers' API endpoints to retrieve patient information via the Provider Access API. Payers could use the information to send a request for patient data to a patient's previous or concurrent payer(s) via the Payer-to-Payer API. Providers could use the information to submit electronic prior authorization requests via the Prior Authorization API. Third-party app developers and providers could use the information to create third-party apps that help patients find in-network providers and enable care coordination between providers using information available via publicly accessible Provider Directory APIs.

3. Use of Information Technology

Payers will (or would, for proposals not yet finalized) use IT to collect Patient Access, Provider Access, Payer-to-Payer, and Prior Authorization API usage metrics data and generate necessary reports to submit to CMS. Similarly, payers will (or would, for proposals not yet finalized) use IT to collect the prior authorization metrics data on non-drug items and services and drugs and publish that information on their publicly accessible websites. Payers may use IT to report API endpoint and API documentation information to CMS, though reporting could be accomplished without the use of IT.

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.

5. Small Businesses

The information collections described in this package 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 $47 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 3 to 5 percent.[5] After reviewing the impacted entities, CMS has determined that this information collection will not have a significant impact on small businesses.[6]

6. Less Frequent Collection

As indicated, the Patient Access, Provider Access, Payer-to-Payer, and Prior Authorization API usage metrics and prior authorization metrics are (or would be, for proposals not yet finalized) reported annually.[7] In addition, impacted payers would be required to verify the reported payer API endpoints and API documentation at least once every 12 months and would be required to update API endpoints and API documentation within one week of any changes to the information.

Annual reporting of API usage metrics to CMS is critical for monitoring the adoption and efficacy of the APIs. Annual reporting of prior authorization metrics on payers' public websites

5 For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions.
6 *See* 89 FR 8758 and 91 FR 20041.
7 *See* 89 FR 8784 and 8879 and 91 FR 19940 and 19942.

furthers the goal of transparency within prior authorization. Reporting of payers' API endpoints and API documentation is essential for the seamless functioning of the Patient Access, Provider Access, Payer-to-Payer, and Prior Authorization APIs. Without reporting up-to-date API endpoints and API documentation, health IT developers, payers, and providers would struggle to identify how to connect with payers via the interoperability APIs. If impacted payers fail to report these metrics and API endpoints and API documentation at the required or proposed intervals, they would be considered non-compliant and would be subject to applicable enforcement mechanisms.

7. Special Circumstances

The information collection could be conducted more often than annually to conform to the proposed requirement outlined in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule for impacted payers to update their API endpoints and API documentation within one week of any changes to the information. Otherwise, there are no special circumstances that would 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 the Office of Management and Budget (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 Notice of Proposed Rulemaking published in the Federal Register (91 FR 19890) on April 14, 2026.

9. Payments/Gifts to Respondents

There will (or would, for proposals not yet finalized) 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 would be maintained in strict accordance with statutes and regulations governing confidentiality requirements. Health Insurance Portability and Accountability Act of 1996 (HIPAA) covered entities subject to information collection under the 2024 CMS Interoperability and Prior Authorization final rule and the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, and their business associates, would be responsible for compliance with the Standards for Privacy of Individually Identifiable Health Information (HIPAA Privacy Rule) and the Security Standards for the Protection of Electronic Protected Health Information (HIPAA Security Rule), the Federal Trade Commission Act (FTC Act), regulations protecting sensitive information under 42 CFR Part 2, 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.

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)

This section provides a summary of the information collections required by the proposed and final rules cited above. This revised Supporting Statement uses data from the U.S. Bureau of Labor (BLS) Statistics' 2024 National Occupational Employment and Wage Estimates (https://www.bls.gov/oes/current/oes_nat.htm). Table 1 presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted hourly wages.

TABLE 1: HOURLY WAGE ESTIMATES

Occupation Title	Occupation Code	Median Hourly Wage (Hour)	Fringe and Overhead ($)	Adjusted Hourly Wage ($/Hour)
Business Operations Specialists	13-1199	$39.07	$39.07	$78.14
Clerical (Office and Administrative Support Operations)	43-0000	$22.27	$22.27	$44.54
Computer and Information Analysts	15-1210	$51.39	$51.39	$102.78
Computer and Information Systems Managers	11-3021	$82.31	$82.31	$164.62
Computer Systems Analysts	15-1211	$49.90	$49.90	$99.80
Database and Network Administrators and Architects	15-1240	$51.67	$51.67	$103.34
Designers, All Other	27-1029	$31.84	$31.84	$63.68
Engineers, All Other	17-2199	$56.61	$56.61	$113.22
General and Operations Managers	11-1021	$49.50	$49.50	$99.00
Medical Records Specialists	29-2072	$24.16	$24.16	$48.32
Operations Research Analysts	15-2031	$43.89	$43.89	$87.78
Pharmacists	29-1051	$66.10	$66.10	$132.20
Software and Web Developers, Programmers, and Testers	15-1250	$62.17	$62.17	$124.34

Occupation Title	Occupation Code	Median Hourly Wage (Hour)	Fringe and Overhead ($)	Adjusted Hourly Wage ($/Hour)
Technical Writers	27-3042	$44.07	$44.07	$88.14

12. Information Collections

Patient Access, Provider Access, Payer-to-Payer, and Prior Authorization API Usage Metrics Reporting

The 2024 CMS Interoperability and Prior Authorization final rule requires impacted payers to annually report metrics to CMS on Patient Access API usage, and the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule would require impacted payers to annually report metrics to CMS on Provider Access, Payer-to-Payer, and Prior Authorization API usage.[8]

The 2024 CMS Interoperability and Prior Authorization final rule requires payers to report Patient Access API usage metrics at the following levels: 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 individual market QHP issuers on the FFEs at the issuer level.[9] If finalized, the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule would require impacted payers to report Provider Access, Payer-to-Payer, and Prior Authorization API usage metrics at the same levels, except that Medicaid managed care plans and CHIP managed care entities would be required to report at both the plan and program level.

The burden estimate related to the Patient Access API usage metrics reporting requirements reflects the time and effort needed to identify, collect, and disclose the information. The burden estimate related to the Provider Access, Payer-to-Payer, and Prior Authorization API usage metrics reporting requirements reflects the time and effort needed for impacted payers to conduct a gap analysis of existing reports they have already prepared, followed by appropriate tasks to develop, produce, and submit reports of the API usage metrics specified in the proposed rule. CMS estimates that it will take a total of 109,120 hours resulting in $11.68 million the first year and 27,280 hours resulting in $2.13 million annually in subsequent years to meet these reporting requirements.[10]

Required Patient Access API usage metrics and proposed Provider Access, Payer-to-Payer, and Prior Authorization usage metrics are as follows:

Required Patient Access API Usage Metrics:

8 The 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule would also require small group market QHP issuers on the FF-SHOPs to report metrics on the use of the Patient Access API. However, CMS determined that the burden for these information collections for payers impacted under the 2024 CMS Interoperability and Prior Authorization final rule would not increase due to this proposal.

9 If finalized, the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule would require Medicaid managed care plans and CHIP managed care entities to report the Patient Access API usage metrics finalized in the 2024 CMS Interoperability and Prior Authorization final rule at both the plan and program level.

10 This is the total aggregate burden of the provisions and proposals included in the 2024 CMS Interoperability and Prior Authorization final rule and 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule. Note, the first-year one-time costs start in different calendar years for each rule based on the finalized and proposed compliance dates, and the burden will eventually be satisfied.

- The total number of unique patients whose data are transferred via the Patient Access API to a health app designated by the patient.
- 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.

Proposed Provider Access, Payer-to-Payer, and Prior Authorization API Usage Metrics:

- The total number of unique providers who requested patient data via their Provider Access API.
- The total number of unique patients whose data were transferred via their Provider Access API to a provider's health IT system.
- The total number of patient data transfers via their Provider Access API.
- The percent of patients who have opted in to the payer to payer data exchange.
- The total number of unique patients whose data have been sent to other payers.
- The total number of unique patients whose data have been received from other payers.
- The total number of unique providers who request a prior authorization for items, services, or drugs through their Prior Authorization API.
- The number of unique prior authorization requests for items, services, and drugs received through their Prior Authorization API.
- The percentage of all prior authorization requests that were received through their Prior Authorization API.

Prior Authorization Metrics Reporting for Non-Drug Items and Services

The 2024 CMS Interoperability and Prior Authorization final rule requires impacted payers to publicly report prior authorization metrics on non-drug items and services on an annual basis.[11] Impacted payers are required to report prior authorization metrics on non-drug items and services at the same levels at which they are required to report Patient Access API usage metrics, as described above.[12] If the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule is finalized, it would require impacted payers to report prior authorization metrics on non-drug items and services and drugs at the same levels but would require Medicaid managed care plans and CHIP managed care entities to report at both the plan and program level.

CMS has released guidance, which includes an optional template that impacted payers can use, on implementation of the requirement in the 2024 CMS Interoperability and Prior Authorization final rule for impacted payers to publicly report prior authorization metrics on non-drug items and services (available here: http://www.cms.gov/files/document/prior-authorization-metrics-reporting-overview-template.pdf).

11 The 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule would also require small group market QHP issuers on the FF-SHOPs to report metrics on the use of the Patient Access API and on prior authorization metrics for non-drug items and services. However, CMS determined that the burden for these information collections for payers impacted under the 2024 CMS Interoperability and Prior Authorization final rule would not increase due to this proposal.

12 If finalized, the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule would require Medicaid managed care plans and CHIP managed care entities to report the prior authorization metrics on non-drug items and services finalized in the 2024 CMS Interoperability and Prior Authorization final rule at both the plan and program level.

The burden estimate related to this proposal reflects the time and effort needed to identify, collect, and disclose the required information. CMS estimates that it will take a total of 109,120 hours resulting in a cost of $11.36 million the first year of reporting and 40,920 hours resulting in a cost of $3.20 million annually in subsequent years to meet these reporting requirements. Required prior authorization metrics on non-drug items and services are as follows:

Required Prior Authorization Information and Metrics, Aggregated for all Non-Drug Items and Services:[13]

- A list of all items and services that require prior authorization.
- 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.

Proposed Additional Prior Authorization Metrics for Non-Drug Items and Services:

- The total number and percentage of standard prior authorization requests for non-drug items and services that remain denied after appeal.
- The total number and percentage of expedited prior authorization requests for non-drug items and services that remain denied after appeal.
- The total number and percentage of standard prior authorization requests for non-drug items and services for which the timeframe for review was extended, and the request was denied.

13 The 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule proposes to require impacted payers to report "the total number and percentage," rather than just the percentage, for all of the below metrics except for: "A list of all non-drug items and services that require prior authorization," "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 non-drug items and services," and "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 non-drug items and services." The 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule also proposes to remove "aggregated for all non-drug items and services."

- The total number and percentage of expedited prior authorization requests for non-drug items and services for which the timeframe for review was extended, and the request was denied.
- The total number and percentage of expedited prior authorization requests for non-drug items and services for which the timeframe for review was extended, and the request was approved.
- The total number and percentage of expedited prior authorization requests for non-drug items and services that were approved after appeal.

Prior Authorization Metrics Reporting for Drugs

The 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule would require impacted payers to publicly report additional prior authorization metrics on drugs. Impacted payers are required to report prior authorization metrics on drugs at the following levels: 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 and program level, and QHP issuers on the FFEs at the issuer level.

The burden estimate related to this proposal reflects the time and effort needed to identify, collect, and disclose the required information specified in the proposed rule. CMS estimates that it will take a total of 109,120 hours resulting in an annual cost of $11.36 million the first year of reporting and 40,920 hours resulting in an annual cost of $3.20 million for all 341 impacted payers in the subsequent years to meet this reporting requirement. Proposed prior authorization metrics on drugs by program are as follows:

Proposed Prior Authorization Information and Metrics for Drugs MA organizations would be required to report:

- A list of all drugs payable under Part B that require prior authorization.
- The total number and percentage of approved standard prior authorization requests for Part B drugs.
- The total number and percentage of denied standard prior authorization requests for Part B drugs.
- The total number and percentage of standard prior authorization requests for Part B drugs for which the timeframe for review was extended, and the request was approved.
- The total number and percentage of standard prior authorization requests for Part B drugs for which the timeframe for review was extended, and the request was denied.
- The total number and percentage of standard prior authorization requests for Part B drugs approved after appeal.
- The total number and percentage of standard prior authorization requests for Part B drugs that remain denied after appeal.
- The average and median time that elapsed between the submission of requests and decisions for standard prior authorizations for Part B drugs.
- The total number and percentage of approved expedited prior authorization requests for Part B drugs.
- The total number and percentage of denied expedited prior authorization requests for Part B drugs.

- The total number and percentage of expedited prior authorization requests for Part B drugs for which the timeframe for review was extended, and the request was approved.
- The total number and percentage of expedited prior authorization requests for Part B drugs for which the timeframe for review was extended, and the request was denied.
- The total number and percentage of expedited prior authorization requests for Part B drugs approved after appeal.
- The total number and percentage of expedited prior authorization requests for Part B drugs that remain denied after appeal.
- The average and median time and elapsed between the submission of requests and decisions for expedited prior authorization requests for Part B drugs.

State Medicaid and CHIP FFS programs, Medicaid managed care plans, and CHIP managed care entities would be required to report:

- A list of all drugs that require prior authorization.
- The total number and percentage of prior authorization requests for all drugs that were approved.
- The total number and percentage of prior authorization requests for all drugs that were denied.
- The total number and percentage of prior authorization requests for all drugs approved after appeal.
- The total number and percentage of prior authorization requests for all drugs that remain denied after appeal.
- The average and median time that elapsed between the submission of requests and decisions for prior authorizations for all drugs.

QHP issuers on the FFEs would be required to report:

- A list of all drugs that require prior authorization.
- The total number and percentage of standard prior authorization requests for all drugs that were approved.
- The total number and percentage of standard prior authorization requests for all drugs that were denied.
- The total number and percentage of standard prior authorization requests for all drugs for which the timeframe for review was extended, and the request was approved.
- The total number and percentage of standard prior authorization requests for all drugs for which the timeframe for review was extended, and the request was denied.
- The total number and percentage of standard prior authorization requests for all drugs approved after appeal.
- The total number and percentage of standard prior authorization requests for all drugs that remain denied after appeal.
- The average and median time that elapsed between the submission of requests and decisions for standard prior authorizations for all drugs.

- The total number and percentage of expedited prior authorization requests for all drugs that were approved.
- The total number and percentage of expedited prior authorization requests for all drugs that were denied.
- The total number and percentage of expedited prior authorization requests for all drugs for which the timeframe for review was extended, and the request was approved.
- The total number and percentage of expedited prior authorization requests for all drugs for which the timeframe for review was extended, and the request was denied.
- The total number and percentage of expedited prior authorization requests for all drugs approved after appeal.
- The total number and percentage of expedited prior authorization requests for all drugs that remain denied after appeal.
- The average and median time that elapsed between the submission of requests and decisions for expedited prior authorizations for all drugs.

Payer API Endpoints and API Documentation

The 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule would require impacted payers to report Patient Access, Provider Directory, Provider Access, Payer-to-Payer, and Prior Authorization API endpoints to CMS for publication, in the form of an Endpoint Resource, as defined by an unexpired version of the Fast Healthcare Interoperability Resources® (FHIR®) standard adopted in 45 CFR 170.215(a), including, if a payer reports multiple endpoints, appropriate use cases for each. In addition, CMS would require impacted payers to report URLs with the following required documentation for each of their interoperability APIs, as applicable: a direct URL to their interoperability APIs' FHIR capability statements, authorization and authentication protocol and implementation details, and API registration information. Impacted payers would be required to report this information no later than 60 days after the effective date of the 2026 CMS Interoperability Standards and Prior Authorization for Drugs final rule. New impacted payers would be required to report no later than 60 days before they begin covering patients under the applicable CMS program. Further, impacted payers would be required to verify the reported information at least once every 12 months, and report updated information to CMS within 1 week of any changes to the reported information. The proposed policy would require 2 hours of labor by a Business Operations Specialist at an hourly rate of $78.14, or $156.28 annually. For all impacted payers, this reporting burden would be 682 hours and $53,291 annually, rounded ($156.28 × 341 respondents = $53,291.48).

Burden Calculation Assumptions

Table 2 provides the total cumulative annual cost for all the collections of information described in this Supporting Statement. Since the requirements to report metrics have differing amounts of burden in the first and subsequent years of implementation, we used the following calculations to arrive at an annual average cost for these provisions:

- We calculate the annual cost using the average of the first, second, and third year estimated time per respondent and distributed the time for all 341 respondents across 3 years to arrive at the total annual burden hours.

- We multiplied the total annual burden hours by the average of the first, second, and third year hourly labor cost to arrive at the total annual burden cost for each requirement.

For the provisions in the 2024 CMS Interoperability and Prior Authorization final rule, Table 3 summarizes costs for the first, second, and third years of these provisions (reflects the primary estimate) and is based on the following assumptions:

- The applicable date for impacted payers to implement the Provider Access, Payer-to-Payer, and Prior Authorization APIs is January 1, 2027. The applicable dates for reporting Patient Access API usage and prior authorization metrics for non-drug items and services are in 2026. Accordingly, Table 3 reflects costs beginning in 2027 for implementation of the APIs and 2026 for Patient Access API usage and prior authorization metrics reporting for non-drug items and services.
- Labor costs are either BLS wages when a single staff member is involved or a weighted average representing a team effort, obtained by dividing the aggregate cost by the aggregate hours.

For the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, Table 4 summarizes costs for the first and subsequent years of these proposals and is based on the following assumptions:

- Proposals would be effective beginning 60 days after the effective date of the 2026 CMS Interoperability Standards and Prior Authorization for Drugs final rule (proposal to report API endpoints and API documentation) and 2028 (proposal to publicly report prior authorization metrics for drugs and proposal to report Provider Access, Payer-to-Payer, and Prior Authorization API usage metrics to CMS). However, we assume impacted payers would conduct certain activities before the compliance date to make appropriate operational, procedural, or system changes.

- We are basing our calculations on a 1-year estimate to accommodate all system, process, and reporting activities. The 1 year reflects the time period from the expected publication of a proposed rule on April 14, 2026, until the compliance dates of 60 days after the effective date of the CMS Interoperability Standards and Prior Authorization for Drugs final rule and in 2028.

TABLE 2: AVERAGE ANNUAL COST FOR ALL COLLECTIONS OF INFORMATION

Item	Regulatory Citations	Number of Respondents	Average Time per Respondent (Hour)	Total Annual Hours	Average Labor Cost ($/Hour)	Average Annual Cost (Millions $)
Average Burden of Reporting Patient Access API Metrics to CMS	(1)	341	80	27,280	$87.80	$2.66
Average Burden for Public Reporting of Prior Authorization Metrics for Non-Drug Items and Services	(2)	341	186.7	63,653	$86.80	$5.92
Average Burden for Public Reporting of Prior Authorization Metrics for Drugs	(3)	341	186.7	63,653	$86.80	$5.92
Average Burden of Reporting Provider Access, Payer-to-Payer, and Prior Authorization API Metrics to CMS	(4)	341	80	27,280	$87.80	$2.66
Payer Endpoint Reporting	(5)	341	2	682	$78.14	$0.05
Total Cumulative Hours and Costs of Collections	**N/A**	**N/A**	**535**	**181,867**	**N/A**	**$17.21**

NOTES: (1) 42 CFR 422.122, 42 CFR 440.230, 42 CFR 438.210, 42 CFR 457.732, 42 CFR 457.1233, and 45 CFR 156.223;
(2) 42 CFR 422.121, 42 CFR 422.122, 42 CFR 431.61, 42 CFR 431.80, 42 CFR 438.242, 42 CFR 457.730, 42 CFR 457.731, 42 CFR 457.732, 42 CFR 457.1233, 45 CFR 156.222, and 45 CFR 156.223;
(3) 42 CFR 422.122, 42 CFR 440.230, 42 CFR 438.210, 42 CFR 457.732, 42 CFR 457.1230, and 45 CFR 156.223;
(4) 42 CFR 422.121, 42 CFR 422.122, 42 CFR 431.61, 42 CFR 431.80, 42 CFR 438.242, 42 CFR 457.731, 42 CFR 457.732, 42 CFR 457.1233, 45 CFR 156.222, and 45 CFR 156.223;
(5) 42 CFR 422.119, 42 CFR 422.120, 42 CFR 422.121, 42 CFR 422.122, 42 CFR 431.60, 42 CFR 431.61, 42 CFR 431.70, 42 CFR 431.80, 42 CFR 457.730, 42 CFR 457.731, 42 CFR 457.732, 42 CFR 457.760, 42 CFR 457.1233, 45 CFR 156.221, 45 CFR 156.222, and 45 CFR 156.223.

TABLE 3: COST FOR FIRST, SECOND, AND THIRD YEARS OF REPORTING PATIENT ACCESS API AND PRIOR AUTHORIZATION METRICS

Item	Regulatory Citations	Number of Respondents	Time per Respondent (Hour)	Total Annual Hours	Labor Cost ($/Hour)	1st Year Cost (Millions $)	2nd Year Cost (Millions $)	3rd Year Cost (Millions $)
Patient Access API Metrics Reporting to CMS (1st Year)	(1)	341	160	54,560	$107.02	$5.84	-	-
Patient Access API Metrics Reporting to CMS (2nd and 3rd Years)	(1)	341	40	13,640	$78.14	-	$1.07	$1.07
Public Reporting of Prior Authorization Metrics for Non-Drug Items and Services (1st Year)	(2)	341	320	109,120	$104.13	$11.36	-	-
Public Reporting of Prior Authorization Metrics for Non-Drug Items and Services (2nd and 3rd Years)	(2)	341	120	40,920	$78.14	-	$3.20	$3.20
Total Hours and Costs for Applicable Impacted Payers	**N/A**	**N/A**	**N/A**	**72,747**	**N/A**	**$17.20**	**$4.26**	**$4.26**

NOTES: (1) 42 CFR 422.119, 42 CFR 431.60, 42 CFR 438.242, 42 CFR 457.730, 42 CFR 457.1233, and 45 CFR 156.221;
(2) 42 CFR 422.122, 42 CFR 438.210, 42 CFR 440.230, 42 CFR 457.732, 42 CFR 457.1230, and 45 CFR 156.223.

TABLE 4: COST FOR FIRST, SECOND, AND THIRD YEARS FOR PROPOSED PRIOR AUTHORIZATION METRICS REPORTING FOR DRUGS, METRICS REPORTING FOR THE ACCESS APIS, AND PAYER ENDPOINT REPORTING

Item	Regulatory Citations	Number of Respondents	Time per Respondent (Hour)	Total Annual Hours	Labor Cost ($/Hour)	1st Year Cost (Millions $)	2nd Year Cost (Millions $)	3rd Year Cost (Millions $)
Public Reporting of Prior Authorization Metrics for Drugs (1st Year)	(1)	341	320	109,120	$104.13	$11.36	-	-
Public Reporting of Prior Authorization Metrics for Drugs (2nd and 3rd Years)	(1)	341	120	40,920	$78.14	-	$3.20	$3.20
Aggregate Burden of Reporting Provider Access, Payer-to-Payer, and Prior Authorization API Metrics to CMS (1st Year)	(2)	341	160	54,560	$107.02	$5.84	-	-
Aggregate Burden of Reporting Provider Access, Payer-to-Payer, and Prior Authorization API Metrics to CMS (2nd and 3rd Years)	(2)	341	40	13,640	$78.14	-	$1.07	$1.07
Payer Endpoint Reporting	(3)	341	2	682	$78.14	$0.05	$0.05	$0.05
Total Hours and Costs for Applicable Impacted Payers	**N/A**	**N/A**	**N/A**	**218,922**	**N/A**	**$17.25**	**$4.32**	**$4.32**

NOTES: (1) 42 CFR 422.122, 42 CFR 440.230, 42 CFR 438.210, 42 CFR 457.732, 42 CFR 457.1230, and 45 CFR 156.223;
(2) 42 CFR 422.121, 42 CFR 422.122, 42 CFR 431.61, 42 CFR 431.80, 42 CFR 438.242, 42 CFR 457.731, 42 CFR 457.732, 42 CFR 457.1233, 45 CFR 156.222, and 45 CFR 156.223;
(3) 42 CFR 422.119, 42 CFR 422.120, 42 CFR 422.121, 42 CFR 422.122, 42 CFR 431.60, 42 CFR 431.61, 42 CFR 431.70, 42 CFR 431.80, 42 CFR 438.242, 42 CFR 457.730, 42 CFR 457.731, 42 CFR 457.732, 42 CFR 457.760, 42 CFR 457.1233, 45 CFR 156.221, 45 CFR 156.222, and 45 CFR 156.223.

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to Federal Government

There are no direct costs to the federal government associated with this collection; however, the cost of the collection would inform the total amount of subsidies, rebates, and premium tax credit (PTC) payment contributed by the federal government to the Medicare Advantage, Medicaid and CHIP, and QHPs. Based on the proposed cost of the information collections, we estimate that government transfers would increase by an average of $12.31 million annually over the next 3 years as a result of these information collections.

15. Changes to Burden

In a previous version of this Supporting Statement, we described the burden on impacted payers to update their policies to reflect the requirements in the 2024 CMS Interoperability and Prior Authorization final rule to communicate the reason for prior authorization denials and make prior authorization decisions within certain timeframes. CMS has since determined that the communication of a prior authorization denial reason and a change to decision timeframes are usual and customary business practices. Since usual and customary business practices do not require a burden calculation pursuant to 5 CFR 1320.3(b)(2), we removed the burden estimates from this Supporting Statement, reducing the overall burden of this collection by $0.35 million (2,920 burden hours at $120.90 an hour).

Additionally, the previous version of this Supporting Statement characterized the burden associated with implementing the finalized APIs to support interoperability and prior authorization as collections of information. To more accurately calculate the burden associated with the proposed and finalized requirements to implement FHIR APIs, CMS has removed API implementation burden erroneously included in the previous versions of this package. These revisions would align the approach for calculating information collection burden across existing interoperability-focused PRA packages and streamline the content of the package for increased accuracy and fidelity to the requirements of the PRA. This change eliminates estimated burden of this package by $684 million. For additional information on this change, see section IV.D.1. in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule.

This Supporting Statement has been updated from the previous version to reflect an estimated 341 respondents for the collections of information related to Patient Access API usage and prior authorization metrics reporting. Previously, this Supporting Statement assumed 365 respondents for these information collections, based on the methodology described in the 2024 CMS Interoperability and Prior Authorization final rule. The reduction of 24 respondents was prompted by a refinement in the methodology which CMS used to quantify the number of parent organizations offering impacted health plans (MA, Medicaid, CHIP, and QHPs).

We note that the changes reflected in this Supporting Statement result from a combination of alterations to the burden estimates: (1) removing burden associated with reason for denial; (2) removing burden associated with implementation of APIs; (3) updating burden associated with reporting Patient Access API usage metrics and prior authorization metrics for non-drug items and services to 341 respondents; and (4) the addition of new proposed collections.

The previous version of this Supporting Statement contained a duplicative reference to the burden

estimates for the Merit-based Incentive Payment System (MIPS) and eligible hospitals and critical access hospital (CAH) programs' Electronic Prior Authorization measure, which was captured under multiple approved OMB control numbers: 0938-1278 and this collection 0938-1437. To address this duplication, OMB control number 0938-1437 will no longer reference burden estimations for Electronic Prior Authorization for eligible hospitals and CAHs. All references and calculations are calculated and provided for under OMB control number 0938-1278.

16. Publication/Tabulation Dates

CMS does not intend to publish any performance-based reports about payers' interoperability related information collections, including reports to CMS on Patient Access, Provider Access, Payer-to-Payer, or Prior Authorization API usage metrics and public reports on prior authorization metrics for non-drug items and services and drugs.

17. Expiration Date

The Office of Healthcare Experience and Interoperability (OHEI) will provide the expiration date and OMB control number for applicable provisions of the PRA package on the top right of the relevant OHEI website pages when that information is provided by OMB.

18. Certification Statement

There are no exceptions to the certification statement.