

Navigating the CMS 0057 Final Rule:
**A Guide for Implementing Prior
Authorization Requirements**





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Introduction

In an era where seamless data integration can significantly enhance patient care, the Centers for Medicare and Medicaid Service Interoperability and Prior Authorization Rule (CMS 0057) emerges as a pivotal milestone in healthcare regulation. This rule mandates the adoption of HL7 FHIR-based APIs to streamline electronic prior authorizations and sets rigorous standards for data exchange and system integration across healthcare settings.

This paper examines critical aspects of implementing the CMS 0057 Final Rule that stakeholders must consider for aligning with the regulatory requirements and to foster an interoperable healthcare environment. The included guidance and recommendations are based on CAQH's long-standing experience with industry standards, collaboration with key stakeholders, and industry-led development of operating rules via the Committee on Operating Rules for Information Exchange (CORE) and Insights initiatives.

Key focus areas include:

- Establishing common connectivity and exchange protocols,
- Implementing optional requirements to further streamline the prior authorization process,
- Evaluating the return on capital investments.

The goal of this approach is to achieve a scalable and intelligent implementation that adheres to regulatory mandates and significantly advances health care industry interoperability.

Background

The CMS 0057 Rule was finalized on January 18, 2024. The rule establishes technical infrastructure and workflow requirements for healthcare data transparency and exchange and aids coordination across care settings and changing health insurance coverage. This is accomplished through new and updated HL7 FHIR-based Application Program Interfaces (API).

The Final Rule takes steps to simplify and automate prior authorizations. Impacted health plans¹ must establish an electronic prior authorization process using a FHIR-based Prior Authorization API and must follow predictable timelines for prior authorization responses. Providers are impacted by corresponding requirements to attest to use of the FHIR-based APIs to earn reimbursement at-risk through the Merit-based Incentive Payment System (MIPS).

Industry alignment to a streamlined approach for electronic prior authorization stimulates automation of complex workflows and increases the proportion of submissions performed fully electronically that — as of 2023 — only reached 31%.^{2,3} Familiar barriers of standards adoption must be overcome to achieve the benefits of full automation, such as the potential for variable implementations and reluctance to make significant capital investments in new – sometimes unproven — technologies.

1.

Basics for Electronic Prior Authorization

CMS 0057 requires impacted health plans to stand up a FHIR-based Prior Authorization API that facilitates the automated submission of prior authorization requests. This allows for a timelier review and determination by health plans. As stated above, providers must use these APIs to earn back at-risk reimbursement through the MIPS program.

As contemplated, ideal development of electronic prior authorization APIs occurs when implementers follow the technical specifications outlined in the HL7 Da Vinci Burden Reduction Implementation Guides (IGs), each briefly detailed below. The three implementation guides are intended to work in concert to automate prior authorization submission and review.

- **Coverage Requirements Discovery (CRD):** Sets specifications for the return of benefit design, coverage, and prior authorization requirements.
- **Documentation Templates and Rules (DTR):** Automates the retrieval and population of forms and questionnaires relevant to the prior authorization request.
- **Prior Authorization Support (PAS):** Facilitates the direct submission of the compiled prior authorization request from the providers electronic health record and the retrieval of a response from the health plan.

CMS 0057 does not require the adoption of the Burden Reduction Implementation Guides, but strongly recommends following their requirements for the development of the prior authorization API. CAQH encourages the adoption of required and optional provisions of the three Burden Reduction Implementation Guides to augment installation and strengthen interoperability. Not only does this unify industry approaches, but it also allows for future updates to be implemented more smoothly, given that iterative additions to foundational implementations are generally easier and less costly.

2.

Considerations for Optimal Implementation

With any standard, implementers have options in how they interpret, blueprint and build requirements. This introduces variation and customization that may slow progress towards true interoperability. CAQH identified several key areas of optionality split across two main categories in the Burden Reduction Implementation Guides. Proactively addressing these areas during business planning and implementation will improve integration of technical infrastructures and workflows.

1. Connectivity and Security Requirements: A secure technical platform is a pre-requisite for any data exchange that potentially includes personal health information (PHI). The Burden Reduction Implementation Guides each require demonstrable use of authorization and authentication protocols when PHI is accessed and exchanged. Though each implementation guide supports secure exchange, minimum requirements are not aligned. This can lead to incompatibilities or the exposure of vulnerabilities as PHI flows through the infrastructure.

Consistent with optional but recommended requirements in the Burden Reduction Implementation Guides, optimal security can be achieved by enacting a certificate bound authentication process. This is recognized as an industry best practice and is often enacted using OAuth 2.0 paired with an X.509 Certificate. These requirements are already part of CORE Connectivity vC.4.0.0, a rule that empowers secure exchange and the population of web-based APIs using SOAP and REST protocols. In addition to best practice authorization and authentication, the CORE Connectivity rule includes other best security and exchange methodologies, like:

- Web-based HTTPS exchange
- TLS 1.2 or higher
- Communication using JSON readable formats
- Requirements universally applied to PHI and non-PHI exchange to reduce vulnerability

Implementation of web-based connectivity and a single security standard is essential to simplify and scale implementation efforts in a way that is protective of sensitive information and promotes system-wide interoperability. Many impacted entities are already following these requirements given the CORE Connectivity Rule is referenced in HIPAA-required CORE Operating Rules for the uniform exchange of electronic standards. Additionally, CORE Certification requires adoption of these requirements and impacts approximately 190 million insured lives.⁴

2. Developing an Ecosystem for Automation: The CRD, DTR, and PAS work in concert to inform, submit, and respond to prior authorization requests. This decreases the burden on submitters and allows for shorter determination timelines. The CRD identifies prior authorization requirements, "triggering" the retrieval and potential pre-population of templates and supporting documentation provided by the DTR. This information is packaged and submitted through the mechanisms included in the PAS. To achieve full, harmonized automation across the three implementation guides, impacted entities must consider several key requirements.

2a. Programming Clinical Quality Language (CQL): CQL is the HL7 standard for the expression of clinical language, and effectively standardizes how unstructured clinical documentation

that supports prior authorization is understood and ingested into the format of the burden reduction implementation guides. CQL is a base specification of the DTR, and the primary driver of how standard and adaptive questionnaires are displayed to and pre-populated for the user. Implementers are responsible for programming CQL to automate the retrieval and population of this information, requiring them to address non-standard documentation of disparate clinical concepts.

2b. Exchange of Supporting Information: The processes for exchanging additional information to support a prior authorization request are often inconsistent, time-consuming, and highly-manual. While there are currently no required attachments standards, prior authorization implementers may consider adopting the corresponding HL7 Da Vinci Clinical Data Exchange (CDEX) Implementation Guide that can automate the collection of clinical documentation dependent on the coverage requirements highlighted in the CRD and templates returned by the DTR. CDEX augments the requirements of CMS 0057 and would require additional implementation beyond the stated requirements and recommendations; however, automating the retrieval and packaging of supporting clinical information reduces burden and simplifies workflows, potentially contributing to \$140 million of medical industry cost-savings.⁵

2c. Communication of Prior Authorization Information and Status: The Burden Reduction Implementation Guides empower the automated exchange of prior authorization status through subscriptions. Avoidance of time-consuming phone calls or portal navigation has clear benefits to provider and plan workflows, but the advantage of automation can be disrupted if information exchange is conducted using ambiguous, non-standard data.

Although clinical information exchanged via the HL7 FHIR IGs aligns to the US CORE dataset, responsibility falls to implementers and users of the APIs to map this information to an exchangeable format. Industry stakeholders impacted by prior authorization reached consensus in CAQH CORE-led work groups to standardize prioritized aspects of prior authorization data content. This information can be considered during implementations and includes:

- Normalization of patient names
- Error code reporting
- Predictable reassociation requirements
- Uniform status code reporting

Some of the above aspects are addressed by virtue of using web-based APIs, such as standard error code reporting; however, other aspects such as prior authorization status can be fulfilled in multiple ways, which allows variation. By extension, this emphasizes the importance of a single agreed upon exchange language, a point broadcast by organizations such as the American Medical Association (AMA) that emphasize the need for transparent, predictable electronic data exchange that is standards-based and not reliant on proprietary solutions.⁶

Solutions include following CMS 0057 recommendations to adopt often used data sets, such as the X12 Health Care Service Review Decision Reason Codes (HCSRDRDC) or compelling vendor stakeholders to standardize how status information is ingested and communicated to align across disparate sources.

3. Benefit of a Phased Implementation

Though the presented barriers do not represent all challenges impacted entities may face, they illuminate specific areas that must be accounted for in business and infrastructure planning. The complexity of this workflow may lend itself to a **phased implementation** where impacted entities can gain experience with implementation leading up to regulatory deadlines. Using a phased approach allows entities to first address common workflows and accommodate incremental refinements to address more complex requirements. Though this necessitates action prior to regulatory deadlines, phasing implementation can help ensure full compliance and automation of complex prior authorization workflows.

Additionally, a phased approach allows impacted entities to investigate their ability to scale processes to business lines not named in the CMS 0057, such as commercial employer-sponsored health plans. The enforcement discretion exercised by the CMS National Standards Group for the HIPAA-required X12 278 allows organizations to accommodate electronic prior authorization using a FHIR-based API for all product lines. Though, in certain circumstances, support for the X12 278 must be maintained — such as when state legislation mandates its use — extending the build to all potential product lines can streamline workflows and reduce spend on maintaining disparate systems. The benefit and scalability of this approach must be carefully considered using real return on investment and value metrics.

4.

Return on Investment and Value Measurement

Though CMS 0057 requires the development of a prior authorization API, impacted entities still must generate business justification for the capital investment — particularly considering ideal implementations may have requirements that go beyond the scope of CMS 0057. An essential aspect of business planning is cataloguing return on investment and value associated with an optimal implementation. CAQH has identified 3 domains that impacted organizations must monitor when preparing their business case.



Implementation impact

The direct effect of implementation on the number and type of resources devoted to prior authorization activities pre- and post-implementation of the required APIs.



Workflow efficiency

The ability to address prior authorization submissions quickly and completely due to the streamlined environment facilitated through an automated infrastructure.



Workflow accuracy

The effectiveness of the automated workflow at streamlining the collection and exchange of information that results in a determination rather than a pending request or return of an error.

Value measurement across these three domains can be achieved through pre- and post-monitoring or by comparing existing workflows with those that are newly implemented. CAQH can support your organization in these efforts, including quantifying capital investment and the reduction of operating costs and pinpointing workflow improvements such as time to authorization determination or the persistence of manual intervention. The metrics recommended for monitoring in the Burden Reduction Implementation Guides complement this approach.

As part of an implementation planning effort, organizations should consider necessary adjustments to enable comprehensive tracking of the implementation. This information can also be treated as an efficiency opportunity as implementers consider ways to fulfill public reporting requirements in CMS 0057, scaling information from what is being used to track success.

5. Call to Action

Though implementers have until January 1, 2027 to adhere to prior authorization API requirements, those who build out the technical requirements, leverage discretion to enact optional provisions, and build-out enhanced workflows — all with a focus on learning and iteration — will encounter fewer roadblocks to automation. Additionally, implementers who address requirements early can effectively track and monitor return on investment and value for this significant capital investment. Contact CAQH for assistance in tracking and monitoring key components of implementation as you approach key regulatory deadlines.

Solutions and Services

CAQH Insights

tracks opportunities to improve healthcare administrative practices.

CAQH Solutions

leverage data insights and technology to reduce costs and optimize healthcare operations.

CAQH CORE

drives interoperability requirements to streamline the business of healthcare.

End Notes

- 1 Includes: Medicare Advantage organizations, state Medicaid and Children's Health Insurance Program (CHIP) Fee-for-Service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally Facilitated Exchange (FFE).
- 2 CAQH Insights (2024). The 2023 CAQH Index Report. CAQH, January 30, 2024. Retrieved from: <https://www.caqh.org/insights/caqh-index-report#download-report/> on April 26, 2024.
- 3 Fully electronic is defined by the proportion of prior authorization transactions carried out fully using the ASC X12N 278.
- 4 CAQH (2024). CORE Certification Progress Report. Retrieved from: <https://www.caqh.org/core/core-certification-progress-report>, 2024.
- 5 CAQH Insights (2024). The 2023 CAQH Index Report. CAQH, January 30, 2024. Retrieved from: <https://www.caqh.org/insights/caqh-index-report#download-report/> on April 26, 2024.
- 6 American Medical Association (2022). Measuring progress in improving prior authorization. Retrieved from: AMA Prior Authorization Survey Update | AMA ([ama-assn.org](https://www.ama-assn.org))

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