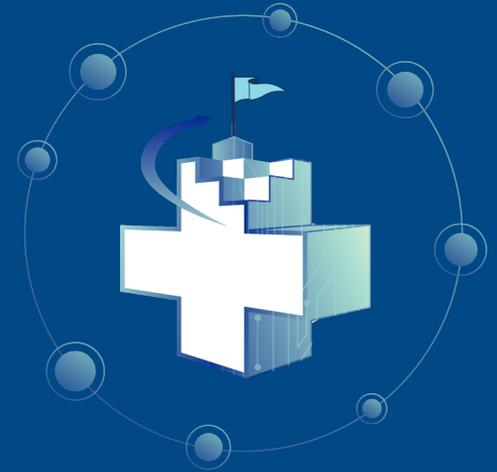


CMS Interoperability and Prior Authorization Proposed Rule

Alex Mugge, Director and Deputy Chief Health
Informatics Officer, CMS

Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information

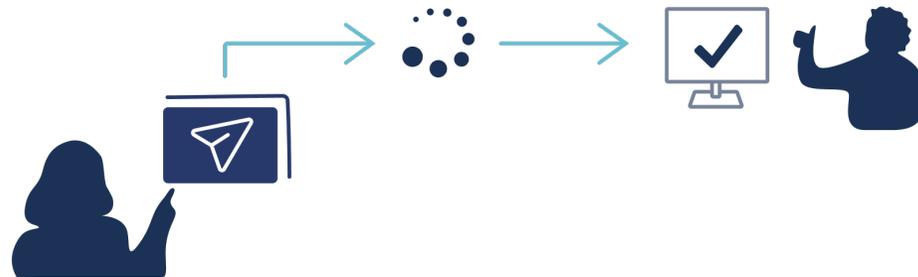


Patient Access API

- In the Interoperability and Patient Access final rule (CMS-9115-F), we finalized our policy to require a select group of CMS-regulated payers to implement a Fast Healthcare Interoperability Resources (FHIR)-based Patient Access API. In this proposed rule, starting January 1, 2023, we would require impacted payers to include, as part of the already established Patient Access API, information about the patient's pending and active prior authorization decisions to ensure patients have a better understanding of the prior authorization process and its impact on their care.
- This proposed rule would also require impacted payers to establish, implement, and maintain an attestation process for third-party application developers to attest to certain privacy policy provisions prior to retrieving data via the payer's Patient Access API.
- And, this proposed rule would require impacted payers to report metrics quarterly about patient use of the Patient Access API to CMS to assess the impact the API is having on patients.

Provider Access API

- In order to better facilitate coordination of care, and in support of a move to value-based care, we are proposing to require impacted payers to build and maintain a Provider Access API for payer-to-provider data sharing of claims and encounter data (not including cost data), a sub-set of clinical data as defined in the U.S. Core Data for Interoperability (USCDI) version 1, and pending and active prior authorization decisions for both individual patient requests and groups of patients starting January 1, 2023. We are proposing the use of the HL7 FHIR Bulk Data Access (Flat FHIR) specification to facilitate the exchange of data for more than one patient at a time.



Payer-to-Payer API

- In the Interoperability and Patient Access final rule (CMS-9115-F), we finalized a requirement that, at a patient's request, CMS-regulated payers must exchange certain patient health information, and maintain that information, thus creating a longitudinal health record for the patient that is maintained with their current payer. While we encouraged the use of a FHIR-based API for this data exchange, we did not require it.
- Payer-to-Payer API: We are now proposing to enhance the previously finalized payer-to-payer data exchange requirements for impacted payers by requiring that such exchange be via a FHIR-based Payer-to-Payer API, and that in addition to a sub-set of clinical data as defined in the USCDI version 1, impacted payers would also be required to exchange claims and encounter data (not including cost data), and information about pending and active prior authorization decisions, at a patient's request.
- Payer-to-Payer Data Exchange at Enrollment: We are proposing to require impacted payers share claims and encounter data (not including cost data), a sub-set of clinical data as defined in the USCDI version 1, and information about pending and active prior authorization decisions at enrollment, for payers that have a specific annual open enrollment period, or during the first calendar quarter of each year. Payers could efficiently exchange information for one or more patients at one time using the HL7 FHIR Bulk specification, allowing patients to take their health information with them as they move from one payer to another.

Leveraging Information about PA Decisions

- As part of the payer-to-payer API proposal we would encourage patients' new impacted payers to consider such information from previous payers when making new prior authorization determinations, potentially eliminating the need for patients and providers to repeat the prior authorization process with the new payer. We are seeking comment on the extent to which impacted payers should be limited from requiring patients to undergo repeat evaluations for the purposes of reaffirming coverage or prior authorization decisions without first reviewing the medical records and notes of the previous payer to determine if and why a repeat test is needed.

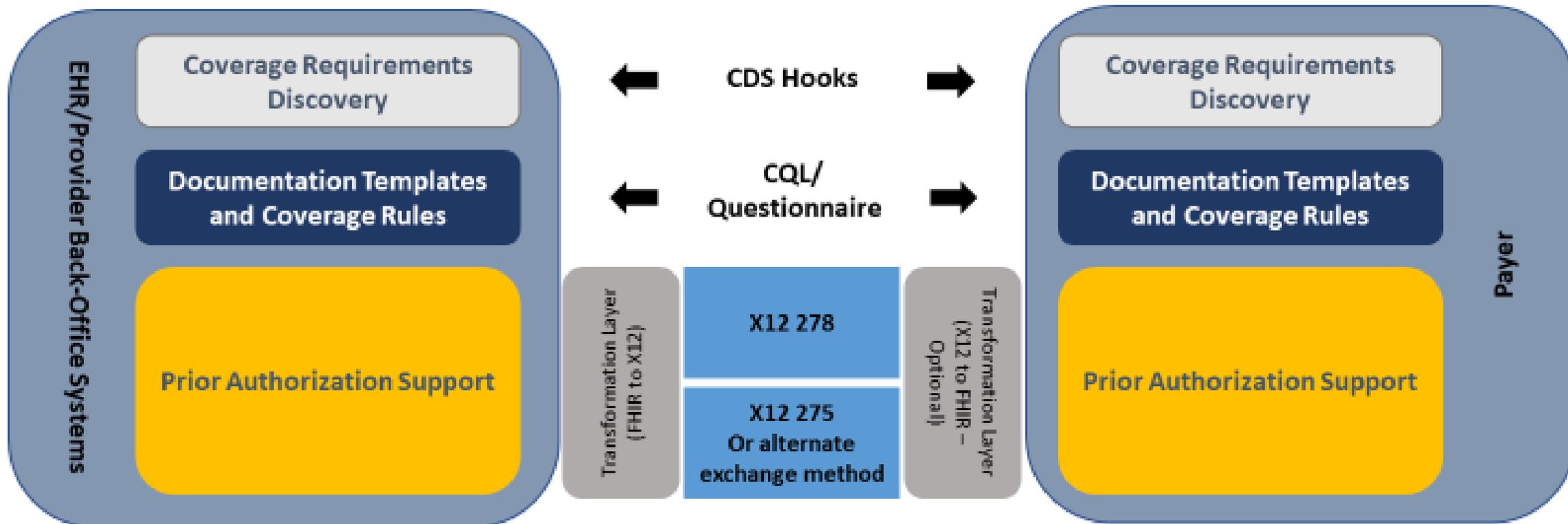


Adoption of Health IT Standards

- On behalf of HHS, the Office of the National Coordinator for Health IT (ONC) is proposing to adopt the implementation specifications described in this regulation at 45 CFR 170.215—Application Programming Interfaces—Standards and Implementation Specifications as standards and implementation specifications for health care operations. ONC is proposing these implementation specifications for adoption by HHS as part of a nationwide health information technology infrastructure that supports reducing burden and health care costs and improving patient care. By ONC proposing these implementation specifications in this way, CMS and ONC together work to ensure a unified approach to advancing standards in HHS that adopts all interoperability standards in a consistent manner, in one location, for HHS use. Proposing to adopt the specified implementation guides (IGs) to support implementation of the proposed APIs would ensure full interoperability of the APIs and reduce implementation burden.

Prior Authorization APIs

- Document Requirement Lookup Service (DRLS) API: We are proposing to require impacted payers build and maintain a FHIR-enabled DRLS API -- that could be integrated with a provider's electronic health record (EHR) -- to allow providers to electronically locate prior authorization requirements for each specific payer from within the provider's workflow.
- Prior Authorization Support (PAS) API: We are proposing to require impacted payers build and maintain a FHIR-enabled electronic Prior Authorization Support API that has the capability to send prior authorization requests and receive responses electronically within their existing workflow (while maintaining the integrity of the HIPAA transaction standards).



Improve Transparency

Reduce Effort for Prior Authorization

Leverage Available Clinical Content and Increase Automation

Prior Authorization Proposals



- Denial Reason: We are proposing to require impacted payers include a specific reason for a denial when denying a prior authorization request, regardless of the method used to send the prior authorization decision, to facilitate better communication and understanding between the provider and payer.
- Shorter Prior Authorization Timeframes: We are proposing to require impacted payers (not including QHP issuers on the FFEs) to send prior authorization decisions within 72 hours for urgent requests and 7 calendar days for standard requests.
- Prior Authorization Metrics: We are proposing to require impacted payers publicly report data about their prior authorization process, such as the percent of prior authorization requests approved, denied, and ultimately approved after appeal, and average time between submission and determination, to improve transparency into the prior authorization process, which will help patients understand.

RFIs

- Methods for Enabling Patients and Providers to Control Sharing of Health Information
- Electronic Exchange of Behavioral Health Information
- Reducing Burden and Improving Electronic Information Exchange of Documentation and Prior Authorization
- Reducing the Use of Fax Machines for Health Care Data Exchange
- Accelerating the Adoption of Standards Related to Social Risk Data

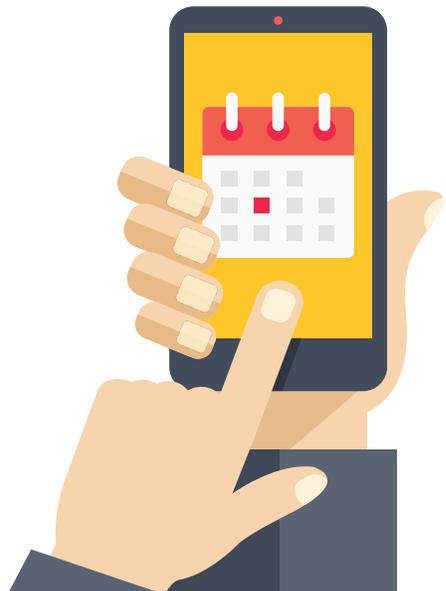


ONC API Specifications Proposed Rule

Steve Posnack, Deputy National Coordinator

ONC Proposal for Adoption of FHIR-Based API Implementation Specifications

- ONC has proposed to adopt implementation specifications on behalf of HHS under ONC's authority at PHSA sec 3004(b).
- These are proposed for adoption at 170.215(c), "Standards for Health Care Operations."
- ONC is not proposing new or revised certification criteria, nor are we proposing to require testing and certification to these implementation specifications
- The proposal to adopt the DaVinci FHIR IGs for Coverage Requirements Discovery, Documentation Templates and Rules, and Prior Authorization Support align with the ICAD Task Force report and recommendations approved in November 2020.



Specifications Proposed for Adoption at 170.215(c)

1. HL7 FHIR® Da Vinci - Coverage Requirements Discovery (CRD) Implementation Guide
2. HL7 FHIR® Da Vinci - Documentation Templates and Rules (DTR) Implementation Guide
3. HL7 FHIR® Da Vinci - Prior Authorization Support (PAS) Implementation Guide
4. HL7 FHIR® Da Vinci - Payer Coverage Decision Exchange (PCDE) Implementation Guide
5. HL7 FHIR® Common Payer Consumer Data Set (CPCDS) Implementation Guide
6. HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Implementation Guide
7. HL7 FHIR® Da Vinci - Payer Data Exchange (PDex) US Drug Formulary Implementation Guide
8. HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide