ELECTRONIC PRIOR AUTHORIZATION CAPABILITIES

NEW CERTIFICATION CRITERIA FOR HEALTH IT

The Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization (HTI-4) Final Rule has adopted new certification criteria to support more efficient management of electronic prior authorization tasks and reduce administrative burden for providers. This resource outlines the new electronic prior authorization requirements added to the ONC Health IT Certification Program (Certification Program) and considerations for developers seeking to certify to these new capabilities.

Background

Current prior authorization processes have caused significant burdens for patients and providers. A 2022 AMA survey highlighted care delays, treatment abandonment, and excessive time spent on prior authorizations. Furthermore, only 28% of prior authorization transactions were fully electronic in 2022.

In 2024, CMS issued the CMS Interoperability and Prior Authorization Final Rule, which required eligible payers to implement and maintain a Prior Authorization API to facilitate electronic prior authorization (ePA) processes. Furthermore, the rule added the Electronic Prior Authorization measures to the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, with measures included in reporting beginning in 2027.

Adopted Certification Criteria for API-Based Prior Authorization

Three new certification criteria, under 45 CFR 170.315(g)(31), (32), and (33), have been added to support electronic prior authorization. These new ePA criteria include standardized capabilities for provider systems in alignment with the Fast Healthcare Interoperability Resources (FHIR®) implementation specifications developed by the HL7® Da Vinci project.

Table 1: Provider Prior Authorization API Criteria

§ 170.315(g)(31) Provider Prior Authorization API – Coverage Requirements Discovery (CRD)	Enables a healthcare provider to request information from payers about coverage requirements.
§ 170.315(g)(32) Provider Prior Authorization API – Documentation Templates and Rules (DTR)	Provides a mechanism for clinicians and other EHR users to navigate and quickly assemble the information needed to support a prior authorization request according to a payer's requirements.
§ 170.315(g)(33) Provider Prior Authorization API – Prior Authorization Support (PAS)	Enables submission of prior authorization requests from health IT systems as well as checking the status of a previously submitted request.

These certification criteria are intended to support real-time access for providers to payer approval requirements, documentation, and rules at point of service, as well as enable providers to request and receive authorization. ASTP/ONC believes that technology certified to these capabilities will help automate and streamline prior authorization for healthcare providers and payers, enable more timely treatment decisions, avoid delays in care, and reduce administrative burden for providers and payers associated with processing required documentation.

Additionally, the HTI-4 Final Rule adopted two modular API criteria under 45 CFR 170.315(j)(20) and (21). These criteria include standardized capabilities to support real-time decision support in provider workflows and efficient notification of data updates, respectively, using the FHIR® standard. Furthermore, the capabilities included in these new criteria support the standardized ePA workflows defined in the § 170.315(g)(31) and (33) criteria. Health IT Modules may be certified to the § 170.315(j)(20) and (21) criteria individually or as part of certification to the § 170.315(g)(31) and (33) ePA criteria. Health IT Modules presented for certification to § 170.315(g)(31) and (33) will demonstrate conformance with and be certified to the § 170.315(j)(20) and (21) as part of certification to § 170.315(g)(31) and (33), respectively.

Table 2: Modular API Criteria

§ 170.315(j)(20) Workflow triggers for clinical decision support - clients	Referenced in § 170.315(g)(31) Provider Prior Authorization API – Coverage Requirements Discovery
§ 170.315(j)(21) Subscriptions – client	Referenced in § 170.315(g)(33) Provider Prior Authorization API – Prior Authorization Support

Referenced Standards

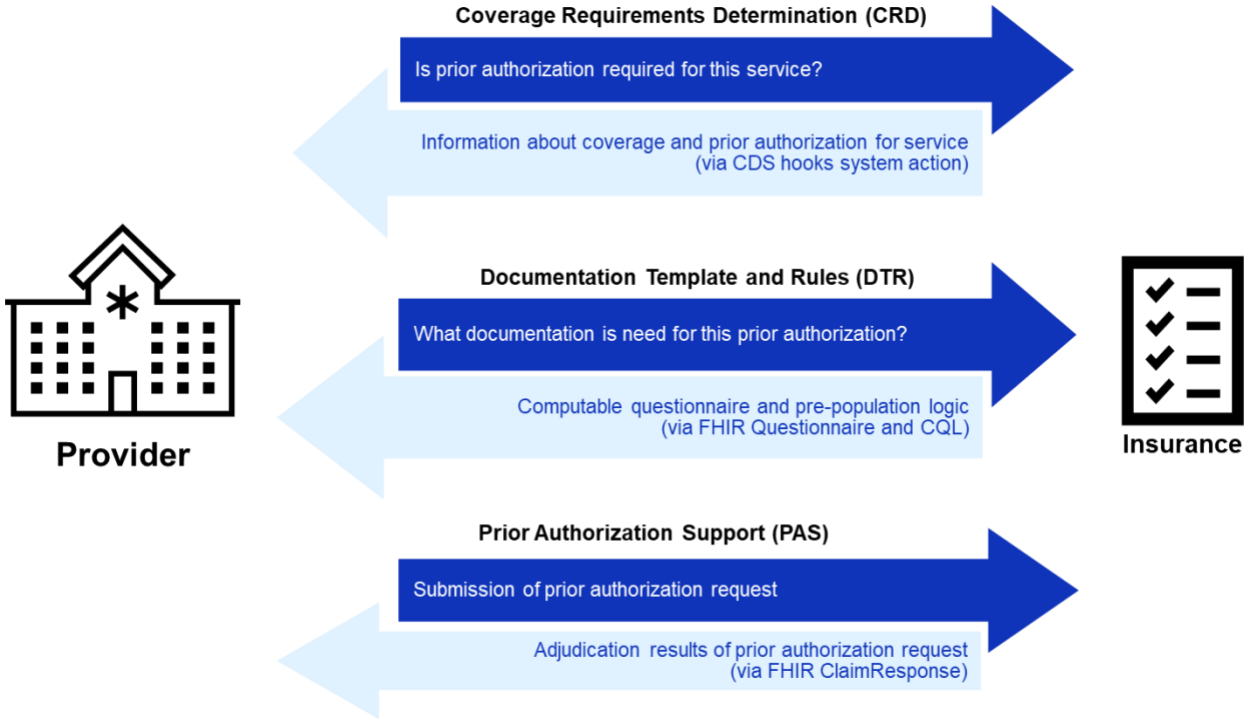
Several implementation specifications are referenced in the new ePA criteria, specifically implementation guides (IGs) developed by the HL7® Da Vinci Project as part of their burden reduction efforts.

Table 3: Standards Referenced in the Provider Prior Authorization API Criteria

(g)(31)	HL7 FHIR® Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide, Version 2.1.0—STU 2.1
(g)(32)	HL7 FHIR® Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide, Version 2.1.0—STU 2.1
(g)(33)	HL7 FHIR® Da Vinci—Prior Authorization Support (PAS) Implementation Guide, Version 2.1.0—STU 2.1

The three ePA criteria adopted in the final rule were designed as separate criteria to allow for customized and modular certification of health IT. Developers can certify to the ePA criteria applicable to their specific product capabilities. Used together, these three criteria and their corresponding specifications support a comprehensive workflow for conducting electronic prior authorization transactions and build on HL7 FHIR® Release 4, Version 4.0.1: R4.

Figure 1: How the HL7 FHIR® Da Vinci Burden Reduction implementation guides support electronic prior authorization.



In addition to these FHIR specifications, the modular API capabilities outlined in the (j) criteria reference the following standards.

Table 4: Standards Referenced in the Modular API Criteria

(j)(20)	HL7® CDS Hooks Implementation Guide, Version 2.0.1—STU 2 Release 2
(j)(21)	HL7 FHIR® Subscriptions R5 Backport Implementation Guide, Version 1.1.0—Standard for Trial Use

The new ePA criteria and modular API criteria have been added as eligible for the Real World Testing Condition of Certification requirements, allowing them to be considered in the Standards Version Advancement Process (SVAP). This will give developers the opportunity to adopt newer approved versions of these FHIR® IGs as they become available, ensuring systems can further refine their systems for ePA capabilities.

Conditions and Maintenance of Certification Requirements

§ 170.315(g)(31)-(33) ePA criteria have been added as applicable criteria throughout the API Condition and Maintenance of Certification requirements outlined in § 170.404. Additionally, the definition of Certified API technology has been updated to include reference to these new criteria. This means that any developer that chooses to certify to these new ePA criteria must comply with the API Condition and Maintenance of Certification requirements.

Technical Documentation

Developers certifying to § 170.315(g)(31) and (g)(33) specifically have additional expectations related to the publication of accompanying technical documentation, as defined in the criteria regulation text. These criteria describe the requirements of such technical documentation that must be published as part of the Certified API Developer's complete business and technical documentation.

For the purposes of these documentation requirements, complete accompanying technical documentation includes as applicable:

1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns;
2) the software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s); and
3) all applicable technical requirements and attributes necessary for an application to be registered with a Health IT Module's authorization server.

Authenticity Verification and Registration

The HTI-4 Final Rule finalized authenticity verification and registration requirements for § 170.315(g)(31) and (g)(33) specifically within the API Maintenance of Certification requirements at § 170.404(b)(1). Note that the requirements at § 170.404(b)(1) are not applicable to health IT certified to § 170.315(g)(32).

Implementation Timelines

There are currently no requirements for developers to implement these criteria within their Health IT Modules. However, developers with clients participating in the CMS Promoting Interoperability programs may want to review CMS requirements for certified health IT to support future electronic prior authorization measures added in the CMS Interoperability and Prior Authorization Final Rule in 2024. **Providers will be required to report on an electronic prior authorization measure beginning in 2027.**