ASTP/ONC's Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization (HTI-4) Final Rule implements new and revised standards and certification criteria in the ONC Health IT Certification Program. These revisions include criteria and standards that support electronic prior authorization, electronic prescribing, and real-time prescription benefit information. The HTI-4 final rule also includes several related criteria for application programming interface (API) functionality. HTI-4 is published as part of the FY2026 CMS Hospital Inpatient Prospective Payment System (IPPS) final rule (CMS-1833-F). Please see the HTI-4 Final Rule Fact Sheet for a high-level summary of the below information. The HTI-4 Final Rule is effective October 1, 2025.

ELECTRONIC PRESCRIBING AND PRESCRIPTION BENEFITS

The HTI-4 Final Rule finalized updates related to prescription capabilities in Health IT Modules that improve coordination and electronic information exchange among prescribers, pharmacies, intermediaries, and payers. These changes update the requirements in the § 170.315(b)(3) Electronic prescribing criterion and introduce a new § 170.315(b)(4) Real-time prescription benefit (RTPB) criterion. Together, these program updates aim to streamline medication workflows, reduce prior authorization burden, and support timely, transparent prescribing decisions.

Updated Criteria

§ 170.315(b)(3) Electronic Prescribing

The HTI-4 Final Rule updates the § 170.315(b)(3) Electronic prescribing certification criterion to adopt the NCPDP SCRIPT Version 2023011 and updated RxNorm and National Drug Code (NDC) minimum standard code sets. Health IT developers certified to § 170.315(b)(3) must update their certified Health IT Modules to support these standards **by December 31, 2027**.

These updates align with requirements for Medicare Part D plan sponsors, promoting consistency across prescribing systems and enhancing interoperability.

Additionally, developers certified to § 170.315(b)(3) must also certify to the § 170.315(b)(4) Real-Time Prescription Benefit criterion, as specified in § 170.550(g)(6).

Removal of Optional Transactions

The HTI-4 Final Rule removes the following transactions at § 170.315(b)(3)(ii)(B)(1) - (8), where they were previously identified as optional:

- Create and respond to new prescriptions (NewRxRequest, NewRxResponseDenied).
- Send fill status notifications (RxFillIndicator).
- Ask the Mailbox if there are any transactions (GetMessage).
- Request to send an additional supply of medication (Resupply).
- Communicate drug administration events (DrugAdministration).
- Request and respond to transfer one or more prescriptions between pharmacies (RxTransferRequest, RxTransferResponse, RxTransferConfirm).

- Recertify the continued administration of a medication order (Recertification).
- Complete Risk Evaluation and Mitigation Strategy (REMS) transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse).

These transactions are no longer part of the certification program as of the **October 1, 2025,** effective date.

Newly Required Transactions

The HTI-4 Final Rule finalizes the requirement to remove the optional electronic prior authorization transactions previously under 45 CFR 170.315(b)(3)(ii)(B)(9) and require the following electronic prior authorization transactions under 45 CFR 170.315(b)(3)(ii)(A)(*3*)(*x*):

- PAInitiationRequest
- PAInitiationResponse
- PARequest
- PAResponse
- PAAppealRequest
- PAAppealResponse
- PACancelRequest
- PACancelResponse
- PANotification

These requirements apply when a Health IT Module is presented for certification using the standard adopted at § 170.205(b)(2), which incorporates NCPDP SCRIPT Version 2023011.

New Criteria

§ 170.315(b)(4) Real-Time Prescription Benefit (RTPB)

The HTI-4 final rule adopts a new § 170.315(b)(4) RTPB certification criterion to enable access to prescription drug information that providers and their patients can use to compare the cost of a drug of a suitable alternative. The certification criterion is based on the NCPDP Real-Time Prescription Benefit standard version 13 and references the RxNorm and NDC minimum data code sets also referenced in § 170.315(b)(3). Any Health IT Module presented for certification to the § 170.315(b)(3) Electronic prescribing criterion must also be certified to the "real-time prescription benefit" criterion

Base EHR Definition Update

ASTP/ONC has updated the Base EHR definition, to include certification to the § 170.315(b)(4) RTPB criterion **on and after January 1, 2028**.

KEY DATES:

- Optional transactions are no longer available for certification in the § 170.315(b)(3) Electronic prescribing criterion as **of October 1, 2025**.
- Developers certifying a Health IT Module to the § 170.315(b)(3) Electronic prescribing criterion may use either the NCPDP SCRIPT Version 2017071 or 2023011 during a transition period ending **December 31, 2027**.
- After **January 1, 2028**, Certified Health IT developers certifying a Health IT Module to the § 170.315(b)(3) Electronic prescribing criterion may only be certified to the updated version of the criterion using NCPDP SCRIPT standard version 2023011.
- After **January 1, 2028,** Certified Health IT Modules certified to the § 170.315(b)(3) Electronic prescribing criterion must also complete certification to the § 170.315(b)(4) RTPB criterion.

ELECTRONIC PRIOR AUTHORIZATION

The HTI-4 Final Rule adopts three new certification criteria to support more efficient management of electronic prior authorization tasks and reduce administrative burden for providers. Using health IT certified to these criteria will enable providers to interact with the Prior Authorization API requirements CMS established for impacted payers in the 2024 CMS Interoperability and Prior Authorization Final Rule. These criteria will also support healthcare providers participating in the Medicare Promoting Interoperability program and the MIPS Promoting Interoperability performance category – who will be required to report on an electronic prior authorization measure beginning in 2027.

§ 170.315(g)(31) Provider Prior Authorization API – Coverage Requirements Discovery

This new criterion enables a healthcare provider to request information from payers about coverage requirements. This criterion references the following standard:

- HL7 FHIR® Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide, Version 2.0.1 – STU 2

This criterion also requires, through cross-reference, support for the § 170.315(j)(20) "workflow triggers for decision support interventions — clients" criterion. Developers seeking certification to § 170.315(g)(31) will also demonstrate conformance with and certify to § 170.315(j)(20) as part of certification.

§ 170.315(g)(32) Provider Prior Authorization API – Documentation Templates and Rules

This new criterion 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. This criterion references the following standards:

- HL7 FHIR® Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide, Version 2.0.1 – STU 2
- HL7 FHIR® IG: SMART Application Launch Framework

§ 170.315(g)(33) Provider Prior Authorization API – Prior Authorization Support

This new criterion enables submission of prior authorization requests from health IT systems as well as checking the status of a previously submitted request. This criterion references the following standards:

- HL7 FHIR® Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide, Version 2.0.1 – STU 2
- HL7 FHIR® IG SMART Application Launch Framework

This criterion also requires, through cross-reference, support for the § 170.315(j)(21) Subscriptions — client criterion. Developers seeking certification to § 170.315(g)(31) will also demonstrate conformance with and certify to § 170.315(j)(21) as part of certification.

NEW MODULAR API CRITERIA

The HTI-4 Final Rule adopts two additional health IT certification criteria (and related standards) for API functionality that are referenced in the criteria for electronic prior authorization included in the HTI-4 Final Rule. These criteria are modular to support various health IT product needs and support the new API criteria outlined in § 170.315(g)(31) and (33).

§ 170.315(j)(20) Workflow Triggers for Decision Support Interventions — Clients

This criterion enables clinical decision support tasks through an API, allowing decision support results to be integrated into a provider's EHR workflow. This criterion references the following standard:

- HL7 FHIR® CDS Hooks Implementation Guide, Version 2.0.1—STU 2 Release 2

§ 170.315(j)(21) Subscriptions — Client

This criterion enables a user or system to be notified by a server of a particular event or data update of interest. This criterion references the following standard:

- HL7 FHIR® Subscriptions R5 Backport Implementation Guide, Version 1.1.0—Standard for Trial Use

CONDITIONS AND MAINTENANCE OF CERTIFICATION

API Condition and Maintenance of Certification Eligible Criteria Updates

ASTP/ONC adopted new API-related certification criteria at § 170.315(g)(31-33), which 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 criteria must comply with the API Condition and Maintenance of Certification requirements.

Real World Testing Eligible Criteria Updates

ASTP/ONC adopted the § 170.315(b)(4) RTPB criterion, and adds the RTPB criterion to the list of eligible criteria for which a Certified Health IT developer must complete Real World Testing. Additionally, the Real World Testing Condition of Certification requirement has been updated to add new criteria listed under § 170.315(g)(31-33), and (j)(20-21) to support Real World Testing for new API criteria. For example, Health IT Modules certified to any of these criteria prior to August 31, 2026, would be required to conduct Real World Testing on those criteria for the calendar year 2027 and submit results based on that testing in March 2028.

Inclusion in Real World Testing allows these new criteria to be considered for future SVAP updates, allowing ASTP/ONC to assess the application of new versions of their regulatory standards for voluntary adoption in the Certification Program.

KEY DATES:
These updates to the API and Real-World Testing criteria are effective as of **October 1, 2025**, but will only apply to Health IT Modules once they certify to the applicable criteria.

ADDITIONAL INFORMATION

Additional details on the certification criteria, including Certification Companion Guides (CCGs), Test Procedures, Test Tools, and Test Data, are available through the ONC Health IT Certification Program Test Method webpage. This resource outlines the structure for evaluating conformance to certification criteria and supports developers and testing labs in preparing for certification.