

Health Data, Technology, and Interoperability (HTI-4) Final Rule

Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization



Disclaimers

- The materials contained in this presentation are based on the finalized proposals in the "Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization" (HTI-4) final rule. While every effort has been made to ensure the accuracy of this restatement of those finalized proposals, this presentation is not a legal document. The official rules are contained in the final rule.
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AGENDA

- Brief Review: Purpose of HTI-4 Final Rule
- Electronic Prescribing
- Real-Time Prescription Benefits
- Electronic Prior Authorization
- Modular API Criteria
- Patient, Provider, and Payer APIs Implementation Specifications
- Minimum Standards Code Sets Updates

HTI-4 Final Rule

Published as part of the FY 2026 Hospital Inpatient Prospective Payment System (IPPS) Final Rule (CMS-1833-F)

Date: August 4, 2025

URL: https://www.federalregister.gov/documents/2025/08/04/2025-14681/medicare-program-hospital-inpatient-prospective-payment-systems-for-acute-care-hospitals-ipps-and







Health Data, Technology, and Interoperability (HTI-2) Proposed Rule (August 5, 2024)

Proposed a wide-ranging set of updates to the ONC Health IT Certification Program, including:



- Minimum standards code set updates
- Electronic prescribing and public health exchange
- Electronic prior authorization
- United States Core Data for Interoperability (USCDI) v4
- Exceptions related to information blocking
- Provisions of the Trusted Exchange Framework and Common Agreement (TEFCA)

Proposed to expand standards and certification for:



- Real-time benefit tools
- Modular and foundational API capabilities
- Access to billing and payment transactions
- Implementing the 21st Century Cures Act Real-Time Prescription Benefits



What does the HTI-4 Final Rule do?

- Finalizes a limited subset of the proposals from the <u>HTI-2 proposed rule</u>:
 - Electronic prescribing
 - Real-time prescription benefit
 - Electronic prior authorization
- ➤ These updates intersect with and support CMS policy initiatives.
- ➤ Published as part of the FY 2026 Hospital Inpatient Prospective Payment System (IPPS) Final Rule (CMS-1833-F)

What is the purpose of the HTI-4 Final Rule?

- > Support HHS efforts to reduce administrative burdens for clinicians
- > Improve patients' ability to receive timely, affordable, and evidence-based care
- > Facilitate exchange of electronic health information across the care continuum

Electronic Prescribing







Electronic Prescribing

BENEFITS

- The "electronic prescribing" criterion supports the availability of certified health IT to enable the exchange of prescription information among prescribers, pharmacies, intermediaries, and payers.
 - With electronic prescribing, health care providers can securely transmit prescription information to pharmacies.
 When a pharmacy receives a request, it can begin filling the medication right away.
- New NCPDP SCRIPT standard version 2023011 has new benefits and enhancements to the existing standard
 - Improved extensibility & organization that will support more granular and logical structuring of product and drug information, supporting advanced clinical decision support and analytics.
 - Enhanced support for electronic prior authorization and medication history, supporting faster, more accurate, and transparent prescription workflows.
- Aligns with recent updates to the Medicare Part D program.



Electronic Prescribing

PROVISION

- ASTP/ONC finalized updates to the "electronic prescribing" criterion in 45 CFR 170.315(b)(3) to incorporate an updated version of the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2023011.
- Developers certifying a Health IT Module to 45 CFR 170.315(b)(3) may use either the NCPDP SCRIPT standard version 2023011 or the NCPDP SCRIPT standard version 2017071 up to and including December 31, 2027.
- After January 1, 2028, Health IT Modules certified to the "electronic prescribing" criterion must be updated to the Health IT Module to the NCPDP SCRIPT standard version 2023011.
- ASTP/ONC also finalized a requirement to support previously optional electronic prior authorization transactions when using the NCPDP SCRIPT standard version 2023011.
- ASTP/ONC also removed transactions currently identified as optional for the certification criterion, simplifying Program requirements and focusing on priority functionalities.

Real-Time Prescription Benefit







Real-Time Prescription Benefit

BENEFITS

- Real-time benefit tools empower providers and their patients to address affordability issues at the time
 that a product is prescribed, by comparing the patient-specific cost of a product to the cost of a suitable
 alternative and comparing prescription costs at different pharmacies.
- Will improve the ability of pharmacy benefit managers to provide cost and coverage information in a format that all EHRs certified to the criterion will be able to consume, reducing their need to implement specific, proprietary APIs for different health IT vendors.
- Research has shown that patients and clinicians want this information and that access to real-time prescription benefit may increase medication adherence and reduce out-of-pocket costs.
- Aligns with requirements for real-time benefit tools established by Medicare Part D plans to adhere to the NCPDP standard version 13.



Real-Time Prescription Benefit

PROVISION

- ASTP/ONC finalized a new "real-time prescription benefit" certification criterion in 45 CFR 170.315(b)(4).
- Supports certified health IT which allows clinicians to access patient-specific out-of-pocket costs and coverage information for the prescription drugs, vaccines, and Medicare Part D-covered medical supplies that they order.
- Implements Section 119(b)(3) of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260).
- Incorporates the NCPDP Real-Time Prescription Benefit (RTPB) standard version 13.
- Will be included in the Base EHR definition after January 1, 2028.
- Any Health IT Module presented for certification to the "electronic prescribing" criterion must also be certified to the "real-time prescription benefit" criterion.

Electronic Prior Authorization







Electronic Prior Authorization

BENEFITS

- Supports HHS agency-wide approach to electronic prior authorization that meets the Department's interoperability and burden reduction goals.
- Addresses processes that have contributed significantly to patient and provider burden, for instance, delays experienced by patients and clinicians as they seek to satisfy the requirements associated with prior authorization rules set by payers.
- Multiple criteria support certification flexibility for developers wishing to support only a part of electronic prior authorization technology stack.
- Use of technology meeting the certification criteria for electronic prior authorization will help to enable exchange of information that promotes a more effective marketplace, increases competition, and provides benefits to patients.



Electronic Prior Authorization

PROVISION

- ASTP/ONC adopted three new certification criteria in 45 CFR 170.315(g)(31) (33) to support more
 efficient management of electronic prior authorization tasks and reduce administrative burden for
 providers.
- These criteria are based on Fast Healthcare Interoperability Resources (FHIR®)
 implementation specifications developed by the HL7® Da Vinci project
 - Provider Prior Authorization API Coverage Requirements Discovery: Defines a workflow to allow health care providers to request information from payers about coverage requirements.
 - Provider Prior Authorization API Documentation Templates and Rules: 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.
 - Provider Prior Authorization API Prior Authorization Support: enables direct submission of prior authorization requests from health IT systems using FHIR, as well as supporting follow-up tasks such as checking the status of a previously submitted request.



Intersection with CMS Initiatives on Electronic Prior Authorization

2024 CMS Interoperability and Prior Authorization Final Rule

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.

Medicare Promoting Interoperability
Program and the MIPS Promoting
Interoperability performance category

Health IT certified to these criteria will 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.



Modular API Criteria







Modular API Criteria

PROVISION

ASTP/ONC finalized two supporting certification criteria (and two FHIR specifications) referenced by other criteria for electronic prior authorization included in HTI-4.

- 45 CFR 170.315(j)(20) Workflow Triggers for Decision Support Interventions Clients
- 45 CFR 170.315(j)(21) Subscriptions Client

BENEFITS

- These criteria establish minimum requirements to support CDS Hooks and Subscriptions FHIR capabilities for prior authorization, though these capabilities may be applicable to many other use cases
- CDS Hooks provides a framework for fast decision support in provider workflows (e.g., payer coverage at order sign).
- Subscriptions enable a user to be proactively notified of an event or data update of interest.



Patient, Provider, and Payer API Implementation Specifications







Adoption of Standards for Patient, Provider, and Payer APIs

- ASTP/ONC finalized a series of implementation specifications related to the exchange of clinical and administrative data with payers as well as the sharing of formulary and provider directory information.
- In addition to the three specifications supporting the criteria finalized for electronic prior authorization, ASTP/ONC adopted other specifications recommended by CMS for use by payers implementing the APIs established in the Interoperability and Patient Access and the Interoperability and Prior Authorization Final Rules.
- Only the prior authorization IGs are referenced in certification criteria at this time.

- HL7 FHIR® Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide, Version 2.0.1—STU 2
- HL7 FHIR® Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide, Version 2.0.1—STU 2
- HL7 FHIR® Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide, Version 2.0.1—STU 2
- HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide, Version 2.0.0—STU 2 US
- HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Implementation Guide, Version 2.1.0—STU 2.1
- HL7 FHIR® Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.0.1—STU 2
- HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide, Version 1.1.0—STU 1.1 US

Minimum Standards Code Set Updates







Minimum Standards Code Set Updates

PROVISION

ASTP/ONC finalized a proposal to adopt an updated baseline version of RxNorm.

Consistent with 45 CFR 170.555, health IT developers may use newer versions of the adopted baseline version of a standard identified as a minimum standard on a voluntary basis.

BENEFITS

• RxNorm is referenced in the "electronic prescribing" and "real-time prescription benefit" health IT certification criteria. Use of the updated version of RxNorm will ensure accurate transfer of information between Pharmacy Benefit Managers (PBM), electronic health records (EHR), and pharmacies.

Questions?







Resources Available on HealthIT.gov!

RESOURCES AVAILABLE

Visit https://healthIT.gov/HTI4 for more information.

- → HTI-4 Final Rule Blog
- → HTI-4 Final Rule Fact Sheet
- → URL to view the Final Rule at the Federal Register



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