



# **Health Data, Technology, and Interoperability (HTI-2) Proposed Rule**

Patient Engagement, Information Sharing, and  
Public Health Interoperability Proposed Rule

**August 15, 2024**

# Disclaimers and Public Comment Guidance

- The materials contained in this presentation are based on the proposals in the “Health Data, Technology, and Interoperability (HTI-2): Patient Engagement, Information Sharing, and Public Health Interoperability” proposed rule. While every effort has been made to ensure the accuracy of this restatement of those proposals, this presentation is not a legal document. The official proposals are contained in the proposed rule.
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## AGENDA

- Purpose of HTI-2 Proposed Rule
- Patient, Provider, and Payer APIs

# Purpose of HTI-2 Proposed Rule



## Implementing the 21<sup>st</sup> Century Cures Act

- APIs that allow EHI to be accessed, exchanged, and used without special effort
- Reasonable and necessary activities that do not constitute information blocking
- Establish the qualifications necessary for an entity to receive and maintain designation as a QHIN capable of trusted exchange pursuant to TEFCA



## Achieving the Goals of the Biden-Harris Administration Executive Orders

- E.O. 13994 “Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats”
- E.O. 13985 “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” and E.O. 14091 “Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government”
- E.O. 14036 “Promoting Competition in the American Economy”
- E.O. 14058 “Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government”



## Leveraging Health IT and Advancing Interoperability

- HITECH Act
- Interoperability Advancement
- ONC Health IT Certification Program

# What Are We Proposing to Do?

- Advance health IT infrastructure nationwide
- Minimize data silos so health IT users can access information from various settings
- Emphasize technology solutions that are easier to adopt, particularly in settings with limited resources
- Enhance interoperability across health care and public health
- Advance equity
- Support patients' access to lawful reproductive health care, and
- Strengthen support for actors honoring patients' individual privacy preferences



# Patient, Provider, and Payer APIs

# Patient, Provider, and Payer API Capabilities

- In the HTI-2 NPRM, ONC proposes certification criteria in § 170.315(g)(30) through (36) to support the availability of health IT that can enable payers and health care providers to meet requirements established by CMS in recent Interoperability rulemakings.
- The proposed criteria would enable implementers to ensure that APIs developed to meet the CMS regulations adhere to relevant interoperability standards and support other features important to effective information sharing.
- In general, use of technology meeting these certification criteria would help to enable exchange of information that promotes a more effective marketplace, increases competition, and provides benefits to patients such as increased consumer choice and better care coordination.
- The certification of any Health IT Module by a health IT developer is voluntary. The proposals in this proposed rule would not establish requirements for health IT beyond those Health IT Modules submitted for certification for these criteria under the Program, nor does the availability of these certification criteria require any individual or entity to use certified health IT, including payers subject to the CMS requirements.

# Background on CMS Interoperability Rulemaking

- CMS Interoperability and Patient Access Final Rule (May 2020)
  - Patient Access API
  - Provider Directory API
- CMS Interoperability and Prior Authorization Final Rule (January 2024)
  - Provider Access API
  - Payer-to-Payer API
  - Prior Authorization API
- CMS requires impacted payers to use certain standards and implementation guides which ONC has adopted in § 170.215, as well as the USCDI standard in § 170.213.
- CMS also recommended a number of implementation guides that may be used to support effective implementation of the required payer APIs.



# Standards to Support Patient, Provider, and Payer APIs

- The proposed certification criteria in HTI-2 reference a set of FHIR implementation specifications that ONC has adopted, or proposes to adopt, on behalf of the Secretary. These implementation specifications align with the required and recommended specifications identified in CMS' finalized policies for payer API requirements.
- ONC proposes to adopt current versions of the IGs that CMS recommended in the CMS Interoperability and Prior Authorization Final Rule and proposes to require these IGs as part of the certification criteria proposed in § 170.315(g)(30) - (36).
- These specifications are based upon HL7® FHIR® R4. Many of these proposed implementation specifications were developed by the HL7® Da Vinci Project.
- If these IGs are finalized, ONC will review future versions of these standards under the Standards Version Advancement Process (SVAP) to enable voluntary use in the Program as updated versions become available.
- The proposed certification criteria also incorporate certification criteria for modular API capabilities proposed in § 170.315(j) of HTI-2, including capabilities for registration (§ 170.315(j)(1)-(2)), authentication and authorization (§ 170.315(j)(5)-(7)), workflow triggers for decision support interventions (§ 170.315(j)(20)-(21)), and subscriptions (§ 170.315(j)(23)-(24)).

# Patient Access API §170.315(g)(30)

## PROPOSAL

ONC proposes to adopt the “Patient access API” certification criterion in § 170.315(g)(30) to specify requirements for health IT that can be used by payers to enable patients to access health and administrative information using a health application of their choice, including payer drug formulary information, and patient clinical, coverage, and claims information.

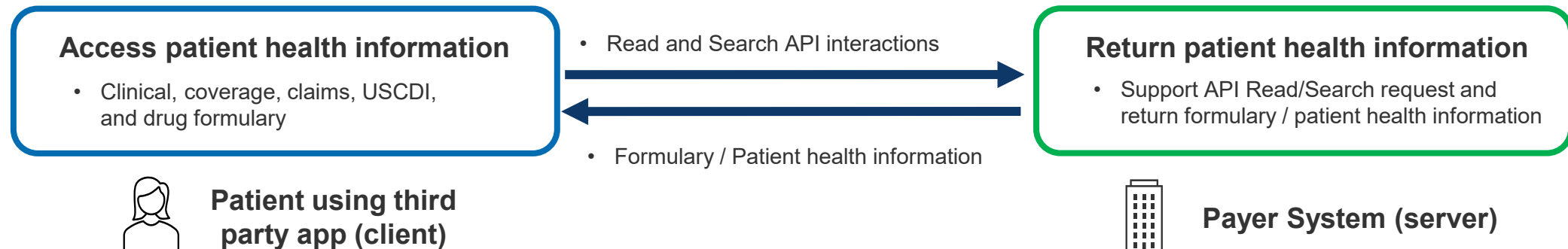
The proposed criterion references standards including CARIN Blue Button IG, Da Vinci PDex IG, Da Vinci US Drug Formulary IG, and the US Core IG.

## BENEFITS

- Access to data held by payers can increase patient understanding of their health and health care, helping patients to be more informed when making decisions about their care.
- Aligns with CMS requirements for payers to establish Patient Access APIs originally finalized in CMS’ Interoperability and Patient Access final rule.

# Patient Access API §170.315(g)(30)

- **Registration**
  - Functional registration
  - Dynamic registration according to UDAP
- **Authentication and authorization: Patient access**
  - Authentication and authorization for patient access according to SMART App Launch
  - Asymmetric certificate-based authentication for patient access according to UDAP
- **Content**
  - Drug formulary API
  - Clinical and coverage information by supporting Resources in "PDEX Server CapabilityStatement"
  - Claims information by supporting Resources in CARIN IG for Blue Button "C4BB CapabilityStatement"
  - USCDI and US Core IG Profiles according to the "US Core Server CapabilityStatement"



# Provider Access API “client” and “server” §170.315(g)(31)/(32)

## PROPOSAL

ONC proposes to adopt the “Provider access API – client” and “Provider access API – server” certification criteria at § 170.315(g)(31) and (g)(32) to specify requirements for provider and payer systems to support provider access to payer information. This information can include patient clinical, coverage, and claims information.

The proposed criterion references standards including CARIN Blue Button IG, Da Vinci PDex IG, and US Core IG.

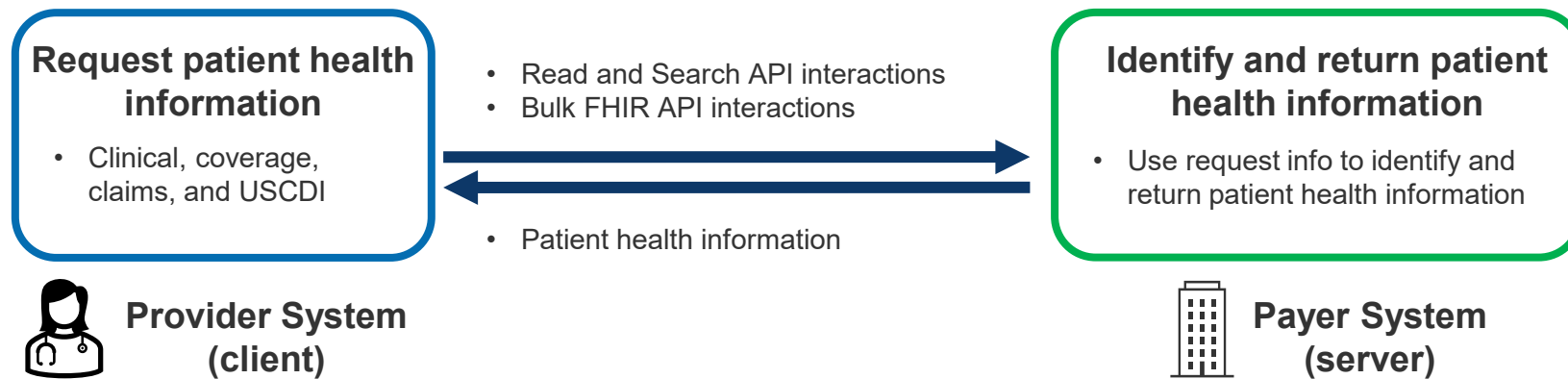
ONC proposes to include the “Provider access API – client” in the Base EHR definition.

## BENEFITS

- Provider access to data held by payers about their patients can help inform better care coordination as well as higher quality care and can support provider participation in value-based care.
- Aligns with CMS requirements for payers to establish a Provider Access API finalized in CMS’ Interoperability and Prior Authorization final rule.

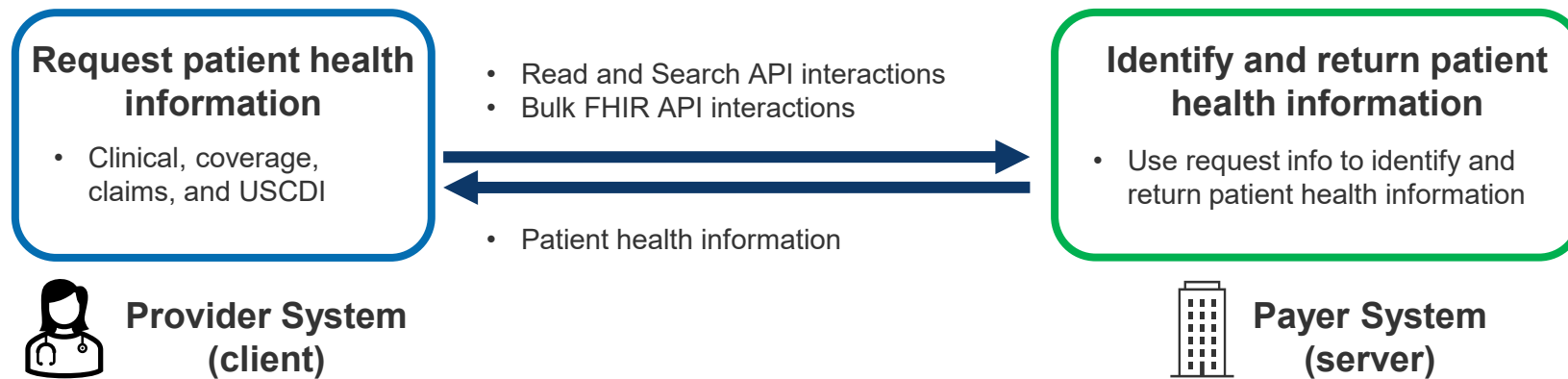
# Provider Access API “client” and “server” §170.315(g)(31)/(32)

- Support ability to request, lookup, and return patient history according to PDEX FHIR IG
- **API interactions**
  - Read and Search API
  - Bulk FHIR API
- **Content**
  - Clinical and coverage information by supporting Resources in "PDEX Server CapabilityStatement"
  - Claims information by supporting Resources in CARIN IG for Blue Button "C4BB CapabilityStatement"
  - USCDI and US Core IG Profiles according to the "US Core Server CapabilityStatement"



# Provider Access API “server” §170.315(g)(32) - Security

- **Registration**
  - Functional registration
  - Dynamic registration according to UDAP
- **Authentication and authorization: User access**
  - Authentication and authorization for user access according to SMART App Launch
  - Asymmetric certificate-based authentication for B2B user access according to UDAP
- **Authentication and authorization: System access**
  - SMART Backend Services system authentication and authorization according to SMART App Launch
  - Asymmetric certificate-based system authentication and authorization according to UDAP



# Payer-to-Payer API §170.315(g)(33)

## PROPOSAL

ONC proposes to adopt a “Payer-to-payer API” certification criterion in § 170.315(g)(33) to specify requirements for health IT that can be used by payers to support electronic exchange between payer systems.

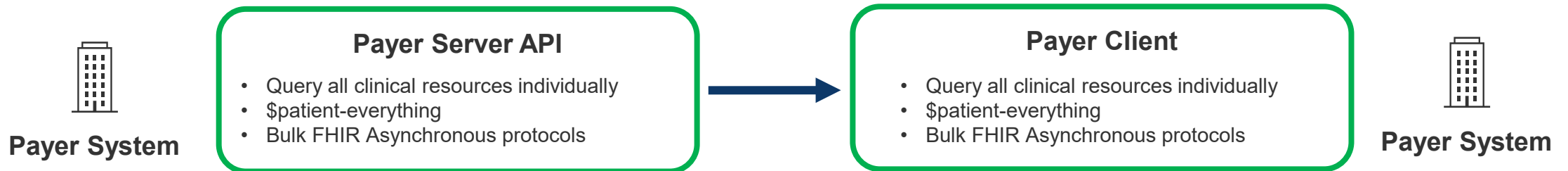
The proposed criterion references standards including CARIN Blue Button IG, Da Vinci PDex IG, and US Core IG.

## BENEFITS

- The exchange of patient information between payers can allow health information to follow a patient when they switch insurance plans and can enable improved coordination of care, increased patient empowerment, and reduced administrative burden.
- Aligns with CMS requirements for payers to establish Payer-to-Payer Access APIs originally finalized in CMS’ Interoperability and Patient Access and final rule and updated in the Interoperability and Prior Authorization final rule.

# Payer-to-Payer API §170.315(g)(33)

- **Registration**
  - Functional registration
  - Dynamic registration according to UDAP
- **Authentication and authorization: System access**
  - SMART Backend Services system authentication and authorization according to SMART App Launch
  - Asymmetric certificate-based system authentication and authorization according to UDAP
- **Information access**
  - PDEX FHIR IG support for: Query all clinical resource individually, \$patient-everything, Bulk FHIR Asynchronous protocols
  - Clinical and coverage information by supporting Resources in "PDEX Server CapabilityStatement"
  - Claims information by supporting Resources in CARIN IG for Blue Button "C4BB CapabilityStatement"
  - USCDI and US Core IG Profiles according to the "US Core Server CapabilityStatement"





# Prior Authorization API “provider” and “payer” §170.315(g)(34)/(35)

## PROPOSAL

ONC proposes to adopt “Prior authorization API – provider” and “Prior authorization API – payer” certification criteria in § 170.315(g)(34) and (g)(35).

The proposed provider certification criterion specifies requirements for providers to request coverage requirements and assemble and submit documentation for prior authorization, while the payer criterion supports payers’ ability to provide information about coverage and documentation requirements and receive prior authorization requests from providers.

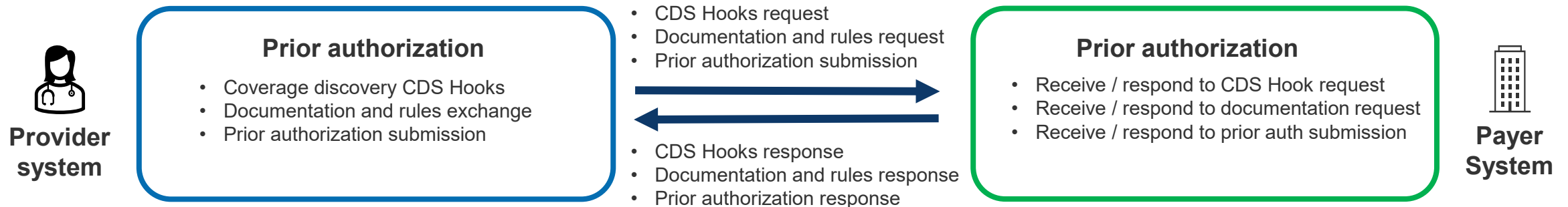
The proposed criterion references standards including Da Vinci Coverage Requirements Discovery IG, Da Vinci Documentation Templates and Rules IG, and Da Vinci Prior Authorization Support IG.

## BENEFITS

- These criteria have the potential to reduce administrative burden associated with prior authorization process. By streamlining the electronic prior authorization process, patients can receive more rapid information about whether treatments are approved.
- Criteria align with CMS requirements for payers to establish Prior Authorization APIs, and with requirements for participants in the Promoting Interoperability programs to report on new Prior Authorization measures, both finalized in CMS’ Interoperability and Prior Authorization final rule.

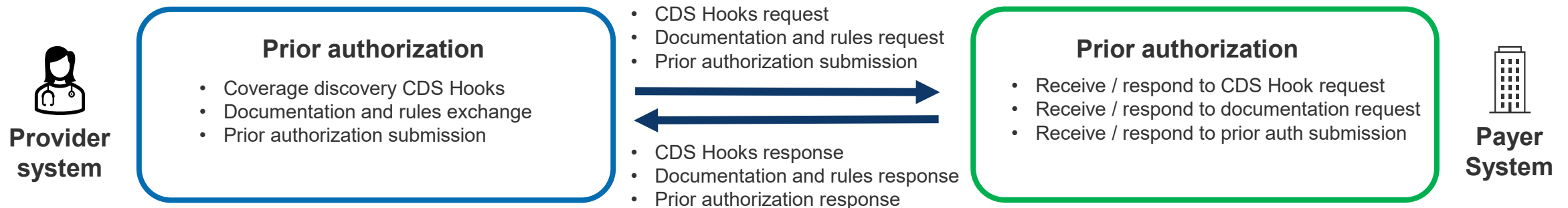
# Prior Authorization API “provider” §170.315(g)(34)

- **Coverage discovery**
  - Support “appointment-book”, “encounter-start”, “encounter-discharge”, “order-dispatch”, “order-select,” and “order-sign” CDS Hooks
- **Documentation and rules exchange**
  - Full DTR EHR: “Full DTR EHR” CapabilityStatement
  - Light DTR EHR: Functional registration, dynamic registration; SMART user auth, UDAP B2B user auth
- **Prior authorization submission and receive response**
  - Support the ability to submit a prior authorization request to a payer system including “EHR PAS Capabilities”
  - Support the ability to consume and process a “ClaimResponse”



# Prior Authorization API “payer” §170.315(g)(35)

- **Coverage discovery**
  - Support the identification of coverage requirements by receiving and respond to decision support requests as a service
  - Support for "CRD Server" CapabilityStatement
- **Documentation and rules exchange**
  - Functional registration, dynamic registration, SMART Backend services, UDAP system auth
  - Receive / respond to prior auth documentation request with documentation templates and rules; support “DTR Payer Service” CapabilityStatement
- **Prior authorization receipt and response**
  - Functional registration, dynamic registration, SMART Backend services, UDAP system auth
  - Support the ability to receive, process, and respond to a prior authorization request



# Provider Directory API - Health Plan Coverage §170.315(g)(36)

## PROPOSAL

ONC proposes to adopt a “Provider directory API – health plan coverage” certification criterion in § 170.315(g)(36), which specifies technical requirements for health IT that can be used by payers to publish information regarding the providers that participate in their networks.

The proposed criterion references standards including Da Vinci PDex Plan Net IG.

## BENEFITS

- Ability for patients to understand which providers, facilities, and pharmacies are covered by their current or future plan can improve patients’ ability to find the right provider and health care plan.

# Provider Directory API - Health Plan Coverage §170.315(g)(36)

- **Support the ability to publish according to PDEX Plan Net:**
  - Payer's insurance plans
  - Associated networks
  - Organizations and providers that participate in these networks
- **Support “Plan-Net CapabilityStatement”**



# Proposed Condition and Maintenance of Certification requirements

- **170.404 Application programming interfaces**
  - Condition and Maintenance of Certification requirements apply to developers of Health IT Modules certified to any of the certification criteria adopted in § 170.315(g)(7) through (10), (20), and (30) through (36), and (j), unless otherwise specified in this section
- **170.404(b)(1) Authenticity verification and registration for production use**
  - Applies to: (g)(30) Patient Access API, (g)(32) Provider Access API “server”, (g)(33) Payer-to-Payer API, (g)(34) Prior Authorization API “provider”, (g)(35) Prior Authorization API “payer”
- **170.404(b)(2) Publication of API discovery details for patient access**
  - Certified API Developers with Health IT Modules certified to § 170.315(g)(30) must meet the requirements in paragraphs (b)(2)(i) API discovery terms, (iii) API discovery in user-access brand format, and (iv) Trust community discovery for dynamic registration
- **170.404(b)(3) Publication of API discovery details for payer information**
  - Applies to (g)(32) Provider Access API “server”, (g)(33) Payer-to-Payer API, (g)(35) Prior Authorization API “payer”, (g)(36) Provider Directory API - Health Plan Coverage
  - Certified API Developer must publicly publish API discovery details for all of its customers
  - Published according to the “User-access Brands and Endpoints” section of SMART App Launch Framework IG
  - All API discovery details for payer information published according to this section must be reviewed quarterly and, as necessary, updated by the Certified API Developer

# Resources Available on HealthIT.gov!


## RESOURCES AVAILABLE

Visit <https://healthIT.gov/proposedrule> for additional information. More updates will be added over time.

- General Overview
- USCDI v4
- Electronic Prescription
- Information Blocking (Exceptions)
- Information Blocking (Definitions)
- Public Health Reporting
- TEFCA
- Modular API
- Patient, Provider, and Payer API
- Key Compliance Dates

JULY 2024  
Health Data, Technology, and Interoperability (HTI-2): Patient Engagement, Information Sharing, and Public Health Interoperability PROPOSED RULE

**HTI-2 Proposed Rule Overview**



**Overview**


Since the passage of the 21st Century Cures Act (Cures Act), the health IT and health care industry has made significant strides towards data interoperability throughout health care. The Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule builds on this foundation through new proposals that enable better and more equitable patient care through systemic improvements in the access, exchange, and use of data.

**Key Proposals:**

- A New Baseline Version of USCDI
- Minimum Standards Code Set Updates
- Bulk Data Enhancements
- Electronic Prior Authorization
- Information Blocking
- TEFCA™
- New and Revised Standards and Certification Criteria Proposal

JULY 2024  
Health Data, Technology, and Interoperability (HTI-2): Patient Engagement, Information Sharing, and Public Health Interoperability PROPOSED RULE

**HTI-2 Proposed Key Dates**



**HTI-2 Proposed Key Dates**

Health IT developers with a Health IT Module certified to any revised certification criterion, as defined in 45 CFR 170.102, must update their certified Health IT Module and provide such updated health IT to their customers in accordance with the timelines defined for a specific criterion and/or standard included in § 170.315. Below are key dates for the certification criteria we propose to revise in HTI-2. Note, the new certification criteria proposed in HTI-2 have specified timelines for adoption in the ONC Health IT Certification Program (Program), but have been purposefully omitted from this fact sheet.

We propose that by January 1, 2026, a health IT developer of a Health IT Module certified to the following criteria must update their Health IT Module and provide the updated version to their customers in order to maintain certification of that Health IT Module.

- § 170.315(d)(7) "privacy and security – health IT encryption"
- § 170.315(d)(8) "privacy and security – trusted connection"
- § 170.315(d)(12) "privacy and security – protect stored authentication credentials"

We propose that by January 1, 2021, a health IT developer of a Health IT Module certified to the following criteria must update their Health IT Module and provide the updated version to their customers in order to maintain certification of that Health IT Module.

- § 170.315(f)(6) "public health – antimicrobial use and resistance reporting – transmission to public health agencies"
- § 170.315(f)(7) "public health – health care surveys – transmission to public health agencies"

We propose that by January 1, 2028, a health IT developer of a Health IT Module certified to the following criteria must update their Health IT Module and provide the updated version to their customers in order to maintain certification of that Health IT Module.

<ul style="list-style-type: none"> <li>• § 170.315(a)(2) "computerized provider order entry – laboratory"</li> <li>• § 170.315(a)(12) "family health history"</li> <li>• § 170.315(b)(1) "transitions of care"</li> <li>• § 170.315(b)(2) "clinical information reconciliation and incorporation"</li> <li>• § 170.315(b)(3) "electronic prescribing"</li> <li>• § 170.315(b)(6) "real-time prescription benefit"</li> <li>• § 170.315(c)(4) "clinical quality measures – filter"</li> <li>• § 170.315(d)(13) "privacy and security – multi-factor authentication"</li> <li>• § 170.315(e)(1) "patient engagement – view, download, and transmit to 3rd party"</li> <li>• § 170.315(f)(1) "public health – immunization registries"</li> </ul>	<ul style="list-style-type: none"> <li>• § 170.315(f)(2) "public health – syndromic surveillance – transmission to public health agencies"</li> <li>• § 170.315(f)(3) "public health – reportable laboratory results"</li> <li>• § 170.315(f)(4) "public health – cancer registry reporting"</li> <li>• § 170.315(f)(5) "public health – transmission to public health agencies – electronic case reporting"</li> <li>• § 170.315(g)(9) "design and performance – application access – all data request – functional requirements"</li> <li>• § 170.315(g)(10) "design and performance – standardized API for patient and population services – data response"</li> </ul>
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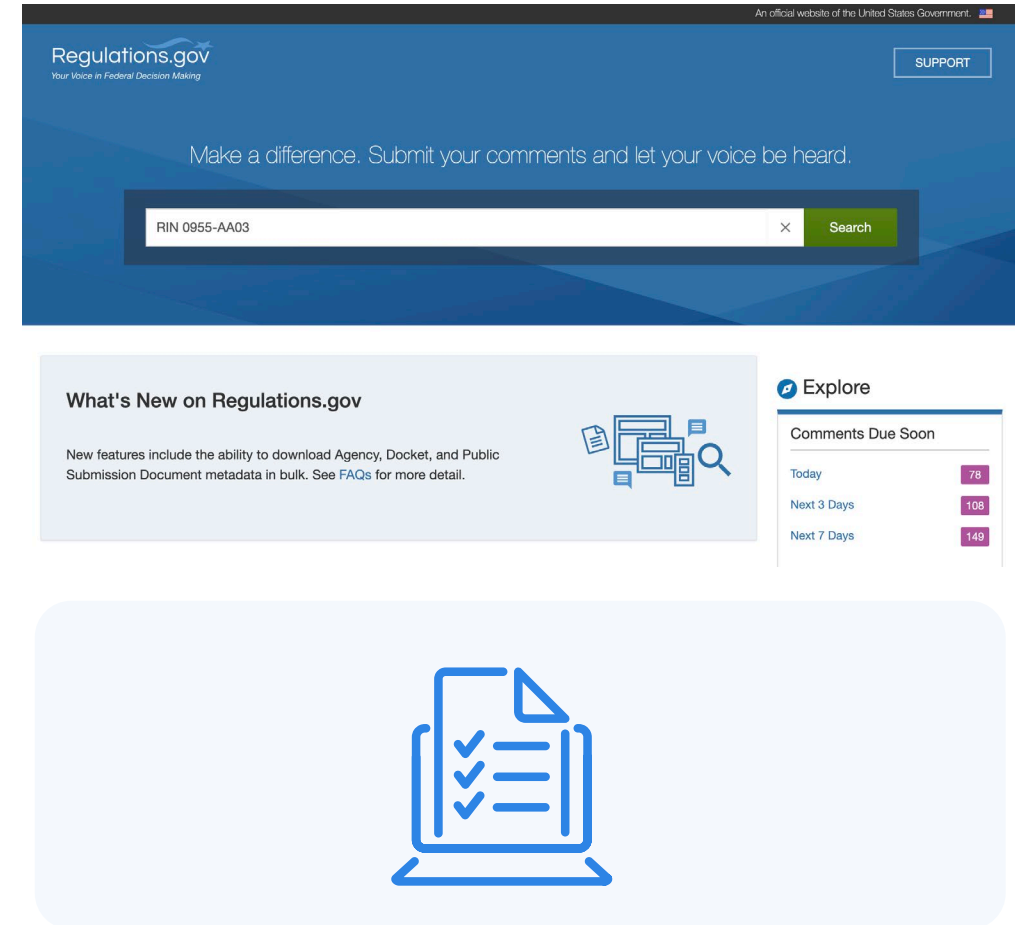
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# How to Submit a Comment

## Federal eRulemaking Portal

You may submit comments, identified by RIN 0955-AA06, through <http://www.regulations.gov>. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word.



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