



# ONC HTI-2 Proposed Rule Task Force 2024

## Group 2: Standards and Certification

Mark Sendak, Co-Chair

July 24, 2024





# Call to Order/Roll Call

Peter Karras, Acting Designated Federal Officer, ONC

# HTI-2 Proposed Rule Task Force 2024 Roster

## Group 2: Standards and Certification



| Name                           | Organization                                      |
|--------------------------------|---|
| <b>Mark Sendak* (Co-Chair)</b> | Duke Institute for Health Innovation              |
| Suresh Balu                    | Duke Institute for Health Innovation (DIHI)       |
| Hans Buitendijk*               | Oracle Health                                     |
| Steven Eichner*                | Texas Department of State Health Services         |
| Rajesh Godavarthi*             | MCG Health, part of the Hearst Health network     |
| Mary Beth Kurilo               | American Immunization Registry Association (AIRA) |
| Hung S. Luu*                   | Children's Health                                 |
| Meg Marshall**                 | Department of Veterans Health Affairs             |
| Alex Mugge**                   | Centers for Medicare and Medicaid Services        |
| Shantanu Nundy                 | Accolade  |
| Dan Riskin*                    | Verantos  |
| Fillipe Southerland*           | Yardi Systems, Inc.                               |
| Naresh Sundar Rajan*           | CyncHealth  |
| Sheryl Turney                  | Elevance Health                                   |

\* HITAC Member

\*\* HITAC Federal Representative



# Opening Remarks

Mark Sendak, Co-Chair

# Agenda

- 11:00 AM**      **Call to Order/Roll Call**
  - Peter Karras, Acting Designated Federal Officer, ONC
  
- 11:05 AM**      **Opening Remarks**
  - Mark Sendak, Co-Chair
  
- 11:10 AM**      **Standardized API for Patient and Population Services**
  - Rob Anthony, ONC
  - Matt Rahn, ONC
  - Jeff Smith, ONC
  
- 11:50 AM**      **Discussion**
  - Mark Sendak, Co-Chair
  
- 12:05 PM**      **Task Force Recommendation Worksheet**
  - Mark Sendak, Co-Chair
  
- 12:20 PM**      **Public Comment**
  - Peter Karras, Acting Designated Federal Officer, ONC
  
- 12:25 PM**      **Next Steps**
  - Mark Sendak, Co-Chair
  
- 12:30 PM**      **Adjourn**



# HTI-2 Proposed Rule Task Force 2024: Charge

**Overarching Charge:** The HTI-2 Proposed Rule Task Force will evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule.

## **Specific Charge:**

- Review and provide recommendations on the HTI-2 proposals on public health, standards and certification, and information blocking and TEFCA.
- Recommendations are due prior to the end of the 60-day public comment period.

## Subgroup 2: Standards and Certification

The Standards and Certification Subgroup will review and provide preliminary recommendations for Task Force consideration on the following HTI-2 proposed rule sections.

- **ONC Health IT Certification Program Updates**
  - **Standardized API for Patient and Population Services**
    - The United States Core Data for Interoperability Version 4 (USCDI v4)
    - SMART App Launch 2.2
    - User-Access Brands and Endpoints
    - Bulk Data Enhancements
    - New Requirements to Support Dynamic Client Registration Protocol in the Program
  - Modular API capabilities certification criteria in § 170.315(j) + Structure of § 170.315(g)(10)
    - New Certification Criteria for Modular API Capabilities –
    - Revised structure for Patient and Population Services Criterion to Align with Modular API Capabilities
  - Patient, Provider, and Payer APIs
    - Patient, Provider, and Payer APIs
- Select Revised Certification Criteria and New Certification Criteria
  - New Real-Time Prescription Benefit Criterion
  - New Imaging Requirements for Health IT Modules
  - Revised Clinical Information Reconciliation and Incorporation Criterion
  - Revised Electronic Prescribing Certification Criterion
- Security Certification Criteria Revisions
  - Multi-factor Authentication Criterion
  - Revised End-User Device Encryption Criterion + related standards
  - Revised Criterion for Encrypt Authentication Credentials
- Conditions and Maintenance of Certification
  - Insights
  - Attestations



# HTI-2 Proposals Related to the Standardized API for Patient and Population Services

Rob Anthony, ONC  
Matt Rahn, ONC  
Jeff Smith, ONC





# HTI-2 Proposals Relevant to Standardized API for Patient and Population Services

# Revised certification criterion at 170.315(g)(10) for standardized API for patient and population services

## PROPOSAL

ONC proposes to revise the “standard API for patient and population services” certification criterion at § 170.315(g)(10) by requiring support of several updated standards, including USCDI v4 and SMART App Launch 2.2, by requiring support for dynamic client registration, and by requiring support for several new standard API workflow capabilities, such as workflow triggers, verifiable health cards, and subscriptions.

Additionally, ONC proposes that such Health IT Modules support multi-factor authentication for patient-facing authentication, imaging links in data response requirements, support for read and search API for system applications and support for “\_type” query parameter for Bulk FHIR API.

## BENEFITS

- These enhancements and updates would ensure that patients have access to more information, such as diagnostic images via imaging links, more granular control of their data through US Core Scopes, and more modern experiences connecting apps of their choice to their health information via dynamic client registration.
- Clinicians would benefit from an expanded use of standard APIs, required by USCDI v4, including access, exchange, and use of data elements salient to behavioral health and underserved communities. Clinicians would also have a range of tools, including CDS Hooks and Subscriptions with which to support decision-making and manage patient information. Public health, researchers, and others would benefit from improved access to bulk data through required support for the Bulk FHIR IG version 2.

# Proposed revisions to (g)(10) API certification criterion



- **Updating existing standards for information access and authentication / authorization**

- USCDI v3 → v4
- US Core IG v6.1.0 → v7.0.0
- Bulk Data Access IG v1.0 → v2.0
- SMART App Launch IG v2.0 → v2.2



- **Adding new standard for dynamic registration**

- Dynamic client registration using HL7 FHIR® Unified Data Access Profiles (UDAP™) Security IG v1.0.0



- **Adding new standards-based API workflow capabilities**

- API-based workflow triggers using HL7® CDS Hooks Release 2.0
- Verifiable health records using SMART Health Cards Framework v1.4.0 and HL7® SMART Health Cards: Vaccination and Testing IG v1.0.0
- API-based event notifications using HL7® FHIR® Subscriptions R5 Backport IG v1.1.0

# Additional revisions to (g)(10) API include

## Reorganization of (g)(10) API regulation text to:

- Create consistency across (g)-criteria for public health and payer APIs
- Reference (j)-criteria requirements in **Registration** and **Authentication / Authorization** sections
- Enable tailored **Information Access** requirements to support the criterion's use case
- Support (j)-criteria references for **API workflow capabilities**

**Registration**

**Authentication / Authorization**

**Information Access**

**API workflow capabilities**

# Revised standards for (g)(10) API criterion: Information access and authentication / authorization

## USCDI Version 4



- Version 4 includes 20 additional data elements beyond USCDI v3
- Focus on data elements for SUD care, labs, and a facility identifiers

## US Core IG Version 7.0



- Version 7 supports USCDI v4
- Includes instructions for finer-grained scopes for the first time

## SMART App Launch v2.2



- Includes User-access Brands specifications that supports a model user experience (UX) that help users connect their apps to specific entities (e.g., hospital, payer, etc.)

# USCDI Version 4



























## PROPOSAL

ONC proposes to adopt USCDI v4 as part of the Certification Program and require that Health IT Modules certified to criteria that reference the USCDI (at § 170.213) update and provide their customers with such technology by January 1, 2028.

## BENEFITS

- The adoption of USCDI v4 would add 20 new data elements, some of which are specifically relevant to behavioral health and marginalized and underserved communities, including:
  - Goals and preferences
    - Treatment intervention preference, care experience preference data elements
  - Health Status Assessments
    - Alcohol use, substance use, and physical activity data elements
- USCDI v4 would also support data users' abilities to identify, assess, and analyze gaps in care, which could in turn be used to inform and address the quality of healthcare through interventions and strategies.

# USCDI Version 4

|   |  |  |  |  |
|---|--|--|--|--|
| <p><b>Allergies and Intolerances</b></p> <ul style="list-style-type: none"> <li>• Substance (Medication)</li> <li>• Substance (Drug Class)</li> <li>• Substance (Non-Medication) </li> <li>• Reaction</li> </ul> <p><b>Care Team Member(s)</b></p> <ul style="list-style-type: none"> <li>• Care Team Member Name</li> <li>• Care Team Member Identifier</li> <li>• Care Team Member Role</li> <li>• Care Team Member Location</li> <li>• Care Team Member Telecom</li> </ul> <p><b>Clinical Notes</b></p> <ul style="list-style-type: none"> <li>• Consultation Note</li> <li>• Discharge Summary Note</li> <li>• History &amp; Physical</li> <li>• Procedure Note</li> <li>• Progress Note</li> </ul> <p><b>Clinical Tests</b></p> <ul style="list-style-type: none"> <li>• Clinical Test</li> <li>• Clinical Test Result/Report</li> </ul> <p><b>Diagnostic Imaging</b></p> <ul style="list-style-type: none"> <li>• Diagnostic Imaging Test</li> <li>• Diagnostic Imaging Report</li> </ul> <p><b>Encounter Information</b></p> <ul style="list-style-type: none"> <li>• Encounter Type</li> <li>• Encounter Identifier </li> <li>• Encounter Diagnosis</li> <li>• Encounter Time</li> <li>• Encounter Location</li> <li>• Encounter Disposition</li> </ul> | <p><b>Facility Information</b> </p> <ul style="list-style-type: none"> <li>• Facility Identifier </li> <li>• Facility Type </li> <li>• Facility Name </li> </ul> <p><b>Goals and Preferences</b> </p> <ul style="list-style-type: none"> <li>• Patient Goals</li> <li>• SDOH Goals</li> <li>• Treatment Intervention Preference </li> <li>• Care Experience Preference </li> </ul> <p><b>Health Insurance Information</b></p> <ul style="list-style-type: none"> <li>• Coverage Status</li> <li>• Coverage Type</li> <li>• Relationship to Subscriber</li> <li>• Member Identifier</li> <li>• Subscriber Identifier</li> <li>• Group Number</li> <li>• Payer Identifier</li> </ul> <p><b>Health Status Assessments</b></p> <ul style="list-style-type: none"> <li>• Health Concerns</li> <li>• Functional Status</li> <li>• Disability Status</li> <li>• Mental/Cognitive Status</li> <li>• Pregnancy Status</li> <li>• Alcohol Use </li> <li>• Substance Use </li> <li>• Physical Activity </li> <li>• SDOH Assessment </li> <li>• Smoking Status</li> </ul> | <p><b>Immunizations</b></p> <ul style="list-style-type: none"> <li>• Immunizations</li> </ul> <p><b>Laboratory</b></p> <ul style="list-style-type: none"> <li>• Tests</li> <li>• Values/Results</li> <li>• Specimen Type</li> <li>• Result Status</li> <li>• Result Unit of Measure </li> <li>• Result Reference Range </li> <li>• Result Interpretation </li> <li>• Specimen Source Site </li> <li>• Specimen Identifier </li> <li>• Specimen Condition</li> <li>• Acceptability </li> </ul> <p><b>Medical Devices</b> </p> <ul style="list-style-type: none"> <li>• Unique Device Identifier - Implantable </li> </ul> <p><b>Medications</b></p> <ul style="list-style-type: none"> <li>• Medications</li> <li>• Dose</li> <li>• Dose Unit of Measure</li> <li>• Indication</li> <li>• Fill Status</li> <li>• Medication Instructions </li> <li>• Medication Adherence </li> </ul> | <p><b>Patient Demographics/ Information</b></p> <ul style="list-style-type: none"> <li>• First Name</li> <li>• Last Name</li> <li>• Middle Name (Including middle initial)</li> <li>• Name Suffix</li> <li>• Previous Name</li> <li>• Date of Birth</li> <li>• Date of Death</li> <li>• Race</li> <li>• Ethnicity</li> <li>• Tribal Affiliation</li> <li>• Sex</li> <li>• Sexual Orientation</li> <li>• Gender Identity</li> <li>• Preferred Language</li> <li>• Current Address</li> <li>• Previous Address</li> <li>• Phone Number</li> <li>• Phone Number Type</li> <li>• Email Address</li> <li>• Related Person's Name</li> <li>• Relationship Type</li> <li>• Occupation</li> <li>• Occupation Industry</li> </ul> <p><b>Patient Summary and Plan</b> </p> <ul style="list-style-type: none"> <li>• Assessment and Plan of Treatment</li> </ul> | <p><b>Problems</b></p> <ul style="list-style-type: none"> <li>• Problems</li> <li>• SDOH Problems/Health Concerns</li> <li>• Date of Diagnosis</li> <li>• Date of Resolution</li> </ul> <p><b>Procedures</b></p> <ul style="list-style-type: none"> <li>• Procedures</li> <li>• Performance Time </li> <li>• SDOH Interventions</li> <li>• Reason for Referral</li> </ul> <p><b>Provenance</b></p> <ul style="list-style-type: none"> <li>• Author Organization</li> <li>• Author Time Stamp</li> </ul> <p><b>Vital Signs</b></p> <ul style="list-style-type: none"> <li>• Systolic Blood Pressure</li> <li>• Diastolic Blood Pressure</li> <li>• Average Blood Pressure </li> <li>• Heart Rate</li> <li>• Respiratory Rate</li> <li>• Body Temperature</li> <li>• Body Height</li> <li>• Body Weight</li> <li>• Pulse Oximetry</li> <li>• Inhaled Oxygen Concentration</li> <li>• BMI Percentile (2 - 20 years)</li> <li>• Weight-for-length Percentile (Birth - 24 Months)</li> <li>• Head Occipital-frontal Circumference Percentile (Birth - 36 Months)</li> </ul> |
|---|--|--|--|--|

 New Data Classes and Elements  Data Element Reclassified  Renamed Data Element or Class

# USCDI v4 and US Core v7

- HTI-2 proposals would require:
  - Adoption of USCDI v4 and US Core IG v7
    - Require use of IGs at § 170.315(g)(10)(ii) to support the read and search API for patient and user access
    - § 170.315(g)(10)(iii) to support the bulk and read and search APIs for system access
  - Certified API Developers with Health IT Modules currently certified to § 170.315(g)(10) to update and provide such technology to their customers by December 31, 2027
- US Core IG v7 specifies which Profiles must be supported at “sub-resource” or granular-level scopes for read and search
  - Would support more granular exchange of specific FHIR-based data elements (e.g., a patient’s lab results, rather than all of a patient’s observations)
- Note: ONC also proposes to require support for the C-CDA Edition 3 standard for Health IT Modules supporting USCDI in non-API-related certification criteria



## SMART App Launch 2.2

- ONC proposes to update the SMART App Launch standard in § 170.215(c) to SMART App Launch version 2.2 (SMART v2.2 Guide) and require compliance by January 1, 2028.
  - Applies to existing and newly proposed certification criteria for API capabilities, in § 170.315(g) and § 170.315(j), that reference § 170.215(c).
- The adoption of the SMART v2.2 Guide incorporates new features and guidance that helps improve standardization and interoperability
  - For example, a more detailed and standardized "fhirContext" launch parameter which allows for application flexibility and helps maintain backwards compatibility.
- Introduces the User-Access Brands and Endpoints (Brands) specification
  - Allows API providers to publish Brands associated with their FHIR Endpoints to enable apps to collect and present these Brands to users (e.g., patients).

# User-Access Brands and Endpoints

- ONC proposes to adopt the User-Access Brands and Endpoints (Brands) FHIR specification for publication of API discovery details.
  - E.g., publication of service base URLs (FHIR endpoints) and organization details.
  - Applies to API Maintenance of Certification requirements at § 170.404(b)
  - Compliance date of January 1, 2028.
- Benefits include:
  - Enhanced app connectivity to health data providers.
  - Improved patient access to their health data using third party apps.

# Bulk Data Enhancements

- Bulk Data Access IG support currently required for (g)(10) multiple patient API requirements
- We propose to adopt a new version of Bulk Data Access Standard and new export filter requirements for specific FHIR resource types
- We propose to require such support under (g)(10)(iii) to support bulk export of groups of patients for system apps
- We propose to require support and rollout for these proposed bulk capabilities by December 31, 2027.

# New standards for (g)(10) API criterion

- New standards for (g)(10) support **registration** and **API workflow capabilities**
  - **Registration**
    - Dynamic client registration – UDAP Security IG
  - **API workflow capabilities**
    - Workflow triggers – CDS Hooks
    - Verifiable health records – SMART Health Cards
      - Vaccination and testing use case
    - Event notifications – Subscriptions

# Summary of Dynamic Client Registration Proposal

## PROPOSAL

- Require several certification criteria in the Program to support dynamic client registration and subsequent authentication and authorization for dynamically registered patient-facing, user-facing, and system confidential applications.
- Impacted criteria would include: § 170.315(g)(10), (20), (30), and (32) – (35), § 170.315(j)(2), (5), (8), (11) proposed certification criteria.
- Adopt the HL7® Unified Data Access Profiles (UDAP™) Security for Scalable Registration, Authentication, and Authorization Implementation Guide Release 1.0.0 implementation guide (UDAP Security IG v1).
- Add new requirements in the API Conditions and Maintenance of Certification in § 170.404.
- Require support for these proposed dynamic registration capabilities by December 31, 2027.

## BENEFITS

This proposal would facilitate timelier patient, provider, and system access to health information using applications by requiring Health IT Module support for a more uniform, standardized, and automated application registration pathway.

# Trust Communities

- The proposal for dynamic registration relies upon the concept of a “trust community”
  - Trust communities enable scalable trust by establishing common policies that all participants agree to abide, reducing the need for individual agreements between organizations for establishing trusted relationships.
  - Participation in a trust community can be represented in a secure manner in the form of cryptographically secure digital certificates. These certificates enable an application to prove to a server that it and its developer are trusted to meet the expectations of the trust community.
  - With the certificate as proof of the trustworthiness of an API User and their application, registration can proceed in an automated manner (e.g., dynamic registration) without the need to perform manual or non-standardized trust verification.

## Publication of Trust Community Information

- To enable API access, exchange, and use of health data “without special effort,” we propose to require as part of the API Maintenance of Certification requirements at § 170.404(b)(2)(iv) that Certified API Developers publish trust community information.
- Specifically, we propose Certified API Developers publish trust community information necessary to enable scalable dynamic registration of patient-facing apps with API technology certified to § 170.315(g)(10) or § 170.315(g)(30).
- We propose trust community details such as trust community name, contact information, web address, and identifying Uniform Resource Identifier (URI) must be publicly published in a computable format at no charge for each service base URL published in accordance with § 170.404(b)(2).

# Authentication of Dynamically Registered Apps

- We propose to require support for dynamic registration according to the UDAP Security IG v1 and to require support for authentication of dynamically registered apps according to the UDAP Security IG v1.
- Distinct from SMART App Launch authentication, this proposed authentication process for dynamically registered apps would include the use of digital certificates to establish trust.
- For dynamically registered apps, we propose to require that the same app authentication mechanism for dynamic registration be supported for the authorization process as well.
- This requirement would keep the app authentication mechanism for dynamic registration and authorization of dynamically registered apps consistent.



## Workflow Triggers – CDS Hooks

- We propose to require support for workflow triggers for decision support interventions under proposed (g)(10)(iv).
- We propose that the Health IT Module must support capabilities to enable workflow triggers to call decision support services, including support for "patient-view" and "order-sign" CDS Hooks according to at least one of the versions of the implementation specification adopted in § 170.215(f)(1).
- We propose support for "patient-view" and "order-sign" because these CDS Hooks are at maturity level "5 – Mature" according to the CDS Hooks IG and can be used to support a wide variety of workflow processes.
- We propose to require support and rollout for these workflow triggers for decision support interventions by December 31, 2027.

# Event Notifications – Subscriptions

- We propose to adopt support for FHIR subscriptions for the single patient and multiple patient (g)(10) criterion FHIR APIs.
  - All patient-related US Core IG Resources filtered by patient identifier and code
  - Exchange: "Rest-hook", Content: HL7 FHIR Resource "id"
- The proposed capabilities include support for subscriptions according to the FHIR Subscriptions R5 Backport IG v1.1.0 for specified FHIR Resources and data elements as specified in the proposed (j)(23) criterion.
- The subscriptions requirements are proposed at § 170.315(g)(10)(ii)(B)(3) for patient and user access use cases, and for § 170.315(g)(10)(iii)(B)(3) system access use cases.
- We propose to require support and rollout for these subscription capabilities by December 31, 2027.

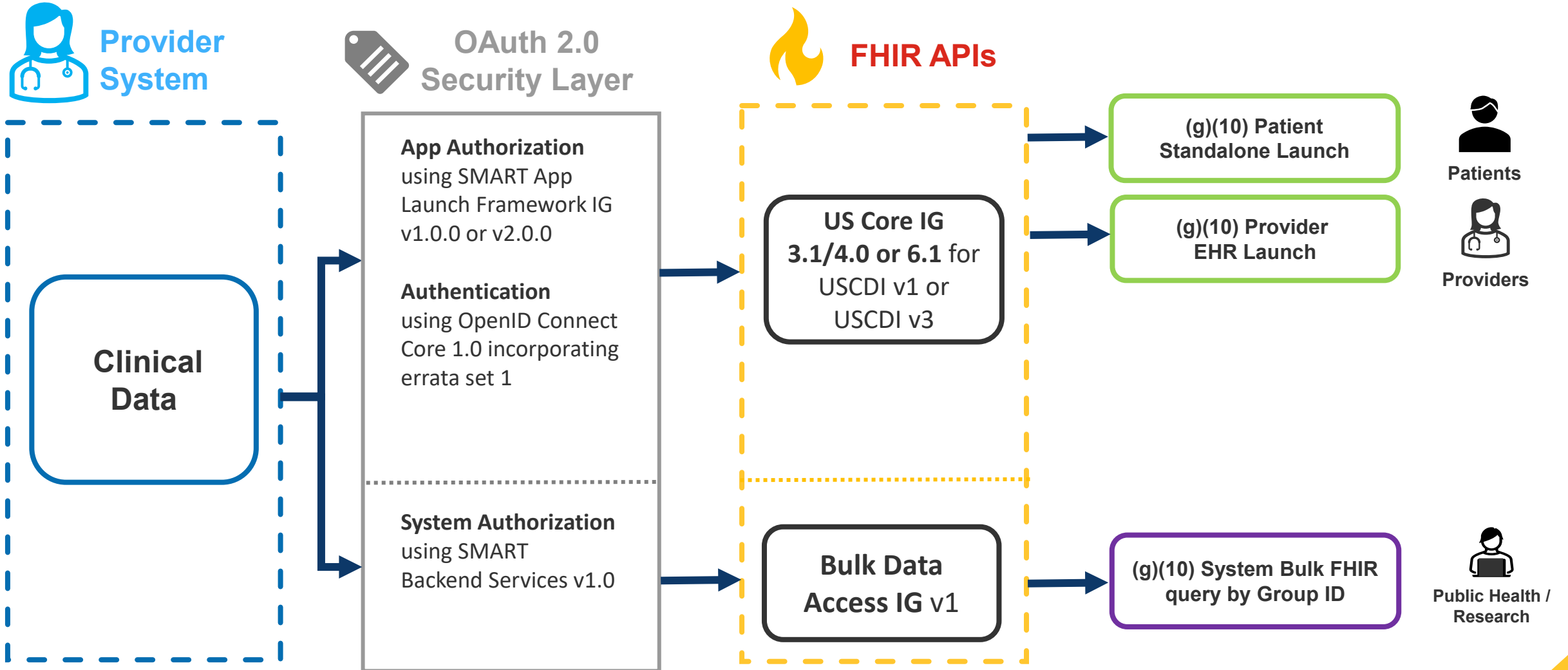
## Verifiable Health Records – SMART Health Cards

We propose requiring support for the issuance of verifiable health records to patients to support the ability for patients to access their immunization and infectious disease-related laboratory test information in a format that is easily portable and verifiable by third parties.

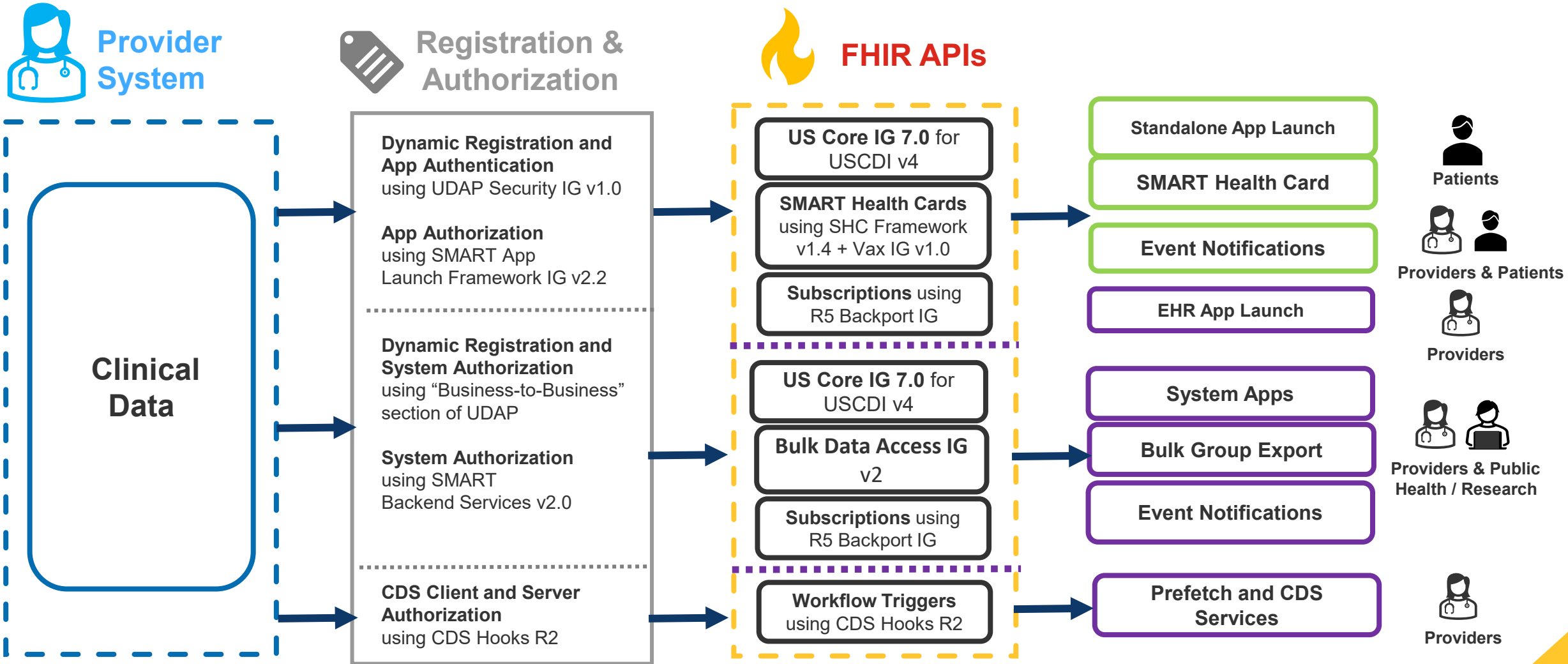
This proposal includes supporting HL7® FHIR® SMART Health Cards Framework v1.4 and SMART Health Cards: Vaccination and Testing IG v1 according to the proposed (j)(22) criterion.

We propose to require support and rollout for these the issuance of verifiable health records capabilities by December 31, 2027.

# Current (g)(10) API criterion



# Proposed revised (g)(10) API criterion



# Restructuring (g)(10) criterion with modular API capabilities, revising with new functionality

- **Registration**

- Functional registration
- Dynamic registration

- **Patient and user access**

- Authentication and authorization for patient access: SMART Standalone Launch, asymmetric certificate-based
- Authentication and authorization for user access: SMART EHR Launch, asymmetric certificate-based
- Read and search API
- Issuance of verifiable health records
- Subscriptions

- **System and information access**

- Authentication and authorization for system access: SMART Backend Services, asymmetric certificate-based
- Read and search API
- Bulk FHIR API
- Subscriptions

- **Workflow triggers for decision support interventions**

- “patient-view” and “order-sign” hooks



# Discussion

Mark Sendak, Co-Chair



# Task Force Recommendation Worksheet

Mark Sendak, Co-Chair



# Public Comment

To make a comment please

## Use the Hand Raise Function

**If you are on the phone only, press “\*9” to raise your hand**

*(Once called upon, press “\*6” to mute/unmute your line)*

**All public comments will be limited to three minutes**

You may also email your public comment to [onc-hitac@accelsolutionsllc.com](mailto:onc-hitac@accelsolutionsllc.com)

*Written comments will not be read at this time,  
but they will be delivered to members of the Task Force and made part of the public record*



# Next Steps

Mark Sendak, Co-Chair

# Upcoming Meetings

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## Task Force Meeting Date/Time

7/31 11 AM - 12:30 PM

8/7 11 AM - 12:30 PM

8/13 2 - 3:30 PM

8/22 1 - 2:30 PM

8/28 11 AM - 12:30 PM

9/3 11 AM - 12:30 PM (Full Task Force Meeting)

9/4 11 AM - 12:30 PM (Full Task Force Meeting)

9/5 11 AM - 12:30 PM (Full Task Force Meeting)

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## HITAC Meeting Date

8/15 TF provides updates to HITAC

9/12 TF delivers recommendations to HITAC

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**Adjourn**