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

Modular API

Modular API Capabilities

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. "Modular API capabilities" is a new category of certification criteria in the HTI-2 proposed rule. This proposal would define several modular and foundational capabilities necessary to support APIs across **clinical**, **public health**, **administrative**, and **other use cases**. We believe that this approach enables more modularity and flexibility for health IT developers that wish to certify to more discrete functions, rather than large, multi-functionality, and all-encompassing certification criteria.

Several of the criteria in § 170.315(j) reference newly proposed standards for adoption within the ONC Health IT Certification Program, such as:

- HL7® Clinical Decision Support Hooks;

- SMART Health Cards;

- HL7 FHIR Subscriptions;

- Unified Data Access Profiles (UDAP™); and

- Capabilities historically referenced in § 170.315(g)(10), including SMART App Launch.

What Is Being Proposed?

ONC proposes to add a subsection to § 170.315 titled "Modular API capabilities" in § 170.315(j). This certification criteria category promotes the ONC Health IT Certification Program's modular certification approach and enables different combinations of capabilities across Health IT Modules depending on use case needs. Capabilities in § 170.315(j) would be standards-based, except for the criterion at § 170.315(j)(1) "Functional registration," and include a combination of new and existing standards many of which are currently referenced in § 170.315(g)(10).

Additionally, the capabilities in § 170.315(j) would better support a growing number of clinical, public health, and administrative use cases and foster innovation and competition in these spaces by providing flexibility for modular development approaches among developers of certified health IT.

Modular Capabilities – Similar to Existing § 170.315(g)(10) Capabilities

ONC proposes to include 14 new certification criteria as modular API capabilities in § 170.315(j). These certification criteria would be available for certification based on certain contexts or other programs requiring the use of the specified certified capabilities. The first eight of these certification criteria are substantially similar to capabilities currently referenced in § 170.315(g)(10)(iii) through (vii).

- § 170.315(j)(1) "Functional registration" would require a Health IT Module to demonstrate the ability for applications to register with its authorization server.

- § 170.315(j)(2) "Dynamic registration" would require a Health IT Module to demonstrate the ability to register confidential clients using dynamic processes according to the HL7 UDAP Security IG v1.

- § 170.315(j)(5) "Asymmetric certificate-based authentication" would require a Health IT Module's authorization server to support authentication during the process of granting access to patient data according to the implementation specification adopted in § 170.215(e).

- § 170.315(j)(6) "SMART App Launch user authorization" would support user authentication according to at least one of the implementation specifications in § 170.215(c).

- § 170.315(j)(7) "SMART Backend Services system authentication and authorization" would support system authentication and authorization in accordance with the "Backend Services" section of at least one of the implementation specifications adopted in § 170.215(c).

- § 170.315(j)(8) "Asymmetric certificate-based system authentication and authorization" would support system authentication and authorization according to the UDAP specification in § 170.215(o) for dynamic registration.

- § 170.315(j)(9) "SMART Patient Access for Standalone Apps" would support patient authorization and authorization revocation at a patient's direction according to the requirements according to newer versions of the SMART App Launch IG on specified timelines.

- § 170.315(j)(10) "SMART Clinician Access for EHR Launch" would support EHR launch authorization according to the requirements according to newer versions of the SMART App Launch IG on specified timelines.

- § 170.315(j)(11) "Asymmetric certificate-based authentication for B2B user access" would support asymmetric certificate-based authentication during the process of granting dynamic registration access to patient data according to the implementation specifications adopted in § 170.215(o).

Modular Capabilities – Not Similar to Existing § 170.315(g)(10) Capabilities

Beginning at § 170.315(j)(20) ONC proposes a set of new standards-based capabilities that are not substantially similar to existing capabilities in § 170.315(g)(10). Rather, they reflect more advanced capabilities enabled by the HL7 FHIR standard and related implementation guides.

- § 170.315(j)(20) & (21) "Workflow triggers for decision support interventions" proposes to adopt the CDS Hooks Release 2.0 implementation specification at § 170.215(f) to support Program requirements for API-based workflow triggers for decision support interventions in proposed certification criteria.

- § 170.315(j)(22) "Verifiable health records" would require a Health IT Module to support the issuance of verifiable health records according to the SMART Health Cards Framework standard.

- § 170.315(j)(23) & (24) "Event notifications" would require Health IT Modules to support API-based subscriptions according to the HL7 FHIR Subscriptions Framework included in the Subscriptions R5 Backport Implementation Guide version 1.1.0.

We cross-reference various criteria in § 170.315(j) as part of API-based criteria for public health in § 170.315(g)(20), health insurance and coverage APIs in § 170.315(g)(30) through (36), as well as in the reformatted standardized API for patient and population services at § 170.315(g)(10).

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