

Conditions of Certification

A White Paper from Dynamic Health IT, Your Strategic Partner

Problem

As mandated by the 21st Century Cures Act, CMS introduced a final rule that lays out Conditions of Certification (CoC) and Maintenance of Certification requirements (MoC). The program's initial requirements target Health IT developers and their certified Health IT Module(s). With the COVID-19 pandemic and all the challenges it presents, Health IT vendors are challenged with developing new functionality and navigating confusing timeline changes.

Goals

Provide health IT developers with consulting services and software certified for the 2015 Cures Act Edition. Be a Strategic Partner by taking the lead for Conditions of Certification through the changing deadlines and requirements. Provide updates to timelines, plans and test plans Real World functionality. Maintain certification requirements.

Results

DHIT provides bolt-on solutions which meet the requirements for multiple criteria including but not limited to, 170.315 (b)(10) EHI Export, 170.315 (c)(1-4) Quality Measures, (170.315 (g)(7-9) API and more. Solutions can be hosted by DHIT and/or integrated in the clients environment. DHIT provides Real World Test plans for all applicable criteria we've certified. DHIT's Real World Testing consulting division provides test plans and testing services for Health IT Modules certified to § 170.315(b), (c)(1) through (3), (e)(1), (f), (g)(7) through (10), and (h). We test the real world use of technology for interoperability in the settings where your technology is marketed.

Background

Founded in 1999, Dynamic Health IT (DHIT) specializes in integration and exchange of healthcare data. Since the beginning of Meaningful Use, DHIT has assisted clients achieve HITECH and CEHRT certification. In addition to consulting services, DHIT provides our ConnectEHR, Dynamic FHIR API, Patient Portal, and CQMsolution pre-certified bolt-on software applications with flexible deployment and hosting options. As DHIT works with more vendors, we continue searching for additional ways to help clients with meet certification requirements.

The Challenge

Our challenge was to enhance existing functionality for the 2015 Edition Cures Update, then certify early-on to ensure adequate time for our Health IT partners to deploy and certify while coping with the stress of the COVID pandemic. We also strive to provide guidance and leadership for our clients.

The Solution

At DHIT, we attacked the CoC and MOC requirements as follows:

- Information blocking as it pertains to USCDiv1: Dynamic FHIR API, ConnectEHR and Patient Portal are certified for USCDiv1 export capabilities under our Cures Update versions.
- Assurances involving attestation and documentation of ongoing compliance: A big part of this is export of all ePHI. We can advise you on best practices and provide guidance in this area.
- Communication: You must remove or void contractual provisions that contravene the COC requirements. DHIT has added consulting services to advise and provide guidance.
- APIs: Our Dynamic FHIR API is certified for the 170.315(g)(7) through (g)(9) Cures Update criteria and development is under-way for (g)(10).
- Real World Testing: DHIT provides Real World Test plans for all applicable criteria we've certified. In addition, we offer consulting for developing complimentary test plans for Health IT modules and for guiding and executing your RWT efforts.

As newer standards versions like USCDiv2 are approved, DHIT will provide enhancements to keep pace with these updates



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INFORMATION BLOCKING

DHIT Strategic Partnership:

Dynamic FHIR API, ConnectEHR and Patient Portal are certified for USCDiv1 export capabilities under our 2015 Edition Cures Update. Our 170.315(b)(10) certification ensures export of all USCDiv1 data with an option to add payer data for future interoperability requirements. All C-CDA requirements can be met with ConnectEHR.

Effective Date: April 5, 2021

<https://www.healthit.gov/condition-ccg/information-blocking>

To avoid penalties, a developer must provide the capability to export all ePHI. However, until October, 2022, the ePHI definition is limited to USCDiv1.

ASSURANCES

DHIT Strategic Partnership:

We support your compliance through:

- Flexible deployment options, including Single Sign on, Active Directory integration and Dynamic Footprint, that support cost-effective distribution
- A long track record of providing leading edge bolt-on CEHRT, including 170.315(b)(10)
- Strong consulting services to advise and provide guidance in this area

Effective Date: April 5, 2021

<https://www.healthit.gov/condition-ccg/assurances>

A health IT developer must:

1. Provide assurances that it will not take any action that constitutes information blocking, or inhibit the appropriate exchange, access, and use of electronic health information.
2. Ensure full compliance and unrestricted implementation of certified capabilities
3. Not take any action to interfere with a user's ability to access or use certified capabilities, and
4. Certify a health IT product which electronically stores EHI to the §170.315(b)(10) criteria.

COMMUNICATIONS

DHIT Strategic Partnership:

DHIT focuses on industry-standard and requirement changes to provide our strategic partners with consulting services. Our guidance enables you to focus on the usability and function of your EHR.

Effective Date: April 5, 2021

<https://www.healthit.gov/condition-ccg/communications>

A health IT developer may not prohibit or restrict communication regarding the following subjects for certified Health IT Modules



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ATTESTATION

DHIT Strategic Partnership:

DHIT consulting services focus on industry-standards and requirements changes to assist and guide our strategic partners. Our guidance allows you to focus on the optimizing usability and functionality of your EHR, rather than on regulatory requirements.

Effective Date:

A health IT developer must submit their attestations every six months with the first attestation window in April, 2022.

Note: this is not taking the place of the quarterly Surveillance we have to do with ATCB

<https://www.healthit.gov/condition-ccg/attestations>

A health IT developer must attest, as applicable, to compliance with the Conditions and Maintenance of Certification related to:

- (1) Information Blocking,
- (2) Assurances,
- (3) Communications,
- (4) API, and
- (5) Real World Testing

APPLICATION PROGRAMMING INTERFACES (APIs)

DHIT Strategic Partnership:

Our [Dynamic FHIR API](#) is certified for 2015 Edition Cures Update 170.315(g)(7-9) criteria. We've upgraded to FHIR R4.0.1 as mandated by CMS Final Rule. If you can supply a version 2.1 C-CDA with USCDIV1 data or use ours, no additional development is needed. Flexible hosting and deployment complement our "FHIR on the Fly" strategy of consuming data from a C-CDA.

Effective Date:

Rollout of (g)(10)-Certified APIs by December 31, 2022 and

Compliance to API CoC for existing certified API technology by April 5, 2021.

<https://www.healthit.gov/condition-ccg/application-programming-interfaces>

A health IT developer of a Health IT Module that meets the requirements outlined in the Condition of Certification must comply with the following requirements:

- Authenticity verification and registration for production use,
- Service Base Uniform Resource Locator (URL) publication,

Please see our [Dynamic FHIR API documentation here](#) for full details.

REAL WORLD TESTING

DHIT Strategic Partnership:

DHIT provides Real World Test (RWT) plans for all applicable criteria we've certified. DHIT's Real World Testing consulting division provides test plans and testing services for Health IT Modules certified to § 170.315(b), (c)(1) through (3), (e)(1), (f), (g)(7) through (10), and (h). We test the real world use of technology for interoperability in the settings where your technology is marketed. Plus, we offer tiered service subscriptions for developing complimentary test plans, submitting plans and reporting RWT results to your ONC-ACB.

Effective Dates: Submit initial plan by December 15, 2021 and initial results by March 15, 2023.

<https://www.healthit.gov/condition-ccg/real-world-testing>

A health IT developer with Health IT Module(s) certified to § 170.315(b), (c)(1) through (3), (e)(1), (f), (g)(7) through (10), and (h) must successfully test the real world use of the technology for interoperability in the type of setting in which such technology would be marketed.