CURES ACT FINAL RULE

Application Programming Interfaces (APIs) Conditions and Maintenance of Certification

The 21st Century Cures Act (Section 4002) requires the Secretary of HHS to establish Conditions and Maintenance of Certification requirements for health IT developers participating in the ONC Health IT Certification Program.

API Conditions of Certification Requirements

ONC has established specific API Conditions of Certification that address the practices developers of certified health IT may engage in with respect to certified API technology. Per the 21st Century Cures Act, the API Conditions of Certification seek to minimize the "special effort" necessary to access, exchange, and use electronic health information via certified API technology. Notably, the API Conditions of Certification only apply to developer practices associated with certified API technology and do not generally apply to other software interfaces.

Scope of Electronic Health Information for Certified API Technology

The United States Core Data for Interoperability standard (USCDI) is the scope of patients' electronic health information that must be supported via certified API technology.

Key Definitions:

- **API Information Source:** Health care organization that deploys certified API technology

- **Certified API Technology:** Capabilities of health IT that fulfill any of the API-focused certification criteria adopted in § 170.315(g)(7) through (10) in the ONC 2015 Edition Certification Criteria

- **API User:** Persons and entities that create or use software applications that interact with "certified API technology"

- **Certified API Developer:** Health IT developer that creates the "certified API technology"

Transparency Conditions

Fees Conditions

Openness and Pro-Competitive Conditions

API Conditions of Certification

API Maintenance of Certification Requirements

What **DOCUMENTATION** *is required from certified API developers?*
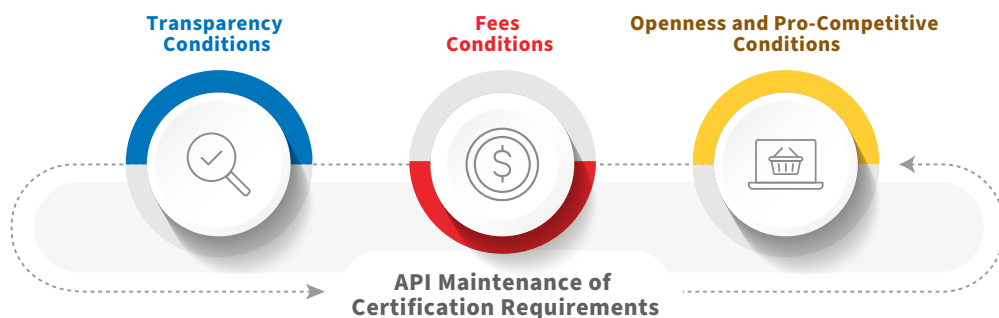
Transparency Conditions:

This condition requires Certified API Developers to publish specific business and technical documentation necessary to interact with their certified API technology and make such documentation publicly accessible via a hyperlink.

The Office of the National Coordinator for Health Information Technology

Permitted Fees Conditions:

With respect to certified API technology, this condition sets criteria for allowable fees, guidelines for the fees certified API developers would be permitted to charge, and to whom those fees could be charged.

- Certified API Developers are permitted to charge fees to API Information Sources for the development, deployment, and upgrade of their certified API technology, and towards recovering API usage costs (if applicable).
- Certified API Developers are also permitted to charge API Users for value-added services related to certified API technology, so long as such services are not necessary to efficiently and effectively develop and deploy production-ready software that interacts with certified API technology.

In general, any fees not permitted by this condition are prohibited from being imposed by certified API developers with respect to their certified API technology.

*What **FEES** related to certified API technology are allowed?*

Openness and Pro-Competitive Conditions:

These conditions establish practices that certified API developers must follow to enable an open and competitive marketplace.

- In general, Certified API Developers must grant API Information Sources (i.e., health care organizations) the independent ability to permit API Users to interact with the certified API technology deployed by the API Information Source.

*What are the requirements of Certified API Developers to promote Open and Competitive **MARKETPLACE?***

- There are additional specific requirements for Certified API Developers related to ensuring that the terms associated with certified API technology are non-discriminatory, that the API Information Source and API Users are provided with the necessary rights to access and use the certified API technology, and certain prohibited conduct is expressed for Certified API Developers to ensure open and competitive environment.
- Additionally, Certified API Developers need to adhere to specific service and support obligations in order to enable the effective use of certified API technology by API Information Sources and API Users.

API Maintenance of Certification Requirements

The API Maintenance of Certification requirements address ongoing requirements that must be met by Certified API Developers in order to remain in good standing under the ONC Health IT Certification Program.

Compliance Responsibilities:

- A Certified API Developer with API technology certified to the certification criteria in § 170.315(g)(7), (8), or (9) must comply with the API Conditions of Certification within six months of the Cures Act Final Rule's publication date.
- A Certified API Developer with certified API technology previously certified to the certification criterion in § 170.315(g)(8) must provide all API Information Sources API technology certified to the certification criterion in § 170.315(g)(10) by no later than 24 months from the Cures Act Final Rule's publication date.

Ongoing Practices:

- Certified API Developers for the purposes of API technology certified to § 170.315(g)(10) may put in place processes to verify the authenticity of the API Users for the purposes of app registration and, if they do, they must follow certain rules.
- Certified API Developers must publish the service base URLs (i.e., FHIR endpoints) for all Health IT Modules certified to § 170.315(g)(10) that can be used by patients to access their electronic health information.