The Office of the National Coordinator for
Health Information Technology

21ST CENTURY CURES ACT:
INTEROPERABILITY, INFORMATION BLOCKING, AND
THE ONC HEALTH IT CERTIFICATION PROGRAM PROPOSED RULE

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 the ONC Health IT Certification Program

ONC proposes an approach whereby the Conditions and Maintenance of Certification express initial requirements and ongoing requirements for health IT developers and their certified Health IT Module(s). Any noncompliance with the proposed Conditions and Maintenance of Certification requirements would be subject to ONC direct review, corrective action, and enforcement procedures under the ONC Health IT Certification Program.

There are seven Conditions of Certification with accompanying Maintenance of Certification Requirements. They are:

1. **Information Blocking**
2. **Assurances**
3. **Communications**
4. **Application Programming Interfaces (APIs)**
5. **Real World Testing**
6. **Attestations**
7. *(Future) Electronic Health Record (EHR) Reporting Criteria Submission*

1. Information Blocking

CONDITION OF CERTIFICATION
- A health IT developer must not take any action that constitutes information blocking as defined in section 3022(a) of the PHSA and § 171.103.

MAINTENANCE OF CERTIFICATION
No accompanying Maintenance of Certification requirements beyond ongoing compliance with the Condition.

2. Assurances

CONDITION OF CERTIFICATION
- A health IT developer must provide assurances to the Secretary (unless for reasonable and necessary activities identified by the Secretary) that it will not take any action that constitutes information blocking or any other action that may inhibit the appropriate exchange, access, and use of electronic health information (EHI)

a. Full Compliance and Unrestricted Implementation of Certification Criteria Capabilities

- A health IT developer must ensure that its certified health IT conforms to the full scope of the applicable certification criteria
- Developers of certified health IT must provide assurance that they have made certified capabilities available in ways that enable them to be implemented and used in production environments for their intended purposes

b. Certification to the "Electronic Health Information (EHI) Export" Criterion

A health IT developer that produces and electronically manages EHI must certify health IT to the 2015 Edition "electronic health information (EHI) export" certification criterion in § 170.315(b)(10)

MAINTENANCE OF CERTIFICATION
- Such developer must provide all of its customers with certified health IT with the functionality included in § 170.315(b)(10) within 24 months of the final rule's effective date or within 12 months of certification for a health IT developer that never previously certified health IT to the 2015 Edition, whichever is longer

c. Records and Information Retention

MAINTENANCE OF CERTIFICATION
- Health IT developers would have to retain records and information necessary to demonstrate ongoing compliance

d. Trusted Exchange Framework and the Common Agreement - *Request for Comment*

- ONC is requesting comment as to whether certain health IT developers should be required to participate in the Trusted Exchange Framework and adhere to the Common Agreement
- This requirement would apply to health IT developers that certify to capabilities used for interoperability (i.e., §§ 170.315(b)(1), (c)(1) and (c)(2), (e)(1), (f), and (g)(9) through (11))

3. Communications (Gag Clauses)

CONDITIONS OF CERTIFICATION

- Requires that a health IT developer does not prohibit or restrict communication regarding the following subjects for the health IT:

  - Usability
  - Interoperability
  - Security
  - User experiences
  - Business practices
  - The manner in which a user of health IT has used such technology

- The Condition includes very limited exceptions to the prohibition (e.g., certain prohibitions and restrictions on communications by the health IT developer could be permissible when it would infringe upon the intellectual property rights existing in the developer's health IT)

MAINTENANCE OF CERTIFICATION

- A health IT developer must notify all customers within six months of the effective date of a subsequent final rule, that any communication or contract/agreement provision that violates the Communications Condition of Certification will not be enforced by the health IT developer
- Notice to customers would need to be provided annually up to and until the health IT developer amends the contract or agreement to remove or void any contractual provisions that violate this Condition of Certification
  - Developer must amend their contracts or agreements within a reasonable period of time, but not to exceed two years

4. Application Programming Interfaces (APIs)

CONDITIONS OF CERTIFICATION

- Requires health IT developers to publish APIs and allow health information from such technology to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law
  - Through the APIs, a developer must also provide access to all data elements (i.e., the United States Core Data for Interoperability (USCDI)) of a patient's EHR to the extent permissible under applicable privacy laws
- An API Technology Supplier must make business and technical documentation necessary to interact with their APIs in production freely and publicly accessible
- All fees related to API Technology, not otherwise permitted, are prohibited from being imposed by an API Technology Supplier.
- API Technology Suppliers must grant API Data Providers (i.e., health care providers who purchase or license API technology) the sole authority and autonomy to permit API Users to interact with the API technology

MAINTENANCE OF CERTIFICATION

- An API Technology Supplier must register and enable all applications for production use within one business day of completing its verification of an applications developer's authenticity
- An API Technology Supplier must Support the publication of "Service Base URLs" (i.e., FHIR® server endpoints) for all of its customers, regardless of those that are centrally managed by the API Technology Supplier or locally deployed by an API Data Provider, and make such information publicly available at no charge

API TECHNOLOGY ROLES

API Technology Supplier
Health IT developer that creates API technology presented for certification in the ONC Health IT Certification Program

API Data Provider
Health care organization that deploys the API technology

API User
Persons and entities that use or create software applications that interact with API technology

5. Real World Testing

CONDITIONS OF CERTIFICATION

- Requires that health IT developers have successfully tested the real-world use of the technology for interoperability in the type of setting in which such technology would be marketed
- This Condition of Certification applies to health IT developers with Health IT Module(s) certified to certain certification criteria focused on interoperability and data exchange (i.e., §§ 170.315(b), (c)(1) through (c)(3), (e)(1), (f), (g)(7) through (g)(11), and (h))

MAINTENANCE OF CERTIFICATION

- Health IT developers must submit publicly available prospective annual real world testing plans and retrospective annual real world testing results for certified health IT products focused on interoperability
- Standards Version Advancement Process: permits health IT developers to voluntarily use newer versions of adopted standards. Please also see the Standards Version Advancement Process fact sheet for more details.

6. Attestations

CONDITION OF CERTIFICATION

- A health IT developer must provide an attestation, as applicable, to compliance with the Conditions and Maintenance of Certification, except for the "EHR reporting criteria submission" Condition of Certification
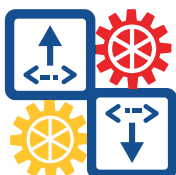
MAINTENANCE OF CERTIFICATION

- Health IT developers must submit their attestations every six months

7. (Future) EHR Reporting Criteria Submission

- The Cures Act specifies that health IT developers be required, as a Condition and Maintenance of Certification under the ONC Health IT Certification Program, to submit reporting criteria on certified health IT in accordance with the EHR reporting program established under section 3009A of the PHSA, as added by the Cures Act

- We have **not** yet established an EHR reporting program. Therefore, we have **not** proposed an associated regulatory Condition and Maintenance of Certification requirement. Once ONC establishes an EHR reporting program, we will undertake rulemaking to propose and implement the associated Condition and Maintenance of Certification requirement(s) for health IT developers