



The Office of the National Coordinator for  
Health Information Technology  
Health IT Advisory Committee

# Conditions and Maintenance of Certification Requirements Task Force

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# Agenda

- Call to Order/Roll Call
- Discussion of Outstanding Recommendations
- Public Comment
- Next Steps and Adjourn

# Discussion of Outstanding Recommendations

# Real World Testing

- **Recommendation 8**: The CMC TF recommends ONC provide clarification in the final rule preamble in section VII.B.5 around testing the use of information received through exchange versus testing the exchange of information (sending and receiving). When there are no end users of the health IT product being tested, use-based testing would not be pertinent.

The TF recommends ONC expect that if health IT developers are testing the use of data received through exchange, the health IT vendors should have intended users involved in usability testing.

Users (providers) were not considered in the cost estimates for real world testing in the proposed rule preamble. Therefore, the TF recommends ONC revise real world testing cost estimates in the final rule preamble section XIV.C.2.a.3.6 to incorporate this.

To reduce cost, the TF further recommends ONC prioritize real world testing criteria based on risk.

# Real World Testing

- **Recommendation 12:** The CMC TF recommends ONC elaborate and provide more clarity in the final rule preamble section VII.B.5 on the standards version advancement process when a version of standards is available under this process but does not yet have testing tools available to determine conformance. It is fairly clear vendors must factor all claimed versions of standards into their real world testing, but the final rule preamble should clarify how the health IT developers are to address new versions for which tooling does not exist yet that they have attested to support and how the health IT developer and ONC-ACBs will judge or determine conformance. The TF further recommends ONC clarify whether testing will be required in a subsequent year's real world testing plan once tooling is available or whether the health IT developer's previous attestation is sufficient.

# Real World Testing

- **Recommendation 13**: The CMC TF recommends ONC clarify in the final rule preamble the role and expectations of third parties over which the health IT developers have no control or authority over. For example, some third parties (immunization registries) and EHR developers are likely to receive many requests to participate in other parties' real world testing. While these entities can try to be helpful, they will have limited resources to assist other groups. The TF further recommends ONC clarify whether declining to participate in real world testing is considered to be information blocking. The TF recommends ONC consider and clarify in the final rule preamble how reasonable protections can be provided for those who have limited resources and, therefore, are unable to participate in an unlimited set of tests. The final rule preamble should provide reasonable assurances for health IT developers who have tried to engage third parties in testing yet were not successful in getting their commitment to participate.

# Application Programming Interfaces

- **Recommendation 22**: The CMC TF has concerns over ONC not proposing a standard way for a request for multiple patients' data and recommends ONC specify a standard approach that will be available in FHIR R4. Otherwise, each developer could implement this differently and invest time in non-standard ways and then likely have to spend time/money transitioning to the standard way. The CMC TF also recognized that there is an immediate need now to satisfy this type of request. If ONC identifies FHIR R4 for implementation in the final rule, the FHIR R4 standard could be used for bulk queries but on a different timeline than implementation of more established R4 implementation guides that support a search for a single patient's data. The TF would like to see successful implementations of products that search for multiple patients using the FHIR R4 standard prior to requiring adoption across the industry of this 2015 Edition certification criterion for multiple patients.

# Applicability of Conditions and Maintenance of Certification Requirements for Self-Developers

- **Recommendation 25 [Placeholder]**: The CMC TF will be advancing a recommendation to the HITAC for consideration at the May 13 HITAC meeting regarding the applicability of the Conditions and Maintenance of Certification requirements for real world testing, APIs, and attestations to self-developers and their certified Health IT Modules. The TF is still deliberating on this recommendation and has not come to consensus yet.



To make a comment please call:

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**“Public Comment”** field below this presentation.

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*Written comments will not be read at this time, but they will be delivered to members of the Workgroup and made part of the Public Record.*



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## Meeting Adjourned

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