

RELIED UPON SOFTWARE

PROGRAM GUIDANCE #17-01-A

Issued and Effective Date: June 30, 2020
(Updated Date: December 5, 2024)

RELIED UPON SOFTWARE OVERVIEW

Health information technology (health IT) developers are permitted to use “relied upon software” [76 FR 1276] to demonstrate compliance with certification criteria adopted at 45 CFR Part 170, Subpart C. These certification criteria are those that are tested and certified as part of the ONC Health IT Certification Program (Certification Program).

Relied upon software is typically third-party software not developed by the Certified Health IT developer presenting its health IT for testing and certification. Relied upon software may be used to demonstrate compliance with a portion of an adopted certification criterion or an entire certification criterion. To be clear, a developer must present its own health IT for certification but may also use other software (“relied upon software”) to meet certification requirements. When a health IT developer relies upon third-party software to demonstrate compliance with a certification criterion, such relied upon software must be included in the scope of the certification issued to the Health IT Module (hereafter “health IT” or “certified health IT”).

ONC-Authorized Certification Bodies (ONC-ACBs) are required to report to the Certified Health IT Product List (CHPL) any relied upon software the certified health IT used to comply with part or all of a criterion. Certified health IT must be implemented with the relied upon software used to meet certification requirements in order for its certification to remain valid and a health IT developer always remains responsible for its product’s conformance even when relied upon software was used. Thus, if the relied upon software the Certified Health IT developer implemented with its certified health IT is found nonconforming or causes or contributes to a non-conformity in the certified health IT, the certified health IT would be subject to corrective action.

In general, ONC-Authorized Testing Laboratories (ONC-ATLs) and ONC-ACBs are required to capture (for their records) the name and version of the relied upon software used during testing and certification. ONC-ACBs are only expected to report to the CHPL the relied upon software’s name unless a Certified Health IT developer indicates that the specific version presented is the only known (at that time) version of the relied upon software that will maintain its product’s conformance. In these limited instances, the CHPL listing is expected to include the relied upon software’s name and version. Though as a general rule, any version of relied upon software is, in practice, permitted to be used so long as the health IT remains conformant to the criteria to which it was certified. Lastly, any limitations and types of costs/fees associated with the purchase and/or use of the relied upon software must be disclosed pursuant to 45 CFR 170.523(k)(1).

Software Considered as “Relied Upon Software”

If health IT presented for testing needs to use additional software (in whole or in part) to demonstrate it can perform the capabilities specified by a certification criterion, then the additional software used is considered “relied upon software” for the purposes of certification and must be disclosed. This kind of software could be a different suite of software by the specific health IT developer or a third-party software and can include software that integrates with the health IT and operating systems.

The following represent four examples where additional software would be considered “relied upon software” in the context of the Certification Program:

- If Developer A presented a Health IT Module for certification to the “Drug-drug, drug-allergy interaction checks for CPOE” certification criterion (45 CFR 170.315 (a)(4)) and integrated a third-party’s best-of-breed interaction checking software to perform the capabilities required by the certification criterion, the third-party’s software would be considered “relied upon software.”
- If Developer B presented a Health IT Module for certification (via Approach one of the privacy and security certification framework) to the “Automatic access timeout” certification criterion (45 CFR 170.315 (d)(5)) and, instead of building this feature into the Health IT Module, relied upon an operating system’s security functions to perform this capability, then the operating system would be considered “relied upon software” for the purposes of demonstrating compliance with this criterion (see also 76 FR 1277).
- If Developer C presented a Health IT Module for testing and certification to the “View, download, and transmit to third party” certification criterion (45 CFR 170.315 (e)(1)) and relied upon another system to create a Consolidated Clinical Document Architecture (C-CDA) document formatted in accordance with the Continuity of Care Document (CCD) document template, the system creating the C-CDA document would be considered “relied upon software” for the purposes of demonstrating compliance with this criterion.
- If Developer D uses a Health IT Module certified to the “Standardized API for patient and population services” criterion (45 CFR 170.315(g)(10)) as “relied upon software” as part of creating another Health IT Module to certify to § 170.315(g)(10), then Developer D’s Health IT Module must undergo certification testing to be certified to § 170.315(g)(10). The certification testing in this context occurs regardless of if Developer D chooses to use the authorization server of the “relied upon software” or their own authorization server.

Software Not Considered “Relied Upon Software”

If health IT must connect to or use additional software (or service) as part of testing in order to demonstrate that it can perform the capabilities specified by a certification criterion, but the additional software (or services) does not perform any capabilities specified by a certification criterion, then the additional software (or service) is not considered “relied upon software.” ONC-ATLs would still note the software used in testing as part of their documentation, but since the additional software (or service) is not necessary to perform the capabilities specified by a certification criterion, it would not be listed on the certificate by an ONC-ACB or disclosed as part of the CHPL listing as “relied upon software.” The following represents two examples where additional software (or services) would not be considered “relied upon software” in the context of the Certification Program:

- Developer A presents a Health IT Module for testing and certification to the “Electronic prescribing” certification criterion (45 CFR § 170.315(b)(3)) and demonstrates the capabilities for each of the transactions specified in the certification criterion. The certification criterion is agnostic to the method/network through which these e-prescribing transactions are routed and is specifically focused on a Health IT Module’s ability to perform the standards-conformant transactions. Thus, an electronic prescribing network used during testing or typically associated with the Health IT Module when implemented would not be considered “relied upon software.” Such an electronic prescribing network would not be performing any of the capabilities specified by the criterion and could be substituted with another network or method without impacting any of Health IT Module’s conformant capabilities.

Certification Requirements for Using Multiple Relied Upon Software Products

In cases where a Health IT Module may be paired with multiple “relied upon software” products for the same capability, it must be tested with at least one such product to demonstrate compliance with a certification criterion’s requirements. Afterwards, the Certified Health IT developer is permitted to list all additional “relied upon software” products for the same capability paired with the Certified Health IT Module without having to test with the ONC-ATL to each one. Each “relied upon software” is listed on the CHPL. A Certified Health IT developer always remains responsible for its product’s conformance to a criterion even when the “relied upon software” contributes to, or is the cause of, a non-conformity.

Real World Testing Requirements for “Relied Upon Software”

Any developers that are certified to one or more criterion(a) eligible for Real World Testing, and use “relied upon software” for those criterion(a), must account for the use of “relied upon software” in the design of their Real World Testing plans and results reports. For more information on these requirements, please review the [Real World Testing Resource Guide](#).

Version History

Term	Definition	Date Published
1.0	Initial Publication	May 4, 2017
2.0	Revised to include a third example of “relied upon software” for the 2015 Edition “view, download, and transmit” certification criterion and provided additional guidance about testing and certification when Health IT Modules seek to use more than one “relied upon software” product for the same capability	August 21, 2017
3.0	Revised to remove reference to a criterion removed by the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule	June 30, 2020
4.0	Revised to remove reference to editions and expired criterion, and add language related to Real World Testing requirements.	December 5, 2024