

RELIED UPON SOFTWARE

Program Guidance #17-01-B

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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 Office of the National Coordinator for Health Information Technology (ONC) Health IT Certification Program.

Relied upon software is typically 3rd party software that is not developed by the 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 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 or Complete EHR (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 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 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 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 will be 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).

When is software used as part of testing considered “relied upon software” for the purposes of certification?

If health IT presented for testing needs to use additional software (in whole or in part) to demonstrate that 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 3rd party and can include software that integrates with the health IT and operating systems.

The following represent three examples where additional software **would be** considered “relied upon software” in the context of the ONC Health IT Certification Program (Program):

- If Developer A presented a Health IT Module for testing and certification to the 2015 Edition “drug-drug, drug-allergy interaction checks for CPOE” certification criterion (45 CFR 170.315(a)(4)) and integrated a 3rd party’s best-of-breed interaction checking software to perform the capabilities required by the certification criterion, the 3rd party’s software would be considered “relied upon software.”
- If Developer B presented a Health IT Module for testing and certification (via approach one of the security and privacy certification framework) to the 2015 Edition “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 2015 Edition “view, download, and transmit to 3rd 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.

When is software used as part of testing **NOT** considered relied upon software for the purposes of certification?

If health IT must connect to/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) **do 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 Program:

- Developer A presents a Health IT Module for testing and certification to the 2015 Edition “clinical decision support” certification criterion (45 CFR 170.315(a)(9)). In order to demonstrate the capabilities associated with (a)(9)(iv), (i.e., conformance with the HL7 V3 Context Aware Knowledge Retrieval Application (“Infobutton”) standard) the developer uses the freely and readily available MedlinePlus Connect to show that its Health IT Module can connect to and receive data from this Infobutton-enabled source using the required standard. MedlinePlus Connect would **not** be considered “relied upon software” because MedlinePlus Connect does not perform the capabilities specified by the criterion. Rather, it is used during testing as a

means to demonstrate that those capabilities have been met and could be substituted with a different service without impacting any of the Health IT Module's conformant capabilities.

- Developer B presents a Health IT Module for testing and certification to the 2015 Edition "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.

What is required for testing and certification when a Health IT Module seeks to use more than one similar "relied upon software" product to demonstrate compliance with the same capability (i.e., part of a certification criterion or entire certification criterion)?

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 Health IT Module 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" will be listed on the CHPL. A 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.