Applicability of Inherited Certified Status
Program Guidance #16-01-A
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Inherited certified status (ICS) is an approach for the testing and certification of health IT under the ONC Health IT Certification Program (Program). ICS may provide efficiencies and reduce the costs of testing and certification by permitting ONC-Authorized Certification Bodies (ONC-ACBs) to consider the reuse of prior test results for a new certification request.

ICS for health IT:

(1) Applies to newer versions of previously certified health IT;
(2) Is available only within an edition (e.g., within the 2015 Edition and any subsequent releases); and
(3) Requires no further testing of the certified capabilities included in the previously certified health IT if the ONC-ACB determines that they have not been adversely affected.

ICS is only available within the same edition, including newer versions of the certification criteria. This means that all previously certified criteria within an edition and its releases are eligible for ICS. However, if the product has undergone changes or modifications since its initial certification that adversely impact the certified capabilities, it will not be eligible, and the decision to grant ICS is at the ONC-ACB's discretion. ONC-ACBs have procedures in place, consistent with ONC-issued guidance, for processing ICS requests. It is up to the ONC-ACB to determine whether the capabilities for which certification criteria have been adopted have not been adversely affected.

ICS Process

The ICS process is meant to streamline the certification process and reduce the burden on Certified Health IT Developers of additional testing or action to prove conformity by seeking certification to a newer version of an already certified Health IT Module. It permits ONC-ACBs to grant certified status to a newer version of previously certified health IT by using the previously issued certificate's scope as the basis for the new certificate.

When submitting an ICS request, the health IT developer must describe why the newer version does not adversely affect any certified capabilities. Similarly, upon receipt of an ICS request, an ONC–ACB must review the attestation to determine (in its judgment) whether the modifications described could have adversely affected any certified capabilities (and that retesting may be necessary) or whether to issue a certification to the newer version of the previously certified Health IT Module. ONC-ACBs must consider a health IT developer's request for ICS. However, the granting of ICS is at the discretion of ONC-ACBs (45 CFR 170.545(d) and 170.550(k); *see also* 76 FR 1306).

Examples

- A health IT developer could request ICS for a newer version of a Health IT Module certified to the "CPOE - medications" (§ 170.315(a)(1)),) "Clinical Decision Support" ("CDS") (§ 170.315(a)(9)), "Electronic Prescribing" (§ 170.315(b)(3)), "Automated Measure Calculation" ("AMC") (§ 170.315(g)(2)), "Safety-Enhanced Design" ("SED") (§ 170.315(g)(3)), and "Quality Management System" ("QMS") (§ 170.315(g)(4)) certification criteria. In this scenario, the health IT developer may have added new uncertified capabilities to the newer version and/or made improvements to the interfaces. If the ONC-ACB determines that the certified capabilities were not adversely

affected by these changes, the ONC-ACB may grant ICS to the newer version without re-testing of the previously certified capabilities.

- A health IT developer could request ICS for a newer version of a Health IT Module previously certified to the "CPOE – Medications" (§ 170.315(a)(1)), "CDS" (§ 170.315(a)(9)), "AMC" (§ 170.315(g)(2)), "SED" (§ 170.315(g)(3)), "QMS" (§ 170.315(g)(4)), and "Accessibility-Centered Design" (§ 170.315(g)(5)) certification criteria. This request could also include a request for certification to a new certification criterion as part of the newer version. In this scenario, the Health IT Module would not need to be re-tested against the above-mentioned certification criteria if the ONC-ACB determines that the certified capabilities were not adversely affected. However, the ONC-ACB would need to use new test results for any new certification criteria added to the Health IT Module.

ICS Requests and Surveillance

ONC-ACBs have a responsibility to conduct surveillance on Certified Health IT for repeated ICS requests. As outlined in the ONC-ACB Surveillance Resource, developers that request ICS three or more times on a Health IT Module will be subject to ONC-ACB surveillance.. To clarify, if a health IT developer requests ICS for a Health IT Module three times, subsequent to the initial certification, there is no obligation for an ONC-ACB to conduct surveillance on that product. However, if the developer submits a fourth request for ICS for the same Health IT Module, the ONC-ACB is required to conduct surveillance on that product. The specific approach to conducting surveillance on a product associated with multiple ICS requests is at the discretion of the ONC-ACB. However, the ONC-ACB is responsible for ensuring that the product maintains its conformity to certification requirements and standards. To that end, ONC-ACBs may choose to conduct various types of surveillance activities to assess conformity, such as testing, documentation review, and site visits, among others, to determine if the certification still adheres to the Certification Program requirements.