

APPLICABILITY OF INHERITED CERTIFIED STATUS AND GAP CERTIFICATION

Program Guidance #16-01-A

Issued and Effective Date: November 2, 2016

Revised and Updated: June 30, 2020

SUMMARY

Gap certification and inherited certified status (ICS) are two approaches for the testing and certification of health IT under the ONC Health IT Certification Program (Program). With the retirement of the 2014 Edition, Gap certification is not currently available within the Program. However, ICS may provide efficiencies and reduce the costs of testing and certification by permitting ONC-Authorized Certification Bodies (ONC-ACBs) to consider 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) 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.

The ICS process is meant to expedite the reissuance of a certification to a newer version of an already certified Health IT Module. 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).

ICS

- Only WITHIN the same edition, including its releases.
- 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.
- The ONC-ACB must determine that the capabilities for which certification criteria have been adopted have not been adversely affected.
- All previously certified criteria within an edition and its releases are eligible.
- Granting ICS is at the ONC-ACB's discretion.
- Must be consistent with any ONC-issued guidance.

EXAMPLES¹

ICS

- A health IT developer could request ICS for a newer version of a Health IT Module certified to the 2014 Edition "CPOE" (§ 170.314(a)(1)), "Medication List" (§ 170.314(a)(6)), "Clinical Decision Support" ("CDS") (§ 170.314(a)(8)), "Electronic Prescribing" (§ 170.314(b)(3)), "Automated Measure Calculation" ("AMC") (§ 170.314(g)(2)), "Safety-Enhanced Design" ("SED") (§ 170.314(g)(3)), and "Quality Management System" ("QMS") (§ 170.314(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 2015 Edition "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 2015 Edition 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 2015 Edition certification criteria added to the Health IT Module, unless those new criteria are eligible for gap certification (see gap certification guidance above).

Gap certification of health IT:

NOTE: As of June 30, 2020, with the retirement of the 2014 edition certification criteria, there are no available editions eligible for gap certification.

- (1) Applied to previously certified health IT;
- (2) Was available for certification criteria that were adopted through rulemaking at different points in time (i.e., between editions or between releases of editions); and
- (3) Required no further testing for “unchanged” certification criteria.

[45 CFR 170.502; *see also* 76 FR 1307-1308, 80 FR 62608-62609, and 81 FR 72446]

The option to provide and grant gap certification was at the discretion of ONC-ACBs (76 FR 1308).

We identified the 2015 Edition health IT certification criteria (“unchanged” certification criteria) that were eligible for gap certification in Table 6 of the 2015 Edition final rule (80 FR 62602), which can also be found [here](#).

Gap certification was permitted based on the use of test results from a 2011 or 2014 Edition certification. We expected, however, that an ONC-ACB would have considered the temporal nature of test results and other relevant changes in the health IT brought forward for gap certification when determining whether to grant gap certification (*see* 81 FR 72447).

Gap Certification Examples

- A Health IT Module certified to the 2014 Edition “Computerized Provider Order Entry” (“CPOE”) certification criterion (§ 170.314(a)(1)), among other certification criteria, could have been presented for gap certification to the 2014 Edition “CPOE – Medications” certification criterion (§ 170.314(a)(18)), which was part of the 2014 Edition Release 2.
- A Health IT Module certified to the 2014 Edition CPOE certification criterion (§ 170.314(a)(1)) or the 2014 Edition “CPOE – Medications” certification criterion (§ 170.314(a)(18)), among other certification criteria, could have been presented for gap certification to the 2015 Edition “CPOE – Medications” certification criterion (§ 170.315(a)(1)).

¹ Examples include certification criteria from retired editions (i.e. 2014 edition).