

2015 Edition Final Rule: Advancing Patient Safety

Rule Reference: 2015 Edition Health Information Technology (Health IT) Certification Criteria, Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications Final Rule (The “2015 Edition”)

The [2015 Edition final rule](#), published by the Office of the National Coordinator for Health Information Technology (ONC), updates the [ONC Health IT Certification Program](#) and finalizes health IT certification criteria to continue to support the [Medicare and Medicaid EHR Incentive Programs](#) and to make the program more open and accessible to other types of health IT and settings—such as long-term and post-acute care (LTPAC), behavioral health, and pediatric settings.

The 2015 Edition final rule includes provisions that continue our commitment to addressing safety-related usability and enhancing safety-related requirements for certified health IT. The final rule includes:

- **Safety-focused Usability:** Increases safety-enhanced design requirements for health IT through:
 - Pairing more health IT capabilities—those that pose the greatest opportunity for error prevention—to certification for safety-enhanced design.
 - Providing precise requirements for the submission of comprehensive data about health IT design processes and usability testing results, which enables ONC and partners to better analyze and address patient safety and usability functionality issues.
 - Setting a minimum threshold of no less than 10 test participants for summative usability testing, which will make it significantly more likely that developers will be able to identify and remedy design flaws.
- **Quality Management System:** Requires developers to identify the quality management system (QMS) used in the development, testing, implementation, and maintenance of certified capabilities (e.g., computerized provider order entry (CPOE), drug-drug, drug-allergy interaction checks for CPOE, and clinical decision support). The QMS identified by the developer must be consistent with federal QMS standards or QMS standards developed by standards developing organizations.



- **Additional and More Precise Patient Information:** Includes new patient-matching criteria to help ensure that accurate and precise patient data is available for information exchange. In addition, the rule requires that health IT be able to record, access, and exchange the Unique Device Identifiers of patients' implantable devices in a standardized way—which will facilitate access for providers across the patient's care continuum to the implantable device information and allow providers to consider more information about the patient when making care decisions.

The final rule builds on the recommendations of an [Institute of Medicine \(IOM\) report](#) on patient safety and the [2014 Edition's safety-enhanced design and quality management system certification criteria](#).

We encourage stakeholders to review the final rule for a full discussion of the provisions related to patient safety and to determine the criteria that best suit their needs.
