

**Health IT Implementation, Usability, and Safety (IUS) Workgroup**

**Certification NPRM Comment Template (Group #3)**

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**IUS Group 3 Assignment:**

***Broadening the Scope of the Certification Program beyond the EHR Incentive Program:***

* Subpart E – ONC Health IT Certification Program - 250
* The ONC Health IT Certification Program and Health IT Module - 12
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***Specific Certification Program Elements***

* “Removal” of Meaningful Use Measurement Certification Requirements - 253
* Base EHR Definition and Certified EHR Technology Definition - 8, 240
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* Design and Performance (§ 170.315(g)) – 261 *(needs full IUS WG input)*

**IUS Group 3 Overarching Comments:**

The approach outlined in the NPRM creates a Certification Program with significantly broader scope and applicability across the healthcare eco-system to be inclusive of any stakeholder that sends and receives health information. While the EHR Incentive Program targeted specific professionals and providers, the Affordable Care Act and goals of healthcare reform requires the broader healthcare community to use and exchange electronic health information to reduce care fragmentation and improve coordination. We see potential for the modular approach to health IT certification described in the NPRM to engage a much broader set of stakeholders and set foundational interoperability requirements for sending and receiving electronic health information.

Redesigning the Program into a modular approach provides the flexibility to increase its applicability to the various stakeholders and technologies that must interoperate. We recognize that there is risk inherent to this flexibility. The program will likely be more complex particularly for stakeholders who must address multiple modules and certification requirements from various agencies/regulators/payers. For this reason, the role of ONC as a “coordinator” to facilitate alignment between federal program requirements and related Health IT Modules is critical to mitigate complexity and cost.

We also recognize that this is the next evolutionary step for certification that will include new challenges and/or repercussions:

* A more complex program will likely drive up costs for certification particularly those who certify and test to multiple health IT modules that might be considered a single large system.
* There may be challenges to keeping the modules and their requirements at the foundational (building block) level and not expand their scope unnecessarily.
* Other parties that identify Certification paths and/or require compliance with a Certification module(s) could erode the foundation/building blocks by requiring a module with modifications and add-ons.

"Everything should be made as simple as possible, but not simpler." - Albert Einstein

| **A. Subpart E – ONC Health IT Certification Program Page #250** |
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| We propose to replace the term “HIT” with the term “health IT” wherever it may occur in subpart E. While “HIT” is a term used in the HITECH Act, we believe the term “health IT” offers more clarity than “HIT” for stakeholders. Similarly, we propose to replace the “ONC HIT Certification Program” with “ONC Health IT Certification Program” wherever it may occur in subpart E. In referring to the certification program, the term “health” is capitalized. We also propose to remove § 170.553 “Certification of health information technology other than Complete EHRs and EHR Modules” as we believe this section is no longer relevant based on our proposals for the ONC Health IT Certification Program discussed in more detail below. (Continued on page #251) |
| **Public Comment Field – IUS Group 3:**  The workgroup recognizes that changes are needed to support the Certification Program changes described in the NPRM and has no concerns with the following revisions:  1) Replace the term “HIT” with the term “health IT”,  2) Replace the term “ONC HIT Certification Program” with the term “ONC Health IT Certification Program.”  3) Removal of § 170.553 “Certification of health information technology other than Complete EHRs and EHR Modules” |

| **The ONC Health IT Certification Program and Health IT Module Page #12** |
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| As part of our approach to evolve the ONC Health IT Certification Program, we have replaced prior rulemaking use of “EHR” and “EHR technology” with “health IT.” The term health IT is reflective of the scope of ONC’s authority under the Public Health Service Act (§ 3000(5) as “health information technology” is so defined), and represents a broad range of technology, including EHR technology. It also more properly represents some of the technology, as noted above, that has been previously certified to editions of certification criteria under the ONC Health IT Certification program and may be certified to the proposed 2015 Edition in the future. Similarly, to make the ONC Health IT Certification Program more open and accessible, we propose to rename the EHR Module as “Health IT Module” and will use this term throughout the proposed rule. |
| **Public Comment Field – IUS Group 3:**  We agree with the replacement of the term EHR and EHR Technology with health IT which is more inclusive of a broad range of technologies including EHRs. We see great potential with the approach described in the NPRM to engage a broader set of stakeholders beyond ambulatory and inpatient settings to include others that must also have systems that meet foundational interoperability requirements. We agree that this approach will allow other programs (e.g. HHS, public, private entities, associations) to reference certification requirements and/or certified health IT. However, we are also aware that the expansion of the program and use of health IT modules will likely increase the complexity of the program drive up costs for certification particularly for those vendors who certify to multiple health IT modules that might be considered a single large system.  In addition to the other providers and services identified in this section (HIEs, HISP, LIS, LTPAC providers, Behavioral Health providers), we offer additional examples of providers and services that send and receive health information and may find the Certification requirements/modules described in the NPRM applicable to them:   * Services: Pharmacy information systems, long-term services and support providers (transport, meals, care management services, etc.), ambulance providers, blood banks * Other providers: End-stage Renal Disease Facilities, Free-standing Cancer Hospitals, Visiting Nurse Services, Outpatient Surgical Centers * Devices/Device Makers: Telehealth and monitoring, personal health devices (e.g. bands, watches, monitors), biomedical tech devices (e.g pacemakers) * Health and Wellness: Personal Health Record Systems, Health and Fitness Centers, free-standing Weight-loss Centers   We encourage ONC and HHS agencies to explore the levers/authorities available to them to discourage bad behaviors such as proactive blocking of information sharing where the practice creates a barrier to advancing interoperable exchange. We agree that one of the actions to discourage bad behaviors should include a process to decertify health IT. We also recognize that by doing so, it will create tension and apprehension in the industry that will need to be considered and addressed (e.g. escape clauses if a system is decertified, recognition of the disruption and expense, etc.). To be transparent, ONC should be open about the types of “bad behaviors” that discourage sharing of information to inform the industry.  While decertification of health IT systems could be handled by the ONC-ACB with testing, ONC could also investigate a reporting process. We recommend the reporting process not be limited to vendors but also include providers/services that block sharing or engage in bad behaviors. The process needs to be sensitive enough to detect or differentiate when sharing is blocked/limited due to legitimate factors (e.g. limited by regulation due to sensitive nature of data; limitations in technology and/or standards with data segmentation that doesn’t allow parsing at a granular level thus requiring non-disclosure at a document or record set level). |

| **B. Modifications to the ONC Health IT Certification Program Page #251** |
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| In the Voluntary Edition proposed rule (79 FR 10929-30) we recited our authority and the history of the ONC Health IT Certification Program, including multiple requests for comment and significant feedback on making the program more accessible to health IT beyond EHR technology and health care settings and practices not directly tied to the EHR Incentive Programs. With consideration of stakeholder feedback and our policy goals, we attempted to make the ONC Health IT Certification Program more open and accessible through a proposal in the Voluntary Edition proposed rule (79 FR 10918-20) to create MU and non-MU EHR  Modules. (Continued on page #251) |
| **Public Comment Field – IUS Group 3:**  The workgroup agrees that the ONC Health IT Certification Program should be accessible to health IT beyond EHR technology, and healthcare setting and practices not directly tied to the EHR Incentive Programs. Removing the EHR Module definition and replacing it with a Health IT Module definition is more inclusive and accommodates this shift. The workgroup discussed the need for individual modules to be interoperable with one another and not just stand alone. However, the workgroup recognizes that testing for this is difficult and does not see a practical way to incorporate this into the certification program. |

| **CEHRT Definition Page #10, Page #244** |
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| We propose to remove the Certified EHR Technology (CEHRT) definition from §170.102 for the following reasons. The CEHRT definition has always been defined in a manner that supports the EHR Incentive Programs. As such, the CEHRT definition would more appropriately reside solely within the EHR Incentive Programs regulations. (Continued on page #10) |
| **Public Comment Field – IUS Group 3:**  The workgroup agrees that the ONC Health IT Certification Program should be accessible to health IT beyond EHR technology, and to healthcare setting and practices not directly tied to the EHR Incentive Programs. We agree with the approach that regulatory provisions should be defined by the rulemaking authority for the program. |

| **4. Referencing the ONC Health IT Certification Program Page #256** |
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| Our proposals throughout this proposed rule, including the proposed adoption of various criteria that support functionality for different care and practice settings and the proposals to make the ONC Health IT Certification Program open and accessible to more types of health IT and health IT that supports a variety of care and practice settings, would permit further  referencing and use of certified health IT. (Continued on page #257) |
| **Public Comment Field – IUS Group 3:**  The workgroup agrees that the ONC Health IT Certification Program should be accessible to health IT beyond EHR technology, and to healthcare setting and practices not directly tied to the EHR Incentive Programs. We agree with the approach would permit further referencing and use of certified health IT by other HHS agencies, other public entities, private entities, payers, etc.  We appreciate that the NPRM provides examples of how other regulatory processes would reference the health IT certification program and/or build on the requirements to meet other program needs and objectives. In addition to those listed in the NPRM, we would like to note that the industry has already begun to advance a process that identifies modules consistent with the approach of the NPRM. For example, SAMHSA has required grantees in specific programs to meet specific modules (e.g. e-prescribing). Some states have passed legislation requiring all providers (not just those who are eligible for the EHR Incentive Program) to adopt CEHRT; and New York has established health IT requirements related to their health homes. The Certification Program’s original design created challenges for non-ambulatory and inpatient providers and services from acquiring the relevant certification to show compliance.  While we see the advantages, we are concerned that this approach could open the door for many organizations/programs to set their own rules and possibly conflict with requirements of the base certification. We ask that ONC consider approaches to help ensure alignment and consistency across programs and payers (e.g. HHS agencies, Medicare/Medicaid payers, etc.). For example, ONC could request that CMS encourage state Medicaid programs to align with the base requirements.  We request clarification that the regulatory process in the NPRM to remove the reference to CEHRT will suffice where other laws or regulations reference the specific term “CEHRT” and would not require new rule/regulation development to also change their terminology. |

| **3. Types of Care and Practice Settings Page #254** |
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| As noted above, the HITPC issued recommendations generally supporting certification for a variety of care and practice settings under the ONC Health IT Certification Program, particularly focusing on long-term post-acute care (LTPAC) and behavioral health settings. Consistent with those recommendations, we have made proposals to make the ONC Health IT  Certification Program more agnostic to care and practice settings (e.g., the proposals to revise § 170.300 and “remove” “meaningful use measurement” certification requirements) and we have proposed new “data segmentation” certification criteria (§§ 170.315(b)(7) and (8)) that include capabilities that can support care and practice settings that service patients with sensitive health information, including behavioral health. (Continued on page #254) |
| **Public Comment Field – IUS Group 3:**  With respect to broadening the Health IT Certification Program to include a variety of care and practice settings, we agree with this approach to have one program for all types of settings and services (HIEs, HISP, LTSS, lab and pharmacy information systems) in healthcare rather than a program tied only to meaningful use eligible providers. Establishing a base set of building blocks for all will provide a better foundation for advancing and testing interoperability across the many stakeholders who hold and share health information. We believe this approach also sets a future for the program beyond the end of the EHR Incentive Program.  Establishing new Data Segmentation certification criteria is important for engaging not only the behavioral health setting, but also all settings and services that handle information that is sensitive in nature. We recognize that the standards work completed to date support a narrow use case related to re-disclosure to meet the 42CFR Part 2 Federal Rule and recommend that on-going work be completed to include support increased functionality to limit disclosure/re-disclosure of machine-actionable data (versus read-only, document level limitations).  There are additional certification criteria that would be useful to the settings called out in the NPRM (LTPAC, BH, Pediatrics) including those related to identity matching, bi-directional exchange, advanced directives, telehealth/telemonitoring (including personal health tracking/monitoring devices), and assessments. We encourage ONC and HHS to align federally required assessment instruments for LTPAC and new developments as a result of the IMPACT Act with the certification process. The assessments should be mapped and aligned with existing standards identified by ONC including transport standards. By building all of these required assessments with a common platform, it would allow the documents and/or data elements to be shared with care and service providers, payers, oversight agencies, etc. and provide a foundation for clinical quality measure development.  Specifically related to behavioral health assessments, there is an opportunity to incorporate health IT standards for SAMHSA required assessments and reporting (e.g. NOMS – National Outcome Measurement System). Currently Behavioral Health providers maintain a duplicative process double keying in the assessment data for reporting. If the assessment items were mapped to existing vocabularies and content formats the data could more efficiently be reused for reporting transmitted via appropriate transport standards. Like LTPAC, a certification module for assessments would support the process. |

**2. “Removal” of Meaningful Use Measurement Certification Requirements Page #253**

| We propose to not require ONC-ACBs to certify Health IT Modules to the 2015 Edition “meaningful use measurement” certification criteria (§ 170.315(g)(1) “automated numerator recording” and § 170.315(g)(2) “automated measure calculation”). This is a change from prior certification policy, such as with the certification of technology to the 2014 Edition and the  requirements of § 170.550(f)(1). We believe this will make the ONC Health IT Certification more accessible to the certification of health IT for other purposes beyond the EHR Incentive Programs. (Continued on page #253) |
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| **Public Comment Field – IUS Group 3:**  We agree with the rationale to remove the Meaningful Use Measurement Certification requirement to make the Health IT Certification process more broadly accessible beyond the EHR Incentive Program. This approach will allow the Certification program to provide the building blocks and the minimum technology needs to the broad healthcare community. We request clarification that removing the capability to calculate meaningful use measurement will not create frustration for the Meaningful Use Program providers if they still need to report the calculations as part of program requirements. |

| **Base EHR Definition and Certified EHR Technology Definition Page #8, Page #240** |
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| We propose to adopt a Base EHR definition specific to the 2015 Edition (i.e., a 2015 Edition Base EHR definition) at § 170.102 and rename the current Base EHR definition at §170.102 as the 2014 Edition Base EHR definition. For the proposed 2015 Edition Base EHR definition, it would differ from the 2014 Edition Base EHR definition in the following ways: (Continued on page #8) |
| **Public Comment Field – IUS Group 3:**  We request clarification from ONC how privacy and security requirements are applied in the new approach. It was not clear whether there is a separate module or the requirements were integrated in each module. We request additional information on how privacy and security requirements are integrated.  Regarding the inclusion of smoking status, implantable device list and application access to Common Clinical Data Set, we would like to highlight that the information/data may not be applicable to the expanded list of care settings and service providers targeted with the proposed program modification. ONC should consider separately data creation from the need to receive/handle these types of data elements. The process should not require sharing of a full data set if the data is not relevant to the care provider and/or service provider. It creates a process where the setting/service collects data that is not appropriate and creates an unnecessary burden.  We agree with including the acceptability of using Direct as an option to share information. |

| **Pharmacogenomics Data – Request for Comment Page #236** |
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| Pharmacogenomics data identifies genetic variants in individuals that alter their metabolism or other interactions with medications and can lead to serious adverse events. This information is being included in an increasing number of FDA-approved drug labels. Health IT systems that can capture pharmacogenomics information could be used to increase patient safety and enhance patient outcomes. ( Continued on page #237) |
| **Public Comment Field – IUS Group 3:**  The workgroup encourages a process that highlights priorities but stops short of requiring certification for important issues such as pharmacogenomics where there is a lack of foundational standards for a certification program. This early prioritization would allow the industry and/or ONC to address the gaps prior to fully integrating into the Certification Program at a future date. |

| **2. Design and Performance (§ 170.315(g)) Page #261** |
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| We propose to revise § 170.550 to add paragraph (g), which would require ONC-ACBs to certify Health IT Modules to certain proposed certification criteria under § 170.315(g). We propose to require ONC-ACBs to certify Health IT Modules to § 170.315(g)(3) (safety-enhanced design) and § 170.315(g)(6) (Consolidated CDA creation performance) consistent with the requirements included in these criteria. Paragraph (g) also includes a requirement for ONC-ACBs to certify all Health IT Modules presented for certification to the 2015 Edition to § 170.315(g)(4) (quality system management) and (g)(8) (accessibility-centered design). Continued on page #262 |
| **Public Comment Field – IUS Group 3:**  The Workgroup reviewed this section and did not have specific recommendations or concerns with adding the new modules.  *We request additional comments, recommendations, and/or concerns by the full IUS work group regarding new modules related to Safety-Enhanced Design, Consolidated CDA Creation Performance, Quality Management System, and Accessibility-Centered Design.* |