Health IT Policy Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

Health IT Implementation, Usability and Safety Workgroup

Presentation to the HIT Policy Committee: IUS Workgroup NPRM Comments

May 12, 2015

David Bates, chair

Larry Wolf, co-chair

Workgroup Members

- **David W. Bates**, Brigham and Women's Hospital (Chair)
- **Larry Wolf**, Kindred Healthcare (Co-Chair)
- **Joan Ash**, Oregon Health & Science University
- **Janey Barnes**, User-View Inc.
- **John Berneike**, St. Mark's Family Medicine
- **Bernadette Capili,** New York University
- **Michelle Dougherty**, American Health Information Management Association
- **Paul Egerman**, Software Entrepreneur
- **Terry Fairbanks**, Emergency Physician
- **Tejal Gandhi**, National Patient Safety Foundation
- **George Hernandez**, ICLOPS
- **Robert Jarrin**, Qualcomm Incorporated
- **Mike Lardieri**, North Shore-LIJ Health System
- **Bennett Lauber,** The Usability People LLC
- **Alisa Ray,** Certification Commission for Healthcare Information Technology
- **Steven Stack,** American Medical Association
- **Mickey McGlynn**, Cerner

Ex Officio Members

- **Svetlana Lowry,** National Institute of Standards and Technology
- **Anne Pollock,** Centers for Disease Control and Prevention
- **Jeanie Scott,** Department of Veterans Affairs
- **Ed Lomotan,** Agency for Healthcare Research and Quality-Health and Human Services

ONC Staff

- **Ellen Makar,** (Lead WG Staff)

IUS Certification NPRM Assignments

Health IT Policy Committee
A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

Group 1	Group 2	Group 3

• Principles of Proper Conduct for ONC-ACBs -262
  • Surveillance and maintenance – 262
  • Transparency and Disclosure Requirements - 276
  • Complaints Reporting -296
  • Open Data Certified Health IT Product List (CHPL) - 288
  • Adaptations and Updates of Certified Health IT -296
• Decertification - 298
	• Safety-enhanced design - 191
	• Summative testing - 196
	• Retesting – 197
	• Quality Management System -197
	• Accessibility Technology Compatibility – 199
	• Accessibility-centered Design – 210, 406
		• Pharmacogenomics Data – Request for Comment - 236
		• Subpart E – ONC Health IT Certification Program -251
		• Modifications to the program - 250
		• "Removal" of Meaningful Use Measurement Certification Requirements - 253
		• Types of care and practice settings -254
		• Base EHR definition – 8, 240
		• CEHRT Definition -10, 244
		• The ONC Health IT Certification Program and Health IT Module - 12
		• Referencing the ONC Health IT Certification Program -256
		• Design and Performance -261

IUS Certification Work Group Contact List

Health IT Policy Committee
A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

Group 1	Group 2	Group 3
1. **Steven Stack, lead** 2. David W. Bates 3. Paul Egerman 4. Terry Fairbanks 5. Anne Pollock 6. Alisa Ray	1. **Janey Barnes, co-lead** 2. **Bennett Lauber, co-lead** 3. Joan Ash 4. John Berneike 5. Tejal Gandhi 6. George Hernandez 7. Robert Jarrin 8. Lana Lowry 9. Mickey McGlynn	1. **Michelle Dougherty, lead** 2. Mike Lardieri 3. Ed Lomotan 4. Jeanie Scott 5. Larry Wolf 6. Betty Mims Johnson 7. Bernadette Capili

Food for Thought: 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

Food for Thought: Overarching Comments, continued

Utility of CHPL:	We appreciate the recognition in the NPRM that current ONC Certified Health IT Product list (CHPL) is difficult to use. The NPRM describes that ONC will rewrite the CHPL in approximately 12 to 18 months. An opportunity to provide helpful data in a more usable format is welcomed. Evaluation of the significantly expanded dataset and redesign should be included in the redesign plans so that the value to purchasers, developers, usability professionals providers and other interested parties can be determined. ONC should apply to the CHPL development the User Centered Design principles that it is asking of health IT developers.
Other software sources:	Some on the committee emphasized that not all HIT software is provided by vendors. Providers do use self-developed software and open-source software. There are also vendors with a hybrid of software from multiple source-types. As a result, the proposals may be inappropriate in some situations. The proposals may favor some sources of software over other sources.
Expansion of the use of certification:	Efforts are being made to expand the use of certification to address public policy concerns such as HIT safety, vendor business practices, and helping individuals with disabilities. These are all areas that are important to address. There were members of the workgroup who strongly voiced the view that the certification process is not the appropriate way to address these issues, especially if done by attestation. Attestation is a subjective aspect to the certification testing process. A member of the WG expressed interest in understanding where in the statute ONC had the authority to expand the Certification Program beyond the EHR Incentive Program.

Food for Thought: Overarching Comments, continued

Shift from functional requirements to interoperability and privacy/security	In response to industry feedback, a shift away from functional requirements to interoperability and privacy/security requirements is noted. There were workgroup members who suggested that in this version, the criteria focused solely on interoperability and privacy/security and that functional capabilities should not be included (ex: CPOE for medications and diagnostic imaging).
Timeline	The timeline outlined in the NPRM may not allow sufficient time for eligible providers to begin their reporting period for Meaningful Use Stage 3 on January 1, 2017. While this start date is optional for providers, health IT suppliers would have to deliver fully operational software to providers well in advance of that date to allow for implementation by the provider. While a reduction in scope might make this timeline achievable, a longer development and implementation timeline could well improve software capabilities and effective implementation.
Complexity	Some workgroup members felt that this version of certification was not responsive to feedback that previous iterations of certification were too complex.

Food for Thought: Overarching Comments, continued

Maturity of Standards	Workgroup members voiced concerns that proposed standards have not sufficiently matured to be promulgated through regulations. Suggest that ONC and CMS find mechanisms supportive of pilots and limited deployments in production environments. This will serve to assess the applicability, practicality, and consistent, wide deploy- ability of standards and implementation prior to being considered for national rulemaking and avoid a situation where the certification rule is in effect acting as a national pilot program .
Variations among Partners	Certification requirements that impact one segments of the market should also apply to the "partner" segment to be certified. This will add significant cost and complexity when providers and EHR developers will be required to develop and implement multiple interfaces rather than one standard interface. (e.g. population health requirements that vary by geography or registry). The point was made regarding how Certification would address the challenges of interoperable health IT adoption by LTPAC and BH providers who were left out of the EHR Incentive Program. There was acknowledgement that the sectors requested this approach in hearings to the HIT Policy Committee, but also recognition that this is one approach while others (e.g. incentives) may still be needed to support adoption.

Food for Thought: Overarching Comments, continued

Requiring teams to use a User Centered Design (UCD) process **Intent of the regulation and the integrity of a sound UCD process.**	The NPRM requirements if adopted contain instances where the basic definition of a UCD process would be violated. (e.g. replacing summative testing requirements with greater emphasis on only formative activities) this is in fact suggesting that a UCD process is not required. • Developer Teams must carry out activities in an iterative manner that are aimed at informing the usability goals, user requirements and design of HIT and include actual end users in that process. • Developer Teams must carry out activities that are aimed at evaluating the success of meeting usability goals and gathering objective performance evidence that the Health IT is safe, effective, efficient, and satisfying to use. • The certifying boards should be required to demonstrate that they are equipped to review and evaluate submissions in regard to UCD. The Safety-Enhanced Design requirements set forth in earlier versions did lay a foundation for requirements of a UCD process (on the identified safety areas). With this new NPRM there are opportunities for improvement related to the implementation and certification process of Safety-Enhanced Design requirements.
Requiring teams to use a User Centered Design (UCD) process **Safety-Enhanced Design requirements**	Missing in the Safety-Enhanced Design requirements is the mechanism that requires a process that includes all of the following : • Identification of usage errors + an analysis of usage errors (e.g., frequency and severity) • Identifying and implanting mitigations aimed at reducing risks associated with identified errors • Tracking/auditing this process even through post-market surveillance. • Inclusion of patient history as a safety element

Group 1

Group 1 Assignments

- Principles of Proper Conduct for ONC-ACBs -262
  - Surveillance and maintenance – 262
  - Transparency and Disclosure Requirements -269
  - Complaints Reporting -296
  - Open Data Certified Health IT Product List (CHPL) - 274
  - Adaptations and Updates of Certified Health IT -296
- Decertification - 298

Highlights: Group 1

- Proper conduct
  - Surveillance-maintenance—number of areas where clarification needed listed
  - Transparency-some members favored, others were skeptical about whether charge comparisons would be helpful
  - Complaints—recommend ONC develop a more rigorous and protocol-driven complaint process
  - Open data—generally supportive, suggested adding several specific data elements
  - Adaptations—one substantial group felt these recommendations were already in place, so these would be redundant/duplicative. Another group felt these recommendations could be helpful

Highlights: Group 1, continued

- Decertification, related to blocking interoperability—generated substantial discussion
  - Requires further consideration and study
  - Providers could block
  - Blocking by providers or vendors could be appropriate
  - If decertification were implemented, would be major provider and patient burden

Highlights: Group 2

Group 2

- Safety-enhanced design - 191
- Summative testing - 196
- Retesting – 196
- Quality Management System -197
- Accessibility Technology Compatibility – 198
- Accessibility-centered Design – 209, 405

Highlights: Group 2

- Safety-enhanced design
  - Debate in group re use of certification vs. guidance/best practice
  - Prior criteria led to variability among ATCBs; NPRM adds 7 new criteria which will be helpful
  - NIST should supply standard scenarios for usability to enable comparisons
  - Clarifications requested regarding a number of points
  - Debate about n of 15 test participants but science supports

Highlights: Group 2, continued

- Summative testing
  - To replace summative usability test with only formative testing would not be a nationally recognized user design test—do not recommend
- Retesting
  - Already addressed through existing processes. No change required to consider user interface changes
- Quality management systems
  - Great potential in risk management processes—most support proposed language. Some felt this just increased complexity of certification
- Accessibility technology
  - Most supported, but some felt overly burdensome
- Accessibility-centered design
  - Most supported, but some felt overly burdensome

Group 3

- Pharmacogenomics Data – Request for Comment - 236
- Subpart E – ONC Health IT Certification Program -250
- Modifications to the program - 250
- "Removal" of Meaningful Use Measurement Certification Requirements - 252
- Types of care and practice settings -253
- Base EHR definition - 8
- CEHRT Definition -10
- The ONC Health IT Certification Program and Health IT Module -13
- Referencing the ONC Health IT Certification Program -256
- Design and Performance -261

Highlights: Group 3

- Pharmacogenomics
  - Need a process to advance standards that highlights priorities but doesn't require certification
- Health IT Certification
  - Agree with "Health IT" to replace "HIT"
- Modifications to Certification Program
  - Need for modules to interoperate, but testing for this would be difficult and impractical
- Removal of MU Certification
  - Support—do request clarification that removing capability to calculate MU measurement will not frustrate users

Highlights: Group 3, continued

- Types of care
  - Certification would be helpful to the settings called out in the NPRM and these are enumerated
- Base EHR definition
  - Want clarification regarding how privacy and security will work—not clear if need to be included in each module
- ONC HIT Certification
  - Overall concern about complexity and driving up costs of certification

APPENDIX 1:
Detailed
IUS Workgroup Comments

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

Certification NPRM Comment Template (Group #1)

Health IT Policy Committee
A Public Advisory Body on Health Information Technology

"In-the-Field" Surveillance and Maintenance of Certification P #262

We propose to adopt new requirements for "in-the-field" surveillance under the ONC Health IT Certification Program. Our proposal would build on ONC-ACBs' existing surveillance responsibilities by requiring ONC-ACBs to initiate in-the-field surveillance of certified Complete EHRs and certified Health IT Modules in certain circumstances and in accordance with certain standards and procedures described below. Our proposal would also clarify ONCACBs' responsibilities for requiring certified Health IT Module and certified Complete EHR developers to take corrective action in instances where the technology fails to conform to the requirements of its certification. (Continued on page #263)

The process must be reasonable and considerate with regard to burden placed on end user. It is unclear how this will be evaluated in the field, especially in the context of the uniqueness of each user group and context of use.
A crucial clarification: "unit of analysis" for certification. This regulation could change the unit of analysis to "the software as implemented".

Users/providers make many configurations and customization decisions, each of these affecting the performance against the certification criteria. Are each Lab/Cert Body to test and certify each custom implementation? Who is accountable—vendor/developer or user/provider? Is the vendor accountable for providing guidance in best practices and lessons learned from prior implementations?
When the EHR is not working as expected, the end user is not easily aware of the cause of the dysfunction (may not be aware the dysfunction exists). We agree with intent of the statement "Requiring Complete EHR developers to take corrective action in instances where the technology fails to conform to the requirements of its certification" . Caution that there is the potential for unintended consequences and should not produce additional burdens to providers or health system purchasers. ACB skill set in this area is lacking and retraining would be needed.

Areas of clarification needed:

- HIPAA impacts: onsite surveillance, patient/provider protections. How can the audit be performed without disrupting service to patients?
- What weight should Certifiers give to poor product implementation by providers? How can "poor" or "good" performance be objectively determined? What compels providers to participate? Is this an official "audit"?
- What federal ruling gives Certifiers the authority to "audit" the vendor product implementation at the provider site?
- Is this voluntary or mandatory on the part of a provider?
- How will this criteria prevent "cherry picking" of customers –
- As part of Lab/Certifier vendor relationship, the new surveillance process will need to be built into new customer agreements at time of application, and current vendor customers agreements must be altered to reflect new charges this could add to costs.

Recommendation: Many of the concerns can be addressed by a more rigorous and protocol driven complaint process, with periodic public reporting mediated and monitored by the ACBs. This may be a more cost-effective method of gathering the information. ONC-ACBs do not have access to vendor customer lists to promote this on their own. But ONC, working with CMS, could do this effectively.

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #1), con't.

Transparency and Disclosure Requirements Page #276

We propose to revise the principles of proper conduct for ONC-ACBs in order to provide for greater and more effective disclosure by health IT developers of certain types of limitations and additional types of costs that could interfere with the ability to implement or use health IT in a manner consistent with its certification. We believe that these additional disclosure requirements are necessary to ensure that existing and potential users and implementers of certified health IT are fully informed about these implementation considerations that accompany capabilities certified under the ONC Health IT Certification Program. (Continued on page #276)

The work group agrees there is need for further certification/ product transparency, and appreciate ONC referencing AMA regarding costs associated with health IT /information exchange (pg. 278). We appreciate ONC's acknowledgment: "health IT developers not disclosing known material limitations or additional types of costs associated with implementation or use of certified health IT creates a substantial risk…" and support expanding the information health IT developers must disclose.

Most WG members support the notion (pg. 283) of a more specific cost structure to include all costs and fees physicians would be required to pay for any EHR function (MU related or not) outside monthly service contracts. Cost information should include factors such as volume of transmissions, geography, interfaces, and exchange partner technology. Eligible providers need clear understanding of costs ($$) without the burden of calculating their own estimation of vendor fees/prices. Have vendors publish a range of prices for each service, interface, or extra function. Eligible providers/hospitals should be able to easily understand the overall cost for their system implementation, customization and costs associated with transmitting data and performing daily functions of patient care.

In the spirit of transparency, vendors should collect HISP/HIE fees and/or pricing information and provide it to customers. ONC should list this information publically and known issues from previous implementations (flaws, safety risks, functional deficiencies) shared openly with potential and existing customers. Contracts should not prohibit customers from sharing information on their own (positive or negative) including screen shots and other information (helpful to demonstrate lessons learned) regarding aspects of a custom feature, training and implementation questions or reporting tools, and other functional elements.

The group did have a difference of opinion with some members feeling that this proposal is not limited to EHR vendors, but also impacts all HIT vendors. It represents a major expansion of the certification program scope is burdensome and an overreach. First consider the value of the current process, addition/change should be fully evaluated against cost and incremental value gained.

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #1), con't.

Complaints Reporting Page #296

We propose that ONC-ACBs provide ONC (the National Coordinator) with a list of complaints received on a quarterly basis. We propose that ONC-ACBs indicate in their submission how many complaints were received, the nature or substance of the complaint, and the type of complainant (e.g., type of provider, health IT developer, etc.). We believe this information will provide further insight into potential concerns with certified health IT or the ONC Health IT Certification Program and give ONC a better ability to identify trends or issues that may require action including notification of the public. We propose to include this new requirement in § 170.523(n). (Continued on page #296)

The work group is generally supportive and agrees with complaint information publically posted online. In order to be actionable and meaningful, Vendor/ complainant should be identified. However the group also noted that this seems to suggest that all/most of the issues are vendor caused and/or fixable by the vendor. The broad set of reasons for complaint would need to be fully considered before this would be implemented and the expected actions as a result of the trend analysis would need to be fully assessed. Ultimately, the value of the information would need to be weighed against the cost of creating it.

This exercise must be carefully thought out, with well-defined measurement objectives, and very clearly documented methodologies. The process must be reasonable and considerate in regard to burden placed on end user as well as the vendor.

A process that uses the ACBs through ANSI Accreditation standards might include:

- Publically available records of customer complaints and their outcomes (ongoing or closed).
- Include detailed transparent processes. (e.g. standard categories : by product and version number).
- Ease of complaint process, complaint categorization includes certification elements and service related elements
- User complaints within the scope of the certification criteria or testing process should be the priority,
- Complaints about problems beyond the scope of certification, such as poor customer service, should be logged and counted, (additional action by the ACBs or ONC may not be warranted).

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #1), con't.

Open Data Certified Health IT Product List (CHPL) Page #288

In the initial rulemaking that we used to establish the Temporary Certification Program, we indicated that the National Coordinator intended to make a master CHPL of all Complete EHRs and EHR Modules tested and certified by ONC-ATCBs available on the ONC Web site and that the CHPL would be a public service and would be a single, aggregate source of all the certified product information ONC–ATCBs provide to the National Coordinator (75 FR 36170). Since 2010, we have maintained the CHPL and as the ONC Health IT Certification Program has matured, ONC-ACBs have continued to report the products and information about the products they have certified to ONC for listing on the CHPL. (Continued on page #289)

Some work group members thought it best that regulation regarding additional data in the CHPL should be postponed until ONC completes its redesign and shows that the data in the CHPL is used and is beneficial. Vendors have provided significant feedback to ONC already to make it more usable. To the best of our knowledge, none of that feedback has been implemented. Consideration should be given to whether or not implementing the feedback to date versus this new open format will have the most value for the users of the CHPL.

Generally however, the workgroup is supportive of ONC's open data initiative. Opening the CHPL up to further public consumption will help the industry and health IT consumers compare and contrast products—leading to better design and enhanced competition. It may also open up innovation with assistive apps that make use of that data. There is a need for more clarity on the API functionality mentioned on pg. 290. Will the ACBs use this feature to upload data onto the CHPL or is it intended for download only?

Developers/Vendors at ATL/ACBs should know at program launch what the open data elements are and how defined. Note that ATLs/ACBs maintain contracts with their customers with confidentiality provisions—they may encounter proprietary information in the course of their inspections. Defining what is "open" up front simplifies liabilities for all.

The work group believes that additional data element should be required in the open data file as an important step in transparency and consumer choice.
Listing the number of times the same version of health IT has been tested
The facility where the testing took place.
Audit of the CHPL data by ACBs for completeness of submission

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #1), con't.

Adaptations and Updates of Certified Health IT Page #297

We propose a new principle of proper conduct (PoPC) that would serve to benefit ONCACBs as well as all stakeholders interested in the ONC Health IT Certification Program and the health IT certified under the program. We propose to require that ONC-ACBs obtain monthly reports from health IT developers regarding their certified health IT. Specifically, we propose to
require that ONC-ACBs obtain a record of all adaptations and updates, including changes to user-facing aspects, made to certified health IT (i.e., Complete EHRs and certified Health IT Modules), on a monthly basis each calendar year. We request comment on whether we should require even more frequent reporting. (Continued on page #296)

Some work group members felt this proposal was redundant . This process is already covered in the existing structures. Vendors need to provide information to the ACBs when they update their solutions in the current environment. No new process/requirements are needed.

Other workgroup members are supportive of the new principle of proper conduct (PoPC) and believe it will help provide updated information to ACBs on status and progress of health IT as it improves. In addition this will provide important information to alert ACBs to irregular events (e.g., multiple updates in a short period of time / few updates over a number of months) that may warrant in-the-field surveillance or further attention.

- Distinctions between “minor” and “major” changes need definitions. These methods should be documented in a protocol that all ATL/ACBs follow. The developer/vendor community varies tremendously in their development cycles and how they count “updates” or “version revs”. Some developers issue patches/updates almost daily. Other shops have a philosophy where there is no version number change until the next major release. A method for understanding how this variability impacts the utility of the data and comparisons should be identified and piloted prior to mandating a count of changes.
- There may be situations where health IT vendors make small, inconsequential changes to software code - these may or may not need to be reported and could add undue burden on health IT vendors.

Specific instances where health IT products are deployed in the field and software changes are made for only one site or installation- would these specific adjustments be included in the requirement to submit multiple reports? (for each site where different “tweaks” of health IT products are in place?)

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #1), con't.

"Decertification" of Health IT – Request for Comment Page #298

In the explanatory statement accompanying Public Law 113-235 (Consolidated and Further Continuing Appropriations Act, 2015) the Congress urged ONC to use its certification program to ensure certified electronic health record technology (CEHRT) provides value to eligible hospitals, eligible providers and taxpayers. It also stated that ONC should use its authority to certify only those products that clearly meet current meaningful use program standards and that do not block health information exchange. Further, it stated that ONC should take steps to "decertify" products that proactively block the sharing of information. (Continued on page #298)

The group appreciates that ONC was instructed by Congress to report on products blocking interoperability and to decertify them. We agree this concept requires further consideration and study. This action of decertification would raise real concerns for all stakeholders. There would almost certainly be unintended consequences resulting from this approach:

Concern for end users, using a vendor's system only to find they are not able to comply with the CMS EHR incentive program because their EHR becomes newly de-certified. In cases where the de-certification leads to a vendor's business failure or abandonment of a product, where patient data lies on vendor-controlled servers,…what provisions to preserve or archive these data for future use will be in place?

Burden on providers who must spend time and funds to purchase and deploy a new EHR or accept a CMS penalty if vendor they are using is decertified. Alternatives should be considered. Decertification would impact all stakeholders: vendors, hospitals, providers as well as patients would all likely experience disruptions.

Information on process and planning for consequences must be outlined before the workgroup could support this element. (ACBs have the authority to terminate a product's certification . This new measure increases the likelihood of decertification; In a situation where a health IT product is marked for decertification there should be consideration regarding the circumstances (e.g., in-the-field surveillance repercussions), due process, and associated remedies e.g. a correction plan process).

The decertification process must be well thought out: violations, process, review, appeal, notification and other possible effects – many of which could be more harmful in the big picture. (Patients unable to retrieve data, specialists unable to share records, etc.). There is no generally accepted definition of data blocking. What objective information would be used to determine an entity is blocking information? We acknowledge the value of certification in meeting standards and efficacy of EHRs. We would like to increase the emphasis on current regulations that states the expectation that vendors will be transparent in their requirements/contractual terms and will make info available to their customers and prospects, openly portable and transportable, as well as the proposal to enhance the information available on the CHPL site addressed in previous comments.

Group 2

Group 2
• Safety-enhanced design - 191 • Summative testing - 196 • Retesting – 196 • Quality Management System -197 • Accessibility Technology Compatibility – 198 • Accessibility-centered Design – 209, 405

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #2)

Health IT Policy Committee

170.315(g)(3) Safety-enhanced design Page #191

(3) Safety-enhanced design.

(i) User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: § 170.315(a)(1) through (10) and (18), (20), (22), (23), and (b)(2) through (4).

(ii) The following information must be submitted on the user-centered design processed used:

(A) Name, description and citation (URL and/or publication citation) for an industry or federal government standard; or

(B) Name the process(es), provide an outline of the process(es), a short description of the process(es), and an explanation of the reason(s) why use of any of the existing user-centered design standards was impractical.

Regarding Identify industry recognized/federal user centered design (UCD) standard: Differences of opinion existed within the group .Some members believed that Instead of certification, this matter should be handled with guidance and best practice recommendations, that the proposed regulation effectively creates a law that requires Health IT vendors to use a certain development process which is an inappropriate role for the government, especially in consideration that developmental process evolve with technology advances. However most members of the work group believed the NPRM did not go far enough in this area and that Following a UCD process will be applying formative, iterative UCD activities to inform the design + conducting a summative test(s) to validate safe and effective use of production user interface. Both formative and summative activities are required as part of a UCD process.

- Artifacts from formative activities may be appropriate as evidence for applying a UCD process. (e.g. submit artifact that includes audit trail identifying a potential usage error through validation and that mitigation decreased/removed the potential for usage error). Providing an artifact from a formative usability activity is not going to “make the product better”.
- ONC-ACB review for certification was very focused on report format and inclusion of data fields not related to safe and effective use. Per the NPRM there are seven new certification criteria that strengthen safety-enhanced design. The inclusion of additional criteria with a safety focus is a positive effort in the right direction.
- There also needs to be an emphasis on formative evaluation. This may be covered when a Quality Management System is used, but should be specifically mentioned in this section as well.

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #2), con't.

§ 170.315(g)(3) Safety-enhanced design Page #191

(3) Safety-enhanced design. continued

(iii) The following information/sections from NISTIR 7742 must be submitted for each capability to which user-centered design processes were applied:

(A) Name and version of the product; date and location of the test; test environment; description of the intended users; and total number of participants;

(B) Description of participants, including: sex; age; education; occupation/role; professional experience; computer experience; and product experience;

(C) Description of the user tasks that were tested and association of each task to corresponding certification criteria;

(D) List of the specific metrics captured during the testing, including; task success (%); task failures (%); task standard deviations (%); task performance time; and user satisfaction rating (based on a scale with 1 as very difficult and 5 as very easy);

(E) Test results for each task using metrics listed above in paragraphs (g)(3)(ii)(A) through (D) of this section;

(F) Results and data analysis narrative, including: major test finding; effectiveness; efficiency; satisfaction; and areas for improvement.

(iv) Submit test scenarios used in summative usability testing.

As part of a UCD process, teams must identify intended users of features/prioritized criteria and recruit that user role to participate in formative and summative activities. The regulation would be contradictory if it states apply UCD process but only for clinical users! NISTIR 7804 guidance for recruiting representative test participants for each category of anticipated clinical end users does not account for elements of the Safety-Enhanced Design criterion whose cohort of intended users are not clinical. Recommend providing summary descriptor information that demonstrates participants are representative of clinical users such as occupation/role and professional experience.

Regarding user tasks: We recommend NIST provide standard scenarios for usability test tasks so summative test reports can be compared to each other. Risk-based analysis of test tasks should be included as part of the test task description.

Regarding metrics captured at testing: (3)(iii)(D) Task Standard Deviations (%) does not make sense in the context provided as a metric by which to measure User Centered Design. The reference standard of NISTIR 772 uses Task Deviations as a metric for effectiveness, which is not reported as a percentage. Request clarification on whether this portion of the rule is defining the statistical procedure to use for measuring effectiveness (which would not make sense in the context of Successes or Failures) or the Effectiveness metric (which is not standard deviations, but simply task deviations).

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #2), con't.

§ 170.315(g)(3) Safety-enhanced design Page #191 (3) Safety-enhanced design. continued

(iii) The following information/sections from NISTIR 7742 must be submitted for each capability to which user-centered design processes were applied:

(A) Name and version of the product; date and location of the test; test environment; description of the intended users; and total number of participants;

(B) Description of participants, including: sex; age; education; occupation/role; professional experience; computer experience; and product experience;

(C) Description of the user tasks that were tested and association of each task to corresponding certification criteria;

(D) List of the specific metrics captured during the testing, including; task success (%); task failures (%); task standard deviations (%); task performance time; and user satisfaction rating (based on a scale with 1 as very difficult and 5 as very easy);

(E) Test results for each task using metrics listed above in paragraphs (g)(3)(ii)(A) through (D) of this section;

(F) Results and data analysis narrative, including: major test finding; effectiveness; efficiency; satisfaction; and areas for improvement.

(iv) Submit test scenarios used in summative usability testing.

Task Performance Time : Needs clarification- Mean Task Performance Time (and SD of Task Performance Time).

User Satisfaction Rating : This is a task-based measure from the NISTIR 7742. Content is suggested as an example and is not representative of an industry standard questionnaire for analyzing software usability. The primary scientifically recognized single task-based satisfaction rating is the Single Ease-of-use Question which uses a 7-point scale. The work group also recommends supporting the ability to use literature-recognized satisfaction measures (e.g. Single Ease-of-use Question, System Usability Scale, or Software Usability Measurement Inventory) all of which use different measurement scales and do not specify which satisfaction measure is used nor do they specify task-based satisfaction measures versus a post-session satisfaction measures.

Results and data analysis narrative: (3)(F) asks for the major findings related to Effectiveness, Efficiency, Satisfaction, and Areas of Improvement. The focus is on areas identified to be at risk for error, but no requirement for error analysis as part of the report? We recommend a specific results section be required, focused on error analysis.

N**umber of, and user cohort for, test participants :** We recommend the establishment of minimum number(s) and user cohort(s) for test participants for the purposes of testing and certification to the 2015 Edition under the ONC Health IT Certification Program. A sound UCD process requires a sufficient number of test participants so as a team is confident in making/stating their conclusions. It is our recommendation that organizations follow industry accepted guidelines on compliance with a number of test participants for formative testing as well as summative testing. Several elements are crucial in determining sample size: the type of test, the representative users for that test/type of work, type of task, context, and risk factors (patient safety versus cosmetic).

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #2), con't.

Health IT Policy Committee

§ 170.315(g)(3) Safety-enhanced design Page #191, continued

(3) Safety-enhanced design. continued

(iii) The following information/sections from NISTIR 7742 must be submitted for each capability to which user-centered design processes were applied:

(A) Name and version of the product; date and location of the test; test environment; description of the intended users; and total number of participants;

(B) Description of participants, including: sex; age; education; occupation/role; professional experience; computer experience; and product experience;

(C) Description of the user tasks that were tested and association of each task to corresponding certification criteria;

(D) List of the specific metrics captured during the testing, including; task success (%); task failures (%); task standard deviations (%); task performance time; and user satisfaction rating (based on a scale with 1 as very difficult and 5 as very easy);

(E) Test results for each task using metrics listed above in paragraphs (g)(3)(ii)(A) through (D) of this section;

(F) Results and data analysis narrative, including: major test finding; effectiveness; efficiency; satisfaction; and areas for improvement.

(iv) Submit test scenarios used in summative usability testing.

Summative testing : The work group recommends that a minimum of 15 participants should be the standard. Summative testing is a benchmark test so more users are required; Per NIST IR 7804, 15-20 are suggested per user group for which the application is being designed. If organizations use smaller samples, justification with rationale is needed since this would be outside industry standards and best practice recommendations. This is also consistent with language in the 2011 FDA guidance on validation testing (see Appendix B). " If users with distinctly different characteristics [e.g., use responsibilities, age ranges, skills sets or experience levels] will use the device, validation testing activities should include 15 from each major user group."[1].

Need for formative testing with a focus on implementation due to the safety issues that arises from customization was not specifically addressed in the NPRM , and the workgroup wanted to call attention to this omission.

Issues of hardship and possible need for exceptions to the above:

- Small companies producing individual modules- might not have enough customers and users able to participate in testing.
- Self-developed software? A programmer creates a customize module … (is there need for 15 people to test it?)
- Open source software (perhaps using software developed for the VA*).*

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #2), con't.

Request for Comment on Summative Testing Page # 196

We understand that some health IT developers are concerned that the summative testing report may not adequately reflect the design research that has been performed throughout a product's lifecycle. We request public comment regarding options that we might consider in addition to – or as alternatives to – summative testing. For example, if formative testing reflects a thorough process that has tested and improved the usability of a product, could a standardized report of the formative testing be submitted for one or more of the 17 certification criteria for which summative testing is now required? What would be the requirements for this formative testing report, and how would purchasers evaluate these reports?

Applying a nationally recognized user centered design process, means attesting to carrying out formative activities and attesting to conducting a summative usability test. (validation that the product has met identified usability goals). To replace the summative usability test with only formative testing is prescribing a process that is **not a nationally recognized user centered design process.** Formative activities are required as a part of UCD attestation. Formative evaluation must be required. Formative activities are included when a quality management system is implemented. Both formative and summative are needed. Summative testing with summative metrics is the only standard for the usability validation. In addition, the work group also believes risk management processes if implemented, also embrace formative testing.

INTERNATIONAL STANDARD ISO/IEC 25062 A.22 A usability test of a completed product to determine how well it meets its usability objectives. The report format assumes sound practice [1, 2] has been followed in the design and execution of the test. Test procedures which produce measures that summarize usability should be used, i.e. the test is summative in nature. Some usability evaluation methods, such as formative tests, are intended to identify problems rather than produce measures; the format is not structured to support the results of such testing methods.

ANSI/AAMI HE 75:2009 Human Factors Engineering-Design of Medical Devices 9.3.1.1 Formative usability testing. Formative usability testing is performed early, using simulations and early working prototypes; it is intended to explore whether usability objectives are attainable, but does not have strict acceptance criteria. 3.89 summative usability testing: Usability testing performed in the late stages of design. NOTE—Summative usability tests include verification and validation, and it is a recommended best practice to have formal acceptance criteria (e.g., usability objectives for human performance and satisfaction ratings). 5.6 Identification of use-related hazards 5.6.1 Overview

Extent of testing effort: Usability testing can involve varying degrees of structure, complexity, and realism. Tests can consist of informal, "quick and dirty" preliminary testing (sometimes called formative evaluations) or more comprehensive. We recommend continued use of Summative Test reports. It is important that *ONC show evidence that having that information in the CHPL is useful to Health IT purchasers and others.*

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #2), con't.

Retesting and Certification Page #197
We believe that ONC-ACB determinations related to the ongoing applicability of the SED certification criterion to certified health IT for the purposes of inherited certified status (§ 170.550(h)), adaptations and other updates would be based on the extent of changes to user interface aspects of one or more capabilities to which UCD had previously been applied. We believe that ONC-ACBs should be notified when applicable changes to user-interface aspects occur. Therefore, we include these types of changes in our proposal to address adaptations and updates under the ONC-ACB Principles of Proper Conduct (§ 170.523). Please see section IV.D.6 of this preamble for further discussion of this proposal.
This is already addressed through the existing processes. Release notes include a summary of the software changes; including user interface changes. No change is required to the current process to consider user interface changes.

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #2), con't.

§ 170.315(g)(4) Quality management system Page #197

(4) Quality management system.

(i) For each capability that a technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation, and maintenance of that capability must be identified that is:

(A) Compliant with a QMS established by the Federal government or a standards developing organization; or

(B) Mapped to one or more QMS established by the Federal government or standards developing organization(s).

(ii) If a single QMS was used for applicable capabilities, it would only need to be identified once.

(iii) If different QMS were applied to specific capabilities, each QMS applied would need to be identified.

Most on the work group agreed that there is great potential in risk management and quality improvement processes being required via a certification process. Wile there's potential, there's a lot of work to be done. Convening diverse groups to develop a risk management process for EHRs is appealing. Recommend supporting the proposed language.

Others felt the regulation adds more complexity to an already complicated certification process. It increases the cost of certification, but the expenses are not included in the NPRM's cost section. The tie in to self-developed software or open-source software is not apparent. ONC's regulations should not apply to all software sources and not penalize any potential source. Recommend against the proposed language until ONC completes its redesign of the CHPL and shows that the information that it is already gathering for Stage 2 is being used by purchasers who find it effective.

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #2), con't.

§ 170.315(g)(5) Accessibility technology compatibility Page #199
(5) Accessibility technology compatibility. For each capability technology includes that is specified in the certification criteria at § 170.315(a), (b), and (e), the capability must be compatible with at least one accessibility technology that includes text-to-speech functionality.
Most of the work group members support the proposed language for capability technology. Others felt this regulation is burdensome and an over-reach. Text-to-speech capabilities are frequently not appropriate for many health care work-flows, especially when one considers privacy issues. With this regulation, ONC is trying to expand the certification process to impact public policy about disabled health care workers. Certification should not be used for that purpose.

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #2), con't.

§ 170.315(g)(8) Accessibility – centered design Pg #210

(8) Accessibility-centered design. For each capability that a Health IT Module includes and for which that capability's certification is sought, the use of a health IT accessibility-centered design standard or law in the development, testing, implementation and maintenance of that capability must be identified.

(i) If a single accessibility-centered design standard or law was used for applicable capabilities, it would only need to be identified once.

(ii) If different accessibility-centered design standards and laws were applied to specific capabilities, each accessibility-centered design standard or law applied would need to be identified. This would include the application of an accessibility-centered design standard or law to some capabilities and none to others.

(iii) If no accessibility-centered design standard or law was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

Most of the work group members support the proposed language for capability technology. Others felt this regulation is burdensome and an over-reach. With this regulation, ONC is trying to expand the certification process to impact public policy about disabled health care workers. Certification should not be used for that purpose.

Group 3

Group 3
• Pharmacogenomics Data – Request for Comment - 236 • Subpart E – ONC Health IT Certification Program -250 • Modifications to the program - 250 • "Removal" of Meaningful Use Measurement Certification Requirements - 252 • Types of care and practice settings -253 • Base EHR definition - 8 • CEHRT Definition -10 • The ONC Health IT Certification Program and Health IT Module -13 • Referencing the ONC Health IT Certification Program -256 • Design and Performance -261

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #3)

Pharmacogenomics Data – Request for Comment Page #236
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)
The workgroup encourages a process that highlights priorities but does not require certification criteria for areas where there is a lack of foundational standards for a certification program. Issues such as pharmacogenomics are so important to the personalized medicine i9nitiatives- early prioritization allows the industry and/or ONC to address the gaps prior to fully integrating into the Certification Program at a future date.

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #3), con't.

Subpart E – ONC Health IT Certification Program Page #250

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)

The workgroup recognizes that changes are needed to support the Certification Program . We agree with the changes described in the NPRM, and have 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"

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #3), con't.

Modifications to ONC Health IT Certification Program Page #251

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)

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.

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #3), con't.

Health IT Policy Committee
A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

"Removal" of MU Measurement Certification Requirements P #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)

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.

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #3), con't.

Types of Care and Practice Settings Page #254

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)

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 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. Building all of these required assessments with a common platform, 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.

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #3), con't.

Base EHR Definition & CEHRT Definition P #8, P #240

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)

We request clarification regarding how privacy and security requirements are applied in the new approach.

It is not clear whether there is a separate module or the requirements were integrated in each module. Please provide additional information on how privacy and security requirements are expected to be 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 data creation separately 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, doing so - 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.

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #3), con't.

Health IT Policy Committee
A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

The ONC HIT Certification Program & HIT Module Page #12

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.

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. The approach described in the NPRM to engage a broader set of stakeholders beyond ambulatory and inpatient settings to include others that also have systems meeting foundational interoperability requirements 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, and 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 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

ONC and HHS agencies are encouraged to explore levers/authorities available to discourage bad behaviors (e.g. proactive blocking of information sharing where the practice creates a barrier to advancing interoperable exchange). An action to discourage bad behaviors should include a process to decertify health IT. We recognize it will create tension and apprehension in the industry.(e.g. escape clauses if a system is decertified, recognition of the disruption and expense, etc.). ONC should be open about the types of "bad behaviors" that discourage sharing of information. 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 .The process needs to be sensitive enough to detect/ 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).

Health IT Implementation, Usability, and Safety (IUS) Workgroup Certification NPRM Comment Template (Group #3), con't.

Design and Performance (§ 170.315(g)) Page #261

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 #262)

The Workgroup reviewed this section and did not have specific recommendations or concerns with adding the new modules.

APPENDIX 2:

References

IUS Workgroup Comments

Evidence: Safety Enhanced Design requirements have increased awareness re: importance of SED

Application of UCD process: Terry Fairbanks and Raj Ratwani. Human Factors Perspective on Advancing EHR Usability & Safety. Health IT Implementation, Usability and Safety Workgroup October 10, 2014. http://www.healthit.gov/facas/calendar/2014/10/10/policy-hit-implementation-usability-safety-workgroup.

Summative Usability Methods: Christine Buchanan, Anthony Threatt, Matthew B. Weinger, & Anne Miller, Vanderbilt U. Medical Center, High Variability in Summative Usability Test Methods & Reporting Among Clinical Informatics Vendors Complying With Federal Certification Requirements. Presented at International Annual meeting of Human Factors and Ergonomics October 2014 http://www.hfes.org/web/HFESMeetings/2014HFESAnnualMeetingProgram.pdf.

Findings reported on the CHPL site for 9 EHR products: Caleb Furlough, Janey Barnes, Jennifer Mauney, Alisha Belk, Laura Blanchard, Teri Brooks, Megan Brown, Naomi Glasscock, Merryl Gross, Ellie Hunt, and Hasmik Mehranian. Observed Usage Errors during Meaningful Use Stage 2 Safety-Enhanced Design Summative Testing. Proceedings of the International Symposium of Human Factors and Ergonomics in Healthcare June 2014 3: 81-86, doi:10.1177/2327857914031012. **Ranking of prioritized features (e.g., eMAR, Reconciliation, etc.) based on findings reported on the CHPL site for 9 EHR products. The rankings take into account task failures x error analysis score (frequency x severity)** http://hcs.sagepub.com/content/3/1/81.full.pdf+html

Summative test vs using a full UCD process: Gary Gartner. Improving the Safety of HIT with a User-Centered design Process. Poster presented at the International Symposium of Human Factors and Ergonomics in Healthcare June 2014 Id of critical usage errors that might harm patients using summative test vs using a full UCD process + traditional Solution Development Lifecycle: http://www.hfes.org/web/HFESMeetings/HCSPresentations/HCS2014Gartner.pdf

Resources on sample size:

- FDA. Draft Guidance for Industry and Food and Drug Administration Staff - Applying Human Factors and Usability Engineering to Optimize Medical Device Design. Washington DC2011.
- Falkner L. Beyond the five user assumption: Benefits of increased sample sizes. Behavior Research, Methods and Computers 2003:379-83.
- Virzi. Refining the test phase of usability evaluation: How many subjects is enough Human Factors 1992;34:457-69.