Health IT Policy Committee

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

Certification/Adoption Workgroup
HIT Policy Committee

Summary of Comments
2015 Ed. NPRM

Certification and Adoption Workgroup Members

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Member	Organization
Marc Probst, Co-Chair	**Intermountain Healthcare**
Larry Wolf, Co-Chair	**Kindred Healthcare**
Joan Ash	Oregon Health & Science University
John Derr	Golden Living, LLC
Carl Dvorak	Epic Systems Corporation
Paul Egerman	Businessman/Entrepreneur
Joseph Heyman	Whittier IPA
George Hripcsak	Columbia University
Stanley Huff	Intermountain Healthcare
Elizabeth Johnson	Tenet Healthcare Corporation
Charles Kennedy	Aetna
Michael Lardiere	National Council for Community Behavioral Healthcare
Donald Rucker	Ohio State
Paul Tang	Palo Alto Medical Foundation
Micky Tripathi	MA eHealth Collaborative
Maureen Boyle, ex officio	Substance Abuse and Mental Health Services Administration (SAMHSA)
Jennie Harvell, ex officio	Office of the Assistant Secretary for Planning and Evaluation (ASPE)

Overview

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- Overarching CAWG Comments

1. Incremental Rule Making
2. Discontinuation of Complete EHR Definition
3. Certification Packages
4. ONC Certification Mark
5. Non-MU Certification (Numerator Calculation)
6. Non-MU HIT Certification
   (Children's & Practice Transformation)
7. Additional Patient Data Collection
8. Blue Button +

Key Questions

How do we achieve the goal of a Learning Health System and the Triple Aim using policy levers that make a difference and technology that has proven value?

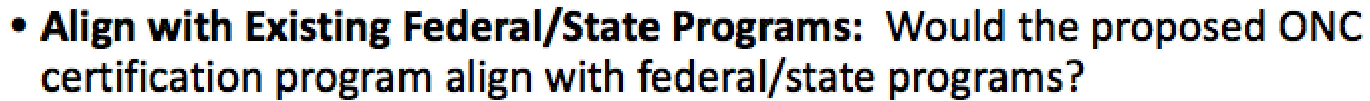
What is the role for the ONC certification program?

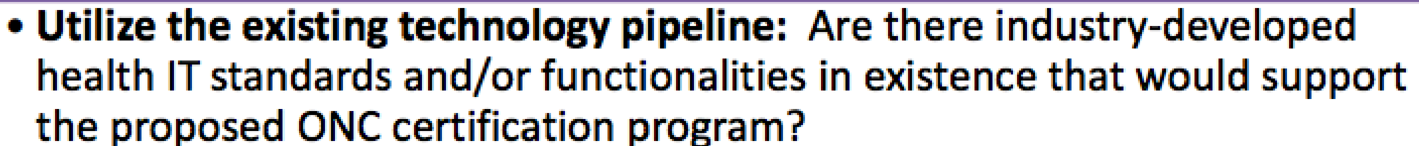
Overarching Comments

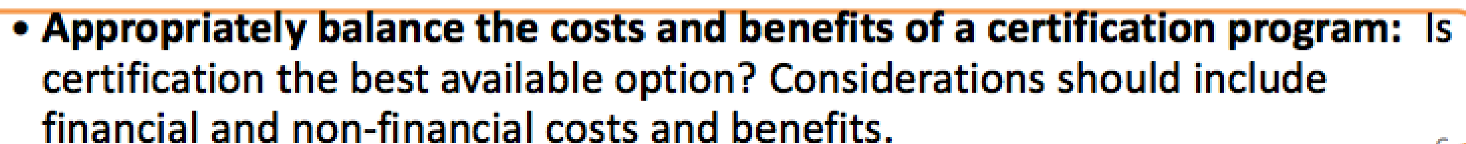
- The WG is supportive of ONC's intention to ease the burden of regulations and have a more incremental process. However, many of the proposals do not seem to achieve that goal.
- Overall, the WG did not think certification was the appropriate avenue to explore innovations.
- The WG stated that certification is often prescriptive and overly burdensome. In and of itself, it will not incline technology developers to enter the field.
- In order to support and stimulate development of HIT, ONC could, for example, provide a roadmap, continue its efforts with the S&I Framework, support pilot programs and build on innovations in the marketplace.
- When considering costs, ONC should include
  - Software development and certification costs
  - Provider implementation, training and rollout costs
  - On-going use, maintenance, support and service/subscription costs

Overarching Comments - Continued

- The WG urges ONC to use its 5 Factor Framework:







Incremental Rule Making

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- Overall, the CAWG supported ONC's goals of providing clear signals and incremental changes to increase opportunities for innovation and updates to standards.
- The WG did not support ONC's model of incremental rule making, and did not believe incremental rules would achieve the stated goals. The WG cited the following issues:
  - As regulatory process, certification involves long time periods and significant testing costs.
  - Certification should not use "Version 1" of standards or new functionalities. Before certification is proposed, significant operational usage should be required—not just "pilots" and not just "balloting".
  - "Mandated" standards can actually interfere with consensus-driven stakeholder standards development (less careful consideration given to feedback and input once adoption of the standard is a given)
  - Frequency of regulatory update makes it difficult for vendors and providers to keep up.
- If ONC chooses to pursue incremental rule making, the CAWG believes it should *only* make:
  - Incremental certification program updates
  - Minor technical updates and fixes , including minor updates to referenced standards, vocabularies and data definitions
  - Error corrections
- For all other items, an RFI or ANPRM is better suited to solicit early feedback.

Discontinuation of Complete EHR Definition

- The WG did not achieve consensus on this issue.
- The WG noted that the goal of a “Complete EHR” include everything that is needed for MU under one certification.
- The workgroup identified several items for ONC’s consideration:
  1. Continue to have a concept of a complete EHR
  2. Single vs multiple certifications
  3. Separate process for CQMs
  4. Value in modular certification
  5. Value in components that work well together
  6. Indicate if certified as modules but not sold separately

Discontinuation of Complete EHR Definition – Continued

1. Continue to have a concept of a complete EHR for Stage 3, however, prioritize tailoring it to include all of the needs for the Stage it's associated with.
   - Members agreed that the current Complete EHR definition was not appropriate, citing the fact that the current definition doesn't represent "Complete," it will continue to be a growing disconnect, and it inconsistent/more than what is necessary to meet the CEHRT definition. In addition, the current definition presumes that elements of a Complete EHR are well integrated although there is no testing for integration and providers may still have to purchase multiple products that do not function well together.
   - Members believed that there needs to be some way to easily convey that a product has everything needed for MU, either by using the "complete" label or finding a new name for it.
   - Some members are okay with the fact that providers will have more than they need, while others are not.
   - Members cited the need to give purchasers, with fewer burdens to vendor, the ability to assemble options with complete functionality that is integrated, for a specialty, by stage and reports QMs.

Discontinuation of Complete EHR Definition – Continued

2. Single vs Multiple Certifications: One vendor representative opined that certification is/will be more burdensome and costly for them if there was no "Complete EHR" certification. When a vendor needs to apply for certification and is using a complete EHR there is only one set of paperwork and one charge, with an EHR Module you have to do it over and over again for each module. Unless EHR vendors can apply for all the modules in the same way they used to apply for the Complete EHR it seems the cost will be much more expensive. Cost, research and regulatory burden to vendor is very expensive.
   - Based upon the belief that "complete" is less of a regulatory burden on developers.
3. Have a separate certification process for CQMs or a process by which CQMs must be specified, since CQM's represent much of the disparity in product requirements for providers.
4. Continue to allow modular capability as it has value by itself.

Discontinuation of Complete EHR Definition – Continued

5. Providers value components that work well together. This is implied by a complete EHR although depending on the actual construction of the EHR, it might not be well integrated. Similarly, some modules might work well together even from different vendors. In any case, testing for integration is complex and the WG recommended in the past that ONC not test or certify for integration. We continue with that recommendation.
6. Vendors may certify components of their product as modules but do not sell the individually. Providers would like the CHPL to indicate if the module is available individually or only in combination with other modules.
7. If ONC discontinues use of the Complete EHR definition, it must find a way to effectively represent technology that was given a Modular certification but is “complete” on the CHPL.

Certification Packages

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- The CAWG did not support the proposal around "Certification Packages."
- Members noted:
  - Packages were not addressing underlying needs of providers (what they need for MU).
  - Packages were more likely to create confusion since the terminology used for packages ("care coordination" and patient engagement") doesn't fully represent the breadth of those concepts.
  - Transmission requirements in packages were debated. Members opined that having more than one transmission criteria for care coordination undermines concept of what we are trying to do with standardizing systems so they can talk to each other. The receiving system may not be able to do anything with it cause it doesn't accept that. A fundamental concern is why separate out transmission and allow more than one transmission process. This undermines what we are trying to accomplish with standardizing.
  - Packages would be useful for non-MU providers if they are going to be required some MU functionality in a grant setting. Would better to say these are still module functions, leave them as modules, then be specific in the grant opportunity as to which module you need to have. Putting together care coordination packages is going to be confusing.
  - Its hard to define package titles. For example, what constitutes patient engagement?

ONC Certification Mark

- The WG understands this to be primarily an issue between ONC and the Authorized Certification Bodies. ONC wants a single Certification Mark rather than having each ACB issue its own mark.
- The WG commented that a singular certification mark would be beneficial for consumers by providing certainty, clarity, and confidence that the product they are buying is certified.
- The WG also noted that a singular certification mark might lead consumers to assume the product is an MU product.
- Vendor representatives within the WG voiced concerns about the proposal's clarity. Specifically, they didn't believe the proposal was clear what the requirements would be for vendors and where they would have to display the mark. In addition, vendors voiced concerns about having to display someone else's logo.

Non-MU Certification

- The topic here is the calculation of the numerators for MU objectives.
- Overall, the WG could not determine the impact of having non-MU certification on the market and the vendor community.
- The WG supported taking a step forward to support non-MU adoption of EHR technology. However, the WG believes the proposal creates a binary certification program. Instead, the WG supports conceptualizing the expansion as multi-factor, with many other programs and needs for CEHRT arising.
- The WG noted that there is likely a smaller development requirement and cost for the non-MU certification, for vendors who are newly developing functionality. However, if a vendor is developing products for MU and non-MU certification, the cost will likely increase.
- Non-MU users might find value in the usage statistics in the MU Version.

Non-MU Certification – Continued

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- The WG noted the additional issues:
  - Many factors go into price setting. It is unclear what impact the difference in MU v. non-MU certification will have on overall product price.
  - Even if the price for development will be lower with non-MU products, it's not clear if it will be low enough to incentivize vendors to enter the space. It's also unclear if the distinctions will increase or decrease complexity in the development of products.
  - It's unclear if consumers will understand the distinction between the two types of products. It's also unclear if this will create a tiered understanding of products, with consumers viewing the MU products as somehow better than non-MU products.
  - This might create an environment where MU products begin competing against non-MU products due to consumer misunderstanding.
  - This distinction might create confusion on the CHPL.

Non-MU HIT Certification

- The WG sees value in voluntary certification program for other types of HIT.
- The WG encourages ONC to work with other agencies to collaboratively develop programs and funding specific to the needs of the partner agency before certification criteria are created.
- In this section of the NPRM, the terms setting was used for the Children's EHR and Practice Transformation. These are not settings.
- Certification continues to grow and require new features that increase cost and may decrease usability of HIT. ONC should seek ways to manage this complexity.
- We have come from the EMR which focused on the providers needs for a electronic medical record to a much broader concept of a larger EHR ecosystem. The expanded concept can create a usability burden on the core EMR functionality.
- Children's EHR Format:
  - It was initially unclear to the WG what a Children's EHR Format is.
  - The WG understands that a Children's EHR might decrease the patient safety risks of using adult EHRs for pediatrics and is pleased that HHS has undertaken a trial and evaluation of such technology.
  - This is an approach the WG supports.
  - However, due to time limitations, the WG has not reviewed this work.
- Practice transformation certification:
  - Certification may be too prescriptive and limit innovation in this area.
  - Creating certification criteria and incentivizing use of technology with no evidence it will improve care is risky. The WG would like to see successful operational pilots as large as possible before initiating certification requirements.

Additional Patient Data Collection

- Overall, the WG agreed that there was value in collecting disability, sexual orientation and gender identity, occupational, and military data about patients.
- The reasons for collecting each of these data elements differed, and are likely not a good fit for a demographics criterion.
- The collection of these additional data elements raised privacy, implementation, and workflow concerns.
- If this information is collected, it is important to focus on the capture of data, and not how it is collected or where it is stored. That is, to not predetermine who collects the information and the workflow they use.
- The collection of this data could be valuable for assessing health disparities.
- In addition, the WG believes the information needs to be coordinated with CCDA requirements and coded in accordance with the CCDA.

Additional Patient Data Collection – Continued

- Disability data:
  - The type of questionnaire is not in line with other types of information collection within EHRs.
  - If the purpose of this information is to accommodate the patient, the information is better collected during intake.
  - The proposal is too prescriptive.
  - Disability information changes over time and the NPRM does not include a proposal for how to deal with longitudinal changes.
  - May be a better idea to take this issue to the S&I Framework for more review on how to implement.
- Sexual Orientation and Gender Identity data:
  - This type of information requires heightened security and privacy and therefore should not be a part of the demographics criteria.
  - The WG did not have the expertise to know which vocabulary to use.
- Military Service data:
  - This is an example of a need to exchange data and match patients with existing DoD and VA databases and not collect repetitive information.
  - It’s unclear the level and detail needed for this data element.
- Occupation data:
  - In order to make this information useful in clinical care, several years of information is needed.
  - Collect that much information will likely severely interrupting clinical workflow and add administrative burden.
  - Some members thought this information was valuable and didn’t necessarily have to include prior occupations.
  - Allow for the capture of multiple jobs at the same time.

Blue Button+

- The WG saw potential value in BB+ but thought it was premature to consider including BB+ in certification. Members did not believe enough consumers were using the "transmit" function in VDT in order to warrant including BB+.

- In this case, there could be problems with the current VDT leading to its low level of us. It is not clear that the proposed solution is part of a proven approach to meeting the consumer need for access to and re-use of their information. The S&I Framework, looking at innovations in the market outside of ONC sponsored activities, funding R&D, are among the alternate methods discussed by the WG. As these explorations demonstrate value and operationalize standards, then certification can have value.

Blue Button+ Continued

- The WG noted the following in support of certification:
  - BB+ certification would increase trust among consumers in using VDT.
  - BB+ will be helpful to automate information exchange to non-MU providers including LTPAC and BH.

- The WG noted the following drawbacks to certification:
  - There is not enough evidence from Stage 2 that consumers are using VDT.
  - The WG noted that they would like to see more consumers using the BB functionality, examine the results of the current S&I Initiative around BB+, and see some piloting in order to make the functionality relevant for 2017.
  - Technology developers are critical of the requirements to implement the transmit functions for VDT that no one is using, they will not support creating additional functionality that will not be used.
  - The standards, implementation guides, and work flows around BB are not established enough for a nationwide rollout of BB+.