Certification Hearing
FINAL
Report of the May 7, 2014 Hearing

Attendance

Members present:

- Carl Dvorak
- Paul Egerman
- Jennie Harvell
- Joseph Heyman
- George Hripcsak
- David Kates
- Michael Lincoln
- Nancy Orvis
- Marc Probst
- Donald Rucker
- Paul Tang
- John Travis
- Charlene Underwood
- Larry Wolf
- Michael Zaroukian

Hearing Goal

The overall goal of this public hearing was to understand the successes and challenges associated with ONC's electronic health record (EHR) certification program. Panelists were asked how to improve the certification program to first, accomplish what is needed to work within the new care model, and second, be interoperable so that health information can be shared in a meaningful way.

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), explained that this hearing was jointly sponsored by the HIT Standards Committee's Implementation Workgroup as well as the HIT Policy Committee's Certification/Adoption and Meaningful Use Workgroups. She reminded participants that this was a Federal Advisory Committee (FACA) public hearing and described the opportunity for public comment. She called the roll and asked participants to identify themselves for the transcript before speaking.

Welcome and Introductions

HIT Policy Committee Vice Chair Paul Tang welcomed the group, explaining that one of the requirements of Meaningful Use (MU) is the use of a certified EHR. The goals of ONC's EHR certification include having a minimum amount of functionality and following a common standard. Hearing Vice Char Mike

Zaroukian also welcomed the group and thanked the panelists for sharing their written testimony in advance of the hearing. Tang added that following this hearing, a debriefing session would be held on Thursday, May 8, 2014, to develop recommendations to ONC based on input from the panelists from this hearing.

Overview of ONC Health IT Certification Program

Lee Stevens, ONC, provided a brief overview of the ONC Health IT Certification Program, noting that there is an ONC sequence and a CMS sequence. As part of the ONC sequence, when a developer creates an EHR there is typically an intention to meet certification criteria—the developer submits the EHR to an accredited testing laboratory (ATL) that tests for the criteria and generates a test report. The developer then submits the test report and other documentation to an ONC-authorized certification body (ACB), which issues the certificate for the scope of the capabilities that have been tested. The next phase involves the ACB submitting the certified EHR products to ONC, which lists them on the Certified Health IT Product List (CHPL). The next part of the process is the CMS sequence. The eligible provider, eligible hospital, or critical access hospital selects a certified product from the CHPL that can then be used to demonstrate MU and that generates a CMS EHR ID for the selected product. The provider then submits that certification ID to CMS as a part of MU attestation and CMS validates as part of the process. Stevens defined the test method as a critical component made up of three parts: (1) the test procedure, (2) the test data, and (3) the test tool. The tools are mostly at the National Institute for Standards and Technology (NIST); ONC works with NIST frequently to assess how the tools are working.

Panel 1 – Providers/HIE Organizations

Ginny Lorenzi, New York-Presbyterian Hospital, explained that the hospital has been busy preparing to attest for Stage 2 MU in the fall using a component approach (i.e., they have multiple certified products and are also doing some self-certification). She expressed enthusiasm that standards are being built into EHRs at physicians' offices and hospitals across the country—this activity is transformative with respect to interoperability and information reuse. ONC's certification program offers support to those going through the process. There are implementation guides, tools, forums, and associated organizations (e.g., IPSA, Drummond) that provide valuable assistance with regard to certification regulation and the entire process. She has noticed a significant improvement in quality since the certification process began and commented that she is very impressed with how much more rigorous the testing has become with clinical quality measures (CQMs). Lorenzi briefly summarized the 2012 Institute of Medicine (IOM) report *Health IT and Patient Safety Building Safer Systems for Better Care.* The report discusses how implementing the vendor system can result in improved quality and safety or pose serious risks to patients. She noted that her organization and others like it do not benefit from the support that vendors receive with regard to the certification process. It is often unclear how these groups should implement their systems, in their own unique environments, to meet MU requirements. She commented that all of the good work being done by ONC's certification program is in vain if implementers with certified HIT products do not receive better support. In designing a certification program that would achieve benefits and minimize burden on participants, she suggested enhancing the entire process, beginning with EHR development, through provider implementation, all the way to MU.

Chad Jensen, LaTouche Pediatrics, LLC, explained that ONC's certification program is a major benefit and helps groups like his by allowing them to have a level of confidence that an EHR will meet a certain level of guidelines and demonstrate that the vendor has a level of commitment to meeting those standards and is also committed to meeting MU. The certification helps indicate if implementers are spending their money on a quality product that is going to give them value. Certification allows implementers to provide the highest quality of patient care while keeping costs down. Implementers are also looking for certification that indicates a quality of meeting the standards, which is currently missing

from ONC's certification program. While an EHR product may meet the certification criteria, there may be some components of the workflow within the product that work well in some settings but not at all in others. Jensen provided the example of printing inside the EHR—there is a requirement for providing third-party education out of an EHR product. Although the IT portion with regard to certification is in place, real-world testing has not been fully carried out on multiple standards within certification. This represents a significant challenge moving forward. He suggested introducing an indication of quality on a scale for meeting measures into the certification program. He also expressed concern that from the vendors' perspective, there is an emphasis on reaching the point of meeting certification criteria but not necessarily providing a useful, quality product in every instance.

John Berneike, Utah HealthCare Institute, reminded the group that there has been a paradigm shift in terms of what EHRs are expected to do, going from electronic SOAP note generators and data repositories to all of the new functionality in terms of chronic disease management, preventive care management, population health management, care coordination and transition of care, exchange and interoperability, and patient engagement. These new functions require significant implementation work on the part of vendors that they previously did not need to address. Some of the main challenges he sees in this area include reporting and tracking registry and analytics functionality within the EHR. Berneike pointed to the importance of ONC continuing to work with other HHS organizations on issues related to coding, billing, and payment reform. Although ONC should continue to serve as the *de facto* standards organization for EHR technology, the rapid pace of HIT adoption needed for the system-wide changes that are envisioned lies beyond the capabilities and scope of any individual software vendor— some outside influences are needed to help drive the functionality, changes, standards, and definitions being sought. Human factors and usability issues also remain significant issues to address. The certification process currently is geared towards the vendor checking the boxes to indicate that "yes, the functionality can be met," but it does not focus on how the functionality can be met and how effective is it for the end user. He suggested that the certification program include some type of quality measurement in terms of the human factors and usability components. One of the benefits of the certification process is that it can be used as a surrogate for practices that do not have the skills or resources to thoroughly evaluate vendors and their products. Challenges to the certification process remain and include interoperability and exchange issues that exist even when vendors have met the certification requirements. Berneike suggested that a shift in the certification process is needed to lessen the burden on the end users of these products.

Colin Banas, Virginia Commonwealth University Health System, noted that his organization considered, but ultimately decided not to pursue, modular self-certification. VCU has already incurred great cost with its current vendor-based solution and relies heavily on vendor certification and processes that often lock it into non-value added requirements simply to satisfy the report that demonstrates compliance with the attestation measure. The second reason for not seeking self-certification is that research had revealed a prohibitive expense in terms of man hours and dollars, a timeline taking months, and an excessive test burden to achieve certification. In his view, self-certification appears best left to vendors and large custom institutions seeking certification for an entire EHR. There is continued confusion regarding the blurred lines between a certified technology and how one uses it to achieve attestation. In his written testimony, he provided examples of how certification drives the manner of adoption for attestation in an unintended way. The biggest challenge associated with the current certification process is that there is no guarantee that the certified EHR product will result in a clinician's ability to meet MU requirements, especially for veteran users of this technology with years of pre-existing customization and concrete workflows. Very often, meeting the measures outlined in MU requires data and input from systems such as disparate billing, registration, and scheduling. The certification process does not and most likely cannot take into account all of these variables. VCU has a

number of examples in which the health system already meets the intent of the measure but its certified technology was approved for said function in a different manner. The perception of the MU program has started to shift. The exuberance over the prospect of new technology to benefit patients is slowly eroding to a state of fear—fear of being penalized for failure to comply. At times, it feels as though VCU is being penalized for being an early adopter of EHR technology. VCU is not alone in this frustration. Banas noted that a new phenomenon has emerged as a byproduct of MU and certification, which he called "code chasing." Clinicians and hospitals are forced to load and test code at an unprecedented pace and this can introduce problems in the system.

Howard Hays, Indian Health Service, explained that from his perspective, certification programs offer assurance that an EHR product meets some basic objective functional requirements and as a starting point for the shopping list for a hospital or practice, they check the certification off and then they begin to compare products on functionality, life cycle, costs, supportability, configurability, etc. An ideal certification program could also serve to help conduct like-to-like comparisons between products in terms of their functionality. Hays commented that that ONC's certification program should not be so prescriptive that it forces all of the EHR systems to do the same thing; rather, it would be more useful to help customers distinguish the capable systems from those that are not capable. One challenge he described was the requirement to provide clinical summaries in Stage 1, which added to the workflow and added time to the encounter, but did not necessarily add value to the encounter. Additional challenges include requirements to adopt under unrealistic timeframes, requirements to implement incomplete standards or those that have not been fully vetted in the marketplace, the inability for users to configure a system to their business workflow because of a certification constraint, the inability of vendors to respond to user enhancement requests, and any requirements that limit the vendors' ability to innovate. With regard to certification and quality, Hays reminded the group that certified software is not the same as quality software. Certification only means that the developer could make it past the test scripts. Quality is not just about the user-facing interfaces and the usability functions, it is about the data (e.g., are the data accessible and usable for analytics, how easy is it to access the data, etc.?). A balance is needed between the essential functions that need to be present in an EHR and then allowing for innovative capabilities that allow vendors to distinguish themselves in the marketplace. Hays suggested that the group consider levels of certification (e.g., "bronze" certification could indicate what is only necessary for MU).

Cletis Earle, St. Luke's Cornwall Hospital, commented that small systems have to communicate and work with other care providers in their communities. MU standards have provided a platform for sharing information across the continuum and getting in front of care coordination initiatives. From a quality perspective, certification requires EMR systems to push in frivolous data at times that in essence do not necessarily reflect what the physician wants to do in taking care of a patient. This issue needs to be addressed moving forward because it creates a significant quality issue related to patient care. The certification process is not establishing reliable code from vendors and implementers are often forced to wait for vendors to catch up. When his institution was working towards MU Stage 2, it had to incorporate more than 10,000 different codes and then a few months later, had to do a revision of about 6,000-8,000 codes. Small systems often do not have the resources to accommodate such changes. There are also challenges associated with connecting to regional extension centers (RECs) and health information exchanges (HIEs). Earle commented that in certain areas of the country, it is very difficult to gather enough resources to address the various changes in certification. He suggested focusing more on usability and addressing the different interpretations of the standards. He also noted that early adopters should not be penalized, and some understanding is needed regarding the level of resources required to accommodate changes and the burdens associated with implementing these changes.

Q&A

Paul Egerman asked the panelists about their definition of the term "quality" when used in the context of certification. Jensen explained that for him, quality refers to the stability of the product. Usability is also a consideration, and he gave the example of wait time, noting that waiting 30 seconds for software to perform a task would be an indication of poor quality within a product. Berneike agreed, adding that quality also plays into the human factor's usability point of view and achieving the intended result through efficient, effective workflow. He reminded the group that the goal of MU from a provider's point of view is not just to check off boxes so that payment can be received; it is to achieve higher-quality, safer, more cost-effective healthcare. Banas noted that vendors often get stuck having to not only provide the function but then prove the function—sometimes, the proving of the function is actually what diminishes quality. In response to a question regarding innovation, Banas commented that in his opinion, regulatory reform has stifled innovation in the space of informatics.

Larry Wolf asked about the challenges associated with early adoption since the MU program began. Hays explained that those facilities that only adopted an EHR in part of a practice or clinic because of the availability of the MU incentives were driven to become more full adopters and so the meaningfulness of their use of EHRs actually increased.

Marc Probst asked the panel if certification should drill down to the level of actually testing code and how useful it is. He also asked panelists to describe their perspectives on the purpose of certification. Berneike indicated that certification does not need to address the quality of the code; that already falls under the vendors' responsibilities. His opinion is that the goal of certification should be more about addressing the burden on the end user in terms of taking care of patients and less about the vendor checking a box indicating that their product can achieve a given functionality.

In response to a question from Tang, Posnack explained CMS published an FAQ indicating that if there are alternative workflows that are designed into the system for a certified capability, those alternative workflows could be used. The developers would be in the best position to indicate that some of those alternative workflows are the customization that is permitted of the product for alternative workflows and could lead to additional burden on the provider to count for the purposes of a numerator/denominator type of situation. Tang noted that the Meaningful Use Workgroup has heard concerns regarding usability and with documenting compliance. The certification process could include the ability for users to compare vendors. He further explained that as developers go through the certification process and get a product certified for objective X, they could publish exactly how they were certified and information on the required workflow. This would give providers a chance to determine how the developer implemented the objective and what the required workflow is. Banas noted that most institutions are not able to change EHR system vendors quickly, easily, or inexpensively. Berneike agreed, adding that most institutions are captive audiences of their vendors. He pointed to the need for vendors to work with users and providers to determine their workflow and design products that measure, track, and report on existing workflows.

Banas noted that the MU framework and process represents a good guideline for how this country should improve the care of patients using HIT, but there is a disconnect between realistic expectations and the specified pace of adoption/implementation.

Zaroukian asked panelists for suggestions regarding a possible focus on usability related to certification. Hays noted that from the developer's side, it is relatively straightforward to develop software to meet

requirements for which standards have been published. It is more difficult to adapt software into an existing system. From the providers' standpoint, usability is key. He suggested that vendors be given enough flexibility to meet the rules without being constrained to a particular behavior. Berneike clarified that MU is not the end goal, it is a means to an end (that end being high-quality, cost-effective, efficient, safe patient care). He suggested that more effort needs to be made in terms of advertising this goal and how MU will help reach it.

Nancy Orvis asked if any of the panelists have been able to work with their region, accountable care organization (ACO), or local HIE to agree on the numerator and denominators for the quality measures. She noted that a group in Oklahoma has been able to convince all of the providers and insurers there to use the same quality measures to report out. Earle noted that his institution has been working collaboratively with two state health associations and has also found some success working with RECs and HIEs.

John Travis asked for comments on what would be an appropriate role for certification with regard to improving scenarios in which there is a change in a standard that brings with it either data migration or data mapping. Banas noted that this question ties into the legacy problem list and acknowledged that ONC has been forward thinking in terms of considering legacy data moving forward. At present, industry is still wrestling with deciding what items belong on a problem list. He noted that he has more faith in the billing data right now, at least from a hospital perspective, than in the problem list. The value of the problem list is not yet well appreciated by providers and patients.

Carl Dvorak asked if any of the panelists have been audited on Stage 1 and what their experiences were. Banas reported that VCU has been pre-payment and post-payment audited on both the Medicaid and Medicare sides. He reported that the process went relatively smoothly. Earle offered a different perspective, explaining that his institution's audit was difficult, in large part because the auditor appeared to be inexperienced and was not familiar with many of the logistics associated with MU. Jensen and Berneike indicated that their institutions' audits went smoothly. Banas commented that providers would benefit from additional guidance regarding the relationship between certification criteria and the audit process, particularly as the stages change. It would allow providers to be more confident that the way that their systems are implemented fulfills both the certification criteria and how they are deployed for MU.

Egerman asked whether the certification process should be used for practice transformation and EHR innovation. Banas explained that at present, there is a plea from developers and providers to slow the process down but that eventually, this framework could be used for innovation. Charlene Underwood commented that one challenge is enabling providers to meet the intent of MU through certified products. Hays commented that in general, he does not favor the concept of IT driving business process change—in his view, the business process change should come from the business side. The IT should not be adopted for the sake of IT, it has to be intelligently thought out and then there has to be some leverage to get the adoption to occur. Banas agreed, adding that decisions are needed on how to define a problem list and identify who can contribute to it.

Donald Rucker asked the panelists to identify a few key areas where the MU process needs to change most. Berneike commented that there is a bottleneck with regard to the lack of final exchange and interoperability standards that is delaying vendors' ability to implement interfaces. Banas suggested including as much flexibility in the process as possible. Earle emphasized the need to focus on quality and examining potential national standards of care from a quality perspective. Hays commented that it would be beneficial to allow more time for implementation.

Panel 2 – Vendors

Mickey McGlynn, Electronic Health Record Vendor Association (EHRA) and Siemens Healthcare, emphasized that the EHR vendor community understands how important certification is to their customers. While the obvious benefit of ONC's certification program is to enable providers to meet MU requirements and the growing number of reimbursement models that might be based on the use of certified technology, the real benefits of such a program should accrue to the providers and the patients in the form of higher quality and more efficient care delivery. The vendors' primary goal is to produce high-quality software that meets a broader set of their customers' needs, only some of which relate to MU or those defined by the ONC certification program. As currently defined, the processes, deliverables, and tools for certification, although very well intended, are not effectively enabling EHR suppliers to achieve this goal. McGlynn reviewed some of concerns on the part of the EHRA (the full list appears in her written testimony):

- The full set of requirements is not provided with adequate time for development. And as they do become available, these deliverables have added and changed the requirements that were defined in the initial certification rule. This forces vendors to reconcile these matters and incorporate the new requirements into the software late, ultimately impacting the quality and usability of the software. In addition, it causes delay and when certified software is available in the market.
- The certification criteria for the MU objectives, the requirements for the reports that measure these objectives, and the clinical quality measures are not aligned with each other and are not necessarily aligned with clinical practice.
- The testing tools and associated data are not properly tested before they are rolled for use in the vendor community.

There are a number of opportunities to improve these issues and certification broadly for all key stakeholders while also maintaining the integrity of the program. For example, all the materials that impact the requirements must be available much earlier (ideally, concurrent with the release of the final rules) and remain stable or the timeline for the program needs to accommodate when the information is actually final. The EHRA also recommends that the overall complexity of the program be reduced and that a Kaizen process be used to support an effective review of the certification program, considering the recommendations and experiences of all of the stakeholders represented at this hearing.

Sasha TerMaat, Epic Systems Corporation, discussed the potential benefits of an ideal certification program using clinical quality measures as an example certification criterion. In an ideal state, certification of clinical quality measures would first bring together all of the requirements for clinical quality measures as a function in a single source that could be used to inform the development. Next, certification would assure a user that this particular EHR could capture all of the data necessary for a particular quality measure. It would test the accuracy of the measure calculation and check the conformance of electronic file to standard format. And most importantly, certification would ultimately assure a hospital or physician that files generated by a certified EHR would be accepted by CMS for participation in the program. However, key elements of this ideal state are missing today. Certification is not a single source for quality measurement requirements. In fact, months after certification criteria were finalized CMS has published clinical quality measurement requirements in their implementation guides that directly conflict with certification and has also added new development needs. This discrepancy challenges developers, confuses EHR users who do not understand why they cannot submit files that were generated out of their certified EHR, and causes CMS to spend additional effort on separate clinical quality measurement validation tools. In addition, the certification program requires the development and testing of clinical quality measurement formats that cannot actually be used for submission. For example, CMS does not accept the QRDA file for hospitals, but this is part of the

certification criteria. An ideal certification program would align and define the requirements that will be used with sufficient lead time that they can be developed and implemented efficiently. TerMaat suggested that there is a disconnect related to certification scope. For example, ONC estimates that the updates to standards for lab ordering and sending labs electronically will take an average of 100 to 300 hours per EHR product developed and certified. Accounting for some certification listings to be inherited, this estimates to about one developer working on the project for 15 weeks. When EHRA surveyed EHR developers, they estimated on average that this same project would take about one developer 93 weeks. It is difficult to select appropriate timelines with such a discrepancy. TerMaat recommended a thorough review of the MU program and the certification process in particular. In this review, the focus of certification should be narrowed to the highest priority criteria (which she sees as interoperability and clinical quality measurement). There is also an opportunity to consider more efficient testing models for certification.

Emily Richmond, PracticeFusion, Inc., explained that by the time PracticeFusion began working towards 2014 certification the ONC had clarified many EHR developers' questions through the use of sub-regulatory guidance. However, PracticeFusion was still faced with a huge volume of product changes and very specific implementation criteria that needed to be researched, analyzed, designed, developed, and tested before it could begin preparing for the ATL certification test. Had the company started the process sooner, it would have had to change course quickly and on multiple occasions, expending time and resources as updates to test methods . These updates ultimately changed the acceptance criteria needed to develop the software. Despite starting the process after clarifications had been made, PracticeFusion still had to locate and analyze six different sources of information, including test procedures, CMS specification sheets, standards documents, and various FAQs before being able to determine, with some level of confidence, how the software would need to function so that it could move forward with design and development. Non-software developer stakeholders often underestimate the time and effort required to overcome the challenge of simply understanding what needs to be built in order to certify. Another challenge PracticeFusion faced was integrating the certification requirements into its product without compromising usability and our customer's ability to provide high-quality patient care. The current certification program challenges usability in two ways: one through dictating prescriptive functional requirements that allow little room for innovation, and another by requiring that healthcare providers adapt large volumes of products and clinical workflow changes in a short amount of time. Some prescriptiveness is necessary to support interoperability and some feature additions are needed to support MU, but certification is moving in a direction of incorporating higher volumes of requirements that do not serve either of these goals, which in the long run may have a negative impact on both providers and patients. PracticeFusion has seen a 60% increase in support cases related to dissatisfaction or confusion with MU required features during the first quarter of 2014 compared to the same timeframe after the release of its 2011 certified product. PracticeFusion proposed several changes to the certification program, including: (1) reducing the overall scope and complexity, (2) incorporating the feedback and expertise of EHR developers early and often, and (3) the creation of certification requirements and testing criteria. This will help ensure that the requirements are aligned with the capabilities of EHR technology and that the program is fostering the development of software that meets the true needs of healthcare providers, not just EHR systems that can "pass the test." PracticeFusion is supportive of the earlier suggestion that the certification program be reviewed using the Kaizen approach.

Joseph Geretz, SRSsoft, commented that the bulk of the burden that is placed on vendors today can be traced to the vast and varied scope of the objects and measures upon which certification is ultimately based. Since 2010, the vendor community has experienced a progression of development from one peak to the next without seeing any valleys. Vendors have lost their capacity to innovate on anything above

and beyond the mandates of MU. Since embarking upon this program, vendors have generally been unable to devote resources to features their customers are requesting, and customers ultimately bear this burden in terms of higher costs and lost productivity as the program with its tight deadlines trumps the desire to focus on the ease of use and productivity. Geretz stated that a broader evaluation of the entire scope of MU objectives and measures, together with the demands of certification requirements, is warranted. From the vendor perspective, the beneficial aspects of certification are those which align progressive policy with commercial interest. The convergence of commercial motivators with proper healthcare policy will be the most effective combination of factors to advance the cause of HIT via private industry. The most beneficial aspects of certification are those that govern relationships between vendors and those that help to promote relationships with customers. These are certification of interoperability and certification of suitability. Geretz noted that among the challenges is assimilating specifications from a wide range of sources, those that are out of sync with the state of the industry, those that are in conflict with typical practice workflows, or those based on immature standards. Additionally, vendors are challenged by requirements to interoperate with unregulated partners and certification utilities and testing tools that are defective or overly strict with respect to the requirements. SRSsoft recommends a narrowly focused certification that places emphasis on those aspects of EHR technology that are the drivers for the most important items among the wide range of prescriptive criteria to which vendors must certify today. These are interoperability and quality measures. This concise set of criteria represents the convergence of progressive healthcare policy with commercial interests. With this framework in place, vendors in cooperation with market forces will naturally produce their EHRs to the standard that will advance the cause of HIT. SRSsoft supports the suggestion tendered by Mickey McGlynn on behalf of EHRA, as well as other panelists, for the initiation of a holistic Kaizen process to review the combined MU and certification programs with an eye toward improvement.

Sarah Corley, NextGen Healthcare Systems, explained that as constraints on providers' time become more prevalent, healthcare professionals are turning to technology-driven solutions that can increase practice efficiencies and allow them to focus on delivering quality care to their patients. A certification program can give providers the assurance that the software product will meet baseline standards for compliance with regulatory requirements as well as the functionality that stakeholders think is important for supporting improved care. Meticulous testing of EHR products is critical to their optimal performance and to maintain the highest standards of patient safety possible. The current certification timelines and cycles do not allow time necessary to safely develop content focused on user workflows. Given today's limited timelines, EHR developers do not have all the necessary requirements available prior to beginning their work, resulting in extensive wasted effort when late guidance is issued. In addition to the 18-month period that vendors require from the final release of all requirements, test scripts, and testing tools to safely develop the software, there must be time for healthcare providers to thoroughly test the software in their unique environments—that process includes testing all interfaces and connected software and devices, adjusting workflows, and training their end uses. Corley recommended returning to the certification process that was followed in the CCHIT model, which included key elements such as broad stakeholder participation, an environmental scan of the availability of functions, maturity of proposed standards, and a published roadmap. Extensive stakeholder input by clinicians, vendors, academicians, developers, payers and consultants is essential to ensure that the certification is relevant to those purchasing and using the products and services. A successful certification program must provide a forward-looking roadmap of certification requirements and clearly detailed additional criteria that vendors should expect in the future. In addition to predictable timelines, test scripts need to be published well in advance and pilot testing of the test scripts and testing tools must be done before the final version is released to catch and address any potential problems. The

current program includes many requirements not relevant to large segments of the healthcare provider community; certification requirements should be limited to the core to which all physicians or hospitals must adhere. If there is a need for additional requirements for certain types of healthcare providers, add-on items can be certified separately so that vendors who do not serve that market are not forced to develop software that their clients do not want or need.

Marc Probst, Intermountain Healthcare, explained that if a system is self-developed for use by its organization with no intent to market the product, it is difficult to find utility in the certification program. As long as self-developed systems are: (1) not available to the market for purchase, and (2) able to the meet MU objectives, it seems an unnecessary expense to require the self-developed system to move through the certification process. The MU requirement to use a certified product should be significantly relaxed if not removed for self-developed systems. One of the greatest challenges with the certification program is the compressed timeframes. The current regulatory pace between final rule publication and the beginning of compliance is unrealistic and does not match the reality of safe development. There are very real patient safety implications when HIT development and implementation is rushed. Probst cited an American Hospital Association survey of approximately 500 hospitals indicating that the majority of hospitals had not yet received from their vendors all of the needed 2014 edition certified EHR components. Nearly one-half of the hospitals found that the majority of the technology received from vendors to date required additional software code upgrades to make the technology functional. The majority of hospitals were missing modules that support MU objectives that are new in the 2014 edition certified EHRs and at the time of the survey, 40% of hospitals were at risk of failing to meet MU in fiscal year 2014 if current timelines remain. Requiring providers to upgrade in 2014 regardless of their point on the MU journey has created unnecessary pressure for vendors and providers as well as unnecessary costs for providers who are not at Stage 2 in 2014. Going forward, the provider certification requirements should be based on the provider's stage of MU and not the fiscal year. The cycle of software development to meet specified functionalities tends to impede innovation. Developers are working so fast to meet the demands of MU that little time remains for life and cost saving innovation. Probst suggested that the MU program is unfolding incrementally—providers and vendors do not share a long-term strategic view for the program. Probst argued that all of the expertise in the federal government must be leveraged to develop a long-range plan and architecture for a national healthcare information technology infrastructure and outline the pathway to comprehensive use of meaningful standards to facilitate national interoperability.

John Halamka, Harvard Medical School and Beth Israel Deaconess Medical Center, thanked those at NIST responsible for developing and hosting the testing tools, but commented that in his experience, the tools were not always available or responsive (and in once instance, actually changed from one server to another, leading to a certificate mismatch that rendered the tools unusable for some time). This resulted in a need to reschedule certification activities on multiple occasions, and missed milestones because of the instability and unavailability of the tools. Halamka also pointed to the need for a more agile method for the development of test procedures that follows the workflow of data from point of origin to point of use, ensuring that a continuous process along the way enables a physician to meet policy goals. Overall, he commented that the burden of testing was immense. Additionally, the timeframe from the publication of the criteria to the expectation of having mature products was so abbreviated that usability suffered. His institution was able to achieve certification and get through every procedure, but was unable to optimize workflow. This resulted in artifacts such as pop-up screens or checkboxes that interrupted the physicians' workflow. With more time, a more elegant implementation would have been possible. It is hoped that moving forward, scripts are better aligned with workflow and there is an opportunity to optimize the usability experience so that the end result is that the physician is made more efficient rather than less efficient through advances in technology.

Certification in the future is hopefully not an attempt to exhaustively test every single possible variation on data entry and results, but instead a deep and narrow focus on a few items such as interoperability or quality measures.

Q&A

Tang noted that one of the themes that arose during this panel was use of the Kaizen process, which has been utilized with good effect in HHS with regard to quality measures. Panelists suggested that the integrated lifecycle should be reviewed in total, from MU objectives to the measure, to the certification, to the testing, and to the audits. Other themes that arose relate to the complexity of the certification process, eliminating waste in the process, and the need for realistic timelines so that quality products can be developed safely. McGlynn explained that the Kaizen process would bring many of these issues together and may represent the best opportunity to get to the root causes of the problems/challenges identified in the hearing to this point. She noted that vendors are treated separately from providers in the certification program, which creates conflicts. Geretz added that there is an overwhelming amount of prescriptivity associated with the certification program. If there could be a focus on key outcomes, the process would be improved greatly. Wolf asked about approaches for informing the Kaizen process and introducing real-life experiences that could be used to guide the regulatory process. McGlynn suggested that many of these experiences can be found in the written testimony panelists provided. She also emphasized the recurring theme that there is a need to narrowly focus the certification program on the important outcomes. Geretz noted that focusing on quality measures would make the program highly customizable from the perspective of the type of practice being targeted (e.g., certification that shows that a certain EHR is delivering measures on certain scopes of quality that will tell customers which EHR is most suitable to their practice).

Corley noted that basic functionality no longer needs to be certified. Users are more sophisticated, although with the increase in adoption with MU there are many providers who are not so willing who have adopted, and that probably contributes to dissatisfaction. The measures should be narrowed. Quality measures need to be eMeasures that are part of the normal workflow and not include such things as requiring an exclusion to identify the drug that would have been selected if the patient was not allergic to the drug, which is a significant burden to providers. The quality measures should focus on areas in which this country has poor performance and are costing money rather than having a quality measure for every specialty.

Dvorak commented that in his view, certification is not driving adoption up nearly as much as stimulus funding. He asked if certification could be eliminated for those who could demonstrate MU regardless of the origin of their software. Could certification be eliminated entirely? Probst suggested that this question warrants further reflection. Egerman suggested that there could be a situation in which it would be appropriate to have certification for interoperability only and then meet MU requirements for other items.

Egerman asked about the extent to which the Stage 2 criteria fulfill needs of the organizations represented at this hearing. Probst explained that there are components of Stage 2 that are incrementally beneficial to clinicians at his institution. However, there are many aspects of Stage 2 that required retrofitting systems and processes to accommodate and allow for certification and attestation. Although in aggregate Stage 2 may not be beneficial to his institution, Probst acknowledged that there has been significant benefit to the greater community.

Richmond commented that many of the usability issues can be traced back to short timelines; the expectation of the customers is that products are available to them in 2014 so that they can meet certain deadlines and requirements associated with MU. EHR developers work to create products to

meet the certification standards, but because of time constraints, usability is sometimes compromised. Although developers can and do release product updates, preparing and staying on schedule for certification often precludes carrying out these improvement activities. In some ways, the certification process is an obstacle to implementing product improvements. McGlynn agreed that usability is one of the top issues—usability needs to be addressed with an overarching approach, because the term "usability" is defined differently by different providers. One of the major contributors to usability issues on the part of providers is the lack of training and education for providers who are about to use a new system. Another relates to the certification criteria being released after development has begun.

Halamka noted that he recently co-authored a paper for JAMA that outlines a quantitative method for evaluating standards maturity, readiness, and adoption. This approach was used in response to some of the proposed MU Stage 3 criteria and the standards that might apply, providing ratings on standards maturity. Richmond acknowledged that at times, there is an appropriate reason for including less-than-mature standards; however, it is challenging when a future regulatory cycle will be introducing a newer version of the same standard before it is used in the market and learned from. The 2015 certification proposals introduce many different types of standards or new standards from the 2014 edition without there being an opportunity to examine in the market where current standards are effective and where they need to be changed. Geretz agreed, offering eMeasures and direct messaging as examples.

Underwood asked panelists if there are any lessons learned from external sources of certification (e.g., SureScripts, IHE, etc.) that could be used to inform OCN's certification process. Geretz noted that the SureScripts certification is much narrower in scope. TerMaat commented that the quality measurement issues are a priority and that some of the certification programs that offer more flexibility can serve as models, especially in areas for which no certification currently exists.

Panel 3 – Certification/Accreditation Bodies

Amit Trivedi, ICSA Labs, explained that it is important to recognize that the industry has faced a major transition progressing through Stage 1 and at this time, before plunging forward, perhaps the industry needs some time to take stock of where it is given the current inventory of standards and newly implemented functionalities. ONC certification requirements create a solid standards-based foundation to build upon—Trivedi suggested focusing resources not solely on new functionality, but also concentrating on doing what has just been implemented, and doing it better. There are number of differences between the 2011 and 2014 editions of certification criteria, and they highlight a number of areas that are positive trends including a better emphasis on standards and implementation guides, more use of conformance testing, and tools for self-attestation. However, there are also some areas that should be monitored to prevent requirements from becoming overly burdensome. These include verbose and complex test procedures that are at times left open to interpretation, test data procedures and tools that are constantly in flux, a lack of robust support for some of the testing tools, and the increasing administrative burden around data collection requirements for ACBs that have questionable value at times for purchasers and implementers. Trivedi offered suggestions for improving the certification program:

- Pilot test new procedures and test tools prior to publication. It damages the credibility of the program if vendors are debugging unstable test tools after they are deemed ready for use. Pilot testing should include ample time to recruit participants, validate test procedures, validate test data, and thoroughly test out the tools.
- Improve consistency between test labs. Pilot tests should be a venue for all ATLs and ACBs to observe testing to understand the expected results, learn how the test tools operate, and then provide feedback to ONC. To date, this has never been done prior to publication of the certification test procedures.

- Focus on certification criteria related to interoperability and security testing.
- Testing tools need to be more automated to efficiently handle more test cases, reuse test data sets, and employ more robust types of testing methodologies including negative testing and testing the security of products.
- How EHRs handle various functionality should be left to developers to innovate on. What information EHRs should be consuming and providing should continue to be a focus of the certification criteria.

Kyle Meadors, Drummond Group, Inc., noted that one aspect that worked well in the 2011 edition but changed in 2014 was the testing timeframe, which was reduced by about a factor of five. Another effective approach from 2011 involved putting forth standards and test procedures for the entire industry. The 2011 edition included some good guidelines that were attainable for most vendors, but the level of complexity increased dramatically in the 2014 edition. Beta or pilot testing the test procedures is an area worth exploring, but in some ways it leads to a "chicken and the egg" dilemma: Why should a vendor develop its product based on draft test procedures when they can wait it out and let a different vendor do so first? Final test procedures, however, cannot be developed until vendors have products that can be tested. Meadors suggested slowing the entire certification process down. Expected timeframes are still necessary, but there is a need to be fair to the vendors' resources. He also suggested working backwards and starting with the major end-goal criteria (e.g., CQMs) followed by spot checking the underlying criteria that feed into them. A more collaborative test procedure lifecycle is needed that involves different stakeholders, more end users, and clinician feedback. Meadors commented that a major for any certification program is to enable a marketplace that is vibrant and robust both for small vendors and large vendors to encourage innovation. ONC, especially in the beginning, enabled that type of marketplace and can do so again going forward.

Mark Shin, InfoGard Laboratories, Inc., said that it is encouraging to see the large-scale adoption of EHR technology within the community over recent years. However, rapid development brings with it a risk of unexpected challenges that become amplified due to the large number of participants. From the inception of the program there have been two major editions with a third edition soon to be released, all within a short period of time. Such frequency is challenging for vendors as well as for testing and certification bodies because they conduct conformance-based testing that is dependent on consistency and repeatability. The current release pattern prevents consistency and repeatability, thereby reducing the quality of service and guidance that certification/accreditation bodies strive to provide to their vendor communities. Reducing the frequency of major updates while introducing trial and transition periods for minor revisions would lessen the burden and benefit the program as a whole. Application of the surveillance program has been challenging. Although the surveillance requirements are well intended, the lack of guidance from ONC leads to inconsistent surveillance plans among ACBs. Over the past two years, the majority of EHR developers have claimed the inheritance provision, resulting in significant implementation changes from the originally certified products. Without reconstructing or re-conducting tests or introducing a programmatic mechanism to enforce configuration management for product version control, the surveillance efforts will be ineffective. Work is needed on this front to develop a single, well-defined surveillance plan that all ACBs can support and enforce. The current program lacks a well-defined and proper set of security controls. These issues should not be deflected to another entity or organization to address, and cannot be undervalued. Personal health information is a sensitive asset that requires well thought-out protection measures. With the multiple high-profile breaches that have been reported in the media, it would be naïve to think that EHR technology would be exempt.

Q&A

Rucker asked Shin to elaborate on the security issues he described. Shin offered the hashing mechanism as an example and explained that there are available mechanisms and tools to address security concerns. There are numerous security standards that are proven and have been in place in both the federal and private sectors that can be leveraged. There is a need to ensure that there is some degree of sensitivity accountability to make sure that there is a layered security approach that starts from the EHR application all the way through the system and to the end users.

Trivedi commented that one common complaint tied to some of the procedures is that EHR vendors are often required to generate or transmit a document, message, or other information, but oftentimes the receiving entities are not available or able to connect. Connecting the ecosystem is important. The ability of registries to receive quality information was cited as an example. Alisa Ray pointed to the need to test valuable functions in the most efficient way so that developers' time and resources are optimized. Meadors agreed, emphasizing that testing puts a considerable strain and burden on vendors, to the point where it can stifle innovation.

Egerman asked about the prospect of changing the process so that it would be possible for a vendor to make minor changes without getting recertified. Meadors noted that ONC has done some work in this area and recently issued an FAQ clarifying how certain maintenance activities such as patches can be incorporated without the requirement for certification. Ray agreed that the FAQ from ONC has helped, and that the guidance could probably be further protocolized. There is wide variation in the vendor community in terms of development processes. Some may issue patches every two weeks while others may carry out two well-planned upgrades per year. Trivedi noted that consistency among test labs has been a significant concern; Ray added that there are likely areas in which ONC could create protocols to manage this issue and assure greater consistency (e.g., in the area of how gap certifications are granted). Meadors commented that ONC could have a more active role in witnessing and learning from test environments.

Joseph Heyman asked if there would be value in changing the certification process such that before an MU requirement is created, the certification body had some input into whether or not that was going to be a problem for certification, and vendors had some input into that requirement to indicate whether or not it would represent an impediment to workflow. Trivedi noted that all stakeholders have an opportunity to engage during the public comment sessions that have occurred throughout the rulemaking process. Heyman explained that his concern relates to unintended consequences that may originate at the very beginning of the process. Ray agreed with Heyman's comments, adding that it is a more efficient approach to begin the process with the end in mind, ensuring that all of the interdependencies and workflows align. Egerman asked if there would be value in having representatives from certification/accreditation bodies serve as members of the Certification/Adoption and/or Meaningful Use Workgroups. Trivedi indicated that this community would be willing to participate, given that the certification/accreditation bodies are the ones executing the procedures developed with input from these workgroups. Trivedi also commented that industry is moving away from attestation, and so testing in some way, shape, or form is probably always going to be necessary. Perhaps with more robust test tools that are continuously available, new versions can be tested and verified to indicate that the capabilities have not been degraded. This may be an effective alternative to pursuing recertification after every update.

Ray commented that surveillance offers an opportunity for ONC and policymakers to inform strategies—for example, knowing more about what is taking place at the implementation level. There are efficient ways to gather that kind of information without necessarily going onsite, and this would provide

tremendous value for guiding the future directions of ONC and the MU program. This would require coordinated leadership and ensuring that the same information is being collected across the board.

Given the concerns voiced regarding the frequency of changes required as part of the MU program, Wolf asked panelists about how other testing programs manage the interval between major changes. Shin noted that the frequency of major changes in the FIPS 140-2 program is every five years. Intermittently within that period, FIPS looks at the standard and the requirements. Based on either innovative technology or changing priorities, minor alterations or suggestions may be made; these are termed "implementation guidance." Trivedi noted that ICSA Labs administers another certification program in HIT, the IHE USA Certification Program. One of the objectives of this relatively new program is providing a roadmap and giving clear guidance to the industry with regard to major updates and refreshes. It is important to inform the community regarding the scope of the certification moving forward and how many criteria are being added or removed.

Panel 4 – Private Sector Representatives

Alisa Ray, Certification Counsel for Health Information Technology, reminded the group that the CCHIT was awarded a federal contract in 2005 to develop EHR certification criteria as well as the certification testing methodology. CCHIT received federal recognition in 2006 as an RCB and during the following three years, more than 250 ambulatory and inpatient EHR products were testified and certified. In January of 2014, CCHIT determined that its mission would be best served by voluntarily withdrawing from ONC's HIT Certification Program. Ray compared CCHIT's independently developed certification program with the ONC's certification program. CCHIT was originally created with the mission of accelerating adoption as a collaborator to ONC, contributing to the adoption component of the federal HIT strategic plan. From 2005 to 2010, CCHIT worked in this capacity with an emphasis on engaging the community of provider, vendor, payer, and government stakeholders to develop criteria and testing processes that establish the benchmark for that system. Capabilities were also published for forward-looking roadmaps or future requirements two-to-three years out. This independent development process included a high degree of transparency during the frequent development phase supported by multiple rounds of public comment, a rigorous pilot testing of both criteria and testing methods, and CCHIT's full certification also allowed a validation of successful provider implementations of EHR products at live sites. CCHIT's work pioneered testing and certification methodologies which formed the basis of today's ONC program. This includes the use of remote testing methods via observation of capabilities or functions, open-source development of tools to encourage and validate interoperability, a volunteer expert juror program to witness and validate testing, and the first introduction of EHR usability testing. CCHIT developed criteria with volunteer subject manner expert (SME) panels. The panel composition represented a broad range of stakeholders. Multiple public comment rounds were conducted so there was iteration at least three different cycles and forward-looking roadmaps were published at the same time which allowed the providers and the vendor community to plan their future and look at requirements. The test process followed a similar cycle. The testing method development was community-based by subject matter SMEs or volunteers, moreover the tests were thoroughly validated with public comment and a public pilot testing process. Once they were finalized and launched, they were never changed until the next cycle. The CCHIT believes that the community views certification more as a technical compliance check associated with the administration of the incentives and less as an assurance mechanism for providers purchasing IT as when CCHIT originally started.

David Kibbe, DirectTrust.org, Inc., and American Academy of Family Physicians, compared and contrasted the accreditation program run by DirectTrust and EHNAC with the ONC certification program and also provided some feedback on testing that might shed some light on the attesting and certification done by ONC. In February of 2013, DirectTrust in partnership with EHNAC established an

accreditation and audit program for direct exchange service providers including HISPs, CAs and RAs. The purpose of the program was to set a single national benchmark for the assurance of privacy, security and trust, and identity controls practiced by known counterparties in direct exchange. Accreditation and audit transparently signals a high level of achievement and practice of these controls, thereby permitting voluntary reliance on accreditation and audit to create a network of scalable trust without the need for further one-off legal contracts or single one-on-one connectivity arrangements. There are now 52 organizations engaged in the process of accreditation, 13 of which have achieved full accreditation in all three programs for HISP, CA and RA. Another 30 organizations are in candidate status for accreditation. Of the accredited and candidate status HISPs, 26 are not participants in the DirectTrust anchor certificate bundle. Distribution of this trust anchor bundle permits subscribers of these HISPs and all 50 states to send and receive Direct messages and attachments with one another. This network now serves more than 5,000 healthcare organizations and has provisioned over 200,000 Direct addresses in the past nine months. HISP-to-HISP interoperability testing is active and ongoing. DirectTrust's accreditation program is voluntary and is not a requirement of the federal government for participation in MU programs, unlike ONC certification. Another difference is that ONC is testing software for compliance with specific functions and specifications, whereas DirectTrust and EHNAC are testing organizations that use software against a set of standards, policies, and controls that taken together aim at assurances for privacy, security, and trusted identity. However, the ONC EHR Certification Program and the EHNAC DirectTrust Accreditation programs have evolved a parallel and highly related relationship in the market for EHRs in 2014 and beyond. The major EHR vendors certified for the 2014 edition are also either themselves accredited HISPs or are relying on accredited HISPs to provide their customers with the Direct exchange services. These parties' Direct capability along with over 25 state and regional HIEs operating accredited HISPs virtually guarantee the ability of the nation's healthcare providers to achieve widespread interoperability of IT systems via Direct in 2014. Kibbe presented a slide presenting a snapshot of the current DirectTrust network, which features a total of 650 HISP-to-HISP connections. Lessons learned from the past four months of testing strongly suggest that ONC, NIST, and DirectTrust members collaborate quickly over the next 14-16 months in order to make it possible for better ONC certification and testing to be carried out to prevent downstream problems.

Christopher Carr, Radiological Society of North America and IHE USA, explained that IHE began as an initiative to bring together healthcare professionals in industry to improve the interoperability of HIT systems. It now oversees committees in 11 clinical and operational domains, 24 national committees, and over 650 member organizations. IHE promotes the use of standards such as DICOM, W3C, and HL7 to address specific clinical needs by developing implementation guides, called IHE profiles. It also conducts a testing process for HIT developers to help them implement those profiles. In the last two years, IHE has begun to expand its testing services to include a product certification program. The IHE Certification Program grows out of an established peer-to-peer interoperability testing process with more than 15 years of experience and many hundreds of vendor systems tested. IHE profiles and the IHE testing process focus on interoperability and information exchange and avoid, as far as possible, prescribing system functional behavior or evaluating usability. To support this testing, IHE developed a testing platform and an extensive suite of testing tools in collaboration with an international team of developers including the Interoperability Testing Laboratory at NIST as well as other research organizations and commercial developers. The IHE profiles on which testing is based go through a development cycle of at least 18 months and often through multiple development cycles. The profiles selected for certification testing have been selected based on the maturity of the specifications and tooling, as well as industry demand and clinical significance. IHE is partnering with an accredited testing laboratory, ICSA Labs, to conduct a pilot program and establish a clear definition for an ongoing certification program. The certification program is a coordinated set of regionally implemented

programs administered by IHE USA, IHE Europe and potentially other national IHE organizations. The IT profiles on which these programs are based are international in scope and common across all the programs—IHE is developing a schema to ensure uniformity and reciprocity in these programs. The program is being implemented incrementally and the intent is to continue to grow it gradually over time. It is designed to be complementary with certification programs of ONC in this country and similar national programs in other countries. Carr offered the following recommendations: (1) ensure that test methods are developed with sufficient time and resources to provide quality, stability, and detailed coverage; (2) focus on baseline functional requirements and especially testing standards-based interoperability; and (3) leverage complementary testing programs by other organizations, including their ability to extend testing into specialty areas and continue to work with establish standards bodies to develop and disseminate the standards that provide the foundation for certification criteria.

Jitin Asnaani, AthenaHealth and CommonWell, explained that the CommonWell Health Alliance is an independent not-for-profit trade association devoted to the vision that health data should be available to individuals and providers regardless of where care occurs. CommonWell believes that provider access to this data must be built into HIT at a reasonable cost for use by a broad range of healthcare providers and the people that they serve. The Alliance currently consists of 10 technology vendors who collectively represent more than 40% of the acute EHR and 20% of the ambulatory EHR markets. The alliance plans to define and promote a national infrastructure with common standards and policy which today include identity management services to accurately identify patients as they transition through care facilities, record locator service to help providers locate and access their patient records regardless of where the encounter occurred, consent management services to deliver a patient authorized means to simplify management of data sharing, consents and authorizations and trusted data access to provide authentication and auditing to facilitate trusted data sharing. Their certification process is administered by the CommonWell Health Alliance Services provider which certifies each of the edge EHR systems that connect to those core set of services. As CommonWell services are added or significantly change, an update to the edge system, depending on the complexity of those changes to the service implementations, is required. As a result of this approach, updated certifications are expected to be driven by the release of new API versions rather than the version of the edge system. They do not plan to certify workflows off the edge systems, but do plan to provide guidance and best practices to help drive value and usage of the CommonWell network. The certification processes of the CommonWell Health Alliance and ONC's EHR certification program are both aimed at ensuring that HIT systems are built with out-of-the-box interoperability that enables providers to truly focus on providing the best of healthcare, but there are some very notable differences. CommonWell's certification focus can be more responsive as standards evolve and market expectations change. Also, because it provides the services that are actually used day-by-day, CommonWell is positioned to rapidly address weaknesses in the standard specification criteria, especially when implementation guidance is poor or outdated. Another notable difference is that the Alliance is focused on certification of interoperability only and not on the functional behavior of individual vendor applications. CommonWell believes that the greatest value is created by standardizing on interoperability and then letting vendors compete on how to best deliver the user's experience. Through standing up and executing its certification process, CommonWell has discovered interoperability issues that should be on ONC's certification radar. One example is the C-CDA, which is fast becoming the core content packet for health information exchange nationwide beyond those just recommended or required for MU. Asnaani indicated that ONC's certification process itself needs to conduct much deeper testing of C-CDAs. C-CDAs can include a wealth of information or very little information—unless the system was designed to understand whether historical or active data are received, a poor user experience could result.

Mariann Yeager, Healtheway, Inc., described Healtheway's experiences running a highly automated testing program in support of eHealth Exchange, a large-scale nationwide network that began as one of ONC's longest standing initiatives related to the Nationwide Health Information Network. In October 2012, Healtheway assumed responsibility for supporting the eHealth Exchange. Healtheway designed, developed, and launched a rigorous, efficient, objective, and repeatable testing program intended to: (1) support the trajectory of growth, (2) improve the efficiency of the process by leveraging automation in lieu of manual verification, and (3) increase the level of assurance of interoperability by testing conformance and focusing on verifying known interoperability issues. The concept is to test once and exchange with many without subsequent configurations. Participation with the new testing program now in place as doubled. There are now 51 organizations in production, and that number is expected to exceed 100 by the end of this year, such that Healtheway will connect more than one-third of the country's hospitals and nearly 30% of the U.S. population. Yeager noted that ONC certification focuses on certifying products that are sold out of the box, focusing on conformance related to transport and content as well as the many other features and functions related to MU. In contrast, Healtheway supports a testing program for participants and products as configured or as implemented for production-level interoperable exchange of health information. In addition, Healtheway's testing program is much deeper and much broader with respect to interoperability testing. Healtheway recently launched a product testing program that will offset the amount of testing that participants need to complete because it ensures that those capabilities are supported in production. Yeager reported that the savings and efficiencies are substantial and offered the following areas of consideration for ONC:

- Consider using a public-private sub-regulatory process as a more flexible approach to maintain the criteria.
- Maintain a multiyear roadmap so there is sufficient visibility, time, and notice for vendors to plan for that criteria as well as time to employ and upgrade systems.
- Test and pilot criteria test scripts and tools thoroughly.
- Ensure that the standards and specifications required for certification are mature, piloted, and draw a sharp distinction between emerging standards and those that are broadly supported.

Q&A

In response to a question from Underwood, Kibbe explained that Direct as a protocol is a required standard in the ONC certification for 2014. Most of the EHR vendors in the market today not only want their products to be certified and usable in terms of their Direct capability, but they want to mitigate the risk associated with their users, their customers using Direct as a means of sending messages and content out over the Internet. Although certification to the software capability is important it is not sufficient in order for Direct exchange to occur at scale across multiple different vendors, products, and their subscriber bases.

Carr noted that IHE has the benefit of a great deal of breadth—in specialty areas such as diagnostic technologies, it convenes expert groups that are addressing issues that have not yet been considered by ONC. IHE promotes a regular cycle of testing and development that is voluntary and as such allows for innovation. Carr also noted that IHE specifications have become the underpinning for much of what ultimately have become ONC regulations. Kibbe noted that DirectTrust's testing in interoperability is identifying problems that ONC testing has not uncovered. An example is the problems DirectTrust is finding when testing a production-level address going from one HISP to another HISP, to another production-level address. He explained that more than 90% of the problems are associated with various small interpretations and sometimes misinterpretation of the applicability statement itself. ONC needs to revise the applicability statement and the specifications, and provide clarification in a number of areas. Failure to do so may put the entire program of interoperability via Direct, upon which much of

Stage 2 MU interoperability depends, at risk. Posnack described how test procedures are adjusted in response to issues that arise. Changes can be made and a new test procedure can be developed to better test or accommodate different aspects that need to be addressed. Kibbe noted that the Direct applicability statement is a federal standard upon which 127 private-sector organizations participating in DirectTrust are testing. Although it is a good standard, some minor changes are needed. He noted that curation of this and other standards moving forward needs to be considered.

In response to a question from Egerman, Ray indicated that mid-cycle revisions are disruptive to the overall program. Additional up-front testing and quality assurance is needed. Kibbe agreed, further suggesting that greater success may be achieved if ONC's certification program considered including only two or three items of critical importance to the MU trajectory rather than 15-20. He also reminded the group that it generally takes much longer than ONC anticipates to develop a product on the vendor's side, test it, modify it, and deploy it. Enhanced collaboration between the private sector and the federal government can help address this.

In response to a question about the relationships between and roles of the organizations represented on the panel, Kibbe explained that Direct exchange is very simple—e-mail plus attachments with a public key infrastructure overlaid for encryption and identity validation. eHealth Exchange is a much more complicated set of query capabilities. These are complimentary to one another and institutions will likely use both. He commented that DirectTrust and eHealth Exchange are cooperating very well with one another and reminded the group that IHE is the basis of the eHealth Exchange protocol. Asnaani added that a number of overlaps have been identified through the work of each of these independent organizations.

Carr noted that some of the most widely implemented IHE profiles have benefited greatly from having reference implementations built early on, especially so that vendor developers could test their systems against them. It is helpful in many instances to have a proof of concept in place, and this is an area in which IHE is working with a broader array of profiles.

Closing and Next Steps

Tang thanked all participants and explained that the next morning, the Workgroups would discuss the testimony from this hearing and develop recommendations. He reminded the group that ONC wants to improve the certification process, and that the purpose of this hearing was to obtain expert input to inform the Workgroups' recommendations. Deputy National Coordinator for HIT Jacob Reider asked Workgroup members to consider explicit recommendations to ONC in two domains: (1) what near-term improvements can be made to the certification program and what lessons learned can inform these improvements, and (2) in the longer term, how the certification program can become more agile, responsive, and flexible.

Public Comment

Mari Savickis, American Medical Association, thanked ONC for hosting the hearing. She expressed concern, given the number of problems identified by panelists associated with MU overall and the certification program, that CMS was not represented at the hearing. She summarized that physicians are dissatisfied with their EHRs and the requirements in the MU program. Physicians do not view certification and MU as two different programs. EHRs are viewed as cumbersome and adding extra steps into physicians' workflows, often with little identification of how they provide value back to the care of the patient. EHR vendors want to provide high-quality products to their customers and be agile enough to address changes while still providing innovative technology. Most of their time and attention is directed at meeting certification requirements that are too prescriptive and require equally significant allocations of resources. The AMA strongly agrees with several commenters who recommended that the

focus should be more on a streamlined MU and certification program that is focused on promoting meaningful data exchange and improving the ability to report clinical quality measures, areas that are mandated under HITECH. To realize this goal, a less prescriptive approach must be taken. Streamlining the MU and certification programs will open up the possibility for greater innovation. Well established and well understood Web technologies as suggested by a panelist and other industry experts will create more agility for vendors to develop better products and for doctors to use them. In the meantime, however, unless more flexibility is offered to physicians and other healthcare providers to meet MU, they are going to drop out. If changes are not made now, the program could sink under its own weight. The AMA strongly urges ONC and CMS to introduce the flexibility being sought by the AMA—allowing physicians to meet 75% of the requirements to obtain an incentive and 50% in order to avoid a penalty.

Meeting Materials

- Agenda and questions
- Meeting presentation slides
- Written testimonies
- Bios