HIT Policy Committee
FINAL
Summary of the May 12, 2015, Meeting

ATTENDANCE (see below)

KEY TOPICS

Call to Order

Michelle Consolazio, Office of the National Coordinator (ONC), welcomed participants to the Health Information Technology Policy Committee (HITPC) meeting. She reminded the group that this was a Federal Advisory Committee (FACA) meeting being conducted with opportunity for public comment (limited to 3 minutes per person) and that a transcript will be posted on the ONC website. She instructed members to identify themselves for the transcript before speaking. Members introduced themselves. Consolazio said that beginning in June, members will be asked to state potential conflicts of interest.

Remarks

National Coordinator and Acting Assistant Secretary of Health Karen DeSalvo personally thanked members Marc Probst, David Bates, Christine Bechtel, and Charles Kennedy, whose terms expire this month.

Review of Agenda

Vice Chairperson Paul Tang introduced new members Kathleen Blake, AMA (quality reporting slot); Donna Cryer, Global Liver Institute (consumers); and Brent Snyder, Adventist Health System (providers). The agenda was distributed in advance of the meeting and was devoted exclusively to comments on the stage 3 and certification NPRMs. Tang asked for a motion to approve the summary of the April meeting as circulated. A motion for approval was made by Deven McGraw and seconded. The motion was approved unanimously by voice vote.

> **Action item #1: The summary of the April 2015 HITPC meeting was approved unanimously by voice vote.**

Meaningful Use Stage 3 NPRM Comments

When the NPRM was published, its eight objectives and key questions were assigned among four workgroups for comments. Those workgroups gave preliminary reports at the April meeting, at which time members had opportunity to ask questions and give opinions. Only a few changes were requested prior to the committee's preliminary approval. The HITPC voted to accept each of the four reports. Following the April meeting, the workgroups met to complete their comments and recommendations. Last week, the chairpersons of the three workgroups met with the Advanced Health Models and Meaningful Use Workgroup to identify and reconcile any differences in the recommendations across workgroups. The workgroup's reports consisted of many slides and, for several, additional supplemental materials. They typically summarized the sections of the NPRM on which they were commenting; the process for formulating comments; evidence (if any) and considerations taken into account; and, finally,

overall and specific recommendations. This meeting summary contains recommendations only. A virtual meeting is scheduled for May 22 to resolve any issues that remain at the conclusion of this meeting.

In his role as **Advanced Health Models and Meaningful Use (AHMMU) Workgroup (WG)** Chairperson, Tang reported that three subgroups had been convened to comment. Subgroup 1 on overall approach recommended simplification, reduction of burden, and more flexibility. The workgroup agreed with the proposal to unify stages to single stage (stage 3) by 2018 and to align reporting periods. It agreed to reduce the number of objectives emphasizing advanced functionality, remove duplicate and topped-out measures, remove paper-counting measures, and focus on electronic only. Regarding flexibility, it agreed to allow providers to attest to MU3 in 2017 and, with modifications, to require all providers to attest to MU3 in 2018. It agreed with the 1-year reporting period and flexibility on health information exchange, consumer engagement, and public health reporting. Continuing to report on objective 2 (e-Prescribing), he showed another slide. The workgroup agreed with the proposed threshold increase and to allow for inclusion of scheduled drugs where such drugs are permissible to be electronically prescribed. It recommended against the exclusion of OTC medicines in this objective to make it optional and also recommended that the measure not be limited to only new and changed prescriptions. The workgroup agreed with the overall measures and objectives for objective 3 (CDS). On objective 4 (CPOE), the workgroup agreed to expand the objective to include diagnostic imaging, to allow but not require providers to limit the measure to patients whose records are maintained by using CEHRT, and on the need for additional exclusion due to technology barriers. It disagreed on the likelihood of certain EHs or CAHs having a zero denominator.

Workgroup Co-chairperson Joe Kimura reported on Group 3: Population and Public Health and objective 8. In general, the AHMMU WG agreed with the direction and goals of the six objective 8 measures, but with major concerns centering on the need for more clarity around timing and what qualifies as eligible and the focus on unidirectional reporting to public health agencies (PHA) when bidirectional exchange may be required for timely tangible benefits to patients and communities. Recommendations were made by measure:

Measure 1:

- Since more clinically relevant forecasting may be from either IIS or EHR, clarify the CMS rule that says that the forecast and history need to be received but is silent on what is done with the information. The ONC certification rule certifies display, but the CMS rule does not require it.
- If the state or IIS is not ready to do bidirectional exchange, clarify in the exclusion that providers could take exclusion.

Measure 2:

- Keep EH and urgent care as noted.
- Syndromic surveillance for public health issues (e.g., infections, violence, trauma) is distinct in both content and required timing from syndromic surveillance for chronic conditions (e.g., diabetes, hypertension, obesity). If chronic condition surveillance is required, consider a new measure.
- To support benefits to patients or communities, consider support of an iterative loop between providers and PHA around suspected and established.
- Ambulatory chronic condition syndromic surveillance appears to have more population health (Measure 4) meaning and may combine ambulatory and hospital data.

Measure 3 (Case Reporting):

- With differences in data collected, ensure that jurisdictions have the capacity to receive the data (CDC/ASTHO Public Health Community Platform).
- Consider a bidirectional component (e.g., use of knowledge management systems for triggers) in the measure definition to drive value to both parties. If there is no bidirectional exchange capability from PHA, then there is potential for exclusion.

Measures 4 and 5:

- Regulation of what registries would count needs to be expanded. Only registries with standards called out are specific to measure 4 and not measure 5. Currently, many stage 2 specialized registries appear not to count (e.g., FDA [Mini-sentinel], PCORI [PCORnet]).
- No bidirectional component to registries has been discussed.
- The PHR and CDR distinction needs a better definition.
- Exclusions for both needs to acknowledge the existence of national registries independent of jurisdiction.

On measure 6 (electronic reportable laboratory result reporting), the workgroup agreed with active engagement option 1 but recommended a change in option 2 (testing and validation) to define response for the validation phase to allow for acknowledgement and intent to fix within 30 days of request and not a code change. It recommended a change in option 3 to address requirements if active production engagement is disrupted on either the PHA/CDR or EP/EH/CAH side and to provide support to providers seeking to meet the requirements of this objective by creating a repository of national, state, and local PHA and CDR readiness. In addition, it should be required that national, state, and local PHA and CDRs register readiness or ability to accept each measure or intent to accept future registry data within 12 months prior to reporting period. Registration must include the type of settings currently accepting or intending to accept, including any exclusion or specialties from which they are not accepting. If an implementation guide other than the CEHRT guide is required by the registries or through state flexibility, a link to the required implementation guide must be included. To ensure options, a minimum of three PHA registries and three CDR registries must be available as currently accepting or intending to accept in the future. An EP/EH/CAH sending the same data to multiple unique registries should get credit for active engagement in each registry as long as the data sent to each registry satisfy the data criteria and purpose of each specific registry. It should not matter that an EP/EH/CAH has used the same data.

Kimura continued with Group 4 on quality measures. The workgroup recommended option 1, conditional on HITPC promotion of pathways to test, share, and implement new and innovative measures in order to address, in part, time constraints involved with vendor implementation cited as part of conditional support for option 1 and adequate implementation time (18 months) to allow for EHR vendor implementation, certification and rollout, and provider implementation. The workgroup recommended that HITPC support efforts to align the EHR Incentive Programs with CMS quality reporting programs that use certified EHR technology regarding measures, measure specifications, and reporting requirements (i.e., reporting formats, standards utilized, and reporting periods and data submission timelines). It recommended that the HITPC support proposed criteria included in the ONC 2015 Edition Health IT Certification NPRM. A phased approach to increasing the number of CQM vendors must certify that it does not reduce vendor burden. CQM specification and certification tools must be accurate, complete, and fully tested prior to release. A period of 18 months should be allowed for EHR vendor implementation, certification and rollout to providers, and provider implementation. There should be flexibility to allow EHR vendors to certify specialty EHRs to those measures that are relevant to the particular specialty, because not all CQMs are relevant to all providers or practice

settings. To more rapidly increase the development and implementation of CQMs that are meaningful to providers, the workgroup supported a previous recommendation for ONC and CMS to consider an optional innovation pathway to allow EPs and EHs to waive one or more objectives by demonstrating that they are collecting data for innovative or locally developed eCQMs. The workgroup supported greater alignment of quality measurement across private and public payer initiatives to reduce the burden on providers. Alignment should include using the same measure specifications and data collection requirements for measures that address the same concept and alignment of reporting formats, standards, and reporting periods and data submission timelines. The current CMS IPPS NPRM, ONC Certification 2015 NPRM, and ONC Common Clinical Data Set lack alignment among age (e.g., birthdate, age at admission), gender (sex), and vital signs, for example. The workgroup supports the proposed clinical quality measure filter criterion in the ONC 2015 Edition Health IT Certification NPRM especially as it furthers health disparity measurement. CMS annual updates should be limited to changes that do not have a significant impact on clinician workflow or provider implementation time or require extensive software code changes or recertification of the EHR software due to the compressed time between the release of annual eCQM updates and required use of the measures in an EHR. If an eCQM requires more extensive modification, and for any new CQMs introduced to any program, the scheduling of such changes should provide ample time to accommodate these activities. It is essential to improve the availability of standards to further interoperability, as it pertains to the ability to measure the quality of care across settings and time for a patient. Pilots for new standards being worked on via the Clinical Quality Framework focus on CDS and do not yet pilot the effectiveness of the standards to advance quality measurement. Electronic quality measurement should look across longer periods; utilize more data sources; and consider care in other settings beyond hospitals and ambulatory care, such as long-term post-acute care, behavioral health, and palliative care. It is important to broaden the focus of measurement and the reporting and use of data beyond EPs and EHs and recognize other providers, individuals and family as contributing to (input) and accessing information systems (throughput and output).

DeSalvo allowed questions. David Lansky called for making longitudinal quality measures a priority for stage 3 recommendations. He said that the registries in measure 5 are one such opportunity. Tang agreed, citing a recent IOM report and the NQF incubator. Paul Egerman talked about using data currently being collected to measure quality, saying that changes in definitions of eCQMs limit the usefulness of the data and possibly affect patient safety. In response to a question from Anjum Khurshid, Kimura talked about the role of and exchange with public health agencies in registries. Khurshid suggested that the comments call for clarification on interaction of public health agencies with registries.

Troy Seagondollar read the WHO definition of health and said that the definition of care planning must be solidified. In sharing information across interdisciplinary teams, no one is looking at what health means. Tang said that ONC had convened a listening session on care planning. DeSalvo said that sharing information is important. Bechtel wondered when the workgroup will discuss care planning. Tang said that it is on the agenda. Bechtel offered the expertise of the Consumer Workgroup. Bates said that a recent trial in which he was involved indicated that much more research is needed before a standard can be set. More support for research is needed.

Interoperability and Health Information Exchange (IOWG) Workgroup Chairperson Micky Tripathi showed slides and presented comments on objective 7 (health information exchange and specific questions on HIE governance). He explained that the workgroup considered the relationships between exclusions and thresholds. He described each of the three measures and the rationale for the

recommendations, and listed the recommendations. Objective 7 comprises three measures, and providers have to meet only two out of three (but must report on all three): send electronic summary of care record for 50% of outgoing transitions or referrals, receive and incorporate electronic summary of care record for 40% of incoming transitions or referrals, and reconcile clinical information for 80% of transitions or referrals. Stage 2 experiences suggest that the stage 3 thresholds are higher compared with performance to date—perhaps significantly higher, given the small sample results to date.

IOWG recommended the following on Measure 1:

- Lower threshold to 40% (from 50%): disagree with NPRM
- Allow any electronic transport: agree with NPRM
- Allow patient self-referrals: agree with NPRM
- Do not allow "selfies": disagree with NPRM
- Allow flexibility in CCDS payload: disagree with NPRM
- Allow exclusion for <100 transitions/referrals: disagree with NPRM
- Do not allow exclusion for low broadband penetration: disagree with NPRM

IOWG recommended the following on Measure 2:

- Lower threshold to 25% from 40%: disagree with NPRM
- Allow for provider discretion in what to incorporate: disagree with NPRM
- Allow for active or passive receipt; allow any type of query: agree with NPRM
- Allow never before encountered in measure denominator: agree with NPRM
- Allow exclusion for information unavailable: agree with NPRM
- Allow for queries outside of specific transition and referral episodes: disagree with NPRM
- Allow exclusion for transitions and referrals from entities not using CEHRT: disagree with NPRM
- Do not allow utilization alerts: agree with NPRM
- Do not allow exclusion for low broadband penetration: disagree with NPRM

IOWG recommended the following on measure 3:

- Set threshold at 80% for medications and medication allergies: agree with NPRM
- Lower threshold for problems to 10%, or make problems optional: disagree with NPRM
- Remove never before encountered patients from denominator: disagree with NPRM
- Allow either automated or manual reconciliation: agree with NPRM
- Allow credentialed MAs to perform reconciliation: disagree with NPRM
- Allow exclusions for some specialists: disagree with NPRM

Regarding the governance questions, Tripathi explained why the workgroup agreed with allowing any electronic means and *not* tying EHR incentives to governance mechanisms that may be established by ONC.

Members had the opportunity to ask questions. DeSalvo asked about measure 2, part 6. Tripathi said that providers should get credit for querying to obtain information for care managing. Bates disagreed with the recommendation on referrals in integrated systems. He said that in this own integrated system, 90% of referrals are within the organization. Most externals referrals are very different, and they include self-referrals and are often clinically inappropriate. Co-chairperson Chris Lehmann asked Bates how this would improve care in his organization. Bates said that the organization examined internal referrals and found that about half the time, the internal referral questions were not answered. More than access to information, answers to specific questions are needed. Tripathi acknowledged that there may be better

ways to address that problem. He indicated that he will take it back to the workgroup for more discussion.

Seagondollar wondered about countable transitions for the denominator. He expressed concern about the proposed process for med and problem reconciliations. The NPRM and the workgroup's comments refer to credentialed medical assistants. A definition of credentialed medical assistant should have been provided. He explained that he had submitted that question during a workgroup meeting, but it was not answered. The definition of a reconciled problem list is an accurate list of problems, which is probably beyond the scope of medical assistants. His organization allows medical assistants to add meds to the list, with the EP making the final decision about the accuracy of the list. The definition of reconciliation is the issue.

Following up on Bates' comment on selfies, Cryer wondered how a physician would know where to look in the medical record to find information on referrals and outcomes. Tripathi responded that the best way to solve internal problems of referrals and transitions is not to generate CCDAs and send them back to the original provider. Lehmann explained that members of the workgroup wished to ensure that large integrated systems did not have an unfair advantage over other organizations, an explanation also given by Tripathi when he presented the recommendations. In response to another question about specialist exclusion, Tripathi said that the workgroup did not consider criteria for exclusion of specialties. He offered to take the question up with the workgroup. Neal Patterson said that the committee should not tell integrated systems how to work; they can figure this out for themselves. He indicated his agreement with the exclusion of selfies. Egerman said that providers in integrated systems do not necessarily use the same EHR. Data segmentation may have an impact on self-referrals and should be examined. Tripathi said that the recommendation does not apply when different EHRs or platforms are used. He seemed to agree to ask the workgroup members to look at the topic of segmentation and self-referrals.

Blake observed that in half of referrals, patients do not make the follow-up appointments. It is difficult for a provider to sort out questions and answers, even using the same EHR. Someone should think about how to tailor the process so that everyone involved knows the questions and receives answers. Integrated systems should be included. The AMA is looking at ways to move care outside of the office to pre-visit planning, and that process should be included. Tang noted that the selfie issue is inflating several functionalities.

Bechtel asked whether the reference to electronic transport on slide 9 is a policy or standards recommendation. Tripathi explained that the proposal is appropriate. Bechtel asked about the reduction of the reporting period, which may affect a number of measures, especially those affecting consumers. She requested that a comment to that effect be added.

Tang said that to the extent possible consensus is desired. The HITPC will vote on the recommendations. Points on which consensus is not reached will be on the agenda for the May 22 virtual meeting.

Privacy and Security Workgroup Chairperson Deven McGraw described those sections of the NPRM assigned to the workgroup, explained points of discussion and concern considered, and presented the recommendations. Regarding objective 1 (protect patient health information), the workgroup supported the proposed stage 3 security requirements. Adding administrative and physical safeguards to the current requirements more closely aligns the CEHRT risk assessments and attestations with the compliance requirements of the HIPAA Security Rule. Considering privacy and security issues related to increasing patient access to data through either VDT or APIs, recommendations are as follows:

1. ONC and CMS reference and leverage previous recommendations on best practices for view and download.* (See backup slides.)
2. ONC continues to work with FTC and OCR to develop guidance for key stakeholders to adopt the use of mobile IT, apps, and APIs.
3. ONC and OCR produce educational materials for both patients and providers on the safe use of apps and APIs.
4. ONC and OCR produce educational materials for private industry application developers about methods for clearly communicating their privacy policy and security practices to patients and providers.
5. Reference prior recommendations on identity proofing and authentication of patients, family members, friends, and personal representatives.
6. ONC and OCR should issue guidance addressing the intersection between the MU patient engagement objectives, the certification requirements, and HIPAA's patient access rights. Issues include the extent to which a provider may reject a patient's request for electronic access due to a perceived security risk for the provider, the extent to which a provider may reject a patient's request for electronic access in the absence of a security risk, and the ability of the provider to charge fees for meaningful use access.
7. Have a voluntary yet meaningful and robust effort by the industry to certify patient-facing health apps to help patients choose apps. ONC and other federal agencies could advise such an initiative, particularly on privacy and security policies, which could help facilitate greater standardization. FTC already has authority to enforce voluntary best practices for those who adopt.

Egerman commented that data blocking is often used for security. Many customers do not understand how apps work. There is a server behind the app. Data go from EHRs to servers to apps. Apps data are often sold without explicit knowledge of the consumer. McGraw talked about deceptive business practices. Apps vary greatly in protections applied to data. Guidance is needed. Providers have the capability under HIPAA to protect patients from using a dangerous app, but they must have good reasons for doing so. She said that the situation is such that hard and fast rules cannot be applied. Lucia Savage, ONC, explained that guidance can be a rule, an outcome of litigation, or educational materials. ONC plans to offer education materials on apps. Tang asked McGraw how the workgroup determined that education was the preferred approach. She said that the members considered risks and determined that an educational website is appropriate for the rapidly changing environment. Savage reported that prior to the ONC's publication of educational materials approval is sought from various agencies. Bechtel said that the federal government needs to pay attention to this concern and encouraged ONC to do something quickly. Egerman said that the storage and sale of information may include identifiable data. McGraw noted that some platforms are setting their own standards. Free apps are frequently supported by these sales. Without the sale of data, the consumer would incur charges. It is a tradeoff. In anticipation of voting, Tang asked what the ask is for voting. McGraw said that guidance should be mentioned in the next NPRM preamble. Tang probed for specific changes that committee members wanted. Bethel wanted to add that the final rule should be consistent with Consumer Workgroup recommendations and for ONC to act immediately on guidance. According to Tang, the type of guidance should be specified. McGraw asked for more clarification as to what is wanted. She emphasized that the workgroup had deliberated on these issues. The workgroup did not want to be overly directive to the government. Tang wanted something said about urgency, the possible harm in the absence of intervention, and whether education or regulation was the better approach to intervention. DeSalvo suggested that they coordinate with the work that Jodi Daniel is doing with FDA and FTC. Balance is

important. Savage suggested that ONC report to the HITPC on this work. McGraw said that if the committee wants to propose something more, she can take it back to the workgroup for discussion. She emphasized that the workgroup deliberated on these topics and believes that the recommendations are sufficient as made. The HITPC has the authority to add something on its own initiative. Bechtel referred to prior recommendations that were not implemented. She mentioned that during the AHMMU WG call last week, she had asked what "guidance" means. She understood that FTC deceptive trade practices include practices that are unfair to consumers. McGraw talked about ongoing litigation on the unfairness of not having security protections. It is more like common law. States can have a role as well. FTC has recently been more proactive on consumer protection. Bechtel asked that with the final rule the expectations for guidance be more specific. Tang asked whether other options were discussed and to include those options in the workgroup's report. McGraw insisted that other options were not suggested by workgroup members and therefore did not belong in the report. Lehmann noted that many industries are self-regulating, an example being board certification for physicians. McGraw said that one recommendation (#7 on slide 8) endorses a voluntary certification process. The FTC can advance self-regulation codes of conduct. A member of the Privacy and Security Workgroup reported that McGraw was accurately representing the workgroup's consensus. Regarding guidance, timeliness was the major factor under consideration. A list of best practices was recommended. Savage said that relevant recommendations were given in the response to the Interoperability Roadmap. McGaw offered to respond to any forthcoming specific requests.

Consumer Workgroup (CWG) Chairperson Christine Bechtel reminded the members that the workgroup reviewed objective 5 (patient electronic access to health information) and objective 6 (coordination of care through patient engagement). She said that in general, the CWG agreed with providing to at least 80% of patients access to their health information within 24 hours. It recommended that EPs and EHs offer both the view and download options and an ONC-certified API, although with caveats, which were listed on slides. It agreed with measure 2 as proposed: providing electronic access to clinically relevant, patient-specific educational resources for more than 35% of patients. But instead of an exclusion, CMS should consider requiring providers in low-broadband counties to offer patients online access to their health information and promote it actively. She said that the workgroup strongly supported patient engagement and care coordination (objective 6) as two distinct concepts. Both are key components of new models of care and delivery system reform. But the two concepts should be separated. The workgroup presented three options for separation and recommended Option B. Regarding measure 2, members agreed with the proposal for a secure message sent to more than 35% of all unique patients by using the electronic messaging function of CEHRT or in response to a secure message sent by the patient. Regarding measure 3, the workgroup agreed that patient-generated health data (PGHD) be incorporated into the certified EHR technology for more than 10% of all unique patients but proposed that "or data from a nonclinical setting" be moved to the HIE objective 7. The workgroup agreed with not allowing administrative or financial data to count as patient-centered communication toward the secure message threshold. She went on to recommend a list of revisions if option 3 were selected.

In response to a question about option 2, Bechtel said that in the absence of more information about the definition of PGHD in the EH environment, members believed that 10% is achievable. The data could be acquired in various ways.

Discussion and Action on Stage 3 NPRM Recommendations

Consolazio announced that the three new members were not allowed to vote. Tang asked whether there was any disagreement with the AHMMU WG recommendations. He was reminded about Lansky's comment on longitudinal measures. He said that it would be included. No disagreement was heard.

Tang said that they will return to the IOWG recommendations, because there were several unresolved concerns. They will also return to the Privacy and Security Workgroup recommendations to talk about the level and type of guidance on apps. He asked whether anyone disagreed with the Consumer Workgroup's recommendations. None were heard.

> **Action item #2: The recommendations by the Advanced Health Models and Meaningful Use Workgroup and the Consumer Workgroup on the stage 3 NPRM were accepted.**

Public Comment

Tom Bizarro, First Data Bank, referred to the AHMMU WG recommendations and commented that drug-drug interactions require customization of individual alerts to make them more appropriate to the practice, provider, and institution. Appropriate alerts increase usability.

Adrian Gropper, Patient Privacy Rights, commented on interoperability for patient-centered care. The fragmentation of transports and ad hoc governance mechanisms in meaningful use introduce numerous compromises when viewed from the patient perspective. These compromises are most evident in a lack of transparency, inadequate accounting for disclosures, overreliance on consent instead of authorization, inability to segment information, interoperability with non-HIPAA services, and loss of provenance in patient-mediated exchange. He urged that stage 3 take the spirit of the JASON Task Force to heart and define the public API in terms of the HIPAA patient right of access. The public API must require the ability of the patient, as known to the practice, to completely specify the endpoints that will be allowed bidirectional access by using policy-neutral FHIR/OAuth2 standards.

Kelly Cochran, American Nurses Association, commented on care plans. She read a long statement submitted by Laura Heermann Langford, Intermountain Healthcare, a member and expert with the Care Plan HL7 Workgroup. The statement described the differences in the ways different health disciplines define and use the care plan. She was concerned that the proposed checkbox approach would be implemented and miss the point of interdisciplinary patient-directed care. One suggestion was to remove the reference to care plan field.

Madeline Jay, Johns Hopkins Hospital, was concerned about disallowance of self-referrals, which in integrated systems would result in a loss of essential patient information.

Tang reduced the period allocated for lunch, as the agenda schedule had not been adhered to.

2015 Certification NPRM

Privacy and Security Workgroup Chairperson McGraw reported on data segmentation. She outlined many concerns, some of which had been expressed in past recommendation. It was recommended that the HITSC assess the maturity of the DS4P standard for inclusion in the 2015 Edition that ONC educate providers and patients on the features and limits of DS4P technology, and that ONC continue to pilot and test in order to refine technologies that enable the sharing of sensitive data in compliance with law. Regarding pharmacogenomics data, introducing certification for this functionality in the 2015 Edition is premature. The workgroup recommended that ONC continue to review issues around accessing, sharing, and using pharmacogenomics data as the science evolves. McGraw went on to give responses to specific questions in the NPRM. Regarding the application of different rules for the use and exchange of pharmacogenomics data (e.g., behavioral health), the workgroup strongly cautions ONC against promoting policies that require higher or more complex protection than what is provided for in current law. The workgroup said that DS4P is not currently useful for providers to comply with more sensitive

laws governing pharmacogenomics data. Currently, DS4P does not enable the use of decision support software.

Egerman said that even if the standard were mature, certification would be a mistake because it would hamper innovation. Blake referred to medication and problem lists reconciliation, and wondered about medications that indicate behavioral health and HIV diagnoses. McGraw said that part 2 data are restricted unless provided by the patient directly. Protection of HIV information varies by state. As a result, establishing rules for exchange of these data is difficult.

Implementation, Usability, and Safety Workgroup Chairperson David Bates reported that the approach outlined in the NPRM creates a certification program with significantly broader scope and applicability across the health care ecosystem to include any stakeholder that sends and receives health information. Redesigning the program into a modular approach provides the flexibility to increase its applicability to the various stakeholders and technologies that must interoperate. There is risk inherent to this flexibility. The program will likely be more complex, particularly for stakeholders who must address multiple modules and certification requirements from various agencies, regulators, or payers. For this reason, the role of ONC as a coordinator to facilitate alignment between federal program requirements and related health IT modules is critical to mitigate complexity and cost. A more complex program will likely drive up costs for certification, particularly for those who certify and test multiple health IT modules that might be considered a single large system. There may be challenges to keeping the modules and their requirements at the foundational (building block) level and not expand their scope unnecessarily. Other parties that identify certification paths and/or require compliance with a certification module(s) could erode the foundation by requiring a module with modifications and add-ons. Specific comments were made:

> Utility of CHPL: Evaluation of the significantly expanded dataset and redesign should be included in the redesign plans so that the value to purchasers, developers, usability professionals, providers, and other interested parties can be determined. ONC should apply to the CHPL development the user-centered design principles that it is asking of health IT developers.
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> Other software sources: Some members emphasized that not all HIT software is provided by vendors. Providers do use self-developed software and open-source software. There are also vendors with a hybrid of software from multiple source types. As a result, the proposals may be inappropriate in some situations. The proposals may favor some sources of software over other sources.
>
> Expansion of the use of certification: Some members strongly voiced the view that the certification process is not the appropriate way to address these issues, especially if done by attestation. Attestation is a subjective aspect to the certification testing process. A member expressed interest in understanding where in the statute ONC had the authority to expand the certification program beyond the EHR Incentive Program.
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> Shift from functional requirements to interoperability and privacy and security: Some workgroup members suggested that, in this version, the criteria focused solely on interoperability and privacy and security and that functional capabilities should not be included (e.g., CPOE for medications and diagnostic imaging).
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> Timeline: The timeline may not allow sufficient time for EPs to begin their reporting period stage 3 on January 1, 2017. While this start date is optional for providers, health IT suppliers would have to deliver fully operational software to providers well in advance of that date to allow for

implementation by the provider. While a reduction in scope might make this timeline achievable, a longer development and implementation timeline could well improve software capabilities and effective implementation.

Complexity: Some members said that this version of certification was not responsive to feedback that previous iterations of certification were too complex.

Maturity of standards: Workgroup members voiced concerns that proposed standards have not sufficiently matured to be promulgated through regulations and suggested that ONC and CMS find mechanisms supportive of pilots and limited deployments in production environments. This will serve to assess the applicability, practicality, and consistent, wide deployability of standards and implementation prior to being considered for national rulemaking and avoid a situation where the certification rule is in effect acting as a national pilot program.

Variations among partners: Certification requirements that affect one segment of the market should also apply to the partner segment to be certified. This will add significant cost and complexity when providers and EHR developers will be required to develop and implement multiple interfaces rather than one standard interface (e.g., population health requirements that vary by geography or registry). The point was made regarding how certification would address the challenges of interoperable health IT adoption by LTPAC and BH providers who were left out of the EHR Incentive Program. There was acknowledgement that the sectors requested this approach in hearings to the HITPC, but also that this is one approach, while others (e.g., incentives) may still be needed to support adoption.

Co-chairperson Larry Wolf continued. Missing in the safety-enhanced design requirements is the mechanism that requires a process that includes all of the following:

- Identification of usage errors plus an analysis of usage errors (e.g., frequency, severity)
- Identification and implantation of mitigations aimed at reducing risks associated with identified errors
- Tracking/auditing of this process, even through post-market surveillance
- Inclusion of patient history as a safety element

To replace summative usability tests with only formative testing would not be a nationally recognized user design test. Retesting is already addressed through existing processes. No change is required to consider user interface changes. Regarding quality management systems, although most members supported the proposed language, some felt that this would just increase complexity of certification. Members had different opinions on accessibility technology and accessibility-centered design. Regarding types of care, certification would be helpful to the settings called out in the NPRM. The workgroup called for clarification of the base EHR definition on whether privacy and security need to be included in each module. Overall, members are concerned about complexity and driving up costs of certification

Discussion and Action on Stage 3 Certification NPRM Recommendations

DeSalvo asked whether the recommendations will come forward in the same format as shown on the slides. Bates acknowledged that the workgroup was unable to provide clear recommendations because of the diversity of opinions among the members and inability to arrive at consensus.

Bates responded to a question about situations in which blocking by providers or vendors may be appropriate by saying that an organization may believe that someone is attempting to access

information inappropriately or illegally. Wolf added that denial of service attacks can generate blocking to protect the infrastructure.

Bechtel asked about certification being inappropriate for certain things, including for accommodating disabilities. Bates said that there was no consensus on that proposal. It should be a decision for vendors. Developers may have a competitive advantage in dealing with such functions. Bechtel was concerned about such a general statement about certification. Bates explained that certification is a floor, not a solution for all problems. Wolf agreed that certification is a powerful tool when there are clear standards. Both Bates and Wolf emphasized the very different opinions held by the workgroup members. Bechtel asked for a change in the slides to better represent Wolf's explanation.

DeSalvo asked for suggestions of strategies to resolve problems and differences, such as certification for non-meaningful users. Information blocking is a topic the U.S. Congress, and others have asked ONC to deal with. She requested strategies within the certification program. She is also interested in strategies for user-centered design. Egerman acknowledged his membership in the Implementation, Usability, and Safety Workgroup and his participation in discussions preliminary to the report. He said that certification should be for software testing only. To go beyond that is outside of ONC's role and is an attempt to regulate the industry. Tang told Bates to respond to DeSalvo's request in preparation for the May 22 virtual meeting to resolve all outstanding issues on the comments on the NPRMs.

No action was taken.

A public hearing is scheduled for June 2.

Public Comment

Tim Schmoyer, Jericho Systems, said that he had submitted written comments. ("Jericho Systems is implementing DS4P and extending data labeling and segmentation to fusion centers. The demand is growing.") Before he could say more, he was cut off or lost.

Tang said that staff will send information on conflict of interest disclosures in preparation for the June meeting.

Bechtel thanked everyone.

SUMMARY OF ACTION ITEMS

Action item #1: The summary of the April 2015 HITPC meeting was approved unanimously by voice vote.

Action item #2: The recommendations by the AHMMU WG and the CWG on the stage 3 NPRM were accepted.

Meeting Materials

- Agenda
- Summary of April 2015 meeting
- Presentations and reports slides
- Workgroup reports and background materials

Meeting Attendance							
Name	05/12/15	04/07/15	03/10/15	02/10/15	02/10/15	01/13/15	12/09/14
Alicia Staley			X				X
Anjum Khurshid	X	X	X	X	X	X	X
Aury Nagy							X
Brent Snyder	X						
Charles Kennedy		X		X	X	X	
Chesley Richards		X	X			X	
Christine Bechtel	X	X	X	X	X	X	X
Christoph U. Lehmann	X	X	X			X	
David Kotz		X	X	X	X	X	
David Lansky	X	X	X	X	X	X	X
David W. Bates	X		X	X	X		
Deven McGraw	X	X	X	X	X	X	X
Devin Mann			X	X	X	X	X
Donna Cryer	X						
Gayle B. Harrell	X	X	X	X	X	X	X
Karen DeSalvo	X	X	X	X	X	X	X
Kathleen Blake	X						
Kim Schofield		X		X	X	X	X
Madhulika Agarwal		X					
Marc Probst	X	X	X	X	X	X	X
Neal Patterson	X	X		X	X		X
Patrick Conway							
Paul Egerman	X	X	X	X	X	X	
Paul Tang	X	X	X	X	X	X	X
Scott Gottlieb		X		X	X		
Thomas W. Greig		X	X			X	

Troy Seagondollar	X	X	X	X	X	X	X
Total Attendees	**16**	**19**	**17**	**17**	**17**	**17**	**14**