Health IT Policy Committee

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

June 16, 2011

Farzad Mostashari, MD, ScM
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. Mostashari:

In this letter, the Health Information Technology Policy Committee (HITPC) presents our recommendations regarding stage 2 of CMS's incentive program for the meaningful use (MU) of electronic health records (EHRs). In the discussion below, we outline these recommendations and explain why we believe that these changes from stage 1 will continue the momentum of the EHR incentive program, and provide support to the Secretary's National Quality Strategy and the objectives of health reform.

As background, the HITPC held seven full-day public hearings in 2010 and 2011 related to many high-priority issues related to the EHR incentive program, including specialty issues, hospital concerns, small practices, health disparities, engaging patients and families, population and public health, care coordination, and experience from the field. This public testimony from nearly 100 people representing numerous stakeholders proved invaluable to the committee in addressing the wide range of objectives and challenges of the EHR incentive program. The HITPC's MU Workgroup held dozens of conference calls and in-person meetings over the last nine months and released a 45-day request for comment through the *Federal Register*, which generated thoughtful submissions from 422 organizations. All of this input has contributed to our collective thinking that is represented in the recommendations below.

HIT POLICY COMMITTEE RECOMMENDATIONS:

I. RECOMMENDATIONS RELATED TO THE TIMING OF STAGE 2

The HIT Policy Committee has always maintained its focus on the legislative intent of HITECH to accelerate the adoption and meaningful use of HIT to improve health outcomes. We recognize that the sense of urgency to adopt effective HIT is to support the imperatives of health reform and the provisions of the Affordable Care Act.

Therefore, the HITPC agrees with the HHS philosophy of an escalator to ensure that the MU bar continues to rise over time in order for the country to realize the full benefits of health IT, and to support the information needs of

health reform. The HITPC recognizes that the slope of the escalator is a function of two elements: the complexity of the MU objectives and the time required to develop, implement, and meaningfully use the functionality required.

The HITPC has heard from both the vendor community and the provider community that the current schedule for compliance with stage 2 meaningful use objectives in 2013 poses a nearly insurmountable timing challenge for those who attest to meaningful use in 2011. With the anticipated release of the final rule for stage 2 in June, 2012, it would require EHR vendors to design, develop, and release new functionality, and for eligible hospitals to upgrade, implement and begin using the new functionality by the beginning of the reporting year in October of 2012. After careful consideration of the trade-offs between the urgency with which new functionality is needed and the ability to safely deliver and to effectively use the new functionality, the HITPC recommends that—only for those who begin to attest to MU in 2011—an extra year be provided to phase in the stage 2 expectations (ie., Stage 2 for those who attest in 2011 would begin in 2014). We understand that despite this relatively short delay for a limited number of participants, the meaningful use requirements for stage 2 need to be robust enough to maintain progress towards the information support needed for health reform (ie., to maintain the slope of the escalator). This will ensure that stage 2 MU establishes the IT infrastructure necessary to prepare EPs and hospitals adequately for the delivery systems' reforms that are central to the Affordable Care Act (ACA). As part of that IT infrastructure, the HITPC also supports the stage 1 final rule expectation of moving all menu set MU objectives to the core set.

Specifically, the HITPC's stage 2 MU recommendations were developed in the context of the country's recently released National Quality Strategy (NQS) as well as the Department of Health and Human Services' (HHS) ACA proposed rules, such as the Medicare Shared Savings Program for Accountable Care Organizations. The HITPC sought to align its recommendations to the key aims, priorities and principles of the NQS and to ensure that EPs and hospitals that achieve stage 2 MU will be well positioned to meet the expectations of key ACA reforms.

The proposed delay in stage 2 would only affect those EPs and hospitals who attest to stage 1 MU in 2011. Those who attest to stage 1 for the first time in 2012 would continue to have the same expectation for meeting the stage 2 criteria in 2014.

Finally, in some cases the HITPC has made specific references to recommendations for stage 3 and the HITPC would be happy to provide additional stage 3 guidance if you would like. The HITPC believes that there would be substantial value in HHS outlining its long-term MU strategy beyond stage 2 in order to give guidance, with additional details, to providers,

vendors and all industry stakeholders. To the extent that the final rules published in mid-2012 can provide specific criteria for stage 3, it would allow market leaders to launch future development and workflow changes earlier.

II. RECOMMENDATIONS RELATED TO HEALTH OUTCOME PRIORITY 1—IMPROVE QUALITY, SAFETY, EFFICIENCY AND REDUCE HEALTH DISPARITIES:

Stage 1	>30% of unique patients with at least one medication order have at least one medication order entered using CPOE.
Stage 2 Proposed	Raise threshold to >60% for medication orders (i.e., >60% of unique patients with at least one medication order have at least one medication order entered using CPOE) and include at least one lab order for 60% of unique patients who have at least one lab test result; at least one radiology test is ordered using CPOE so that it is "in use" (≥ 1 order) (unless no radiology orders)
Discussion	Stage 1 focuses on initiating the use of CPOE. Stage 1 only includes medication orders and the denominator only includes patients with a medication list in the EHR. • The HITPC recommends an expansion of the role of CPOE to include labs and radiology. Because reporting of electronic radiology *results* are not mandated in Stage 2, a denominator may be difficult to obtain. Therefore, CPOE for radiology should be *"in use"*. That is, CPOE should be used for at least 1 radiology order during the reporting period (unless no radiology orders are made). This will indicate that the capabilities exist with the EHR. • Medication orders should remain on the escalator from stage 1 and have an increased threshold from 30% to 60%: 60% of all unique patients who have at least one medication on their medication list have at least one medication order done using CPOE. • Because CPOE is a function of the EHR, it is believed that labs can also be ordered at the same rate as medication orders: 60% of all unique patients with at least one structured lab result have at least one lab order done using CPOE.
Stage 1	Implement drug-drug and drug-allergy interaction checks (enabled functionality).
Stage 2 Proposed	Employ drug interaction (drug-drug, drug-allergy) checking; Providers have the ability to refine drug-drug interaction (DDI) rules.
Discussion	Stage 1 enabled the functionality in the EHR. Drug-drug and drug-

allergy interaction checks performs reviews of drugs that may affect the patient's welfare and inform the provider as the best drug to provide.

- Providers should have the ability to refine the list of DDI decision support to better align with their patient population and clinical needs. The refinement should be at least at the organization level for EHs and at the practice level for EPs.
- *Signal for stage 3*: The goal is to have nationally endorsed lists of DDI with higher positive predictive value and ability to record reason for overriding alert.

Stage 1	**EP**: Generate and transmit permissible prescriptions electronically for >40% of prescriptions.
Stage 2 Proposed	**EP:** 50% of medication orders transmitted as an electronic prescription. **EH:** 10% of hospital discharge medication orders (for new or changed prescriptions) transmitted as an electronic prescription.
Discussion	Building on stage 1, EPs should continue to use eRx, the threshold should move up to 50% of all medication orders. • Stage 2 should provide the same capability in the EHR technology to allow hospitals access to the eRx functionalities. • As hospitals were exempt from this objective in stage 1, they should start out at a 10% threshold for the measurement.
Stage 1	>50% of all unique patients have demographics recorded as structured data. (preferred language, gender race ethnicity, DOB, (for hospitals) date and preliminary cause of death).
Stage 2 Proposed	80% of patients have demographics recorded and can use them to produce stratified quality reports.
Discussion	More granular and specific demographic data are needed in order to produce detailed quality reports. The IOM recommended that standards be created for more granular race and ethnicity data. • Critical for addressing disparities, especially in areas with very diverse populations. For stage 3, develop and use new standards for granular demographics (as recommended in 2009 IOM report).
Stage 1	Implement 1 clinical decision support (CDS) rule relevant to specialty or high clinical priority along with ability to track compliance.
Stage 2 Proposed	Use CDS to improve performance on high-priority health conditions.

Discussion	As a signal to the HIT Standards Committee: Establish CDS attributes for purposes of certification: 1. Display source/citation of CDS 2. Configurable based on patient context (e.g., inpatient, outpatient, problems, meds, allergies, lab results) 3. Presented at a relevant point in clinical workflow 4. Alerts presented to users who can act on alert (e.g., licensed professionals) 5. Integrated with EHR (i.e., not standalone)
Stage 1	Menu for EH Only: Record advance directive (AD) for 50% of all unique patients 65 years and older
Stage 2 proposed	**Move to Core EH (not including emergency department):** 50% of patients 65 years and older have recorded whether an advance directive exists (with date and timestamp of recording) and an electronic copy of the directive itself if it exists (or have direct access to it or instructions for how to access the most recent copy). **Move to Core EP:** >25 unique patients have recorded whether an advance directive exists (with date and timestamp of recording) and access to a copy of the directive itself if it exists (or have direct access to it or instructions for how to access the most recent copy); (signal ability to store and retrieve AD for Stage 3)
Discussion	Advance directives contain important information for both inpatient and ambulatory settings. The HITPC believes this objective should apply to both the hospitals and eligible professionals. It is the intent that both the EP and hospital have the ability to indicate the following elements within the certified EHR technology. • Indicate within the EHR if an AD exists. • Indicate, with time and date, the last time the AD was updated or reviewed. • If an AD does exist, provide an electronic copy or provide direct access to the document or instructions for how to access the most recent copy. This could be a scanned copy that then gets incorporated into the EHR or accessed in another form. **For EPs Only:** • *For stage 3*, signal the need to provide the capability to store and/or retrieve the AD from the EHR.
Stage 1	New

Stage 2 Proposed	**EH**: Hospital labs provide structured electronic lab results to outpatient providers for ≥ 40% of electronic orders received and use LOINC where available.
Discussion	• Request to HITSC: Specify where LOINC codes are available. • It is recognized that this objective may be more difficult for CAHs to achieve, which may require exclusions. • Structured lab results help aid CDS.
Stage 1	Menu: Send an appropriate reminder for preventive/follow up care to more than 20% of all unique patients 65 years or older or 5 years or younger.
Stage 2 Proposed	**EPs**: 10% of all active patients are sent a clinical reminder.
Discussion	Clinical reminders should be clinically relevant information specific to the patient (reminders about existing appointments do not satisfy this criteria). Rather than raising the threshold, the HITPC recommends extending the denominator to include all age groups. Request to HITSC: Define "active patient" (e.g., all patients seen within 24 months)
Stage 1	New
Stage 2 Proposed	30% of EP visits have at least one electronic EP note and 30% of EH patient days have at least one electronic note by a physician, NP, or PA; scanned notes that are not text-searchable do not qualify.
Discussion	The purpose here is to allow other providers of care to easily search for and retrieve pertinent information from a patient's records. Therefore, notes should be in a format that is searchable and easily accessed. Use broad definition of qualifying note types so that discretion is left to individual providers.
Stage 1	New
Stage 2 Proposed	For EH Only: medication orders automatically tracked via electronic medication administration record (eMAR is in-use in at least one hospital ward/unit).

Discussion	eMAR automatically implies patient identifier and medication is passed without a manual transcription and that this is done within the certified EHR technology. eMAR is defined as technology that automatically documents the administration of medication in the EHR via electronic tracking of the medication, e.g., bar code or RFID technology. For the Standards Committee, the tracking system should be able to: • Check for right patient • Check right medication • Check right dose • Check right route • Record time medication administered
Stage 1	New
Stage 3 Signaling	Consider adding recording of family health history in stage 3 (due to absence of standards for FH).
Discussion	Currently there are no accepted standard codes to structure family history with semantic interoperability. It has been proposed to delay this objective until stage 3 to allow further development time on this issue. However, the HITPC would like to signal that this is targeted objective for future rule making.

III. RECOMMENDATIONS RELATED TO HEALTH OUTCOME PRIORITY 2—ENGAGE PATIENTS AND FAMILIES IN THEIR CARE:

The HITPC recommends consolidation of some objectives to improve clarity. For stage 2, the HITPC proposes a shift in framing from "access & copy" to "view & download." In addition, the HITPC suggests that hospitals and EPs each be responsible for providing immediate access to available data and a prompt access for pending information shortly after it becomes available to the provider.

Stage 1	**EH:** Provide >50% of all discharged patients who request an electronic copy of their discharge instructions with their electronic copy.
Stage 2 Proposed	**This objective is now combined with other objectives.**
Discussion	For the sake of parsimony, this objective should be dropped as long as the discharge instructions are included in the EH view and download objective.
Stage 1	New

Stage 2 Proposed	**EH:** 10% of patients/families view and are provided the capability to download information about a hospital admission; information available for all patients within 36 hours of the encounter.
Discussion	Important to understand the distinction between "view" and "provided the capability to download" information. Every patient who views their information must also have the capability to then download that information if they so wish. This should be done without any further manual process and the download functionality should be provided to the patient at the time of viewing. • It is not intended that the hospital be measured on the number of downloads, rather the percentage of patients who view the information. • Exclusions should be permitted for providers practicing in zip codes with little or no connectivity. • Request to HITSC: It should also be clear to the Standards Committee that the number of views and the number of downloads should be electronically counted for issues of compliance and measurement.
Stage 1	**Menu item for EPs:** Provide > 10% of all unique patients with timely electronic access to health information.
Stage 2 Proposed	**Move to Core EPs:** 10% of unique patients/families view and are provided the capability to download their longitudinal health information; information available to all patients within 24 hours of an encounter (or 4 days after information is available to EPs).
Discussion	Longitudinal information is intended to be information that is electronically available post-EHR implementation. Because patients/families will have the ability to download protected health information, the Privacy and Security Tiger Team should consider including a warning message about the privacy risks of downloading health information, including having unencrypted information on freestanding devices (e.g., USB drives, CDs) to be included as part of EHR standards and certification criteria. • The download should maintain the structure of the recorded data where interoperability standards exist.
Stage 1	Provide clinical summaries to patients for >50% of all office visits within 3 business days.
Stage 2 Proposed	**EPs**: Patients are provided a clinical summary after 50% of all visits, within 24 hours (pending information, such as lab results, should be available to patients within 4 days of becoming available to EPs).

Discussion	Required data will be dependent on the information available within 24 hours. Labs results may not be immediately available. In this situation, where lab results are not provided within 24 hours, the results should then be made available to the patient within 4 days of their becoming available to the EP. • Electronic delivery (e.g., patient portal, PHR, etc.) satisfies this objective.
Stage 1	**Menu:** Use certified EHR technology to identify patient-specific educational resources and provide to patient if appropriate for >10% of all unique patients.
Stage 2 Proposed	**Move to Core:** >10% of patients are provided with EHR-enabled patient-specific educational resources.
Discussion	Stage 1 MU used language "if appropriate". The HITPC feels patient education is an important element and should be included with all patient encounters. Therefore "if appropriate" has been removed from the language in lieu of raising the threshold.
Stage 1	New
Stage 2 Proposed	**EPs**: Patients are offered secure messaging online and ≥25 patients have sent secure messages online.
Discussion	The intent here is that secure messaging capabilities are offered via the EHR technology. • If this capability exists, it is the assumption of the HITPC that providers will use this functionality to communicate with patients. A small threshold of ≥25 patients would introduce this information to the provider and patient and encourage future use on a widespread basis. • Secure messaging provides a vehicle for information reconciliation, which allows the patient to identify inaccuracies in their medical record.
Stage 1	New
Stage 2 Proposed	**EPs**: Patient preferences for communication medium recorded for 20% of patients.
Discussion	The EHR technology should allow the provider to collect, in structured data fields, the patient preference for communication medium.

- This should only include the medium for the communication and not language or other criteria.

Stage 1	New
Stage 3 Signaling	**Stage 3:** Provide mechanism for patient-entered data (supply list); consider "information reconciliation" for stage 3 to correct errors

IV. RECOMMENDATIONS RELATED TO HEALTH OUTCOME PRIORITY 3—IMPROVE CARE COORDINATION:

Stage 1	**Menu**: Perform medication reconciliation for >50% of transitions for receiving provider.
Stage 2 Proposed	**Move to Core:** Medication reconciliation conducted at 50% of transitions by receiving provider.
Discussion	Medication reconciliation should be done by the receiving provider of a transition of care.
Stage 1	Menu: Provide summary of care record for >50% transitions of care for the referring EP or EH.
Stage 2 Proposed	**EH and EP**: Record and provide (by paper or electronically) a summary of care record for >50% transitions of care for the referring EP or EH. **EH and EP**: Record care plan fields (goals and instructions in Stage 2) for 10% of patients. **EH and EP**: Record team member (including PCP, if available; unstructured in Stage 2) for 10% of patients. **EH**: 10% of all discharges have care summary (including care plan and care team if available) sent electronically to EP or post-acute care facility. **EP**: at least 25 transactions sent electronically.
Discussion	Although the majority of the HITPC voted to support a 10% threshold for recording care plans since it was a new practice-standard requirement, a minority voiced an opinion to support a higher threshold, up to 50%, because the requirement is perceived as being easy to fulfill (simple addition of care goals and instructions to the patient to an existing summary of care document). This objective is now a combination of care plan, care team, and care

summary.

- Provide exclusion for lack of electronic recipients. In this case paper must be sent.
- It should be clear that this objective has two components – a "record-data" component and a "send-data" component, with different thresholds.
- The requirement is not for a dynamically maintained shared care plan in stage 2 (in the absence of ubiquitous HIE). This will be considered for stage 3.
- S&I Framework, ONC, HITPC have worked together with other organizations to identify structured data elements to be included in care plan for stage 2, with signaling for stage 3.
- Lists of care team members may be unstructured data for stage 2. In stage 3, will code by NPI.
- The list of care team members will be defined by the provider. At a minimum, it should include the PCP, if available. It may include nursing staff and home care providers if the provider deems it appropriate.
- Providers should meet electronic exchange requirements through some form of connectivity; use of portable media (e.g., USB, fax, CD, etc.) does not constitute electronic data exchange.

Stage 1	New
Stage 2 Proposed	(care team included in summary of care objective)
Discussion	(care team included in summary of care objective)

V. RECOMMENDATIONS RELATED TO HEALTH OUTCOME PRIORITY 4—IMPROVE POPULATION AND PUBLIC HEALTH:

In moving from stage 1 to stage 2, the intent is to demonstrate the capability to successfully submit immunization. This should no longer be a test of a systems capability; rather an actual submission should be required. In addition, all of the public health objectives should be moved to the core set, subject to the availability of public health agencies that can receive the information electronically.

The HITPC also would like the Standards Committee to include a single standard be used for submission of public health data for each objective.

Stage 1	Capability to submit electronic data to immunization registries or immunization IS – Perform a test.
Stage 2	**EH and EP:** Submit immunization data (attest to at least one) in

Proposed	accordance with applicable law and practice.
Discussion	The phrase "in accordance with applicable law and practice" is meant to indicate that this objective is subject to local state law and the availability of public health agencies that can accept electronic submission of data. Signal for Stage 3: View cumulative immunization record and recommendations.
Stage 1	**EH**: Capability to submit electronic lab data on reportable lab results to public health agencies – Perform a test.
Stage 2 Proposed	**EH**: Submit reportable lab results (attest to submitting to at least one organization) in accordance with applicable law and practice.
Discussion	The phrase "in accordance with applicable law and practice" is meant to indicate that this objective is subject to local state law and the availability of public health agencies that can accept electronic submission of data.
Stage 1	Capability to submit electronic syndromic surveillance data to public health agencies - Perform a test.
Stage 2 Proposed	**EH**: Submit syndromic surveillance data (attest to at least one) in accordance with applicable law and practice.
Discussion	The phrase "in accordance with applicable law and practice" is meant to indicate that this objective is subject to local state law and the availability of public health agencies that can accept electronic submission of data. CMS may consider the following objective for EPs: Submit syndromic surveillance data (attest to at least one) in accordance with applicable law and practice. CMS may also consider the following objective for EPs: Submit reportable cancer conditions (attest to at least one) in accordance with applicable law and practice. (Such a requirement would use the IHE cancer reporting implementation guide.) The latter objective highlights the need for the development of standards by Stage 3 for public health case reporting by eligible providers and hospitals of those conditions that are not associated with a diagnostic laboratory test.

Stage 1	New
Stage 3 Signaling	For Stage 3: Patient-generated data submitted to public health agencies.

VI. RECOMMENDATIONS RELATED TO HEALTH OUTCOME PRIORITY 5—ENSURE ADEQUATE PRIVACY AND SECURITY PROTECTIONS FOR PERSONAL HEALTH INFORMATION:

Stage 1	Conduct or review a security risk analysis and implement security updates as necessary and correct identified security deficiencies as part of the its risk management process.
Stage 2 Proposed	Perform, or update, security risk assessment and address deficiencies. Attest to addressing encryption of data at rest (see Tiger Team recommendations set forth in 4/18/11 transmittal letter).

Discussion

Additional privacy and security recommendations adopted on April 13 2011 for consideration by the HITSC (see 4/18/11 transmittal letter for details):

-Authentication of individual users of provider EHRs:

- At least two factors for remote access
- Two factor authentication consistent with DEA rule for e-prescribing of controlled substances

-Authentication of provider entity – entity must have digital certificate, and certification process should include testing of use of digital certificates for appropriate transactions.

-Authentication of patients accessing data in a provider's EHR (such as for view and download objectives):

- Single factor authentication (user and password) as minimum standard.
- EHRs should have capability to detect and block programmatic attacks or attacks from known but unauthorized person.

-Other functionalities for patient view and download capability should include:

- Audit trails for access to patient online account.
- Provisions for data provenance.
- View and download function should be secure.

-With respect to improving data matching accuracy, certification of EHRs in stage 2 should include testing regarding the sending and receiving of demographic data in correct formats and the rejection of incorrectly entered values.

In addition, the Policy Committee will consider in Stage 3 whether to require EPs and/or EHs to meet the conditions of trust and interoperability for the Nationwide Health Information Network (NwHIN).

All of the above items are recommended as "core."

The committee voted 12 to 5 in favor of the above recommendations. The 5 members who opposed the recommendations stated reasons of wanting an additional delay in the effective date for stage 2 and/or more limited requirements for stage 2.

Finally, in its request for comment, the HITPC sought input on whether the public believes that a group reporting option should be available in future MU stages. The HITPC posed this question because group reporting fits more appropriately into HHS's broader delivery system reform goals around group accountability and team-based care. Public comment overwhelmingly supported EPs having the option to do MU reporting on a group or individual basis. The HITPC is passing on this public feedback.

The HITPC appreciates the opportunity to provide input into the development of the stage 2 MU regulation. The committee respectfully submits the recommendations contained in this letter, which we believe would strengthen the criteria and provide a pathway toward a safer, more effective and more efficient health care delivery system.

We remain available and willing to assist the Office and the Department in any way we can.

Sincerely,

/s/

Paul Tang, MD
Vice Chair, Health IT Policy Committee
Palo Alto Medical Foundation