Federation of American Hospitals®

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Via Electronic Submission

David Blumenthal, MD, MPP
National Coordinator for Health Information Technology
Chair, HIT Policy Committee
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: Meaningful Use Workgroup Request for Comments Regarding Meaningful Use Stage 2

Dear Dr. Blumenthal and Members of the HIT Policy & Standards Committees:

The Federation of American Hospitals ("FAH") is the national representative of investor-owned or managed community hospitals and health systems throughout the United States. Our members include teaching and non-teaching hospitals in urban and rural America, including inpatient rehabilitation, long-term acute care, cancer and psychiatric hospitals.

On behalf of our nearly 1,000 member hospitals, we are pleased to offer the following comments on the HIT Policy Committee "Meaningful Use Workgroup Request for Comments Regarding Meaningful Use Stage 2." Although hospitals have not yet begun attesting to meeting stage 1 meaningful use, the implementation process is yielding important findings about the barriers and challenges providers are facing in meeting the initial requirements. This early implementation experience, as well as the actual experience we will gain from attesting providers, should be the guiding force behind the policy decisions made about how to move the Electronic Health Record ("EHR") Incentive Program forward.

A survey of FAH members conducted in January 2011 found several major challenges in meeting stage 1 meaningful use, including:

- Timeline Compression

- Navigating the Certification Process
- Vendor Issues/Delivery Delays

These overarching challenges were largely common across our members. We also received feedback on the specific objectives FAH members saw as the greatest barriers to achieving stage 1 meaningful use, including the lack of guidance on the clinical quality reporting requirements and health information exchange functionality. These two critical areas are addressed in greater detail below.

The FAH has, and continues to be, a strong supporter of the HITECH law. We commend the federal government's investment not only to spur the adoption of health information technology ("HIT"), but also to build the infrastructure necessary to support nationwide exchange of health information. However, we are seeing early evidence that there may be a need to rethink the current staging of the program and build in additional time for providers to meet the high bar set for stage 1. The President's FY 2012 budget estimates that only $640 million will be spent on Medicare incentive payments to providers in 2011. This is in stark contrast with the 2009 Congressional Budget Office score of $2.7 billion for 2011 Medicare incentive payments. This discrepancy assumes that only one-fourth of the providers originally expected to achieve meaningful use in 2011 will reach that goal.

The EHR Incentive Program and the development of a nationwide exchange infrastructure are both at a critical stage. We should move forward cautiously and strategically, based on actual experience from the field, and seize this opportunity to make needed mid-course corrections. The FAH believes this is the time to ensure the meaningful use policies put in place moving forward will lead to the best possible chance for a successful migration to widespread use of interoperable EHR technology across the healthcare system. It is in this spirit that we make the following recommendations to the Office of the National Coordinator ("ONC") and the HIT Policy & Standards Committees regarding stage 2 meaningful use:

- Make the stage 1 menu items mandatory, but do not add any new meaningful use objectives (this would not prevent raising usage thresholds for current objectives or enhancing the functionality of current objectives as recommended for CPOE).
- Institute a 90-day EHR reporting period for the first year of each new stage of meaningful use.
- ONC, in collaboration with the HIT Policy & Standards Committees, should make strategic decisions about where to focus first to get health information flowing.
- ONC should work with providers and the National Quality Forum ("NQF") to carefully study early experience with electronic quality measurement using certified EHR technology prior to adding additional clinical quality measures to meaningful use.
- Vendors with quality reporting products that cannot produce quality measures from the documentation in the electronic record <u>should not</u> be certified.

- Compliance with HIPAA, which was significantly expanded and strengthened under HITECH, should continue to be enforced by the Office of Civil Rights ("OCR"), not through additional meaningful use requirements.

TIMELINE ISSUES

The FAH has growing concerns about the ability of hospitals to meet meaningful use stage 1 in FY 2011 and then add a new set of applications to meet stage 2 by October 1, 2012. According to a survey of our members, it generally takes 18- 24 months to implement a set of applications across a hospital system (we only received one response indicating this could be achieved in a shorter timeframe). Given our experience with the stage 1 regulatory process, we are concerned there will not be enough lead time from publication of the stage 2 final rule to allow for vendor development and certification, delivery of new applications, upgrades to current systems, and implementation in the hospital. The implementation process requires extensive training and workflow redesign to ensure patient safety and quality are not jeopardized. This timeline compression presents a real possibility that hospitals will "fall off the escalator" between stages. We believe this could be addressed in part by instituting a 90-day reporting period for the first year of each new stage of meaningful use. The first year 90-day reporting period was a critical enabler for many of the hospitals that will attest in FY 2011 and we believe this policy should be applied to all future stages of meaningful use.

In the FAH's March 2010 comment letter to CMS on the stage 1 proposed rule, we advocated for extending the transition to full meaningful use, defined as stage 3, beyond the proposed 2015 date to 2017 (the final rule was silent on stage 3). If stage 1 were to be effectively extended through stage 2 (with some enhancements), ONC and CMS would have ample lead time to produce a rule for stage 3 that could add additional requirements, and incorporate steps to make a concrete plan for robust information exchange a reality. By making the stage 1 menu items core and increasing the utilization thresholds (as was recommended by the Meaningful Use Workgroup for many objectives), we believe the regulatory agencies would be in compliance with the HITECH statute which requires the Secretary to "improve the use of electronic health records and health care quality over time by requiring more stringent measures of meaningful use." The movement toward widespread adoption of EHRs is headed in the right direction. The goal for stage 2 should be to sustain the current momentum, not add to the complexity facing providers.

Further, we believe this approach would provide for additional time for ONC and CMS to both bring greater focus to health information exchange activities and gain real world experience with electronic quality measurement and reporting. We do not think these two critical areas of meaningful use have received the strategic attention necessary to ensure they become successfully ingrained in the electronic health care system envisioned under the HITECH law.

PROPOSED MEANINGFUL USE OBJECTIVES FOR STAGE 2

Below are our specific comments on the Meaningful Use Workgroup's proposed stage 2 objectives. As recommended above, we do not believe any new objectives should be added to stage 2. However, we have asked for clarification and recommended modifications to new

objectives, should the HIT Policy Committee choose to formally submit them as part of their stage 2 recommendations to the ONC.

The FAH was pleased to see that the administrative functions proposed for stage 1, but not ultimately finalized by CMS, were not included in the Workgroup's recommendations. As stated in our comment letter on the stage 1 proposed rule, hospitals are already widely using electronic systems to perform functions covered under the HIPAA administrative simplification regulations, such as electronic claims submission. We continue to believe it is inefficient to require hospitals to abandon their long-standing administrative systems to perform these functions through certified EHR technology, or to have these administrative systems certified, when the two are almost always integrated.

PROPOSED STAGE 2 OBJECTIVE	**COMMENTS**
CPOE (by licensed professional) for at least 1 medication, and 1 lab or radiology order on 60% of patients who have at least 1 such order (order does not have to be transmitted electronically)	The FAH has growing concerns about vendor products being certified for CPOE without the ability to transmit the order electronically. While we understand why electronic transmission is not currently required part of meaningful use, we are troubled by the prospect of products coming to the market without this capability.
E-prescribing: 50% of orders (outpatient and hospital discharge) transmitted as eRx	The FAH would ask for clarification on the intent of this objective. We are interpreting it to mean that hospitals would be required to install eRx software within the walls of the facility. We believe the 50% threshold for this new hospital measure should be lowered to 30%, the threshold set for CPOE for medication orders in stage 1. There are numerous reasons why a patient would want a paper prescription upon discharge and this should be considered when setting the initial threshold for this objective.
Record Demographics: 80% of patients have demographics recorded and can use them to produce stratified quality reports	The FAH requests clarification of the definition of a "stratified quality report."
Report Clinical Quality Measures Electronically	See Comments Below
Maintain Active Medication Allergy List: Continue Stage 1	The FAH continues to have concerns around the lack of a clear and consistent definition of what constitutes a "medication allergy." This will result in inconsistent application of this objective and should be an area where the ONC works with stakeholders to develop a

	consensus definition that can be applied uniformly across the health care system.
Record Smoking Status: 80% of unique patients have smoking status recorded	The definition of "smoking status" for this objective should be consistent with the smoking cessation quality measure included in the Hospital Inpatient Quality Reporting Program.
Clinical Decision Support: Use CDS to improve performance on high-priority health conditions. Establish CDS attributes for purposes of certification: 1. Authenticated; 2. Credible, evidence-based; 3. Patient-context sensitive; 4. Invokes relevant knowledge; 5. Timely; 6. Efficient workflow; 7. Integrated with EHR; 8. Presented to appropriate party who can take action	The FAH would like to clarify that this objective could be satisfied through an electronic core measures system. Further, we would appreciate additional clarity around what the workgroup means by "use CDS to improve performance." How would this "improvement" be measured for the purposes of meeting meaningful use? We are concerned that "improving performance" in this context could tie to specific quality benchmarks which we strongly oppose for the purposes of achieving meaningful use. We believe the stage 1 framework for CDS should continue in stage 2 with a higher threshold set for the number of rules a hospital must implement (*e.g.*, raise threshold from 1 to 4 rules). The hospital should be able to continue to select CDS rules based on the unique clinical priorities for the patient population they serve.
Record Existence of Advance Directives: 50% of patients 65 and older have recorded in the EHR the result of an advance directive discussion and the directive itself if it exists.	The FAH would recommend that the objective be revised to read "…and the directive itself, <u>if available.</u>" An advance directive may in fact exist but be inaccessible at the time of the discussion. We believe the goal should be to capture the intent. We further recommend that this objective be aligned with the Joint Commission's requirements for advance directives.
Generate Patient Lists for multiple patient-specific parameters	The FAH requests clarification of the definition of "multiple patient-specific parameters." The Workgroup should define the use case and primary consumers for action. Is the request for multiple parameters for the list (*i.e.*, lab and vital signs) to define patient populations at risk? Or rather is the intent multiple lists defined by a single parameter (*i.e.*, a condition) for chronic disease

	management?
Send Patient Reminders	The FAH would like clarification that this objective applies to EPs only, consistent with stage 1 meaningful use.
NEW: 30% of EH patient days have at least one electronic note by a physician, NP, or PA	The FAH requests further clarification on this objective. We are interpreting this to mean "progress notes" but it is unclear. Can the note be in any form? Could it be transcribed?
NEW: 30% of EH medication orders automatically tracked via electronic medication administration recording (eMAR)	The FAH would like to clarify that this objective only requires eMAR, and does not require bar-coding.
NEW: 80% of patients offered the ability to view and download via a web-based portal, within 36 hours of discharge, relevant information contained in the record about EH inpatient encounters. Data are available in human-readable and structured forms.	The FAH has serious concerns with this objective. • What are the implications of this objective for certification? Does the vendor need to be certified to provide this capability? Does the portal itself need to be certified if developed by the hospital? • This will place a heavy operational burden on hospitals to manage the portal, including unique patient IDs and passwords. Would hospitals be required to provide access to this information about the inpatient stay indefinitely? We believe some parameter, such as 6 months, should be in place if this objective moves forward. • We believe that 80% is too high for a new objective and should be lowered. In general, we do not believe this objective is appropriate for all hospitals and would seem to be a function that could be offered by a state or regional HIE. <u>We recommend removal of this proposed objective.</u>
EP Objective: 20% of patients use a web-based portal to access their information at least once.	The FAH is extremely concerned that the Meaningful Use Workgroup is recommending objectives that are outside of the control of the provider. EPs have no control over a patient's access to the internet, nor is there any way to manage this to ensure compliance. All meaningful use objectives should be achievable through direct actions that can be

	taken by the provider and managed internally.
NEW: Connect to at least 3 external providers in "primary referral network" or establish an ongoing bidirectional connection to at least one HIE	The FAH requests clarification of the definition of a "primary referral network." Clarify the context – is this a provider network referring a hospital or a provider network to which the hospital refers (potentially other hospitals or physicians in either case)?
NEW: List of care team members available for 10% of patients in EHR	The FAH requests clarification of the definition of a "care team"? We believe there should be some parameters put around the degree to which a clinician has interacted with the patient to render them part of the "care team" (*e.g.*, circulating nurses in the operating room should not be included). By way of example, teams defined by episode of care (acute care team), longitudinal care (case management team), organ system (cardiovascular team), disease state (oncology team), venue of care (home health team) or procedure (dialysis team) could each be valid teams for the same patient. Further, we believe that the workgroup should clarify that the PCP would be listed "if known."
NEW: Record a longitudinal care plan for 20% of patients with high-priority health conditions	The FAH does not believe this objective is appropriate for hospitals and we are unsure how this objective would fit into an acute episode. We could envision a hospital updating a longitudinal care plan, if available, but we do not believe hospitals should own construction of the care plan.
Privacy & Security	See Comments Below

HEALTH INFORMATION EXCHANGE

The FAH has long-supported the adoption of interoperable HIT as a means of improving the quality, safety, and efficiency of health care delivered to patients in the United States. However, without a concrete plan to get information flowing, we are unlikely to realize the full potential of HIT to achieve these goals. *We believe that in order to begin this flow of information, the regulatory agencies, in collaboration with the HIT Policy & Standards Committees, need to make strategic decisions about where to focus first (i.e., public health reporting, transitions of care, etc.).* In the context of health reform, this may include looking at what information would be needed by an Accountable Care Organization ("ACO") to manage a population.

Delaying the addition of new meaningful use requirements will give ONC time to make these strategic choices about where to focus first, and to determine whether to continue with the

current document-focused "push" model of exchange or to harmonize the "pull" model recommended by the PCAST report with the current work of HIT Policy & Standards Committees. Regardless, there needs to be a strong federal backbone established to achieve nationwide exchange and it's unclear whether the NHIN will achieve this. In our view, to achieve a nationwide system of interoperable HIT, the ONC will need to rein in the creativity of the disparate state exchanges, set priorities for what should be exchanged first, get that information flowing, and expand from there.

There are several case examples of countries (*e.g.*, Germany, Israel, Australia) around the world that have relatively high rates of EHR adoption, yet no ability to exchange the information contained in those records. Much of the value of HIT, for patients seeking care and for providers, will be in the ability to access needed information at the point of care. Getting health information flowing, in many ways, is just as important as having the technology in place and entering the data. We would strongly urge the ONC to bring focus to the effort to build nationwide exchange capability.

REPORTING CLINICAL QUALITY MEASURES

Clinical quality measurement is a complex area that has grown organically over the last decade, rooted in evidence-based measures endorsed through the NQF consensus standards development process and a strong partnership between the federal government and private stakeholders. Hospitals have been a key partner in the establishment of this quality enterprise, beginning with the voluntary reporting of quality measures and ongoing support for the establishment and enhancement of the HHS *Hospital Compare* website by the Hospital Quality Alliance.

Our members have expressed concerns that the specifications for the stage 1 clinical quality measures are not complete and have significant gaps, which will result in data that cannot be reliably used for comparing hospital performance. While we believe that quality reporting through EHRs has the potential to reduce burden on providers and improve access to quality information within institutions, we are concerned that the lack of complete, fully tested specifications will lead to issues with data quality, completeness, and validity. This is especially concerning given that this data is likely to be used in public reporting and payment programs coming on-line in the near future.

The health care quality community needs to better understand the discrepancies, if they exist, between chart-abstracted measures and eMeasures. This cannot occur without gaining real world experience in the field with these measures. *Therefore, we strongly recommend that ONC work with providers and the NQF to carefully study early experience with quality measurement using certified EHR technology prior to adding additional clinical quality measures to meaningful use.* The findings from this analysis should be widely disseminated and used to inform changes to the eMeasure specifications as well as any needed technical enhancements to the EHR applications.

It is important to keep in mind that when a hospital goes live on an EHR system and discontinues use of their paper record, that hospital is still required to produce all of the measures

for the Hospital Inpatient Quality Reporting Program (as well as numerous other private reporting programs), including those that are not part of meaningful use. At this point, the technical capability of the EHR to produce valid quality measures has a material impact on the hospital's quality data beyond meaningful use. Hospitals do not want dual documentation streams and need technology solutions capable of producing valid quality measures pulled directly from the electronic medical record.

On this point, the FAH is extremely concerned about reports from the field of vendor products being certified for electronic quality measurement that cannot produce measures as a byproduct of the care process. For example, we know of certified products that provide checklists to produce numerators and denominators, but cannot actually pull the data elements to produce the quality measure from the medical record. We do not believe these types of "work-a-rounds" were intended by Congress in the HITECH law or by the ONC when the certification program was established. *We strongly believe that vendors with quality reporting products that cannot produce quality measures from the documentation in the electronic record should not be certified.*

PRIVACY & SECURITY

While the FAH acknowledges that recommendations for stage 2 related to privacy and security fall under the purview of the Privacy and Security Tiger Team, we would still like to offer our thoughts as they relate to the intersection of meaningful use with broader privacy and security policy.

From a process perspective, we are very concerned by the Privacy and Security Tiger Team's record of discussions of privacy related to meaningful use that are outside the scope of authority given to HHS in the HITECH law. In our opinion, the Tiger Team is taking the opportunity to attempt re-write HIPAA under the pretext of meaningful use recommendations on privacy and security. For example, discussions around informed consent for treatment, payment, healthcare operations ("TPO"), and other information exchanges outside of HIPAA, appear to have been on the table as potential areas in which consent could be recommended by the Tiger Team. Despite legislating on several privacy topics, Congress did not include in HITECH a new requirement to obtain patient consent for disclosures related to TPO. Requiring patient consent for these health care activities has long been recognized as unworkable. We are concerned the Tiger Team is seeking to circumvent the longstanding concerns of health care providers that have been widely recognized by both legislators and HHS and the recent, conscious decision of Congress not to legislate on this issue.

In the proposed rule on stage 1 meaningful use, CMS indicated that the agency "does not believe meaningful use of certified EHR technology is the appropriate regulatory tool to ensure such compliance with the HIPAA Privacy and Security Rules." The FAH continues to agree strongly that the meaningful use requirements should not be used to ensure compliance with the HIPAA Privacy and Security Rules. *We would therefore recommend that compliance with HIPAA, which was significantly expanded and strengthened under HITECH, continue to be enforced by OCR, which has various sanctions available to address non-compliance, rather than through additional meaningful use requirements.*

ADDITIONAL SPECIFIC QUESTIONS FOR PUBLIC COMMENT

What strategies should be used to ensure that barriers to patient access – whether secondary to limited internet access, low health literacy and/or disability – are appropriately addressed?

FAH member hospitals recognize there are a variety of barriers to patient access, especially in rural and low-income communities. While the vast majority of these barriers are outside the control of providers, we do believe it is important to structure meaningful use in a way that does not exacerbate a growing digital divide and impede access to health information for patients. Therefore, we believe it is important to retain the ability to send information by U.S. mail. It is reasonably secure and will likely need to continue to be used to reach patients who do not have access to electronic methods for receiving information.

For future stages of meaningful use assessment, should CMS provide an alternative way to achieve meaningful use based on demonstration of high performance on clinical quality measures?

The FAH welcomes the Workgroup's thoughts about flexibility in meaningful use policy and appreciates conceptually the idea of recognizing results related to high performance. However, we would need additional information and further clarification around how this concept would interact with the various quality and payment programs coming online in the next 2-3 years. We would be concerned that hospitals could potentially be subjected to a double jeopardy situation, depending on how the alternative is structured.

What additional meaningful use criteria could be applied to stimulate robust information exchange?

See "Health Information Exchange" comments above. As requested in prior comment letters, the FAH is eager to see a roadmap to the end goal of having all of the necessary technologies in place to promote safe, efficient, high quality care. This roadmap should align functional goals with a growing set of focused information exchange targets, clearly outlining the priorities at each stage of meaningful use. We envision a roadmap that is broader than listing specific recommended objectives, but far more detailed than the original schema of "data capture and sharing, advanced clinical processes, and improved outcomes."

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Our comments reflect a strong desire to see the EHR Incentive Program be the catalyst Congress envisioned when it passed the HITECH law in 2009. We believe Congress' primary goal was to see providers succeed at implementing and using certified, interoperable EHR technology to improve the quality, safety and efficiency of care. We do not believe Congress' intent was to grow a digital divide among providers or set unachievable requirements that would result in financial penalties for providers that want to be a partner with the federal government in bringing the U.S. healthcare system into the 21st Century.

The FAH appreciates the opportunity to comment on this proposal for stage 2 meaningful use and we look forward to continuing to work with the HIT Policy & Standards Committees, the ONC, and CMS moving forward. If you have any questions about our comments or need further information, please contact me or Samantha Burch of my staff at (202) 624-1500.

Sincerely,