American Hospital Association

Liberty Place, Suite 700
325 Seventh Street, NW
Washington, DC 20004-2802
(202) 638-1100 Phone
www.aha.org

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Submitted Electronically

Farzad Mostashari, M.D., ScM
Chair, Health Information Technology Policy Committee
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Suite 729-D
Washington, DC 20201

Re: Health Information Technology; HIT Policy Committee: Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records (EHRs) - HHS-OS-2012-0007

Dear Dr. Mostashari:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to respond to the request for comment (RFC) from the Health Information Technology Policy Committee (HITPC) regarding the Stage 3 definition of meaningful use of electronic health records (EHR) published in the Nov. 26 *Federal Register*. The RFC includes a very ambitious set of preliminary recommendations for the definition of Stage 3 meaningful use that would make more than 40 changes to the Stage 2 requirements.

The AHA believes it is too soon to define the meaningful use requirements for Stage 3. As of September 2012, fewer than one-third of hospitals had met the Stage 1 requirements and received a Medicare incentive payment. In addition, hospitals have not yet had experience with Stage 2, given that the full set of final rules and specifications were just released last fall and no products to support Stage 2 are currently available.

Congress established the EHR Incentive Programs in the *American Recovery and Reinvestment Act of 2009* (ARRA) to provide needed funds **to accelerate the widespread adoption and use of EHRs to improve health and health care**. We share these goals, and America's hospitals have invested tremendous financial and human resources to make them reality. Hospitals also work every day to ensure adequate privacy and security for patients and their health information. To date, the incentive programs and promised incentives have provided a focused approach to the use of EHRs and led to greater adoption. However, they have not yet achieved their goal of widespread adoption.

Rather than rushing ahead to set Stage 3 requirements, the HITPC should recommend that the Department of Health and Human Services (HHS) fund a comprehensive, external evaluation that highlights progress to date, but also seeks to understand why, more than two years into the program, the large majority of hospitals and physicians have yet to attest to meaningful use. We urge the HITPC to refrain from finalizing Stage 3 recommendations until it has reviewed the results of such an evaluation and can develop an implementation plan for Stage 3 that addresses the issues raised in Stage 1.

In addition, we recommend that the HITPC focus its attention on the mandate it was given in statute "to make recommendations to the National Coordinator relating to the implementation of a nationwide health information technology infrastructure." The Stage 2 meaningful use rules contain significant health information exchange requirements that promise great benefits for patients and the health care system as a whole. However, three years after the passage of the ARRA, we are still without affordable exchange networks and other key components necessary for true interoperability. Addressing the current limits to interoperability will bring far greater benefits than rushing into a definition for Stage 3 that is not built on lessons learned from Stage 1, let alone Stage 2.

The remainder of this letter sets out the current regulatory and fiscal context for the EHR Incentive Programs, highlights the need for a comprehensive evaluation of experience to date, and draws attention to work remaining to build the infrastructure to support the interoperability requirements in meaningful use. We then provide overall comments on the scope of the Stage 3 recommendations being considered by the HITPC, offer design principles for future stages of meaningful use to improve predictability, and recommend ways to improve reporting of clinical quality measures through EHRs. Four attachments provide specific responses to the preliminary recommendations for Stage 3 objectives and measures and the many questions raised on meaningful use, quality reporting, and privacy and security.

REGULATORY AND FISCAL CONTEXT

To date, the incentive programs have not closed the digital divide between urban and rural communities, and may unintentionally have served to widen it. According to data provided by the Centers for Medicare & Medicaid Services (CMS), at the close of fiscal year (FY) 2012, slightly fewer than a third of all eligible hospitals had met Stage 1 of meaningful use.[1] Notably, only 15 percent of the 1,300 critical access hospitals (CAHs) that provide essential access to care in rural and frontier communities had met the requirements. Only CAHs that successfully attested to meaningful use in FYs 2011 or 2012 will benefit fully from the incentives; the vast majority will come on board later and receive incentives for fewer years. There are many reasons providers have not yet met Stage 1, including the high bar set in regulation, the high

[1] The data provided for end-September 2012 show that 1,474 hospitals had attested to meaningful use and received a Medicare incentive payment. Of those, 204 were CAHs. All data released by CMS since then do not allow for a unique count of hospitals that have met meaningful use under Medicare, but rather combine payments for meeting MU in FYs 2011 and 2012. The data presented by CMS at the January 2013 HITPC meeting show that an additional 580 hospitals received Medicare incentive payments in October and November, but does not differentiate between those receiving a Year 2 payment versus a Year 1 payment. About 800 hospitals attested to meaningful use in FY 2011, and would be receiving a Year 2 payment in this timeframe.

costs of buying and implementing systems, limits to vendor capacity and documented workforce shortages.

Further, beginning with Stage 2, any provider that fails to meet the requirements will receive a significant payment penalty. Hospitals must successfully attest by July 1, 2014, and eligible professionals (EPs) must attest by Oct. 1, 2014, or face penalties that grow with time and do not end. Thus, the Medicare EHR Incentive Program is **not** voluntary and applies to all hospitals and EPs that see Medicare patients – 5,011 hospitals and about 525,000 physicians, according to CMS. Ironically, meaningful use criteria that are too hard or expensive to meet could result in cuts to payments that reduce providers' ability to implement EHRs and, therefore, limit the benefits of EHRs for patients and consumers.

The Medicare EHR Incentive Program is part of the Medicare payment system and must be placed within the regulatory and fiscal context of all programs impacting hospitals. These include the move to ICD-10 on Oct. 1, 2014, the launch of hospital value-based purchasing, the implementation of the Hospital Readmissions Reduction Program, and the introduction of accountable care organizations, among others. Each of these programs, while valuable in its own right, introduces a web of new regulations that, together, threatens to overwhelm providers.

In addition, federal policymakers are cutting Medicare spending. The *Patient Protection and Affordable Care Act of 2010* (ACA) included significant reductions to hospitals that are now beginning to take effect. Since then, hospitals have faced additional large reductions to Medicare and Medicaid funding. For example, the *Budget Control Act of 2011* included a "sequester" policy that will decrease all Medicare payments – including the EHR incentives – by 2 percent in each of the next 10 years. More recently, the *American Taxpayer Relief Act of 2012* reduced inpatient hospital payments by $11 billion in FYs 2014 through 2017 – a reduction of 2.4 percent in each year. These cuts are additive and pose very significant fiscal challenges and limit hospitals' ability to fund new initiatives.

At the same time, the costs of implementing EHRs are remarkable and growing. According to data from the AHA's annual survey of hospitals, hospitals experienced dramatic increases in IT expenditures between 2009 and 2011 that simply are not sustainable given our fiscal realities. In an analysis of a matched set of 3,025 hospitals reporting information on IT expenditures in 2009 and 2010, the per bed operating expenditures for IT grew 24.2 percent in one year, while per bed capital expenditures for IT grew 13.9 percent. Capital expenses per bed then spiked between 2010 and 2011 – growing by 62 percent in a single year across all hospitals. Spending per bed, however, is much higher among large and teaching hospitals, which are generally further ahead in EHR adoption. Teaching hospitals saw two consecutive years of remarkably large growth in IT capital spending per bed – an increase of 65.8 percent from 2009 to 2010, and 92.6 percent from 2010 to 2011. In comparison, between 2010 and 2011, total expenses per bed across all categories of expense grew only 4.0 percent and total capital expenses per bed grow only 2.6 percent.

On average, between 2010 and 2011, hospitals spent $45,600 on IT operations and $20,200 on IT capital per bed. For a 200-bed hospital, that equates to $13.2 million in combined IT expenses in a single year. Hospitals and the trade press report continued large expenditures on

EHRs in 2011 and 2012, well above the value of the possible incentives. On average, hospitals estimate that the Medicare and Medicaid EHR incentives will offset only 10 to 15 percent of the total costs of adoption. Given these high costs and the looming payment cuts, some hospitals are weighing whether the investment in IT is financially feasible, and many more will face that question in the near future.

EVALUATION OF MEANINGFUL USE

Before advancing regulatory requirements, policymakers should rigorously evaluate the experiences of providers during Stage 1 and publicly report the results. An evaluation should investigate why some providers have not yet met meaningful use, despite their considerable efforts to do so, and what steps are needed to overcome the identified barriers.

A rigorous evaluation of the program also must include the capacity of federal and state governments to receive the data reported by providers. Hospitals continue to face barriers to successful registration and attestation to meaningful use. For example, some hospitals have met meaningful use but have been prevented from attesting due to CMS systems issues. The agency's systems are cumbersome and require manual data entry to attest. While meaningful use requirements push vendors to build capacity and providers to report data, the agencies must be able to receive the data, use it and share findings with providers. In addition, states' capacity to receive public health data electronically varies widely, and there is no centralized source of information on which public health reporting measures each agency can accommodate. Our members report that most public health departments cannot receive all of the Stage 1 public health data, nor accommodate all of the providers in their jurisdictions who want to report.

We recommend that policymakers evaluate which government agencies are able to support the current stages of meaningful use and then build and repair the processes that would enable that support to be more widespread. In particular, **no additional public health measures should be required of providers until all public health departments can receive all of the Stage 1 meaningful use data electronically.**

BUILDING INFRASTRUCTURE TO SUPPORT INTEROPERABILITY

The AHA urges the HITPC to prioritize policy recommendations to HHS that advance the more robust data exchange infrastructure necessary to support the interoperability required in Stage 2 meaningful use and beyond. Greater interoperability will facilitate the sharing of health information so that clinicians and patients have the information they need to provide treatment and promote health, in the form and at the time they need it. The "Direct Protocol" in Stage 2 supports the start of data exchange, but the anticipated future volume of exchange will require greater capacity than point-to-point exchange. Providers need to exchange information across affiliated and unaffiliated settings of care. Key pieces of the infrastructure for exchange are still missing, such as affordable exchange networks and widely accessible provider directories.

We also urge the HITPC to prioritize the policy recommendations to HHS that will advance patient matching, specifically a national approach for requirements that all parties

can draw on to improve the accuracy and cost-effectiveness of patient matching. The issue of how to match patients with their medical records needs to be solved as we accelerate information exchange on the regional and national level. Currently, hospitals and health systems are forced to expend significant resources on expensive, proprietary solutions to develop master patient indexes that apply only to that particular hospital or health system's patients. The inability to match patients across silos raises safety concerns from mismatches – incorrectly matching patients, or missing a match that should have been made.

STAGE 3 REQUEST FOR COMMENT

In the RFC, the HITPC provides a set of preliminary recommendations for the Stage 3 objectives and measures of meaningful use, including more than 40 new or changed requirements. Taken together, they are far too numerous to be sustainable. An ever-expanding and changing list of requirements will result in significant cost and burden at a time when policymakers are looking to reduce expenditures on health care.

In addition, the recommendations are presented as a list that is not accompanied by evidence-based justifications for their inclusion, consideration of their feasibility, or presentation of a cost-benefit analysis. We do not believe the HITPC should finalize such a broad list of new requirements without first asking HHS to gather much more information about what the expected benefits, costs and operational impacts will be, and whether the objectives are included in the core or menu set. Only then can the HITPC consider which recommendations will add value, be feasible and be cost-effective. Regulatory requirements that turn out to be unworkable in practice have significant unintended consequences, including wasting resources invested by those trying to comply, lost opportunities for innovation or investments in other areas, delays in actually reaching widespread use of interoperable EHRs, and erosion of support for the goal.

That said, the preliminary recommendations include good ideas that merit further investigation. However, they are not sufficiently developed or proven to become regulatory requirements. The HITPC should consider alternative ways to further these ideas, such as federally funded development of new uses of EHRs, pilot programs to better understand feasibility and costs of new uses, or grants to state departments of public health to build the infrastructure to receive information electronically. See Attachment A for detailed comments on Stage 3 objectives and measures.

PROPOSED DESIGN PRINCIPLES FOR MEANINGFUL USE

By Stage 3, the EHR Incentive Program should be a mature regulatory structure that makes incremental improvements in a sustainable fashion. To make any future stage of meaningful use more feasible, less burdensome and more predictable, the AHA urges the application of the following principles to all of the objectives and measures for both hospitals and EPs:

- Preserve the existing approach of a core set of required objectives accompanied by a menu set with limited choice among objectives.
- Introduce any new objectives through the menu set.

- Move menu items to the core at the same performance threshold set in previous stages of meaningful use.
- Remove measures that make the performance of hospitals and EPs contingent on the actions of others.
- Remove all measures that have been "topped out," meaning that they are essentially fully deployed in a previous stage.

Given the many steps needed to develop and implement each stage of meaningful use, the AHA continues to recommend that each stage last three years. This would mean that Stage 3 would begin in FY 2017 rather than FY 2016.

REPORTING CLINICAL QUALITY MEASURES THROUGH EHRS

The AHA strongly urges policymakers to focus on making the current automated clinical quality measure reporting process viable. Hospitals have demonstrated their commitment to successful participation in multiple Medicare payment and quality reporting programs that together require reporting on almost 90 quality measures. EHRs have the potential, if done right, to ease the burden of quality reporting, while increasing access to real-time information to improve care.

To advance hospitals' commitment in the form of electronic quality reporting, we need processes that support valid, reliable and feasible data collection and reporting of clinical quality measures (CQMs). In Stage 1, a rushed timeline and insufficient testing of certified EHRs led to an inability to generate useable clinical quality data out of the certified EHRs to meet the Stage 1 regulatory requirements. The agencies are to be commended for initiating infrastructure improvements for Stage 2 intended to address several Stage 1 data capture and reporting challenges. However, at this time, the infrastructure improvements have been created but not fully tested. Moreover, the publication and re-publication of Stage 2 e-specifications for electronic CQMs in less than two months points to a timeline that is still too accelerated to produce thoroughly vetted requirements. In the absence of evidence that Stage 1 challenges to CQM reporting have been successfully addressed, it is premature to comment on additional clinical quality measurement requirements or a new clinical quality measurement framework for Stage 3.

We specifically recommend a thorough, independent evaluation of the Stage 1 CQM experience to illuminate the challenges addressed and the challenges remaining to successful electronic data collection and reporting of CQMs. We also recommend continued outreach and enhanced collaboration opportunities for measure developers, vendors and providers early in the e-CQM process, particularly in the development of e-specifications. Likewise, continued outreach and collaboration is needed between providers, vendors and agencies receiving the data to ensure that data receipt and analysis of data from EHRs is occurring.

Aligning Clinical Quality Measure Requirements. **The AHA recommends policymakers focus on aligning meaningful use clinical quality reporting requirements with the requirements in other quality reporting and payment programs.** On Jan. 3, 2013, CMS released a request for information on the ability of EHRs to support quality reporting in CMS programs. In addition, the Agency for Healthcare Research and Quality (AHRQ) has recently requested input on e-CQMs and is sponsoring research on the impact of health IT on improving the quality, effectiveness and efficiency of health care. The findings from these projects should inform the ongoing effort to refine requirements for the use of certified EHRs in the meaningful use program. Therefore, we urge policymakers to defer consideration of a new framework for the inclusion of automated CQMs in the meaningful use program. The goal should be the optimization of the investment in EHRs to support hospital success in accurate, reliable, feasible and meaningful data capture and reporting for all quality and payment programs and to avoid wasteful investments of financial and human capital on the generation of unusable data.

We recommend the inclusion of only the National Quality Forum (NQF) -endorsed measures in meaningful use to underscore the alignment of meaningful use and other quality reporting and payment programs. The ACA authorized HHS to contract with the NQF to convene the multi-stakeholder Measure Applications Partnership (MAP) to review and recommend quality measures for inclusion in federal health care programs. The MAP is reviewing more than 500 quality measures and will share recommendations in a report to HHS in February. Meaningful use requirements for clinical quality reporting should defer to the MAP process to promote a harmonization of the reporting across hospital quality reporting and payment programs, such as Inpatient Quality Reporting (IQR), Outpatient Quality Reporting (OQR), and the hospital value-based purchasing (HVBP). Of the 29 clinical quality measures available for hospitals in meaningful use, 24 are in use in the IQR, OQR or HVBP with chart-abstracted specifications. These measures must be reported separately for meaningful use versus the other programs, creating duplication. In total, hospitals must report more than 90 quality measures. Given the explosion of quality measure reporting requirements, coordination is vitally needed.

It is clear that considerable work needs to be done by measure owners and developers to make electronic CQM reporting ubiquitous. Completing electronic specifications for measures, pilot testing, reliability and validity testing, and subsequent inclusion of such e-specifications into EHR technology is a lengthy process but one in which shortcuts are not viable.

We appreciate the opportunity to provide input on the deliberations of the HITPC. If you have any questions or need further information, please do not hesitate to contact me, Chantal Worzala, director of policy (cworzala@aha.org), or Diane Jones, senior associate director of policy (djones@aha.org).

Sincerely,

/s/

Linda E. Fishman
Senior Vice President, Public Policy Analysis and Development

cc: Dr. Paul Tang, Vice Chair, HITPC

Attachments:

A. Detailed Comments on Specific Objectives and Measures.
B. Responses to Clinical Quality Measures Questions.
C. Responses to Broader Meaningful Use Questions.
D. Responses to Privacy and Security Questions.

Attachment A: Detailed Comments on Specific Objectives and Measures

Ref.	Stage 3 Preliminary Recommendation from the Health Information Technology Policy Committee (HITPC)	AHA Comments
	Improving Quality, Safety, and Reducing Health Disparities	
SGR P101	Objective: Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders. CPOE for medications includes drug-drug interaction (DDI) checking for "never" combinations as determined by an externally vetted list. Measure: More than 60% of medication, lab, and radiology orders entered through CPOE.	Evaluate experience in Stage 1 and Stage 2 before increasing the thresholds from 30% (lab and radiology orders). To simplify measurement and reporting, remove the inclusion of DDI checking as part of the objective, but include it as a certification requirement. Experience in Stage 1 suggests that complicated measures are difficult to generate and to verify during an audit, leading to excessive administrative costs (see related comment in Attachment C under automated measures).
SGR P130	Objective: Use CPOE for referrals/transition of care orders. Measure: More than 20% of referrals/transition of care orders are recorded using CPOE.	This is a new objective that should begin as a menu item. At the end of a hospital stay, physicians generally enter an order for discharge or referral to another setting of care (such as home health, skilled nursing or rehabilitation). Case managers then work with patients to ensure placement. Policymakers should convene a panel of clinicians and discharge planners to give guidance on the specification of a measure that reflects actual experience, is helpful to the care process and is feasible to collect.
SGR P103	EH Objective: Generate and transmit permissible discharge prescriptions electronically (eRx). EH Measure: More than 30% of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are compared to at least one drug formulary and transmitted electronically using Certified EHR Technology (CEHRT)	This objective is moving from menu to core and should keep the same threshold as Stage 2 (10%). To simplify measurement and reporting, remove the inclusion of drug formulary checking, but include it as a certification requirement. Experience in Stage 1 suggests that complicated measures are difficult to generate and to verify during an audit, leading to excessive administrative costs (see related comment in Attachment C under automated measures).
SGR P104	Retire prior demographics objective because it is topped out (achieved 80% threshold). Add new fields to certification criteria: occupation and industry codes; sexual orientation; gender identity (optional fields); disability status; ability to differentiate between patient reported & medically determined information.	It is appropriate to remove topped-out objectives and to add the new demographic fields only to certification requirements. New fields should be adopted only when open-source consensus standards have been developed and shown to be mature through use in practice.

Ref.	Stage 3 Preliminary Recommendation from the Health Information Technology Policy Committee (HITPC)	AHA Comments
SGR P105	Certification criteria: EHR systems should provide functionality to help maintain up-to-date, accurate problem list Certification criteria: Use of lab test results, medications, and vital signs (BP, ht, wt, BMI), to support clinicians' maintenance of up-to-date accurate problem lists. Systems provide decision support about additions, edits, and deletions for clinicians' review and action. It would not automatically add anything to the problem list without professional action.	While promising, this type of "problem list decision support" must be tested and evaluated before it is made a regulatory requirement. Testing parameters should include occurrence of Type I versus Type II errors, usability, applicability in various settings, etc. The concept of an "up-to-date" problem list is problematic in the inpatient setting and should be reconsidered. Patients in acute care settings may have complex illnesses that are accompanied by time-limited problems. In addition, clinicians may need to rule out suspected problems during a stay.
SGR P106	Certification criteria: EHR systems should provide functionality to help maintain up-to-date, accurate medication list Certification criteria: Use of problems and lab test results to support clinicians' maintenance of up-to-date accurate medication lists. Systems provide decision support about additions, edits, and deletions for clinicians' review.	While promising, this type of "medication list decision support" must be tested and evaluated before it is made a regulatory requirement to avoid unintended consequences. Testing parameters should include occurrence of Type I versus Type II errors, usability, applicability in various settings, etc.
SGR P107	Certification criteria: EHR systems should provide functionality to code medication allergies including its related drug family to code related reactions.	This functionality would be helpful if mature standards exist to support it.
SGR P108	Retire vital signs objective because it is topped out (achieved 80% threshold). Track progress to improve outcomes via CQM NQF 0018	It is appropriate to remove a topped out measure, but it should not be replaced with a mandatory quality measure. Further, quality reporting for hospitals should be harmonized across all payment programs and the choice of measures should be made through the Measure Applications Partnership process, not meaningful use.
SGR P109	Retire smoking status objective because it is topped out (achieved 80% threshold). Track progress to improve outcomes via CQM NQF 0028	It is appropriate to remove a topped out measure, but it should not be replaced with a mandatory quality measure. Furthermore, quality reporting for hospitals should be harmonized across all payment programs and the choice of measures should be made through the Measure Applications Partnership process, not meaningful use.

Ref.	Stage 3 Preliminary Recommendation from the Health Information Technology Policy Committee (HITPC)	AHA Comments
SGR P112	EP MENU/EH Core Objective: Record whether a patient 65 years old or older has an advance directive (same measure)	It is appropriate to move this item to the core set.
SGR P 113	Objective: Use clinical decision support (CDS) to improve performance on high priority health conditions Measure: 1. Implement 15 CDS interventions or guidance related to five or more clinical quality measure (CQMs)s that are presented at a relevant point in patient care for the entire EHR reporting period. The 15 CDS interventions should include one or more interventions in each of the following areas, as applicable to the EP's specialty: • Preventative care (including immunizations) • Chronic disease management • Appropriateness of lab and radiology orders • Advanced medication-related decision support (e.g., renal drug dosing) 2. The EP, eligible hospital, or CAH has enabled the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	Evaluate experience in Stage 1 and Stage 2 before increasing number of CDS interventions from 5 to 15. Remove tie to CQMs in favor of high-priority safety and quality improvement objectives of the hospital. This will better allow hospitals to use EHRs to meet their quality improvement goals and remove the measurement burden of tracking the links between CDS and CQMs. It also will give hospitals the flexibility to start and stop their use of specific CDS tools in accordance with their unique quality improvement activities, rather than to be in compliance with regulatory requirements. To simplify measurement and reporting, remove tie to "entire EHR reporting period." Experience in Stage 1 suggests that complicated measures are difficult to generate and to verify during an audit, leading to excessive administrative costs (see related comment in Attachment C under automated measures). Remove second measure on drug-drug and drug-allergy interaction checks as a topped-out functionality that was required in both Stage 1 and Stage 2, while keeping the functionality in certification. If it is maintained, remove tie to "entire EHR reporting period" to simplify measurement and reporting.
SGR P114	Objective: Incorporate clinical lab-test results into EHR as structured data. Measure: Increase threshold to 80%.	Evaluate experience in Stage 2 before increasing threshold from 55%.
SGR P115	EP/EH Objective: Generate lists of patients for multiple specific conditions and present near real-time (vs. retrospective reporting) patient-oriented dashboards to use for quality improvement, reduction of disparities, research, or outreach reports. Dashboards are incorporated into the EHR's clinical workflow for the care coordinator or the provider. It is actionable and not a retrospective report.	Remove patient lists as a topped-out functionality that was required in both Stage 1 and Stage 2, but keep the functionality as part of certification. Clinical and quality improvement objectives of the hospital will determine the types of reports that are used. Reports may be generated in systems other than the EHR, such as analytic engines.

Ref.	Stage 3 Preliminary Recommendation from the Health Information Technology Policy Committee (HITPC)	AHA Comments
SGR P117	EH Objective: Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR) Measure: Increase threshold to 30% of medication orders. Add requirement that mismatches (situations in which a provider dispenses a medication and/or dosing that is not intended) are tracked for use in quality improvement.	Evaluate experience in Stage 2 before increasing threshold from 10 percent.
SGR P118	Objective: Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through CEHRT. Measure: More than 10 percent of all tests whose result is an image (including ECGs) are accessible through Certified EHR Technology	Evaluate experience in Stage 2 before moving this objective to the core. If the objective moves from menu to core, it should keep the same threshold as Stage 2 (10%).
SGR P119	Objective: Record high priority family history data Measure: Record high priority family history in 40% of patients seen during reporting period	Evaluate experience in Stage 2 before moving this objective to the core. If the objective moves from menu to core, it should keep the same threshold as Stage 2 (20%).
SGR P120	Record electronic notes in patient records for more than 30% of office visits within four calendar days.	Evaluate experience in Stage 2 before moving this objective to the core. If the objective moves from menu to core, it is appropriate to keep the same threshold as Stage 2 (30%).
SGR P121	EH CORE Objective: Provide structured electronic lab results to eligible professionals. EH CORE Measure: Increase threshold to 80%.	Evaluate experience in Stage 2 before moving this objective to the core. If the objective moves from menu to core, it should keep the same threshold as Stage 2 (20%).
SGR P122	Objective: The EHR is able to assist with follow-up on test results Measure: 10% of test results, including those which were not completed are acknowledged within 3 days	It is unclear if this objective applies to EHs/CAHs.

Ref.	Stage 3 Preliminary Recommendation from the Health Information Technology Policy Committee (HITPC)	AHA Comments
	Engage Patients and Families in their Care	
SGR P204 A	Objective: Provide patients the ability to view online, download, and transmit (VDT) information about a hospital admission. Measure: The HITPC is considering an increase in the Stage 2 thresholds, which are: • More than 50 percent of all patients who are discharge have their information available within 36 hours of discharge • At least 5 percent of patients access the portal. Additional MENU item: Automated Transmit: (builds on Automated Blue Button Initiative (ABBI)): Provide 50% of patients the ability to designate to whom and when (i.e. pre-set automated & on-demand) a summary of care document is sent to patient-designated recipient.	CMS must fully evaluate experience in Stage 2 across all settings before expanding the requirements. Regarding "automated transmit," the Stage 2 requirements already include a requirement for transmit that should be sufficient to meet patient and provider needs. Evaluation of Stage 2 experience should consider whether there is a real need for and value to additional transmit functionality that would outweigh the operational and financial impacts of requiring new functionality. The results of the ABBI pilot should include an assessment of how generalizable the experience has been across all settings, from small and/or rural hospitals to specialty physicians of all types. Consideration of requiring new functionality must involve a detailed understanding of the process issues and steps involved to make an automated transmit function operational and secure. This includes a precise understanding of the security risks involved in an automatic transmit and who should bear responsibility when incorrect and/or outdated contact information for the automated transmit is supplied by a patient.
SGR P204 B	MENU: Provide 10% of patients with the ability to submit patient-generated health information to improve performance on high priority health conditions, and/or to improve patient engagement in care (e.g. patient experience, pre-visit information, patient created health goals, shared decision making, advance directives, etc.). This could be accomplished through semi-structured questionnaires, and EPs and EHs would choose information that is most relevant for their patients and/or related to high priority health conditions they elect to focus on.	While this is a promising concept, it has not yet been implemented widely or proven feasible, beneficial and cost-effective. The HITPC should recommend that HHS fund pilot projects of this functionality that include rigorous evaluation components before any regulatory requirement is considered, even as a menu item.
SGR P204 D	Objective: Provide patients with the ability to request an amendment to their record online (e.g., offer corrections, additions, or updates to the record) through VDT in an obvious manner.	The HIPAA rules appropriately provide for the right of patients to request amendment to their medical records, but the rules do not specify or otherwise limit the means by which covered entities are required to meet their obligations to provide for that right. The meaningful use requirements should not be used to establish a precise means or limit the flexibility providers have to provide patients with the ability to make requests for

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		amendment. While the functionality for making requests for amendment online may be valuable to some patients and providers, an online process should not be a mandatory requirement imposed upon every provider and patient as a meaningful use objective.
SGR P206	Objective: Use EHR to identify patient-specific education resources and provide them to patients. New: Additional language support: For the top 5 non-English languages spoken nationally, provide 80% of patient-specific education materials in at least one of those languages based on EP's or EH's local population, where publically available.	Hospitals already have an obligation to provide language services under the Civil Rights Act that is fulfilled in many different ways, including use of live translators and other approaches. The HITPC should recommend that HHS pilot test the usefulness of translated written materials available through EHRs in addressing language barriers before making this a regulatory requirement. Additional investigation also is needed to understand whether the top 5 non-English languages spoken nationally would actually address the needs of each health care provider's population.
SGR P208	Objective: Communication preferences. EP and EH Measure: Record communication preferences for 20% of patients, based on how (e.g., the medium) patients would like to receive information for certain purposes (such as reminders, referrals, after visit summaries and test results).	This measure builds on a reminder objective that is only for EPs in Stage 2. If the objective is being extended to hospitals, this is new, and should be placed in menu set.
Improve Care Coordination		
SGR P302	EP / EH / CAH Objective: The EP, eligible hospital or CAH who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform reconciliation for: - medications - medication allergies, and problems EP / EH / CAH Measure: The EP, EH, or CAH performs reconciliation for medications for more than 50% of transitions of care, and it performs reconciliation for medication allergies, and problems for more than 10% of transitions of care in which the patient is transitioned into the care of the EP or admitted to the eligible hospital's or CAH's inpatient or emergency department).	It is unclear what the HITPC means by the term "problem reconciliation" using an EHR, which implies that changes will be made to a problem list based on clinical knowledge embedded in the EHR. The HITPC should direct HHS to fund a pilot project to test the concept and identify the critical process steps needed to build useful, usable electronic tools for this purpose. A key question would be the source of clinical knowledge embedded in the tool to determine which problems should be maintained, added, or removed. The pilot also should consider how this tool would be used in different settings. For example, is electronic problem reconciliation appropriate for a critically-ill individual in intensive care, where problem identification is a key clinical goal? What about trauma victims who may have time-limited problems that are subsequently resolved? At what point is it useful to remove past problems? Based on what electronically available guidance?

Ref.	Stage 3 Preliminary Recommendation from the Health Information Technology Policy Committee (HITPC)	AHA Comments
SGR P303	EP/ EH / CAH Objective: Expand the Stage 2 transition of care summary requirements to include all transitions and referrals with available information. The summary must include the following four items for transitions of site of care, but only the first for referrals (with the others as clinically relevant): 1. Concise narrative in support of care transitions (free text that captures current care synopsis and expectations for transitions and / or referral) 2. Setting-specific goals 3. Instructions for care during transition and for 48 hours afterwards 4. Care team members, including primary care provider and caregiver name, role and contact info (using DECAF - Direct care provision, Emotional support, Care coordination, Advocacy, and Financial) Measure: The EP, eligible hospital, or CAH that site transitions or refers their patient to another setting of care (including home) or provider of care provides a summary of care record for 65% of transitions of care and referrals (and at least 30% electronically).	Improved care coordination is a priority for a transformed health care system, and EHRs will play an important role in facilitating that transformation. It is unclear, however, whether this highly specified regulatory requirement is the best approach to achieve that goal. Experience in Stage 2 should be evaluated before expanding the transition of care summary requirements. Before expanding these requirements, the HITPC and HHS should ensure there is sufficient infrastructure to exchange this information. For EHs, this requirement is duplicative of other commonly used care summaries, including the discharge instructions and the discharge summary. The HITPC and HHS should consult with a panel of clinicians and discharge planners to understand the information needed to facilitate transitions of care, which may vary by patient. For EHs, it is unclear who would receive the summary when a patient is discharged to home, and how the requirement would or would not overlap with the patient portal requirements, which include discharge instructions. The HITPC should direct HHS to conduct extensive field testing of the proposed measure to determine cost and impact on work flow, as it is highly complex to generate and could lead to extensive, redundant data entry screens to operationalize.
SGR P304	Proposed Stage 4 Recommendation on transitions of care	It is premature to consider Stage 4 items.
SGR P127	Proposed Stage 4 Recommendation on interdisciplinary problem list	It is premature to consider Stage 4 items.
SGR P125	Proposed Stage 4 Recommendation on medication reconciliation with prescription benefit managers.	It is premature to consider Stage 4 items.

Ref.	Stage 3 Preliminary Recommendation from the Health Information Technology Policy Committee (HITPC)	AHA Comments
SGRP 308	EH Objective: The EH/CAH will send electronic notification of a significant healthcare event in a timely manner to key members of the patient's care team, such as the primary care provider, referring provider or care coordinator, with the patient's consent if required. EH Measure: For 10% of patients with a significant healthcare event (arrival at an Emergency Department (ED), admission to a hospital, discharge from an ED or hospital, or death), EH/CAH will send an electronic notification to at least one key member of the patient's care team, such as the primary care provider, referring provider or care coordinator, with the patient's consent if required, within 2 hours of when the event occurs.	Improved care coordination is a priority for a transformed health care system and EHRs will play an important role in facilitating that transformation. It is unclear, however, whether this highly specified regulatory requirement is the best approach to achieve that goal. Before adding electronic notification requirements, the HITPC and HHS should ensure there is sufficient infrastructure to support exchange, such as affordable exchange networks and accessible provider directories. Any new objective of this type should start in the menu set. It is important to note that the EHR may not be the system used to provide these kinds of alerts. For example, some hospitals use their physician portal technology to alert both their employed and affiliated physicians about patient status and events.
Improve Population and Public Health		
SGRP401A	EP/ EH Objective: Capability to receive a patient's immunization history supplied by an immunization registry or immunization information system, and to enable healthcare professionals to use structured historical immunization events in the clinical workflow, except where prohibited, and in accordance with applicable law and practice. Measure: Documentation of timely and successful electronic receipt by the CEHRT of vaccine history (including null results) from an immunization registry or immunization information system for 30% of patients who received immunizations.	This new objective is premature. It is unclear how often external data is needed for immunization history, particularly in the hospital setting. No evidence is presented to suggest that 30% of immunized patients is the right number. The HITPC should recommend that HHS fund a study to determine the extent of need for external immunization history data and the readiness of public health departments and immunization registries to supply it. No requirement should be made of providers until predominantly all registries can do so.

Ref.	Stage 3 Preliminary Recommendation from the Health Information Technology Policy Committee (HITPC)	AHA Comments
SGR P401 B	EP/EH Objective: Capability to receive, generate or access appropriate age-, gender- and immunization history-based recommendations (including immunization events from immunization registries or immunization information systems). Measure: Implement an immunization recommendation system that: 1) establishes baseline recommendations (e.g., Advisory Committee on Immunization Practices), and 2) allows for local/state variations. For 20% of patients receiving an immunization, the EP/EH practice receives the recommendation before giving an immunization.	This new objective is premature. It is unclear how often external recommendations are needed for immunizations, particularly in the hospital setting. No evidence is provided to suggest that 20% of immunized patients is the right number. The HITPC should recommend that HHS fund a study to determine readiness of public health departments and immunization registries to supply this information. No requirement should be made of providers until predominantly all registries can do so.
SGR P402 A	EH Objective (unchanged): No change from current requirement for electronic lab reporting to public health departments, which generally is sent from the laboratory information system.	Reporting of lab results will be topped out in Stage 2 (ongoing reporting is required), and therefore the objective should be removed, while keeping the functionality in certification.
SGR P402 B	Proposed Stage 4 Recommendation on electronic submission of case reports to public health.	It is premature to consider Stage 4 items. The HITPC should recommend that HHS fund a study to determine readiness of public health departments to receive electronic case reports. No requirement should be made of providers until predominantly all public health departments can do so.
SGR P403	No change from current requirements to submit electronic syndromic surveillance data to public health agencies.	Reporting of syndromic surveillance will be topped out in Stage 2 (ongoing reporting is required) and the objective should be removed, while the functionality remains in certification.

Ref.	Stage 3 Preliminary Recommendation from the Health Information Technology Policy Committee (HITPC)	AHA Comments
SGR P404	EH/EP Objective: Capability to electronically participate and send standardized (i.e. data elements and transport mechanisms), commonly formatted reports to a mandated jurisdictional registry (e.g., cancer, children with special needs, and/or early hearing detection and intervention) from Certified EHR to either local/state health departments, except where prohibited, and in accordance with applicable law and practice. This objective is in addition to prior requirements for submission to an immunization registry. Measure: Documentation of ongoing successful electronic transmission of standardized reports from the CEHRT to the jurisdictional registry. Attestation of submission for at least 10% of all patients who meet registry inclusion criteria during the entire EHR reporting period.	This objective is premature. Considerable development is needed to specify report formats and specific registry reporting requirements. The HITPC should recommend that HHS fund a study to determine readiness of registries to receive these reports. No requirement should be made of providers until predominantly all public health departments can do so. Before adding additional information exchange requirements, the HITPC and HHS should ensure there is sufficient infrastructure to support exchange. Regarding the Stage 2 measure of reporting to immunization registries, it will be topped out in Stage 2 (ongoing reporting is required), and therefore the objective should be removed in future stage, while the functionality remains in certification.
SGR P407	EH Objective: Capability to electronically send standardized Healthcare Associated Infection (HAI) reports to the National Healthcare Safety Network (NHSN) using a common format from the Certified EHR, except where prohibited, and in accordance with applicable law and practice. Measure: Documentation of successful electronic transmission of standardized healthcare acquired infection reports to the NHSN from the Certified EHR Technology. Total numeric count of HAI in the hospital and attestation of Certified EHR electronic submission of at least 10% of all reports during the entire EHR reporting period as authorized, and in accordance with applicable State law and practice.	This objective is premature. Our understanding is that the pilot of electronic transmission to NHSN is currently only conceptualized, and has not yet been competed or produced results. The pilot must be finished and the results evaluated for accuracy and usefulness of the data exchanged, operational requirements, costs, and generalizability before this is required. The pilot should rigorously test the feasibility of generating these reports and the ability of NHSN to accept them at the volume that would be expected from a national mandate for all hospitals. No requirement should be made of hospitals until NHSN has that capacity operational.
SGR P408	Proposed Stage 4 Recommendation on sending adverse event reports to the FDA and CDC	It is premature to consider Stage 4 items.

Ref.	Stage 3 Preliminary Recommendation from the Health Information Technology Policy Committee (HITPC)	AHA Comments
Information Exchange		
IEW G101	MENU objective: For patients transitioned without a care summary, an individual in the practice should query an outside entity. The intent of this objective is to recognize providers who are proactively querying.	Before adding additional information exchange requirements, the HITPC and HHS should ensure there is sufficient infrastructure to support exchange, including widespread availability of provider directories and affordable mechanisms for query. In addition, ONC should publish the results of its query pilot projects and the HITPC should consider the success and generalizability of the pilots before recommending that use of query be required, even as a menu item.

Attachment B: Responses to Clinical Quality Measures (CQM) Questions

Ref.	General Questions from HITPC	AHA Comments
QMW G 01	As we propose to expand the features of the eCQM measure set, how can it be done in ways to minimize health care costs and reduces burden on health care providers?	Given the Stage 1 experience and the ongoing work to build systems to support success with 2014 eCQM requirements, it is premature to propose an expansion of the eCQM measure set. Automated quality measurement must be feasible, generate valid and reliable results and have benefits that outweigh the costs. Early experience from the hospital field does not indicate that current eCQMs meet these criteria.
QMW G 02	Furthermore, when considering the finite resources available to technology developers, what measures, types of measures or attributes of measures should be a high priority?	Meaningful use should defer to the National Quality Strategy and the Measure Applications Partnership (MAP) that drives measures identification for federal health care programs.
QMW G 03	Are there innovations or technological capabilities for measure development or specification that the HITPC could support that would reduce the burden on technology developers?	Welcomed innovations include facilitating collaboration among measure developers, vendors and providers early in the e-measure process; field testing of e-measures and use the results as a metric for inclusion of the respective measure as eCQM; disallowing certification of EHRs without evidence of successful testing of the accuracy of the embedded measure calculations and confirmation that the necessary data is available in the EHR. The HITPC query does not appear to consider the burden on the end-users of the measures, which is at least commensurate with that of the technology developer.
QMW G 04	Meaningful Use program has used menu objectives and menu CQMs to provide flexibility for providers. Should there be core CQMs for high priority health conditions, such as controlling hypertension?	The prioritization of measures for reporting should be done through the existing regulatory process used by the HHS Secretary to select measures for inclusion in inpatient and outpatient quality reporting programs, the Readmissions Reduction Program and the Hospital-Acquired Conditions Program. These processes importantly include the ACA-mandated opportunity for input from the multi-stakeholder MAP, the group created by Congress to advise the Secretary and the very decisions you are asking about. Once measures have been identified as important enough for inclusion in these public reporting and pay-for-performance programs, the next question should be "which of these measures can be best collected through an EHR" or, more broadly, "which data elements used in the

Ref.	General Questions from HITPC	AHA Comments
		calculation of these selected measures can best be captured through an EHR?" The answers to these questions should drive the decisions on which measures or data elements EHR vendors should be required to certify their products can produce accurately before hospitals are required to report that data out of their EHR to HHS.
Patient Centeredness - Broader Stakeholder Input		
QMW G 05	How can the HITPC and QMWG capture input from a wide variety of providers, patients, organizations and societies?	The HITPC should focus its recommendations on efforts that build an infrastructure for health information exchange supporting automated reporting of quality measures that hospitals and clinicians are currently required to report. Additionally, support the ability of the exchange infrastructure and EHRs to advance provider quality improvement activities within their sites. Such a focus will reduce reporting burden and provide real-time information to hospitals and clinicians and will result in greater input to the HITPC from a variety of interested parties.
QMW G 06	What additional channels for input should we consider?	Ongoing, coordinated and transparent discussions among providers, measure developers, informaticians, vendors and the consumers of quality reports, particularly those working on concurrent quality initiatives, will increase the prospect that quality measurement enabled by health IT will support care delivery transformation. The HITPC should recommend that HHS provide funding for the technical development of the quality measures given their importance across federal health care programs.
CQM Pipeline: Process and Outcome Measures		
QMW G 09	Please provide comment on how the HITPC should proceed with our focus on clinical outcomes. Should the HITPC focus its efforts on building point-of-care process measures or value-centered outcome measures?	The HITPC should not focus on building measures. The HITPC should gather evidence used to support recommendations on policies that enable health information exchange and EHRs to support accurate data capture of data elements and accurate reporting of eCQMs that support the direction of the National Quality Strategy and the MAP.

Ref.	General Questions from HITPC	AHA Comments
QMW G 10	Is this a false or unnecessary dichotomy? Should we instead consider a third approach, to promote process-outcome measure "suites", combinations of end outcome measures that are potentially associated with process measures? For example, Stage 2 eCQM set will include three HIV measures. The outcome of viral load suppression is accompanied by two related process measures for an HIV medical visit and for Pneumocystis Pneumonia prophylaxis.	The FACA should support CMS by offering recommendations on policies to enable the infrastructure that supports electronic capture and reporting of data included in measures quality reporting and value-based purchasing initiatives.
CQM Pipeline: Measure Development Lifecycle		
QMW G 11	Please comment on challenges and ambiguities in retooling legacy paper abstracted and claims based eCQMs.	Data for inpatient measures come from physician documentation that currently is contained in written or dictated notes. The measures include concepts not easily captured in structured format and therefore all of the necessary data is not gathered electronically during the course of care. A key component of success in widespread use of EHRs for quality measurement is a step in the development process that maps the data elements required for the measure to the data available in certified EHRs. Sufficient time for this mapping is necessary to build successful eCQMs.
QMW G 12	Is this a shift away from retooling legacy paper-based CQMs in exchange for designing CQMs de novo a reasonable course of action?	A shift from retooled paper CQMs to designing CQMs de novo will not address the current challenge that retooled eCQMs and abstracted CQMs may not measure the same thing. If a given measure is used in accordance with its specification yet yields different results if chart abstracted or automated, it is not measuring the same thing. The National Quality Strategy and the MAP determine the reporting requirement.
QMW G 13	Please comment on the provider/payer/patient experience with using retooled measures as opposed to experience with de novo measures designed and intended for EHR-based measurement	AHA members report that measures and decision support tools that build on structured data such as medications and specific laboratory values could represent opportunities for short-term action. For example, some hospitals are using their EHRs to monitor the laboratory markers for patients who are taking blood-thinners like Coumadin to ensure that they are within therapeutic ranges.

Ref.	General Questions from HITPC	AHA Comments
CQM Pipeline: MU Alignment with Functional Objectives		
QMW G 14	Please comment on aligning CQMs with MU Objectives. Would eCQM-MU Objective alignment be clinically valuable to providers or might this be a redundant exercise in shifting resources?	Rigorous field-testing to ensure feasibility of collection is likely to increase interest in using EHR-enabled quality measures. If the data are burdensome to collect, do not appear to be valid, or will not support timely quality improvement, clinicians will be less inclined to use them.
CQM Pipeline: Domains and Exemplars		
QMW G 16	Which, if any, high priority domains should receive prioritized attention in Stage 3? What measure concepts, addressing these domains, should be considered for development? What EHR capabilities should be leveraged to realize these concepts?	The FACA should support the prioritization of health conditions identified by public and private payers and offer recommendations on policies to enable the infrastructure that supports electronic capture and reporting of data included in measures quality reporting and value-based purchasing initiatives.
CQM Pipeline: MU and Innovation		
QMW G 18	Please comment on the desirability and feasibility of such an innovation track as a voluntary, optional component of the MU CQM requirement.	The AHA supports the inclusion of NQF-endorsed measures, recommended by the MAP, in federal health care programs. AHA also supports the feasibility testing of the e-specifications of the endorsed measures prior to embedding them in EHRs that are submitted for certification. NQF has a critical role to play in providing reassurance that an endorsed measure will provide valid and reliable results once implemented and in use. A new process to accelerate availability of new eCQMs separate from this statutorily created measure recommendation process for federal health programs creates new challenges and will not eradicate the current operational challenges to valid and feasible CQM reporting. Providers, measure developers, vendors, informaticians will be challenged to leverage innovative measures if the EHRs do not support verifiable and accurate embedded measure calculations. Moreover, approaches other than federal regulation should be deployed to foster innovation in the development of new quality measures. Regulations impose requirements on all

Ref.	General Questions from HITPC	AHA Comments
		participants subject to the jurisdiction of the regulation, and potential sanctions for failures to meet the regulatory requirements. Experimentation is not appropriate within this construct.
QMW G 20	What information should be submitted with a locally developed CQM to help CMS and other healthcare providers assess the innovative measure? For example, should the submission form include a brief description of: 1) importance/rationale of the measure domain; 2) evidence basis for the specific measure; 3) feasibility, and 4) usefulness of the measure?	The AHA believes the following framework will support assessment of eCQMs: measure developers and the NQF initially should consider whether a measure can be automated or requires a level of clinical judgment that makes automation difficult. The endorsement process should include independent testing to determine whether e-specifications are valid and reliable. It should also include field testing to ensure that the needed data are in the EHR and vendor products can capture it. The certification process should validate that vendor products can, in fact, accurately calculate the measures based on test data sets. CMS, NQF and measure developers should work together to establish a structured feedback and update process.
QMW G 23	For the existing and/or in the proposed expanded institution-initiated CQMs, how can federal agencies better support consistent implementation of measures for vendors and local practices (e.g., test case patients, template workflow diagrams, defined intent of measure and value set)?	To support success with current eCQM, funding for "learning laboratories" in the field that build provider experience using a variety of EHR vendor platforms would be beneficial. For example, AHRQ is examining the infrastructure needed to ensure development of quality measures of interest that are challenging to generate. The AHA would be pleased to assist AHRQ in the development of this vehicle for gathering and disseminating best practices.
QMW G 24	Stage 3 may increase the number of measures EPs and EHs calculate and report. Considering provider burden, is there a limit to the number of measures that a provider should be expected to calculate? Is there evidence to support a limit?	The transition to greater standardization of health information must balance the burden and benefit of the changes in practice and investments in technology that are required to support standards. An increase in the number of measures for meaningful use must be considered within the context of concurrent federal value-based payment and quality reporting initiatives. Alignment of program requirements that result in multiple uses of data accurately collected once is recommended. The HITPC should not recommend any increase in measure burden until there is evidence that the current measure requirements and processes to support measure reporting work. Moreover, the HITPC should defer to the MAP that makes recommendations for quality measures for federal health care programs in accordance with the ACA.

Ref.	General Questions from HITPC	AHA Comments
Quality Improvement Support: Architecture and Standards		
QMW G 25	Please comment on the value and feasibility of the eCQM and EHR features listed below: - Ability to accept downloaded specifications for new measures with little tailoring or new coding - Minimal manual data collection or manipulation - Ability to aggregate measure data to varying business units (practice, episode, ACO, medical home, MA plan, etc.) - Ability to build measures that incorporate cross-setting records for episodes, medical homes, outcomes (e.g., readmissions) - Ability to build multi-source data records, including claims, patient reported data - Ability to implement machine-readable HQMF that minimizes manual vendor coding	In the area of measurement across care settings, field experience will need to build in order to identify the available data types, the best practices in data collection across settings. Hospitals and health systems currently forming accountable care organizations (ACOs) are developing tools to integrate data across ACO participants. Examining the practices of these market leaders can inform perceptions on the value of EHR features and health information exchange capabilities that support standardized data capture from multiple contributors across several settings of care.

Attachment C: Responses to Broader Meaningful Use Questions

This attachment provides specific responses to some of the general questions asked about meaningful use (MU01 through MU07).

Flexibility (MU01). The RFC asks about the need for additional flexibility in the meaningful use construct. Currently, providers must meet all requirements or they will fail. Today, failure results in a missed incentive. Starting on July 1, 2014, for hospitals, failure will result in large financial penalties. Limited flexibility is currently provided through the menu set items. The AHA believes that there is tremendous need for additional flexibility in the program. We would recommend that the menu set items be continued, and that providers be considered in compliance if they meet 75 percent of the objectives. This flexibility should not be construed as an opportunity to increase the list of objectives and measures, which should be small in number, and focused on those things that have been proven to be essential and cost-effective. Rather, flexibility would recognize that not all providers find all of the objectives applicable to their environment, and would avoid unfair situations where providers miss the mark by a small amount but face large penalties.

Safety (MU02). The RFC seeks input on how to improve safety of EHRs, and asks whether there should there be a MU requirement for providers to conduct a health IT safety risk assessment. America's hospitals take their safety obligations very seriously, and the AHA supports and promotes the adoption of a culture of safety that spans all aspects of care, including the use of technology of all sorts. One key component of safety is to be holistic, and address all aspects of care. A separate "safety risk assessment" for EHRs would be at odds with a holistic approach to ensuring patient safety and we believe it would be counter-productive. That said, we recognize the concerns raised by the Institute of Medicine, and concur with the conclusion that we need much more learning and sharing of best practices in the design, implementation, and use of EHRs to ensure the safest possible care. We also note that both the ONC and the Food and Drug Administration are producing plans and reports on the safety of EHRs. Those reports will draw on the full spectrum of approaches that can be used to ensure and improve safety, rather than the very narrow construct of meaningful use. We recommend that the HITPC evaluate those plans before making and recommendations in this area.

Patient Consent (MU04). The RFC seeks input on how EHRs can be leveraged to overcome variations in patient consent laws across states. Many studies and reports have identified variation in privacy laws across states as a key barrier to information exchange. The AHA urges the HITPC to recommend that HHS work toward a single set of federal privacy laws. Having the same laws in place across the country would facilitate information exchange and improve efficiency, while still protecting privacy.

Automated Measures (MU06). The RFC seeks input on whether EHRs should be required to give providers evidence that a capability was in use during the EHR reporting period for measures that are not percentage based. It should not be

necessary for providers to rely on automated systems to document yes/no measures. We note that ONC proposed this functionality for certification in Stage 2, but chose not to finalize it based on comments about the challenges associated with implementing this seemingly simple capability in a complex environment where many systems may be in place, such as multiple modules from different vendors. For example, an EHR audit trail could not easily identify "enabling" or "disabling" of something as complex as drug-formulary checks. Multiple drug formularies derived from different sources may be in use, and the applicability of alternative formularies to an individual patient will vary. In addition, of course, drug formularies are updated periodically. Thus, something that a responsible individual could easily ascertain – yes, we are checking against drug formularies – would be challenging to program a computer to determine, given the many variables at play. We would recommend a different approach, which eliminates the phrase "during the entire EHR reporting period" from the meaningful use measures. This is not because we believe the functionality should or would be used for a shorter period, but because it is burdensome to document. It also raises many technical questions that present compliance problems, such as how to count outages due to factors beyond the control of the provider. For example, should hospitals affected by Hurricane Sandy be considered out of compliance if they lost power for two weeks? While that example is dramatic, absolute requirements such as "during the entire period" raise real compliance burdens in practice. Hospitals are already facing meaningful use audits in which these questions are being raised.

Information Exchange Beyond EHRs (MU07). The RFC seeks input on what can be done to foster innovation to share information and receive intelligence from other, non-EHR applications and services that could be built on top of the EHR data architecture, and asks whether the standards used to communicate between EHR systems (e.g., Direct, Exchange) are adequate for communication between EHRs and other kinds of systems. We appreciate the innovative intent behind the question, but would urge the HITPC to limit the breadth of its efforts to EHRs until we have gotten to a point where we have reached widespread adoption and efficient, ubiquitous interoperability. We note that the HITPC's mandate provided in the ARRA is to "make recommendations to the National Coordinator relating to the implementation of a nationwide health information technology infrastructure." Now that the meaningful use program has been launched, the focus must be on ensuring we have the infrastructure in place to share data rather than expanding the types of data to share.

Attachment D: Responses to Privacy and Security Questions

Security Requirements (PSTT04). The RFC asks what, if any, security risk issues (or *Health Insurance Portability and Accountability Act* (HIPAA) Security Rule provisions) should be subject to meaningful use attestation in Stage 3. Examples include training on the security rule and sending of security reminders. The AHA continues to believe that the meaningful use rule should ***not*** be used as a means to enforce compliance with all HIPAA privacy and security requirements, including those for making staff and workforce members aware of the HIPAA Security Rule and to train them on Security Rule provisions. We therefore believe that meaningful use attestation about implementing the HIPAA rules is unnecessary. It is the Office of Civil Rights (OCR) that regulates and enforces HIPAA, and they do so admirably. A back-up system of enforcement via the meaningful use rules is inappropriate and may lead to a potentially different or conflicting set of compliance obligations enforced by multiple agencies through multiple and uncoordinated means. We urge the HITPC to reject requirements for EPs/EHs/CAHs to attest to implementing HIPAA Security Rule provisions regarding workforce/staff outreach and training and sending periodic security reminders.

Accounting for Disclosures (PSTT05 to PSTT08). The HITPC's preliminary recommendations related to meaningful use Stage 3 seem to conflate audit logs with the HIPAA regulatory requirement to produce an accounting for disclosures. Audit logs may capture and supply some important data that may be useful in producing an accounting of disclosures report for a specific patient as required by the HIPAA regulations. However, the mere electronic capture of data elements by the EHR does not equate directly to the generation of an accounting of disclosures report that can be read and understood by an individual patient as the HIPAA regulation requires. Captured and stored electronic data must be "translated" for human consumption, which requires dedicated staff resources – specifically, staff with specific knowledge and skill to decipher and process machine readable data – and considerable time to generate an individualized report that can be provided to a patient. Creation of a patient-friendly individualized accounting report therefore is likely to remain a heavy administrative burden for all hospitals.

Moreover, current systems are unable to automate the "purpose" of the disclosure, making it impossible for the system to easily distinguish between a "use" that does not need to be included in the accounting and a "disclosure," which does.

The OCR, which is charged specifically with development and enforcement of all HIPAA privacy and security law obligations including those related to accounting of disclosures, has not issued a final accounting for disclosure rule. In order for hospitals to successfully implement an accounting for disclosures, it will be critical that HIPAA and the meaningful use incentive programs work together and provide a consistent standard. Acting on certification criteria in advance of a final rule from OCR is premature. Any technical criteria relevant to audit log content and standardized formats issued by ONC must be aligned fully with the specifics of OCR's final accounting rule if

EHRs are to have appropriate functionality to facilitate compliance with the privacy rule's obligations.

The OCR, the agency that is specifically responsible for establishing and enforcing the HITECH mandate for accounting of disclosures, should first establish in regulation the proper scope of the accounting for disclosures standard. ONC could then use the resulting final rules to create criteria for EHR functionality to support and facilitate compliance with that OCR accounting standard. We note that ONC recently recognized the importance of this alignment in its final rule on the 2014 edition of certification, and encourage the HITPC to do the same.

> After consideration of the comments received, **we agree with those commenters that recommended we wait and consider how best to align this certification criterion with the provisions of an ''accounting of disclosures'' final rule issued by OCR.** We appreciate the suggested revisions offered by commenters, but believe that alignment with an ''accounting of disclosures'' final rule will provide the most certainty and useful functionality for EPs, EHs, and CAHs, while also mitigating any EHR technology development and implementation burdens that may accrue through compliance with potential multiple adopted versions of this certification criterion. **(54251 Federal Register,** Vol. 77, No. 171, Tuesday, September 4, 2012, p. 54251.) *[Emphasis added.]*

Further, we understand that currently there is significant variability in the level of detail captured in the audit trails within the various subparts of the system at the same hospital. Significant changes to current systems would be required to generate standardized audit logs across the multiple technical systems that comprise the EHR. The experiences of hospitals suggest that making significant changes to information systems of this type requires considerable time and effort to design, code and test and often involves months of installation and staff training in the hospital environment after the hospital gets in the vendor's queue for the product or system upgrade. We believe that consideration of whether, and when, to impose audit log content and standardization criteria and deadlines for compliance with them should take into account those significant burdens.