American Hospital Association

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February 25, 2011

Submitted Electronically

Office of the National Coordinator Health Information Technology
Department of Health and Human Services
Attention: Joshua Seidman
Mary Switzer Building
330 C Street, S.W., Suite 1200
Washington, D.C. 20201

Re: HIT Policy Committee: Meaningful Use Workgroup Request for Comments Regarding Meaningful Use Stage 2

Dear Mr. Seidman:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 45,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the preliminary recommendations for Stage 2 Meaningful Use under consideration by the Health Information Technology Policy Committee (HITPC). While the AHA strongly supports the accelerated adoption and use of electronic health records (EHRs) to improve patient care, we have significant concerns with some of the recommendations being considered by the HITPC and the 2013 proposed date for beginning of Stage 2. Successful completion of Stage 1 for the majority of providers and thorough analysis of its impact are necessary before the adoption of additional objectives and more stringent measures.

In the *American Recovery and Reinvestment Act of 2009* (ARRA), Congress authorized incentive payments under Medicare and Medicaid to "meaningful users" of certified EHRs beginning in fiscal year (FY) 2011. Beginning in FY 2015, the ARRA also phases in penalties for those who fail to meet federal requirements for "meaningful use." The Medicare EHR Incentive Program for hospitals began October 1, 2010. In the final rule governing the initial years of these programs (42 CFR parts 412, 413, 422 et al), the Centers for Medicare & Medicaid Services (CMS) indicated that it intended to implement the program in three, two-year stages:

- Stage 1 – FY 2011-2012;
- Stage 2 – FY 2013-2014; and
- Stage 3 – FY 2015 and beyond.

The Stage 1 requirements for eligible hospitals included 14 "core," or required objectives and 10 "menu set" objectives, of which hospitals must meet 5 (including at least 1 of 3 public health objectives).

If accepted by CMS, the HITPC's preliminary recommendations would form the basis of requirements for hospitals and eligible professionals in Stage 2 and determine how quickly, and aggressively, the bar will be raised. The HITPC's recommendations are very detailed, and generally fall into three categories: increasing the requirements for core objectives included in Stage 1, moving menu set items into the core set, and adding new objectives.

The AHA appreciates – and shares – the goals of the EHR incentive programs: motivating hospitals and physicians to move further and faster in using EHRs to improve all aspects of health care, while ensuring that needed funds authorized as part of the economic stimulus bill flow in a responsible and appropriate way to support continued and timely advances in health IT. Hospitals across the country are deploying EHRs as part of their overall strategies to improve patient care and meet community needs. The flow of meaningful use incentive payments to support those deployments is central to realizing the care transformation objectives of health reform.

This comment letter recommends guiding principles for decision-making on Stage 2 of meaningful use and provides a summary of the AHA's specific comments on the HITPC's preliminary recommendations, which are attached (Attachment A). As context for our comments, we also attach the results of a January 2011 AHA survey of hospitals' current ability to meet the meaningful use requirements (Attachment B). This comment letter does not address two important areas of meaningful use – use of EHRs to report clinical quality measures and privacy and security of protected health information – as these areas are not covered in the HITPC's preliminary recommendations. We welcome future opportunities to comment on these issues. We also note that the HITPC has not recommended inclusion of electronic claims submission and eligibility verification as part of Stage 2 of meaningful use. The AHA strongly supports keeping administrative transactions out of meaningful use as they are generally not part of EHRs and are already subject to regulation by CMS.

GUIDING PRINCIPLES

As the HITPC considers recommendations for Stage 2 of meaningful use, the AHA recommends the following guiding principles.

Learn from actual experience in Stage 1. The HITPC is making recommendations before information on actual Stage 1 incentive payments can be collected and processed. All recommendations made at this time should be revisited as data are collected. Financial, technical, and workforce challenges will affect how quickly and successfully hospitals can meet the meaningful use requirements.

To provide a snapshot of the hospital field's current capacity to meet the meaningful use requirements, the AHA conducted a survey of all community hospitals. Data were collected between January 6 and January 20, 2011 with 1,297 hospitals (about 25 percent) responding to the survey. Respondents were broadly representative of the universe of community hospitals (Attachment B).

The survey found great commitment to the incentive programs, with 95 percent of respondents reporting that they plan to pursue meaningful use. However, the survey found that only 1.6 percent of hospitals (21 of the hospitals responding) can meet the meaningful use and certification requirements today. As detailed in Attachment B, hospitals are making progress on specific objectives. In general, hospitals have made the most progress on objectives that improve clinical care, such as those ensuring medication safety. Objectives that center on reporting information to others, such as automated quality measures, pose greater challenges. Hospitals have not generally used their EHRs for this purpose and will need time to transition. When asked if they can meet all of the 14 core objectives and an additional 5 menu set objectives using EHRs certified for all 24 objectives, few can put it all together to meet the meaningful use requirements. **Clearly, the Stage 1 requirements are challenging; raising the bar significantly in Stage 2 risks limiting the success of the EHR incentive programs.**

The experiences of specific subgroups of providers, such as rural and critical access hospitals, and safety-net hospitals, also must be examined to ensure that the incentive programs close the existing digital divide, not widen it. Our recent survey shows that only 0.8 percent of rural hospitals (7 out of 598 rural hospitals responding) currently meet all of the meaningful use and certification requirements. Previous surveys have also shown that smaller and rural hospitals have, on average, lower rates of EHR adoption.

The Office of the National Coordinator for Health Information Technology (ONC) has provided limited funding through the Regional Extension Centers to support small rural hospitals. The best approach to ensuring patients in rural America have access to wired hospitals, however, is to reduce the requirements for rural hospitals in the early stages of the EHR incentive programs. These hospitals could then use their incentive payments to further adoption over time.

Ensure adequate timelines to achieve transitions. The start of the incentive programs was marked by short timelines that created significant disruptions in the health IT market, implementation issues for providers, and the potential to introduce patient safety issues by rushing installations. Current experience is marked by limited vendor and workforce capacity, with some hospitals reporting that vendors cannot implement systems until well into FY 2013. In addition, only 12 states have begun their Medicaid EHR incentive programs, which are meant to serve as a source of capital financing to support adoption, implementation and upgrading of systems in the first year. While hospitals are working hard to implement systems, the transition will take time.

Stage 2 of meaningful use should not start until at least 75 percent of all eligible hospitals and physicians/professionals have successfully reached Stage 1, and not before FY 2014. There is no legal requirement that Stage 2 for hospitals begin on October 1, 2012, as planned.

To give vendors sufficient time to modify systems and providers sufficient time to implement upgrades, final meaningful use and certification requirements must be known at least 24 months before providers are expected to be in compliance. Therefore, to begin in FY 2014, final requirements would need to be known by October 1, 2011. It is not sufficient to "signal" the market with proposed requirements, as significant investments and effort must be undertaken and can be dramatically impacted by what appear to be small changes in the rules. We also recommend that, given the many steps needed to prepare for Stage 2, providers should be required to report only on a 90-day period in the first year of Stage 2.

Consider meaningful use in a broader context. Change in the health information sector is accelerating, moving toward what some have termed a "perfect storm" of overlapping requirements that threatens to overwhelm providers. To clearly depict the numerous IT initiatives the health care field is facing, we have attached a timeline (Attachment C). In addition to EHR adoption, hospitals and physicians are also overhauling their IT systems to meet:

- Introduction of new versions of the *Health Insurance Portability and Accountability Act* (HIPAA) transactions standards (5010) and associated business rules by January 2012;
- A transition to the new ICD-10 coding standard by October 1, 2013;
- Changes to support myriad reporting requirements and information transfers for the current quality reporting program under Medicare, as well as numerous initiatives introduced through the *Patient Protection and Affordable Care Act* (ACA), such as reductions in readmissions, value-based purchasing, accountable care organizations, and bundling of payments; and
- Participation in state-level health information exchange initiatives funded by ONC.

Examination of this timeline highlights that the current plan of beginning Stage 2 meaningful use in FY 2013 would mean that the first year of Stage 2 would occur under ICD-9, while the second year would occur under ICD-10. These coding systems are the basis for health care billing, but are also embedded in many of the meaningful use and quality metrics. By straddling the switch to ICD-10, the proposed timing would result in considerable re-work for vendors and hospitals to accommodate meaningful use objectives under two different sets of diagnosis and procedures codes in the same stage of meaningful use.

Establish consistent meaningful use and certification requirements. The early implementation of meaningful use has been marked by tremendous confusion over the relationship between the meaningful use requirements for providers and their obligation to have certified EHR technology (CMS has posted more than 100 FAQs on its website, while ONC has posted 23, some of which have dramatically reinterpreted the regulations). The regulatory morass for these programs has become a major barrier to adoption for many hospitals. In our

recent survey, more than half of hospitals found the complexity and lack of clarity in the regulations to be a key barrier to adoption.

Moving forward, the certification and meaningful use requirements imposed on providers must be consistent and simplified. Providers should be required to possess only technology certified for the stage of meaningful use that they are meeting. For example, if a provider is meeting Stage 1 meaningful use in FY 2013, they should only have to possess an EHR certified for Stage 1 (and not Stage 2). Additionally, the current complexity and interaction between the CMS and ONC Stage 1 rules must be addressed.

Follow the principle of parsimony or minimum necessity. The preliminary recommendations increase the total number of objectives for eligible hospitals from 24 in the Stage 1 Final Rule to 32, introducing eight new objectives – a 33 percent increase. But since hospitals have to meet 19 of the 24 objectives to reach meaningful use in Stage 1, an increase to 32 required objectives actually represents a 70 percent increase over the number required for Stage 1 (19 required in Stage 1 versus 32 proposed for Stage 2). Regulation should be about minimum necessity, and the sheer volume of requirements poses a significant compliance burden in tracking and reporting. We ask the HITPC to consider whether certain objectives from Stage 1 can be removed, and whether all of the proposed new objectives for Stage 2 are necessary. Our comments include specific recommendations to remove five hospital measures. Hospitals and physicians can and will move beyond the regulatory requirements to ensure the best possible care, harness innovations, and meet competitive demands.

Provide continued flexibility. The notion that all participants must score 100 percent on meaningful use requirements is not consistent with how health IT systems function in the real world and fails to recognize that meeting the Stage 2 criteria will require upgrades and changes to workflows and clinical practice that will take time to deploy across all providers. Stage 2 should continue the flexibility initiated in Stage 1. The AHA recommends that in Stage 2 providers be required to meet only 80 percent of the meaningful use objectives. This approach will allow them to continue to build their EHR capacity and ensure that a provider missing just one objective is not penalized. The approach taken in Stage 1 effectively required hospitals to meet 80 percent of the objectives, as well (19 out of 24).

Field test the meaningful use measures. Stage 1 of meaningful use was deployed under intense time pressure, leading to significant short cuts in the development process. Stage 2 need not, and should not, continue in that vein. Medicare payments, and eventually payment cuts, will be tied to these metrics, suggesting a need for scientifically valid and reliable measures. CMS should follow a process similar to that used for development of quality measures, which includes detailed specifications and active testing of measures before they are used by the Medicare program. Vendors and providers must know exactly which data are required and the data required for measurement must be available in the electronic health record. Hospitals and physicians should have assurance that different vendor products get the same value if provided with the same sample data set. Simple measures are preferred.

Simplify requirements for providers. In most cases, measuring whether a provider has met a meaningful use objective requires less specificity than establishing certification requirements. Early experience from Stage 1 suggests that the proposed requirements for determining provider compliance in Stage 2 are too detailed. The layers of detail make for difficult measurement, sometimes force unnecessary changes in workflow to accommodate reporting, and can make compliance very difficult. These measurement burdens also divert scarce human and financial resources from the more important goal of deploying technology to improve care.

Certification requirements can and should include more functional specificity. Standards development organizations (SDOs) should be relied on to specify that functionality through open, consensus-based processes. For example, the SDO Health Level Seven (HL7) has developed a standard specifying the required fields and formats for a continuity of care document (CCD). Certification should include the ability to generate and fully populate the CCD. The meaningful use requirement for providers, however, should measure only whether information was shared in the required standard format and not which fields are populated. Clinical needs of patients will determine what data elements are shared. For example, the information included in a CCD for a patient referred for lab work is different than information needed for a patient referred to an oncologist for cancer treatment.

Provide clarity. Stage 2 meaningful use requirements should be fully described in the rule-making process. Early implementation in Stage 1 has been marked by considerable confusion and repeated issuance of guidance that have significant impact on operations. We recommend that the clarification come in the form of examples, rather than specific requirements and be included in the final rule, not promulgated through guidance. For instance, meaningful use rules could provide examples of the kinds of information that could be transmitted through a CCD, without making it a requirement that all of the elements cited in the example be part of each CCD.

Include only objectives that apply to all providers. It is not appropriate to apply medical home or primary care objectives to acute care settings. For example, a hospital is not likely to be in charge of the longitudinal care plan of a patient seen in the emergency room for a broken leg. Similarly, the hospital EHR is likely not the logical place for maintaining a list of the patient's full care team across all settings. Most care is provided in ambulatory settings and care coordination activities should be anchored by a patient's primary care provider, not the hospital.

DETAILED COMMENTS ON SPECIFIC OBJECTIVES

The AHA has a number of comments and concerns about specific recommended objectives and measures, as well as responses to the additional questions posed for public comment. Our recommendations are detailed in Attachment A, which should be considered an integral component of our comments.

Once at least 75 percent of eligible hospitals and professionals have met Stage 1 of meaningful use, the AHA recommends including the following 26 objectives in Stage 2, with specific

modifications to the definition, scope or measurement, as described in Attachment A. To provide continued flexibility, hospitals should be required to meet only 80 percent of the Stage 2 meaningful use measures, or 21 measures in all.

- CPOE for medication, laboratory, and radiology orders
- Drug-drug/drug-allergy interaction checks
- Record demographics
- Report clinical quality measures electronically (future comments expected)
- Maintain problem list
- Maintain active medication allergy list
- Record vital signs
- Record smoking status
- Implement clinical decision support rules
- Implement drug formulary checks
- Advance directives
- Incorporate lab results as structured data
- Generate patient lists for specific conditions
- Provide electronic copy of health information
- Provide electronic copy of discharge instructions
- EHR enabled patient-specific educational resources
- Record patient preferences for communication media (NEW)
- Perform test of health information exchange (HIE)
- Perform medication reconciliation
- Submit immunization data to public health
- Submit reportable lab data to public health
- Submit syndromic surveillance data to public health
- Conduct security review and analysis
- E-prescribing of discharge prescriptions (NEW)
- Electronic clinical notes (NEW)
- Electronic medication administration recording (NEW)

The AHA recommends that the HITPC remove five of the proposed hospital objectives to achieve parsimony, ensure that Stage 2 is achievable, and avoid promulgating regulations that duplicate the responsibilities of other agencies or other Medicare programs. These objectives are:

- Maintain active medication list, which will be achieved through medication reconciliation and maintenance of an electronic medication administration record.
- Establish a web-based portal for access to the inpatient medical record, which is duplicative of existing requirements of the Health Insurance Portability and Accountability Act (HIPAA) implemented by the Office of Civil Rights (OCR), unrealistic in its scope, and difficult and costly to achieve.

- Provide summary of care record, which is unclear in the hospital context, and duplicative of other objectives addressing discharge instructions and health information exchange.
- Maintain electronic list of care team members, which should be the responsibility of the physician who is coordinating a patient's overall care across settings. Hospital EHRs generally record the list of treating physicians for a specific stay or ED visit, as well as the primary care provider, if named by the patient.
- Maintain electronic longitudinal care plan, which is more appropriate for inclusion in health reform programs such as accountable care organizations, medical homes or pilot projects under the new Center for Medicare and Medicaid Innovation.

In addition, we ask for confirmation that, consistent with Stage 1, the objective to send patient reminders electronically will continue to apply only to eligible professionals, and not to hospitals.

The AHA also is concerned about proposed recommendations that would inappropriately duplicate, or contradict, regulations properly established and enforced by other agencies with primary jurisdiction over aspects of health care that are beyond the scope of the adoption of EHRs. Specifically, the AHA recommends that the HITPC, and by extension CMS and ONC, defer to the OCR to establish and enforce regulations that fall into its purview, including:

- HIPAA requirements to provide patients access to their medical records, including those in electronic form (OCR will release a set of final rules on this requirement in Spring 2011);
- HIPAA requirements to ensure the security of protected health information held in electronic form; and
- Requirements under the Civil Rights Act and Executive Order 13166, Sec. 504 of the Rehabilitation Act, and the Americans with Disabilities Act regarding provision of culturally appropriate health services, including language services, and access to care for patients with disabilities.

Finally, our specific comments identify areas where the HITPC is inappropriately attempting to define clinical documentation and medical record formats and requirements – such as discharge instructions, advanced directives, care summaries and longitudinal care plans – through government regulation. The AHA recommends that the HITPC rely on open, consensus-based standards development processes that engage all relevant stakeholders to develop these templates. Consistent with the provision of the HITECH act that established the HITPC, the Committee should limit its work to identifying and recommending to the Department of Health and Human Services (HHS) areas where additional standards development is needed to support standards adoption by the federal government (42 USC 300jj-12).

America's hospitals are working toward an e-enabled health care system where all hospitals meaningfully use EHRs to improve patient care and safety and achieve national goals for improved health. We believe the recommendations presented in this letter will move the nation

forward in adoption of EHRs and greater information exchange by establishing achievable requirements for Stage 2 of meaningful use that will enable more providers to benefit from the much-needed federal funds Congress intended to be disbursed in support of incremental progress.

Thank you for the opportunity to share our concerns and comments. If you have any questions, please contact me or Chantal Worzala, director for policy, at (202) 626-2313 or cworzala@aha.org.

Sincerely,

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

Attachments

ATTACHMENT A:
SPECIFIC COMMENTS ON PROPOSED MU OBJECTIVES AND MEASURES FOR STAGES 2 AND 3

The following table provides the AHA's comments on the specific preliminary recommendations put forward by the HITPC, which comprise the first three columns. Answers to the additional questions posed by the HITPC follow the table. The first column identifies those objectives that apply to hospitals (H1, H2, etc.). In the table, EP refers to eligible professionals, while EH denotes eligible hospitals.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
H1: CPOE for Medication orders **(30%)**	CPOE (by licensed professional) for at least 1 medication, and 1 lab or radiology order for 60% of unique patients who have at least 1 such order (order does not have to be transmitted electronically)	CPOE (by licensed professional) for at least 1 medication, and 1 lab or radiology order on 80% of patients who have at least 1 such order (order does not have to be transmitted electronically)	Expanding CPOE to lab and radiology orders is appropriate for hospitals. However, we recommend simplifying this objective to reduce measurement burden. It is unclear how the denominator will be calculated if some lab and radiology orders are placed via paper. Will this require full chart review to identify paper-based orders? Recommended alternative measure: Hospital has CPOE activated for laboratory and radiology and providers have placed at least 50 laboratory or radiology orders through this mechanism. This formulation, which relies on reporting a specific number of orders, follows a precedent set in the Medicare Physician e-Prescribing Program, which requires physicians to report on their e-prescribing activities for at least 25 encounters. Hospitals will, no doubt, order many more laboratory and radiology tests through CPOE. This measure specification is intended to limit reporting burden. It would be appropriate to recommend that in Stage 3, orders must be transmitted electronically within an institution (e.g., from CPOE module to radiology department). Stage 2 certification should require vendors to include the ability to transmit electronically, in anticipation of the Stage 3 requirement on providers.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
H2: Drug-drug/drug-allergy interaction checks	Employ drug-drug and drug-allergy interaction checks on appropriate evidence-based interactions	Employ drug-drug and drug-allergy checking, drug age checking (medications in the elderly), drug dose checking (e.g., pediatric dosing, chemotherapy dosing), drug lab checking, and drug condition checking (including pregnancy and lactation) on appropriate evidence-based interactions	The AHA recommends continuing the Stage 1 objective and measure without change. We do not have a definition of "appropriate evidence-based interactions," but would caution that a fine balance point exists between alerts that improve safety and those that are triggered too frequently, causing "alert fatigue." Certification requirements on vendors for Stage 2 may include specifications of specific types of drug interaction checks to be supported, and sources of evidence-based information to be incorporated into products. Enabling alerts in the pharmacy IS should be allowed, as pharmacists are generally the most knowledgeable about medications.
H3: E-prescribing (eRx) (EP) **(40%)** **(NEW)**	50% of orders (outpatient and hospital discharge) transmitted as eRx	80% of orders (outpatient and hospital discharge) transmitted as eRx Note: If receiving pharmacy cannot accept eRx, automatically generating electronic fax to pharmacy OK	The relevant population for hospitals is hospital discharge and emergency department patients (not outpatient). E-prescribing for discharge patients is new for hospitals. Therefore, the percentage for discharge prescriptions should be reduced to 20 percent in Stage 2, increasing to 50 percent in Stage 3. Community-based physicians may be reluctant to use the hospital's inpatient EHR to e-prescribe. Currently, some physicians who use e-prescribing for discharged patients do so through the ambulatory EHR, not the inpatient EHR. In addition, many hospitals treat patients who live in other communities and will want to take their prescriptions to a local pharmacy.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
H4: Record demo-graphics **(50%)**	80% of patients have demographics recorded and can use them to produce stratified quality reports	90% of patients have demographics recorded (including IOM categories) and can use them to produce stratified quality reports	Stratification of quality reports should be part of the objective on quality reporting measures, not the objective on recording demographics. Ability to stratify will depend on cell size, which will vary by provider. For many hospitals, the stratification of quality reports will be done using business analytics software applied to a clinical data warehouse. Providers should **not** be required to certify their data warehouses and business analytics tools for this function. The federal government has not yet developed a standard for preferred language, although the AHA has supported efforts to do so. In stage 3, providers should be able to identify the subsets of IOM categories that apply to their population (IOM has hundreds of race and ethnicity options. It will not be workable for providers to choose among all of those for each patient.)
H5: Report CQM electronically	Continue as per Quality Measures Workgroup and CMS	Continue as per Quality Measures Workgroup and CMS	The AHA will submit separate comments on quality measures for meaningful use. CMS must fully specify and test all quality measures before they are included in meaningful use. Quality measures must be coordinated across all Medicare programs, including current quality reporting requirements and new programs established as part of health reform. For many hospitals, the calculation of quality measures will be done using business analytics software applied to a clinical data warehouse. Providers should **not** be required to certify their data warehouses and business analytics tools for this function.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
H6: Maintain problem list **(80%)**	Continue Stage 1	80% problem lists are up-to-date Note: Drive list to be up to date by making it part of patient visit summary and care plans	The AHA recommends removing "up to date" as a specification for Stage 3, as it will be difficult to define and operationalize "up to date." Clinicians will exercise clinical judgment in reviewing and updating problem lists. The inpatient problem list includes many diagnoses that accumulate during a hospital stay, including some that are later resolved or ruled out. A patient admitted to the ICU, for example, can have hundreds of problems. If this concept is pursued, for hospitals the most relevant specification is whether the discharge diagnoses associated with a stay are up to date.
H7: Maintain active med list **(80%)**	Continue Stage 1	80% medication lists are up-to-date Note: Drive list to be up to date via medication reconciliation	The AHA recommends removing this objective. EHRs will continue to populate medication lists.However, the updating of the list in the hospital setting will be achieved through medication reconciliation and maintenance of an electronic medication administration record (eMAR), making this objective redundant. If this objective is retained, we recommend deleting the term "up to date" as it will be difficult to define and operationalize.
H8: Maintain active medication allergy list **(80%)**	Continue Stage 1	80% medication allergy lists are up-to-date Note: Drive the list to be up to date by making it part of visit summary	The concept of "up to date" in stage 3 will be difficult to define and operationalize and should be dropped.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
H9: Record vital signs **(50%)**	80% of unique patients have vital signs recorded	80% of unique patients have vital signs recorded	Stage 2 should be consistent with Stage 1 and include height, weight, and blood pressure. For some hospitals, the 80 percent threshold in Stage 2 will mean that special populations with vitals recorded through medical devices must have those data linked into the EHR. Currently, this type of medical device interoperability is not widely available. For example, women and babies in the obstetrics units have their vital signs recorded through fetal monitoring systems that are generally not integrated with the EHR. While medical device integration with EHRs is a long-term goal, it will take time. To avoid penalizing hospitals with large populations that are monitored through medical devices, we recommend keeping the same measure, but clarifying that vital signs (height, weight, blood pressure) must be recorded in the EHR at least once for each unique patient. This specification would allow hospitals flexibility to store streaming vital signs data from medical devices in a separate application, or integrate them into the EHR, as appropriate and feasible.
H10: Record smoking status **(50%)**	80% of unique patients have smoking status recorded	90% of unique patients have smoking status recorded	This objective should continue to apply only to patients aged 13 or older.
H11: Implement 1 clinical decision support (CDS) rule	Use CDS to improve performance on high-priority health conditions. Set CDS attributes for purposes of certification: 1. Authenticated (source cited); 2. Credible, evidence-based; 3. Patient-context sensitive; 4. Invokes relevant knowledge; 5. Timely; 6. Efficient workflow; 7. Integrated with EHR; 8. Presented to the appropriate party who can take action	Use CDS to improve performance on high-priority health conditions. Set CDS attributes for purposes of certification: 1. Authenticated (source cited); 2. Credible, evidence-based; 3. Patient-context sensitive; 4. Invokes relevant knowledge; 5. Timely; 6. Efficient workflow; 7. Integrated with EHR; 8. Presented to the appropriate party who can take action	It is unclear how CMS would operationalize "use CDS to improve performance on high-priority conditions." We recommend that Stage 2 continue the approach in Stage 1, but increase the required number to 5 CDS rules. It is unclear how the "CDS attributes" would apply to those CDS tools that are developed by the clinical staff of a hospital, such as development of order sets to be used in specific clinical scenarios. Generally, clinical teams meet, consider evidence and best practices, and develop order sets to standardize care. This approach is valuable for care process improvement and internal efficiency, and should be encouraged without requiring hospital-specific certification of internally developed CDS tools.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
H12: *Implement drug formulary checks*	Move current measure to core	80% of medication orders are checked against relevant formularies Note: What is the availability of formularies for eligible professionals?	This objective is appropriate for hospitals, as long as the hospital can refer to its own formulary. For Stage 3, we recommend continuation of the current approach to measurement (implement checks) to minimize reporting burden. For EPs, it is unclear whose formulary would be checked. How many formularies must be checked? What if payer formularies are not accessible?
H13: *Record existence of advance directives (EH)* ***(50%)***	Make core requirement. For EP and EH: 50% of patients >=65 years old have recorded in EHR the result of an advance directive discussion and the directive itself if it exists	For EP and EH: 90% of patients >=65 years old have recorded in EHR the result of an advance directive discussion and the directive itself if it exists Potential issues include: state statutes; challenges in outpatient settings; age; privacy; specialists; be accessible and certifiable; need to define a standard	The AHA is committed to engaging patients in advanced care planning and has a specific education campaign on advance directives (see www.putitinwriting.org). We recommend keeping the Stage 1 measure specifications for this objective (POS=21), but increasing the percent to 80% in Stages 2 and Stage 3. Significant workflow changes and reporting burdens will be associated with documenting and measuring the concept of "have recorded in the EHR result of advance direction discussion," without clear benefit compared to the current measure specification. Furthermore, given variations in state law, it will be difficult to define a standard advance directive. Development of a standard should be done through an open, consensus-based standards development process that engages all relevant stakeholders. The HITPC could recommend that HHS pursue development of an appropriate standard.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
H14: I*ncorporate lab results as structured data* ***(40%)***	Move current measure to core, but only where results are available	90% of lab results electronically ordered by EHR are stored as structured data in the EHR and are reconciled with structured lab orders, where results and structured orders available	This objective is appropriate for Stage 2, as long as it is clarified that local codes count as structured data. The proposed Stage 3 objective is unclear. For eligible hospitals we recommend as an objective "lab results are linked to their orders." Research is needed to determine the correct percentage for Stage 3. Some lab results, such as pathology reports, may not be easily structured. The share of reports that fall into this category may vary by facility type and physician specialty.
H15: *Generate patient lists for specific conditions*	Generate patient lists for multiple patient-specific parameters (move to core)	Patient lists are used to manage patients for high-priority health conditions	This objective is appropriate. However, for many hospitals, generation of patient lists will be done using business analytics software applied to a clinical data warehouse. Providers should **not** be required to certify their data warehouses and business analytics tools for this function.
H16: *Send patient reminders* ***(20%)*** **(EP ONLY in Stage 1)**	Move to core	20% of active patients who prefer to receive reminders electronically receive preventive or follow-up reminders	Consistent with Stage 1, this objective should only apply to EPs.
(NEW)	30% of visits have at least one electronic EP note	90% of visits have at least one electronic EP note Note: Can be scanned, narrative, structured, etc.	The denominator used for this objective should be consistent with that used for other objectives– percent of unique patients (rather than percent of visits). Changing denominators across objectives is a source of unnecessary confusion and creates additional reporting burdens. Providers must have flexibility in how the note is entered and stored. The requirements also should allow for use of technologies that deploy voice recognition and natural language processing. The content of a note will vary considerably by physician specialty and clinical scenario and is best left to the clinical judgment of the provider. Vendors will work with their clients to develop products that support provider needs.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
H17 (NEW)	30% of eligible hospital (EH) patient days have at least one electronic note by a physician, NP, or PA	80% of EH patient days have at least one electronic note by a physician, NP, or PA Note: Can be scanned, narrative, structured, etc.	The concept of patient days would not include patients seen in the ED. We recommend that the denominator used for this objective be consistent with that used for other objectives– percent of unique patients (rather than percent of days). Changing denominators across objectives is a source of unnecessary confusion and creates additional reporting burdens. It is appropriate to retain flexibility in how providers enter and store their clinical notes. In addition to scanned and directly entered notes, providers may also choose to deploy other technologies, such as voice recognition and natural language processing. The content of a note will vary considerably by physician specialty and clinical scenario and is best left to the clinical judgment of the provider. Vendors will work with their clients to develop products that best support provider needs.
H18 (NEW)	30% of EH medication orders automatically tracked via electronic medication administration recording	80% of EH inpatient medication orders are automatically tracked via electronic medication administration recording	This objective is appropriate, as long as medication orders can be tracked using local codes. As specified for Stage 3, only inpatient orders should be included in this measure.
H19: Provide electronic copy of health information, upon request **(50%)**	Continue Stage 1	90% of patients have timely access to copy of health information from electronic health record, upon request Note: Only applies to information already stored in the EHR	This objective should be modified to be consistent with forthcoming rules from OCR on HIPAA requirements to provide patients with copies of their medical records. OCR will release a set of final rules on this requirement in Spring 2011. Specifically, the meaningful use objectives should not impose any requirements beyond those established by OCR, including the time periods in which electronic copies of records must be provided.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
H20: Provide electronic copy of discharge instructions (EH) at discharge **(50%)**	Electronic discharge instructions for hospitals (which are given as the patient is leaving the hospital) are offered to at least 80% of patients (patients may elect to receive a printed copy of the instructions)	Electronic discharge instructions for hospitals (which are given as the patient is leaving the hospital) are offered to at least 90% of patients in the common primary languages (patients may elect to receive a printed copy of the instructions) [The RFI also proposed specific data elements be included in electronic discharge instructions.]	The AHA recommends using a consistent measure from Stage 1 to Stage 2, with an increase in the threshold from 50% to 80%. Hospitals have already changed workflows and systems to track patients who have requested an electronic copy. A change in the measure would present a significant burden to establish a new workflow to track whether an electronic copy is "offered." For Stage 3, the AHA recommends that the HITPC defer to OCR on provision of language services in health care. Requirements under the Civil Rights Act and Executive Order 13166, Sec. 504 of the Rehabilitation Act, and the Americans with Disabilities Act govern provision of culturally appropriate health services, including language services, and access for patients with disabilities. Furthermore, the health reform law introduces new provisions on reducing disparities in health care. Finally, it is unclear whether current technologies can accurately conduct automated translations. It is out of scope for the HITPC /HITSC to determine the contents of discharge instructions. Discharge instructions will include different information based on the patient's clinical condition and next setting of care. They are used by patients, discharge planners, post-acute care providers, and primary care physicians. Development of a standard should be done through an open, consensus-based standards development process that engages all relevant stakeholders. For example, HL7 has worked on standards for discharge summaries.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
H21: EHR-enabled patient-specific educational resources **(10%)**	Continue Stage 1	20% offered patient-specific educational resources online in the common primary languages	This objective is appropriate for Stage 2. For Stage 3, we recommend that the HITPC defer to OCR on provision of language services in health care. Requirements under the Civil Rights Act and Executive Order 13166, Sec. 504 of the Rehabilitation Act, and the Americans with Disabilities Act govern provision of culturally appropriate health services, including language services, and access for patients with disabilities. Furthermore, the health reform law introduces new provisions on reducing disparities in health care. Finally, it is unclear whether current technologies can accurately conduct automated translations.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
H22: NEW for EH	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 (HITSC to define).	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 (HITSC to define). [The RFI also proposed specific data fields to be included in inpatient summaries.]	This objective should be removed. HIPAA includes provisions on provider obligations to provide patients with an electronic copy of their medical record. OCR implements the HIPAA rules. OCR will release a set of final rules on this requirement in Spring 2011. Each covered entity should have the flexibility to determine the variety of electronic formats it will offer. Use of a portal is one way, but not the only way, that providers may choose to meet these obligations. In addition, establishing a web portal of this magnitude is unrealistic and premature, particularly for hospitals that are building up their EHR capability. The scope of required content is too large, particularly in the context of patients who have been admitted to the hospital and may have multiple days of full vital sign monitoring in the ICU. Before establishing a requirement of this magnitude, more research is needed on patient demand for this information, and the type of information that is valuable to them. Realizing this objective would involve significant efforts to establish and manage processes to distribute and process consent forms, provide patients with passwords, and establish other tools for authentication. In addition, web portals pose additional challenges for protecting the security of health information. What is the obligation of the provider in the event that a patient's identity is stolen or his/her downloaded data are not stored securely? Furthermore, significant workflow changes and reporting burdens would be involved in measuring detailed facets of this objective, such as measuring "offered the ability to view and download," and determining whether data are up to date within 36 hours of discharge. In addition, in many cases, hospitals will not be able to get approved, dictated reports from doctors, radiologists and pathologists in this timeframe. In some cases, providers will need to review information to ensure that it can be released according to state laws.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
Provide clinical summaries for each office visit (EP) **(50%)**	Patients have the ability to view and download relevant information about a clinical encounter within 24 hours of the encounter. Follow-up tests that are linked to encounter orders but not ready during the encounter should be included in future summaries of that encounter, within 4 days of becoming available. Data are available in human-readable and structured forms (HITSC to define).	Patients have the ability to view and download relevant information about a clinical encounter within 24 hours of the encounter. Follow-up tests that are linked to encounter orders but not ready during the encounter should be included in future summaries of that encounter, within 4 days of becoming available. Data are available in human-readable and structured forms (HITSC to define). [The RFI also proposed specific data elements to be included.]	This objective should be removed. HIPAA includes provisions on provider obligations to provide patients with an electronic copy of their medical record. OCR implements the HIPAA rules. OCR will release a set of final rules on this requirement in Spring 2011. Each covered entity should have the flexibility to determine the variety of electronic formats it will offer. Use of a portal is one way, but not the only way, that providers may choose to meet these obligations.
Provide timely electronic access (EP) **(10%);**	Patients have the ability to view and download (on demand) relevant information contained in the longitudinal record, which has been updated within 4 days of the information being available to the practice. Patient should be able to filter or organize information by date, encounter, etc. Data are available in human-readable and structured forms (HITSC to define).	Patients have the ability to view and download (on demand) relevant information contained in the longitudinal record, which has been updated within 4 days of the information being available to the practice. Patient should be able to filter or organize information by date, encounter, etc. Data are available in human-readable and structured forms (HITSC to define). [The RFI also proposed specific data elements to be included.]	This objective should be removed. HIPAA includes provisions on provider obligations to provide patients with an electronic copy of their medical record. OCR implements the HIPAA rules. OCR will release a set of final rules on this requirement in Spring 2011. Each covered entity should have the flexibility to determine the variety of electronic formats it will offer. Use of a portal is one way, but not the only way, that providers may choose to meet these obligations.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
This objective sets the measures for "Provide timely electronic access (EP)" and for "Provide clinical summaries for each office visit (EP)"	EPs: 20% of patients use the EHR's secure portal or the private and secure service of a business associate (that treats patient information confidentially and in accordance with HIPAA business associate expectations), to access their information (for an encounter or for the longitudinal record) at least once. Exclusions: patients without ability to access the Internet	EPs: 30% of patients use the EHR's secure portal or the private and secure service of a business associate (that treats patient information confidentially and in accordance with HIPAA business associate expectations), to access their information (for an encounter or for the longitudinal record) at least once. Exclusions: patients without ability to access the Internet	This objective should be removed. It is inappropriate to hold the physician accountable for patient use of the web portal. In addition, it is unclear how this measure would be operationalized. How is the provider's patient population calculated? How will an EP know if a patient does not have the ability to access the internet? Is the EP responsible for ensuring that those without access have it?
(NEW)	EPs: online secure patient messaging is in use	EPs: online secure patient messaging is in use	This objective should be removed. Medicare does not pay for e-visits. It is inappropriate to include a requirement that physicians use secure messaging without addressing payment issues.
H23: (NEW)	Patient preferences for communication medium recorded for 20% of patients	Patient preferences for communication medium recorded for 80% of patients Note: How should "communication medium" be delineated?	The delineation of patient preferences for communication should have a small set of choices, including phone, mail, and email. Providers must weigh patient preferences, clinical needs, and operational concerns when determining how to communicate with patients.
(NEW in Stage 3)		Offer electronic self-management tools to patients with high priority health conditions	More work must be done to understand the demand for these tools and the attributes that make them useful in improving health.
(NEW in Stage 3)		EHRs have capability to exchange data with PHRs using standards-based health data exchange	More work must be done to understand the role of PHRs. Currently they are used by few individuals.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
(NEW in Stage 3)		Patients offered capability to report experience of care measures online.	The AHA strongly advises against the inclusion of HCAHPS patient experiences with care survey information into patients' EHRs. In answering the HCAHPS survey, and providing hospitals with valuable feedback on their perceptions of the care they received, patients should be assured that their responses remain confidential and not revealed to their providers and caregivers. For patients to feel comfortable with providing honest feedback on their surveys, they must be assured of confidentiality, and that feedback must never be included in patients' medical records. Hospitals already report HCAHPS to Medicare.
(NEW in Stage 3)		Offer capability to upload and incorporate patient-generated data into EHRs and clinician workflow	More research is needed on this topic. The type of patient data must be carefully delineated. Providers have concerns about the accuracy and volume of patient-generated data that could be involved. For data generated from remote monitoring devices, such as biometric data from a home monitoring device, standards are not yet commonly available to support integration. Most remote monitoring systems in use today include an intermediary that organizes biometric data before it is presented to the clinician. Policymakers must also consider the obligations on providers to act on patient-generated data that is introduced into EHRs.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
H24: Perform test of HIE	Connect to at least three external providers in "primary referral network" (but outside delivery system that uses the same EHR) or establish an ongoing bidirectional connection to at least one health information exchange	Connect to at least 30% of external providers in "primary referral network" or establish an ongoing bidirectional connection to at least one health information exchange Note: Successful HIE will require development and use of infrastructure like entity-level provider directories (ELPD)	"Primary referral network" is not well-defined and should be removed. If included, it will create a measurement burden. A simple measure is preferred, such as exchange a CCD with three providers outside the delivery system, or demonstrated ability to exchange a CCD with a testing database. Stage 2 should be limited to unidirectional exchange, where a provider can send data to an HIE, but may not be able to receive it and incorporate it into the EHR. While standard document templates and data fields are needed to support exchange, the content of information to be exchanged should be determined by providers, based on clinical needs. Achieving this objective is dependent on EHR and HIE adoption by other providers. In some areas, state-designated HIEs may not be ready. The requirement should include exceptions in areas without an operational HIE, and in areas where the cost to join an HIE is prohibitive.
H25: Perform medication reconciliation **(50%)**	Medication reconciliation conducted at 80% of care transitions by receiving provider (transitions from another setting of care, or from another provider of care, or the provider believes it is relevant)	Medication reconciliation conducted at 90% of care transitions by the receiving provider	As with the other Stage 1 menu set items, this objective should be moved to the core at the same threshold as in Stage 1 (50%). The measure definition should be consistent from Stage 1 to Stage 2.
H26: Provide summary of care record **(50%)**	Move to Core	Summary care record provided electronically for 80% of transitions and referrals	This objective should be removed for hospitals. Survey data indicate that only 12 percent of hospitals can meet this objective and have an EHR certified for this functionality today. The purpose of this objective is unclear for the hospital setting. It is duplicative of the discharge instructions and HIE requirements.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
H27: (NEW)	List of care team members (including PCP) available for 10% of patients in EHR	List of care team members (including the PCP) available for 50% of patients via electronic exchange	This objective should not apply to hospitals. Maintaining the list of care team members is the responsibility of the physician who is coordinating the patient's care (generally, but not always, a PCP). We recommend that this measure apply only to the EP responsible for coordinating the patient's care. EHs generally record the list of treating physicians for a specific stay or ED visit, as well as the PCP, if named by the patient.
H28: (NEW)	Record a longitudinal care plan for 20% of patients with high-priority health conditions	Longitudinal care plan available for electronic exchange for 50% of patients with high-priority health conditions Note: What elements should be included in a longitudinal care plan including: care team members; diagnoses; medications; allergies; goals of care; other elements?	Remove this objective. Additional research is needed to develop the concept of a longitudinal care plan, which is more appropriate for inclusion in health reform programs such as accountable care organizations and medical homes. Maintaining the longitudinal care plan is the responsibility of the physician who is coordinating the patient's care (generally, but not always, a PCP). It is out of scope for the HITPC to define a longitudinal care plan. Development of a standard should be done through an open, consensus-based standards development process that engages all relevant stakeholders. The HITPC could recommend that HHS pursue development of an appropriate standard. The definition of a longitudinal care plan will vary with the patient's clinical condition and setting of care. For example, a patient undergoing treatment for cancer may have a treatment plan listing chemotherapy and radiation treatments, while a patient with a hip replacement may have a treatment plan listing needed therapy and follow-up visits. For patients receiving home health benefits, Medicare requires a care plan that has been approved by a physician.

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
H29: Submit immunization data	EH and EP: Mandatory test. Some immunizations are submitted on an ongoing basis to Immunization Information System (IIS), if accepted and as required by law	EH and EP: Mandatory test. Immunizations are submitted to IIS, if accepted and as required by law. During well child/adult visits, providers review IIS records via their EHR.	CMS should maintain the exclusion if the public health department cannot receive the data. Providers should be able to achieve this objective through their laboratory information systems without needing to have them separately certified.
H30: Submit reportable lab data	EH: move Stage 1 to core EP: lab reporting menu. For EPs, ensure that reportable lab results and conditions are submitted to public health agencies either directly or through their performing labs (if accepted and as required by law).	Mandatory test. EH: submit reportable lab results and reportable conditions if accepted and as required by law. Include complete contact information (e.g., patient address, phone and municipality) in 30% (EH) of reports. EP: ensure that reportable lab results and reportable conditions are submitted to public health agencies either directly or through performing labs (if accepted and as required by law)	CMS should maintain the exclusion if the public health department cannot receive the data. Providers should be able to achieve this objective through their laboratory information systems without needing to have them separately certified.
H31: Submit syndromic surveillance data	Move to core.	Mandatory test; submit if accepted	CMS should maintain the exclusion if the public health department cannot receive the data. Providers should be able to achieve this objective through their laboratory information systems without needing to have them separately certified.
[NEW in Stage 3]		Patient-generated data submitted to public health agencies	The purpose of this objective is unclear. In what scenarios would patient-generated data be submitted to public health agencies through a provider's EHR?

Stage 1 Final Rule	Proposed Stage 2	Proposed Stage 3	AHA Comments and Recommendations
H32: Conduct security review analysis & correct deficiencies			Privacy and security obligations should be limited to existing HIPAA requirements that are promulgated and enforced by the Office of Civil Rights.

ADDITIONAL SPECIFIC QUESTIONS FOR PUBLIC COMMENT

As part of the request for comment, the HITPC asked for specific input on a number of questions. The AHA's feedback on some of those questions is below.

1. ***How can electronic progress notes be defined in order to have adequate specificity?***

   Clinical notes represent the documentation of patient treatment as care is being rendered. As such, the content of notes will vary significantly by the type of provider, the treatment setting, and the clinical scenario and is best left to the clinical judgment of the provider. Vendors will work with their clients to develop products that best support provider needs. It is appropriate to retain flexibility in how providers enter and store their clinical notes. In addition to scanned and directly entered notes, providers may also choose to deploy other technologies, such as voice recognition and natural language processing.

2. ***How should "common primary languages" be defined and should there be regional variation allowances (also applies to electronic discharge instructions)?***

   Addressing disparities in care and providing culturally appropriate health care services are key national objectives and a strategic goal of the AHA. The AHA recommends, however, that the HITPC defer to OCR on provision of language services in health care. The Civil Rights Act already requires provision of language services in health care, which OCR enforces. Furthermore, the health reform law introduces new provisions on reducing disparities in health care. Introducing duplicative – or contradictory – regulatory requirements under meaningful use would create confusion and compliance burdens for providers. Finally, it is unclear that current technologies can accurately conduct automated translations.

3. ***For patient/family access to personal health information, what standards should exist regarding accessibility for people with disabilities (e.g., interoperability with assistive technologies to support those with hearing, visual, speech, or mobile impairments)?***

   Addressing disparities in care and providing culturally appropriate health care services are key national objectives and a strategic goal of the AHA. For Stage 3, we recommend that the HITPC defer to OCR on provision of language services in health care. Requirements under the Civil Rights Act and Executive Order 13166, Sec. 504 of the Rehabilitation Act, and the Americans with Disabilities Act govern provision of culturally appropriate health services, including language services, and access for patients with disabilities.

4. ***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?***

   The HITPC should recommend that HHS conduct a study of this issue that includes a catalogue of existing federal programs, both within and outside HHS, to address these important needs.

5. ***What are providers' and hospitals' experiences with incorporating patient-reported data into EHRs?***

   The HITPC should recommend that HHS conduct a study of this emerging area.

6. ***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 (e.g., can either satisfy utilization measures for recording allergies, conducting CPOE, drug-drug interaction checking, etc, or demonstrate low rates of adverse drug events)?***

   Any proposed alternative approach would need to carefully consider how proposed metrics relate to other Medicare programs, including quality reporting requirements, value-based purchasing initiatives, payment penalties linked to readmission rates or hospital-acquired conditions. The choice of metrics would have to be supported by scientific evidence linking use of the EHR, specifically, to performance on the metrics.

7. ***Should Stage 2 allow for a group reporting option to allow group practices to demonstrate meaningful use at the group level for all EPs in that group?***

   Many group practices share the care of patients, and have difficulty assigning patients to a single provider within the group. This approach to care, which increases care coordination, makes it difficult to create meaningful use measures for each provider. CMS should develop mechanisms that allow group practices to choose how they demonstrate meaningful use, either individually or as a group.

8. ***In stage 1, as an optional menu objective, the presence of an advance directive should be recorded for over 50% of patients 65 years of age or older. We propose making this objective mandatory and to include the results of the advance directive discussion, if available. We invite comment on this proposal or to offer suggestions for alternative criteria in this area.***

   See our comments in the table above.

9. What are the reasonable data elements that should make up a care plan, clinical summary, and discharge summary?

It is out of scope for the HITPC to define clinical documentation and medical record formats and requirements – such as discharge instructions, advanced directives, care summaries, and longitudinal care plans – through government fiat. The AHA recommends that the HITPC rely on open, consensus-based standards development processes, such as those undertaken by HL7 Clinical Document Architecture, that engage all relevant stakeholders to develop these templates. Consistent with the provision of the HITECH Act that established the HITPC, the Committee should limit its work to identifying and recommending to HHS areas where additional standards development is needed to support standards adoption by the federal government (42 USC 300jj-12).

Once standards are developed and adopted, the meaningful use requirement for providers should measure only whether information was shared in the required standard format, as clinical context will determine what data elements are needed. The parties to a specific information exchange will work together to determine needed content. Clinical needs of patients will determine what data elements are shared. For example, the information included in a CCD for a patient referred for lab work is different than information needed for a patient referred to an oncologist for cancer treatment. Providers should not be required to document whether all fields are populated for all document formats that are generated for these measures.

10. What additional MU criteria could be applied to stimulate robust information exchange?

Experience with the existing information exchange objectives must be evaluated before additional criteria are applied. The HITPC should work with HHS to ensure that sufficient infrastructure to support information exchange is built and readily available to providers at a reasonable cost. Imposing additional regulatory requirements through meaningful use risks the unintended consequence of limiting the ways in which exchange and future innovation occur.

11. There are new objectives being considered for stage 3 where there is no stage 2 "stepping stone" objective suggested. We invite suggestions on appropriate stage 2 objectives.

See our comments in the table above.

ATTACHMENT B:
SURVEY ON CURRENT ABILITY TO MEET MEANINGFUL USE

To provide a snapshot of the hospital field's current capacity to meet the meaningful use requirements, the AHA conducted a survey of all community hospitals. Data were collected between January 6 and January 20, 2011 with 1,297 hospitals (about 25 percent of all hospitals) responding to the survey. Respondents were broadly representative of the universe of community hospitals.

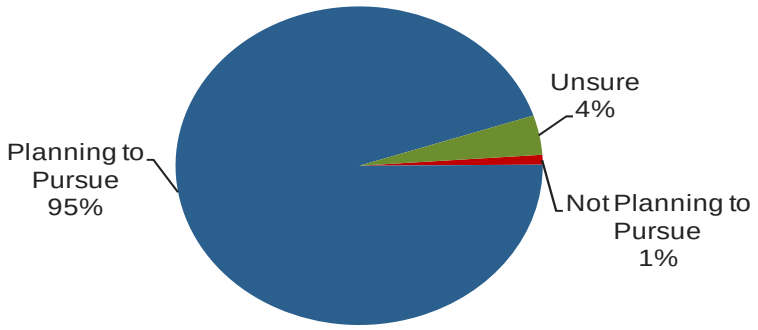
The survey found great commitment to the incentive program, with 95 percent of respondents reporting that they plan to pursue meaningful use (Chart 1). However, the survey found that only 1.6 percent of hospitals (21 of the survey respondents) can meet the meaningful use and certification requirements today. Only 0.8 percent of rural hospitals (7 of the survey respondents) could do so (Chart 2). **Clearly, the Stage 1 requirements are challenging; raising the bar significantly in Stage 2 risks limiting the success of the EHR incentive programs.**

The survey also includes information on the extent to which hospitals have met the specific requirements for meaningful use. To receive incentive payments under Medicare, a hospital must meet all of the following regulatory requirements set out by CMS:

- Possess an EHR certified against each of the 24 required objectives (or functions);
- meet specific performance requirements for each of the 14 core objectives, and at least five of the menu set objectives (to include at least one public health objective); and
- report on each of 15 quality measures successfully generated directly from the EHR.

Failure to meet any one of these requirements will disallow a hospital from receiving incentives. Therefore, to assess current ability to meet meaningful use, the survey asked hospitals to separately identify whether their EHRs were certified for each objective and whether the hospital could meet the objective, regardless of certification.

Chart 1. 95 percent of hospitals report that they plan to pursue qualifying as meaningful users



Source: AHA analysis of survey data from 1,297 non-federal, short-term acute care hospitals collected in January 2011.

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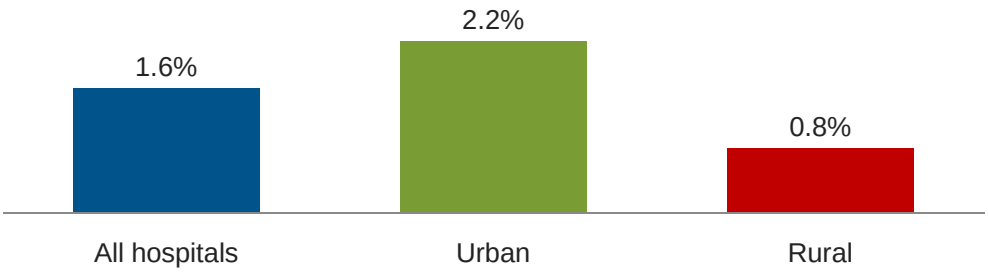
Chart 2. 1.6 percent of hospitals report that they can meet requirements for meaningful use and have a certified EHR today



Source: AHA analysis of survey data from 1,297 non-federal, short-term acute care hospitals collected in January 2011. Hospitals were asked to separately identify whether their EHRs were certified for each objective and whether the hospital could meet the objective, regardless of certification. To meet meaningful use, a hospital must (1) possess an EHR certified against all 24 objectives of meaningful use, (2) meet at least 19 of the objectives, and (3) successfully report quality measures generated directly from the EHR. Nationally, there are approximately 2,800 urban hospitals and 2,300 rural hospitals.

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Hospitals are making progress on meeting specific objectives, but when asked if they can meet all of the 14 core objectives and an additional 5 menu set objectives, including at least one public health measure, few can put it all together to meet the meaningful use requirement. In addition, while hospitals have made progress in using their EHRs to meet the meaningful use objectives, the percentage using certified EHR technology to do so is lower. For example, while 61 percent of hospitals reported implementing drug-drug and drug-allergy checks, only 43 percent of hospitals reported both having an EHR certified for this function and successfully enabling it (Chart 3).

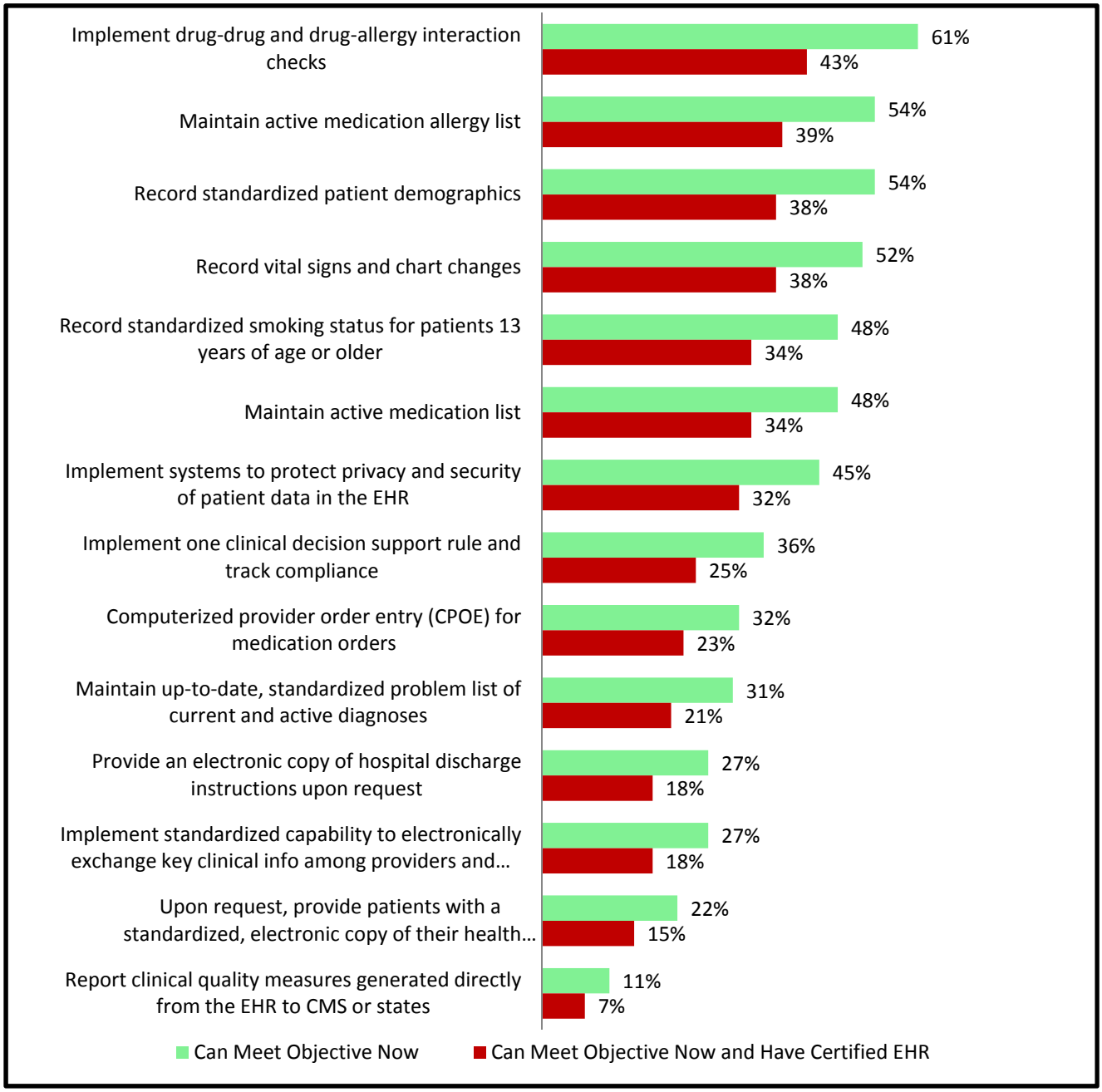
Installing and upgrading systems is a time-consuming process, and the certification requirements mean that all hospitals must either upgrade or install new systems before they can meet the meaningful use regulations. In addition, vendors' capacity to work with hospitals is stretched, given the current high demand generated by the incentive programs. Hospitals and vendors face significant shortages of trained IT and clinical informatics staff.

In looking at the 14 core objectives, hospitals reported the most progress in using their EHRs to ensure medication safety – for example, implementing drug-drug and drug-allergy checks – and maintaining active medication and medication allergy lists. The majority of hospitals also reported using their EHRs to record demographic and clinical data. Hospitals' ability to meet each core objective using certified EHR technology was lower (Chart 4).

Several of the core objectives pose significant challenges to hospitals. Most of these objectives center on reporting of information, such as quality measures or electronic copies of records, rather than using technology to improve care. Hospitals have not generally used their EHRs for this purpose and will need time to transition (Chart 3).

According to the survey respondents, the core measure requiring hospitals to report 15 quality measures generated directly from the EHR is among the most troublesome to meet. Hospitals have a strong commitment to quality reporting, and 97 percent of hospitals currently report data on more than 50 different quality measures to CMS, with data on 43 measures then made available to the public. EHRs have the potential to reduce the burden of quality reporting by automating the process. However, EHR products have not historically had the technical capacity for the quality reporting currently required for meaningful use; vendors have only recently built this function into their products, with very little testing. In fact, the certification process does not even check to see if the calculations are performed accurately. Thus, it will take time and effort for hospitals to understand whether the EHRs they deploy can actually generate valid quality metrics.

Chart 3. Percent of hospitals reporting they can meet each meaningful use **core** objective versus the percent reporting they both have certified EHR technology and can meet each objective



Source: AHA analysis of survey data from 1,297 non-federal, short-term acute care hospitals collected in January 2011. Hospitals were asked to separately identify whether their EHRs were certified for each objective and whether the hospital could meet the objective.

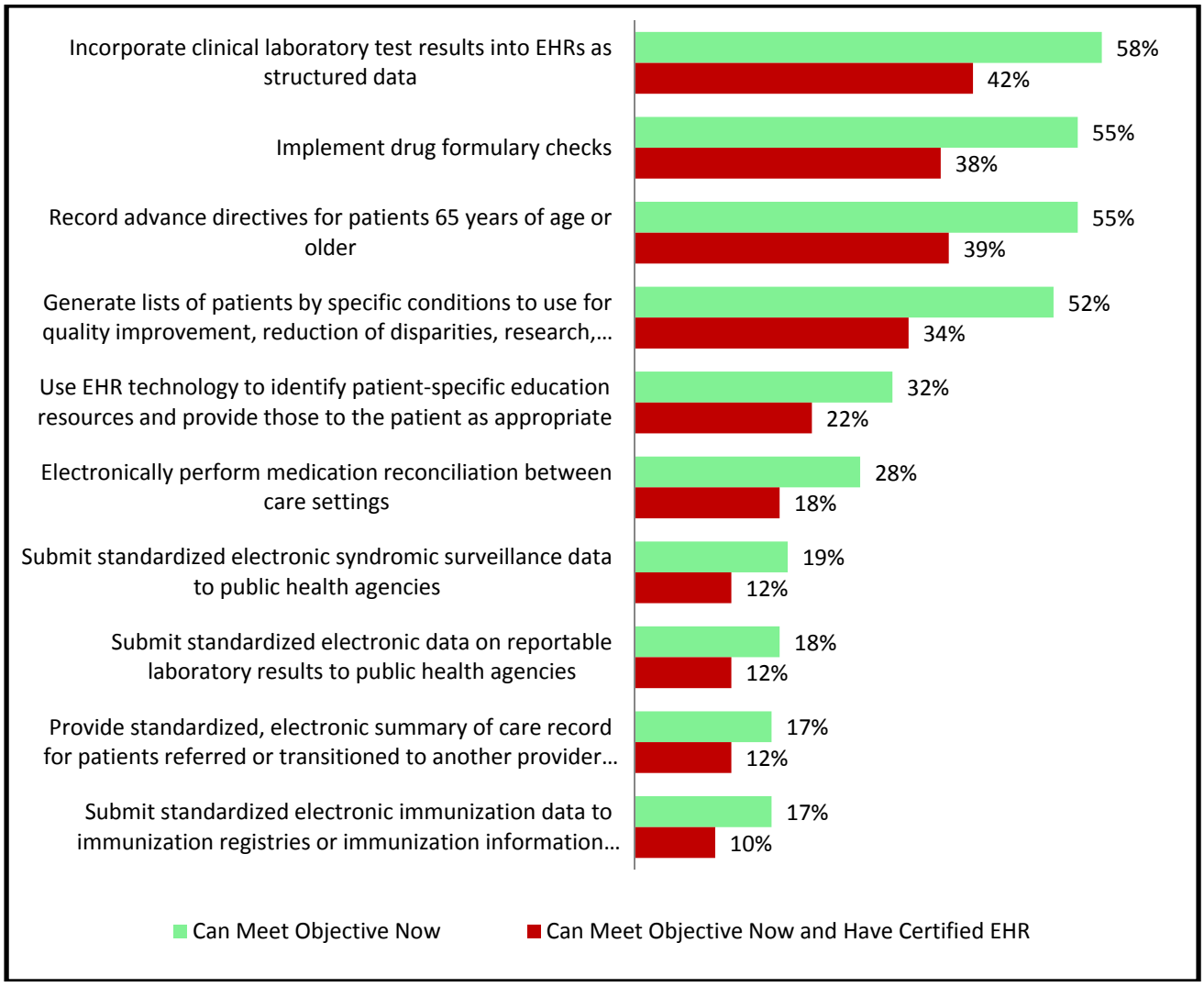
Hospitals report variable progress in meeting the menu set requirements. As with the core objectives, hospitals are more likely to be able to meet the performance standards for meaningful use than to have upgraded or replaced their systems to possess certified EHR technology. For example, while 55 percent of hospitals reported implementing drug formulary checks, only 38 percent of hospitals reported doing so with an EHR certified for that functionality.

Among the menu set objectives, hospitals reported the greatest progress on those objectives tied to the clinical care process, such as incorporating lab results as structured data, implementing drug formulary checks, and recording whether patients 65 and older have advanced directives.

The menu set objectives posing the greatest challenge to hospitals generally focused on sending data to others using the vocabulary and data transmission standards specified by CMS, including all three of the public health reporting objectives. Note that to meet the meaningful use requirements, hospitals must successfully meet at least one of the public health objectives.

Hospitals engage broadly in public health reporting. However, the meaningful use requirements include use of specific vocabulary and data transmission standards for submitting data that are not in common use today, and were not generally supported by EHR vendors. Indeed, most public health departments are not yet able to receive data in the required formats. Thus, as with quality reporting, meaningful use is setting out new ways to share data that hospitals are, in many cases, already providing through other means. The transition to these new approaches will take time and effort. And, in the case of public health reporting, it will take advances in the IT systems of public health departments, not just hospitals.

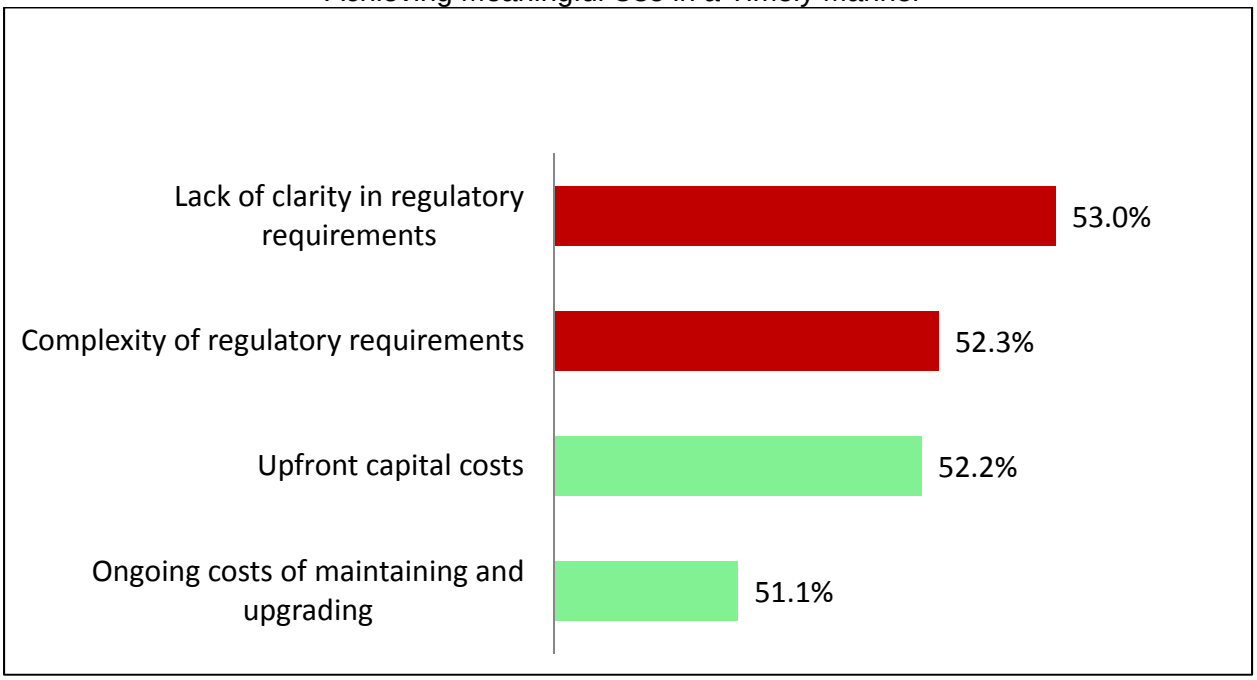
Chart 4. Percent of hospitals reporting they can meet each meaningful use **menu set** objective versus the percent reporting they both have certified EHR technology and can meet each objective



Source: AHA analysis of survey data from 1,297 non-federal, short-term acute care hospitals collected in January 2011. Hospitals were asked to separately identify whether their EHRs were certified for each objective and whether the hospital could meet the objective.

The survey also asked hospitals about barriers to achieving meaningful use in a timely manner. The majority of respondents indicated that lack of clarity (53 percent) and complexity (52.3 percent) of the regulatory requirements were barriers. These issues were cited slightly more often than costs, which were also seen as a barrier by the majority of respondents (Chart 5).

Chart 5. Percent of Hospitals Identifying Complexity of Rules and Costs as Barriers to Achieving Meaningful Use in a Timely Manner



Source: AHA analysis of survey data from 1,297 non-federal, short-term acute care hospitals collected in January 2011.

ATTACHMENT C:

Overlapping Timelines of ICD-10, Meaningful Use of EHRs, and Health Reform Initiatives