



**American Hospital
Association**

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April 30, 2012

Submitted Electronically

Marilyn Tavenner
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Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

***Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 2
Notice of Proposed Rulemaking (CMS-0044-P)***

Dear Ms. Tavenner:

On behalf of our nearly 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 comment on the notice of proposed rulemaking for Stage 2 of “meaningful use” under the Medicare and Medicaid electronic health record (EHR) incentive programs published in the March 7 *Federal Register* (CMS–0044–P).

Congress established the Medicare and Medicaid EHR incentive programs in the *American Recovery and Reinvestment Act of 2009* (ARRA) to provide much-needed funds to support the transition to an e-enabled health care system. The AHA shares the goal of the EHR incentive programs: accelerating adoption and use of EHRs to improve health care by providing needed financial support. However, the vast majority of hospitals — more than 80 percent — have not yet met Stage 1, due to both the high bar set and market factors, such as accelerating costs and limited vendor capacity. Evidence also suggests that the digital divide is widening, with large and urban hospitals reaching much higher rates of adoption than smaller and rural facilities.

Given the experience to date in Stage 1, the AHA is concerned that elements of the proposed rule for Stage 2 would stand in the way of a successful program to support widespread adoption by all hospitals. Many of the proposals put regulatory requirements ahead of actual experience with these technologies — an approach that will likely have unintended consequences. Our major concerns and recommendations pertain to the implementation of the Medicare penalty phase, the proposed timing and staging of meaningful use Stage 2, the specific objectives and measures for Stage 2, and the reporting of clinical quality measures through EHRs. Our comments are summarized below, and described in the attached detailed comments, including Appendix 1,



which provides a grid of comments on each proposed objective and measure for Stage 2.

Medicare Payment Penalties. We urge the Centers for Medicare & Medicaid Services (CMS) to determine penalties for hospitals paid under the inpatient prospective payment system (PPS) using a reporting year that coincides with the payment year, as proposed for critical access hospitals. The proposed approach to implementing the penalties that begin in fiscal year (FY) 2015 is unacceptable because it bases penalties on performance in a prior year, generally with a two-year look-back. This policy unfairly accelerates the date by which PPS hospitals must meet the meaningful use requirements to avoid penalties. Our detailed comments propose feasible methods to base penalties on same-year reporting on meaningful use for both PPS hospitals and physicians and other eligible professionals (EPs). We also suggest additional hardship exceptions to avoid unfair penalties on hospitals and EPs in certain circumstances, particularly when their vendors fail to deliver as promised, or in a timely fashion.

Timing of Stage 2 and Future Stages. The AHA appreciates the proposed one-year delay in the start of Stage 2, but we caution that the delay may not ensure adequate time to transition from Stage 1 to Stage 2 safely and without undue distortions to the market. We recommend two policies to ease the transition: a 90-day reporting period in the first year of Stage 2 and any subsequent stages, and a length of three years for each stage.

Proposed Requirements for Stage 2. Taken as a whole, the proposed requirements for meeting Stage 2 raise the bar too high and are not feasible for the majority of hospitals to achieve. To make Stage 2 more feasible and less burdensome, and to improve the predictability of changes to the program over time, we recommend that CMS apply the following policies 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 all new objectives through the menu set.
- Move menu items to the core at the same performance threshold set in Stage 1.
- Remove measures that make the performance of hospitals and EPs contingent on the actions of others.

Our members are particularly concerned with the proposed objective to provide patients with the ability to view, download and transmit large volumes of protected health information via the Internet (a “patient portal”). The AHA believes that this objective is not feasible as proposed, raises significant security issues, and goes well beyond current technical capacity. We also believe that CMS should not include this objective because the Office of Civil Rights, and not CMS, regulates how health care providers and other covered entities fulfill their obligations under the *Health Insurance Portability and Accountability Act* (HIPAA), including the obligation to give patients access to their health records. Please see our detailed comments for more recommendations on changes to specific objectives and measures.

Ms. Marilyn Tavenner

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Proposed Quality Reporting Requirements. We strongly urge CMS to defer adding new hospital quality measures to the meaningful use program until Stage 3 so that Stage 2 can be used to make the process viable. The AHA shares CMS's long-term vision of an efficient, accurate and aligned automated quality reporting program. However, hospitals have encountered significant difficulty in using EHRs to report the clinical quality measures (CQMs) required for Stage 1, despite making large investments of financial and human resources. Our detailed comments lay out myriad problems faced in Stage 1 — from inaccurate e-specifications to unworkable, but certified, vendor products — and make specific recommendations to improve the process and avoid wasteful spending on generation of unusable CQM data. The AHA believes that Stage 1 of meaningful use was about getting started with automated clinical quality measurement. We want Stage 2 to be about getting it right.

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 these deployments is central to realizing the care transformation objectives of health reform. We believe the recommendations presented in this letter and our attached detailed comments will move the nation forward in adoption of EHRs and greater information exchange by establishing achievable requirements for Stage 2 of meaningful use. They also will ensure that Congress' goal of widespread adoption of EHRs by hospitals large and small, urban and rural, is met by providing much-needed federal funds 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, AHA director for policy, at (202) 626-2313 or cworzala@aha.org.

Sincerely,

/s/

Rick Pollack
Executive Vice President

Enclosure

**AHA DETAILED COMMENTS ON
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AHA DETAILED COMMENTS ON CMS'S PROPOSED STAGE 2 REQUIREMENTS FOR MEANINGFUL USE

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, 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, the Centers for Medicare & Medicaid Services (CMS) indicated that it intended to implement the program in three, two-year stages: Stage 1 – FYs 2011-2012; Stage 2 – FYs 2013-2014; and Stage 3 – FY 2015 and beyond. The proposed rule puts forth regulatory requirements for the following elements of Stage 2: revised timing (including future stages); implementation of future penalties; objectives and measures of meaningful use; and quality reporting requirements. The rule also proposes changes to Stage 1 requirements, program operations and the Medicaid EHR Incentive Program.

The American Hospital Association’s (AHA) detailed comments first address the experience in Stage 1 of “meaningful use” of electronic health records (EHR). We then provide comments on the proposed timing of Stage 2, the proposal for implementation of payment penalties, and the proposed Stage 2 meaningful use objectives and measures. Later sections lay out comments on the quality reporting requirements and other proposed changes in the proposed rule. **Appendix 1 includes a grid of comments on each proposed objective and measure for Stage 2 that is an integral part of our comments.**

EXPERIENCE IN STAGE 1 OF MEANINGFUL USE

The AHA is disappointed that the Centers for Medicare & Medicaid Services (CMS) has not conducted a formal evaluation of the meaningful use program to date nor made reference in the proposed rule to the many sources of data and testimony available on how providers are faring in Stage 1 of meaningful use, which has been in effect for hospitals for more than 18 months. In fact, the only statistical reference to progress in Stage 1 comes on p. 13801 of the proposed rule, where CMS notes that only 8 percent of hospitals and 4 percent of physicians successfully attested to meaningful use and received Medicare EHR incentive payments in the first year of the program.

CMS has at its disposal a number of sources of information on how providers are faring that are useful to inform proposals for Stage 2, including:

- Data on the share and types of hospitals and physicians that have successfully attested to meaningful use over time;
- The menu set objectives that hospitals and physicians have deferred;
- The objectives for which providers have claimed exceptions;

- Data from the AHA's annual survey of hospital use of health information technology (IT), which is partially supported by the Department of Health and Human Services (HHS) as a nationally representative tracking survey; and
- Testimony provided by many hospitals, physicians and Regional Extension Centers (RECs) to the Health Information Technology (IT) Standards Committee and the Health IT Policy Committee in hearings and other sessions. In particular, in January 2011 the Health IT Standards Committee Implementation Workgroup held two days of hearings with testimony from early adopters. In October 2011, the Health IT Policy Committee Meaningful Use Workgroup canvassed experience on Stage 1.

Findings from these sources inform our comments. In particular, Appendix 2 includes analyses from the AHA annual survey of hospital use of health IT from 2008 to 2011, including an analysis of hospitals' adoption patterns, how close they are to meeting Stage 1, and a model of the proposed Stage 2 objectives to determine feasibility. The latest data were collected in Fall 2011 and shared with HHS in December. In a recent *Health Affairs* paper on hospital adoption of health IT a team of researchers finds that:

- The pace of EHR adoption has increased significantly, so that in Fall 2011, 26.6 percent of hospitals had at least a "basic" EHR, up from 15.1 percent in 2010;¹
- Rates of adoption increased across the board but varied widely by hospital type, with large, urban and teaching hospitals having the highest rates; and
- The digital divide has grown across types of hospitals.²

The same paper presents a proxy measure of meaningful use Stage 1 that is less restrictive than the actual requirements. By this measure, only 18.4 percent of hospitals could meet meaningful use Stage 1 in Fall 2011. Small, rural and non-teaching hospitals were much less likely than their counterparts to meet the meaningful use proxy.

These survey results are in line with CMS's data on the number of hospitals that had been paid for meeting meaningful use at the end of March 2012. In its latest monthly payment report, CMS states that 911 hospitals had successfully met meaningful use and received a Medicare payment through the end of February 2012. They represent about 18 percent of the 5,011 hospitals that CMS estimated could be eligible for the program (Stage 1 Final Rule). Of those hospitals that had been paid, CMS reported that 62 were critical access hospitals (CAHs). They represent less than 5 percent of the approximately 1,300 CAHs across the country. Other providers have received payments through their state Medicaid EHR incentive programs but are

¹ These data differ from those presented by HHS in February 2012. The AHA uses the definition of a basic EHR that has been historically used in peer-reviewed publications to preserve the ability to track progress over time, while HHS presented this definition, but highlighted results from a different definition of a basic EHR. The key difference between the two definitions is the inclusion of clinical notes as a functionality. Clinical notes are included in the historical definition, but not in the results presented by HHS.

² DesRoches, et al. *Small, nonteaching, and rural hospitals continue to be slow in adopting electronic health record systems*, Web Exclusive, March 25, 2012.

not required to meet meaningful use in the first year. Thus, when looking at the requirements of meaningful use, the Medicare payments are most germane.

Clearly, the Stage 1 requirements are challenging, and may have overshot the mark in some respects, particularly for small or rural hospitals that started from a lower level of implementation. Raising the bar significantly in Stage 2 risks limiting the success of the Medicare and Medicaid EHR incentive programs. It also could unintentionally discourage providers from adopting EHRs if they do not believe they can meet the requirements. The escalating costs of health IT, limited vendor capacity and workforce shortages also limit providers' ability to achieve meaningful use. HHS and providers have a shared interest in the success of the meaningful use program to support health reform efforts.

TIMING OF STAGE 2 AND FUTURE STAGES

Stage 1 of meaningful use began in fiscal year (FY) 2011 for hospitals and CAHs; for physicians, Stage 1 began in calendar year (CY) 2011. **The AHA agrees with CMS's proposal to delay the start of Stage 2 until FY 2014 for hospitals and CY 2014 for physicians – one year later than previously expected. We caution, however, that this one-year delay may not ensure adequate time to achieve transitions from Stage 1 to Stage 2 safely and without undue distortions to the market. The AHA recommends two changes that would greatly ease the transition:**

- **A 90-day reporting period in the first year of Stage 2 and any subsequent stages, as was done for Stage 1; and**
- **Three years at each stage for all providers.**

The AHA concurs that the one-year delay in the start of Stage 2 will allow a somewhat more realistic timeframe between when the final rules are expected to be released and when hospitals must be meeting the Stage 2 objectives with newly certified products. 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. The market cannot sustain this level of chaos, and the significant challenges that will arise if the proposed timelines and certification requirements – which would require all hospitals to upgrade their EHRs *on the same day* -- are maintained.

The AHA believes that to give vendors sufficient time to modify systems and providers sufficient time to implement upgrades, the final meaningful use and certification requirements must be made public at least 24 months before providers are expected to be in compliance. Therefore, to begin in FY 2014, final requirements would have had to have been issued by October 1, 2011. In a similar vein, the HIT Policy Committee recommended a minimum of 18 months between when final rules are available and when the first providers would need to be in compliance. If the final rules are published in July 2012, providers and vendors would have only

14 months to change and certify software products, negotiate contracts, schedule implementation dates, design and implement workflow changes, test new systems for performance and safety, and begin collecting data for reporting. If the final rules come later than that, the transition period will be shortened and the ability to safely transition from Stage 1 to Stage 2 will be compromised.

A compressed timetable also has an impact on market prices, as providers are forced to compete for limited vendor capacity. The costs of EHRs have increased dramatically since the program began, and our members report that the ability of vendors to provide timely support is decreasing (see discussion of Impact Analysis on page 47). In considering the timeline for Stage 2, CMS should also take into account the impact on the market as vendors seek to bring new providers in at Stage 1, while also supporting a transition to Stage 2 for others.

To achieve a safer, less chaotic transition, the AHA recommends that CMS require a 90-day reporting period in the first year of Stage 2 and any subsequent stages. The success of the transition also will be affected by the length of the reporting period in the first year of Stage 2. CMS has proposed a full-year reporting period in Stage 2, which would mean that the hospitals currently at Stage 1 would need to be in full compliance with the Stage 2 rules on October 1, 2013. The proposals in the ONC certification rule would also require that hospitals still in Stage 1 also upgrade their systems to new certification requirements *on the same day*. Given the limited vendor capacity to work with providers, and the complex nature of the changes proposed, it is unrealistic to ask all hospitals to make the transition to be at Stage 2 on the exact same day as hospitals at Stage 1 upgrade to a new version of certification, and could pose a safety risk if implementations of sensitive clinical applications like computerized provider order entry (CPOE) and clinical decision support are rushed. To address the transition issue in Stage 1, CMS required a 90-day reporting period in the first year of Stage 1. Extending that policy to the first year of each new stage makes sense.

The AHA appreciates CMS's proposal to have hospitals and eligible professionals (EPs) spend two years at Stage 1 before moving to Stage 2, but believes that three years per stage is more realistic. Under the timeline in the Stage 1 final rule, providers that started late faced a rapid escalation to other stages, and in some cases would jump from Stage 1 to Stage 3 in a single year, a situation that would be remedied if the proposed two-year cycle is finalized. However, the one-year delay in the start of Stage 2 means that those first meeting meaningful use in 2011 will receive three years of payment at Stage 1, while hospitals starting later will only receive two years of payment at Stage 1. It would be fairer to apply the same policy to all providers. A three-year cycle also is more realistic, as it provides at least one year for implementation of the current stage before providers and their vendors need to begin to gear up for the next stage. Hospitals and physicians can and will move beyond the regulatory requirements to ensure the best possible care, harness innovations and meet competitive demands. We would hope that CMS will draw on their real-world experience to develop future rulemaking.

Eventually, the focus must shift from meeting the very specific meaningful use criteria to using health IT as the backbone of care delivery transformation. The AHA believes that the meaningful use program was intended to facilitate the transition to widespread use of EHRs, and not to impose a continuous, two-year cycle of mandatory upgrades to EHR products which vendor may not be able to deliver and expanded reporting requirements based on the government's view of what is needed. Providers and vendors agree that the meaningful use program has stifled innovation in the development of new uses of EHRs. It also comes with a high opportunity cost of foregone initiatives within both IT and clinical care, as meaningful use implementations absorb tremendous resources that are needed for other strategic initiatives, including other federal imperatives like the switch to ICD-10.³ In the future, the health care system will benefit most from technology innovations that meet the needs of providers aiming to provide the best possible care for their patients, not to meet regulatory requirements. Accountable care, medical homes and attention to re-hospitalization will drive hospitals to adapt their health IT systems to support these new endeavors – an important task that will require significant resources and room for innovation.

If these two policies are adopted – a 90-day reporting period and a three-year phasing of stages – the meaningful use program has a much better chance of ensuring that all hospitals – and the patients and communities they serve – successfully transition to safe, efficient and effective use of EHRs. There is a policy tension between ensuring widespread EHR adoption and raising the bar on what is done with EHRs. Given all of the competing federal initiatives currently at play, the better approach is to get the vast majority of providers on board with meaningful use Stage 1, while allowing the market to drive innovations that further improvements in care and care processes.

IMPLEMENTATION OF FUTURE PENALTIES

Medicare Payment Penalties for Prospective Payment System (PPS) Hospitals. The AHA believes that CMS's proposal to implement penalties inappropriately accelerates the date by which PPS hospitals must meet the very aggressive meaningful use requirements to avoid penalties. This is unacceptable. In contrast, we urge CMS to determine penalties using a reporting year that coincides with the payment year.

The proposed rule would implement statutory Medicare payment penalties beginning in FY 2015 for inpatient PPS hospitals that fail to meet meaningful use. Specifically, CMS proposes to determine penalties using a reporting year that is two years in advance of the payment year, with one-time exceptions for those in their first year of meaningful use. For example, PPS hospitals would have to successfully attest in FY 2013 to avoid the FY 2015 penalty. If a hospital successfully attested in FY 2011 or FY 2012, but not in FY 2013, it would still incur the

³ See testimony from October 6, 2012 for examples of how meaningful use is limiting providers' ability to pursue other priorities. Available at: http://healthit.hhs.gov/portal/server.pt?open=512&objID=1472&&PageID=17094&mode=2&in_hi_userid=11673&ached=true#100611.

penalties. For each year subsequent to FY 2015, the reporting period for the payment adjustment would continue to be two years before the payment period.

CMS proposes a one-time exception to this two-year look back for those in their first year of meaningful use. For these hospitals, the look back would be 15 months, rather than 24 months. For example, if a hospital had never before attested to meaningful use, CMS proposes to allow it to avoid the FY 2015 penalty by attesting for a continuous 90-day reporting period that begins no later than April 3, 2014 and ends no later than June 30, 2014.

In contrast, the *American Recovery and Reinvestment Act of 2009* (ARRA) set out the penalty structure for hospitals as follows:

(ix)(I) For purposes of clause (i) for fiscal year 2015 and each subsequent fiscal year, in the case of an eligible hospital (as defined in subsection (n)(6)(A)) that is not a meaningful EHR user (as defined in subsection (n)(3)) for an EHR reporting period *for such fiscal year*, three-quarters of the applicable percentage increase otherwise applicable under clause (i) *for such fiscal year* shall be reduced by 33¹/₃ percent for fiscal year 2015, 66²/₃ percent for fiscal year 2016, and 100 percent for fiscal year 2017 and each subsequent fiscal year. (Emphasis added.)

Thus, the law implies that penalties should apply in a given year if a hospital did not meet meaningful use *in that same given year*. In contrast, CMS is generally proposing that penalties apply in a given year if a hospital did not meet meaningful use *two years prior to that given year*. Accordingly, we are very concerned that CMS's proposal does not meet the intent of the law. This is supported by the fact that, under the proposal, a hospital can receive both a penalty and an incentive *in the same year*. For example, if a hospital has not successfully attested prior to FY 2015, it will receive a market-basket penalty in FY 2015. If it then, however, successfully attests during FY 2015, it also will receive an incentive in FY 2015. It seems improbable that Congress intended to apply both penalties and incentives in the same year; such a policy would be nonsensical. Rather, it seems clear that Congress intended to provide incentives for hospitals to meet meaningful use *followed by* penalties for those that do not achieve the requirements.

In addition, under the proposed approach, for FYs 2013 and 2014, certain hospitals that fail to meet meaningful use will face “double jeopardy” by both missing out on the incentive payment for that year, and then receiving a penalty two years down the road tied to that same year. Hospitals may be especially likely to fail to meet meaningful use in these years because the transition to Stage 2, which will occur for certain hospitals, is very aggressive. In addition, the proposed look-back period means that all PPS hospitals risk future penalties if their transition to Stage 2 goes awry, which is not appropriate. The meaningful use standards are hard to meet; hospitals need a substantial amount of time to gather capital, work with overextended vendors, implement technology, train their staffs, and undertake many other activities to successfully meet the requirements.

While we acknowledge the agency's wish to avoid creating a situation in which it might be necessary to make large payment adjustments after the fact, **we believe that the need to provide hospitals with the appropriate amount of time to meet meaningful use requirements far outweighs the concern about large potential payment adjustments.** This is especially true given that hospitals have a mechanism in place to settle payments once actual data are available – the Medicare cost report. **Thus, in a given fiscal year, the AHA recommends the use of an interim market-basket update based on prior-year performance, that is then finalized based on same-year performance, to assess penalties on hospitals that fail to meet meaningful use. Any underpayments or overpayments would be settled on the cost report.**

The agency could administer this process similarly to how it administers other payment adjustments, such as indirect medical education and disproportionate share hospital adjustments, which are subject to cost settlement. Specifically, we urge CMS to use data from the most recently available year for which a hospital has been determined to have either successfully attested (or not) to meaningful use to set the hospital's "interim" market-basket adjustment. Once the determination from a more recent year becomes available, the agency would update that "interim" adjustment. Finally, when the determination for a given year is final, the hospital will settle the market-basket adjustment for that year on its cost report. In practice, this policy would result in CMS using the fiscal year two years prior (or for first-time users, 15 months prior) to determine *interim* penalties, rather than using these years to determine *final* penalties, as it proposed.

For example, at the beginning of FY 2015, the first year in which penalties apply, the most recent determination of meaningful use for a hospital will generally be from FY 2013. Under the AHA's proposed policy, if a hospital successfully attested in that year, CMS would deem it as also successfully attesting in FY 2015 and give it the full market-basket update. Attestations for FY 2014 then must be made by November 30, 2014. If the hospital successfully attests again in FY 2014, CMS would continue deeming it as also attesting in FY 2015 and continue giving it the full market-basket update. If the hospital fails to attest in FY 2014, however, CMS would deem it as not attesting in FY 2015, and would begin applying the market-basket penalty. Finally, once FY 2015 attestations are due on November 30, 2015, CMS would be able to make a final determination of what the hospital's market basket should have been during FY 2015 and would settle the amount on the hospital cost report. This process is summarized in Table 1. The approach of making an interim payment with final settlement is consistent with what CMS has proposed regarding the application of penalties to CAHs. There is no compelling reason that the application should be so markedly different for the two types of hospitals.

Table 1: AHA’s Recommended Reporting Periods to Assess Payment Penalties for PPS Hospitals

	FY 2015	FY 2016	FY 2017
Initial interim market-basket update (made October 1)	FY 2013 or before July 1, 2014 if attesting for first time	FY 2014 or before July 1, 2015 if attesting for first time	FY 2015 or before July 1, 2016 if attesting for first time
Updated interim market-basket update (made around January 1)	FY 2014*	FY 2015*	FY 2016*
Final market-basket update (settled on cost report)	FY 2015**	FY 2016**	FY 2017**

* No update would be necessary for hospitals attesting by July 1 for the first time.

** For those attesting for the first time in this year, the final market-basket update would be able to be set mid-year if the hospital attests by mid-year.

Under this proposal, very large payment adjustments would come into play only in limited instances: for certain hospitals attesting for the first time and for hospitals that do not attest successfully in consecutive fiscal years. We believe such adjustments would be fairly balanced between the hospital owing CMS a large amount upon settlement, and CMS owing the hospital a large amount upon settlement; in addition, these instances would decrease over time as more and more hospitals are able to consistently achieve meaningful use. For example, a hospital attesting for the first time in FY 2015 would be deemed as not attesting in FY 2015 until it does so for a continuous 90-day reporting period. If that 90-day period occurs after mid-year, the hospital would incur the market-basket penalty for most of the fiscal year, and CMS would perhaps owe the hospital a large amount upon settlement. As another example, if a hospital successfully attested in FY 2014, CMS would deem it as attesting in FY 2015 and it would receive the full market-basket update. If that hospital does not successfully attest in FY 2015, however, it would need to pay CMS the penalties it should have incurred. Subsequently, this hospital would be deemed as not attesting in FY 2016 and would receive the penalty in that year. If it does successfully attest in FY 2016, however, the agency would need to repay the hospital for the penalties it incurred.

Medicare Penalties for CAHs. The AHA supports the proposed approach to implementing penalties on CAHs. Statutory penalties also apply to CAHs that fail to meet meaningful use requirements. For CAHs, the penalties would reduce cost-based payments from 101 percent to 100.66 percent in FY 2015, 100.33 percent in FY 2016, and 100 percent in FY 2017 and beyond. CMS proposes to align the reporting year for determining CAH penalties with the payment year. CMS notes that the Medicare cost report process would allow it to make the CAH reduction for the cost-reporting period that begins in the penalty year, with minimal disruption to the CAH’s cash flow and minimal administrative burden on Medicare contractors. For example, any CAH

that is not a meaningful user in FY 2015 will incur penalties for its cost-reporting period that begins in FY 2015.

Hardship Exceptions. CMS proposes to grant exceptions to the penalties for certain hospitals. **We urge the agency to clarify that if a hospital qualifies for an exception after having become a meaningful user, they will not be expected to accelerate their Stage of meaningful use in the year following their exception year.** For example, a hospital that meets Stage 2 in FY 2014, but qualifies for a hardship exception in FY 2015, would be expected to meet Stage 2 (and not Stage 3) in FY 2016.

The first proposed exception could apply to a hospital that is located in an area without sufficient Internet access (as assessed two years prior to the penalty year). **The AHA supports this exception.**

A second proposed exception would apply to new hospitals for at least one full cost-reporting period after they accept their first patients. **We urge CMS to clarify that this exception would apply for at least one cost-reporting period after the hospital accepts its first Medicare patient.** The process for registering for the Medicare program can be burdensome and lengthy. While hospitals are negotiating this arduous process, they often begin seeing non-Medicare patients. However, the fact that they see these patients should not start the “clock” for purposes of their Medicare EHR exception.

In addition, CMS emphasizes that the “new hospital” exception is not available to hospitals that have already been in operation in one form or another, perhaps under a different owner or merely in a different location. It states that the following hospitals would not be considered “new:”

- a hospital that builds new or replacement facilities at the same or another location even if coincidental with a change of ownership, a change in management or a lease arrangement;
- a hospital that closes and subsequently reopens;
- a hospital that has been in operation for more than two years but has participated in the Medicare program for less than two years; and
- a hospital that changes its status from a CAH to a hospital that is subject to the Medicare hospital inpatient PPS (CMS would, however, consider a hospital that changes its status from a hospital (other than a CAH) that is excluded from the Medicare inpatient PPS to a hospital that is subject to the inpatient PPS to be a new hospital for purposes of qualifying for this proposed exception).

CMS then acknowledges that a CAH that becomes an inpatient PPS hospital would, of necessity, receive a new CMS Certification Number (CCN) and states that it would allow the CAH to register its meaningful use designation obtained under its previous CCN in order to avoid being subject to penalties. However, the agency does not clarify whether a hospital would be considered new if a change of ownership has occurred and a new CCN is assigned due to the new owner’s decision not to accept assignment of the prior provider agreement. **We urge CMS,**

similar to its proposed policy for CAHs converting to PPS hospitals, to allow such hospitals to register the meaningful use designation obtained under their previous CCN to avoid being subjected to penalties. Doing so creates consistency within the “new hospital” exception and, quite simply, seems fair.

Finally, CMS proposes an exception for hospitals under extreme circumstances, such as the hospital’s closing, a natural disaster in which the EHR system is destroyed, or the hospital’s EHR vendor goes out of business. **The AHA urges CMS to include the following additional circumstances under this “extreme circumstances” exception.**

- We urge the agency to include an exception for hospitals in severe financial distress, such as bankruptcy/restructuring of debt.
- We also urge the agency to include an exception for hospitals whose EHR vendor (of either a complete or modular EHR) fails to deliver agreed-upon services and equipment. As growing numbers of providers seek to meet meaningful use, the market capacity to serve them will be strained. HHS and the Department of Labor have estimated a large workforce shortage among health IT professionals, and our members are reporting increased prices for products and services, delays in vendor schedules and limited ability to attract and retain needed clinical IT expertise. For instance, Ascension Health reported at a Meaningful Use Workgroup Hearing in May 2011 that, “[s]ince January 1 of this year, 40 of our 61 eligible hospitals have reported delays in their ability to reach their expected dates for Meaningful Use Stage 1 compliance” due to these factors (the full testimony is available at: http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_12811_954637_0_0_18/muwg-davis-testimony-05-13-11.pdf).
- We urge CMS to add an exception for hospitals whose existing vendor (for either a complete or modular EHR) fails to achieve new certification. Having a certified EHR is a baseline requirement of meaningful use. If a vendor with which a hospital has an existing contract or licensing agreement fails to achieve certification, or to do so in a timely fashion, the provider should not be penalized.
- We urge CMS to add an exception for hospitals that have made good faith efforts to purchase certified EHR technology but could not find a vendor willing to work with them, perhaps due to small size or remote location.
- We urge CMS to add an exception for hospitals that determine they must switch EHR vendors to achieve meaningful use.

Medicare Penalties for EPs. The AHA opposes CMS’s proposal to implement the Medicare EP payment penalty based on a reporting period that is two years prior to the payment penalty year. The law requires Medicare payment penalties beginning in CY 2015 for physicians and other EPs that fail to meet meaningful use. The penalty is a 1 percent reduction to an EP’s physician fee schedule (PFS) payments in CY 2015, a 2 percent reduction in CY 2016 and a 3 percent reduction in CY 2017. Thus EPs will receive 99.0 percent, 98.5 percent and 98.0 percent respectively of their Medicare Part B PFS amount for covered professional services. For CY 2018 and beyond, if fewer than 75 percent of EPs meet meaningful use, then the penalty

increases by an additional percentage point (but is capped at a 5 percent reduction). The payment adjustments do not apply to hospital-based EPs.

Similar to PPS hospitals, CMS proposes to determine penalties using a reporting year that is two years in advance of the payment year, with exceptions for those in their first year of meaningful use. This means that EPs would have to successfully attest to meaningful use in CY 2013 to avoid the CY 2015 penalty. For each subsequent year, the EHR reporting period for the payment adjustment would continue to be the calendar year two years prior to the payment period. Also similar to PPS hospitals, CMS proposes a one-time exception to this two-year look back for those in their first year of meaningful use. For these EPs, the look-back period would be 15 months, rather than 24 months. Thus, to avoid the CY 2015 penalty, new EPs would need to attest for a continuous 90-day reporting period that begins no later than July 3, 2014 and ends no later than October 1, 2014. This policy also would continue in subsequent years for EPs who are in their first year of demonstrating meaningful use.

The two-year look-back would inappropriately accelerate the date by which EPs must achieve meaningful use and could result in EPs both getting an incentive and receiving a penalty in the same year for a period of time (CYs 2015 and 2016). As with PPS hospitals, the intent of the law is a same-year reporting period, with penalties based on EP services provided in CY 2015 and beyond. CMS's proposal of basing CY 2015 penalties on CY 2013 activities does not provide EPs with the appropriate amount of time anticipated by Congress to meet meaningful use requirements before significant payment penalties begin.

For the CY 2015 payment penalty, the AHA recommends using any 90-day continuous reporting period during the first six months of CY 2015 (January 1-June 30, 2015) with payment penalties beginning October 1, 2015. All EPs – including those in their first year of meaningful use – would be required to successfully demonstrate meaningful use during a continuous 90-day reporting period during the first six months of CY 2015. This would then allow CMS three months (through September 30), which CMS states in the NPRM is an “adequate time both for the systems changes” and payment adjustments needed to apply penalties (p. 13769). CMS then would be able to implement the payment penalty on October 1, 2015, and the penalty would apply for the remaining three months of CY 2015. Thus, EPs would have a reporting period in CY 2015 *and* would be subject to payment penalties in CY 2015.

Under this scenario, CMS would not need to recoup overpayments or make additional payments after a determination is made about whether the payment penalty applies. In addition, it would not be necessary to recalculate beneficiary coinsurance amounts. It would provide CMS sufficient time to implement the system edits necessary and apply any required penalties correctly. While it would not allow CMS time to inform EPs in advance of the payment year whether they would be subject to a payment adjustment, it would give EPs until CY 2015 to meet meaningful use. Specifically, it would give EPs until July 1, 2015 so that they could complete the 90-day reporting period by June 30 (allowing the EP a 90-day reporting period, followed by one extra day to successfully submit the attestation and any other information necessary to avoid the payment penalty). We believe that this proposal is operational for CMS,

reasonably fair to EPs, and best reflects the intent of Congress. If CMS needs additional time for system changes and other operational considerations, it could shorten the 90-day reporting period.

For the CY 2016 payment penalty, the AHA recommends using an EHR reporting period of the last six months of 2015 (July 1 – December 31, 2015), or the first 90 days of CY 2016 (January 1 – March 30) for EPs in their first year of meaningful use, with payment penalties beginning July 1, 2016. For CY 2016, all EPs would be required to successfully demonstrate meaningful use during the entire last six months of CY 2015. CMS would then have the first six months of CY 2016 (through June 30) to make the appropriate system changes and adjustments. CMS then would be able to implement the payment adjustment on July 1, 2016, and the adjustment would apply for the remaining six months of CY 2016. For the second year of payment penalties, EPs would be subject to a look-back period, as 2016 payments would be based on activities in 2015. However, this look-back period of twelve months (given penalties would start July 1) is much shorter than CMS's proposed 24 months. This policy would allow for EPs to continue demonstrating meaningful use, as the reporting period would not be the same for CY 2015 and CY 2016 payment penalties.

For EPs in their first year of meaningful use, CMS would allow them to successfully demonstrate meaningful use during a continuous 90-day reporting period during the first three months of CY 2016 (January 1 – March 30). CMS would then have 90 days to make the appropriate system changes, and would implement the payment penalty for all EPs on July 1, 2016. The payment penalty would thus apply for the last two quarters of 2016 (July 1 – December 31).

For CY 2017 and all subsequent payment penalty years, the AHA supports using the first six months of the prior calendar year as the reporting period (i.e., January 1 – June 30, 2016) with payment penalties beginning January 1 the following calendar year (i.e., January 1, 2017). Beginning in CY 2017, all EPs would be required to successfully demonstrate meaningful use during the first six months of 2016.

CMS would then have the last six months of the calendar year to make system changes and inform EPs whether or not they will receive a penalty. This would shrink the look-back period from CMS's proposed two-year time period to one. It also would more closely align the EHR penalty program with the e-prescribing program, which uses the first six months of the prior calendar year to assess the following year's payment penalty (for example, the January 1- June 30, 2011 payment year was used for the 2012 payment adjustment). Table 2 summarizes this approach.

Table 2: AHA’s Recommended Reporting Periods to Assess Payment Penalties for Physicians and other EPs

	CY 2015	CY 2016	CY 2017	CY 2018
Reporting Period	90-days continuous period within first 6 months of CY 2015 (Jan 1- Jun 30, 2015)	Last 6 months of CY 2015 (Jul 1- Dec 31, 2015) or first 90-days of CY 2016 for first time meaningful use.	First 6 months of CY 2016 (Jan 1- Jun 30, 2015)	First 6 months of CY 2017 (Jan 1- Jun 30, 2016)
Penalties begin	Oct 1, 2015 (1 quarter)	July 1, 2016 (2 quarters)	Jan 1, 2017 (full year)	Jan 1, 2018 (full year)

The result would be a three-year transition to full penalties. According to CMS’s data, at the end of January 2012 only 22,937 (about 4 percent) of EPs had received an incentive payment for meeting meaningful use requirements. In its regulatory impact statement, CMS projects that between 21 percent (low estimate) and 53 percent (high estimate) of EPs will meet meaningful use requirements in CY 2015. CMS also estimates that the average cost for an EP to adopt/implement/upgrade certified EHR technology is \$54,000 and maintenance is another \$10,000 a year, suggesting that the total incentives available for EPs will not cover the cost and maintenance of the technology.

Physicians should be provided a transition to the implementation of Medicare penalties. It has been difficult for EPs to keep up with the multitude of health IT and other reporting demand affecting their practices. Most are still struggling to meet e-prescribing requirements, even though payment penalties for this program begin in January. Only approximately 20 percent of physicians voluntarily report to the Physician Quality Report System (PQRS); yet, also beginning in 2015, those who elect not to participate in PQRS will be penalized 1.5 percent of their Medicare payments. In addition, many physicians are still transitioning to the 5010 administrative transaction standards in preparation for ICD-10. And, EPs are facing numerous other initiatives including implementing medical homes, bundled payment, accountable care organizations and other delivery and payment system reforms. A transition would meet the requirements of the statute while allowing EPs until CY 2015 to meet meaningful use, and would smooth the implementation of payment penalties.

Hardship Exceptions for EPs. By law, EPs may be exempted on a case-by-case basis from the penalty if the Secretary determines that compliance with the requirements for being a meaningful EHR user would result in significant hardship. This exception is subject to annual renewal, and in no case may an EP be granted an exception for more than five years.

CMS proposes the following exemptions:

- EPs who practice in areas (urban and rural) without sufficient Internet access, as determined two years prior to the payment adjustment year;
- New EPs, for two years after they begin practicing; and
- Extreme circumstances during the two years preceding the payment adjustment year, such as a practice shutting down, a natural disaster in which an EHR system is destroyed or an EHR vendor going out of business.

The AHA supports these three hardship exceptions and recommends expanding the exemption for extreme circumstances to include vendor issues beyond just the vendor going out of business. EPs, especially those who are solo practitioners and those in rural communities, are often at the bottom of vendors' lists for upgrading or installing certified EHR products. We encourage CMS to consider it an extreme circumstance when EPs work with vendors who fail to provide the products and services necessary for physicians to meet meaningful use criteria in the timeframes necessary, or vendors who fail to get their products certified, either at all or in a timely manner. If EPs have made good faith efforts, they should not be penalized. EPs should not have a significant amount of their payments affected by the failure of another party to meet its contractual obligations.

In the proposed rule, CMS also seeks comment on the appropriateness of granting an additional exception for EPs who face all three of the following barriers (regardless of specialty):

- Lack face-to-face or telemedicine interaction with patients;
- Lack follow-up with patients; and
- Lack control of the availability of certified EHR technology at their practice locations.

The AHA recommends that CMS adopt the hardship exemption above, but for EPs who meet two of the three criteria. We believe that certain physician specialties, such as pathology, radiology and anesthesiology, will have an extremely difficult time complying with the meaningful use criteria. These types of specialties have very little patient interaction, making many of the meaningful use objectives (such as generating electronic prescriptions, recording vital signs and smoking status, and performing medication reconciliation) irrelevant. However, there may be certain circumstances when, for example, a pathologist may have a need to follow-up with a patient with a face-to-face encounter. This situation is likely rare, but the EP should not be penalized or disincentivized from doing so if it is in the best interest of patient care. Thus, we believe EPs should have to meet only two of the three barriers listed. In addition, we recommend that CMS apply this exception based on specialty or other groupings that generally meet the above criteria rather than require a case-by-case determination, which is more burdensome for both CMS and EPs. Finally, we encourage CMS to consider whether an additional hardship exemption is warranted for those providers to whom more than one-third of the meaningful use objectives do not apply, which would likely include specialties such as pathology.

OBJECTIVES AND MEASURES OF MEANINGFUL USE

If the proposed two-year look back for assessing penalties is maintained, all PPS hospitals risk the double jeopardy of both missed incentives and future penalties if their transition to Stage 2 is not successful. Therefore, we must ensure that the Stage 2 proposals are clearly achievable to avoid unfairly penalizing hospitals. In Stage 2, CMS proposes to require that hospitals:

- Have certified EHR technology;
- Meet (or qualify for an exception to) each of 16 core objectives and two of four menu set objectives, for a total requirement to meet 18 of 20 Stage 2 objectives; and
- Electronically generate and report on 24 clinical quality measures from a menu of 49 using certified EHR technology. The proposed rule continues the approach of Stage 1 that requires the same set of meaningful use criteria for hospitals large and small, rural and urban.

CMS proposes regrouping and combining objectives from Stage 1 in ways that decrease the total number of objectives in Stage 2, but not the performance requirements. Changes from Stage 1 to Stage 2 include:

- Increasing performance thresholds and/or expanding definitions (such as increasing the CPOE requirement from 30 to 60 percent of medications and expanding the type of orders to include laboratory and radiology);
- Requiring most measures that were optional in Stage 1;
- Combining related objectives;
- Adding five new objectives; and
- Making quality reporting a separate category of requirements, rather than a single objective of meaningful use.

While the total number of objectives has gotten smaller (20 in Stage 2 versus 24 in Stage 1), an AHA analysis shows that the actual functions required have gone up precipitously, as shown in Appendix 3. Two examples illustrate the point; one relatively simple, the other remarkably complex:

- **Clinical decision support (CDS):** In Stage 1, two objectives addressed aspects of CDS and together required hospitals to implement three clinical decision support functions: drug/drug alerts; drug/allergy alerts; and a single clinical decision support rule that met a priority area for the hospital. In Stage 2, however, a single objective includes each of the three Stage 1 requirements, and adds implementation of four additional CDS tools, so that a total of seven CDS tools must be implemented. In addition, the proposed rule would require hospitals to match each of the five non-medication CDS tools to a clinical quality measure (CQM) that is reported for meaningful use. Thus, a “consolidation” of two objectives is actually a more than 100 percent increase in the functional requirements to use CDS tools (from three to seven), with the addition of a requirement – the tie to the CQMs – that complicates both the choice of clinical decision support tools, as well as

reporting on the measure. To report on this single objective, hospitals will need to track seven different CDS functions and also develop a process to measure and report on the relationship between five of the CDS functions and the CQMs. The measure further requires that the hospital implement each CDS “for the entire reporting period,” which will then require an operational process to document and report on the timing for each CDS tool.

- **Patient portal:** The single new objective to provide patients the ability to view online, download and transmit information about a hospital admission subsumes five objectives from Stage 1 and adds five new functionalities as part of the new objective, for a total of 10 functional requirements. The objectives from Stage 1 are:
 - Provide patients with a copy of their health information;
 - Provide patients with discharge instructions;
 - Problem list;
 - Medication list; and
 - Medication allergy list.

The new functionalities added include:

- Care summary;
- Care plan;
- Patient portal view;
- Patient portal download; and
- Patient portal transmit.

This approach makes the relative change in burden appear small (five objectives have been “removed” and “only one” added), but in fact increases it dramatically (from five to 10 functional requirements). We believe this approach will lead to unintended consequences by increasing the complexity of the program, increasing the burden of measurement and reporting, and unnecessarily raising the costs of EHRs to accommodate new combinations and permutations of existing functions. These changes, if adopted, would lead to real costs for product changes, certification, purchase of newly certified products, installation, training and changes to workflow to both meet the objectives and conduct the required reporting.

The AHA is concerned that, taken as a whole, the proposed requirements for Stage 2 would raise the bar too high and are not feasible for hospitals to achieve. Our analysis of the functional requirements in Appendix 3 shows that, while the total number of objectives went down from 24 in Stage 1 to 20 in the Stage 2 proposed rule, the actual number of functions embedded in those objectives increased by about 50 percent overall, from 49 functions in Stage 1 to 73 functions in Stage 2. When the Stage 2 requirements for meeting the core and menu set objectives are applied, the number of functions that are needed to achieve meaningful use increased by more than 60 percent, from 43 functions in Stage 1 to 70 functions in Stage 2. We include reporting of CQMs in this tally to make an apples-to-apples comparison. While others may define the functions differently, the overall point remains: **The proposed rule raises the bar significantly for Stage 2 compliance, and represents more than a 50 percent increase in actual requirements.**

The large number of detailed functional and reporting requirements contained in the rule are at odds with President Obama's Executive Order 013563, issued January 18, 2011, calling on federal agencies to streamline and minimize regulatory burden. They also detract focus from the real goal of implementing EHRs: improving patient care. Regulation should be about minimum necessity, and the sheer volume of requirements in this proposed rule poses a significant compliance burden in tracking and reporting.

In addition, the proposed rule comes very close to replicating the "all-or-nothing approach" that CMS first proposed for Stage 1 but then rejected in the final rule. The proposed rule would require hospitals to meet 18 of 20 objectives (90 percent) and report on 24 clinical quality measures. Looking at it from the perspective of functions, rather than objectives, hospitals would have to successfully deploy and report on 70 functions. Failure to meet any one of those requirements would lead to both a lost incentive payment and a future penalty.

Analysis of the AHA's survey of hospital use of health IT supports the conclusion that the proposed Stage 2 criteria are overly aggressive and create too heavy a burden. As described in Appendix 2, we used data collected in Fall 2011 to model the Stage 2 objectives and measures. Not all objectives and measures could be modeled due to data issues. However, among the 22 objectives (or embedded functions) we could model, only 33 hospitals – or just over 1 percent – could meet all of these requirements in Fall 2011. That means that more than 98 percent of hospitals could not meet Stage 2 today. While hospitals are making good progress on specific EHR functionalities, and progress will continue over the next few years, the sheer breadth of proposed requirements, and the associated thresholds, puts the proposed Stage 2 objectives out of reach for the vast majority of hospitals. The analysis also shows that specific subgroups, including CAHs, other rural and small hospitals, are even less likely to meet the proposed requirements. For example, while 29.7 percent of urban hospitals could meet 17 or more of the 22 Stage 2 requirements we could model, only 23.4 percent of rural and 16.6 percent of CAHs could do so. The same disparities exist by hospital size: 37.2 percent of hospitals with more than 200 beds could meet 17 or more objectives, falling to 23.7 percent among hospitals with 100 to 199 beds, and 17.8 percent among hospitals with fewer than 100 beds. We do not believe that Congress intended the meaningful use program to be out of reach of the majority of hospitals.

The AHA recommends that CMS adopt the following policies to make Stage 2 more feasible and less burdensome, and to improve the predictability of changes to the program over time. These policies should apply to objectives and measures for both hospitals and EPs.

- **Preserve the core/menu approach and use it as a means to introduce new requirements into the program. No new objectives should be placed directly into the core requirements.** Of the five new hospital objectives in the Stage 2 proposed rule, two (eMAR and Patient Portal) were placed directly into the core.

- **Move menu items to the core at the Stage 1 performance threshold.** Hospitals could defer up to five menu objectives in Stage 1. Providers should not be expected to meet a raised performance threshold for these objectives, as some will be new to them.
- **Remove objectives 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, CMS should defer to the Office of Civil Rights (OCR) to establish and enforce regulations that fall into its purview, including: (a) *Health Insurance Portability and Accountability Act* (HIPAA) requirements to provide patients access to their medical records, including those in electronic form; and (b) HIPAA requirements to ensure the security of protected health information held in electronic form.
- **Remove measures that make the performance of hospitals and EPs – and their incentive payments or future penalties – contingent on the actions of others.** Several of the proposed measures for Stage 2 would make the performance of hospitals contingent upon the actions of patients or other providers. Specifically, whether a hospital met the objective to provide a patient portal would be tied to the share of patients who have actually accessed it. In addition, whether a hospital meets the objective to provide a summary of care record for each transition of care or referral would be dependent on the organizational affiliation and specific EHR used by the recipients. For EPs, three measures tie the EP's performance to the actions of others (patient portal, secure messaging and summary of care record). We believe these measures are unreasonable and unfair, as they depend on factors outside providers' control.
- **Ensure that all objectives – and the embedded functions – are supported by a body of evidence on their benefits, and how the benefits outweigh the costs of requiring that every provider across the nation install them.** Some functions proposed for Stage 2 have no current use and have not even been piloted. For example, we are not aware of any commercially available patient portal used in health care today that has the ability to accommodate a patient request entered via the Internet to transmit to a third party the huge volumes of protected health information proposed in the rule using the standards included in the Office of the National Coordinator's (ONC) rule.
- **Simplify and field test the meaningful use measures.** Overwhelming feedback on Stage 1 indicated that the complex measures are difficult to understand. Scoping and operationalizing the measures have diverted scarce human and financial resources from the more important goal of deploying technology to improve care. In addition, Medicare payments – and looming penalties – will be tied to providers' performance on the meaningful use metrics, suggesting that they must be fair and reliable. To ease burden, simple measures that rely on simple counts and deployment of functionality, rather than complex percentages based on multiple denominators are preferred. In the proposed rule, CMS states that Stage 2 will include “only” four “uniform” denominators for the hospital objectives. However, closer analysis of the measures suggests that there are 10 unique

denominator specifications, including: unique patients, patients admitted, patients discharged, transitions of care, medication orders, laboratory orders, radiology orders, permissible discharge medication orders, clinical laboratory test results, and scans and tests whose result is an image. **The AHA recommends that CMS actively test whether the measures are, in fact, feasible to calculate before they are finalized.** What data are required? Can they be drawn from the electronic health record? Do different vendor products get the same value if provided with a sample data set?

Appendix 1 tracks the changes to the Stage 2 objectives that would flow from these policy approaches, and provides data on experience from Stage 1, as well as additional recommendations on how the objectives and measures should be changed to make Stage 2 ambitious but feasible and not overly burdensome. It is an integral part of our comment letter.

In addition, the next section highlights our comments on a limited set of meaningful use objectives that raised significant concerns among our members. These changes are proposed in the spirit of making the program less complex and more feasible for hospitals and EPs. **We urge CMS to seriously consider and act on these recommendations to ensure a successful EHR incentive program.**

COMMENTS ON SPECIFIC OBJECTIVES AND MEASURES

This section provides comments on selected objectives and measures. **See Appendix 1 for comments on each measure.**

Patient Portal. CMS proposes as a new objective: provide patients the ability to view online, download, and transmit information about a hospital admission. **The AHA recommends that this objective be removed for two reasons: (1) CMS does not have regulatory authority over patients' access to their health records; and (2) the objective is not feasible as specified.** We also offer an alternative approach.

The proposed objective has two measures:

1. More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge.
2. More than 10 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the reporting period.

Specifically, CMS proposes to require that the following information be available within 36 hours of discharge:

- Admit and discharge date and location.
- Reason for hospitalization.
- Providers of care during hospitalization.
- Problem list maintained by the hospital on the patient (verified to be up to date)
- Relevant past diagnoses known by the hospital.
- Medication list maintained by the hospital on the patient (both current admission and historical, and verified to be up to date).
- Medication allergy list maintained by the hospital on the patient (both current admission and historical, and verified to be up to date).
- Vital signs at discharge.
- Laboratory test results (available at time of discharge).
- Care transition summary and plan for next provider of care (for transitions other than home).
- Discharge instructions for patient.
- Demographics maintained by hospital (gender, race, ethnicity, date of birth, preferred language and smoking status).

All of these data elements would need to be available for patients to:

- View online;
- Download in both a “human readable form,” as well as coded to the specific vocabulary, document, and other standards adopted by ONC; and
- Request that the hospital transmit the information via secure email to individuals named by the patient.

Regulatory authority. **CMS does not have regulatory authority over patient access to electronic health information.** We again urge CMS not to create in, or facilitate through, the meaningful use rule a potentially different or conflicting set of obligations for privacy and security compliance. Compliance with all HIPAA privacy requirements, including those for electronic access under the *Health Information Technology for Economic and Clinical Health (HITECH) Act*, is mandatory for all hospitals and providers whether or not they participate in EHR incentive programs because they are covered entities under the HIPAA rules. It is the Office of Civil Rights (OCR), and not CMS, that regulates and enforces HIPAA. The inclusion of this particular objective and related measures in the meaningful use rule is inappropriate and we urge CMS not to adopt the proposal. As an alternative, we urge CMS to wait until OCR has finalized its electronic access standards before proceeding to incorporate its own set of objectives and associated measures for electronic access for information in the EHR into the meaningful use requirements.

CMS’s decision to put forward a meaningful use Stage 2 objective with associated measures designed to “provide patients the ability to view online, download, and transmit information about a hospital admission” is at best premature given that no final rule has been issued to implement HITECH’s specific mandate for a right of patients to obtain electronic copies of their

protected health information when that information is part of an EHR. Section 13405(e) of HITECH specifically provides that, “in the case that a covered entity uses or maintains an electronic health record with respect to protected health information of an individual – the individual shall have a right to obtain from such covered entity a copy of such information in an electronic format...” As noted, the Secretary’s authorities under HIPAA privacy and security law, including modifications mandated by HITECH, have been assigned to and are exercised specifically by the HHS OCR. To date, OCR has received comments on its own significantly flawed original proposal to implement this section of HITECH, but has yet to finalize the standard.

It is, therefore, inappropriate to use the meaningful use regulatory process to propose a fundamental change to patients’ rights to access their protected health information without taking into account HIPAA privacy and security requirements, or to do so in a way that may be inconsistent with OCR’s standards for electronic access and ultimately unworkable for hospitals that are obligated to comply with the OCR standard.

Congress mandated in statute that the standards and policies recommended and adopted for meaningful use must “take into account the requirements of HIPAA privacy and security law.” Importantly, Congress also made clear that the meaningful use enabling statute “may not be construed as having any effect on the authorities of the Secretary under HIPAA privacy and security law.” Yet, in making this proposal, CMS fails to take seriously either of these statutory directives.

Not knowing OCR’s standard related to electronic access to protected health information that is part of an EHR, CMS cannot be said to have taken into account in its meaningful use proposal the requirements of HIPAA privacy and security law. Additionally, CMS usurps OCR’s authority by establishing a standard applicable to a certain subset of a patient’s protected health information that equates “electronic format” solely with “mak[ing] this information available online” the means of which may be at the discretion of the hospital “[a]s long as the patient can view and download the information using a standard web browser and internet connection.” Further, CMS specifies that the information shall be “available online within 36 hours of discharge.” Although CMS encourages comment on whether this is an appropriate timeframe for the new measure, the agency makes clear that it sees “no compelling reason to alter” the timeframe which was specifically recommended by the HIT Policy Committee.

Even in OCR’s original proposal to implement HITECH’s access right, electronic format was not equated solely with online access. HHS proposed to require only that covered entities provide an electronic copy of protected health information in a form and format requested by the individual, if it is readily producible, “or if not, in a readable electronic form and format as agreed to by the covered entity and the individual” (see *75 Fed. Reg.* 40923). The AHA, in comments to OCR on the proposal, pointed out that “it is reasonable for covered entities to accommodate the individual’s requested format where possible but [we urge] HHS to clarify that patients do not have unlimited choice if their preferred option is not available. We suggest that each covered

entity should have the flexibility to determine the variety of electronic formats it will offer, and a patient should be required to select from those available formats if his or her preferred format is not readily producible.”

The AHA also supports OCR’s proposal to apply a single timeliness standard to the electronic access right that is consistent with the existing Privacy Rule, requiring response to an access request without unreasonable delay and no later than 30 days following the request. As we pointed out, “[t]his approach is preferable to imposing different timeliness standards based on the manner in which the protected health information is maintained.” Our comments to OCR are equally applicable to CMS’s meaningful use proposal. Different timeliness standards would be complicated to administer. This would be particularly true if different standards were to apply to different types of electronic designated record sets. The uncertainty as to whether a particular electronic system meets the criteria for a 30-day response time (or some other specified time period) would in itself cause delay.

Further, 30 days are necessary to make determinations about how to respond to a request no matter the format of the protected health information. While providing an electronic copy of protected health information maintained in an EHR eventually may be facilitated more easily by technology, the process of determining which records are relevant and appropriate takes the same amount of time as it does for evaluating paper records.

Feasibility. **In addition to concerns about duplicative and contradictory regulations, we do not believe this objective is feasible as specified.** Establishing a web portal or other mechanism to provide patients online access to this magnitude of data is unrealistic and premature. AHA survey data indicate that only 10 percent of hospitals had a patient portal of any kind in Fall 2011. Our members report that none had anywhere near the functionality required by this objective. In canvassing vendors, they report no technology companies can currently support this volume of data or the listed functions. Further, the related measures in Stage 1 that this replaces were among the most challenging to establish, and for hospitals that have attested, there were high rates of exclusion: 68 percent claimed an exclusion of the Stage 1 e-copy of health information and 59 percent claimed an exclusion for the Stage 1 e-copy of discharge instructions. Given that the exclusions were provided if no patients asked for an e-copy of the information, it seems clear that patient demand for this information is not yet strong.

In addition, some of these portal requirements are beyond the scope of functionality required in the other meaningful use objectives. There is also inconsistency between the ONC and CMS rules on this topic. In particular, ONC includes a requirement that the portal make images available to view, download and transmit in a particular standard for radiology images, DICOM. Images are generally very large files, and would require that the individual downloading or receiving the file have specialized, expensive software to access the images. The effort required to make the images available would be tremendous.

Although the performance threshold is set at 50 percent, in practice, hospitals would need to post all patient information to the portal, as the hospital cannot know in advance which patients would

like to access information online. It also is unclear how the time-bound aspect of the measure would work – whether all data need to be accessible via the Internet, even if a patient does not have an account. It is also unclear whether a hospital would be expected to spend resources to post information and verify that all of the data listed are available within 36 hours, even if they are not requested. In the context of a program that is setting regulatory requirements for all hospitals, regardless of size, we are concerned that the resources required to establish and maintain these portals are prohibitive. The objective also raises many operational questions, including: which clinician would decide the information that is appropriate to include; how these large volumes of data would be managed; what mechanisms are needed to create and manage patient accounts; and how to keep the data secure. Furthermore, if the hospital chooses to contract with a vendor to host its portal, or sends data to a personal health record or a health information exchange, it will be very difficult to track both data availability and patient use of the data, as required by the measures.

The online access to what is essentially the full EHR – whether through a portal or a personal health record – also creates tremendous security risks and provides rich targets for those looking to illegally access protected health information. The transmit function also heightens security risks, as the hospital could be asked to send data to an individual with whom it has no existing relationship and no mechanism for authentication of their identity. For hospitals in states with the most rigorous privacy protections, this becomes even more challenging.

Alternative approach. **In light of our recommendation to remove the patient portal requirement, the AHA recommends that CMS keep the problem list, medication list and medication allergy list in the core set.** These three data elements are of vital clinical importance and are rightly called out in the meaningful use program. Our members report, however, that maintaining a problem list in the required structured format is challenging. One reason for this is how physicians currently document their findings, which can include written and dictated notes. Transferring these clinical observations into a structured, coded problem list in the EHR requires significant changes to work flows and training to ensure accuracy. It also increases time demands for documentation by physicians who already are stretched thin. Finally, many inpatient stays involve both confirming specific problems and ruling out suspected problems that can result in dozens of items in the problem list. **Therefore, we recommend that the problem list threshold remain at the Stage 1 level of 50 percent.** The AHA also will recommend to ONC that it maintain the current optionality in the standards used to record problem lists, namely either ICD-9 or SNOMED. ICD-10 should be used once HIPAA-covered entities have transitioned to use of ICD-10, which HHS has recently proposed for October 1, 2014.

If CMS decides to keep the patient portal objective over the AHA’s objection, it should be placed in the menu set, as it represents a new functionality. In addition, CMS should:

- **Scale back the scope to a more limited set of data, such as the information required in the Stage 1 measure of an e-copy of discharge instructions.**
- **Remove the transmit functionality.**

- **Remove the 36-hour timeframe requirement, which is too aggressive, unclear and complicates measurement; and**
- **Remove the measure on patient use of the portal to both minimize measurement burden and eliminate a provision that makes provider performance contingent on actions of others.**

The health care field does not yet have sufficient experience with this technology or sufficient understanding of what data patients really want to access online. The most advanced systems will likely expand their efforts in this area. It is prudent to learn from their efforts, start small and smart, and grow over time. HHS also could fund and evaluate specific pilots to understand consumer demand, feasibility and best approaches to managing the increased security risks associated with online access to health information.

Further, if the objective is maintained, the care team and care plan data elements should not be required. These are clearly important data elements and key to clinical care. Almost all hospital EHRs record who has provided care to a patient during a stay, and many also have approaches to recording the plan of care. However, we are concerned that these data elements do not yet have true, useful standards developed. If the current specifications are maintained, hospitals and providers would be in the position of replacing existing approaches to recording these data with minimally specified, but certified data fields, which would unnecessarily increase costs and disrupt practice in the switch from current approaches to those certified by the vendor. **We recommend further research into true standards to support these elements before any requirements are imposed.**

Summary of Care Record. The AHA supports moving from a test to actual exchange of data but recommends significant changes to this objective. CMS proposes to greatly expand the scope of this Stage 1 objective, which consisted of a test to see if a care summary could be transmitted. The proposed Stage 2 objective is: The eligible hospital or CAH that transitions its patient to another setting of care or provider of care or refers its patient to another provider of care should provide a summary of care record for each transition of care or referral.

CMS proposes to require that all of the following information be available as part of the objective:

- Patient name.
- Referring or transitioning provider's name and office contact information (EP only).
- Procedures.
- Relevant past diagnoses.
- Laboratory test results.
- Vital signs (height, weight, blood pressure, BMI, growth charts).
- Smoking status.
- Demographic information (preferred language, gender, race, ethnicity, date of birth).
- Care plan field, including goals and instructions.

- Any additional known care team members beyond the referring or transitioning provider and the receiving provider.
- Discharge instructions.
- A verified, up-to-date problem list of current and active diagnoses.
- A verified, active medication list.
- A verified, active medication allergy list.

Transition is defined as “the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another,” excluding a transition to home when there is no expectation of follow-up care by another provider. A transition within one setting of care does not qualify as a transition of care. Referral is defined as care “where one provider refers a patient to another, but the referring provider maintains their care of the patient as well.” In addition, the electronic submission must use different transport standards than those used in Stage 1, as specified by ONC. Data from CMS showed that 93 percent of hospitals deferred this objective in Stage 1, and testimony to the HIT Policy Committee and HIT Standards Committee indicated this objective was very hard to achieve. AHA data indicate that only 38 percent of hospitals could create the care summary record as specified in Stage 1 – a much smaller set of information than proposed in the proposed rule. Furthermore, AHA data on information exchange – a key component of this proposed objective – indicates that only 15 percent of hospitals could electronically share the care summary with other providers outside of their system in Fall 2011.

The AHA agrees with CMS that it is appropriate to move from a test in Stage 1 to actually sharing the care summary in Stage 2. However, we recommend limiting the scope of data required to be included in the care summary and propose changes to the measures.

Scope of data. This objective is moving from the menu to core set. Therefore, the data elements in the care summary should stay the same from Stage 1 to Stage 2. That way, providers can focus on sharing the information, rather than building up capacity to include more elements. In addition, we believe that clinicians and clinical context will determine the data that are needed at any given transfer of care. In some cases, sharing a small set of data may be preferred to avoid overwhelming clinicians with information they may already have or do not need given the context of care. The meaningful use requirement for providers should only measure 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. Providers should not be required to document and measure whether all fields are populated for all document formats that are generated.

Measures. **AHA members are concerned about the measurement burden associated with this objective, and the way that the second measure makes the success of the provider contingent on the actions of others.** The objective has two proposed measures:

1. The eligible hospital or CAH that transitions or refers its patient to another setting of care or

provider of care provides a summary of care record for more than 65 percent of transitions of care and referrals.

2. The eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care electronically transmits a summary of care record using certified EHR technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender for more than 10 percent of transitions of care and referrals.

The first measure would require hospitals to track transitions and determine whether each transition is to home (which the proposed rule does not consider as part of the denominator) or to another provider of care. Hospitals also would need to record the extent of information shared and verify for each care summary that the problem list, medication list and medication allergy list are up to date. This poses a significant administrative burden that detracts from the goal of sharing data.

The second measure would pose an even greater and unreasonable reporting burden, as providers would need to count transitions, track the organizational affiliations of the recipients, and track the vendors used by the recipients. This measure also makes provider performance contingent on actions of others, specifically whether they have the ability to receive the data, whether they have any organizational affiliation with the sender, and which vendor they choose. This measure would disadvantage providers working in markets that have heavy penetration by a single vendor. In addition, other HHS policies, such as accountable care organizations, encourage and require providers to create organizational affiliations to better coordinate patient care. This measure runs counter to those policies because sending a summary of care document to an affiliated provider would not count. Finally, by requiring that recipients have certified EHRs, the measure would leave out sectors of the health system that are not part of meaningful use, but would benefit from receiving the data, such as post-acute providers, therapists and pharmacists.

The AHA appreciates the intention behind this second measure – which we believe is to ensure that all vendor systems are capable of creating, sending, and incorporating summary of care documents in standardized form. We believe, however, that the certification process is the more appropriate place to ensure that vendor products are interoperable. The AHA will recommend that ONC address this issue by including specific testing of interoperability, including the use of “test beds,” to ensure that all vendor products can, in fact, easily generate, transmit and incorporate standardized summary of care documents that are sent using the document format and transmission standards specified by ONC.

Finally, AHA members do not understand how their participation in state-designated or other health information exchange activities would be reflected in these measures. Similarly, in places with shared access to an EHR, providers have much richer access to patient data by accessing a shared data system. In other areas, hospitals make their records accessible to affiliated physicians via secure private networks or other mechanisms. All of these approaches facilitate

the goal of this objective – making needed health information available to other care providers – without the need to actively send a summary of care document. An exception is needed to ensure that these providers are not penalized for pursuing more advanced forms of information sharing and exchange.

The AHA recommends the following changes to the summary of care objective:

- **Move this item from menu to core.** Therefore, it should keep the Stage 1 designation of the information to be included in the summary of care record.
- **The first measure should be changed from a percent of transitions to a minimum number of records transferred (for hospitals, 25).** This approach will demonstrate the capacity without imposing undue reporting burden.
- **Remove the second measure on the organizational affiliation and vendor of the receiving provider to decrease reporting burden and avoid penalizing providers based on circumstances outside of their control.**
- **Add an exception for providers that share their health information in other ways (such as participating in health information exchange, or providing other clinicians access to their health record systems).**
- **Add an exception for low-volume hospitals who may find even 25 care summaries hard to reach.**

Electronic Medication Administration Record (eMAR). The AHA recommends specific changes to this objective. CMS proposes a new objective directly into the core set that would require hospitals to use an electronic medication administration record that is supported by “assistive technologies” such as barcoding and radio frequency identification (RFID). The AHA appreciates the safety benefits of these technologies and has promoted their adoption, where appropriate. We are concerned, however, about the high costs of these systems and the feasibility of adopting them in small hospitals with low a daily census and constrained capital resources. We also are concerned about how inclusion in the meaningful use program, with the requisite certification requirements, will affect the costs and availability of these technologies, which are not a core component of the EHR. AHA survey data indicate that 58 percent of all hospitals could perform this function in Fall 2011. Among CAHs, however, the share was 46 percent.

The AHA makes the following recommendations for this objective:

- **Introduce to the menu set, as this is a new objective.**
- **Modify the measure to ensure technology is “in use in one inpatient unit” to limit burdensome measurement requirements associated with a percentage measure.**
- **Provide an exception for hospitals with a low daily census.**

Medication Reconciliation. CMS should keep this item at the Stage 1 threshold when it is moved from the menu to the core. Hospitals have made a significant commitment to medication reconciliation as part of their efforts to improve patient safety. However, the

complexity of the transfers in care that take place, and the lack of good ways to electronically exchange data across settings of care make it challenging to gather the needed information in electronic format. In addition, vendors historically have not had modules to support medication reconciliation. Those products newly available to support meaningful use were developed very rapidly and were not widely tested to ensure that they had reasonable workflows and supported hospital needs. These problems are reflected in data from CMS, which indicate that 75 percent of hospitals that have attested to meaningful use deferred this objective.

Public Health Objectives. CMS proposes to move all three public health objectives from the menu set to the core, and increase the performance threshold to full, ongoing submission. CMS also proposes to modify the exceptions for each objective to indicate that the exception applies if no public health department the provider works with can receive data electronically on the first day of the reporting period. **The AHA welcomes this addition to the exception, as it decreases the current confusion and burden associated with determining which public health departments can and cannot accept the data. However, we are disappointed that CMS has included no information in the proposed rule about the ability of state and local departments of public health to receive data electronically. We urge CMS to make this information available on its website to decrease the burden on providers.** We also are concerned about the discussion in the preamble to the rule that would require public health departments to provide letters to verify that providers have met the public health reporting objective. This requirement represents a significant administrative burden on state departments of public health, which are already pressed for resources to establish their ability to receive data electronically and currently unable to work with all of the providers seeking to achieve meaningful use. CMS should need only to verify the providers' attestations upon audit, as is done with other objectives.

CMS also proposes to add the phrase "except where prohibited" to the regulatory requirement in response to concerns that some providers find themselves in specific situations with contradictory requirements, such as those working with the Indian Health Service. We strongly urge CMS to find a different approach, such as an exclusion, to solving the issues for the small number of providers in those situations. **We are concerned that the proposed approach would unintentionally create a new problem for all providers because of an overlap with the HIPAA privacy rule.** Under HIPAA, covered entities are given specific authority to provide protected health information to public health agencies without obtaining patient consent as long as the public health reporting is required by law. Any public health reporting that is not required by law would require covered entities to obtain informed consent. As noted, Congress specifically instructed HHS to develop the EHR incentive program in the context of existing HIPAA requirements and to refrain from establishing policies that overlap or contradict HIPAA.

Reference Laboratories. **The AHA supports CMS's decision not to propose an objective related to how hospital-based reference laboratories send results to physician practices.** The Medicare EHR Incentive Program for hospitals is authorized in the specific sections of law that govern payment for hospital inpatient services. By contrast, laboratory tests billed separately by hospitals are paid for under a completely different payment system – the clinical

laboratory fee schedule. Therefore, hospital's clinical laboratory services are not within the statutory scope of the EHR incentive programs. Beyond the question of statutory authority, including this objective in meaningful use is inappropriate because the meaningful use regulations do not apply to commercial clinical laboratories, leading to an unlevel playing field between hospitals and others that process laboratory results for physician offices. Finally, the operational impacts of this objective are significant. In the absence of functional health information exchanges, hospitals would need to create and maintain separate, system-to-system interfaces with each physician office that receives laboratory results electronically, at considerable cost and effort. The transition to using standardized code sets in laboratories that must continue to function is challenging and burdensome, particularly for small hospitals. This objective also could have particularly significant implications for rural hospitals, which tend to serve as reference laboratories for their surrounding communities, where commercial laboratories may not operate.

Clinical Notes. The AHA recommends that clinical notes be included in the menu set for Stage 2. CMS chose not to proposed electronic clinical notes as an objective for Stage 2 but asked for comment. We believe that electronic clinical notes are a crucial part of the EHR and will be a key element of ensuring that we can move forward with automated quality measurement. Physician notes represent the documentation of patient treatment as care is being rendered. The intent of this concurrent care record is to reflect what is occurring at that time and the resultant medical decision making. These notes are often used to communicate with other physicians involved in the patient's care. Many quality measures require pieces of information that are most often found in clinical notes, particularly when looking for exclusions. We note that providers will need flexibility in how the note is entered and stored, since the transition to electronic notes is likely to pose considerable challenges. 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. In the early stages, notes should not be required to be in a standardized form but should be searchable. **An appropriate measure would be that physician notes are accessible through the EHR for 10 percent of patients who are admitted (POS = 21).**

Security Risk Analysis. The AHA does not believe that this objective is necessary given hospitals' existing obligations under the HIPAA security and breach notification rules and the enforcement mechanisms available to OCR. Despite its clear conclusion in finalizing Stage 1 that the meaningful use rule is not the appropriate regulatory tool to use to ensure HIPAA privacy and security compliance, the Stage 2 rule proposes to maintain and expand upon a redundant and potentially conflicting process to ensure compliance with HIPAA obligations.

It specifically proposes to expand the measure associated with the meaningful use privacy and security objective by including as part of the measure's existing and otherwise unchanged requirement "to conduct or review a security risk analysis" on the need for "addressing the encryption/security of data at rest in accordance with [existing HIPAA] requirements."

CMS suggests that the addition is to “specifically call out this element” as a result of both a recent HHS analysis of reported breaches suggesting a connection with lost or stolen devices and the specific recommendation from the HIT Policy Committee to highlight the importance of an entity’s reviewing encryption practices as part of its risk analysis in the wake of reported breaches. The agency as always is quick to clarify that this meaningful use measure, like its Stage 1 version, does not change the HIPAA rules and requires no new obligation beyond the requirements of these rules.

We appreciate the clarification. We again point out, however, what CMS too has clearly acknowledged: that compliance with HIPAA requirements is mandatory for all hospitals and providers whether or not they participate in EHR incentive programs because they are covered entities under the HIPAA rules. Determining whether any covered entity is in compliance with these existing obligations is a complex undertaking that cannot be reduced to simple numeric measurement or general attestation, as the meaningful use rule effectively does, and any such determination remains most appropriately under the authority and direction of the OCR. The OCR’s current processes and procedures ensure enforcement of the obligation of hospitals and other providers to be in compliance with all HIPAA privacy and security requirements. CMS should not create in, or facilitate through, the meaningful use rule a potentially different or conflicting set of obligations or enforcement mechanisms for privacy and security compliance.

CLINICAL QUALITY MEASURES AND QUALITY MEASURE REPORTING

The AHA believes automated reporting of quality measures via EHRs is the right *long-term* approach. Automated quality reporting has clear benefits, including efficient measurement, real-time results and the potential to include whole populations in measure calculations, as well as the ability to easily look at sub-groups. Given that we have identified automated reporting as a long-term approach, we are eager for CMS to define “long-term.” **We urge CMS to articulate its intention for the launch date for full, automated quality reporting.** It is essential to allow providers several years of planning in order to devote the necessary resources to ensure a successful transition.

The AHA strongly supports the move toward automated quality reporting to ease burden and provide real-time information. To be useable, however, automated quality measurement must be feasible, generate valid and reliable results and have benefits that outweigh the costs. Early experience in Stage 1 of meaningful use indicates that the current approach to automated quality measurement will not deliver on that promise. Stage 1 focused on getting automated quality reporting started and Stage 2 must focus on getting quality reporting right. We have heard from many member hospitals/CAHs that all stakeholders – measure developers, the National Quality Forum (NQF), CMS, vendors and providers – need much more time to get the process right for the existing 15 EHR quality measures. **For these reasons, we strongly urge CMS to defer adding new quality measures through EHRs until Stage 3 so that Stage 2 can be used to make the process viable.** The AHA stands ready to assist CMS in this effort.

Experience with Stage 1. Hospitals and CAHs experienced many difficulties in implementing automated quality reporting for Stage 1. Despite making tremendous investments to purchase technology and change workflows to input the needed data into the EHR, they find that the resulting data are not useable. It is important to consider each of these difficulties, as they provide the justification for the measure deferral we are urging for Stage 2 implementation.

Inaccuracies within e-measure specifications. Providers and vendors have encountered significant issues with the hospital measure e-specifications, which contain known errors and have never been field tested. In particular, the CQMs for stroke and venous thromboembolism (VTE) were e-specified under contract to CMS, and not by the original measure developer. Although CMS announced its intent to test the feasibility of using the e-specifications in FY 2010, the pilot was never conducted.

Furthermore, the underlying measures were developed for use by specially trained clinicians performing manual abstraction. **The original versions of the measures were endorsed through the NQF process, but the e-specifications were not. The AHA has recommended that NQF separately endorse e-measures.** Only after e-measures have been tested by multiple vendors can providers be assured the e-measures are valid, reliable and feasible to generate.

Despite reservations expressed by the AHA and others, these specifications were finalized by CMS and vendors embedded them into their products using the e-specifications provided. This functionality was completely new for most vendors, who had limited ability to map the needed data elements to where they actually reside in the EHR, or test their products given short time frames. In detailed conversations with AHA members, we have discovered that vendors needed to program many decisions into EHRs that were not included in the e-specifications. Not only has this resulted in rampant inconsistencies between different vendors, it produced inconsistent measure results when the e-measures are compared to their counterparts in the Inpatient Quality Reporting (IQR) Program.

Inability to access necessary clinical information. In practice, the existing CQMs require a level of clinical documentation and the use of coded data fields that are far more extensive than the Stage 1 requirements and are not in common use. Much of the data for the inpatient measures come from physician documentation that is currently contained in written or dictated notes. The measures also include concepts not easily captured in a structured format. Thus, the needed data often are not gathered electronically during the course of care. As a result, AHA members report that the certified EHR products they have purchased do not generate accurate quality data without significant effort, including use of custom fields and screens, significant training and increased work for clinicians to capture the necessary data during the care process, and even the use of abstractors to fill in missing data elements. Even those investing considerable resources to validate and correct the CQMs have little reason to trust the data integrity of the CQMs reported out of certified EHRs not developed in house.

Lack of measure stewards. In many cases, the original measure developer specified measures for non-EHR use. However, the original measure developer did not e-specify the measures for

EHR-use. Instead, an independent third party completed a one-time conversion to an *e*-measure. This process has left us with no real measure steward to continually monitor and update the *e*-measures. No structured process is in place to ensure that corrections or updates are communicated and adopted by vendors, such as the addition of new medications to treat patients with stroke. Many AHA members report working with individual vendors to fix errors they have found during validation processes. However, to have comparable data across vendors and hospitals, we need a systematic process in place to ensure these changes are broadly communicated and systematically incorporated. Our members also report that the updated version of the *e*-specifications still contain errors.

Lack of sufficient testing. Vendor products have been certified for the CQMs with very light testing requirements. The certification process for EHRs does not include testing the accuracy of the embedded measure calculations, nor does it look to see if the needed data are, in fact, available in the EHR. It requires only that vendors, using their own data, show that their product can electronically produce numerators, denominators and exclusions in the required standardized format. More recently, CMS determined that the specified transmission standard “is not feasible to use” for automated transmission of measure data to CMS, further calling into question the value of certification for CQMs. The AHA is pleased that ONC proposes to include testing for the accuracy of CQMs in its proposed rule on certification. However, we are concerned that ONC proposes that a vendor only needs to certify its product to be capable of generating a single CQM. **We urge CMS to work with ONC to ensure that all EHRs are capable of correctly calculating and reporting all *e*-measures finalized. CMS should not require providers to report more *e*-measures than vendors are required to generate.**

Vision for Stage 2. In the proposed rule, CMS articulates its vision for Stage 2 automated quality reporting. CMS states: “A longer term vision would be hospitals and clinicians reporting through a single, aligned mechanism for multiple CMS programs.”

This is the correct long-term vision, and we support moving providers toward it. In this rule, CMS has made some proposals that will better align quality reporting programs for hospitals. Contrary to Stage 1, the proposed measures for Stage 2 significantly overlap with the quality measures required for the IQR program. Specifically, of the measures proposed for Stage 2, 36 overlap with the IQR. Hospitals are familiar with these measures and this type of alignment across programs is an important step forward. We note, however, that in the inpatient PPS proposed rule (put on display on April 24), CMS made several proposals to remove and suspend several quality measures in the IQR program, including four that have been proposed for Stage 2 of meaningful use.

To make advances toward this vision, the hospital field needs much more specific information about CMS’s intent for automated quality reporting moving forward. We urge CMS to address the following concerns in the final rule.

Need for clarification around timing of automated reporting. **We urge CMS to articulate a strategy and timeline to move toward automated quality reporting across programs.** Based

on the interaction of the IQR and meaningful use penalties in statute, it seems likely that CMS intends to transition to automated reporting of quality data by FY 2015. However, CMS has yet to articulate this dynamic in regulation, and, given issues in Stage 1, the FY 2015 date seems unrealistic. It is essential to provide a clear roadmap that allows providers several years of planning in order to devote the necessary resources to ensure a successful transition from quality reporting based primarily on manual abstraction to one that is more fully automated.

Potential overlap between quality programs. Another compelling reason for CMS to clearly articulate its intent regarding transition to automated reporting is to avoid any burdensome overlap of quality data reporting. It is inefficient and wasteful to require all hospitals to submit the same quality data through multiple reporting mechanisms. **We urge CMS to recognize the potential for overlap and use both the final rule and inpatient PPS rules to effectively outline a transition and strategy for quality measure data submission.** Hospitals need a clear understanding of the full set of measures across programs and how they relate to one another. Otherwise, they may be forced to generate data on the same measures through both manual and electronic processes.

Need for comparison between quality programs. If automated reporting is the future of quality reporting, hospitals need a guarantee that the measure results are consistent between current reporting mechanisms (medical record abstraction) and EHR reporting. We have had extensive conversations with AHA members regarding their observations about the differences between the two data collection methods, and members who have attempted this comparison have indicated extreme discrepancies between the reporting methods. **We urge CMS to engage in an independent analysis that directly compares the measure results generated from medical records to results from EHRs for each measure and across all major vendors.** Until this study is done and the results are made public, we cannot be sure of the accuracy of EHR quality measure reporting.

Infrastructure needed for EHR quality reporting. The success of quality reporting through the IQR program is wholly dependent upon the infrastructure that CMS has had in place for nearly a decade. To date, CMS has not built a similar infrastructure for EHR reporting. There are several fundamental processes in place, both managed by CMS and through vendors designated by hospitals, which allow for adequate flow of data. **We urge CMS to make the necessary investment needed to establish an infrastructure for the flow of EHR data.**

Through the hard work of CMS staff and the active involvement stakeholders, including the AHA, the IQR program has evolved into a well-functioning program with clear and articulate expectations, processes and communication between CMS, data vendors and hospitals. Hospitals are well-informed about the requirements of the program and there is a clear mechanism for collecting, reporting and validating the data, as well as an explicit appeals process for when hospitals believe their data should have passed the validation test. Before data collection is implemented through the EHR program, careful consideration needs to be given to how CMS will ensure reliable, valid and complete data collection.

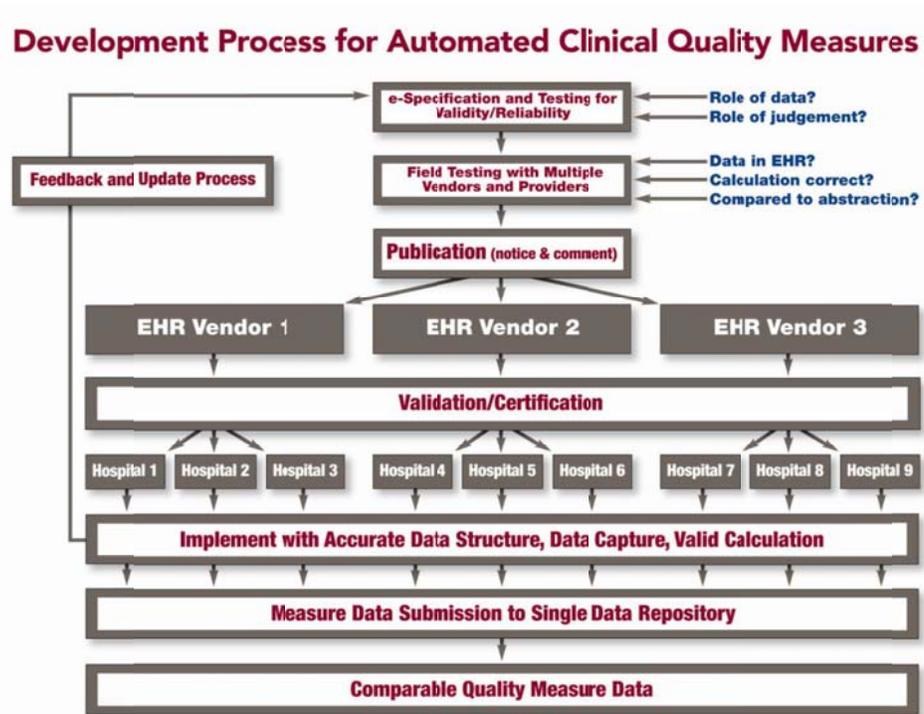
Further, in the current data collection system, when hospitals have any questions or concerns about the measures, and their implementation, they may contact their quality improvement organization (QIO) or the central help desk at the national data warehouse for assistance. Mechanisms need to be put in place for supporting implementation under this proposed rule. Under the IQR program, all data are uploaded through the secure data portal on QualityNet to the central QIO data warehouse, and to protect patient privacy, the data warehouse submits only the aggregated data for each hospital to CMS. The proposed rule provides no insight into how individual patient information will be maintained in a secure environment, as it is in the current IQR program. After hospitals submit their data through QualityNet, they are provided with a Clinical Warehouse Feedback Report and a Program Provider Participation Report that give the hospital assurance that its data were submitted and accepted on time into the data warehouse accurately. These reports have been valuable tools in helping hospitals and their vendors spot missing data and problems with transmission of required information. Similar reports will be needed for quality data submitted from EHRs to ensure hospitals are able to verify that all of the data they intended to submit were received.

Data submitted to the IQR program are independently validated. First, the data vendors with which hospitals contract to submit quality data run their software systems through a series of test cases, which they submit to The Joint Commission for review. The vendors also perform an annual self-verification to ensure that their systems are processing patient cases correctly. This ensures that the calculations of the measures are accurate. CMS also validates the quality of the data entered by hospitals into the system by randomly selecting a group of patient cases from each hospital and checking the data by re-abstracting them to ensure that the documentation in the patient records matches the data entered into the system. Similar checks will be needed to ensure the accuracy of the EHR-collected and -submitted information.

The following figure illustrates the process that CMS and the quality measurement field should follow to develop automated clinical quality measures that will result in comparable data across hospitals. It emphasizes the need to:

- Consider up front whether a measure can be automated or whether it requires a level of clinical judgment that makes automation difficult;
- Field test measures to determine whether the needed data are in the EHR and vendor products can capture it;
- Validate that vendor products can, in fact, accurately calculate the measures based on test data sets; and
- Establish a structured feedback and update process.

Figure 1. – Future Data Submission Model for Automated Quality Reporting



Proof of concept around CMS acceptance of e-measure data. To date, CMS has not demonstrated that it is capable of receiving and processing hospital data generated from EHRs. We understand that CMS recently finalized an EHR pilot reporting program for hospitals in the CY 2012 outpatient PPS final rule. However, as of the date of this comment letter, the pilot program has not yet recruited participants nor collected any data. Further, educational materials on the program indicate participants will not know whether their data submission was acceptable until December 2012 — after they must attest to meaningful use for FY 2012. The proposed rule includes an option on submission of patient-level data from EHRs to CMS. CQM reporting through EHRs is a significant burden for hospitals, and we need reassurance from CMS that it is capable of receiving and using EHR data.

Framework for Stage 2. In the proposed rule, CMS introduces a new framework for considering which quality measures to add for Stage 2. The framework is consistent with the National Quality Strategy (NQS), which is helpful in identifying gaps in quality measurement. The AHA supports the goals of the NQS and CMS’s use of the NQS as a *guiding document* to assess quality measurement across all programs, which currently include more than 90 measures across the IQR, the outpatient PPS, and meaningful use. It is this full measure set that should be compared to the NQS. However, **the AHA does not support CMS’s rigid use of the NQS to generate measurement domains within the EHR incentive program. The AHA also has concerns with the extent of measure choice that is proposed.**

Applying measurement domains as a new framework. **The AHA urges CMS to use a technical expert panel to appropriately classify measures into domains.** In the proposed rule, CMS proposes to require that hospitals report at least one measure from each of six measurement domains: clinical process/effectiveness, efficient use of healthcare resources, population/public health, patient safety, patient and family engagement and care coordination. These six areas are important priorities under the NQS but that does not mean they should be used to force a measure framework within a single quality reporting program, such as meaningful use. Rather, the NQS is a guiding document for the entire portfolio of quality reporting programs and does not need to fully apply to each measurement program. Furthermore, the proposed Stage 2 measures were not initially developed to fit these domains, and in many cases the classifications seem arbitrary. In addition, the requirement to report at least one measure from each domain significantly limits hospital choice of measures, as several domains have few measures. We discuss the pros and cons of measure choice below, but first comment on specific domains.

Care coordination measurement domain. The care coordination domain includes the measure median time from arrival to departure (throughput) for emergency department (ED) patients not admitted as inpatients (0496). Hospitals have limited experience with this measure, as reporting on the measure only began in January. AHA has heard from numerous hospitals and quality measure vendors that this measure is posing many operational challenges and is overly burdensome. Hospitals are having difficulty identifying the proper population for the denominator. For example, one large system accidentally included urgent care visits in initial abstraction to only have to re-sample and re-abstract without the urgent care visits. **This measure is not ready for use in either the IQR or MU programs.**

Further, there are two ED throughput measures for patients admitted as inpatients in Stage 1, and these measures are proposed for Stage 2, but placed in a different domain -- patient and family engagement. Many measurement experts consider these three measures to be a "family" of measures. CMS does not provide any justification for putting very similar measures into different measurement domains, suggesting the need for a more considered approach to classification that includes use of technical expert panel. One reason for the placement may have been to allow measure choice within a domain. However, without measure 0496, this domain would have only one measure, leaving no choice within the domain.

Population/public health measurement domain. In addition to the care coordination domain, the population/public health domain also contains only two measures – pneumonia (1653) and flu (1659) vaccination. Both of these measures are new in the IQR program and reporting on these measures began only in January. We have heard from several hospitals that these measures lack several key exclusions and, as a result, are causing unintended consequences, such as requiring immunization of patients who are unable to consent, and have informed NQF of these issues. NQF is currently reviewing these measures, and they may not be endorsed given technical issues. **Though we support immunization for the prevention of both flu and pneumonia, we do not support these measures because they do not contain all of the necessary exclusions.** If these two measures are not finalized by NQF, there are no remaining measures in the population/public health domain. We also note that the proposed public health objectives for Stage 2

include reporting data on immunization of patients to immunization registries. Incorporating separate quality measures on the same activity is duplicative and burdensome.

Though we fully support the quality measurement priorities of care coordination and population health, we cannot support these as measurement domains for Stage 2 given the serious discrepancies with the measures contained within the domains. As noted, the NQS is a guiding document that should be used across all quality programs in which hospitals participate, including both quality measures and other reporting, such as public health reporting. **It is unnecessary to apply the NQS priorities within the meaningful use program, but is more appropriate to use the NQS to harmonize reporting requirements across all reporting programs.**

Measurement choice is unprecedented. CMS's proposal to allow hospitals/CAHs to choose measures is a major departure from a decade's worth of acute care hospital quality reporting. The IQR program has always required a core set of measures to be reported. This has allowed CMS to build a consistent, nationally representative quality database that is valid and reliable. This database has allowed for evolution into additional programs that tie measurement to payment, such as Hospital Value-Based Purchasing (VBP).

There are pros and cons to allowing hospitals/CAHs the ability to choose measures. The major con is that programs like hospital VBP may be compromised in the future if reporting is done through the EHR because the data may not be nationally representative, thus leading to insufficient benchmarking, reliability and validity. The major positive is that some measures are more or less applicable to the care delivered and the stakeholder that knows best where to focus priority through choice is the hospital/CAH. **On balance, however, we believe that measurement choice in meaningful use will introduce more challenges than it resolves.** We recommend, however, that CMS consult with children's hospitals and CAHs to ensure that meaningful use reporting requirements are workable for them. We also make additional recommendations about minimum cases and sampling approaches below. These policies should make the quality measurement requirements more feasible.

The real level of choice presented by the proposed framework is minimal. CMS proposes that hospitals/CAHs will have a choice of submitting 24 out of a possible 49 measures. However, the proposals within the certification regulation require vendors to incorporate all of the data elements needed to calculate *only one* CQM. There is no proposal to require that certified EHRs be capable of generating all of the relevant CQMs proposed/finalized by CMS. We do not support this requirement and refer CMS to our comments to ONC on the proposed certification rule. The dynamic proposed in the certification regulation puts all responsibility for measure selection in the hands of vendors. If vendors choose not to program a measure, it will not be available to hospitals/CAHs as an option for reporting. **We urge CMS to coordinate with ONC to ensure that the certification requirements support providers in meeting their quality reporting obligations. In the absence of a reversal of policy in the certification regulations, it is false to state that providers have "choice" in quality measure selection.**

Reporting on Quality Data. The AHA supports reporting of quality data in aggregate form on a sample of all patients for Stage 2. CMS has included several options for the reporting of quality data in Stage 2. Each of those options, and the AHA's preference, is noted below.

Reporting of aggregate data is preferable. CMS proposes two options for hospital/CAH data reporting. Option one would require hospitals/CAHs to submit CQM data through a CMS web portal in *aggregate* form (i.e., 75 percent of heart attack patients received an aspirin on arrival) for all patients. Option two would require hospitals/CAHs to submit *all necessary data* that is needed to populate the CQMs directly from the EHR to CMS. This option is a continuation of a pilot program that CMS adopted in the CY 2012 outpatient PPS final rule. At this time, no hospitals/CAHs have elected to participate in the pilot program. **We urge CMS to finalize option one.** As noted, CMS has yet to exhibit proof of concept that it is actually capable of receiving and analyzing hospital/CAH data directly from EHRs. Option one is much less burdensome for hospitals/CAHs and provides all of the information needed to capture quality measure performance.

Though the IQR program requires direct submission of data elements to populate quality measures, the data elements are not accessible to CMS. All data elements flow into a protected clinical data warehouse that is managed by a QIO. The QIO is then responsible for facilitating the transmission of measure results to CMS. Measure results are considered aggregate data, which would be equivalent to option one, described above. Until CMS fully develops an infrastructure for the EHR program that is similar to the QIO's function in the IQR program, hospitals/CAHs cannot be assured the proper data precautions are in place. Therefore, option two is not viable.

We also are concerned option two would take away a key benefit of quality measurement through EHRs – real-time data on performance. If quality measures are calculated by the individual hospital using its EHR, then results can be presented to clinicians immediately, tracked on an ongoing basis, and used to support quality improvement activities. If instead the hospital sends patient-level data to CMS for measure calculation, then waits for the agency to provide feedback on performance, the data become much less timely and less useful for ongoing quality improvement efforts.

All-payer data is necessary to capture performance. CMS seeks comment on collecting data for either all payers or only Medicare patients. **We urge CMS to require data collection across all payers.** Hospitals/CAHs have a long-standing history of collecting quality data representative of all payers. The majority of measures collected in the IQR program reflect care reimbursed by all payers.

Sampling of patients is less burdensome. CMS seeks comment on collecting data for either all patients or a sample of patients. **We urge CMS to require data collection for a sample of patients in both Stage 1 and Stage 2.** We suggest this as a short-term approach and encourage CMS to develop a transition plan that relies upon all-patient data, rather than sampling, in the long-term. We can envision a time when all automated quality reporting will occur effortlessly

in a reliable and valid fashion. However, we are not there yet. Until many of the problems we have identified above are addressed, no stakeholder is ready to submit or receive data across all patients. Further, we urge CMS to consider sampling for successful completion of the Stage 1 requirements. We have heard from several member hospitals that one of the biggest barriers to becoming a successful Stage 1 meaningful user is attesting to quality measure performance across all patients. A sampling methodology would greatly reduce the burden and would ultimately lead to greater participation. A sampling methodology is consistent with the vast majority of quality measure reporting in the IQR program.

We urge CMS to keep the sampling as similar as possible to the IQR program to avoid confusion for hospitals. Under the IQR program, hospitals are required to submit clinical quality data on a quarterly basis; data are due no later than 135 days after the close of a reporting quarter. Hospitals with larger numbers of eligible patients may choose to submit data on a random sample of patients according to specific sampling protocols. All hospitals also are required to submit data on their aggregate population size for both Medicare and non-Medicare patient discharges within 120 days of the close of the reporting quarter. A hospital that has five or fewer quarterly discharges (Medicare and non-Medicare combined) in that topic area is not required to submit clinical quality measures data for that quarter. No details are provided in this proposed rule regarding the handling of these operational aspects of sampling, but they will be needed for the program to function correctly.

Minimum case counts will eliminate wasteful efforts. CMS is seeking comment on whether it should establish a minimum number of cases that must be met before requiring a hospital/CAH to submit quality measures. **We strongly support a minimum case number threshold for quality measure reporting.** We have heard from several CAHs that the stroke measures required for Stage 1 reporting are not responsive to their patient populations. Many CAHs do not encounter even a single case of stroke in a given calendar year. In this situation, CMS does permit CAHs to attest to a zero result for all of the stroke measures. However, it is still burdensome for CAHs to screen all available data for stroke patients. We urge CMS to establish criteria that would allow all hospitals/CAHs the ability to rely upon historical data to determine whether they meet a minimum threshold. For CAHs, in particular, there is no legislative requirement to report quality measures outside of meaningful use due to the challenge of finding appropriate measures for this low-volume setting. We encourage CMS to empirically derive the value of the minimum threshold(s).

Stage 3. As noted above, we urge CMS to defer finalizing any additional quality measures until Stage 3. That said, many of the measures CMS has proposed for Stage 2 may be appropriate for Stage 3. Once the measures have been fully e-specified, field-tested, and vetted through the NQF endorsement process, they may be ready. However, these necessary criteria have not yet been met. In addition, two other policy steps are needed to ensure that the quality measurement piece of meaningful use works well: alignment across Medicare programs, and consideration of the recommendations of the Measure Application Partnership.

Alignment across Medicare quality programs. As noted above, CMS proposes in the inpatient PPS proposed rule – released two months after the Stage 2 rule – to remove four measures from the IQR program that CMS has proposed for meaningful use. Specifically, the agency proposes to remove the Surgical Care Improvement Project (SCIP) measure (0218) for surgery patients who received appropriate VTE prophylaxis 24 hours prior to surgery to 24 hours after surgery end time from both the IQR and VBP programs. In addition, the agency proposes to continue suspension of measures 0132 (aspirin at arrival for heart attack), 0137 (ACE/ARB for left ventricular systolic dysfunction) and 0160 (beta blocker prescribed at discharge for heart attack). **We urge CMS not to include any measures for meaningful use that it plans to remove from the IQR, including 0218, 0132, 0137 and 0160.**

Consideration of recommendations from the Measure Application Partnership (MAP). **We urge CMS to more systematically consider recommendations from the MAP in Stage 3.**

The MAP is a multi-stakeholder board charged with making annual recommendations to the Secretary regarding which measures should be included in national quality reporting programs. The MAP was mandated by the *Patient Protection and Affordable Care Act* and functions under appropriated dollars from HHS. It conducted a review of measures from HHS in early 2012, including 35 possible e-measures that only partially overlap with the proposed Stage 2 measures. We note that none of the measures considered by the MAP had been adequately e-specified, field tested, and separately endorsed as e-measures.

A total of 34 new measures were proposed by CMS for hospital/CAH Stage 2 meaningful use. The MAP did not review the 15 measures carried over from Stage 1. The MAP supported 26 measures and did not support nine measures in its review of 35 measures. Of the 26 measures the MAP supported, one measure was not proposed for Stage 2—neonatal immunization. Of the nine measures the MAP did not support, CMS has proposed eight for Stage 2:

- Aspirin at arrival for acute myocardial infarction (AMI);
- Heart failure discharge instructions;
- ACE or ARB for left ventricular systolic dysfunction for AMI patients;
- Beta-blocker prescribed at discharge for AMI;
- Surgical Care Improvement Project – surgery patients with appropriate hair removal;
- Exclusive breastfeeding at hospital discharge;
- First temperature measured within one of admission to the neo-natal intensive care unit (NICU); and
- First NICU temperature < 36 degrees Celsius.

We understand that CMS had limited time to review the MAP recommendations, submitted to HHS on February 1, before releasing the Stage 2 meaningful use proposed regulation on February 24. It is likely the regulation was well into the clearance process in advance of the MAP recommendations. However, it is important to carefully note where CMS's quality measure proposals differ from the MAP recommendations, and carefully consider the MAP recommendations in proposing measures for Stage 3.

Eligible Professionals. For EPs, CMS proposes several different CQM reporting options. For the majority of EPs, only two proposals would apply. “Option 1a” would allow EPs to choose from a menu of 125 quality measures. Of those measures, EPs must choose 12 measures to report. Similar to the hospital/CAH approach described above, EPs would need to choose at least one measure from each of six measurement domains. “Option 1b” would require EPs to report 11 “core” measures and choose one additional measure from the menu of 125 measures included in option one. **The AHA urges CMS to finalize the “core measure” reporting proposed for “Option 1b”, with one caveat – removal of the menu measure.** Our members have indicated that it is much easier to engage with and facilitate collecting quality data from hospital-based EPs when a small focused set of measures is used. Hospitals/CAHs anticipate that presenting EPs with an option of 125 measures will be overwhelming and may cause unnecessary tension.

CMS proposes an additional option for EPs who participate in the PQRS and submit data via EHRs. As an alternative to the two options referenced above, these EPs would be deemed meaningful users if they are successful in the PQRS program. Under this option, EPs would only need to choose three quality measures to report. **We support this reporting option.**

Finally, CMS is soliciting comment on group practice reporting options for EPs. The group reporting option would be available in CY 2014 for groups with: (1) two or more EPs under one tax identification number (TIN); (2) groups enrolled in the Medicare Shared Savings Program (Accountable Care Organization-ACO) or pioneer ACO program; and (3) EPs participating in the PQRS group reporting option. **We support all of these reporting options for the meaningful use program.**

Quality Measure Reporting in Impact Analysis. There is no detailed breakdown of what the impact of reporting clinical quality measures would be for hospitals/CAHs and EPs. Our members have identified quality reporting as one of the most burdensome requirements included in meaningful use. For example, one hospital system spent more than \$1 million on a quality reporting tool from its vendor that was, for the most part, an unwieldy data entry screen. Even medication orders placed using CPOE needed to be manually re-entered for the CQM calculation. Even then, the data were not reliable, despite seven months of working with the vendor to attempt to get it right. Thus, after tremendous investment of financial and human resources, the data are not useful. As such, it is imperative to see estimates of the financial and workflow burden of quality reporting in the impact analysis. **We urge CMS to include an estimate for the reporting of each quality measure in the Stage 2 final rule.**

OTHER PROPOSED CHANGES

Changes to Stage 1 of Meaningful Use. **The AHA recommends that the definition of Stage 1 stay essentially the same in all years.** We are concerned that changes will create confusion and lead to repeated costly and disruptive upgrades. In addition, the proposed changes significantly add to the current Stage 1 requirements. It seems likely that this expanded Stage 1 will affect most profoundly those providers that have found adoption most challenging, and

could prevent them from entering the program at all. Minor changes, such as redefining the denominator for CPOE for medications, may be needed to streamline the program.

The proposed changes to Stage 1 for hospitals would, for the most part, be in FY 2014. The changes that would be most disruptive include those that greatly increase the requirements on providers:

- Replacing the Stage 1 hospital objectives related to providing patients with electronic copies of their health information and discharge instructions upon request with the Stage 2 “view online, download and transmit” (patient portal) objective.
- Requiring hospitals in Stage 1 to report the same expanded set of clinical quality measures as those in Stage 2.
- Requiring all providers to use EHRs certified to new requirements in 2014, regardless of stage. The AHA will recommend that ONC tie certification requirements to a provider’s stage of meaningful use, not the fiscal or calendar year. We will also recommend that providers be given the choice to use either level of certification to meet Stage 1 in 2014 or later.

Batch Reporting for EPs. The AHA supports CMS’s proposal to allow EPs in a group practice to use a batch file process to submit individual Medicare EP attestations, but urges the agency to make this change in CY 2013, and not wait until CY 2014. We also encourage CMS to explore batch registration processes. CMS proposes to define a group as “two or more EPs identified with unique National Provider Identifiers (NPIs) associated with a group practice identified under one Tax Identification Number.” Although CMS’s definition of group practice is different than that adopted in the CY 2012 PFS final rule (which defined groups as 25 or more EPs), we support the ability of smaller groups of two or more EPs to use a batch file process. CMS proposes that batch reporting would be only for attestation purposes, and that EPs would first need to individually register for the program. Adoption of this policy should help streamline the attestation process for those non-hospital based physicians and physician groups supported by hospitals, decreasing administrative burden and potentially resulting in more EPs participating in the EHR incentive programs.

Medicaid EP Program Eligibility. The AHA supports CMS’s proposals to provide more flexibility to EPs to enhance the likelihood that they may qualify for Medicaid EHR incentive payments. Specifically, we support CMS’s proposal to expand the current definition of a Medicaid encounter to include those services provided to Medicaid patients even if the patients did not pay for the service. We also approve of CMS’s proposal to include individuals receiving medical assistance under 1905(b) of the *Social Security Act*, or Medicaid expansion populations that were approved through state plan amendments. This should add an additional 2.1 million individuals in the Medicaid percentage and allow more EPs to qualify for the Medicaid incentive program.

Medicaid Hospital Incentive Payment Calculations. CMS proposes to revise its policy to allow states to use, for the purpose of calculating the discharge-related amount and other determinations (such as inpatient bed days), the most recent continuous 12-month period for

which data are available prior to the payment year. **The AHA appreciates this change, which would provide more flexibility to states and hospitals in calculating data needed for the Medicaid EHR Incentive Program.**

CMS also proposes to amend the Medicaid incentive payment regulations to state that only acute-care discharges and bed-days are included in calculations of Medicaid EHR incentive payments, and not nursery days and discharges. **The AHA urges CMS to clarify and inform states and providers that neonatal intensive care days are considered acute, and should be included in these calculations.**

Eligibility Requirements for Children's Hospitals. CMS proposes to revise the definition of a children's hospital (for purposes of determining eligibility for Medicaid EHR incentives) to accommodate about 12 children's hospitals that do not have a CCN because they do not treat Medicare beneficiaries. **The AHA appreciates CMS's action to accommodate these hospitals.**

Audits and Appeals. The AHA appreciates the efforts CMS has undertaken to establish audit and appeal processes for the meaningful use program. **We urge CMS to make more explicit information available to providers on the documentation that should be available in the event of an audit.** Better guidance will facilitate the audit process, save time and effort for both providers and auditors, and limit adverse findings that are due solely to missing documentation.

IMPACT ANALYSIS

The AHA is disappointed that CMS did not update the data presented in the impact analysis from the Stage 1 final rule, despite the fact that the incentive programs have been underway for 18 months. CMS has accumulated data on the pace of payments. In addition, it is clear from testimony to the HIT Policy and Standards committees that hospitals and physicians are experiencing rapidly escalating costs for purchase and installation of EHR technology. The anecdotal evidence presented in testimony is confirmed by recent financial data from the AHA's annual survey of hospitals (separate from the AHA health IT survey), which show dramatic increases in expenditures on IT between 2009 and 2010.

Analysis of a matched set of hospitals reporting information on IT expenditures in 2009 and 2010, found operating expenditures per bed grew 24.2 percent, while capital expenditures per bed grew 13.9 percent in a single year. In 2010, the average capital expense per bed was over \$12,000, while the average operating expense was over \$45,000. Together, then, hospitals spent \$57,000 a year per bed on IT in 2010. For a 200-bed hospital, that would translate to over \$11.4 million annually.

Notably, expenditures for the hospital groups that are farthest ahead in their adoption grew at even greater rates. Teaching hospitals saw IT operating costs per bed increase 65.8 percent in a single year, while their IT capital costs per bed grew by 21.6 percent. Combined, the average IT-related operating, plus capital, expense per bed among teaching hospitals was about \$81,000 per

year in 2010. Large increases also were seen among hospitals with 200 or more beds: 31.2 percent increase in operating costs per bed and 12.2 percent increase in capital costs per bed.

The trade press has also reported very large expenditures on EHRs. For example, Henry Ford Health System negotiated the purchase of a \$350 million EHR system in November 2011, building on top of decades of investment in health IT (Crain's Detroit Business, November 14, 2011). The much smaller Cheyenne Regional Medical Center in Wyoming will invest \$19.2 million in capital and operating expenses to acquire a new EHR (Wyoming Tribune-Eagle, November 6, 2011). The Milwaukee Journal Sentinel (October 30, 2011) estimates that the "health systems in just the Milwaukee area will spend well over half a billion dollars moving from paper to electronic medical records."

In addition to software and hardware costs, significant additional costs are incurred on training staff and clinicians, providing ongoing support, and experiencing lost productivity during training and increased documentation demands on clinicians. For example, a Midwestern academic medical center currently undergoing implementation reports that it will have 1,000 people in class every day for many days to support installation, and will train 4,000 individuals overall. Care cannot stop while training occurs, leading to operational challenges and costs to ensure care is not affected.

Hospitals also report devoting considerable staff resources to simply understanding the meaningful use requirements. While this is true of any new program, the meaningful use regulations include very proscriptive requirements and measures that define denominators in ways not generally used in hospital operations. Consequently, hospitals find themselves spending large amounts of time understanding the measures, rather than implementing the technology. The time and resources needed to register and attest are also significant. Some hospitals report that it takes months to clear up data issues that prevent them from registering. The volume and complexity of data needed to register, as well as the sometimes slow performance of the attestation website, mean that just the attestation process itself takes many hours. Hospitals supporting a large group of physicians that must register and attest individually report the need to hire multiple full-time employees to simply perform that function. Hospitals report much greater resources going to generating and tracking the meaningful use reports needed to develop the data for attestation than the impact analysis reflects.

Hospitals report significant cost increases associated with upgrading to certified versions of EHRs, and high price points attached to new, required functionality, such as quality reporting modules and interfaces to support public health reporting. One hospital reported a doubling of costs between vendor negotiations in the summer of 2010, and actual implementation in the summer of 2011. AHA members report that the cost of consultants and trained IT professionals has also accelerated dramatically since the meaningful use requirements were put into place. Like physician offices, hospitals are finding that meaningful use implementation also decreases physician and staff efficiency, at least in the short run. On balance, hospitals expect the incentive payments to only partially offset the costs of implementation, with some estimating the incentive to offset as little as 10 to 15 percent of total costs.

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Smaller and rural hospitals with limited capital resources find managing the costs of implementation particularly challenging given their lower level of available resources. In addition, recruiting and retaining qualified technical and clinical IT staff is a major issue, given the general challenges of lower salaries and fewer amenities in rural areas. Many safety-net hospitals also struggle to find sufficient capital and qualified staff to support meaningful use.

All in all, the complexity of this undertaking should not be underestimated. More than one hospital executive has reported that managing the meaningful use implementation has been more challenging than building a new hospital, even while acknowledging the need to move ahead. While commitment to the goal of using EHRs to support high quality care is strong, the rushed timelines and complex regulatory requirements make the process difficult. We are concerned, in fact, that the complexity may be impeding progress.

**APPENDIX 1. PROPOSED CHANGES TO STAGE 2 OBJECTIVES AND MEASURES,
 BASED ON EXPERIENCE FROM STAGE 1 AND AHA SURVEY DATA**

STAGE 2 OBJECTIVES	MEASURES	EXPERIENCE FROM STAGE 1	AHA COMMENTS AND RECOMMENDATIONS
<i>Core Set: Hospitals must achieve all of the following objectives and meet the required threshold. POS = Place of Service code.</i>			
<p>Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order.</p>	<p>More than 60 percent of medication, laboratory, and radiology orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.</p>	<p>AHA survey indicates that at this scope and level of compliance, only 28 percent of hospitals could perform this function in Fall 2011. In comparison, 50 percent could perform CPOE for medications.</p>	<p>CMS asks for comment on the use of scribes to perform CPOE. The AHA believes that there are some situations that warrant the use of scribes to place orders and that these orders should count toward the numerator. Examples include:</p> <ul style="list-style-type: none"> • Use of a scribe during surgery, • To fulfill verbal orders from an on-call physician to address an emergent problem, • Needed modifications to an existing order, based on patient response to treatment, such as the selection of medication doses from a pre-approved titration (or adjustment) protocol for stabilizing target blood glucose or stabilizing a target blood clotting time, or "pro-time;" • Change or clarification of dose, route, or times of medication administration pursuant to a phone call exchange between a nurse and ordering clinician. <p>Order sets should be "unpacked" to count individual orders.</p>
<p>Record the following demographics</p> <ul style="list-style-type: none"> • Preferred language • Gender • Race • Ethnicity • Date of birth • Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH 	<p>More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have demographics recorded as structured data.</p>	<p>AHA survey indicates 66 percent of hospitals could perform this function in Fall 2011 at the raised threshold.</p>	<p>None</p>

STAGE 2 OBJECTIVES	MEASURES	EXPERIENCE FROM STAGE 1	AHA COMMENTS AND RECOMMENDATIONS
Record and chart changes in vital signs: <ul style="list-style-type: none"> • Height/length • Weight • Blood pressure (age 3 and over) • Calculate and display BMI • Plot and display growth charts for patients 0-20 years, including BMI 	More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.	AHA survey indicates 62 percent of hospitals could perform this function in Fall 2011 at the raised threshold.	None
Record smoking status for patients 13 years old or older	More than 80 percent of all unique patients 13 years old or older admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) have smoking status recorded as structured data.	AHA survey indicates 59 percent of hospitals could perform this function in Fall 2011 at the raised threshold.	None
Use clinical decision support to improve performance on high-priority health conditions	<ol style="list-style-type: none"> 1. Implement 5 clinical decision support interventions related to 5 or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. 2. The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period. 	AHA survey indicates 73 percent of hospitals could perform the drug/drug and drug/allergy checks, as well as at least one additional clinical decision support function in Fall 2011.	<p>Remove tie to clinical quality measures 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 will also 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.</p> <p>Remove "entire EHR reporting period" from the measure specifications to limit unnecessary measurement burden.</p>
Incorporate clinical lab-test results into Certified EHR Technology as structured data	More than 55 percent of all clinical lab tests results ordered by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or	AHA survey indicates 60 percent of hospitals could perform this function in Fall 2011 at the raised threshold.	Maintain the Stage 1 threshold of 40 percent as this objective is moved from the menu to core set of objectives.

STAGE 2 OBJECTIVES	MEASURES	EXPERIENCE FROM STAGE 1	AHA COMMENTS AND RECOMMENDATIONS
	23) during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in Certified EHR Technology as structured data.	Data from CMS indicate that among hospitals successfully attesting to meaningful use, 18 percent deferred this objective.	
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach	Generate at least one report listing patients of the eligible hospital or CAH with a specific condition.	<p>AHA survey indicates 70 percent of hospitals could perform this function in Fall 2011.</p> <p>Data from CMS indicate that among hospitals successfully attesting to meaningful use, 34 percent deferred this objective</p>	None.
NEW - Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR)	More than 10 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are tracked using eMAR.	AHA survey indicates 58 percent of all hospitals could perform this function in Fall 2011. Among CAHs, however, the share was 46 percent.	<p>Introduce to the menu set, as this is a new objective.</p> <p>Given the significant resources required for this technology, we recommend that CMS provide an exception for hospitals with a low daily census.</p> <p>Modify the measure to ensure technology is "in use in one inpatient unit" to limit burdensome measurement requirements associated with a percentage measure.</p>
NEW - Provide patients the ability to view online, download, and transmit information about a hospital admission	<ol style="list-style-type: none"> 1. More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge 2. More than 10 	AHA survey indicates only 10 percent of hospitals had a patient portal in Fall 2011.	<p>Remove this objective as duplicative of OCR regulatory authority under HIPAA. If removed, keep problem list, allergy list, and medication allergy list in the core set. Keep problem list at the Stage 1 performance threshold of 50 percent.</p> <p>If the objective is kept:</p> <ul style="list-style-type: none"> • Place objective in the menu set, as it is new for hospitals • Limit extent of data included to Stage 1 patient e-copy of discharge instructions • Remove transmit function • Remove the 36 hour time period requirement, which is too aggressive

STAGE 2 OBJECTIVES	MEASURES	EXPERIENCE FROM STAGE 1	AHA COMMENTS AND RECOMMENDATIONS
	<p>percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the reporting period.</p>		<p>and complicates measurement</p> <ul style="list-style-type: none"> Remove the measure on patient use of the portal to both minimize measurement burden and eliminate the provision that makes provider performance contingent on actions of others. <p>See additional comments in body of letter.</p>
<p>Use Certified EHR Technology to identify patient-specific education resources and provide those resources to the patient</p>	<p>More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) are provided patient-specific education resources identified by Certified EHR Technology.</p>	<p>AHA survey indicates 72 percent of hospitals could perform this function in Fall 2011.</p> <p>Data from CMS indicate that among hospitals successfully attesting to meaningful use, 62 percent deferred this objective</p>	<p>None.</p>
<p>The 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 medication reconciliation</p>	<p>The EP, eligible hospital or CAH performs medication reconciliation for more than 65 percent of transitions of care in which the patient is admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23).</p>	<p>The AHA survey does not have reliable data on this objective.</p> <p>Data from CMS indicate that 75 percent of hospitals deferred this objective.</p>	<p>Maintain Stage 1 performance threshold of 50 percent as this objective moves from menu to core.</p>
<p>The eligible hospital or CAH who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each</p>	<p>3. The eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than</p>	<p>AHA data indicate that 38 percent could create the care summary record as specified in Stage 1 – a much smaller set of information than proposed in the</p>	<p>This item moves from menu to core. Therefore, it should keep the Stage 1 designation of the information to be included in the summary of care record. New data, such as care summary and care plan, should not be included.</p> <p>The measure should be changed from a percent of transitions to a minimum number</p>

STAGE 2 OBJECTIVES	MEASURES	EXPERIENCE FROM STAGE 1	AHA COMMENTS AND RECOMMENDATIONS
<p>transition of care or referral</p>	<p>65 percent of transitions of care and referrals</p> <p>4. The eligible hospital or CAH that transitions or refers their patient to another setting of care or provider of care electronically transmits a summary of care record using certified EHR technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender for more than 10 percent of transitions of care and referrals.</p>	<p>proposed rule.</p> <p>AHA data on information exchange – a key component of this proposed objective – indicate that only 15 percent of hospitals could electronically share the care summary with other providers outside of their system.</p> <p>Data from CMS showed that 93 percent of hospitals deferred this objective in Stage 1, and testimony to the HIT PC and HIT SC indicated this objective was very hard to achieve.</p>	<p>of records transferred (for hospitals, 25). This approach will demonstrate the capacity, without undue reporting burden.</p> <p>Remove the measure on the organizational affiliation and vendor of the receiving provider to limit burden and remove the measure that makes provider performance contingent on actions of others.</p> <p>Add an exception for providers that share their health information in other ways (such as participating in a HIE or providing other clinicians access to their health record systems).</p> <p>Add an exception for low-volume hospitals who may find even 25 care summaries hard to reach.</p> <p>See additional comments in body of letter, including recommendation to ONC to conduct rigorous testing of this function as part of certification.</p>
<p>Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice</p>	<p>Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period.</p>	<p>AHA data indicate that 45 percent of hospitals could meet this requirement in 2011.</p> <p>Data from CMS showed that 52 percent of hospitals had either claimed an exclusion or deferred this objective in Stage 1.</p>	<p>Remove “except where prohibited.” Reporting beyond applicable law would force providers to seek individual patients’ consent to report their protected health information, as the HIPAA exception for public health reporting applies only to that reporting required by law.</p> <p>See additional comments in body of letter.</p>
<p>Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law</p>	<p>Successful ongoing submission of electronic reportable laboratory results from Certified EHR Technology to public health agencies for the entire EHR reporting period as authorized.</p>	<p>AHA data indicate that 43 percent of hospitals could meet this requirement in 2011.</p> <p>Data from CMS showed that 84</p>	<p>Remove “except where prohibited.” CMS does not have regulatory authority to require reporting beyond applicable law. In addition, reporting beyond applicable law would force providers to seek individual patient consent to report their protected health information, as the HIPAA exception for public health reporting applies only to that reporting required by law.</p>

STAGE 2 OBJECTIVES	MEASURES	EXPERIENCE FROM STAGE 1	AHA COMMENTS AND RECOMMENDATIONS
and practice		percent of hospitals had either claimed an exclusion or deferred this objective in Stage 1.	See additional comments in body of letter.
Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period.	<p>AHA data indicate that 40 percent of hospitals could meet this requirement in Fall 2011.</p> <p>Data from CMS showed that 72 percent of hospitals had either claimed an exclusion or deferred this objective in Stage 1.</p>	<p>Remove "except where prohibited." CMS does not have regulatory authority to require reporting beyond applicable law. In addition, reporting beyond applicable law would force providers to seek individual patients' consent to report their protected health information, as the HIPAA exception for public health reporting only applies to that reporting required by law.</p> <p>See additional comments in body of letter.</p>
Protect electronic health information created or maintained by the Certified EHR Technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data at rest in accordance with requirements under 45 CFR 164.312 (a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the provider's risk management process.		<p>Remove this objective as duplicative of OCR regulatory authority under HIPAA. CMS has delegated enforcement of HIPAA to OCR.</p> <p>See additional comments in body of letter.</p>
Menu Set: Hospitals must achieve two of the following objectives and meet the required threshold			
Record whether a patient 65 years old or older has an advance directive	More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's	AHA data indicate that 69 percent of hospitals could meet this requirement in Fall	Move to core.

STAGE 2 OBJECTIVES	MEASURES	EXPERIENCE FROM STAGE 1	AHA COMMENTS AND RECOMMENDATIONS
	<p>inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data.</p>	<p>2011. Data from CMS showed that 13 percent of hospitals had deferred this objective in Stage 1.</p>	
<p>NEW - Imaging results and information are accessible through Certified EHR Technology</p>	<p>More than 40 percent of all scans and tests whose result is an image ordered by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period are accessible through Certified EHR Technology.</p>	<p>AHA data indicate that 66 percent of hospitals had electronic results viewing for radiology and diagnostic images in Fall 2011. It is not clear, however, that these images are always available through the EHR.</p>	<p>This objective is not sufficiently defined in the proposed rule. It is unclear what types of images are included. In addition to images coming through the radiology department, hospitals generate many other images through surgical suites, catheterization labs, the emergency department, and in patient units. Differentiating among these types of images, and tracking the share of images that come from varying sources, will lead to a significant measurement burden. We recommend changing the measure to attestation that the functionality is available.</p> <p>In addition, the AHA will recommend that ONC explicitly not require that the source of the image be certified, as many images are created in many different modalities.</p>
<p>NEW - Record patient family health history as structured data</p>	<p>More than 20 percent of all unique patients admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives.</p>		<p>It is not clear that these data are most appropriately captured in the acute care setting. The full family health history is better captured by the primary care doctor. We are concerned that by asking all providers to gather this information, the patient will be burdened with providing it in multiple settings, rather than to the PCP, who can then share it with other providers when clinically appropriate.</p> <p>In addition, the AHA will recommend to ONC that the standard be fully tested before it is adopted. The standard referenced has not been widely used.</p>
<p>NEW - Generate and transmit permissible discharge prescriptions electronically (eRx)</p>	<p>More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new or changed prescriptions) are compared to at least</p>	<p>AHA data indicate that 72 percent of hospitals had implemented drug formulary checks in Fall 2011. We do not have data on e-prescribing of</p>	<p>To simplify measurement, separate out drug formulary from e-prescribing of discharge medications as a separate, core objective.</p> <p>Drug formulary was a Stage 1 menu item that should be moved to the core set at the Stage 1 performance threshold.</p>

Ms. Marilyn Tavenner

April 30, 2012

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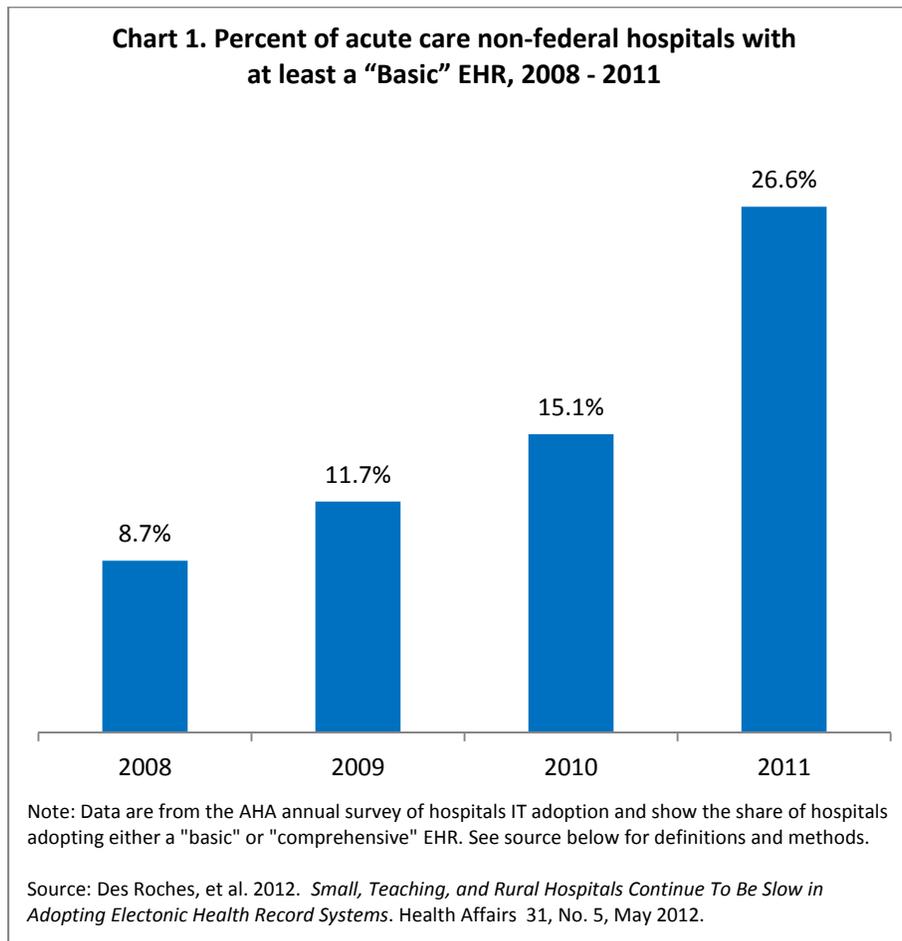
STAGE 2 OBJECTIVES	MEASURES	EXPERIENCE FROM STAGE 1	AHA COMMENTS AND RECOMMENDATIONS
	one drug formulary and transmitted electronically using Certified EHR Technology.	discharge prescriptions, but have heard from our members that it is not yet widely used.	
Clinical Notes			The AHA recommends adding clinical notes as an objective in the menu set. Measure should be that 10 percent of patients admitted have at least one clinical note accessible through the EHR (POS = 21).

APPENDIX 2. TRENDS IN HOSPITAL ADOPTION OF EHRs

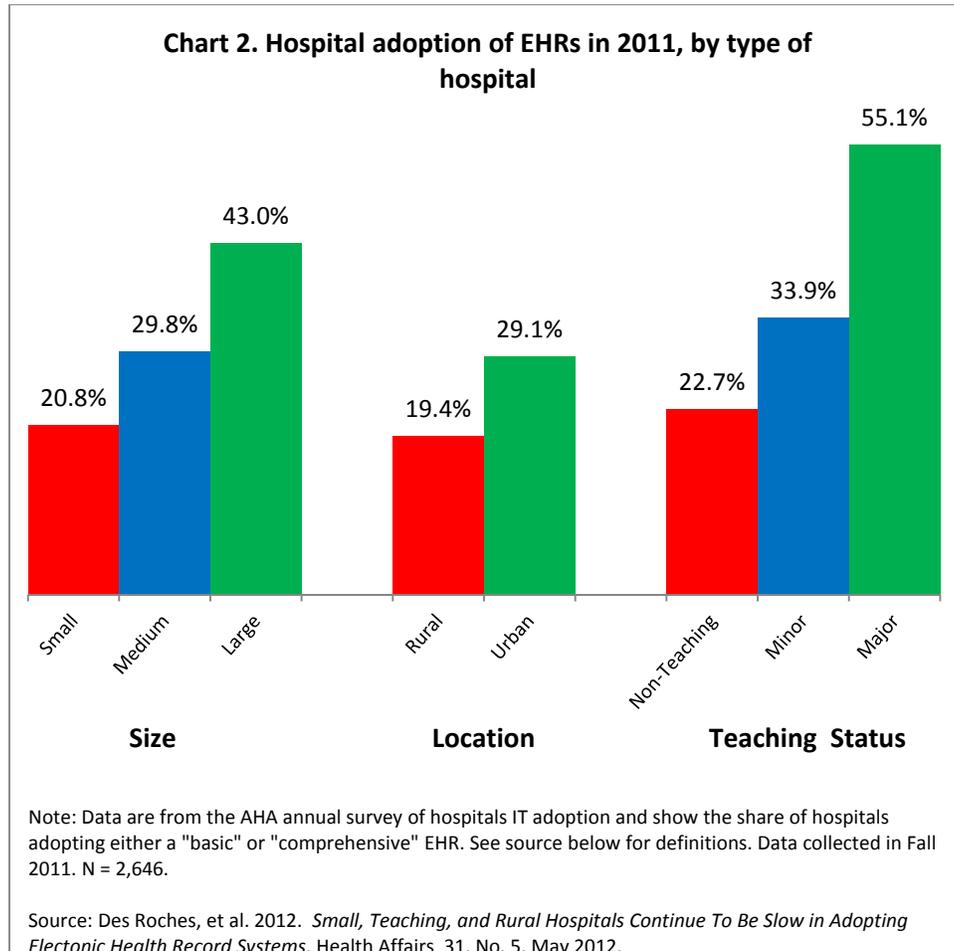
Overview

This appendix includes data from the AHA's annual survey of hospital adoption of EHRs from 2008 to 2011. The AHA survey is the only nationally representative survey of hospitals' use of EHR functions, and has been used in a series of peer-reviewed publications tracking trends in adoption over time. Data from the latest peer-review publication are presented below (Charts 1 through 3). In addition, the AHA conducted its own analysis to model the proposed Stage 2 meaningful use requirements. Those results are presented in Charts 4 through 8.

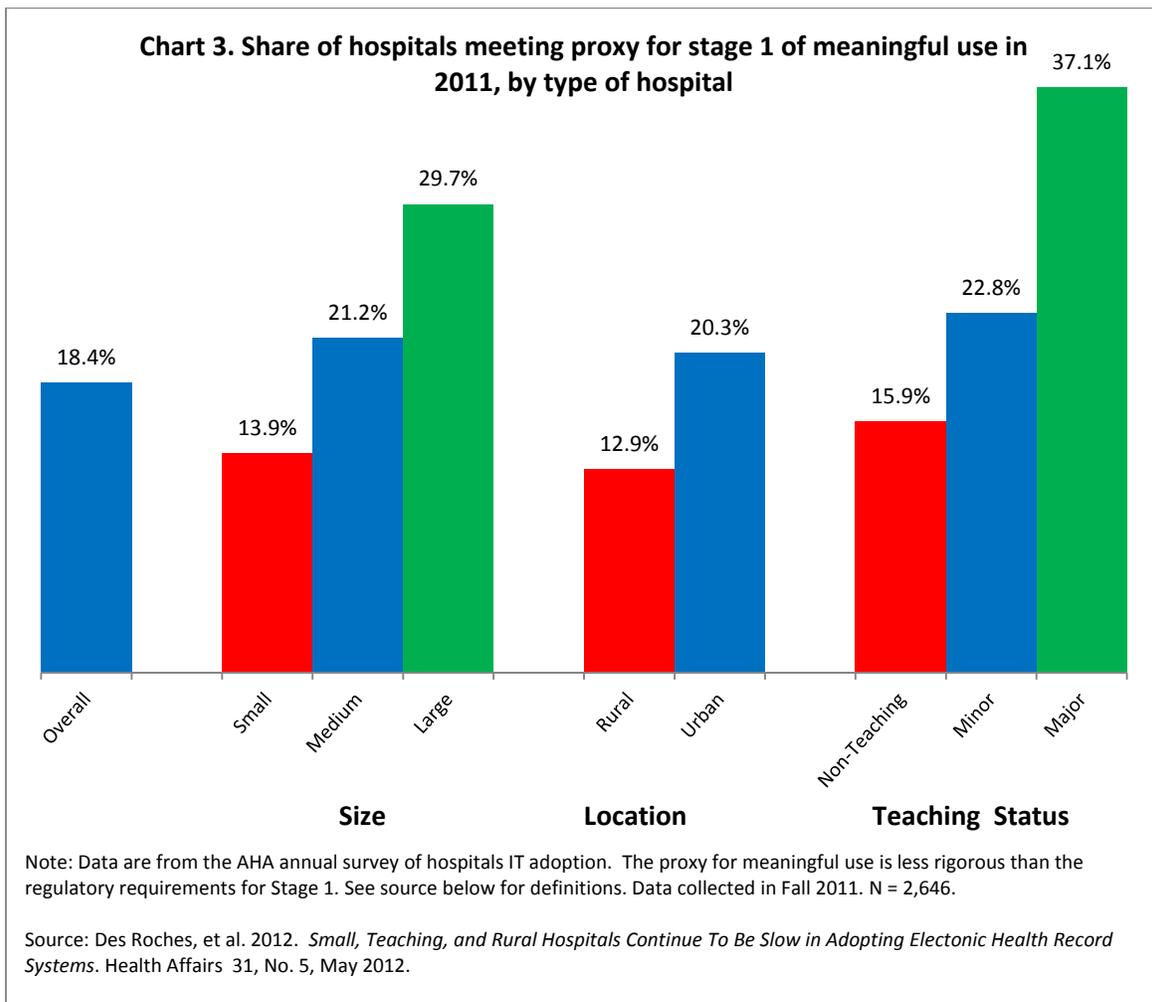
Hospitals are rapidly expanding use of EHRs (Chart 1). Hospitals have increased adoption of EHRs significantly since 2008, with a tremendous increase from 2010 to 2011. The share of hospitals having at least a basic EHR grew from 8.7 percent in 2008 to 15.1 percent in 2010, and 26.6 percent in 2011. These data show an impressive increase in EHR adoption and suggest a clear commitment to the meaningful use program. However, the Stage 1 meaningful use requirements are more rigorous than the definition of a basic EHR. While it is exciting to see rapid progress, adoption takes time and resources to do it right.



However, the digital divide is real (Charts 2 and 3). While many hospitals have been pioneers in harnessing health IT to improve patient care and quality, the challenge now is to extend its use and integrate it in all hospitals. The intention of the EHR incentive program was to provide hospitals with necessary funds for greater adoption of health IT, but the criteria for becoming a meaningful user may actually exacerbate what is a growing digital divide among the hospital field. The regulatory complexity of the rule ignores real world factors that slow adoption, including limited access to capital, lack of vendor capacity to support all of the providers that want to adopt EHRs, and a shortage of experienced health IT workers. Rural, smaller and nonteaching hospitals have fewer financial and technical resources at their disposal. They also are starting from a lower base of adoption. We do not want the meaningful use program to have the unintended consequence of widening the existing digital divide. As can be seen in Chart 2, the adoption rate for large hospitals is more than twice that of small hospitals. Similarly, major teaching hospitals have an adoption rate that is more than twice that of non-teaching hospitals. The gap between urban and rural also is significant.



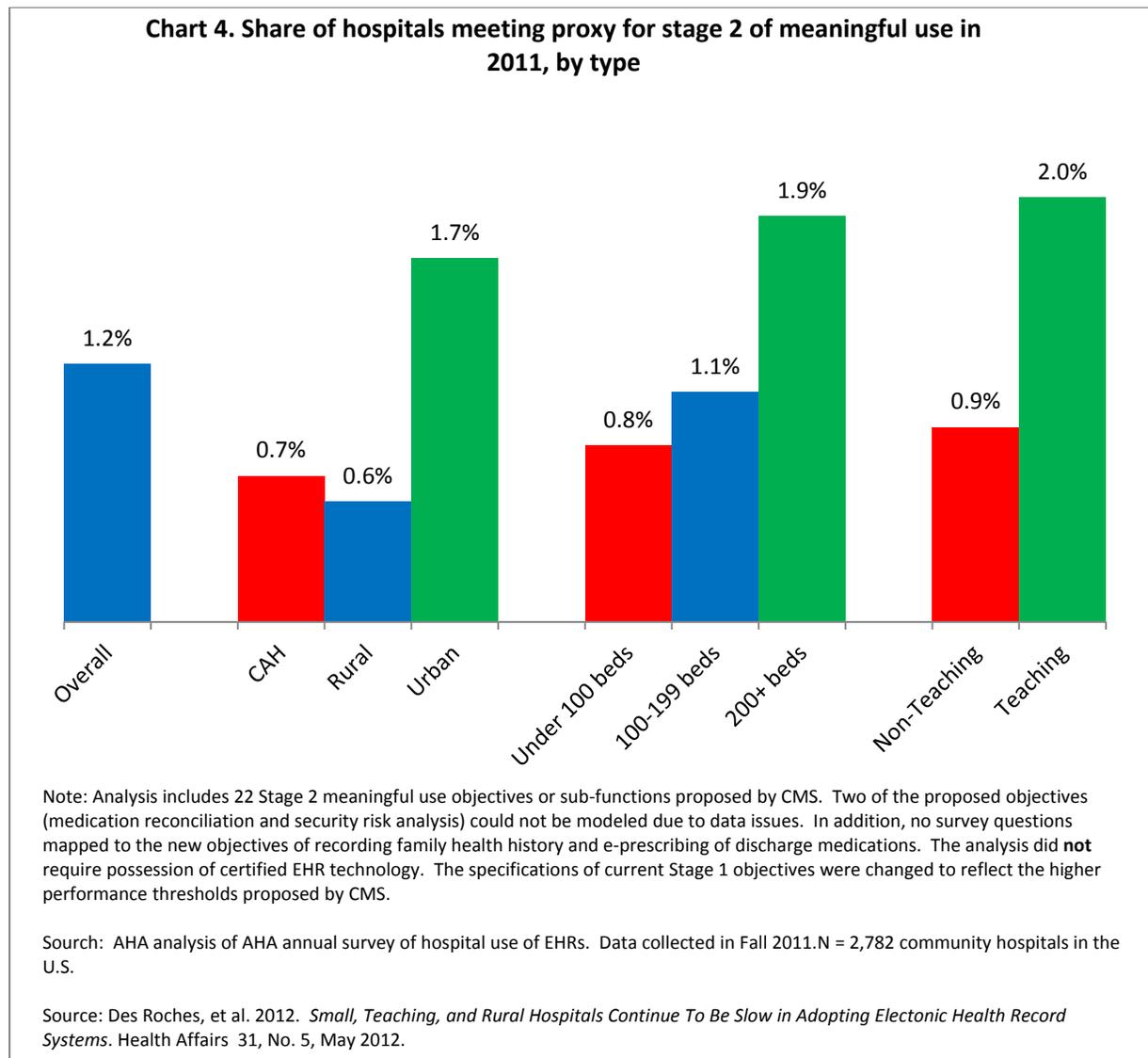
Hospitals with lower adoption rates are less likely to meet meaningful use (Chart 3). As noted above, there is a significant difference between having at least a basic EHR and being able to meet meaningful use. While 26.6 percent of hospitals had at least a basic EHR in 2011, only 18.4 percent could meet a proxy definition of meaningful use that is less rigorous than the actual Stage 1 meaningful use requirements (see full *Health Affairs* article for definitions and methods). The differences in adoption by type of hospital carry over into the analysis of whether hospitals can meet a proxy definition of meaningful use, with small, rural and non-teaching hospitals much less likely to meet the Stage 1 bar.



The proposed Stage 2 bar is even harder to meet. The AHA conducted its own analysis to model the proposed Stage 2 requirements. Our analysis includes 22 Stage 2 meaningful use objectives or sub-functions proposed by CMS. The specifications of current Stage 1 objectives were changed to reflect the higher performance thresholds proposed by CMS (for example, any objective with a threshold of 80 percent or higher was interpreted as requiring full implementation of the function in all units of the hospital, rather than implementation in at least

one unit). Two of the proposed objectives (medication reconciliation and security risk analysis) could not be modeled due to data issues. In addition, no survey questions mapped to the new objectives of recording family health history and e-prescribing of discharge medications. The analysis did **not** require possession of certified EHR technology.

Fewer than 2 percent of hospitals – only 33 of the 2,782 hospitals in the sample – could meet our model of the Stage 2 requirements in Fall 2011. Not surprisingly, they were more likely to be large, urban, and teaching facilities.

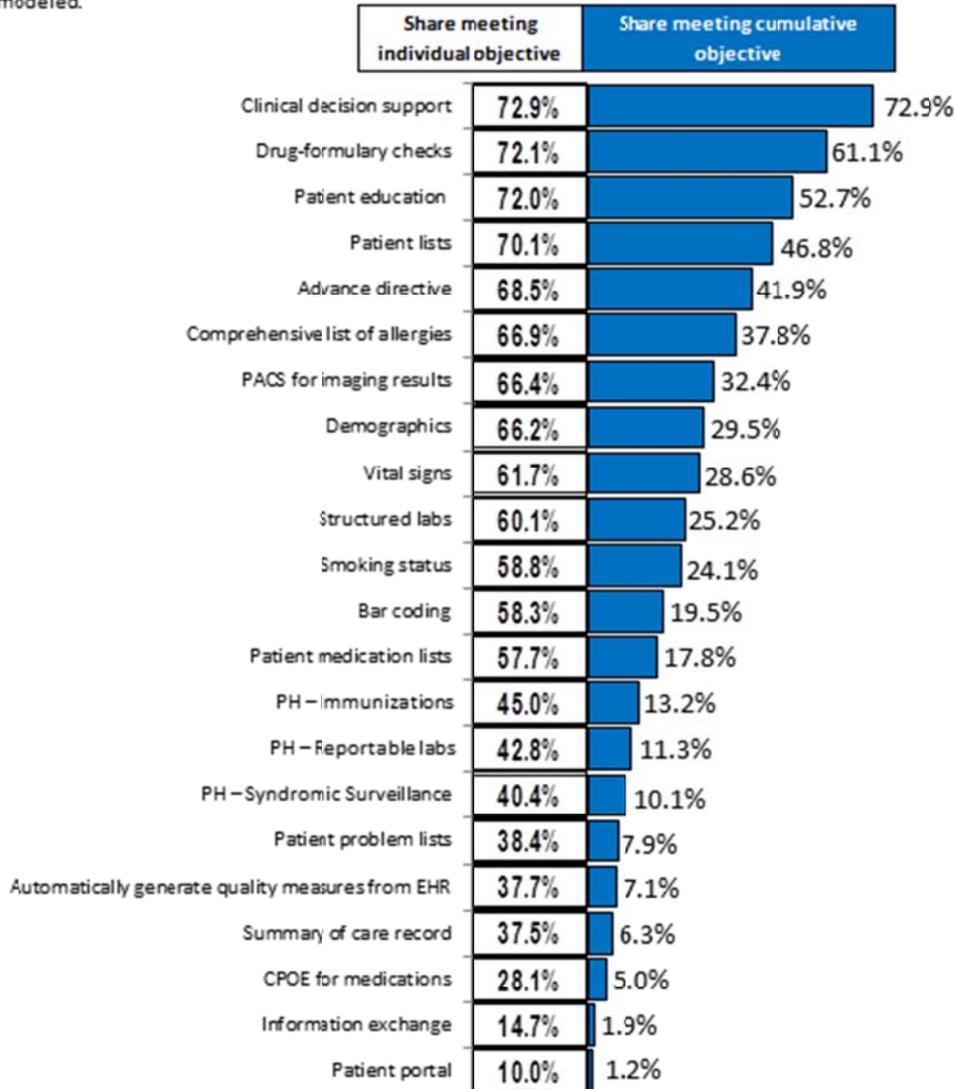


Hospitals are increasing their ability to perform individual objectives, but the sheer number of requirements proposed for Stage 2 limits the number that can meet all of them. Chart 5 shows the share of hospitals that can meet each individual Stage 2 objective or function that we could

model. The most common was the combined clinical decision support objective (drug-drug interaction check, drug-allergy interaction check, plus additional clinical decision support functions such as alerts or order sets), which 72.9 percent of hospitals could meet. The least common was the patient portal, which only 10 percent of hospitals had implemented in Fall 2011. Chart 5 also shows the cumulative impact of the proposed Stage 2 policy that requires a hospital to meet all of the core requirements. Starting with the most common objective, which was clinical decision support (CDS), we then add, in order, the next most common objective, and then the next. The share of hospitals that can meet the cumulative requirements decreases as the number of requirements grows. Thus, while 72.9 percent of hospitals could perform CDS, and 72.1 percent had drug-formulary checks implemented, only 61.1 percent of hospitals had both. When patient education identified using data in the EHR is added, the share able to perform all three drops to 52.7 percent, and so on. As noted above, only 1.2 percent of hospitals could meet all of the 22 proposed requirements that we could model.

Chart 5. Share of hospitals meeting individual Stage 2 objectives, and cumulative objectives, fall 2011

This chart starts with the most commonly met proposed objective. Objectives are then added in order of frequency. For example, 72.9% of hospitals can meet the proposed clinical decision support (CDS) requirements, while 61.1% can do both CDS and drug-formulary checks. When patient education is also added, the share drops to 52.7% that can do all three, and so on. Only 1.2% of hospitals (33 hospitals) can meet all 22 of the proposed requirements that could be modeled.



Note: Analysis includes 22 objectives or sub-functions proposed by CMS. Two of the proposed objectives (medication reconciliation and security risk analysis) could not be modeled due to data issues. In addition, no questions mapped to the new objectives of recording family health history and e-prescribing of discharged medications. The analysis did not require possession of certified EHR technology. The specifications for current Stage 1 objectives were changed to reflect the higher performance thresholds proposed by CMS for Stage 2.

Source: AHA analysis of its annual survey of hospital use of EHRs. Data collected in the Fall of 2011. N = 2,782 US community hospitals.

A significant share of hospitals is far from meeting Stage 2 meaningful use (Charts 6 through 8). Across all hospitals, almost 25 percent have six or fewer of the proposed objectives currently in place. Among critical access hospitals, a much larger share (39.9 percent) are in this group. These hospitals – and the patients and communities they serve – should not be left behind. At the other end of the spectrum, about one in four have 17 or more of the objectives in place. These are the hospitals most likely to meet the Stage 2 requirements. By location, urban hospitals are much more likely to be closer to meeting the Stage 2 requirements, with 29.7 percent falling into this group. That is almost twice the likelihood of CAHs being close to meeting Stage 2, as only 16.7 percent of CAHs fall into this category. Non-CAH rural hospitals fall in between.

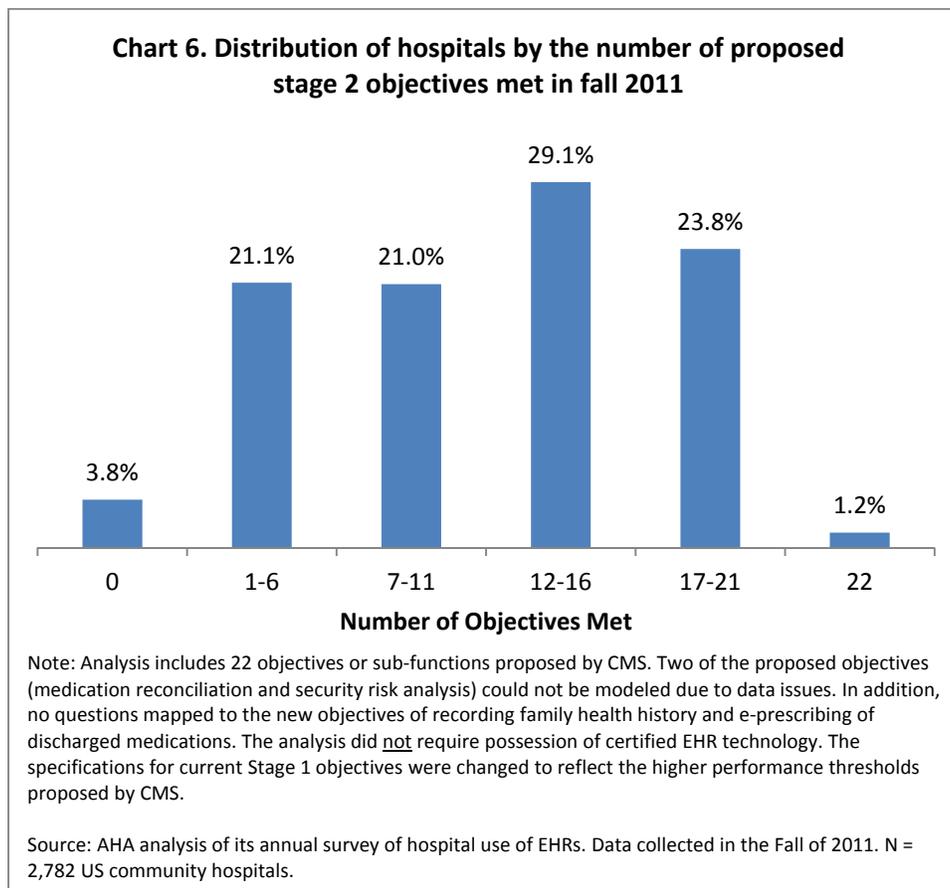
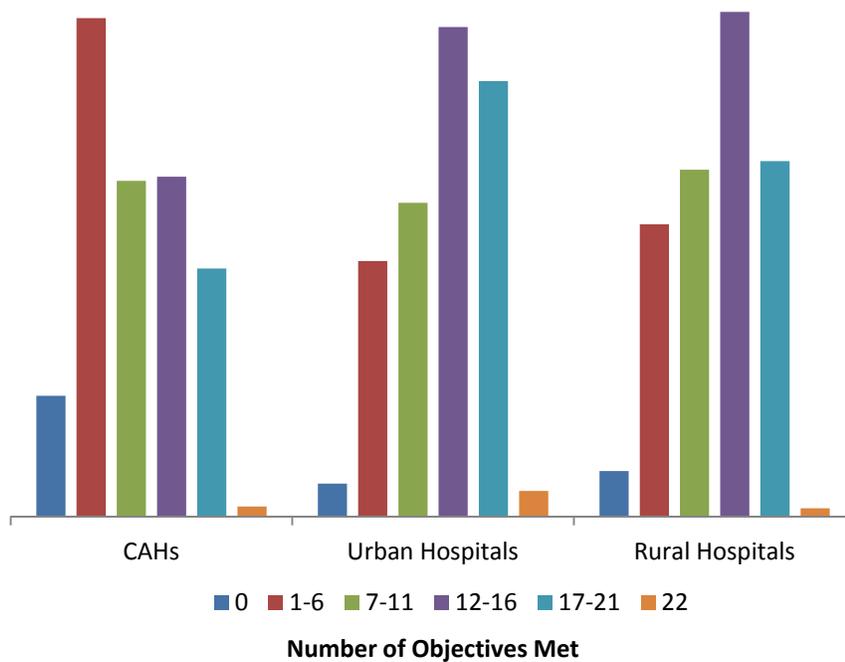


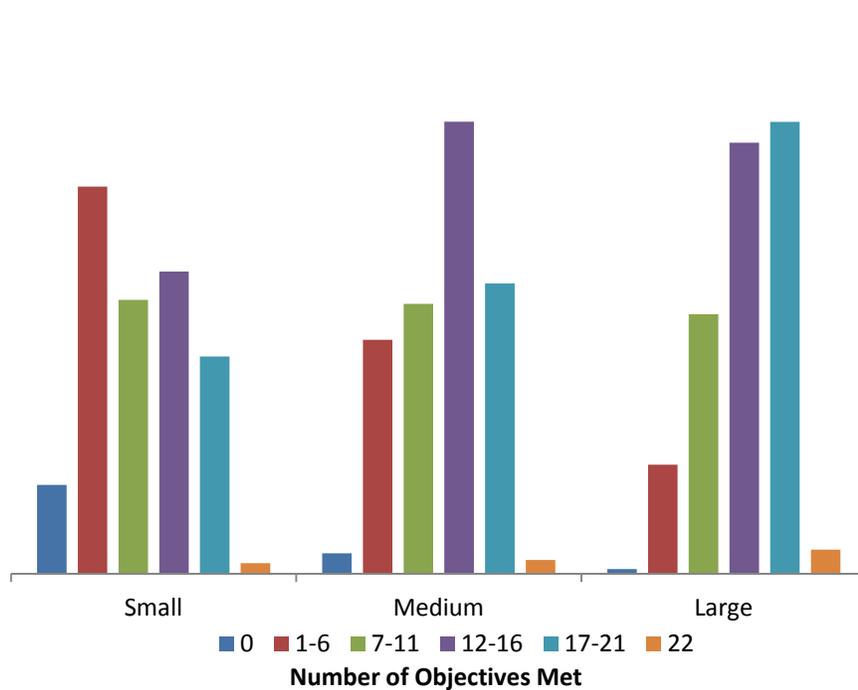
Chart 7. Number of proposed stage 2 objectives met, by location



Note: Analysis includes 22 objectives or sub-functions proposed by CMS. Two of the proposed objectives (medication reconciliation and security risk analysis) could not be modeled due to data issues. In addition, no questions mapped to the new objectives of recording family health history and e-prescribing of discharged medications. The analysis did not require possession of certified EHR technology. The specifications for current Stage 1 objectives were changed to reflect the higher performance thresholds proposed by CMS.

Source: AHA analysis of its annual survey of hospital use of EHRs. Data collected in the Fall of 2011. N = 2,782 US community hospitals.

Chart 8. Number of proposed stage 2 objectives met, by size.



Note: Analysis includes 22 objectives or sub-functions proposed by CMS. Two of the proposed objectives (medication reconciliation and security risk analysis) could not be modeled due to data issues. In addition, no questions mapped to the new objectives of recording family health history and e-prescribing of discharged medications. The analysis did not require possession of certified EHR technology. The specifications for current Stage 1 objectives were changed to reflect the higher performance thresholds proposed by CMS.

Source: AHA analysis of its annual survey of hospital use of EHRs. Data collected in the Fall of 2011. N = 2,782 US community hospitals.

APPENDIX 3. COMPARISON OF TOTAL NUMBER OF FUNCTIONS REQUIRED IN STAGE 1 OF MEANINGFUL USE TO THE FUNCTIONS PROPOSED FOR STAGE 2

Stage 1 Objectives	Stage 1 Related Functions	Stage 2 Objectives	Stage 2 Related Functions
<i>CORE (all required)</i>		<i>CORE (all required)</i>	
CPOE for medication orders	1. CPOE for medications	CPOE for medication, laboratory and radiology orders	1. CPOE for medications 2. CPOE for lab 3. CPOE for radiology
Implement drug-drug and drug-allergy interaction checks	2. Drug-drug interaction checks 3. Drug-allergy interaction checks	Record demographics	4. Record preferred language 5. Record gender 6. Record race 7. Record ethnicity 8. Record date of birth 9. Record cause of death
Record demographics	4. Record preferred language 5. Record gender 6. Record race 7. Record ethnicity 8. Record date of birth 9. Record cause of death	Record and chart changes in vital signs	10. Height 11. Weight 12. Blood pressure 13. BMI 14. Growth chart
Problem list	10. Problem list	Record smoking	15. Smoking status
Medication list	11. Medication list	Clinical decision support	16. Drug-drug interaction checks 17. Drug-allergy interaction checks 18. CDS intervention 1 19. CDS intervention 2 20. CDS intervention 3 21. CDS intervention 4 22. CDS intervention 5
Medication allergy list	12. Medication allergy list	Incorporate clinical lab-test results as structured data	23. Structured lab results
Vital signs	13. Height 14. Weight 15. Blood pressure 16. BMI 17. Growth chart	Generate lists of patients	24. Patient list
Smoking status	18. Smoking status	NEW - electronic medication administration record (eMAR) with barcode/RFID	25. eMAR 26. Use of barcoding/RFID
Clinical decision support	19. Clinical decision support rule	NEW - Provide portal with ability to view, download, and transmit information about a hospital admission	27. Patient portal view 28. Patient portal download 29. Patient portal transmit 30. Problem list 31. Medication list 32. Medication allergy list 33. Care summary 34. Care plan
Report hospital clinical quality measures	20 through 34 – report 15 quality measures	Patient-specific education resources	35. Patient-specific education resources

Provide patients with an electronic copy of their health information	35. Electronic copy of health information	Medication reconciliation	36. Medication reconciliation
Provide patients with an electronic copy of their discharge instructions	36. Electronic copy of discharge instructions	Summary care record	37. Count transitions 38. Summary of care record with expanded data 39. Monitor organizational affiliations of recipients 40. Monitor vendor used by recipients
Capability to exchange key clinical information	37. Test of exchange	Immunization registries	41. Immunization registries
Protect electronic health information	38. Security risk analysis	Electronic reportable laboratory results	42. Electronic lab reporting
		Electronic syndromic surveillance data	43. Syndromic surveillance data
		Protect electronic health information	44. Security risk analysis
		Report hospital clinical quality measures (required as separate element)	45 through 68 – report 24 quality measures
Stage 1 MENU (Report 5 of 10)		Stage 2 MENU (Report 2 of 4)	
Implement drug-formulary checks	39. Drug formulary checks	Advance directive	69. Advance directives
Record advance directives for patients 65 years old or older	40. Advance directives	NEW - Imaging results and information are accessible through EHR	70. Imaging results accessible through EHR
Incorporate clinical lab-test results into certified EHR technology as structured data	41. Structured lab results	NEW - Record patient family health history as structured data	71. Patient family health history
Generate lists of patients	42. Patient list	NEW - Generate and transmit permissible discharge prescriptions electronically (eRx)	72. Drug formulary checks 73. e-prescribing for discharge medications
Patient-specific education resources	43. Patient-specific education resources		
Medication reconciliation	44. Medication reconciliation		
Summary of care record	45. Count transitions 46. Summary of care record		
Immunization registries	47. Immunization registries		
Electronic reportable lab results	48. Electronic lab reporting		
Electronic syndromic surveillance data	49. Syndromic surveillance data		