American Hospital Association

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March 8, 2010

Charlene M. Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–0033–P
P.O. Box 8013
Baltimore, MD 21244-8013

[Submitted electronically]

Ref: CMS-0033-P

Dear Ms. Frizzera:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 40,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Notice of Proposed Rule Making (NPRM) titled "Medicare and Medicaid Programs; Electronic Health Record (EHR) Incentive Program," published by the Centers for Medicare & Medicaid Services (CMS) in the *Federal Register* on January 13, 2010 [CMS-0033-P].

Congress established the Medicare and Medicaid EHR Incentive Program in the *Health Information Technology for Economic and Clinical Health (HITECH) Act*, which was part of the *American Recovery and Reinvestment Act (ARRA) of 2009*, to provide much-needed funds to support the transition to an e-enabled health care system. America's hospitals are very appreciative of the opportunity presented by this program. They share the administration's vision of a health care system where widespread use of interoperable EHRs supports improved clinical care, better coordination of care, fully informed and engaged patients, and improved public health. They also work every day to ensure adequate privacy and security for patients and their personal health information.

The AHA appreciates – and shares – the twin goals that CMS is trying to achieve: motivating hospitals and physicians to move further and faster in using EHRs to improve all aspects of health care, while facilitating the flow of EHR incentive funds in a responsible and appropriate way that fosters continued and timely advancements in health information technology (IT). We are enthusiastic about how health care will be provided in an e-enabled health care system and

want to provide constructive suggestions to make further progress. Our alternative approach will facilitate the flow of much-needed funding and provide a roadmap that all hospitals can use, no matter where they are in their health IT adoption journeys, as they navigate the path to a fully functioning EHR.

Our letter provides feedback on the proposed overall design of the Medicare and Medicaid incentive programs and outlines an alternative approach that we urge CMS to adopt. Our recommendations recognize the efforts currently underway in hospitals, yet provide operational and strategic flexibility, while ultimately resulting in the shared national vision of an e-enabled health care system. Our goal is not to slow down progress toward fully functioning EHRs. Rather, we think our approach will lead to much broader adoption rates of successful EHR systems across the vast majority of hospitals in a sustainable timeframe because hospitals would have more certainty, predictability and flexibility to address both institutional and local community priorities.

The AHA is very concerned that the high bar for achieving "meaningful use" and the limited transitions proposed in the NPRM will severely limit hospitals' ability to access these much-needed resources. We fear that the ultimate impact of the program actually could be the opposite of the goal of an e-enabled health care system, as those who are furthest behind may well be discouraged by the steep adoption curve.

With less than eight months left before the program begins, very few hospitals can meet the proposed "all-or-nothing" approach, even though they have adopted or are adopting EHR systems. In a January 2010 survey with nearly 800 hospital respondents, less than one percent indicated that they could meet all 23 of CMS' proposed requirements to be deemed a "meaningful user" of EHRs today. CMS' rule needs to offer an incremental and flexible plan that will support hospitals and physicians in achieving the ambitious goal that the Congress envisions.

Hospitals also will be hampered in their adoption efforts by inadequate infrastructure and market pressures. The health IT market already suffers from limited vendor capacity, insufficient numbers of trained IT workforce, and shortages of clinical staff trained in IT. These constraints will be even greater in the face of skyrocketing demand from hospitals and physicians seeking to both install new EHR systems and make significant changes to existing, installed EHR systems to meet the certification and meaningful use requirements.

Key concerns and recommendations in our letter include the following issues:

- **Definition of Meaningful Use:** The AHA is concerned that CMS' all-or-nothing approach and the very short timeframes set in the proposed rule are unrealistic. We urge CMS to consider an alternate approach that advances widespread health IT adoption throughout hospitals and sets requirements that are achievable and practical. Our alternative definition of meaningful use includes:
    - Modifying the proposed meaningful use objectives and adding 12 additional objectives;

  - Replacing CMS' proposed adoption year concept with an approach that allows hospitals to satisfy the meaningful use definition if they meet 25 percent of the objectives in 2011 or 2012, and increasing the percentages in future years;
  - Expanding required levels of use and data sharing requirements over time;
  - Changing many of the measures of meaningful use to decrease the reporting burden;
  - Allowing hospitals to meet the meaningful use objectives by grandfathering currently installed and functioning hospital EHR systems as certified; and
  - Relying on existing quality reporting structures until EHR quality measures and products for quality reporting are ready for broad use.

- **Definition of a Hospital-Based Eligible Professional:** The AHA is concerned about the broad definition of a hospital-based professional that, contrary to congressional intent, severely limits the number of professionals that can participate in the programs. We present an alternative that allows more physicians to qualify appropriately for EHR incentives.

- **Definition of a Hospital:** The AHA is concerned about how hospitals are identified for the EHR incentive programs. We ask that each hospital within a system that has a single CMS certification number be evaluated individually for meeting the meaningful use definition and be eligible individually for incentive payments.

- **Critical Access Hospitals (CAHs):** The AHA is concerned that CMS has proposed to exclude CAHs from the Medicaid EHR incentive program. We urge CMS to reverse this decision.

The AHA has a number of other concerns about specific objectives and measures, the burden of the proposed reporting requirements for demonstrating meaningful use, technical issues with the proposed payment methods, the Medicaid incentive program, operational issues, privacy and security policies, and CMS' impact analysis. We detail these concerns in the following pages and the attached documents, which together represent our full comment letter.

America's hospitals want to move toward an e-enabled health care system where all hospitals meaningfully use EHRs to improve patient care and safety and achieve national goals for improved health. We believe the alternatives presented in this letter fulfill the goals of the ARRA legislation and offer a constructive and positive pathway to national EHR adoption. We urge you to accept these recommendations and include them in the final rule.

Thank you for the opportunity to share our concerns and comments. If you have any questions, please contact me or Don May, vice president for policy, at (202) 626-2356 or dmay@aha.org.

Sincerely,

Rick Pollack
Executive Vice President
Enclosure

AHA Detailed Comments on CMS' Proposed Medicare and Medicaid Electronic Health Record (EHR) Incentive Program

OVERALL DESIGN OF THE PROGRAM

The *American Reinvestment and Recovery Act of 2009* (ARRA) provides a combination of Medicare and Medicaid incentives to providers, both hospitals and eligible professionals, for the adoption and "meaningful use" of electronic health records (EHRs). General acute-care, critical access, children's and cancer hospitals can be eligible for one or both programs depending on the type of hospital. Eligible professionals (EPs), who include physicians, dentists, podiatrists, nurse practitioners and other professionals who are not hospital-based, can participate in either the Medicare or Medicaid program, but not both. The Centers for Medicare & Medicaid Services' (CMS) proposed rule defines meaningful use of certified EHR technology through three stages, with the expectation that the requirements will increase over time. The three stages are: Stage 1 (2011 and 2012), Stage 2 (2013 and 2014), and Stage 3 (2015 and beyond).

The proposed rule further specifies 23 EHR and health information exchange (HIE) objectives, or requirements, that must ALL be met by hospitals, including Critical Access Hospitals (CAHs), to be considered "meaningful users" of certified EHRs and receive incentive payments in Stage 1. Some examples of objectives include recording of patient demographic information, maintaining medication lists and up-to-date problem lists, providing patients with electronic copies of their health information, providing care instructions electronically upon discharge, performing medication reconciliation at each transition of care across the continuum, and using computerized provider order entry (CPOE). As discussed in detail below, taken together, these 23 objectives describe a comprehensive EHR system that is more appropriate as the end product of the EHR incentive program, rather than the requirement for the early stages.

Specific measures are associated with each objective, and all 23 objectives would need to be adopted in a manner that meets the measures established for the objective. For example, CPOE must be used for at least 10 percent of all orders. Additionally, all hospitals would need to ensure that their EHR systems are certified against each of the 23 objectives under a yet-to-be-finalized federal process. As a further requirement to be considered meaningful users, the rule proposes to require hospitals to report 35 clinical quality measures to Medicare (or eight measures to Medicaid) through certified EHR technology.

In Stage 2 (2013 and 2014), CMS proposes to expand on the earlier established measures to focus on continuous quality improvement at the point of care and the exchange of information in the most structured format possible. Stage 3 (2015 and beyond) will focus on promoting improvements in quality, safety and efficiency, decision support, patient access to self-management tools, access to comprehensive patient data, and improvements population health. CMS will specify the requirements for both Stages 2 and 3 in future regulations, but the agency will likely require steep increases in the scope and complexity of the EHR objectives.

By statute, providers may enter the EHR incentive program in different years, depending on when they fully meet all 23 objectives. Thus, the actual timing of incentive payments for an eligible hospital will depend on when the provider first becomes a meaningful user (referred to as "first payment year").

CMS' Notice of Proposed Rule Making (NPRM) proposes to provide some transition time for hospitals that first become meaningful users after 2012 by applying the Stage 1 criteria to all hospitals in their first payment year, as long as they become eligible before 2015 (Table 1). Those starting later, however, would need to climb the adoption curve more quickly, so that they meet the Stage 2 and Stage 3 criteria on the same schedule as early adopters.

Table 1. Stage of Meaningful Use Criteria by Payment Year (Adapted from table on p. 1854 of NPRM)

First Payment Year	Payment Year				
	2011	2012	2013	2014	2015 and beyond
2011	Stage 1	Stage 1	Stage 2	Stage 2	Stage 3
2012		Stage 1	Stage 2	Stage 2	Stage 3
2013			Stage 1	Stage 2	Stage 3
2014				Stage 1	Stage 3
2015 and beyond					Stage 3

AHA CONCERNS

The AHA is concerned about numerous aspects of the proposed program design, which raises unrealistic expectations, presents an unachievable timeline and establishes an uncertain process.

Unrealistic Expectations of the "All-or-Nothing" Approach. The proposed rule takes an "all-or-nothing" approach to meaningful use of health information technology (IT) that does not recognize the different paths hospitals may take to achieve a paperless clinical care environment. Further, it makes no distinction between hospitals that have done very little with regard to health IT and those that have implemented many IT functions, but may not meet the full set of 23 objectives mandated by CMS to receive EHR incentive payments.

CMS' 23 hospital objectives describe a comprehensive EHR system with capabilities that are currently beyond even many of the most advanced EHR systems in use today. In fact, the proposed objectives describe an EHR system that is beyond the capabilities of any vendor product currently available in the marketplace. The objectives are more ambitious than the comprehensive inpatient EHR defined by a team of Harvard University researchers and an affiliated expert panel because the proposed objectives include many HIE functions for data sharing and require use of structured data. In a recent *New England Journal of Medicine* article, the Harvard study found that only 1.5 percent of hospitals were using a comprehensive EHR system, which did not include any of the HIE functions proposed in the NPRM.[1]

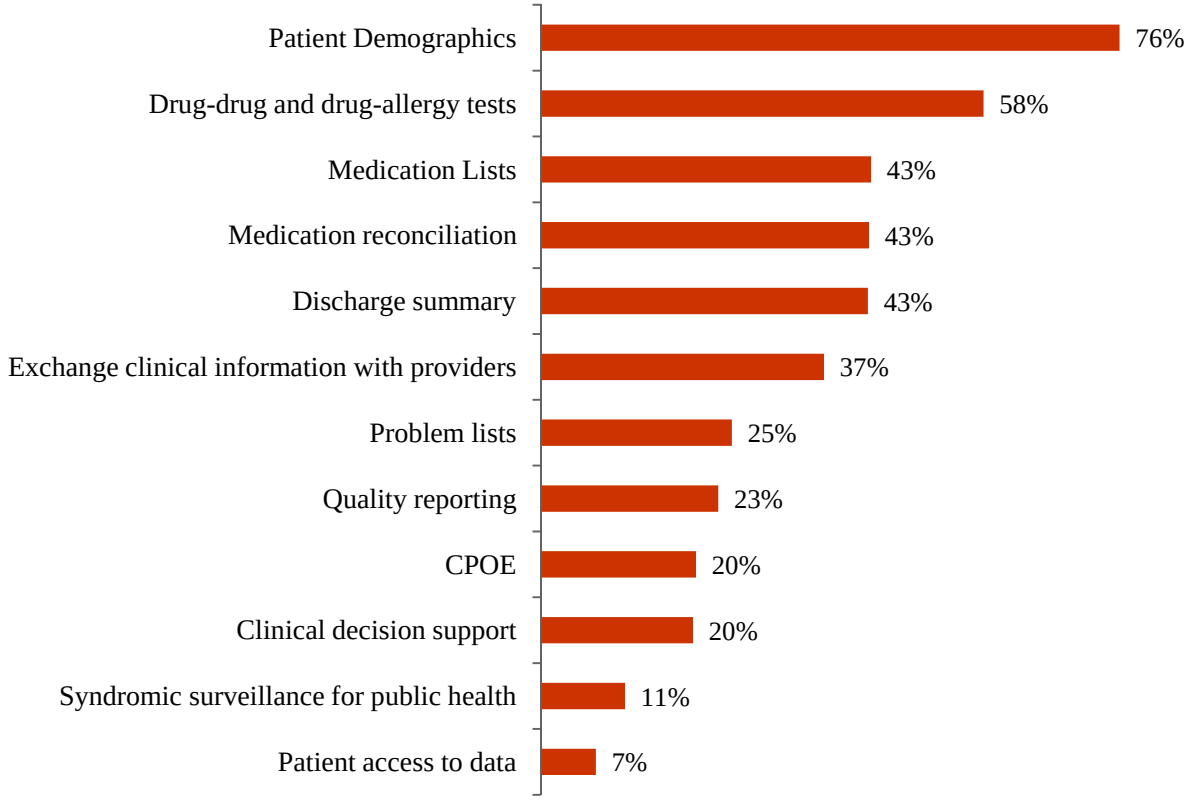
[1] Jha AK, DesRoches CM, Campbell EG, Donelan K, Rao SR, Ferris TG, Shields A, Rosenbaum S, Blumenthal D. Use of electronic health records in U.S. hospitals. N Engl J Med 2009;360:1628-38.

The AHA recently analyzed the same data used by the Harvard researchers (collected from 3,342 hospitals) to determine how current systems match to the 23 proposed objectives. The survey included questions that could be mapped to only 12 of the proposed objectives. The two charts below show how the proposed "all-or-nothing" approach fails to recognize the significant progress hospitals have made in creating and maintaining electronic records to improve patient care and safety.

For example, Figure 1 shows that 76 percent of hospitals have the ability to collect and utilize patient demographic information; 58 percent have electronic medication lists; and 20 percent of hospitals have implemented CPOE.[2]

Figure 1. Hospitals Have Implemented Many of the Meaningful Use Objectives

Percent of Hospitals With EHR Function

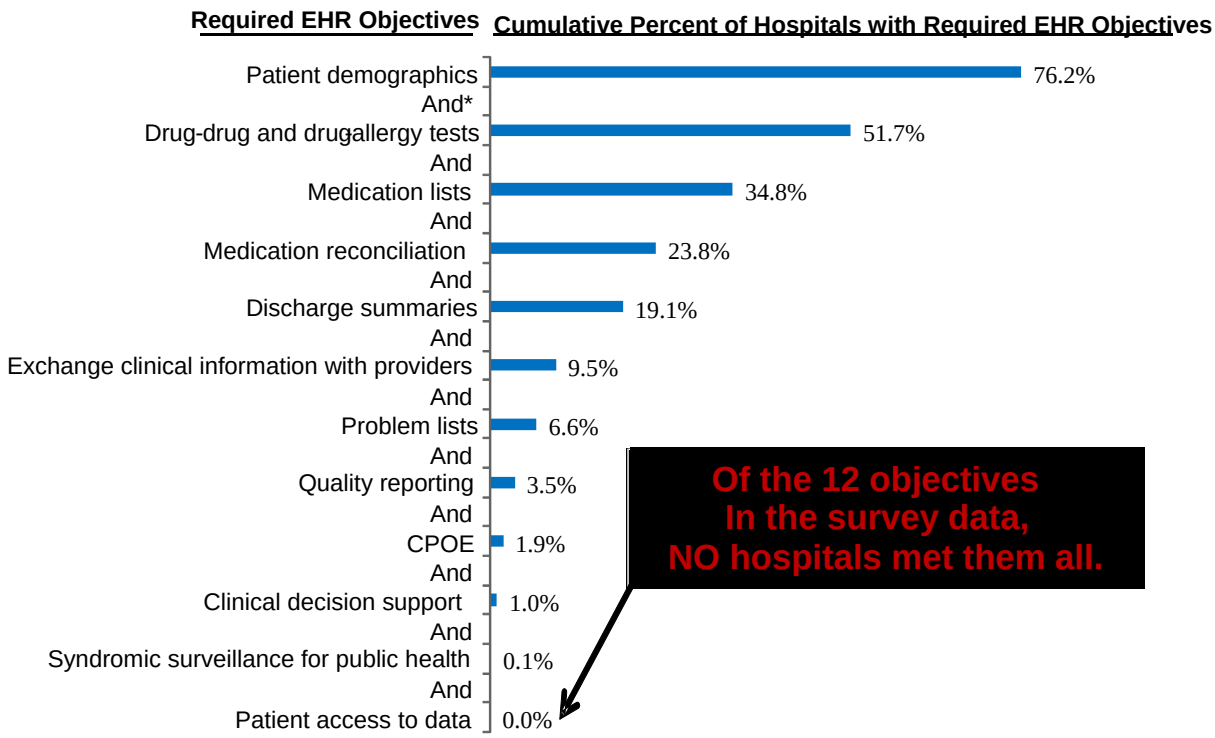


Source: Based on analysis of AHA Annual Survey IT Supplement conducted in mid-2008. Survey contained questions related to only 12 of the 23 proposed objectives . Includes data from 3,342 non-federal hospitals (65% of hospitals).

[2]To approximate the proposed rule requirement that 10 percent of orders be placed through CPOE, the CPOE test included in this analysis required hospitals to have CPOE for at least two of five measured uses (lab tests, radiology tests, medications, consultation requests, and nursing orders) and have at least some share of their medication and laboratory orders written electronically. The data indicated that a larger share of hospitals, about 27 percent, have installed CPOE for medications either across the hospital or in at least one department.

Figure 2, however, shows that while many hospitals have adopted subsets of these technologies, none of the more than 3,300 responding hospitals met all 12 objectives. Adding the 11 objectives not included in the survey (for a total of 23 required objectives) makes meeting the proposed meaningful use definition even more difficult.

Figure 2. "All-or-Nothing" Excludes Most Hospitals



NOTE: Percentages show cumulative effect of adding each additional objective. Based on analysis of AHA Annual Survey IT Supplement conducted in mid-2008. Includes data from 3,342 non-federal hospitals (65 percent response rate). Survey contained questions related to 12 of the 23 proposed objectives.

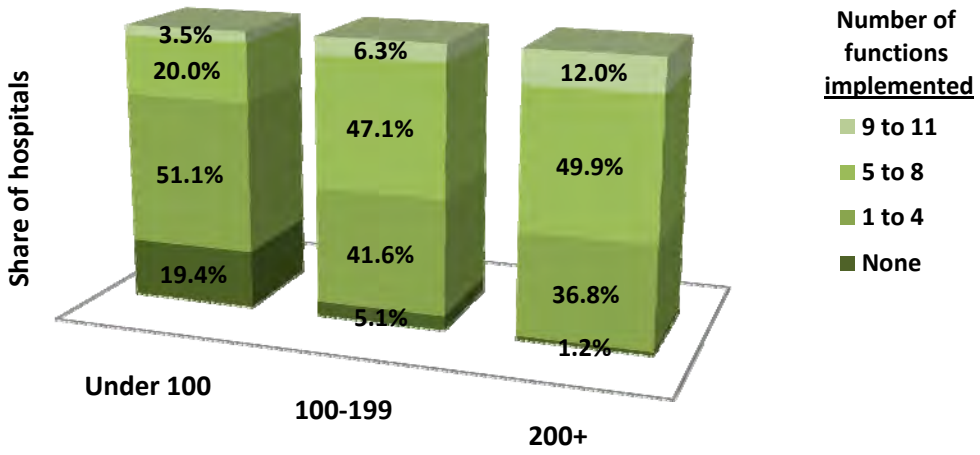
More recently, in January 2010, 795 hospitals responded to an AHA survey of hospitals' current EHR systems. The hospitals responding to the survey were representative of all non-federal, acute care hospitals in size, location, and teaching status." **Fewer than 1 percent of hospitals said that their systems are currently capable of performing all 23 meaningful use functions.** Looking forward, the majority of hospitals – 55 percent – also reported that they would not be capable of performing all 23 functions in 2015. This means that, under the proposed Stage 1 meaningful use criteria and without any increased requirements from Stage 2 or Stage 3, **most hospitals would face reductions in their Medicare payments due to the penalties imposed under the EHR "incentive" program.**

Potential to Widen the Digital Divide. We are especially concerned about hospitals that are just beginning the EHR adoption process. Data from AHA surveys suggest that differential approaches are needed for large and urban hospitals compared to small and rural hospitals, including CAHs. Following the approach proposed by CMS could very well have the

unintended consequence of widening the existing "digital divide" between hospitals that have been fortunate enough to have sufficient resources to make EHR investments, and those that have not. Small, rural, and safety-net hospitals, in particular, face greater capital constraints, as well as other challenges.

The potential for differential impact by hospital size is illustrated in Figure 3 below. Larger hospitals are ahead of their smaller counterparts in meeting the meaningful use objectives. While more than 60 percent of large hospitals (more than 200 beds) had implemented at least five of the 12 objectives we could measure, just over 50 percent of mid-size hospitals (100 to 199 beds) had done so, while fewer than 25 percent of small hospitals (under 100 beds) had attained the same level of adoption. Nationally, there are about 2,600 hospitals with fewer than 100 beds.

Figure 3. Smaller hospitals have implemented fewer of the proposed meaningful use requirements than larger hospitals

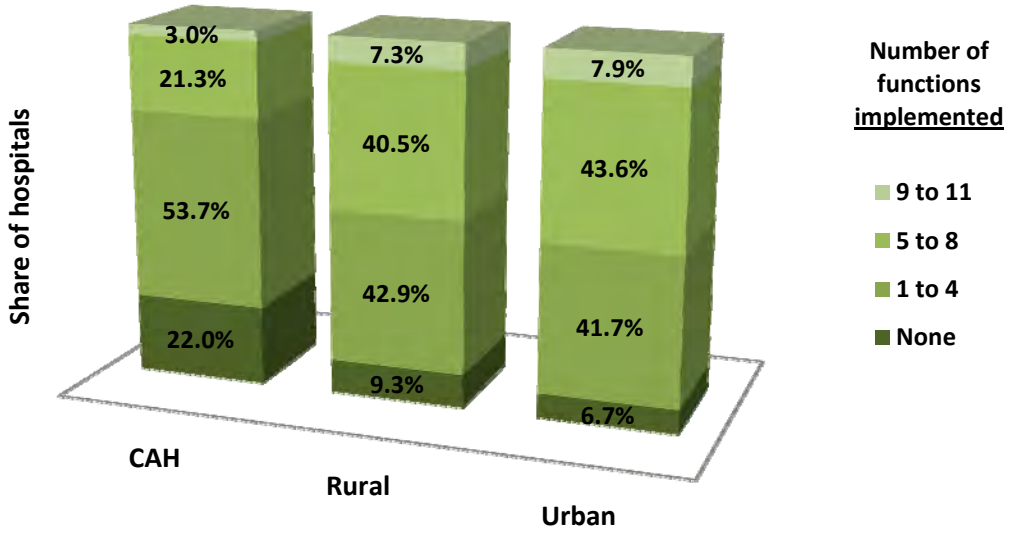


Source: AHA analysis of survey data from 3,342 non-federal, short-term acute care hospitals collected in 2008. The survey modeled 12 of 23 proposed meaningful use requirements on which data were available. Nationally, there are about 2,600 hospitals with fewer than 100 beds, 1,100 hospitals with 100 to 199 beds, and 1,400 hospitals with more than 200 beds.

Similarly, Figure 4 shows that, by location, more than 60 percent of urban hospitals, just over 50 percent of rural (non-CAH) hospitals, and fewer than 25 percent of CAHs had implemented five or more of the proposed meaningful use objectives we could measure. Nationally, there are about 1,300 CAHs. If smaller and rural hospitals cannot meet the requirements in the timelines outlined in the NPRM, they are likely to fall even further behind their larger and urban counterparts, because they often have limited financial and technical resources to adopt EHR systems. **Indeed, in AHA's January 2010 IT survey, 61 percent of small hospitals and 66 percent of CAHs said they expected to be penalized in 2015 under the proposed meaningful use objectives (and that is without any increased requirements from Stage 2 or Stage 3).** In

addition, at least anecdotally, these smaller facilities are at a considerable disadvantage in negotiating with vendors and receiving timely vendor support.

Figure 4. CAHs and rural hospitals have implemented fewer of the proposed meaningful use requirements than urban hospitals



Source: AHA analysis of survey data from 3,342 non-federal, short-term acute care hospitals collected in 2008. The survey modeled 12 of 23 proposed meaningful use requirements on which data were available. Nationally, there are about 1,300 critical access hospitals (CAH), 1,000 non-CAH rural hospitals, and 2,800 urban hospitals.

Unachievable Timelines. Experience in the field has shown that the proposed timelines are unrealistic and do not coincide with the actual pace at which adoption of complex EHR systems and health information exchange can be realized. Successful EHR adoption is a multi-year, incremental process that takes significant capital and operating expenditures and close collaboration with clinical and other staff. Given these realities, a hospital or health system that is only now beginning to undertake the EHR journey will find it very challenging – if not impossible – to receive any Medicare EHR incentive payments under the proposed definition of meaningful use.

Although proposed as a way to lessen the time pressures, CMS' proposed transition approach is too complex and puts later adopters in the untenable position of having to implement the more advanced functions expected in Stages 2 and 3 on an accelerated timeline. Late adopters already face a steeper adoption curve; withholding EHR incentives and, ultimately, applying financial penalties from the statutory payment formulas will make their efforts to implement fully functioning EHRs even more challenging.

The unrealistic timelines are further exacerbated by the requirement that hospitals certify their EHR systems against all 23 objectives. Even with the recent release of the Office of the National

Coordinator's (ONC) proposed rule on the federal certification process,[3] there is great uncertainty and near impossible timeframes to meet. The certification requirement amounts to a need for every hospital to either install new systems or upgrade to certified versions of their existing products at the same time. In addition, once the certification process is established, the increase in demand for certified products will create significant market pressures, many of which are already being felt. Limited vendor capacity and workforce shortages make it highly unlikely that all of these demands can be met by the end of Stage 1, when incentive payments are at their highest level.

Many of the 23 proposed objectives are advanced functions – such as CPOE, clinical decision support and automated medication reconciliation – that generally are implemented at the end of a multi-year transition to EHRs. Significant amounts of capital, work and time are required for hospitals and health systems to move through the entire lifecycle of EHR deployment and management. In the best cases, such an approach requires at least a three-year window from initial projection conceptualization to the point where clinicians are actually using the systems in service of patient care. In most cases, the time required is much longer; even relatively smooth-running EHR initiatives often take between five and seven years to implement fully.

For CPOE specifically, a 2009 study by the independent market research firm KLAS tracked the implementation experience of the health care customers of nine major vendors that had signed contracts to install core clinical systems in large hospitals (200 or more beds) in 2006 or 2007. The KLAS study evaluated how many of those contracted installations were live with CPOE by the end of 2008. The vendor with the best implementation record had successfully gone live with CPOE at only 23 percent of its large hospital clients by the end of 2008 (an implementation window of between 12 to 36 months). Another had gone live in 21 percent of its large hospitals. At the other end of the spectrum, five of the nine vendors had not yet gone live with CPOE at any of their contracted hospitals.[4]

Unintended Consequences. Rushing implementation of advanced clinical systems risks failed implementations, missed opportunities to revise workflows and create sustainable change, and potential risks to patient safety.

We urge CMS to consider the potential unintended consequences as it has laid out a very aggressive timeline for EHR implementation. Providers need ample time to test their EHR systems as they are implementing them to ensure that all safeguards are in place to avoid patient harm. Asking providers to do too much too quickly will challenge their ability to ensure these safeguards.

Some providers who have implemented EHRs have discovered in testing their systems that decision errors that could cause patient harm were inadvertently standardized into their EHR

[3] On March 2, ONC released a proposed rule: Proposed Establishment of Certification Programs for Health Information Technology.

[4] "Meaningful Use Leading to Improved Outcomes," May 2009, www.KLASresearch.com. ©2009 KLAS Enterprises, LLC.

systems. In most cases, the errors were identified before any patients were affected, but these providers discovered that, without careful safeguards in place, the implementation of EHRs with automated decision-support systems could have the potential to harm patients.

A recent article in the *Journal of the American Medical Association* by respected experts in the intersection of health IT and patient safety and health care quality noted that:

> Research and experience gained to date show that [EHR] implementation efforts are difficult, costly, time consuming, and fraught with many unintended consequences. Evaluation of these systems after implementation suggests that they do not routinely meet safety standards of other safety-critical industries. The aggressive timeline proposed in the ARRA bill means that a large number of practitioners and health care organizations will soon be attempting a monumental feat without the time or ability to customize these systems to their local workflows.[5]

In addition, the Leapfrog Group noted in 2008 that given the complexity of CPOE, ongoing quality assurance is needed to ensure that these clinical decision support tools are effective and not introducing harm (News Release, 10/14/2008). In recognition of these issues, the Adoption Workgroup of ONC's HIT Policy Committee announced on February 17 that it will convene a hearing on health IT safety issues.

Disruption of Existing Strategic Plans. Hospitals consider EHR systems as part of their strategic approach to improving patient safety and the quality of care. The specific systems and functionalities they implement, and the timing of those implementations, are driven by local and institutional priorities and conditions. Not all hospitals follow the same path to full EHR implementation and adoption of advanced clinical systems. For example, in some areas of the country, such as the City of New York and the state of North Carolina, hospitals already are sharing electronic data with public health agencies. They have prioritized this functionality in response to local conditions. In other areas, where public health agencies are not ready, hospitals have focused on other priorities.

Most hospitals have included adoption of EHR systems in their strategic plans for a number of years. They have conducted needs assessments, determined staff readiness to adopt health IT, and developed phased implementation plans that take into account the change-management and technical requirements needed to meet their goals, as well as their existing workforce and capital resources. Disrupting existing plans in order to meet a "one-size-fits-all" definition of meaningful use will be costly, and may result in failed implementation.

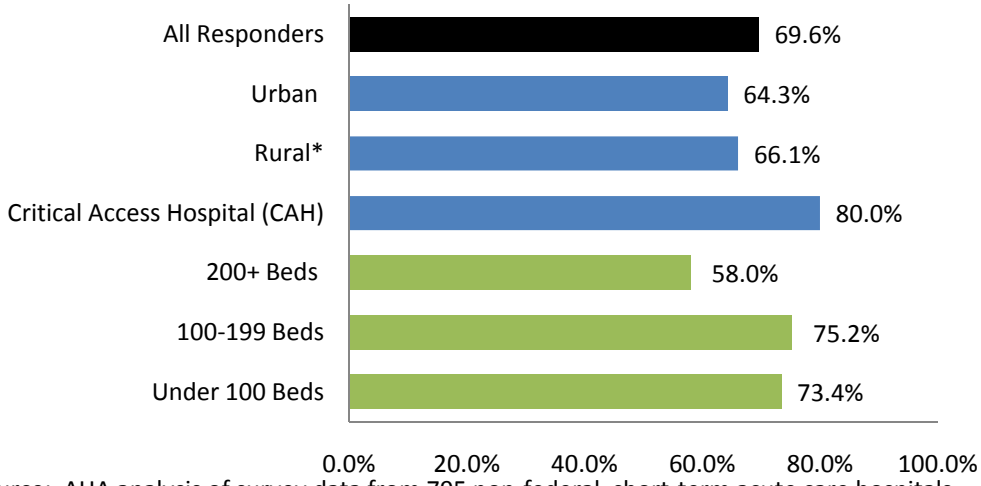
Capital Constraints. The cost and complexity of inpatient EHR systems require long-term planning to raise sufficient capital. The recent tightening of the capital markets, however, will likely constrain hospitals from raising the significant capital required of these multi-phase endeavors. According to *Health Technology Online*, a 500-bed hospital can expect to spend as

[5] DF Sittig; DC Classen. Safe electronic health record use requires a comprehensive monitoring and evaluation framework. *JAMA*. 2010;303(5):450-451.

much $70 million achieving a fully functional EHR.[6] A multi-hospital system can see the costs run into the hundreds of millions, depending on the number of facilities and clinics, and the deployment strategy pursued.[7]

Hospitals have noted access to capital as a key barrier to EHR system adoption. This concern continues, even with the prospect of the federal EHR incentive program. In our recent survey, we found that the vast majority of hospitals (70 percent) continue to see capital as a key barrier to adoption. Capital constraints are even greater for small and rural hospitals (see Figure 5).

Figure 5. Nearly 70% of hospitals cited upfront capital costs as a barrier to achieving the meaningful use requirements



Source: AHA analysis of survey data from 795 non-federal, short-term acute care hospitals collected in 2010. Hospitals were asked to identify barriers to achieiving meaningful use in a timely manner. *Excluding CAHs.

By statute, the Medicare EHR Incentive Program will do little to ease capital constraints, as the payments will be made only after a comprehensive EHR system has been purchased and installed. The AHA appreciates the availability of funds, but hospitals pinched for capital have noted that the funds will not be available to help them reach their goals, even though they have begun implementing health IT systems.

Medicaid EHR incentive payments, however, could be used to partially address hospitals' capital needs for one year. Hospitals greatly appreciate the willingness of Congress to provide those resources. The Medicaid program is, however, voluntary for states. We are concerned that the voluntary nature of the Medicaid EHR Incentive Program, and the complex requirements on

[6] http://www.healthtechnologyonline.com/article.mvc/How-Much-Will-An-EHR-Cost-You-0001?VNETCOOKIE=NO
[7] "Impact of Electronic Medical Records Discussed," October 30, 2009. *Harvard Public Health Now.*

states to establish the programs, could result in states delaying implementation of their programs or deciding not to undertake them at all.

It is our understanding that, as of March 2010, about half of the states have received initial Medicaid planning funds from CMS, but NO states have yet submitted a state Medicaid health IT plan. The formal plan must be reviewed and approved by CMS before significant administrative funds can be received to support the bulk of planning activities. Approval of the Medicaid state plan is just the first step in a lengthy set of requirements and milestones to receive approval to begin a Medicaid incentive payment program. State hospital associations report that only about half of states have begun consultations with stakeholders, and very few have given any indication of when they expect to begin their Medicaid EHR Incentive Programs. Given this situation, it seems unlikely that most states will, in fact, have an operating program by January 2011.

Finally, not all hospitals will be eligible to receive Medicaid dollars. Based on hospital discharge data, the AHA estimates that slightly more than half (51.6 percent) of section (d) hospitals meet the Medicaid volume thresholds.

AHA'S ALTERNATIVE APPROACH

We believe that Congress intended to support EHR system adoption by hospitals and introduced the concept of increasing levels of requirements over time to ensure that providers could be supported through their adoption process. By including this program in the ARRA, Congress also intended to provide in the near term an infusion of funds into the health care sector. If very few hospitals qualify in the earlier years of the program, that objective will not be achieved.

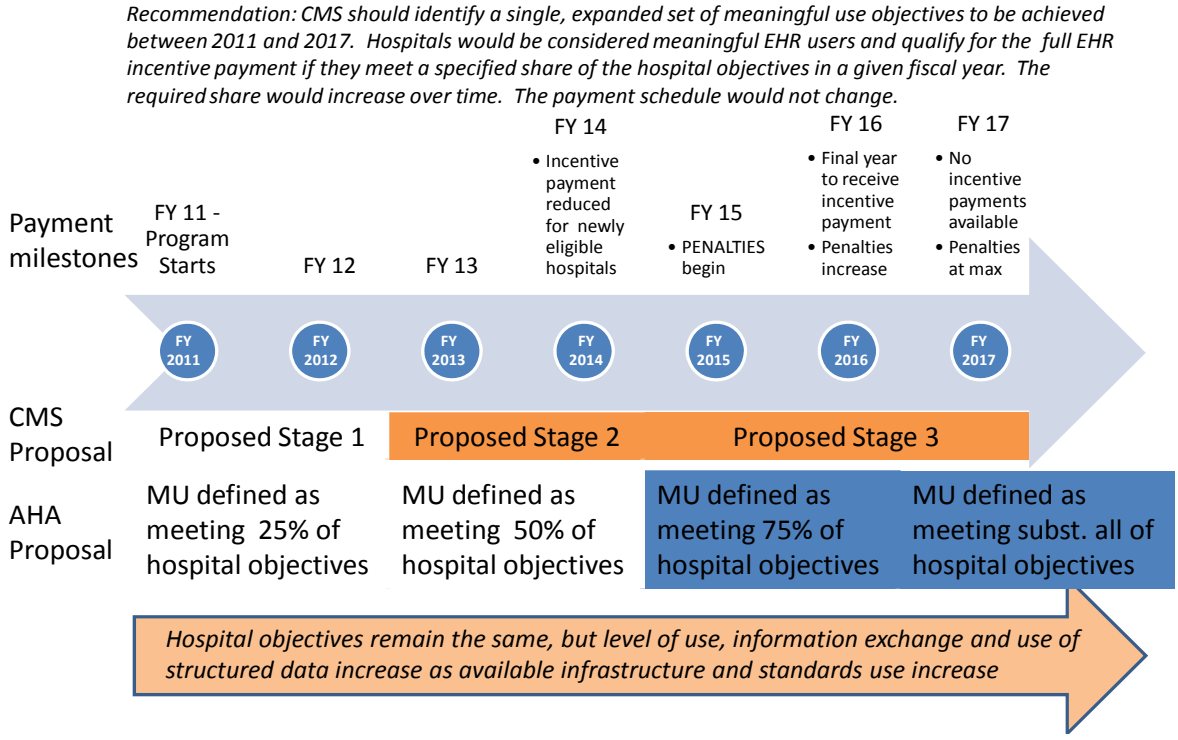
Therefore, we propose an alternative definition of meaningful use and an incremental transition approach. We recommend that CMS identify a single, expanded set of meaningful use objectives to be achieved between 2011 and 2017. Hospitals would be considered meaningful EHR users and qualify for the full EHR incentive payment if they meet a specified percentage of the hospital objectives in a given fiscal year. The required percentage would increase over time.

We propose this alternative because the EHR incentive programs must be:

- Flexible to support organization-specific IT implementation strategies that account for strategic quality improvement goals, capital investment planning, careful approaches to positive work process change, and staff and physician readiness;
- Future-oriented to provide a complete vision of the full set of objectives so hospitals can plan and prioritize their EHR adoption approach;
- Incremental, to mirror the natural health IT adoption process that begins with foundational IT systems and builds to highly advanced clinical decision support systems;
- Focused on objectives that have been proven to promote improved patient safety and quality; and
- Achievable for all hospitals.

Figure 6 illustrates the differences between the approach in the NPRM and the AHA's alternative. The following sections describe the alternative in detail.

Figure 6. Alternative Approach to Defining Meaningful Use



1. Establish the full scope of meaningful use objectives up-front.

As proposed, the requirements for Stage 1 leave out many key EHR functions to support safe, high-quality inpatient care, many of which are necessary precursors to more advanced clinical functions. Additionally, the "yet-to-be-named" objectives for Stages 2 and 3 make it difficult for hospitals to plan their IT adoption activities. The final vision of EHR meaningful use should be specified now to provide hospitals the certainty needed to plan capital needs and implementation plans over the next several years.

The AHA believes the complete list of hospital meaningful use objectives should include those in the proposed rule (with some modifications) and should be expanded to include 12 additional objectives that have been discussed and proposed by the HIT Policy Committee for FYs 2013 and 2015.

While the list of objectives required would remain relatively unchanged over the coming years, the scope of their use should accelerate, so that:

- Levels of use increase over time (such as increased use of CPOE);
- Use of structured data increases over time; and
- Information exchange increases over time.

A final set of 34 recommended objectives, together with the changing requirements over time, is listed in Table 2 on page 23. The AHA's comments on specific changes and additions to CMS' 23 proposed objectives are provided beginning on page 19.

Although specified in advance, the full set of hospital objectives should be reviewed periodically through rule-making. The regulatory requirements would represent the *minimum necessary* to achieve meaningful use and certainly many hospitals would likely achieve a higher number of objectives and greater level of use to meet competitive pressures.

2. Lengthen the timeframe for achieving the ultimate vision for meaningful use.

To support incremental adoption, the goal-line for meeting full meaningful use should be extended to 2017 and encompass four phases of increased functionality and use (2011/2012, 2013/2014, 2015/2016, and 2017). By law, 2017 is the first year in which no incentive payments can be made. Under the ARRA, providers that first become eligible for EHR incentives in 2013 or later will receive payments through 2016. In addition, 2017 is the year in which the penalties have been completely phased in. Although they start in 2015, the penalties increase in size through 2017. Therefore, the statute suggests 2017 as the year when providers should have finished their adoption process.

3. Take a phased, flexible approach to defining meaningful use.

CMS should take a phased approach where hospitals can be considered meaningful users by meeting fewer requirements in the early years of the program, but building toward achieving the full set of meaningful use objectives over time. **We recommend the following glide path for most hospitals:**

- **FYs 2011/2012 – Meet at least 25 percent of the objectives;**
- **FYs 2013/2014 – Meet at least 50 percent of the objectives;**
- **FYs 2015/2016 – Meet at least 75 percent of the objectives; and**
- **FY 2017 and beyond – Meet substantially all of the objectives.**

Small hospitals, with fewer than 100 beds, face special challenges in health IT adoption and have difficulty accessing capital. We recommend that the share of objectives required be lower for these hospitals in the first three stages:

- **FYs 2011/2012 – Meet at least 15 percent of the objectives;**
- **FYs 2013/2014 – Meet at least 30 percent of the objectives;**
- **FYs 2015/2016 – Meet at least 60 percent of the objectives; and**
- **FY 2017 and beyond – Meet substantially all of the objectives.**

To be successful in achieving meaningful use, hospitals must have some choice and flexibility in meeting the objectives. Progress toward full implementation and meaningful use is, by its nature, specific to the staffing, strategy, resource availability and community priorities of each institution. Therefore, **we recommend that CMS allow hospitals to choose the subset of the hospital meaningful use objectives they meet.**

4. Establish a Meaningful Use Technical Expert Panel.

CMS should establish a Meaningful Use Technical Expert Panel with significant representation from hospitals and eligible professionals at various stages of implementation. The Meaningful Use Technical Expert Panel would provide input on the operational issues and feasibility of achieving meaningful use objectives over time, taking into account market conditions, advances in health information exchange, and the constraints facing subgroups of providers. CMS's implementation of this new EHR incentive program is a major undertaking and many issues are likely to occur; having an established group will help CMS quickly identify problems and work on solutions. While the ONC HIT Policy Committee has been created to help set a strategic vision for the ONC, CMS's Meaningful Use Technical Expert Panel would advise CMS on the operational implications of such recommendations.

We strongly urge CMS to adopt this alternative approach. We have talked to hundreds of hospital chief executive officers, chief information officers, chief medical officers and chief financial officers to solicit feedback on the proposed rule. Hospital leaders are energized by the opportunity this program offers to spur health IT adoption and the potential resulting patient care and safety improvements. But most are very concerned that they will not be able to meet the ambitious meaningful use definition in time and will not only miss out on incentive payments, but face the pending program penalties. As we discussed their concerns about the timeframes, the all-or-nothing approach, and the need for a long-term health IT vision, our alternative approach stood out as the most viable mechanism to bring fully functioning EHRs to all hospitals.

Our approach will reach CMS' vision of a complete EHR in all hospitals, and it will accomplish it in a way that allows hospitals to take the necessary time to make the capital investments, workflow changes, and cultural adaptations needed to have successful EHR installations. Our approach will provide much-needed financial resources to hospitals in the short term that they can then use to fund additional health IT improvements. Our approach also gives those hospitals that have already made great strides in EHR adoption the opportunity to push forward with even more advanced systems. By rewarding progress along the adoption continuum, this approach would result in many more hospitals employing advanced EHRs to improve care for their patients and communities.

The ARRA gives the Secretary authority to define meaningful use. Therefore, CMS has the authority to adopt alternative timeframes and requirements that more closely match a realistic implementation timeline. Without significant changes to the requirements and timeline, the goals established in the ARRA and the flow of stimulus funds into the health care sector will not be fully realized.

SPECIFIC MEANINGFUL USE OBJECTIVES FOR AHA'S ALTERNATIVE APPROACH

As discussed above, the AHA's alternative approach would involve describing a set of minimum requirements for meaningful use and allowing hospitals to meet a growing number of them over time. This section of our comment letter discusses and makes recommendations on the definition of specific meaningful use objectives. The HIT functionality measures and quality reporting requirements are discussed separately below.

The 23 objectives included in the NPRM serve as a solid base for ensuring progress toward EHR implementation over time. In our alternative approach, we recommend keeping most of these objectives, with modifications and clarifications discussed below and we recommend adding 12 additional objectives in 2011 that the Health IT Policy Committee recommended for 2013 and 2015.

In Attachment A, we describe in detail the added objectives and related measures we recommend for 2011. **However, it is important to emphasize that these additional objectives are meant to describe the end-goal for 2017. Hospitals follow unique adoption paths and benefit from the flexibility to choose among these objectives. Incorporating these additional objectives into the meaningful use requirements is contingent on adoption of a flexible, incremental approach to achieving meaningful use over a longer time period.**

The AHA recommends the following changes to the set of CMS-proposed objectives to form the set of objectives to be included in our alternative preferred approach:

1. DROP the two measures related to administrative claims:
- **Submit claims electronically to public and private payers; and**
- **Check insurance eligibility electronically from public and private payers.**

These administrative activities already are addressed under the HIPAA Administrative Procedures regulations and overseen by CMS. Hospitals currently face a financial penalty for submitting paper claims and, therefore, the vast majority of hospitals already file claims electronically. These activities are undertaken through existing claims processing systems, which are almost always integrated with clinical EHR systems, although they are rarely part of the EHR installation. For example, in a recent survey of hospitals in New York State, conducted by SUNY-Albany, 95.4 percent of respondents indicated that their hospital financial systems were integrated with their clinical systems.[8]

There is no apparent benefit to this requirement of counting administrative activities as part of the meaningful use definition. Including administrative activities in the meaningful use objectives would result in a requirement that hospitals upgrade existing, functional systems to

[8] The Center for Health Workforce Studies, as a member of the Health Information Technology Evaluation Collaborative (HITEC),conducted an HIT adoption survey of hospitals in New York in 2009. Information was obtained from 148 hospitals in the state, for a response rate of 75 percent.

new products that have been certified through the federal EHR certification process. Such a requirement would create unnecessary work and expense and take hospital IT staff away from implementation of the clinical systems that are at the heart of meaningful use.

Additional concerns with these measures stem from hospitals' lack of control over the actions of public and private payers. The insurance eligibility measure requires that 80 percent of unique patients have insurance eligibility verified and claims submitted electronically. To verify insurance eligibility electronically, hospitals must have an electronic connection with the insurer. Hospitals routinely see patients with dozens, if not hundreds, of different insurers, and cannot be expected to have connections with all of them. This is particularly difficult for hospitals in areas with large part-year populations, such as Florida or Arizona.

In addition, the value of the electronic eligibility verification is often minimal, as insurers provide information only about whether the individual is enrolled, without providing more granular details needed to inform patients of their financial obligations. Hospitals cannot check the eligibility of patients that present without their insurance information or who are uninsured. If a hospital's uninsured patient mix is greater than 20 percent of all patients, they would not meet the objective because of the threshold.

2. SEPARATE the clinically relevant medication alerts (drug-drug interaction alerts, drug-allergy interaction alerts) from the efficiency-related medication alert (drug-formulary alert).

The AHA recommends that drug-drug interaction alerts and drug-allergy interaction alerts be considered one objective and drug-formulary alert be considered a second, separate objective. These alerts have different purposes – preventing medication errors versus encouraging consideration of cost when prescribing medications – and they involve connections to different kinds of resources (drug safety information versus formulary information). To improve the measurement process, these alerts should be separated and distinct.

Additionally, in early stages of IT adoption, these checks may happen in pharmacy systems, not CPOE, or as part of the electronic medication administration record. Even as part of the pharmacy system, these are valuable tools for patient safety. Inclusion of these alerts in the pharmacy system should count toward meeting these objectives, even if they are not met at the bedside. The clinical evidence on the success of these systems is overwhelming and hospitals should be rewarded for using these systems, even if CPOE is not operational at the hospital.

3. DEFER medication reconciliation until 2013.

The NPRM includes the following objective: Perform medication reconciliation at relevant encounters and each transition of care (measure: Perform medication reconciliation for at least 80 percent of relevant encounters and transitions of care).

Medication reconciliation across settings is a critical need. However, the infrastructure to support electronic approaches to this is not yet developed. In the NPRM, the term "transitions of

care" includes an array of transfers across the continuum of care that is not currently supported by information exchange among providers. Consequently, medication reconciliation, as defined, is not possible. **Therefore, we recommend deferring this objective to 2013, when it could be conducted on a pilot basis, with full implementation required in 2015 and later.**

At its core, medication reconciliation is a tool to prevent medication errors. It involves clinicians consulting with patients and other providers making informed judgments about current and new medications. Medication reconciliation is not an automated EHR process. Hospitals have undertaken significant efforts to improve medication reconciliation for the patients through revised workflows, improved medication review processes and better communications. Preventing medication errors in the hospital and post-discharge are important patient safety measures that require ongoing attention.

CMS rightly notes in the NPRM, however, that the medical community lacks a clear, shared understanding of medication reconciliation in general and the use of EHR systems to support this process in particular. In fact, The Joint Commission is revising its National Patient Safety Goal on medication reconciliation and has halted implementation of this initiative pending review. CMS should not attempt to define medication reconciliation processes and requirements separately and differently from The Joint Commission. Doing so will cause confusion and could actually slow efforts to build and spread best practice models of medication reconciliation.

4. DEFER automated quality reporting until 2013.

As discussed in greater detail beginning on page 31, electronic reporting of quality measures through EHRs is a highly valued goal that is not yet possible to meet. We recommend that for 2011 and 2012 hospitals continue to report quality measures through the current pay-for-reporting (RHQDAPU) program using existing approaches, while quality measurement specialists and vendors work to create valid, reliable and field-tested e-measures for deployment in hospital EHRs.

5. ADD additional objectives and measures to better define a more complete vision of a fully functioning and complete EHR.

In addition to the AHA's recommended modifications to the proposed objectives in the NPRM, the AHA has identified 12 objectives that we recommend adding to create a full list of objectives for meaningful use beginning in 2011/2012. The AHA's recommended additions are a subset of objectives that were recommended by the HIT Policy Committee for 2013 and 2015. It is important for CMS to layout a more comprehensive picture of the ultimate vision for meaningful use of EHR systems. Hospital IT system changes are multi-year, multi-million dollar endeavors that require time and planning. Identifying the meaningful use objectives and measures in 2010 that will be required for 2011 and 2012 sets unrealistic timeframes. Meeting these fast turnaround times will mean spending more time and money than necessary. We are concerned that the rule setting expanded objectives and measures for 2013 will be released in 2012, repeating this untenable cycle. Hospitals need to know now what the expectations are for at least the next five years.

The AHA recommends adding the following objectives:

1. Use of evidence-based order sets
2. Electronic medication administration record (eMAR)
3. Bedside medication administration support (barcode/RFID)
4. Record nursing assessment in EHR
5. Record nursing plan of care in EHR
6. Record physician assessment in EHR
7. Record physician notes in EHR
8. Multimedia/Imaging integration
9. Generate permissible discharge prescriptions electronically
10. Contribute data to a PHR
11. Record patient preferences (language, etc.)
12. Provide electronic access to patient-specific educational resources

The expected use in 2011/2012 and the increases, information sharing and incorporation of structured data for these measures are indicated on the next page in Table 2. Attachment A describes each new objective and offers a proposed measure. In 2013 and later, the complete set of hospital objectives also would include automated reporting of some RHQDAPU measures and medication reconciliation across settings of care (pilot in 2013).

Table 2. AHA's Recommended Set of Alternative Hospital Meaningful Use Objectives

2011/2012 Meet 25% (8) of: <100 beds Meet 15% (5) of:	2013/2014 Meet 50% (17) of: <100 beds Meet 30% (10) of:	2015/2016 Meet 75% (26) of: <100 beds Meet 60% (20) of:	2017 Meet substantially all of:
1. CPOE (activated)	1. CPOE (10% or more)	1. CPOE (50% or more)	1. CPOE (substantially all)
2. Drug-drug/drug-allergy checks	2. Drug-drug/drug-allergy checks	2. Drug-drug/drug-allergy checks	2. Drug-drug/drug-allergy checks
3. Drug-formulary checks	3. Drug-formulary checks	3. Drug-formulary checks	3. Drug-formulary checks
4. Structured problem list	4. Structured problem list	4. Structured problem list	4. Structured problem list
5. Structured medication list	5. Structured medication list	5. Structured medication list	5. Structured medication list
6. Structured medication allergy list	6. Structured medication allergy list	6. Structured medication allergy list	6. Structured medication allergy list
7. Record demographics	7. Record demographics	7. Record demographics	7. Record demographics
8. Record vital signs	8. Record vital signs	8. Record vital signs	8. Record vital signs
9. Record smoking status	9. Record smoking status	9. Record smoking status	9. Record smoking status
10. Incorporate structured clinical-lab data (50%)	10. Incorporate structured clinical-lab data (50%)	10. Incorporate structured clinical-lab data (75%)	10. Incorporate structured clinical-lab data (subst. all)
11. Patient lists by condition	11. Patient lists by condition	11. Patient lists by condition	11. Patient lists by condition
12. 5 clinical decision support rules	12. 5 clinical decision support rules	12. 25 clinical decision support rules	12. 25 clinical decision support rules
13. Electronic copy of health information to patients on request	13. Electronic copy of health information to patients on request	13. Electronic copy of health information to patients on request	13. Electronic copy of health information to patients on request
14. Electronic copy of discharge instructions and procedures at discharge, upon request	14. Electronic copy of discharge instructions and procedures at discharge, upon request	14. Electronic copy of discharge instructions and procedures at discharge, upon request	14. Electronic copy of discharge instructions and procedures at discharge, upon request
15. Exchange key clinical information	15. Exchange key clinical information	15. Exchange key clinical information (CCD)	15. Exchange key clinical information (CCD)
16. Summary care record	16. Summary care record	16. Summary care record	16. Summary care record
17. Immunization registries (capability)	17. Immunization registries (capability)	17. Immunization registries (submit data if possible)	17. Immunization registries (submit data if possible)

Table 2. AHA's Recommended Set of Alternative Hospital Meaningful Use Objectives			
2011/2012 **Meet 25% (8) of:** **<100 beds Meet 15% (5) of:**	**2013/2014** **Meet 50% (17) of:** **<100 beds Meet 30% (10) of:**	**2015/2016** **Meet 75% (26) of:** **<100 beds Meet 60% (20) of:**	**2017** **Meet substantially all of:**
18. Reportable lab results (capability)	18. Reportable lab results (capability)	18. Reportable lab results (submit data if possible)	18. Reportable lab results (submit data if possible)
19. Syndromic surveillance data (capability)	19. Syndromic surveillance data (capability)	19. Syndromic surveillance data (submit data if possible)	19. Syndromic surveillance data (submit data if possible)
20. Comply with HIPAA Privacy and Security	20. Comply with HIPAA Privacy and Security	20. Comply with HIPAA Privacy and Security	20. Comply with HIPAA Privacy and Security
21. Use of evidence-based order sets (1 condition)	*21. Use of evidence-based order sets (3 conditions)*	*21. Use of evidence-based order sets (5 conditions)*	*21. Use of evidence-based order sets (substantially all)*
22. Electronic medication administration record (eMAR) (1 nursing unit)	*22. Electronic medication administration record (eMAR) (3 nursing units)*	*22. Electronic medication administration record (eMAR) (5 nursing units)*	*22. Electronic medication administration record (eMAR) (substantially all)*
23. Bedside medication administration support (barcode/RFID) (1 nursing unit)	*23. Bedside medication administration support (barcode/RFID) (3 nursing units)*	*23. Bedside medication administration support (barcode/RFID) (5 nursing units)*	*23. Bedside medication administration support (barcode/RFID) (substantially all)*
24. Record nursing assessment in EHR (1 nursing unit)	*24. Record nursing assessment in EHR (3 nursing units)*	*24. Record nursing assessment in EHR (5 nursing units)*	*24. Record nursing assessment in EHR (substantially all)*
25. Record nursing plan of care in EHR (1 unit)	*25. Record nursing plan of care in EHR (3 nursing units)*	*25. Record nursing plan of care in EHR (5 nursing units)*	*25. Record nursing plan of care in EHR (substantially all)*
26. Record physician assessment in EHR (10% of patients)	*26. Record physician assessment in EHR (10% of patients)*	*26. Record physician assessment in EHR (50% of patients)*	*26. Record physician assessment in EHR (substantially all)*
27. Record physician notes in EHR (10% of patients)	*27. Record physician notes in EHR (10% of patients)*	*27. Record physician notes in EHR (50% of patients)*	*27. Record physician notes in EHR (substantially all)*
28. Multimedia/Imaging integration (e.g., X-Ray viewing)	*28. Multimedia/imaging integration (e.g., X-Ray viewing)*	*28. Multimedia/imaging integration (e.g., X-Ray viewing)*	*28. Multimedia/imaging integration (e.g., X-Ray viewing)*

Table 2. AHA's Recommended Set of Alternative Hospital Meaningful Use Objectives			
2011/2012 **Meet 25% (8) of:** **<100 beds Meet 15% (5) of:**	**2013/2014** **Meet 50% (17) of:** **<100 beds Meet 30% (10) of:**	**2015/2016** **Meet 75% (26) of:** **<100 beds Meet 60% (20) of:**	**2017** **Meet substantially all of:**
29. Generate permissible discharge prescriptions electronically (10% of patients) *30. Contribute data to a PHR* *31. Record patient preferences (language, etc.)* *32. Provide electronic access to patient-specific educational resources* *33. Reporting of RHQDAPU quality measures through existing process*	*29. Generate permissible discharge prescriptions electronically (10% of patients)* *30. Contribute data to a PHR* *31. Record patient preferences (language, etc.)* *32. Provide electronic access to patient-specific educational resources* *33. Reporting of some RHQDAPU quality measures through EHR* *34. Medication reconciliation across settings of care (pilot)*	*29. Generate and transmit permissible discharge prescriptions electronically (50% of patients)* *30.* *31. Contribute data to a PHR* *32. Record patient preferences (language, etc.)* *33. Provide electronic access to patient-specific educational resources* *34. Reporting of some RHQDAPU quality measures through EHR* *35. Medication reconciliation across settings of care (if possible)*	*29. Generate and transmit permissible discharge prescriptions electronically (substantially all)* *30. Contribute data to a PHR* *31. Record patient preferences (language, etc.)* *32. Provide electronic access to patient-specific educational resources* *33. Reporting of all appropriate RHQDAPU measures through EHR* *34. Medication reconciliation across settings of care*

Notes:

1. *ITALICIZED* objectives from the HIT PC recommendations for 2013 and 2015.
2. List excludes proposed objectives on electronic insurance verification and electronic billing in all years, and medication reconciliation in 2011/2012 only.
3. Each of the proposed additional objectives and associated measures is described fully in Attachment A.
4. CCD = Continuity of Care Document.

AHA RECOMMENDATIONS ON THE PROPOSED MEASURES OF MEANINGFUL USE

The AHA convened many dozens of technical experts to review the proposed objectives and measures of meaningful use. Their insightful comments and suggested modifications are summarized in Attachment B, which should be considered a core element of our comments. Attachment B provides comments and concerns for each measure. Recommendations are made about all but four of the measures. We also highlight here several objectives and measures of special concern and speak to the need for a more systematic approach to measurement in the long term to minimize reporting burden.

1. CPOE

CPOE, when implemented appropriately, can be very effective in improving the quality and efficiency of care. It is, however, a challenging application to install and requires time to train clinicians to use appropriately. Under our proposed alternative approach, which supports incremental adoption, we are certain that successful CPOE is possible. We are concerned, however, about the proposed IT functionality measure: "CPOE is used for at least 10 percent of all orders (any type)."

First, we recommend that CMS include in the measure the use of CPOE within a hospital's emergency department (ED) for patients that are subsequently admitted. The CPOE measure in the NPRM excludes the use of CPOE within a hospital's emergency department because the place of service code is different from the inpatient place of service code. CPOE use within an emergency department is important, however, because in many hospitals the majority of hospitalized patients enter the treatment process through the ED. CPOE within the ED helps with care handoffs when a patient is moved to an inpatient department. In addition, the ED is a logical place for many healthcare organizations to begin implementing CPOE.

Second, we recommend that CMS adopt a different measure for use of CPOE that would be less burdensome to report. Our preferred measure for 2011/2012 is that the hospital has CPOE activated. To calculate the percentage of all orders placed through CPOE, hospitals will need to define the denominator of all orders placed via CPOE, in writing, verbally, or by other means. The only way to accomplish this would be through manual chart review of all inpatient charts. This level of reporting burden is clearly not supportable and goes against the overall goal of simplifying measure reporting through automated electronic systems.

For 2013, if CMS wants to use a measure that reports the level of CPOE use, we recommend one of the following approaches that can be calculated from automated systems:

1. At least 10 percent of unique patients have had at least one order placed through CPOE; or
2. At least 10 percent of medication orders were placed through CPOE (can be calculated from pharmacy information system).

2. Medication Reconciliation

In addition to the recommendation to defer medication reconciliation until 2013, we have concerns about the proposed measure of medication reconciliation. Calculation of this measure across all admissions would be overly burdensome to report as it would require manual chart review. Electronic medication reconciliation tools in use today do not generally include a flag or other measure to indicate that medication reconciliation was done or done accurately, so this measure is not currently easy to calculate.

If CMS keeps medication reconciliation as an objective, we recommend the following alternative measure: Hospital is using EHR to support medication reconciliation.

If CMS determines that a percentage measure is required, a sampling methodology MUST be developed to reduce reporting burden. We further recommend inclusion of the ED in the measure, as many patients enter the hospital via the ED and first discuss current medications in that setting. In addition, if a percentage measure is included, CMS and ONC should require measure calculation as part of the EHR certification process.

3. Electronic Information for Patients

The NPRM includes two measures related to providing data to patients:

- Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures) upon request; and
- Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.

Clarification is needed to determine what electronic data are to be given to patients and their families, and in what format. Use of portable media, such as a USB device, presents security problems for hospitals. Securing personal health information (PHI) on the portable media could require the patient to have advanced computing capabilities to access the information at home. In addition, introducing portable media can compromise the security of the hospital's information systems.

The objective on providing patients with an electronic copy of their health information should be modified. The AHA recommends that CMS revise the measure to require provision of an electronic copy of health information "maintained in electronic form," consistent with the ARRA privacy provisions. The ARRA amended the HIPAA statute to require that providers give patients an electronic copy of health information "maintained in electronic form." During the transition from paper to electronic charts, it is not reasonable to ask for information not held in electronic form, as that would necessitate transforming paper records into electronic records.

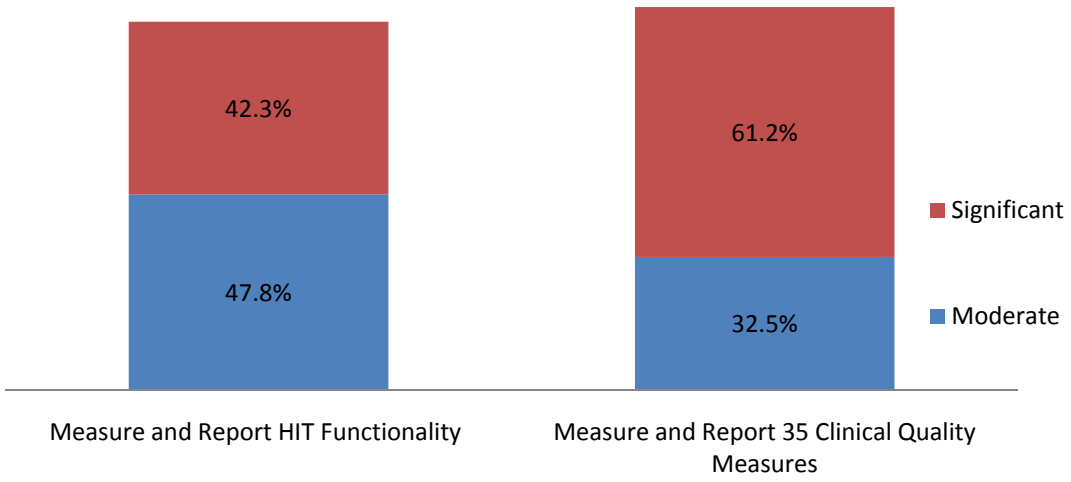
The AHA also recommends that CMS drop the time requirement in favor of existing HIPAA policies on providing patients with copies of medical records. The time period (48 hours) required for hospitals to provide the electronic PHR information is too short and more proscriptive than HIPAA requirements. Clinicians must review information and ensure that they have received all test results and discussed sensitive results with the patient before release, per CLIA and state laws. Staff must be available to receive and fulfill requests, and required workforce may not be available on weekends and holidays.

As with other measures requiring a percentage calculation, the AHA recommends that CMS and ONC require calculation of this measure as part of the EHR certification process.

Reporting Burden

The AHA asked members about the burden of reporting measures in a survey conducted in January 2010. The results clearly demonstrate an unacceptable reporting burden. Fully 90 percent of responding hospitals consider the proposed health IT functionality measure reporting to be either a moderate (48 percent) or significant (42 percent) burden. An even larger share – 94 percent – believes the proposed quality reporting will pose a moderate (32) or significant (61 percent) burden (Figure 7).

Figure 7. The Majority of Hospitals Find Proposed Reporting Requirements to be a "Moderate" or "Significant" Burden



Percent of Hospitals That Indicate Measuring and Reporting of HIT and Quality Measures is a Moderate to Significant Burden

Source: AHA analysis of survey data from 795 non-federal, short-term acute care hospitals (including CAHs) collected in January 2010.

Long-Term Measurement Principles and Development Process

The Medicare program has a strong history of measure development in the context of reporting on hospital quality. Through annual rule-making and meetings of the Hospital Quality Alliance, stakeholders such as CMS, the AHA, and others have developed a transparent, orderly, and collaborative approach to establishing a quality measurement framework. We believe that CMS should draw on that experience in the development of health IT functionality measures.

It generally takes about five years for a quality measure concept to be translated into an actionable measure for widespread data collection and reporting. Briefly, measure development starts with identification of best practice through review of scientific evidence, followed by development of a metric to assess performance. Then, specifications for the patient population of interest and the necessary data elements are developed. These technical specifications are refined through field-testing, which may show the necessity of excluding certain patients or adjusting certain data elements. Field-testing is also critical for assessing whether the data can feasibly be collected in a reliable and valid manner. Consensus-based processes are then used to vet the measures with the scientific and provider communities, and to determine which measures are most suitable for implementation, taking into consideration the burden of reporting versus of the potential clinical benefit of the measurement.

Although the timelines in statute required a fast pace for initial development of health IT functionality measures, the Medicare and Medicaid EHR incentive programs are establishing long-term payment policies that will be based in large part on the submission of IT functionality measures. In that context, it is incumbent upon CMS to ensure that, moving forward, its metrics are developed in a scientific, transparent, orderly and collaborative process.

For the long term, we urge CMS to establish an explicit, consultative process for development and testing of evidence-based HIT functionality measures. Through that process, we believe that CMS should adopt these measurement principles:

- Demonstrate clinical relevance through reference to the scientific literature;
- Specify carefully when the measure applies, what is being included in the numerator, and what is being included in the denominator;
- Consult with those expected to submit the measurement data;
- Test measures thoroughly to ensure reliability and validity of measure calculation;
- Pilot test measures to ensure feasibility of measurement and reporting; and
- Estimate the burden of reporting based on data from field-testing.

Minimizing Measurement Burden

In the short term, we recognize that CMS will likely need to use modifications of the proposed measures when the EHR incentive program begins. Of the 22 proposed hospital health IT Functionality Measures (not including quality reporting), eight require a declarative response, and 14 require calculation of actual performance through use of a percentage.

To estimate the burden of reporting, CMS divides the meaningful use measures into two groups:

- Set A includes those objectives and measures where "the certified EHR technology adopted by the [provider] will capture … and generate automated numerator and denominator information, where required, or automated summary reports." All of the quality reporting is assumed to fall into Set A as a single item.

- Set B includes objectives and measures where reporting may require providers to gather manually the information necessary to be reported as part of the measure.

CMS estimates a combined reporting burden of eight hours for eligible hospitals, as follows:

- Use of certified EHR technology and objectives/measures in Set A – 30 minutes.
- Quality measures – 30 minutes total.
- Objectives in set B – seven hours for eligible hospitals.

Discussions with our members and experience with hospital quality reporting suggests that these burden estimates vastly underestimate the time that would be needed for reporting. Indeed, for some of these measures it is not clear whether the measure can, in fact, be calculated.

To illustrate the burden of reporting through manual processes, consider the CPOE measure (CPOE is used for 10 percent of all orders). To calculate this measure, hospitals would need to specify the types of orders to be counted; configure the EHR to report on the number of orders for each type that were entered through CPOE; review all patient charts for a full year to count written and verbal orders, ensuring that orders entered through CPOE are not counted; establish a process to validate the electronic and manual counting processes; and, finally, combine electronic and manual data to calculate numerator and denominator.

Given CMS' proposal that orders that are part of an inpatient service be included, it is unclear whether orders begun in the ED for a patient who is subsequently admitted would be part of the calculation. We previously stated that patients admitted through the ED should be counted. Experience has shown that the average chart review for quality reporting requires 20 minutes. Given the need to scan charts for all types of orders and distinguish electronic versus paper orders, it is likely that a similar amount of time per chart would be required here. Unlike quality reporting, however, which targets specific cases, the measurement for CPOE would require review of all records created over a calendar year. Thus, for a hospital that has 15,000 admissions in a fiscal year, calculating this measure could require as much as 5,000 hours for a hospital that has not moved fully to CPOE (20 minutes per chart times 15,000 charts). This level of burden is clearly not sustainable. In our detailed comments above, we recommend alternative measures for CPOE.

To ensure efficient reporting, we urge CMS to re-formulate the percentage performance measures so that:

- **Numerators and denominators are explicitly specified;**

- **No measures require hospitals to use paper and electronic processes to develop the measure;**
- **Each measure provides a minimum threshold of cases for reporting; and**
- **Any measure that involves manual processing can be done through a sampling methodology to limit burden.**

Specific comments on how to restructure measures are included in Attachment B.

Generation of Measures from EHRs

We urge CMS <u>not</u> to require submission of health IT functionality measure data that cannot be derived easily from the EHR, and that the EHR has not been certified to produce. Laborious, manual process to report on use of automated technologies detracts from the very efficiencies the EHR incentive program seeks to realize.

CMS states in the proposed rule (p. 1903), that the agency does "not believe that demonstration of meaningful use should require use of certified EHR technology beyond the capabilities certified" through the federal certification process. The interim final rule on certification standards released by ONC, however, does NOT include generation of the health IT functionality measures as a certification requirement, even those included in Set A and presumed by CMS to be generated out of the EHR. The AHA will comment separately to ONC on the inclusion of certification criteria for specific health IT functionality measures in the interim final rule.

QUALITY REPORTING

The AHA firmly believes that automated quality reporting will decrease the burden of quality reporting and potentially allow hospitals to generate an even broader array of quality information. However, much groundwork needs to be completed before clinically reliable measures are able to be collected, reported and used for improvement. No EHR system in common use today can generate the current set of proposed measures. Indeed, most of the proposed quality measures have not yet been specified for automated reporting. Thus, our recommendations include initial steps for the near term, as well as suggestions regarding the best approach to moving forward over time.

Reporting on Clinical Quality Measures for FY 2011

In the proposed rule, CMS states that to fulfill the clinical quality reporting requirements for FY 2011, hospitals must:

1) Attest that they are using certified EHR technology to capture the data elements and calculate the results for the adopted clinical quality measures;
2) Report the results of their measure calculations to CMS by submitting information on the measure numerators and denominators, and information on any patient exclusions, for all patients eligible for any of the adopted quality measures; and

3) Attest to the accuracy and completeness of the summary data submitted to CMS.

While this is a laudable goal, there is not enough time to develop, test and implement certified EHR technology to fulfill these requirements for inclusion in FY 2011. Hospitals strongly believe that the public deserves reliable data on important aspects of hospital quality. That is why the AHA and other hospitals have been involved in the national effort to publicly report quality data on www.hospitalcompare.hhs.gov since the inception of the work. Further, hospitals would be delighted to surrender the administrative burden of manually collecting these data. However, the integrity of the measurement activity, which directly affects the accuracy and reliability of the data that are portrayed, is more important than reducing the reporting burden.

Development of Automated Quality Measures

For EHRs to be able to accurately collect and generate the information needed to create the clinical quality measures being used, the measures need to be specified in a way that will enable electronic collection, the specifications need to be tested to ensure they result in an accurate and clinically reliable set of data, and EHR vendors need to be given the information and sufficient time to program those specifications into the data collection. Once the measures are embedded in vendor systems, hospitals need time to upgrade their own systems, learn how to use the new reporting functions, and ensure that they are capturing all of the data elements needed to generate the quality measures. Collecting all the relevant data elements requires that the EHR be able to capture considerable amounts of clinical documentation, from diagnoses to medication orders to nurse and physician notes. Electronic capture of quality measurement information is really a capstone feature of an EHR, not one that should be in the starter set of activities. **For these reasons, we strongly urge CMS to DEFER clinical quality reporting through EHRs until FY 2013 so that those measures to be collected through EHRs can be re-specified, tested and implemented.**

The process of developing and testing measures for automated reporting takes time. For example, CMS and ONC contracted with Healthcare Information Technology Standards Panel (HITSP) to retool 16 inpatient measures, and that process took from September 2008 until January 2010. HITSP's report on the re-tooling process stresses that development of e-measures takes time and must be done carefully to maintain the scientific integrity of the output. If automated reporting is not valid, reliable, and clinically relevant, it is not useful.[9]

[9] In its report, the HITSP team noted that: "Retooling is not translation; eMeasurement necessarily broadens the set of essential stakeholders needed for performance measure development, refinement and maintenance. The task of associating the concepts incorporated in a performance measure with terms found in one or more vocabularies requires the active collaboration of the measure developers and their clinical experts, terminologists and the vendor community to assure that the clinical and data collection pathways and objectives, and their underlying bases in evidence, are meaningfully preserved even as they are transformed. The complexity of the retooling process and resulting e-specifications raises new challenges for the public review and consensus process of the National Quality Forum and others in order to assure that the resulting eMeasures continue to be consistent with the needs of the broader community." (**HITSP Quality Measures Technical Note ED, VTE, and Stroke Examples for Implementation of the HITSP Quality Interoperability Specification, HITSP TN906, Jan 25, 2010)**.

The 16 new sets of measure specifications for stroke, venous thromboembolism (VTE) and ED through-put measures have not yet been thoroughly tested, although CMS has just begun a pilot test. Engaging hospitals and vendors in a test of the measures gives CMS an opportunity to understand and resolve any issues they encounter with data collection and measures calculation. CMS plans for the testing to be done sometime this summer. Even if the agency can make any necessary adjustments to the specifications and communicate the revised specifications to the vendors and hospitals by early fall, we do not believe there is sufficient time for EHR vendors and hospitals to implement these specifications for FY 2011, which begins on October 1, 2010.

Despite the time needed to re-tool the pilot measures, the proposed rule indicates that CMS will publish specifications on the remaining measures (other than stroke, VTE, and emergency department through-put) by April 1, 2010 – approximately two weeks after the close of the comment period for this rule. Clearly, this timeline will not allow for the careful review and assessment recommended by the HITSP quality measurement team.

Even with this aggressive timeline, we will not have adequate opportunity to review the specifications and comment on their accuracy or feasibility in the context of this comment letter. So, it will be vital that the process used for the stroke, VTE and emergency department measures be replicated for all of the other measures CMS might choose to include for EHR collection. This will allow CMS, hospitals and vendors to move forward in a deliberate, well-planned and executed process that preserves the integrity of the data published on the Hospital Compare website.

Further, while there has been information provided by CMS on its work to re-specify the measures, there has not been any information provided on the form and format in which the data are to be transferred to CMS or its contractor for use in public display. To be able to program the reporting function into the EHR, hospitals and their vendors need information on how the information is to be transmitted.

Even when e-specifications are widely available, gathering this expanded set of quality information from the EHR will not be simple and is likely to involve additional costs to providers. Vendor systems do not currently have these reporting capabilities and our members are reporting that many of them are planning to provide them through add-on modules to their base EHRs at added cost to providers.

Even after vendors have incorporated these measures, some, including those currently being pilot tested, are mapped to standards, such as LOINC and SNOWMED that are not currently supported by installed systems. As noted in the proposed rule, moving to those standards is part of the incremental adoption process but not a current reality.

We agree with CMS that the reporting of clinical quality measures for the EHR incentive program should be harmonized with the current pay-for-reporting program. However, certain provisions in this proposed rule actually create discord between the pay-for-reporting requirements and the IT reporting requirements. For example, CMS proposes that to meet the meaningful use criteria, hospitals need to report on the measures for any 90-day time period. If

CMS' intent was to allow hospitals to submit the hand-abstracted data for public reporting for most of the year and initiate electronic reporting in the last quarter, we understand and appreciate the fact CMS would view this as fulfilling both the pay-for-reporting requirements and the meaningful use provision.

However, the proposed rule reads as if data could simply be reported for any 90 day period in any year and that this submission of just the 90 day information would be acceptable for fulfillment of meaningful use and possibly public reporting requirements. There are important considerations of seasonality, sample size, and other unintended biases that should preclude CMS from accepting 90 days worth of data as sufficient for public reporting purposes unless further study can document that these concerns are not justified. **For the purposes of the pay-for-reporting program, data collection and submission is ongoing throughout the year, and we believe it should continue to be so.** In coordinating the two programs, we support the notion of allowing hospitals to fulfill the RHQDAPU data using the EHR for at least 90 days in their initial year of implementation, but caution against continuous reporting of both the 90-day electronic data and the year-long reporting through the ORYX vendors. This will cause massive confusion for hospitals and leave uncertain the validity of the data reported on *Hospital Compare*.

Selecting Clinical Quality Measures

In selecting clinical quality measures for the EHR incentive program, we urge CMS to establish a standardized process, involving consultation with quality improvement stakeholders, to evaluate potential measures. The selection process should be based on a clear and cohesive long-term vision with accompanying quality improvement goals.

We are concerned that the list of measures proposed in this rule takes a scattershot approach at picking and choosing from among existing measures with no overarching quality improvement vision in mind. It is just as important that the clinical quality measures have value to hospitals for quality improvement purposes as it is that they are capable of being collected through an EHR. Our specific recommendations for the selection of clinical quality measures for the EHR incentive program are outlined below.

1) **Only measures chosen for use in the RHQDAPU program should be considered for implementation in the EHR incentive program.** The measures used in the RHQDAPU program should be considered the core set of hospital quality measures whenever a new policy that involves reporting hospital quality data is initiated – be that new policy an EHR incentive program, value-based purchasing program, bundling or accountable care organization pilot program, or another policy approach. In other words, CMS should not require the reporting of different sets of hospital quality measures for different policies and programs. In this rule, CMS proposes that hospitals report on 35 clinical quality measures, of which only nine overlap with the measures currently used for the RHQDAPU program.

The lack of commonality between these measure sets will lead to an increased burden on hospitals to report on many quality measures. We believe the RHQDAPU program has been refined over the past several years and should be viewed as the model for other hospital quality reporting programs. Developing different policy approaches with disparate sets of reporting measures would be a detriment to quality improvement efforts. While we are suggesting that the RHQDAPU measures form the basis of the core set of EHR measures, this does not suggest that all RHQDAPU measures are necessarily appropriate for reporting through EHRs. In fact, we believe that the clinical complexity of some measures may never make them appropriate candidates for collection and reporting through EHRs. An analysis of the appropriateness of reporting each of the RHQDAPU measures through an EHR-based system is an activity that CMS should undertake with the consultation of quality measurement stakeholders.

2) **Measures should be selected for their potential to advance and improve patient care and with the consultation of quality reporting stakeholders, namely the National Quality Forum (NQF) and the Hospital Quality Alliance (HQA).** Clinical quality measures selected for the EHR incentive program should not be chosen simply because they are capable of being collected through an EHR system, but because they have the capability to improve quality. The AHA agrees with The Joint Commission's recent assessment of quality measures that are appropriate for provider accountability; namely, that excellent measures are those for which there is a large volume of research linking the measures to improved outcomes, the measures accurately assess the relevant clinical processes, and implementation of the measures has minimal unintended adverse events. Excellent measures address known gaps in care where opportunities exist to improve provider performance.

   As part of the process of identifying these measures, CMS should consult with other quality measurement stakeholders, particularly the NQF and the HQA. The NQF's review of the scientific acceptability of a measure is a necessary step toward assuring that selected measures are valid and reliable. The HQA's rigorous, consensus-based adoption process is an important step to ensure that all stakeholders involved in hospital quality – hospitals, purchasers, consumers, quality organizations, CMS and others – are engaged in and agree with the adoption of a new measure.

3) **Measures selected for the EHR incentive program should be comprehensively tested in the field to ensure that they are thoroughly specified, clinically valid when the data are collected through an EHR system, and feasible to collect.** When new measures are developed, or when existing measures are re-tooled for data collection and reporting through an EHR system, they should be thoroughly tested and undergo a dry run in the field before they are broadly implemented. It is critical for hospitals, vendors and CMS to gain experience with the data collection, submission, validation and reporting of new measures before they are included in the EHR incentive program.

   What might work during a data collection process of manual abstraction from clinical medical records may not be feasible through an EHR system. For example, some of the

complex logic applied by experienced nurses in abstracting information from a clinical medical record may not be able to be replicated by even the most sophisticated EHR. Ensuring the data's reliability, validity and credibility with clinicians may necessitate that this complex logic be applied to ensure the patients included in the calculations and the adjustments made to reflect differences in patients' underlying conditions provide fair comparisons across hospitals. In order to determine whether that clinical validity can remain intact when measures are retooled for EHR data collection, robust field-testing must be completed.

4) **Measures should be phased in over time in clinically-related measure sets to allow for a smooth transition.** For hospitals and vendors to develop the capacity to add clinical quality measures into their EHR systems, it will be important for the measures to be phased in over time. The most appropriate way to do so would be to adopt measures over time in clinically related sets.

   We are concerned that the proposed rule would adopt several of the RHQDAPU heart attack, heart failure, pneumonia, and surgical care measures for EHR reporting and yet leave other measures from those measure sets for continued manual abstraction. It would be more logical to re-tool, for example, all of the heart attack and surgical care measures at one time, and then all of the heart failure and pneumonia measures at another. Because measures of the care for a particular condition often use many of the same data elements, implementation would be less burdensome if sets of measures are adopted by condition.

Readmission Rates are Poor Quality Measures for Meaningful Use

CMS solicited comments on the individual measures proposed for Stage I of the meaningful use criteria. Among the measures proposed in this rule, we specifically note that the readmission measures are inappropriate for automated reporting and as required meaningful use criteria. **Thus, we urge CMS not to select any of the readmission measures in the final rule.**

These 30-day, risk-adjusted readmission rates for heart attack, heart failure and pneumonia are currently calculated by CMS based on Medicare claims data. While hospitals could report on patients that are readmitted to their own facilities, hospitals currently have no way of capturing data on patients that were initially admitted to their facilities but later readmitted to another hospital.

In addition, there would be no way for hospitals to apply the risk-adjustment methodology for the readmission measures within their own facilities. They do not have access to the claims information generated by the patients' other care providers in the year preceding admission, which are required to calculate the risk adjustment. This information is not currently available to hospitals, and HIPAA and other privacy laws would preclude hospitals from obtaining it. Readmission measures that are not risk-adjusted are not valid indicators of hospital quality, so while hospitals could report on unadjusted readmission data, it would have no value.

Process for Reporting on Clinical Quality Measures

While for 2011, hospitals merely have to report that they have the capacity to report quality data, for FY 2012, CMS proposes to require an eligible hospital to submit summary information on clinical quality measures using certified EHR technology to be considered a meaningful EHR user. To avoid duplicative reporting requirements with the existing pay-for-reporting program, hospitals would be expected to submit information on any measure included in both the Medicare EHR incentive program and the pay-for-reporting program (of which there are 9 proposed) once only. Submitting data for the Medicare EHR incentive program would fulfill pay-for-reporting program requirements.

We appreciate CMS' intent to lessen the reporting burden on hospitals by allowing the submission of clinical quality measures data for the EHR incentive program to also fulfill pay-for-reporting program requirements for those measures included in both programs. We support moving toward the electronic reporting of quality measures information, and we believe that quality improvement and public reporting would benefit from a process by which all appropriate quality measures are reported through EHRs.

However, in the short term, we believe CMS has not thought through the effects that this change would have on the existing pay-for-reporting program. The EHR incentive program does not have a mechanism for ensuring comparable and complete data collection or for validating the data that are collected. Through the hard work of CMS staff and the active involvement of the organizations included in the HQA, the pay-for-reporting 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 of 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.

The proposed rule also assumes a rather static state for measures and measure specifications. However, in reality, the specifications are updated twice a year on a regular schedule, reflecting changes in the underlying science, innovations in medical care, and clarifications made to promote the usefulness of the measures. Before implementing data collection through EHRs, CMS needs to have crafted a plan for updating the measures. 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 helpdesk at the national data warehouse for assistance. Mechanisms need to be put in place for supporting implementation under this proposed rule.

Under the RHQDAPU 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 particular provisions of the RHQDAPU program either, but will be needed for the program to function correctly.

Under RHQDAPU, 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 RHQDAPU program. After hospitals submit their data through QualityNet, they are provided with a Clinical Warehouse Feedback Report and a Program Provider Participation Report that ensure the hospital that their data was 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 in 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 RHQDAPU 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 and 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 it 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.

All Payer Quality Data are Preferable

CMS solicited comments on the impact of requiring the submission of clinical quality measures data on all patients, not just Medicare and Medicaid beneficiaries, for the EHR incentive program. We agree that data on the clinical quality measures should be collected for patients of all payers. Having data on a non-representative sample of a hospital's patients, such as only Medicare or Medicaid patients, is not helpful for quality improvement purposes. To see the whole picture of the quality of care delivered, information is needed on the whole patient population or a representative sample of that population. Hospitals with larger patient populations should be allowed to report on a random sample of all of their patients, using the established sampling guidance laid out under the RHQDAPU program.

We understand that beginning in FY 2012, CMS proposes that hospitals submit summary data on the clinical quality measures directly to CMS through one of several alternative transmission mechanisms. **Given the sensitivity of the data, and the RHQDAPU program specifications, we believe CMS should never request that hospitals submit patient-level data to CMS, but**

that the data submitted should always be at the aggregated, summary level. We encourage CMS to state specifically that this is its intention in FY 2012 and all future years of EHR incentive program reporting.

Quality Reporting for the Medicaid EHR Incentive Program

The AHA agrees with CMS' statement on pg. 1895 of the proposed rule that fulfilling the reporting requirements for the clinical quality measures listed in Table 20 would be sufficient for meeting the requirements for both the Medicare and Medicaid EHR incentive programs for those hospitals that are eligible for both. The NPRM further states that: "For hospitals eligible for only the Medicaid EHR incentive program, such reporting will be to States. For eligible hospitals to which the measures in Table 20 do not apply to their patient populations, hospitals have the option to select clinical quality measures identified in Table 21 to meet the requirements for the reporting of clinical quality measures for the Medicaid program incentive."

However, we believe the agency contradicts itself on pg. 1900, where the proposed rule states that Medicare-eligible hospitals that also are participating in the Medicaid EHR incentive program will also be required to report on all of the Medicaid measures. **We ask CMS to clarify in the final rule that reporting on the measures listed for the Medicare EHR incentive program will be sufficient to fulfill Medicaid program requirements as well. The Medicaid measures should only be reported by hospitals for which the Medicare measures are not appropriate to their patient population.**

CERTIFICATION REQUIREMENTS

The first requirement of meaningful use is to use certified EHR technology. In the NPRM, CMS accepts the definition of certified EHR technology put forth by ONC in its Interim Final Rule titled "Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology," also published in the *Federal Register* on January 13, 2010.

ONC lays out a multi-stage definition of "certified EHR technology" to mean: "A Complete EHR or a combination of EHR Modules, each of which: 1) meets the requirements included in the [statutory] definition of a Qualified EHR; and 2) has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary."

ONC further specifies that a "**Complete EHR**," has been developed to meet all of the applicable certification criteria adopted by the HHS Secretary, while an "**EHR Module**" can be "any service, component, or combination thereof that can meet the requirements of at least one" of the certification criteria adopted by the Secretary.

ONC states that providers who choose to combine multiple EHR modules must ensure that the modules work together and that, together, they meet all of the certification criteria. Taken

together, the two regulations require that hospitals demonstrate to CMS that the EHR system they are using has been certified for all 23 meaningful use objectives through a federal process that is yet to be established.

However, hospitals generally do not use a single EHR system. Hospitals routinely bring together many different systems from numerous vendors to create an EHR system. Even those that install a main enterprise system routinely supplement with other products meant to achieve specific needs, such as department-specific systems for the operating room or radiology. For example, during testimony in front of the HIT Standards Committee Implementation Workgroup, Allegiance Health in Michigan noted that its EHR incorporates 200 IT systems that involve 75 to 80 vendors (October 29, 2009).

Thus, for hospitals, it will be challenging to look across the various systems in use to determine whether all certification requirements have been met, particularly during the next two or three years, where EHR vendors will be getting products certified and working with their customers to upgrade existing and install new systems.

This regulatory approach also asks hospitals to be accountable for the actions of vendors. Specific vendors may conclude that certain certification criteria are too difficult to meet and decide not to certify against a subset. Hospitals, however, would still be obliged to incorporate a system certified to perform that objective to achieve meaningful use. This may require going to a niche vendor for a new product that may not easily interface with other systems or custom-building that capability.

We ask CMS to provide more guidance on how hospitals should attest to having a certified product when they are relying on EHR Modules. We also recommend that, under the AHA's alternative approach, hospital systems only be required to have certification for the hospital's chosen subset of objectives.

Certification Process

The AHA is very concerned that the current absence of a federal process to certify EHRs will severely limit a hospital's ability to meet the meaningful use requirements in a timely manner. Even after the certification process is in place, and certified products are available, hospitals need time to implement and upgrade to certified systems. Market constraints, including insufficient vendor capacity and existing workforce shortages, will also slow the implementation process.

Given the time needed to establish a certification process and certify products, and install new or upgrade existing EHR systems, we recommend that CMS:

1. **Consider existing but not yet certified EHR systems compliant for a period of three years, as long as the hospital can meet specific meaningful use objectives;**

2. **Require that all upgrades to existing systems be certified; and**

3. In the long-term, provide a transition time of at least two years from when products certified to meet new meaningful use requirements are available to when certification is required for incentive payments.

Other regulatory initiatives requiring information system changes have included considerable transition periods. For example, the use of ICD-10 for claims submission was first proposed by the National Committee on Vital and Health Statistics in November 2003. CMS issued proposed regulations on adoption of ICD-10 in August 2008 and a final rule in January 2009. The final rule provides almost four years of transition time, calling for ICD-10 to be in use by October 1, 2013.

Although a pre-release copy of a proposed rule was made available on March 2, 2010, rulemaking to establish the federal process is ongoing. Even after a rule is finalized, the federal process to accredit certification agencies must be established and certification bodies must be approved. Those administrative steps only set the infrastructure for certification. Vendors must then revise their products and get them certified through the new process. Given all of these sequential steps, it seems highly unlikely that a wide array of certified systems will be available before July 2011. Indeed, the ONC rule estimates that "it will generally take 6 to 18 months for commercial vendors and open source developers…to prepare for testing and certification" (Federal Register Vol. 75, No. 8, p. 2041).

The AHA appreciates the time pressures facing CMS and ONC in developing regulations to establish and support the Medicare and Medicaid EHR incentive programs. The situation is further complicated by the inter-relationships between the three regulations governing separate aspects of the program. CMS has a very strong track record of soliciting and incorporating stakeholder feedback in its rules, and we welcome the opportunity to comment here. We note, however, that changes in the CMS EHR incentive programs rule will in all likelihood result in the need for changes to the interim final rule on certification requirements released by ONC. Therefore, vendors will only know the final certification criteria when ONC issues a final rule. We commend CMS and ONC for working closely together to ensure that these rules are complementary and urge both agencies to continue that cooperation in the next stage of rule-making.

Previous federal efforts suggest that new systems are not easily established in short order. For example, the process of enumerating National Provider Identifiers (NPIs) took longer than the initial two years that was planned and was delayed twice, for a total of 12 additional months. The process also included a transition phase, during which providers were allowed to use either their legacy number or the NPI.

Until certified products are available, making IT investments is risky, as the hospital, not the vendor, will lose out on incentive payments should the technology not be certified later on. Nevertheless, many hospitals across the country are engaged in negotiating multi-million dollar contracts on the promise that a vendor will be certified. While interim steps are being taken by the Certification Commission for Health Information Technology (CCHIT) to prepare for the final certification, these certifications cannot be assumed to meet the final definitions and criteria

for federally approved certification. In addition, since previous CCHIT certification was never a federal requirement, many hospitals are using systems that have not been CCHIT-certified. They should not be penalized moving forward.

The existence of certified products only starts the clock for the incremental installation process. Once certified products are available, hospitals must assess their own systems and determine how to move from their current situation to use of a system certified against all of the meaningful use objectives. The timeframe for completing these steps and implementing newly certified systems spans "years," not "months."

The current policy requires all hospitals to upgrade existing or adopt new systems simultaneously. The AHA is very concerned that vendors will not have the capacity to meet the new level of demand. Our members report that vendor queues for both existing and new clients are long and will likely grow. Vendors may also give preference to larger institutions and existing customers, again putting smaller and rural hospitals at a disadvantage. Vendors and hospitals also face workforce shortages. ONC has already projected a shortage of 50,000 health IT workers.[10] Additional workforce shortages are occurring within hospitals, including clinical staff that can assist in designing new workflows and championing EHR installations.

Hospitals with existing EHR systems will be looking to their vendors for upgrades to a certified version of the products they use. If the vendor will not be certifying the installed version, then the hospital will need to upgrade specific systems. Upgrades require significant financial and human resource investments to achieve and must be rolled out across a system. Often, an upgrade to one piece of a system will necessitate changes to other parts of the EHR system and the purchase and installation of new interfaces to ensure that the system works as a whole. The move toward interoperability will help with this process, but the vision of "plug and play" modules will not be a reality for years to come.

This disruption to installed systems makes sense if the upgrades to certified products bring new functionality. However, in many cases, the installed systems already perform many of the meaningful use objectives, and the upgrade will be needed only to meet the certification requirement. Given the high demands that are foreseen in the EHR market, this kind of requirement seems unnecessary and wasteful.

At the same time, hospitals at the low end of the adoption curve will begin the process of selecting products, arranging financing, and establishing contracts with vendors. They will then be placed in the vendor queue and be scheduled for an installation, which is generally a multi-year undertaking.

We are already hearing reports from members about the growing pressures on the health IT market and how they are affecting implementation timelines. For example, one Midwestern hospital has already achieved HIMSS Level 5 using a version of a vendor product that will not be certified for meaningful use. This hospital currently has CPOE installed and in use. The

[10] Healthcare IT News. Health IT effort to create thousands of new jobs, says Blumenthal. October 6, 2009.

hospital will not qualify for meaningful use in 2011, however, because their vendor does not plan to certify prior versions of their product for meaningful use. The hospital is in negotiations with the vendor to upgrade to the next version that will be certified. The vendor has said that if a contract is signed by the end of March 2010, the vendor will put the hospital in the queue to begin the upgrade of its core clinical system sometime in the first quarter of 2011 – 9 to 12 months after the contract is signed. That upgrade will take 6 to 9 months, and will upgrade only the currently installed applications, infrastructure and database. Additional modules, such as alerts and reminders, nursing care plans and physician progress notes, will be needed on top of that upgrade. Thus, a hospital that is now within the top six percent of performance in use of EHRs will not likely be eligible to receive an incentive payment until FY 2012, at the earliest.[11] Furthermore, the vendor has stated that this customer will be among the first of their large customer base to be scheduled for implementation, due to the hospital's current readiness. This means that 90 percent of this vendor's customer base will be scheduled to begin upgrades and new implementations in FY2012 or later.

This type of scenario is common and we urge CMS to develop a grandfathering policy to relieve some of the pressure on the market and ensure that hospitals' designation as "meaningful users" is not delayed inappropriately due to the developing certification process.

MEDICARE EHR INCENTIVE PROGRAM

Operational Concerns

The NPRM contains limited information on how the EHR Incentive Programs will be operationalized. We appreciate the extreme time pressures on CMS to design the program but request that additional information be provided on operational issues, including:

- The process to apply for meaningful use payments;
- The process to submit meaningful use data;
- The information needed for attestation; and
- The expected timeframe and process for payments.

CMS and its contractors must also give prompt feedback on missing or incomplete data, giving providers an opportunity to correct and re-submit their attestation, in a process parallel to the validation of quality data under the RHQDAPU program.

[11] According to HIMSS Analytics, only 3.8 percent of U.S. hospitals had reached Stage 5 in 2009. About 2 percent of hospitals have reached higher stages. http://www.himssanalytics.org/hc_providers/emr_adoption.asp.

Appeals Process

We recommend that CMS implement for the Medicare program all of the appeals processes it proposes to require of state Medicaid programs in 495.370 (an appeals process for a Medicaid provider receiving electronic health record incentive payments). Specifically, to ensure that the program is implemented fairly, providers must have:

- A process by which to appeal and provide documentation to support the appeal of incentive payments;
- Incentive payment amounts; and
- Provider eligibility determinations.

Given that this is a new and highly complex program, we also **urge CMS to provide vigorous and well-planned contractor and provider education, so as to maximize the likelihood of success.**

Retention Period

CMS proposes that eligible hospitals will need to maintain evidence of qualification to receive incentive payments for 10 years after the date they register for the incentive program. **We maintain that a retention period of 10 years is unacceptable.** Maintaining these records electronically for such a long period of time becomes costly since it requires additional storage as well as programming to catalogue and retrieve the information. There also will be technology changes that occur over 10 years, which could be enormous. These changes will likely require the provider to convert stored data into new data retrieval media and then apply new security protections to safeguard this information.

Other regulations and laws requiring electronic retention of health records are significantly shorter than 10 years. For example, electronic retention for medical records is governed by state laws and is generally five years. **CMS should modify the retention period for evidence of qualification to receive incentive payments to five years, which is consistent with other retention requirements.**

ELIGIBILITY FOR THE MEDICARE EHR INCENTIVE PAYMENTS

Policies proposed by CMS would significantly limit eligibility for the EHR Incentive Programs in unnecessary ways. This section addresses proposed policies to bar hospital-based professionals from participating in the EHR incentive programs and to limit unfairly the incentives paid to hospitals with multiple campuses operating under a single CMS Certification Number (CCN).

Hospital-Based Eligible Professionals

Under the ARRA, hospital-based eligible professionals are not eligible for Medicare EHR incentives or subject to penalties. The majority of hospital-based eligible professionals will not be eligible for Medicaid EHR incentives either.

The law defines hospital-based eligible professionals as those who furnish substantially all of their services in a hospital setting (whether inpatient or outpatient) using the facilities and equipment, including the qualified EHR, of the hospital. CMS proposes to further define hospital-based eligible professionals (for both Medicare and Medicaid purposes) as those who furnish at least 90 percent of their services in the inpatient hospital, outpatient hospital, or emergency department setting. The agency considers as outpatient hospital settings all types of outpatient care settings in the main provider, on-campus and off-campus provider-based departments of the hospital, and entities having provider-based status. Using this definition, CMS estimates that about 30 percent of professionals will not be eligible for incentive payments.

In its proposed rule, CMS states that hospitals' total incentive payments are based on their inpatient services and that its proposed Stage 1 meaningful use criteria apply only to the inpatient setting. Because of this, the agency notes that it is concerned that hospitals' investments in their outpatient primary care EHRs is likely to lag behind their investments in their inpatient EHRs. **We share this concern and believe that this overly broad definition of a hospital-based eligible professional will only exacerbate the problem by inappropriately excluding from health IT incentive payments those eligible professionals who practice in outpatient centers and clinics, merely because they provide patient care in an office or clinic that is located in a facility owned by a hospital.**

Ambulatory-care EHRs are very different from inpatient EHRs because of the inherent differences between the types of care provided in each setting. In addition, implementing an EHR in an ambulatory setting requires a significant cost above and beyond the cost of implementing the inpatient EHR.

Excluding physicians practicing in hospital ambulatory-care settings from eligibility for the EHR incentive payments would limit the benefit of EHR adoption in all communities, and especially in inner-city and rural settings where physicians are often employed. These inner-city and rural practice sites, which utilize an ambulatory EHR that is comparable or equivalent to the EHR platform used in traditional private practice settings, provide anchors to community-based services in their markets. In many cases, they are, in fact, the only source of ambulatory care available to thousands of people.

Our suggested policy for how CMS should define a hospital-based professional incorporates CMS' proposed policy, but with additional steps that constitute an algorithm that is, in part, based on other CMS programs. It is presented in graphic form in Figure 8 on page 47.

Step 1. In defining eligibility for EHR incentives, the ARRA names specific classes of hospitals as eligible, including subsection (d) and critical access hospitals (CAHs). We urge

CMS to take a parallel approach in defining eligible professionals and name specific classes of physicians as eligible for the incentives. The law mentions pathologists, anesthesiologists, and emergency physicians as examples of those who typically furnish substantially all of their services in a hospital setting. Hospitalists, intensivists, and neonatologists also typically furnish substantially all of their services in a hospital setting. Under the first step of the algorithm describing our proposed policy, we urge CMS to deem all physicians that *do not* belong to one of these specialties as non-hospital-based and, therefore, eligible for EHR incentives.

Step 2. For physicians who do belong to one of the specialties listed above, CMS should then examine the services they furnish in more depth to determine if they do, in fact, furnish substantially all of their services in a hospital setting. In the second step of this determination, we urge CMS to apply its already-proposed policy of deeming those physicians who furnish less than 90 percent of their services in the inpatient hospital, outpatient hospital or ED setting as non-hospital-based. For this step, CMS would continue to use the same definition of outpatient care settings and "place-of-service" codes on the professional's claim.

Step 3. The third step is a further examination of the hospital setting. Many physicians practice in outpatient ambulatory centers and clinics that have "hospital-based" status and are therefore billed under a place of service of the hospital outpatient department. While in the proposed rule, CMS states that it is its longstanding policy to consider as outpatient hospital settings all types of outpatient care settings in the main provider, on-campus and off-campus provider-based departments of the hospital, and entities having provider-based status, this is not entirely accurate.

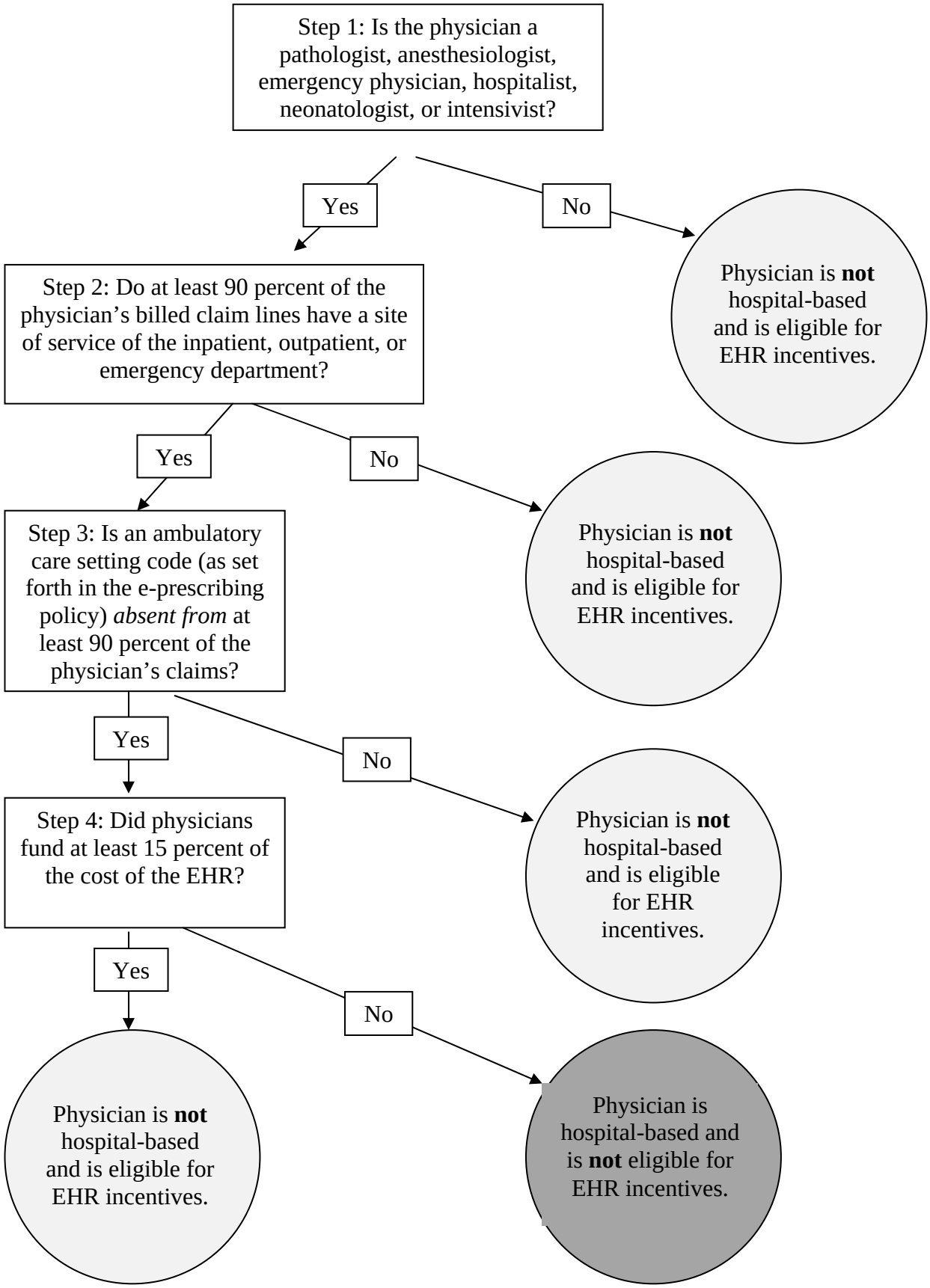
Under its physician e-prescribing incentive program, CMS defines a set of ambulatory services that is applied across physician offices and hospital outpatient settings. CMS uses a specific group of non-ED visit codes to define ambulatory services where site of service is immaterial. Attachment C lists the codes for reporting on e-prescribing under the Medicare physician fee schedule. That is, physicians reporting these codes are incentivized to use e-prescribing in both the physician office and hospital outpatient setting (see 73 *Federal Register* 69849). We urge CMS to follow the same logic in the EHR incentive program, which, for physicians, subsumes the e-prescribing incentive program by law. Specifically, we urge CMS to consider services billed with the e-prescribing visit codes as **not** furnished in the hospital setting and **not** counted as part of the 90 percent volume threshold needed to be considered hospital-based.

Step 4. Finally, to be considered hospital-based, physicians also have to use the hospital facilities and equipment, including the EHR. CMS states that if a professional is providing substantially all of his/her services in the hospital, it believes it is reasonable to assume that the professional is also using the facility and equipment of the hospital, including any EHR. However, in certain cases, physicians may have contributed financially to the development of the EHR used in the hospital setting. In the context of physician self-referral (or "Stark") rules, the Administration has issued specific

regulations that consider a physician contribution of at least 15 percent of the cost of the EHR to be significant (42 CFR 411.357(w)). We recommend a similar threshold here. That is, we recommend that qualified hospital ambulatory EHRs be defined as EHRs for which the hospital funded more than 85 percent of the cost.

Putting this definition together leads us to our recommended definition of a hospital-based eligible professional: a pathologist, anesthesiologist, emergency physician, hospitalist, intensivist, or neonatologist for whom at least 90 percent of his/her billed claim lines have a site of service of the inpatient, outpatient or emergency department and for whom at least 90 percent of his/her claims do not contain an ambulatory-care visit code (as set forth in the e-prescribing policy) and for whom the hospital funded more than 85 percent of the cost of the EHR.

Figure 8. AHA's Recommended Policy for Defining Hospital-Based Physicians



In addition, for Medicare incentive payment purposes, CMS proposes to determine hospital-based status by annually assessing an eligible professional's Medicare claims from the prior year. For Medicaid incentive payment purposes, CMS proposes that State Medicaid agencies make the determination. However, CMS does set forth a specific timeframe for which it or the states will notify eligible professionals of whether or not they are hospital-based.

It is extremely important that CMS make hospital-based determinations and notify professionals of their status before the start of each physician payment year, beginning with calendar year 2011. If this is not done, many professionals will register for EHR incentive payments and begin the burdensome reporting process, only to find out they are hospital-based and not eligible for payments in the first place.

CMS specifies that states must establish an appeals mechanism through which Medicaid providers can appeal various state determinations and decisions, including whether a professional is hospital-based. However, CMS does not establish the same appeals mechanism for Medicare providers to appeal hospital-based determinations. Once CMS notifies professionals of their hospital-based status, **it is critical that CMS give professionals the opportunity to review determinations and challenge those they believe are in error.**

Further, we urge CMS to give professionals the right to petition for a change in their hospital-based status when there is a material change in their organizational affiliation. For example, a physician leaving a hospital-based practice to join a freestanding practice would no longer be providing substantially all of his/her services in the hospital setting and should become eligible for incentive payments.

Definition of an Eligible Hospital or CAH for Medicare EHR Incentive Payments

The ARRA provides for incentive payments to eligible hospitals and CAHs that are meaningful users of certified EHR technology. CMS proposes to provide incentive payments to hospitals as distinguished by provider number on the cost report, which is the CMS certification number (CCN) of the main provider.

For health IT incentive payment purposes, we urge CMS not to use a CCN as the sole criterion to define a hospital or CAH. Instead, we ask CMS to use a multi-pronged approach that allows a "hospital" to be defined in ways that acknowledge the varied organizational structures of multi-hospital systems, including by a distinct CCN, a distinct emergency department or a distinct state hospital license. Under this multi-pronged definition, each distinct hospital in a system would be eligible to qualify separately for the EHR incentives.

Defining hospitals and CAHs solely by CCN could, contrary to the intent of the ARRA, create a barrier to widespread EHR adoption and use. There is no standard policy that defines the specific types of hospital facilities to which a CCN applies; a single CCN could, for example, encompass multiple hospitals within a hospital system. Because the Medicare and Medicaid payment incentives in the ARRA are calculated using a per-hospital base amount, plus a capped

per-discharge amount per hospital, using only a CCN to define a hospital would result in the ARRA incentives being distributed in a manner that does not foster widespread EHR adoption and use. Specifically, a health care system with multiple hospitals but a single CCN would be disadvantaged because the system would be eligible for only one base amount and much more likely to reach the discharge cap. In addition, such a health care system would be subject to the Medicare program's penalties at the system level, even if, for example, only one of the system's multiple hospitals was not found to be a meaningful user.

Linking EHR incentive payments only to a single CCN would not accurately reflect the costs of deploying EHR systems across all hospitals in a system. The total cost of EHR implementation far exceeds the purchase cost of the actual application or software. Even hospitals that are part of the same system often require significant variations in their EHRs, as local policies and processes must be incorporated in EHR utilization. For example, installations must accommodate the differing network infrastructures of legacy software, physician preferences, clinical protocols, expert rules protocols, workflows and ancillary system integration. In addition, a hospital system may encompass both a children's hospital and an adult acute-care hospital, each of which requires a different interface and clinical system. Further, hospitals incur additional administrative costs for necessities such as workstation installation, servers, staff training and differences in clinical services among each of the hospitals, resulting in additional variation among facilities.

CMS could use the hospital cost report, with certain modifications, to collect the hospital-specific data that will be necessary to determine the EHR incentive payment for each hospital. Specifically, hospitals with multiple sites that are under one CCN but in different core-based statistical areas must currently separately report wage data for each site on the cost report. CMS could create a similar worksheet on which hospitals with multiple sites that are under one CCN separately report EHR incentive payment data for each site.

PAYMENT METHODS FOR MEDICARE EHR INCENTIVES

This section addresses a number of technical issues in the proposed approach to calculating the Medicare FFS EHR incentive payments, including:

- Cost reporting periods used;
- Payment form and timelines;
- Calculating Medicare share;
- Calculating charity care; and
- Incentive payment calculations for CAHs.

Cost Reporting Period

To determine a hospital's discharge-related amount, CMS proposes to use cost report data on hospital discharges from the hospital FY that ends during the FY prior to the payment year. The final discharge-related amount would be determined and settled based on the hospital's cost

report from the FY that ends during the payment year. For example, FY 2011 begins on October 1, 2010 and ends September 30, 2011. For hospitals with October-to-September cost reporting periods, CMS would estimate their FY 2011 discharge-related amounts based on their October 1, 2009 through September 30, 2010 cost reports. The agency would then determine and settle the final discharge-related amount using the hospital's October 1, 2010 through September 30, 2011 cost report.

These October 1, 2009 through September 30, 2010 cost reports are not due until February 28, 2011. Yet, under the proposed rule, hospitals can qualify as meaningful users as early as January 1, 2011. This means that hospitals with October-to-September cost reporting periods would have to wait at least an additional two months after they are deemed meaningful users before they receive their interim incentive payments. In addition, hospitals with September-to-August cost reports would have to wait at least an additional month after they are deemed meaningful users before they receive their interim incentive payments. Over one-fifth of subsection (d) hospitals have cost reporting periods beginning on September 1 or October 1. Given the high capital costs of EHRs, we believe it is inappropriate for this large number of hospitals to experience delays in receiving their EHR incentive payments. **Therefore, we urge CMS to estimate a hospital's discharge-related amount based on its most recently filed cost report, and not based on the cost report that ends during the FY prior to the payment year.**

Payment Form and Timelines

Under the ARRA, incentive payments are calculated as Medicare's share of the sum of $2 million and an additional discharge-related amount. A hospital receives $200 for each discharge starting with its 1,150th and continuing through its 23,000th discharge. CMS proposes that the fiscal intermediaries (FIs) and Medicare Administrative Contractors (MACs) will calculate the Medicare incentive payment for each hospital and once the hospital has demonstrated it is a meaningful user, distribute the payment on an "interim basis." **We urge CMS to clarify that the payment distributed will be a *lump sum* payment. This is implied in the text, but additional clarity is necessary. The AHA urges CMS to make timely payments for both the interim and final EHR incentive payments.**

CMS does not set forth a specific timeframe in which the FIs and MACs will distribute the hospital's incentive payment once they have the necessary data, but it is extremely important that this be done in a timely manner. However, for professionals who receive a 10 percent bonus to their incentive payments because they predominantly furnish services in a geographic health professional shortage area, CMS proposes to make the bonus payment no later than two months after the agency has the necessary data. **To be consistent with CMS' proposals around incentive payments for eligible professionals, we urge CMS to direct the FIs and MACs to distribute the interim payment no later than two months after the hospital has demonstrated meaningful use. We also urge CMS to direct the FIs and MACs settle the final payment no later than two months after the hospital submits its cost report from the FY that ends during the payment year.**

Calculating Medicare Share

The statutory formula for calculating a hospital's Medicare share consists of total Medicare Part A and C inpatient days, divided by the product of total inpatient days and hospital charges excluding charity care divided by total charges:

$$\frac{\text{Medicare inpatient days}}{\text{(total inpatient days*((gross revenue - charity) / gross revenue))}}$$

To obtain data on Medicare Part A and C inpatient days and total inpatient days, CMS proposes to use the same cost report fields as it does for direct graduate medical education payment calculations. Specifically the agency will use lines 1, 6 through 9, 10, and 14 in column 4 on Worksheet S-3, Part I as a hospital's Medicare Part A inpatient days. It will use line 2 in column 4 on Worksheet S-3, Part I as a hospital's Medicare Part C inpatient days. Finally, CMS will use lines 1, 6 through 9, 10, and 14 in column 6 on Worksheet S-3, Part I as a hospital's total inpatient days. **We believe these are the appropriate lines to use, as they adequately capture the necessary data, including Medicare days for inpatient PPS-exempt units for which payment is made under Part A, as is required by the ARRA. We do ask, however, that CMS clarify a sentence in the proposed rule which conflicts with both the ARRA and its proposed calculation of the Medicare share.** Specifically, CMS states that lines 1, 6 through 9, 10, and 14 in column 4, Worksheet S-3, Part I include "all patient days attributable to Medicare inpatients, excluding those in units not paid" under the inpatient PPS. However, as noted above, these lines appropriately *include* patient days in units not paid under the inpatient PPS. Further, although gross revenues (total charges) are part of the Medicare share calculation, CMS does not state where it plans to obtain these data. **We urge CMS to use Worksheet C, Part 1, line 103, column 8 on the cost report to obtain gross revenue data.**

Calculating Charity Care

To obtain data on charity-care charges, CMS proposes to use the revised and yet-to-be-released cost report worksheet on Hospital Uncompensated Care (Worksheet S-10). CMS recently proposed changes to this worksheet as part of proposed changes to the cost report as a whole. The agency anticipates the revised cost report will be effective for cost reporting periods beginning on or after February 1, 2010. If a hospital's cost report does not contain the data necessary for CMS to determine its charity care charges, then charity care will be deemed to equal $0.

We are concerned that hospitals with cost reporting periods beginning on November 1, December 1, or January 1 will not have the opportunity to report charity care data for the first year of the incentive program. Specifically, their cost reports ending in FY 2011 (which CMS proposes to use to determine the final discharge-related amount for FY 2011 incentive payments) will run November 1, 2009 through October 31, 2010; December 1, 2009 through November 30, 2010; and January 1, 2010 through December 31, 2010. However, CMS anticipates that the revised cost report that captures charity care data will not be effective until cost reporting periods beginning on or after February 1, 2010. **Thus, the 41 percent of subsection (d) hospitals and**

34 percent of CAHs with cost reporting periods beginning November 1, December 1, or January 1 will not even have the opportunity to report charity care data for FY 2011 incentive payments. This unfairly penalizes these hospitals, because if they do not report charity care data, CMS proposes to deem their charity care charges to equal $0 – even in this case in which the non-reporting is through no fault of their own.

To remedy this situation, we urge CMS to issue an interim final rule containing changes to the cost report stemming from its proposed rule last year, as well as from newly proposed changes related to implementation of the EHR incentive program. In this rule, CMS should accept further comment on proposed changes to Worksheet S-10 so that hospitals and other stakeholders will have the opportunity to weigh in on these changes in the context of EHR incentive payments**. However, CMS should make changes to the Worksheet S-10 retroactive to cost reports beginning on or after October 1, 2009 to remedy the timing problem described above.**

For the Medicare share calculation, CMS proposes to use the charity-care charges reported on line 19 of the revised Worksheet S-10. This line captures the "total initial payment obligation of patients who are given a full or partial discount, based on the hospital's charity care criteria (measured at full charges), for care delivered during this cost reporting period for the entire facility." However, the data in a hospital's accounting system/general ledger do not capture such information. Therefore, hospitals cannot capture the data required for this line unless they begin to maintain a detailed charity-care log for all patients for which charity care has been approved – a task that is extremely difficult and burdensome. We expressed these same concerns in our comments on the proposed cost report and urged CMS to modify line 19 so it instead captures "total charity care charges written-off (as accounted for in the hospital's general ledger)." We stated that this is how the Internal Revenue Service requires charity care to be reported, and that this modification would help streamline and unify charity care reporting across the Federal government, ensure consistency of reporting, and avoid significantly increasing hospitals' administrative burden. (See http://www.aha.org/aha/letter/2009/080821-cl-cms-2552-10.pdf for our comment letter on the proposed cost report.)

Medicare Incentive Payment Calculations for CAHs

Under the ARRA, CAH incentive payments will equal the Medicare share of their reasonable costs incurred for the purchase of certified EHR technology. CMS proposes that the FIs and MACs make incentive payments to qualifying CAHs through a prompt "interim" payment. **We urge CMS to clarify that the payment the FIs or MACs will distribute will be a *lump sum* payment. This is implied in the text, but additional clarity is necessary.**

To obtain the incentive payment, CMS proposes that CAHs must submit the "necessary documentation (as specified by CMS or its contractors)" on health IT acquisition costs to support the computation of the payment amount to its FI or MAC. Its FI or MAC will review such documentation and determine the interim amount of the incentive payment, which will be subject to a reconciliation process. However, CMS has not proposed any specifics as to what constitutes "necessary documentation." **It is critical that CMS propose, obtain comments on, and**

finalize these details before FY 2011 begins so qualifying CAHs can plan appropriately to submit this documentation and receive their interim payment in a timely manner.

In addition, CMS does not set forth a specific timeframe in which the FIs and MACs will distribute the hospital's incentive payment once they have the necessary documentation. It is extremely important that this is done in a timely manner. **To be consistent with CMS' proposals around incentive payments for eligible professionals, we urge CMS to specify that the FIs and MACs distribute the interim payment within two months of the CAH submitting the "necessary documentation." We urge CMS to specify that the FIs and MACs reconcile the final payment within two months of the CAH submitting its cost report from the relevant FY.**

Further, although CMS states that the FIs and MACs will review CAHs' current and subsequent cost reports to ensure incentive payments are made appropriately, CMS does not discuss how it will modify the cost report to allow CAHs to report EHR costs. As noted above, CMS recently proposed changes to the cost report, but has not yet issued its final changes. **We urge CMS to issue promptly an interim final rule on the cost report, which will contain changes from its previously proposed cost report rule, as well as newly proposed changes to, among other things, allow CAHs to report appropriately EHR costs. Cost report changes allowing CAHs to report appropriately EHR costs must be effective for cost reporting periods beginning on or after October 1, 2010, as this is when CAHs are first eligible to receive incentive payments. The actual cost report forms containing these changes must be finalized in advance of October 1, 2010 to allow CAHs to plan appropriately.**

Under the ARRA, the Medicare share for CAHs will be calculated using the same methodology as for subsection (d) hospitals, plus 20 percentage points (not to exceed 100 percent). However, this means that CAHs will experience the same problem with the timing of charity care reporting as subsection (d) hospitals will experience (see above). To reiterate, **the 41 percent of subsection (d) hospitals and 34 percent of CAHs with cost reporting periods beginning November 1, December 1, or January 1 will not have the opportunity to report charity care data for FY 2011 incentive payments. This unfairly penalizes this large number of hospitals, because if they do not report charity care data, CMS proposes to deem their charity care charges to equal $0 – even in this case where the non-reporting is through no fault of their own. As mentioned above, CMS should issue an interim final cost report rule which, in part, accepts further comment on changes to Worksheet S-10. Worksheet S-10 changes should be retroactive to cost reports beginning on or after October 1, 2009.**

CMS proposes to define a CAH's reasonable costs for the purchase of certified EHR technology as 100 percent of "the reasonable acquisition costs, excluding any depreciation expenses..." However, we are concerned that CMS's statement that they will exclude depreciation expenses could cause confusion among CAHs because their reasonable costs for the purchase of certified EHR technology include costs that *would* be depreciation expenses absent the EHR incentive program, as well as similar costs from previous cost reporting periods to the extent they have not been fully depreciated in the present period. **We ask CMS to clarify that they will exclude expenses that have already been depreciated in past cost reporting periods.**

MEDICAID EHR INCENTIVE PROGRAM

Importance of the Medicaid Program

Access to capital is the largest barrier to hospital adoption of EHR systems. In a recent AHA survey, 70 percent of hospitals cited lack of access to capital as a moderate or significant barrier to implementing EHR systems. Capital is a much greater constraint for small hospitals (of which 75 percent see lack of capital as a barrier to EHR adoption), and CAHs (of which 80 percent see lack of capital as a barrier). Given that the Medicare EHR Incentive Program provides funding only after successful adoption has occurred, the one year of Medicaid support for adoption, implementation, or upgrading of EHR systems will be vitally important.

The AHA is very concerned that the voluntary nature of the Medicaid EHR Incentive Program, and the complex requirements on states to establish the programs, could result in states delaying implementation of their programs or deciding not to undertake them at all. It is our understanding that all states have yet to receive approval of their Medicaid health IT planning documents and full administrative funding to establish their programs.

The proposed rule gives states flexibility in deciding how the aggregate Medicaid EHR incentive payment to a hospital is apportioned over years. CMS proposes that states must make payments over a minimum of three years and a maximum of six years. In any given payment year, no annual Medicaid incentive payment to a hospital may exceed 50 percent of the aggregate incentive amount. Likewise, over a two-year period, no Medicaid payment to a hospital may exceed 90 percent of the aggregate incentive.

The AHA urges CMS to take all needed steps to facilitate the timely establishment of state Medicaid EHR Incentive Programs, including expedited review of all planning documents. In addition, we recommend that CMS require states to provide hospitals the maximum payment (50 percent of the aggregate incentive) in the first payment year and the second payment year (40 percent of the aggregate incentive), as a limited source of capital for adoption, implementation, and upgrades.

Common Definition of Meaningful Use

CMS proposes to create a common definition of meaningful use for the Medicare fee-for-service and Medicare Advantage programs that would also serve as the minimum standard for the Medicaid program. CMS proposes to allow states to add additional objectives to the definition or modify existing objectives only if those changes "further promote the use of EHRs and healthcare quality" and do not "require additional functionality beyond that of certified EHR technology." Examples of additional criteria in the proposed rule include requiring providers to participate in health information exchange and requiring that providers link to immunization, lead screening or newborn screening registries. CMS notes that, to be approved, these

information exchange mechanisms must be readily available to providers and not represent a financial burden.

The AHA greatly appreciates this approach and applauds CMS for its efforts to ensure consistency in the EHR incentive program across Medicare and Medicaid. A common definition will avoid the confusion that arises when hospitals must comply with both a federal (Medicare) and state (Medicaid) requirement that can be in conflict. It is also very important for those hospital systems that operate facilities serving multiple jurisdictions. This approach will also allow for efficiencies in reporting.

In implementing the common definition of meaningful use, the AHA requests that CMS NOT approve any additional state criteria. The requirements under the proposed rule are complex and will be extremely challenging for hospitals to meet, particularly under the suggested timelines. In addition, both CMS and the states will be establishing new application, reporting and payment processes, which hospitals will need to master quickly in order to demonstrate meaningful use. The potential for states to layer on additional meaningful use requirements would significantly complicate matters for all hospitals, and particularly for hospitals that serve patients in multiple states.

CMS further proposes to "deem" hospitals that are meaningful users under Medicare as meaningful users under Medicaid, with no obligation to meet any additional or different, State-specific meaningful use requirements approved by the Secretary. While the preamble clearly proposes a "deeming" approach, the specific regulatory language at §495.312, with reference to 495.4, is less clear. **The AHA asks that CMS adopt and affirm the deeming approach in its final rule and ensure that the regulatory language reflects this approach by adding specific language on deeming to the regulatory language at §495.4, §495.8, §495.310, or other appropriate place in the regulation text.**

ELIGIBILITY FOR MEDICAID EHR INCENTIVE PAYMENTS

This section addresses three issues regarding how states will identify hospitals eligible for the Medicaid incentive program:

- The restrictive definition of acute-care hospital that unfairly bars CAHs from eligibility;
- The definition of a children's hospital; and
- The calculations for determining Medicaid patient volumes.

Definition of an Acute-Care Hospital

For purposes of the Medicaid EHR incentive payment program, the ARRA defines an eligible hospital as an acute care hospital or a children's hospital. CMS proposes to define an acute-care hospital as a health care facility where the average length of patient stay is 25 days or fewer and that has a Medicare CCN that has the last four digits in the series 0001 through 0879. These CCN numbers encompass short-term general hospitals and the 11 cancer hospitals in the United States. These numbers do not encompass CAHs because all CAHs have Medicare CCNs with

the last four digits in the series 1300 through 1399. However, under the *Social Security Act*, CAHs are, by definition, general, acute-care hospitals with an average length of patient stay of 25 days or fewer. Section 1820(c)(2)(b)(ii) states that to be eligible to be a CAH, a hospital must make available 24–hour emergency care services – meaning it is a general hospital. Section 1820(c)(2)(b)(iii) states that to be eligible to be a CAH, a hospital must not have "more than 25 *acute care* inpatient beds...for providing inpatient care for a period that does not exceed...*96 hours per patient* [emphasis added]." Thus, CAHs meet both the ARRA definition of being acute-care hospitals, as well as CMS's proposed definition of being short-term general hospitals. **Accordingly, we urge CMS to revise its definition of hospitals that are eligible for Medicaid EHR incentives to include hospitals with Medicare CCNs that have the last four digits in the series 1300 through 1399.**

We estimate that approximately 40 percent of CAHs meet the Medicaid patient-volume threshold and would be eligible for Medicaid EHR incentives if these CCNs are included. For these small, isolated, rural hospitals that are so essential to their communities, receiving Medicaid EHR incentives could be the difference between being able to implement EHRs and not.

In addition, we ask CMS to clarify that the 25-day length of stay limit is based on inpatient, acute-care days only – other inpatient days, such as swing-bed days or those associated with skilled-nursing, inpatient rehabilitation, psychiatric, or chemical dependency recovery stays, should not be included in the length of stay for these purposes. **We recommend CMS and states use Worksheet F-3, line 1, column 6 divided by Worksheet F-3, line 1, column 15 on the cost report to calculate the average length of stay for Medicaid incentive payment eligibility.**

Definition of a Children's Hospital

Children's hospitals are also eligible for Medicaid incentive payments. CMS proposes two possible definitions of children's hospitals. First, CMS could define children's hospitals as separately certified children's hospitals, either freestanding or hospital-within-hospital. The agency would identify these hospitals as those with Medicare CCNs with the last four digits in the 3300 to 3399 series, and which "predominantly" treat individuals under 21 years of age. CMS's second proposed definition would include freestanding hospitals with Medicare provider numbers in an additional CCN series – those for short-term, rehabilitation and psychiatric hospitals – provided they "exclusively" furnish services to individuals under age 21.

The AHA urges CMS to adopt its first proposed definition of children's hospitals – those that are separately certified. This definition is consistent the definition of a children's hospital for graduate medical education funding. In addition, this definition requires that children's hospitals predominantly – rather than exclusively – treat individuals under 21 years of age which gives these hospitals the flexibility to continue to treat patients as they transition to adult care.

Calculating Medicaid Patient-Volume Requirements

The ARRA provides for Medicaid incentive payments to eligible professionals and acute-care hospitals who are meaningful users of certified EHR technology. To qualify for Medicaid EHR incentive payments, CMS proposes that an eligible professional must have a minimum of 30 percent of all patient encounters attributable to Medicaid (or, if a pediatrician, at least 20 percent), or if practicing predominantly in a FQHC or RHC, have a minimum of 30 percent of all patient encounters attributable to needy individuals, over any continuous representative 90-day period. CMS proposes that acute-care hospitals must have a minimum of 10 percent of all patient encounters attributable to Medicaid over any continuous representative 90-day period. In addition, CMS would permit a state to propose to adopt an alternative approach to its proposed timeframe for measuring patient volume, subject to CMS approval.

CMS notes that its proposed definitions provide flexibility to professionals and hospitals, including the ability to capture any seasonal encounter adjustments in the year, while still honoring congressional intent to provide payments to higher-volume Medicaid practitioners. **The AHA thanks CMS for affording this flexibility in calculating patient volume.**

The AHA also believes that additional flexibility would help better meet the purpose of the ARRA – to encourage the adoption and use of EHRs. **Specifically, we urge CMS to allow all professionals associated with a particular FQHC or RHC to be able to meet the patient-volume threshold on average, not individually.** That is, a group of professionals associated with a particular FQHC or RHC would have to meet the patient-volume threshold *on average* in order to qualify for Medicaid EHR incentives. Such a policy also should consider that the patient-volume threshold for a particular FQHC or RHC will depend on the number of pediatricians associated with the facility, as pediatricians must meet a 20 percent, not 30 percent, threshold to qualify for Medicaid incentive payments.

PAYMENT METHODS FOR MEDICAID EHR INCENTIVES

Medicaid Incentive Payment Calculation for Hospitals

The ARRA provides for Medicaid incentive payments to eligible hospitals that are meaningful users of certified EHR technology. At their option, state Medicaid agencies are fully responsible for administering and disbursing these Medicaid incentive payments and may receive 100 percent federal financial participation for these payments. It is critical that these incentive payments be made in a timely manner and not delayed or otherwise affected by any state budget problems or changes to state Medicaid program payments or eligibility, especially given that the federal government is bearing 100 percent of the cost of the EHR incentive payments. **Additionally, these incentive payments should not be included in any calculation of total Medicaid payments for the purpose of determining Medicaid shortfalls, disproportionate share payments, upper payment limits, or any general Medicaid program service. To ensure that this occurs, we ask CMS to consider Medicaid incentives as separate and apart from other Medicaid program payments for patient care.**

The Medicaid EHR incentive payment formula for hospitals is consistent with the formula used under the Medicare incentive payment program. Specifically, incentive payments are calculated as Medicaid's share of the sum of $2 million plus an additional discharge-related amount. Because the formula for calculating the Medicaid share requires a determination of charity care charges, CMS proposes that states use the revised Medicare cost report, Worksheet S–10 or another auditable data source to determine the charity care portion of the formula. However, this means that CAHs will experience the same problem with the timing of charity care reporting as subsection (d) hospitals and CAHs (see above). To reiterate, **the 41 percent of subsection (d) hospitals with cost reporting periods beginning November 1, December 1, or January 1 will not even have the opportunity to report charity care data for FY 2011. As mentioned above, CMS should issue an interim final cost report rule which, in part, accepts further comment on changes to Worksheet S-10. Only Worksheet S-10 changes should be retroactive to cost reports beginning on or after October 1, 2009.**

Medicaid Incentive Payment Calculation for Eligible Professionals

Under the Medicaid EHR incentive payment program, an eligible professional may qualify for incentive payments in year 1 by adopting, implementing, or upgrading certified EHR technology, rather than being a meaningful user of such technology. CMS has proposed that all Medicaid eligible professionals may receive the same maximum payment amount of $21,250 in the first year, regardless of whether they qualify by virtue of adopting, implementing or upgrading certified EHR technology or by being meaningful users of such technology. However, CMS invites comment on the alternative of limiting professionals who qualify as meaningful users to a maximum Medicaid incentive payment of $8,500 in the first year.

The AHA strongly agrees with CMS' proposal to allow all eligible professionals to receive the same maximum payment amount in their first payment year, regardless of how they qualify. As CMS notes, a lower limit for professionals who qualify as meaningful users would put them at a disadvantage. Further, doing so would run contrary to the intent of the ARRA – to encourage the adoption and use of EHRs.

PRIVACY AND SECURITY

While the proposed rule includes a specific objective to "protect electronic health information created or maintained by certified EHR technology through the implementation of appropriate technical capabilities," CMS states that the agency "do[es] not believe meaningful use of certified EHR technology is the appropriate regulatory tool to ensure such compliance with the HIPAA Privacy and Security Rules." **The AHA agrees with and greatly appreciates CMS' conclusion that using the meaningful use rule is not the appropriate regulatory tool to ensuring HIPAA privacy and security compliance.**

As CMS acknowledges, 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 and remains most appropriately under the authority of the HHS' Office for Civil Rights (OCR). The OCR's current processes and procedures ensure enforcement of the existing obligation of hospitals and providers to be in compliance with requirements of both HIPAA rules. The meaningful use rule should not be used to create a redundant and potentially conflicting process to ensure compliance with HIPAA obligations.

The AHA, however, is concerned about the proposed objective's reference to the "fair data sharing practices set forth in the Nationwide Privacy and Security Framework" in addition to the HIPAA privacy and security rules and we question whether such explicit reference in the objective is appropriate. The Framework, which never explicitly uses the phrase "fair data sharing practices," does not establish current regulatory requirements for the privacy and security of health information. Rather it lays out a general set of high-level principles for protecting confidentiality and ensuring transparency about use and disclosure of health information. On the surface, the Framework seems to address at a general level issues already addressed more specifically by the HIPAA privacy and security rules, including general principles about individuals' access to personal health information; correction by individuals of inaccuracies in their personal health information; transparency regarding how personal health information is used and disclosed; limitations on the collection, use and disclosure of personal health information to what is necessary to accomplish a specific purpose; ensuring data quality and integrity; use of safeguards to ensure data confidentiality, integrity, and availability and to prevent unauthorized or inappropriate access; and individual choice about the collection, use and disclosure of individually identifiable health information.

To the extent that these high-level principles reflect nothing more than existing HIPAA privacy and security requirements, the objective's reference to the Framework is redundant and unnecessary. Moreover, to the extent that the reference to the Framework is meant to create different or potentially conflicting obligations for compliance with privacy and security regulatory requirements, the reference is inappropriate. **The AHA urges CMS to clarify that this meaningful use measure requires no new obligation beyond the requirements of the HIPAA privacy and security rules. The AHA recommends that the reference to the "fair data sharing practices set forth in the Nationwide Privacy and Security Framework" be eliminated from the objective.**

We also note that despite CMS' conclusion that meaningful use rule should not be used as a regulatory tool to ensure HIPAA compliance, the agency nevertheless includes in the proposed regulatory text an associated measure "to conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1) and implement security updates as necessary." The inclusion of this measure, according to CMS, is to "ensure that the certified EHR technology is playing its role in the overall strategy of the EP or eligible hospital in protecting health information." The proposed rule would require that meaningful users conduct or review such analysis "at least once prior to the end of the EHR reporting period" – it also could occur prior to the beginning of the reporting period – and attest to having done so. The AHA does not believe that this is necessary, given hospital's existing obligations under the security rule and the enforcement mechanisms available to OCR.

CMS's proposed meaningful use objective to "protect electronic health information created or maintained by certified EHR technology through the implementation of appropriate technical capability" provides the foundation upon which to establish, through ONC's IFR, certification criteria that ensure certified EHR technology provides certain privacy and security capabilities. We support both this meaningful use objective and ONC's alignment of its certification criteria to applicable requirements in the HIPAA Security Rule. We agree with ONC's stated belief that, in doing so, such capabilities "may assist eligible professionals and eligible hospitals to improve their overall approach to privacy and security." (75 Fed. Reg. 2034.)

However, the current measure goes beyond the goals of this objective. Given the thorough nature and important role of the certification criteria, we believe a more appropriate meaningful use measure for the above-stated meaningful use objective would be: “The adoption and use of certified EHR technology that meets ONC's criteria related to privacy and security capabilities.”

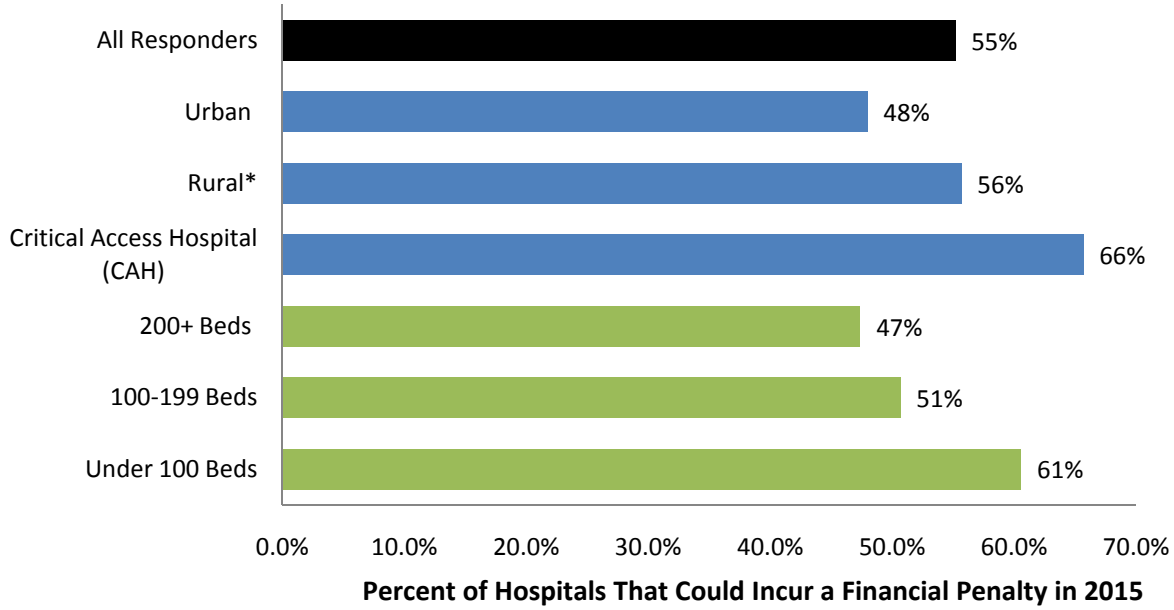
IMPACT ANALYSIS

CMS estimates it will make between $14 and $28 billion in total Medicare and Medicaid EHR incentive payments from 2011 to 2019. This analysis is much lower than the Congressional Budget Office’s original estimate of $34 billion. CMS also estimates that hospitals will receive between $3.8 and $4.1 billion in Medicaid incentive payments (Tables 51 and 52, p. 1989), for total hospital EHR incentives of between $11.2 and $15.3 billion through 2019. It also estimates that, between 2011 and 2019, hospitals will receive between $7.4 and $11.2 billion in Medicare incentive payments net of penalties. CMS indicates in the NPRM that it believes nearly all hospitals will be meaningful users before 2015 because they have a financial incentive to do so. CMS estimates penalties of between $200 million and $1.1 billion through 2019.

The NPRM does not include sufficient information for the AHA to replicate its impact analysis. However, the AHA did estimate expected incentive payments and penalties based on data collected from 795 hospitals surveyed in January 2010. The survey asked hospitals whether their current EHR systems could meet each of the 23 objectives now and in the coming years.

Only 45 percent of hospitals reported that they would be able to meet all 23 of the proposed Stage 1 objectives by 2015, suggesting that 55 percent of hospitals would be subject to penalties even if additional objectives are not added. An even higher percentage of smaller and rural hospitals would likely have their payments reduced (Figure 9, below).

Figure 9. The majority of hospitals are likely to incur a financial penalty in 2015, with smaller and rural hospitals hit harder than larger and urban hospitals



Source: AHA analysis of survey data from 795 non-federal, short-term acute care hospitals collected in January 2010. Hospitals were asked to indicate the number of meaningful use objectives they meet now and expect to meet by 2015. *Excluding CAHs.

Assuming that the adoption trend between now and 2015 will continue at the same pace through 2019, and based on the payment formulas in legislation, **we estimate that only $2.3 billion in net Medicare incentive payments will be made between 2011 and 2019 (versus the CMS estimate of between $7.4 and $11.2 billion)**. That is, a total of $6.64 billion will be distributed in Medicare EHR incentives, while $4.35 billion will be assessed in Medicare penalties. Table 3, on the next page, shows the AHA's estimated impacts overall and by hospital group.

Table 3. Estimated Net EHR Incentives by Hospital Size and Location, 2011-2019 (in millions)

Hospital Group	Total Incentives 2011-2016	Penalties 2015-1019	Net Incentives
Size:			
Under 100 Beds	$1,965.1	$479.3	$1,485.7
100-199 Beds	1,492.5	789.1	703.4
200+ Beds	3,179.7	3,086.9	92.8
Location:			
Critical Access Hospital (CAH)	312.0	78.3	233.7
Rural*	1,320.2	585.8	734.4
Urban	5,005.1	3,691.2	1,313.8
Overall:	6,637.3	4,355.4	2,281.9

*Source: AHA analysis of survey data from 795 non-federal, short-term acute care hospitals collected in January 2010, hospital cost reports, and the IPPS impact file. *Excluding CAHs.*

Given the high bar set in the NPRM, this analysis indicates that far fewer incentive dollars are likely to flow than CMS estimated, and far fewer than Congress intended. In addition, the penalties will likely be significant. The AHA's alternative approach would result in incentive payments more in line with congressional intent.

Attachment A. Recommended Additional Objectives and Measures of Meaningful Use

This attachment provides descriptions and recommended measures for the additional objectives and measures recommended under the AHA's alternative approach to defining meaningful use. It is important to emphasize that these additional objectives are meant to describe the end-goal for 2017. Hospitals follow unique adoption paths and will benefit from the flexibility to choose among these objectives. Incorporating these additional objectives into the meaningful use requirements is contingent on adoption of a flexible, incremental approach to achieving meaningful use over a longer time period. These additional objectives must be considered in the context of the other recommendations that make up the AHA's alternative approach.

1. Evidence-based order sets.

Evidence-based order sets are (groups of) suggested orders relevant to a patient's condition founded on the clinical evidence used in diagnosing or treating such a condition. To suggest that an order set is evidence-based implies that there is a process in place whereby applicable clinicians from the hospital are involved in the definition of the order set, and once defined there is an ongoing process that continues to review and approve their continued use based on clinical effectiveness. Evidence-based order sets are reviewed periodically, and adjusted as new evidence becomes available, either through research, peer-reviewed literature, performance measures or best practice. Automated tools are available to assist in this process. The literature shows that even the adoption of paper-based order sets can significantly improve outcomes and reduce mortality.

Measure: At least one evidence-based order set is in use for a specific patient condition, and is reviewed and approved at least annually following a defined process.

2. Electronic medication administration record (eMAR).

At its core an electronic medication administration record is an automated record of medications ordered and given to a patient. Within a hospital, drug therapy requests move from the prescribing physician to the dispensing pharmacist and then to the nurse for patient administration. A medication cart may or may not be involved. An eMAR tracks the medication from its order to administration and provides the nurse, in real time, access to all available data on patient medications and their administration, from those that have been previously administered, past due, pending as well as future medications scheduled. An eMAR also gives details about medications given on an as-needed basis and continually administered medications such as IV fluids. As the safety check of last resort, nurses supported by eMARs can do much to reduce the adverse effects from medication errors with the use of drug alerts and signaling features on medication safety issues as well as potential patient incompatibilities, including allergies.

Measure: eMARs are in use for all patients on at least one nursing unit with drug/drug and allergy alerting.

3. Barcode bedside medication administration support.

The eMAR can be enhanced by a point-of-care process that utilizes bar code reading technology (or similar) to monitor and record the bedside administration of medications (BPOC, Bar-coding at the Point Of Care). At admission, the patient is given a bar coded ID bracelet to be used for identification. Medications dispensed from the pharmacy are also bar-coded. At the patient bedside and before any medications are administered, if any of the scanned information does not match the doctor's orders a warning message is provided to the clinician. By scanning the patient wristband and the medication the software is capable of detecting a medication interaction, incompatibility or allergy and it alerts the clinician. It also prompts the clinician to check clinical information related to certain medications and records details as to actual time given and by whom. Commonly called the five rights, barcode bedside medication administration automates checking of the right medication, the right dose, the right time, the right route and the right patient. Some providers may choose to implement BPOC using the wireless technology RFID (radio-frequency Identification).

Measure: BPOC in use for all patients on at least one nursing unit for at least 75 percent of the medications dispensed by that nursing station.

4. Record nursing assessment in EHR.

A nursing assessment is a patient interview conducted by a nurse in order to identify the needs, preferences and abilities of a patient. A nursing assessment may include a physical examination. Its purpose is to identify the patient's nursing problems and is a holistic assessment of the patient's needs regardless of the reason for the encounter. During this assessment a nursing history is taken, psychological and social examinations are conducted, specifics depend upon the nursing model in use. A nursing assessment provides the scientific basis for the nursing care plan and is considered the first stage of the nursing process.

Measure: Nursing assessments are recorded in the EHR for at least 80 percent of all patients admitted to a nursing unit in the hospital.

5. Record nursing plan of care in EHR.

A nursing care plan outlines the nursing care to be provided to a patient. The plan begins when the patient is admitted, and, after the initial nursing assessment, a diagnosis is formulated and nursing orders are developed. It has four basic components, the identification of a patient's nursing care

problems, nursing actions to be taken, the expected benefit to the patient and a recording of the patient's response to the nursing care. The goal of the process is to ensure that nursing care is consistent with the patient's needs and is modified as necessary. A recorded nursing care plan adds value when part of every patient's chart.

Measure: Nursing plans of care are recorded in the EHR for at least 80 percent of patients admitted on one nursing unit.

6. Record physician assessment in EHR.

The clinical documentation in a patient's record forms the basis for current and future care of that patient by the healthcare provider. T he documentation in the record will be relied upon by clinicians in the healthcare provider setting to make decisions regarding the patient's care. The extent of information gathered and documented is dependent upon clinical judgment, the patient's history and the nature of the presenting problem. Documentation includes some or all of the following elements: chief complaint; history of present illness; review of systems; past, family, and/or social history and results of a physical examination. In the acute care inpatient setting, the attending physician is the central point for all documentation in the patient's record. It is the responsibility of the attending physician to determine the relevance and importance of all other documentation in the patient's record, both objective and subjective and resultant medical decision making.

Alternative: Physician assessments are recorded in the EHR for at least 10 percent of patients admitted.

7. Record physician notes in the EHR.

Physician notes represent the documentation of patient treatment as care is being rendered. The intent of this concurrent care record is to actually reflect what is occurring at that time and resultant medical decision making. These notes are often used to communicate with other physicians involved in the patient's care.

Alternative: Physician notes are recorded in the EHR for at least 10 percent of patients admitted.

8. Multimedia/Imaging integration.

Multimedia/Imaging integration is a process by which a medical image (e.g. x-ray) or an index to the image is embedded into the EHR and is immediately visible to the physician upon viewing the patient record, or easily accessible via a web link/web viewer or icon presented in the record. To achieve this integration an image must first be captured digitally, either in a direct process with a digital imaging modality or through an intermediate process where the image is converted from an analog state to a digital form. Then a PACS (Picture Archiving and Communication System) transfers the digital image

from the acquisition point to the EHR. The PACS must deliver the image or an index to the image in a data format acceptable by the EHR.

Measure: When digital images exist, physicians must be able to access images from the EHR within one day of the time the radiologist finalizes/signs the report.

9. Generate permissible discharge prescriptions electronically.

E-prescribing is an electronic way to generate prescriptions through an automated medication ordering process utilizing e-prescribing software and a transmission network or intermediary (Surescripts) which links to participating local pharmacies or non-inpatient dispensing entities such as mail order. Medication continuity is challenged by patient discharge and the logistics that go with it. E-prescribing improves patient safety and overall quality of care in terms of legibility, warning and alert systems and access to a patient's medical history at the time of prescribing. Medicare's prescription drug program helped pave the way for widespread adoption of e-prescribing through the medical community, and this includes permissible inpatient discharge prescriptions. However, the health information exchange infrastructure to support e-prescribing of discharge prescriptions is still evolving. In addition, the health care field is still waiting for the Drug Enforcement Agency to publish rules on how to e-prescribe controlled substances. In the absence of that rule, providers must use paper prescriptions for narcotics and other controlled substances. These requirements significantly hamper adoption of e-prescribing for discharge prescriptions.

Measure: Ten percent of discharged patients with permissible discharge prescriptions have their prescriptions electronically submitted.

10. Contribute data to a PHR.

A personal health record or PHR is a computerized application that stores an individual's personal health information focused on the individual's personal use and can be initiated and maintained by the individual. Individuals own and have the ability to manage the information in the PHR, including information which comes from healthcare providers and the individual. PHRs can contain a diverse range of data but usually include information about: allergies and adverse drug reactions, medications, illnesses and hospitalizations, surgeries and other procedures, vaccinations, laboratory test results and family history. Contributing provider based data to an individual's personal health record implies that the patient has a personal health record and that the provider is able to contribute data to the PHR. Regardless of the mechanism to contribute the data, it must be timely and the patient needs to know that the data offering exists and how it may be obtained. What's important is to get timely access to the health information in simple electronic format.

Measure: At least 80 percent of discharged patients are educated as to the offering of PHR data and how it may be obtained. Upon request, laboratory results, radiology reports, and other requested data should be made available to the individual PHR holder, in electronic form.

11. Record patient preferences (language, etc.).

Patient preferences must be recorded per evolving market and social demands. New to this list of preferences are details that not only impact the care delivery process but help with improving it. Knowing the patient's preferences and social history helps engage the patient in their care and facilitate the provision of culturally sensitive care. Knowing and being able to speak to someone in their native language is one such example. Others include the identification of healthcare proxies, treatment options preferences, resuscitation, diet and their preferred communication media.

Measure: A patient's language preference is recorded for at least 80 percent of admissions and incorporated into the EHR.

12. Provide electronic access to patient-specific educational resources.

Multi-media technology today provides a unique opportunity to tailor patient education material to the patient. At the bedside such information can be channeled through a TV and/or pc-based monitor or distributed to the patient in electronic form to be viewed not only as an inpatient, but after discharge via secure links, thumb drives and the like. In electronic form it is also easier to provide such information in a multi-lingual environment.

Measure: Regardless of format, patient-specific education is provided for at least one of the top five reasons for admission at the hospital.

Attachment B. Detailed Comments on Proposed Stage 1 Objectives and Measures of Meaningful Use for Eligible Hospitals

Proposed Objective	Proposed Measure	Clarifying Comments	Draft Recommendation
1. Use of CPOE for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP).	1. For eligible hospitals, CPOE is used for 10% of all orders.	• Need definition of denominator – what is included in orders of "any type"? ONC IFR lists 11 types. • As currently specified, the denominator combines paper and electronic processes. Measurement would require manual review of 100 percent of paper charts to count all orders and distinguish those placed through verbal/paper means from orders placed through CPOE. Efficient chart review for quality reporting takes approximately 20 minutes per chart, resulting in tremendous burden. A hospital with 15,000 discharges would spend 5,000 hours per year reviewing charts. • There are times when orders may be modified or entered by someone other than the authorized practitioner and their use should be counted. Examples include: o Use of a scribe during surgery; o Verbal orders from an on-call physician to address an emergent problem; o 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; o Change or clarification of dose, route, or times of medication administration	• Do NOT use a measure with a denominator that requires review of paper charts. • Replace the proposed measure with one of the following alternatives: 1: Hospital has CPOE activated (preferred). 2: At least 10% of unique patients have had at least one order placed through CPOE. 3: At least 10% of medication orders placed through CPOE (can be calculated from pharmacy information system). *If option 2 or 3 is chosen, require measure calculation as part of EHR certification process.*

Proposed Objective	Proposed Measure	Clarifying Comments	Draft Recommendation
		pursuant a phone call exchange between a nurse and provider. • Order sets should be "unpacked" to count individual orders • Orders placed in the ED for patients that are subsequently admitted should be included in the measure calculation.	
2. Implement drug-drug, drug-allergy, drug-formulary checks.	2. The eligible hospital has enabled this functionality.	• This measure combines two clinical alerts with an efficiency alert. We recommend separating them. • Drug-drug and drug-allergy checks happen in both pharmacy information systems and as part of CPOE. Both approaches contribute significantly to medication safety. • For inpatient settings, the drug-formulary check is generally defined as checking against the hospital's formulary, not external insurer formularies.	Create two measures: • Hospital has implemented drug-drug and drug-allergy checks (clinical). • Hospital has implemented drug-formulary checks (efficiency).
3. Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT ®.	3. At least 80% of all unique patients seen admitted to the eligible hospital have at least one entry or an indication of none recorded as structured data.	• Currently installed EHRs generally use text or proprietary coding today, so there will be an adjustment process. Physician-facing screens will likely continue to be in more "accessible" language than structured code sets, with mapping to standards. Mapping systems must be built and deployed. During transitions, mapping to ICD-9 may happen at the end of a stay. • The HIPAA transactions standards require a move to ICD-10-CM in 2013. The measure should be updated over time to harmonize with this change.	• Require measure calculation as part of EHR certification process.

Proposed Objective	Proposed Measure	Clarifying Comments	Draft Recommendation
4. Maintain active medication list.	4. At least 80% of all unique patients admitted to the eligible hospital have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded as structured data.		• Require measure calculation as part of EHR certification process.
5. Maintain active medication allergy list.	5. At least 80% of all unique patients admitted to the eligible hospital have at least one entry or (an indication of "none" if the patient has no medication allergies) recorded as structured data.		• Require measure calculation as part of EHR certification process.
6. Record demographics: • Preferred language. • Insurance type. • Gender. • Race. • Ethnicity. • Date of birth. • Date and cause of death in the event of mortality.	6. At least 80% of all unique patients admitted to the eligible hospital have demographics recorded as structured data.	• All fields may not be complete for all patients. For instance, some patients may not be willing to report race and ethnicity. Insisting that this data be provided could interfere with care delivery process. Therefore, missing data in two or three of the 7 fields should not disqualify a record from counting toward the numerator. • In Massachusetts, field experience with reporting race and ethnicity according to specific standards (such as OMB definitions) found that significant training across many different staff members is required to achieve uniformity. While clearly important for evaluating and addressing	• Require measure calculation as part of EHR certification process. • Allow records with two to three missing fields to count toward the numerator. • Remove cause of death.

Proposed Objective	Proposed Measure	Clarifying Comments	Draft Recommendation
		disparities in care, the time and resources required to achieve uniform recording of race and ethnicity data should not be underestimated. • Cause of death is determined by the coroner and is not generally available to the hospital at the time of death. Considerable coordination with coroner is required to obtain this data and timely receipt may be beyond the hospital's control. • Date of death is known only when the death occurs at the reporting hospital.	
7. Record and chart changes in vital signs: • Height. • Weight. • blood pressure. • Calculate and display: BMI. • Plot and display growth charts for children 2-20 years, including BMI.	7. For at least 80% of all unique patients age 2 and over admitted to eligible hospital, record blood pressure and BMI; additionally plot growth chart for children age 2-20.	• General acute care inpatient setting not appropriate for plotting growth charts, and most children are admitted infrequently, so no trend data are available. Growth chart is useful in children's hospitals. • Patients admitted to the hospital are not necessarily routinely measured for height. Including this measure would change the requirements for nursing assessments. If maintained as a vital sign for inpatient care, estimated or reported height may be recorded. • Other vital signs are more appropriate to the inpatient setting, such as temperature, blood oxygen levels, heart rate, and glucose levels. EHRs should be capable of showing trend for these values (hourly to daily). • As currently specified, this is a test of 3 measurements being taken, 2 calculations being performed, and two displays viewed. Not all fields may be complete for all patients. Missing two or three of these steps should not disqualify a	• Remove growth charts for children for general hospitals. Add temperature, blood oxygen levels, heart rate, and glucose levels, with capacity to trend values • Allow records missing two or three of the bundled fields and processes to be included in the numerator. • Require measure calculation as part of EHR certification process, including tags that indicate when BMI calculation has been performed and plot has been displayed.

Proposed Objective	Proposed Measure	Clarifying Comments	Draft Recommendation
		patient from the numerator. • Do EHRs provide tag that calculations have been performed and displays viewed?	
8. Record smoking status for patients 13 years old or older.	8. At least 80% of all unique patients 13 years old or older seen admitted to the eligible hospital have "smoking status" recorded.		• Require measure calculation as part of EHR certification process.
9. Incorporate clinical lab-test results into EHR as structured data.	9. At least 50% of all clinical lab tests ordered whose results are in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.	• This measure is poorly specified. Requires specific definitions of tests that are positive/negative and in numeric format. • Automated measurement would require flags in EHR for when a result is in positive/negative or numerical form. • Very challenging to calculate. Unless limited to tests in the EHR, would require looking across electronic and paper processes. • ONC IFR specified LOINC codes, which CHIME survey data indicates is used by 40.5% of its members' institutions.	• Revise objective to read: At least 50% of all clinical lab tests incorporated into the EHR whose results are in a positive/negative or numerical format are incorporated into certified EHR technology as structured data. • Require measure calculation as part of EHR certification process.
10. Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, and outreach.	10. Generate at least one report listing patients of the eligible hospital with a specific condition.	• In the hospital setting, analysis of patient data often drives off of post-discharge coding of diagnoses and procedures, rather than problem lists.	

Proposed Objective	Proposed Measure	Clarifying Comments	Draft Recommendation
11. Report hospital quality measures to CMS or the states.	11. For 2011, provide aggregate numerator and denominator through attestation as discussed in section II(A)(3) of the proposed rule. For 2012, electronically submit the measures as discussed in section II(A)(3) of the proposed rule.	• Many concerns, addressed separately.	• Multiple, addressed separately.
12. Implement 5 clinical decision support rules related to a high priority hospital condition, including diagnostic test ordering, along with the ability to track compliance with those rules.	12. Implement 5 clinical decision support rules relevant to the clinical quality metrics the eligible hospital is responsible for as described further in section II(A)(3) of the proposed rule.	• The medication alert measures are also clinical decisions support rules. • Use of order-sets is a form of clinical decision support. • Tracking compliance can be challenging, as specific clinical scenarios warrant different responses. For instance, patients in an intensive care unit may receive combinations and doses of medications that would be inappropriate in other departments. • Hospitals sometimes implement rules that cannot be overridden, so that there is no measure of compliance (clinician has not made an accept/override choice).	

Proposed Objective	Proposed Measure	Clarifying Comments	Draft Recommendation
13. Check insurance eligibility electronically from public and private payers.	13. Insurance eligibility checked electronically for at least 80% of all unique patients admitted to the eligible hospital.	• Billing systems are not generally part of the hospital EHR system, although they are almost always integrated. • Covered under HIPAA administrative simplification regulations. • Major concern that if this is maintained, will require these systems to be certified, which is unnecessary and wasteful.	• Remove this objective and measure.
14. Submit claims electronically to public and private payers.	14. At least 80% of all claims filed electronically by the eligible hospital.	• Billing systems are not generally part of the hospital EHR system, although they are almost always integrated. • Covered under HIPAA administrative simplification regulations. • Major concern that if this is maintained, will require these systems to be certified, which is unnecessary and wasteful.	• Remove this objective and measure.
15. Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, allergies, discharge summary, procedures), upon request.	15. At least 80% of all patients who request an electronic copy of their health information are provided it within 48 hours.	• Requires separate tracking of who requests copy and when (date stamp). • Use of portable media such as USB presents security problems for the hospital (both security of PHI on the portable media and security of the hospital's IT systems when portable media are introduced). • Use of structured data for this purpose (such as CCD) will be valuable in the future, but not possible for most providers in the near term. • To ensure patients can read the information without needing special software, most likely format in near term is a PDF of electronic/scanned chart. The time period (48	• Require measure calculation as part of EHR certification process. • Revise to be electronic copy of health information "maintained in electronic form" (rationale: consistent with ARRA privacy provision). • Drop the time requirement in favor of existing HIPAA policies on providing patients with

Proposed Objective	Proposed Measure	Clarifying Comments	Draft Recommendation
		hours) is too short and more proscriptive than HIPAA requirements. Clinicians must review information and ensure that they have received all test results and discussed sensitive results with the patient before release, per CLIA and state laws. Staff must be available to receive and fulfill requests, and required workforce may not be available on weekends and holidays.	copies of medical records.
16. Provide patients with an electronic copy of their discharge instructions and procedures at time of discharge, upon request.	16. At least 80% of all patients who are discharged from an eligible hospital and who request an electronic copy of their discharge instructions and procedures are provided it.	• Requires separate tracking of who requests copy and when (date stamp); such tracking is not currently part of EHR systems. • Use of portable media such as USB presents security problems for hospitals (both security of PHI on the portable media and security of the hospital's IS systems when portable media are introduced). • Formats likely to include PDF and Word docs.	• Require measure calculation as part of EHR certification process
17. Capability to exchange key clinical information (for example, discharge summary, procedures, problem list, medication list, allergies, diagnostic test results) among providers of care and patient authorized entities electronically.	17. Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.	• Specificity? Does this need to be a "live" test? • The definition of "key clinical information" should be expanded to include test results and dictated documents (H&P, operative report, diagnostic report, etc.), which are the most in demand by physicians. • The test should involve the specific subset of key clinical information that is most appropriate to meet current local needs and HIE infrastructure (for example, in the context of a local HIE, a collaboration with local ambulatory physician groups, or a pilot to provide data to long-term care facilities).	• Require providers to perform this test only for the subset of clinical information that is most appropriate to meet current local needs and HIE infrastructure, not all listed clinical information.

Proposed Objective	Proposed Measure	Clarifying Comments	Draft Recommendation
18. Perform medication reconciliation at relevant encounters and each transition of care. Medication reconciliation = the process of identifying the most accurate list of all medications that the patient is taking, including name, dosage, frequency and route, by comparing the medical record to an external list of medications obtained from a patient, hospital or other provider. Transition of care = transfer of a patient from one clinical setting (inpatient, outpatient, physician office, home health, rehab, long-term care facility, etc.) to another or from one EP or eligible hospital (as defined by CCN) to another. Relevant encounter = any encounter that the EP or eligible hospital judges performs a medication reconciliation due to new medication or long gaps in time between patient encounters or other reasons determined by the EP or eligible hospital.	18. Perform medication reconciliation for at least 80% of relevant encounters and transitions of care. The numerator for this objective is the number of relevant encounters and transitions of care for which the eligible provider or an inpatient facility/department (POS21) that falls under the eligible hospital's CCN was a participant during the EHR reporting period where medication reconciliation was performed. The denominator for this objective is the number of relevant encounters and transitions of care for which the EP or an inpatient facility/ department (POS 21) that falls under the eligible hospital's CCN was a participant during the EHR reporting period.	• The proposed definition does not match current hospital medication reconciliation processes. • Medication reconciliation is not an automated EHR process. It is a human workflow process that is supported by the EHR. • Availability of a single medication list in the EHR that is available to all clinicians at the point of care makes medication reconciliation within the institution unnecessary. • The term "transitions of care" includes an array of transfers across the continuum of care that are not currently supported by information exchange among providers. Consequently, medication reconciliation as defined is not possible. Med reconciliation across settings (hospital to LTC or hospital to physician office, etc) is not possible given current levels of information exchange • Calculation of this measure across all admissions would be overly burdensome to report. Inclusion of ED in measurement is important as many patients enter hospital via ED and first discuss current medications in that setting. • Electronic medication reconciliation tools in use today do not generally include a flag or other measure to indication that med reconciliation was done or done accurately, so not currently easy to	• Defer this measure until health information exchange supports it • If objective is kept, measures on medication reconciliation should be limited to appropriate transfer points internal to hospital, such as ED to ICU, ICU to general med/surg unit, etc. (including on admission and discharge) • Recommended alternative measure: Hospital is using EHR to support medication reconciliation • If a percentage measure is included, a sampling methodology should be developed to reduce reporting burden. • If a percentage measure is included, require measure calculation as part of EHR certification process

Proposed Objective	Proposed Measure	Clarifying Comments	Draft Recommendation
We encourage comments on whether our descriptions of "transition of care'' and ''relevant encounter'' are sufficiently clear and medically relevant.		calculate. • The Joint Commission is currently revising its National Patient Safety Goal on medication reconciliation. CMS should not attempt to define medication reconciliation processes and requirements separately and differently from The Joint Commission. Doing so will cause confusion and could actually slow efforts to build and spread best practice models of medication reconciliation.	
19. Provide summary care record for each transition of care and referral. Transition of care = transfer of a patient from one clinical setting (inpatient, outpatient, physician office, home health, rehab, long-term care facility, etc.) to another or from one EP or eligible hospital (as defined by CCN) to another. Referral is not defined.	19. Provide summary of care record for at least 80% of transitions of care and referrals The numerator for this objective is the number of transitions of care and referrals for which the EP or an inpatient facility/department (POS 21) that falls under the eligible hospital's CCN was the transferring or referring provider during the EHR reporting period where a summary of care record was provided. The summary of care record can be provided through	• How does this measure relate to the inpatient setting? How is transition of care different from discharge? Would discharge instructions and summary care record both be required when a patient leaves the hospital? • What is a referral in context of an inpatient stay? Would specialty consult during a stay require provision of a summary care record? For referrals post-discharge, it is unclear how a hospital could do this before a patient has a visit scheduled or even has selected a specific provider selected from a short list of referrals. • Who does the summary care record go to? The patient or the next provider to care for the patient? • How do you count transitions of care and referrals? • Use of portable media such as USB presents security problems for the hospital (both security of PHI on the portable media and security of the	• The concept behind this measure and its measurement must be clarified, particularly in the context of inpatient care. If something other than discharge is intended, require provision of summary care record on request only. • Require measure calculation as part of EHR certification process.

Proposed Objective	Proposed Measure	Clarifying Comments	Draft Recommendation
	an electronic exchange, accessed through a secure portal, secure e-mail, electronic media such as CD or USB fob, or printed copy. The denominator for this objective is the number of transitions of care for which the EP or an inpatient facility/ department (POS 21) that falls under the eligible hospital's CCN was the transferring or referring provider during the EHR reporting period.	hospital's IT systems). • Use of structured data for this purpose (such as CCD) will be valuable in the future, but not possible for most providers in the near term.	
20. Capability to submit electronic data to immunization registries and actual submission where required and accepted.	20. Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries.	• Does this need to be a "live" test? • Who decides when actual submission is required and accepted?	

Proposed Objective	Proposed Measure	Clarifying Comments	Draft Recommendation
21. Capability to provide electronic submission of reportable laboratory results (as required by state or local law) to public health agencies and actual submission where it can be received.	21. Performed at least one test of the EHR system's capacity to provide electronic submission of reportable laboratory results to public health agencies (unless none of the public health agencies to which eligible hospital submits such information have the capacity to receive the information electronically).	• Does this need to be a "live" test? • Who decides when actual submission is required and accepted?	
22. Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.	22. Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies (unless none of the public health agencies to which an eligible hospital submits such information have the capacity to receive the information electronically).	• Does this need to be a "live" test? • Who decides when actual submission is required and accepted? • Public health departments at local, state and national levels must move toward standard data elements, formats, and information exchange protocols. Hospitals currently submitting electronic data to public health are overwhelmed by overlapping and conflicting requests from multiple agencies, resulting in significant burden. For instance, some syndromic surveillance systems rely on demographic and limited symptom data, while other systems want real time laboratory and pharmacy feeds.	• Require test for submission to a single public health agency only • Require actual submission of only demographic information and key lab findings.

Proposed Objective	Proposed Measure	Clarifying Comments	Draft Recommendation
23. Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities.	23. Conduct or review a security risk analysis per 45 CFR 164.308 (a)(1) and implement security updates as necessary.		

Attachment C. Denominator CPT/HCPCS Codes for Reporting on E-Prescribing Under the Medicare Physician Fee Schedule

CPT/HCPCS	Short Description	CPT/HCPCS	Short Description
90801	Psy dx interview	99308	Nursing fac care, subseq
90802	Intac psy dx interview	99309	Nursing fac care, subseq
90804	Psytx, office, 20-30 min	99310	Nursing fac care, subseq
90805	Psytx, off, 20-30 min w/e&m	99315	Nursing fac discharge day
90806	Psytx, off, 45-50 min	99316	Nursing fac discharge day
90807	Psytx, off, 45-50 min w/e&m	99324	Domicil/r-home visit new pat
90808	Psytx, office, 75-80 min	99325	Domicil/r-home visit new pat
90809	Psytx, off, 75-80, w/e&m	99326	Domicil/r-home visit new pat
90862	Medication management	99327	Domicil/r-home visit new pat
92002	Eye exam, new patient	99328	Domicil/r-home visit new pat
92004	Eye exam, new patient	99334	Domicil/r-home visit est pat
92012	Eye exam established pat	99335	Domicil/r-home visit est pat
92014	Eye exam & treatment	99336	Domicil/r-home visit est pat
96150	Assess hlth/behave, init	99337	Domicil/r-home visit est pat
96151	Assess hlth/behave, subseq	99341	Home visit, new patient
96152	Intervene hlth/behave, indiv	99342	Home visit, new patient
99201	Office/outpatient visit, new	99343	Home visit, new patient
99202	Office/outpatient visit, new	99344	Home visit, new patient
99203	Office/outpatient visit, new	99345	Home visit, new patient
99204	Office/outpatient visit, new	99347	Home visit, est patient
99205	Office/outpatient visit, new	99348	Home visit, est patient
99211	Office/outpatient visit, est	99349	Home visit, est patient
99212	Office/outpatient visit, est	99350	Home visit, est patient
99213	Office/outpatient visit, est	G0101	CA screen;pelvic/breast exam
99214	Office/outpatient visit, est	G0108	Diab manage trn per indiv
99215	Office/outpatient visit, est	G0109	Diab manage trn ind/group
99304	Nursing facility care, init		
99305	Nursing facility care, init		
99306	Nursing facility care, init		
99307	Nursing fac care, subseq		