



**American Hospital
Association**

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June 6, 2011

Sent Electronically

Members of the HIT Policy Committee
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Suite 729-D
Washington, D.C. 20201

Re: HIT Policy Committee: Comments Regarding Meaningful Use Stage 2

Dear Members of the HIT Policy Committee:

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) greatly appreciates the hard work and advice that the Health Information Technology Policy Committee has provided to the Department of Health and Human Services (HHS) on how our country might best realize the promise of health information technology (IT). As your committee considers recommendations on the timing of and requirements for Stage 2 Meaningful Use, we hope you will take into consideration data on hospitals' and physicians' readiness to meet "meaningful use," their experiences under Stage 1, and the need to map out a realistic path forward.

Given hospitals' experience with Stage 1 and competing federal priorities, such as adoption of ICD-10 by October 1, 2013, we urge the committee to recommend that Stage 2 begin no sooner than fiscal year (FY) 2014, and only when at least 75 percent of all eligible hospitals and physicians/professionals have successfully reached Stage 1. We also urge you to be parsimonious in your recommendations for new requirements in Stage 2, maintain flexibility, avoid complexity, and ensure that the benefits of any new requirements outweigh the costs.

Congress authorized incentive payments under Medicare and Medicaid to "meaningful users" of certified electronic health records (EHRs) beginning in FY 2011 in the *American Recovery and Reinvestment Act of 2009* (ARRA). Beginning in FY 2015, and continuing in future years, the ARRA also phases in penalties for those who fail to meet federal requirements for meaningful use. The penalties do not expire and are a mandatory and permanent element of the Medicare payment policies.



The AHA appreciates – and shares – the goals of the EHR incentive programs: motivating hospitals and physicians to move further and faster toward using EHRs to improve health care delivery, while ensuring that needed funds authorized as part of the economic stimulus bill flow in a responsible and appropriate manner to support continued and timely advances in health IT. Hospitals across the country are deploying EHRs as part of their overall strategies to improve patient care and meet community needs.

The flow of meaningful use incentive payments to support those deployments is central to realizing the care transformation objectives of health reform. Congress' estimate of spending for the EHR incentive programs demonstrates its clear intent to support provider investments in EHRs from the beginning of the program. For FY 2011, which ends September 30, the Congressional Budget Office (CBO) estimated that \$4.7 billion would be spent in support of EHR adoption and use (CBO estimate of H.R. 1, February 13, 2009). The latest numbers from the Centers for Medicare & Medicaid Services (CMS) indicate that through April 2011 only \$158.3 million has been invested (CMS press release, May 26, 2011). With only four months remaining in this fiscal year, CMS and the states have disbursed only 2 percent of the FY 2011 funds Congress intended to support the transition to an e-enabled health care system.

Our comments below address the timing issues and Stage 2 requirements that the committee will discuss on June 8. The AHA previously submitted detailed comments on Stage 2 meaningful use in response to the committee's request for comments, which can be found at <http://www.aha.org/aha/letter/2011/110225-cl-meaningful-use-stage2.pdf>.

TIMING ISSUES

The AHA believes that Stage 2 should not start before FY 2014, and only when at least 75 percent of all eligible hospitals and physicians/professionals have successfully reached Stage 1. We also recommend that, given the many steps needed to transition all providers from one stage to another, providers should be required to report compliance only on a 90-day period in the first year of Stage 2, and all subsequent stages.

While the AHA strongly supports the accelerated adoption and use of EHRs to improve patient care, we have significant concerns with the proposed October 1, 2012 date for the beginning of Stage 2 of the incentive programs.

The committee will consider three possible start dates for Stage 2 for hospitals:

- Begin on October 1, 2012 for hospitals, with a full year of reporting on compliance with the requirements (FY 2013);
- Begin in FY 2013, with a 90-day reporting period on compliance ; or
- Begin in FY 2014 (October 1, 2013).

Meaningful use is not the only federal initiative that requires changes to hospitals' IT systems. The scope of change currently underway is creating a "perfect storm" of overlapping requirements that threatens to overwhelm providers. In addition to EHR adoption, hospitals and physicians also are overhauling their IT systems to implement: new administrative transactions standards (5010) and associated business rules by January 2012; a new ICD-10 coding standard by October 1, 2013; and changes to support myriad reporting requirements and information transfers for the current quality reporting program under Medicare, as well as numerous initiatives introduced through the *Patient Protection and Affordable Care Act* (ACA), such as reductions in readmissions, value-based purchasing, accountable care organizations and bundling of payments. Hospitals also are participating in state-level health information exchange initiatives. As implementations for ICD-10 and other projects begin, our members report significant financial, staffing and change management challenges. The full array of policies and their overlapping timelines are depicted in Attachment A.

Furthermore, the start of the incentive programs included short timelines that created significant disruptions in the health IT market, implementation issues for providers, and the potential to introduce patient safety issues by rushing installations. Hospitals had built EHRs into their strategic plans, but the EHR incentive programs forced them, in many instances, to accelerate and alter those plans. The added urgency has been a positive accelerating force, but it also has significantly changed market dynamics in ways that pose financial, technical and workforce challenges for hospitals. Our members already are reporting increased prices for products and services, delays in vendor schedules and limited ability to attract and retain needed clinical IT expertise. For instance, Ascension Health reported at a recent Meaningful Use Workgroup Hearing that, "[s]ince January 1 of this year, 40 of our 61 eligible hospitals have reported delays in their ability to reach their expected dates for Meaningful Use Stage 1 compliance" due to these factors (the full testimony is available at http://healthit.hhs.gov/portal/server.pt/gateway/PTARGS_0_12811_954637_0_0_18/muwg-davis-testimony-05-13-11.pdf). In addition, only 16 states have begun their Medicaid EHR incentive programs, which are meant to serve as a source of capital financing to support adoption, implementation and upgrading of systems in the first year. While hospitals are working hard to implement systems, the transition will take time. A realistic timeline that facilitates orderly change management processes that ensure safe care will lead to the best outcomes.

STAGE 2 REQUIREMENTS

As you consider recommendations for Stage 2, the AHA urges you to establish a specific plan to learn from the actual experiences of Stage 1, pursue parsimony, consider both the costs and benefits of each recommendation, provide ongoing flexibility and avoid complexity. In our Feb. 25 letter, we provided specific comments on each of the proposed objectives and measures. Our members have urged us to comment on recommendations that have arisen since the request for comment; they are addressed below.

Learn from actual experience in Stage 1. **We urge the committee to discuss on June 8 its plan for gathering input over the course of the year, including feedback from those who have not successfully met the meaningful use requirements, and the concerns faced by sub-groups of providers, such as small facilities, rural and critical access hospitals, and hospitals serving a disproportionate share of the disadvantaged and uninsured.** The committee is making recommendations before information on the actual Stage 1 experience can be collected and processed. All recommendations made at this time should be revisited as data are collected and reviewed. The experiences of specific subgroups of providers, such as rural, critical access and safety-net hospitals, must be examined closely to ensure that the incentive programs close the existing digital divide, not widen it. **The AHA stands ready to assist in gathering information on hospitals' implementation experiences.**

To assess hospitals' readiness to meet the Stage 1 meaningful use requirements, the AHA conducted a survey of all community hospitals. Data were collected between Jan. 6 and Jan. 20, 2011 with 1,297 hospitals (about 25 percent of U.S. community hospitals) responding to the survey. Respondents were broadly representative of the universe of community hospitals (see Attachment B).

The survey found great commitment to the incentive programs, with 95 percent of respondents reporting that they plan to pursue meaningful use. However, the survey also found that only 1.6 percent of hospitals (21 respondents) could meet the meaningful use and certification requirements in January. Only 0.8 percent of rural hospitals (seven out of 598 rural hospitals responding) met all of the meaningful use and certification requirements in January.

As detailed in the attachment, hospitals are making progress on specific objectives. In general, hospitals have made the most progress on objectives that improve clinical care, such as those that seek to ensure medication safety. Objectives that center on reporting information to others, such as automated quality measures, pose greater challenges. Hospitals have not generally used their EHRs for this purpose and will need time to build that capacity. However, consistent with previous peer-reviewed studies, few hospitals indicated that they can meet the meaningful use requirements of 14 core objectives and an additional five menu set objectives using an EHR certified for all 24 objectives (see, for example, "A Progress Report on Electronic Health Records in U.S. Hospitals by Jha et al., *Health Affairs*, Aug. 2010). **Clearly, meeting the Stage 1 requirements is challenging; raising the bar quickly and significantly in Stage 2 risks limiting the success of the EHR incentive programs.**

Follow the principles of parsimony and focus. **We ask the committee to consider whether certain objectives from Stage 1 can be removed, and whether all of the new proposed requirements for Stage 2 are necessary.** The preliminary recommendations discussed at the committee's May 11 meeting included a total of 28 hospital objectives for Stage 2, which were presented as all being mandatory. This would represent an approximately 50 percent increase in the number of requirements for hospitals compared to Stage 1.

The sheer volume of requirements poses a significant compliance burden in tracking and reporting. Recent discussions by the meaningful use workgroup would combine new

requirements, or fold them into existing objectives, which decreases the number of objectives, but does not achieve parsimony. In addition, the broad array of objectives also dilutes the focus of the program. Regulation generally focuses on the minimum necessary to allow room for innovation and flexibility in operations. Hospitals and physicians can and will move beyond the regulatory requirements to ensure the best possible care, harness innovations and meet competitive demands. In our Feb. 25 letter, we recommend removing five specific hospital measures.

Weigh the costs and benefits of proposals. **We encourage you to ask the Office of the National Coordinator (ONC) to collect reliable data on the feasibility and costs of each objective under consideration.** The set of objectives being considered by the committee has presumed benefits that all actors in the health care field want to realize. However, to date, the committee has not systematically considered either the feasibility of implementing these objectives or the associated costs.

For example, for the objective of providing patients with the capacity to electronically view and download up-to-date inpatient data within 36 hours of discharge, answers to the following questions would inform your deliberations:

- What inpatient data are feasible and helpful to present to patients after discharge from the hospital? Data collected during an inpatient stay often include multiple days of continuous biometric data from the monitors in the Intensive Care Unit, results of tests that ruled out suspected conditions, medications given during surgery, then discontinued, and large imaging studies that require special software to view.
- What are the vendors' costs for product development and certification of this capacity?
- What steps will providers need to take to implement and maintain this capacity?
- What costs will providers face to purchase certified technology and integrate it into their existing systems? To make this operational, hospitals will need to hire technical staff, train clinical and administrative staff, study and change operational flows and revamp systems to collect and share patient data in new, standardized formats.
- What are the steps and costs associated with securing the protected health information available through the Internet?
- What steps will be needed to establish and maintain patient accounts (distributing and processing consent forms, providing patients with passwords, managing authentication processes, etc.)?
- Are other approaches, such as sharing data with a health information exchange organization that has a patient portal, more appropriate for some?
- What are the trade-offs between investments in view and download functionality versus other activities that better engage patients, such as investing in care managers or creating new programs to support shared decision-making with patients?

Provide continued flexibility. **Stage 2 should continue the flexibility initiated in Stage 1.**

The notion that all participants must meet 100 percent of the meaningful use requirements is not consistent with how health IT systems function in the real world and fails to recognize that

meeting the Stage 2 criteria will require upgrades and changes to workflows and clinical practice that will take time to deploy across all providers.

Avoid complexity. **Wherever possible, we recommend that the meaningful use measures include simple counts and avoid hard-to-calculate percentages. Guidance to vendors on certification requirements can and should include more functional specificity to support product development.** Early experience from Stage 1 suggests that the proposed requirements for determining provider compliance in Stage 2 are too detailed. The layers of detail make for difficult measurement, sometimes force unnecessary changes to workflow to accommodate reporting, and can make compliance very challenging. Early implementation also has been marked by considerable confusion and repeated issuance of guidance that has impacted operations significantly. For example, CMS has issued more than 150 frequently asked questions, while ONC has issued 23. The committee should carefully weigh the benefits of detailed specifications against the costs.

COMMENTS ON NEWLY INTRODUCED OBJECTIVES

With input from dozens of member organizations, the AHA carefully reviewed the proposed objectives included in the request for comment. Our Feb. 25 comment letter recommended specific modifications to the definitions, scope or measurement of many measures, and deletion of others. We also recommended that, to provide continued flexibility, hospitals be required to meet only 80 percent of the Stage 2 meaningful use measures. Please see our comment letter for the specific recommendations.

Laboratory Reports. Since the request for comment, the meaningful use workgroup has recommended a new objective that we would like to comment on explicitly: “Hospital labs *send* structured electronic lab results to outpatient providers for ≥ 40 percent of labs sent electronically, using LOINC where available.” The goal of this objective, to accelerate the electronic standard of laboratory data, is laudable. However, using meaningful use as a “back door method” of regulating hospital reference laboratories is both inappropriate and beyond the statutory scope of the EHR incentive programs.

Rather than include this objective in Stage 2 of meaningful use, we recommend that the committee ask the Department of Health and Human Services (HHS) to commission a full study of the laboratory sector, including both hospital and commercial laboratories, to understand the resource requirements and operational steps involved in moving to electronic transfer of structured laboratory data, develop a reasonable timeline for moving in this direction, and identify resources to support this transformation, if needed.

The Medicare meaningful use incentive program for hospitals is authorized in the specific sections of law that govern hospital inpatient services paid under the inpatient hospital prospective payment system (PPS) and the reimbursement system for inpatient services provided by critical access hospitals. The meaningful use regulations for hospitals focus on meaningful use of EHRs in the care of patients served in inpatient and emergency departments (POS= 21 and

23), and specifically exclude patients treated in outpatient settings, whether owned by the hospital or another health care provider. By contrast, laboratory tests billed separately by hospitals are paid for under a completely different payment system – the clinical laboratory fee schedule that is prescribed in a different section of the Medicare statute. **Therefore, we believe that hospitals' clinical laboratory services are not within the statutory scope of the Medicare and Medicaid EHR Incentive Programs.**

Beyond the question of statutory authority, including this objective in Stage 2 will redefine the EHR and create significant certification issues. For most hospitals, the laboratory information system is a separate, specialized application that sends data to the EHR but is not an integral part of the certified EHR. It is our understanding that many EHR vendors do not have laboratory information system products, and have not developed core competencies in this area.

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

Security Requirements. **The AHA believes it would be more productive for the committee to focus on developing tools and strategies for providers to best secure health information, rather than adding requirements.** In the final meaningful use rule, CMS states that it “do[es] not believe meaningful use of certified EHR technology is the appropriate regulatory tool to ensure such compliance with the [Health Insurance Portability and Accountability Act of 1996] Privacy and Security Rules.” The AHA agrees. The Office of Civil Rights (OCR) enforces whether hospitals, physicians, and other covered entities are meeting their obligations under the security rule. OCR’s enforcement mechanisms were greatly strengthened in the ARRA and OCR is implementing those enhancements. Duplicating enforcement through meaningful use could, at best, result in redundant regulations; at worst, it could lead to conflicting rules.

Administrative Transactions and Quality Reporting. We note that the committee has not recommended inclusion of electronic claims submission and eligibility verification as part of Stage 2 of meaningful use. **The AHA strongly supports keeping administrative transactions out of meaningful use, as they are generally not part of EHRs and already are subject to regulation by CMS.**

We also note that the committee’s current deliberations do not include an important objective of meaningful use – use of EHRs to report clinical quality measures. **We welcome future opportunities to comment on clinical quality measures and encourage the committee to consider experience from the field on this important function.** While the efficiency of

automated reporting is highly desired by all stakeholders, Stage 1 experience has shown that this is a very complicated objective that, according to our January survey, only 7 percent of hospitals could achieve using certified EHRs. Providers and vendors have encountered significant issues with the e-specifications and the high level of clinical documentation needed to calculate the measures that suggest that the hospital clinical quality measurement data generated from EHRs will not be accurate. Further, the certification test scripts specifically state that certification does **not** include testing the accuracy of the measure calculations.

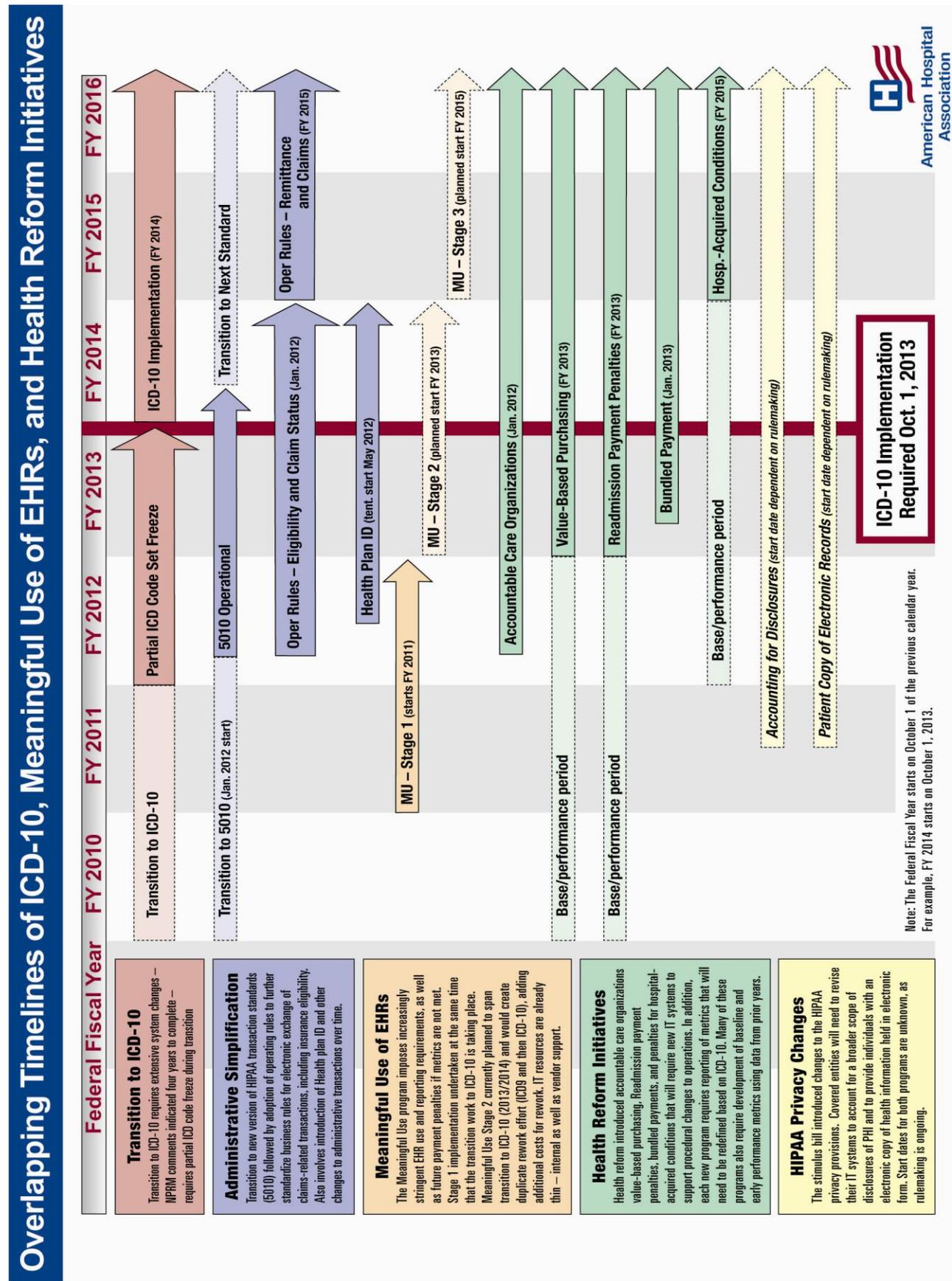
America's hospitals are working toward an e-enabled health care system where all hospitals meaningfully use EHRs to improve patient care and safety and achieve national goals for improved health. We believe our recommendations will move us toward this goal by establishing an achievable timeline and requirements for Stage 2 of meaningful use that will enable more providers to benefit from the much-needed federal funds Congress intended to be disbursed in support of progress.

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

Sincerely,

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

ATTACHMENT A



ATTACHMENT B: SURVEY ON CURRENT READINESS TO MEET MEANINGFUL USE

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

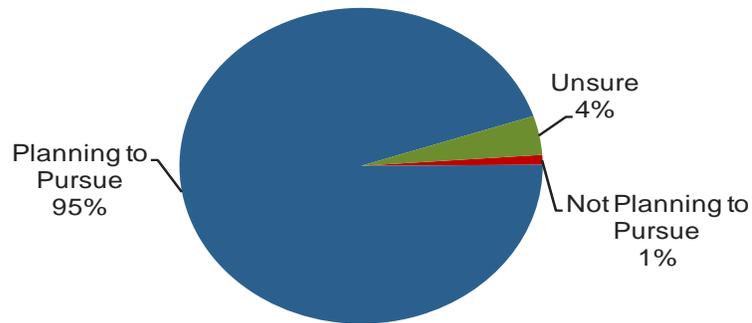
The survey found great commitment to the incentive program, with 95 percent of respondents reporting that they plan to pursue meaningful use (Chart 1). However, the survey found that only 1.6 percent of hospitals (21 respondents) can meet the meaningful use and certification requirements today. Only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

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

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

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

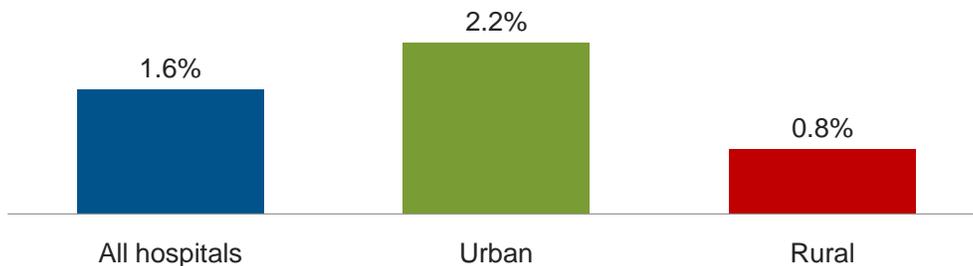
Chart 1. 95 percent of hospitals report that they plan to pursue qualifying as meaningful users



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

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



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

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

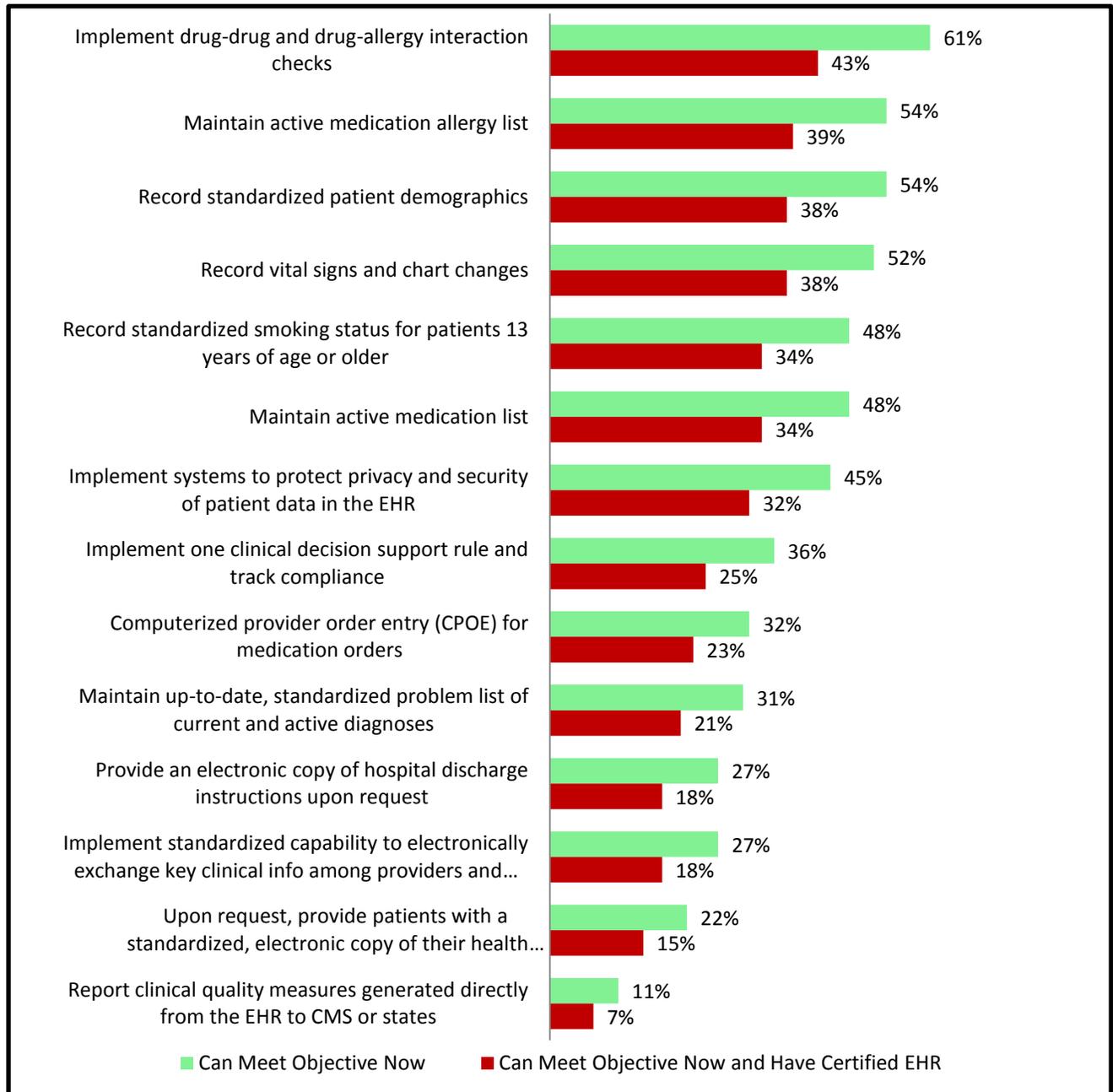
Installing and upgrading systems is a time-consuming process, and the certification requirements mean that all hospitals must either upgrade or install new systems before they can meet the meaningful use regulations. In addition, vendors' capacity to work with hospitals is stretched given the current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

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

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

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

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



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

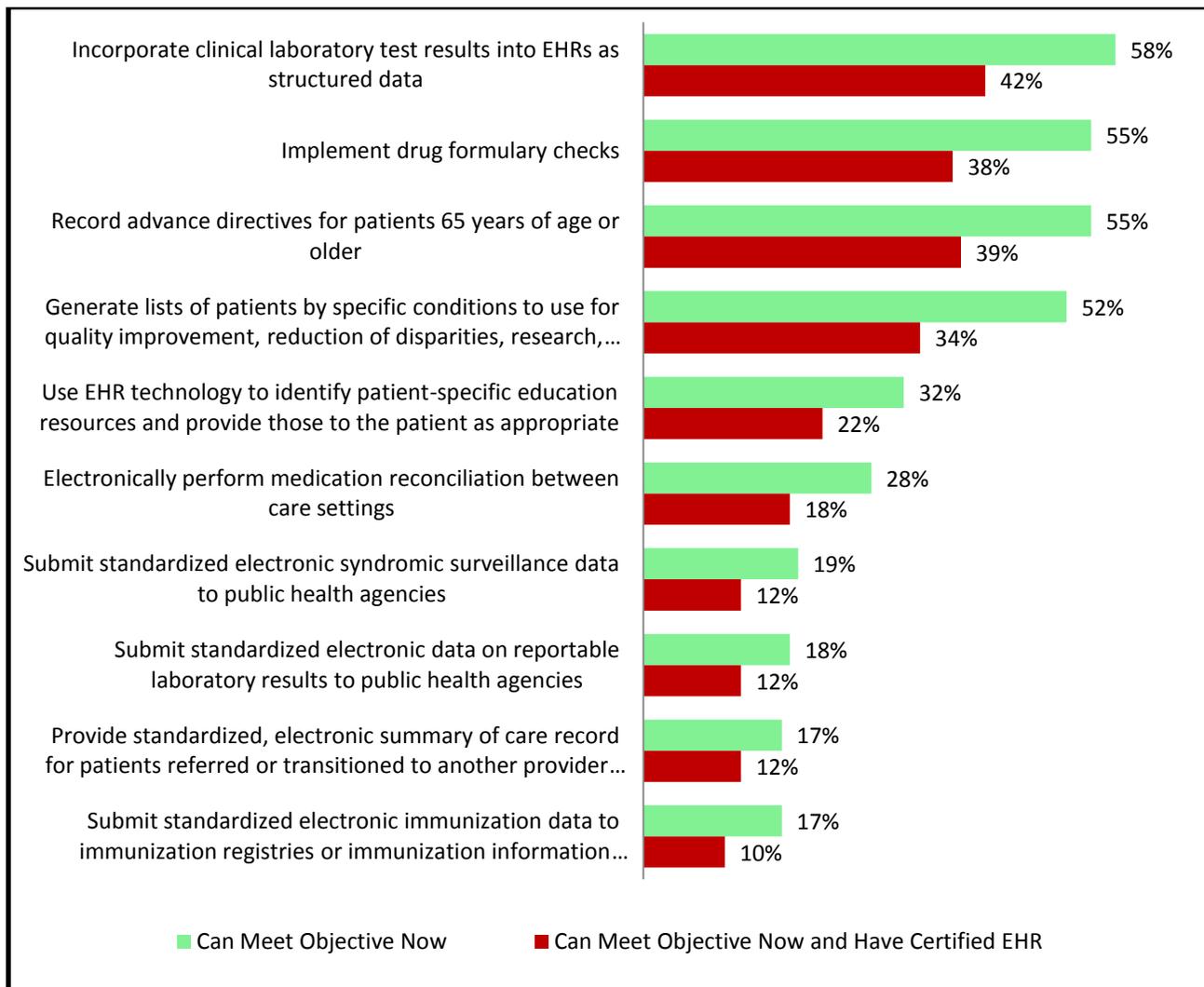
Hospitals report variable progress in meeting the menu set requirements. As with the core objectives, hospitals are more likely to be able to meet the performance standards for meaningful use than to have upgraded or replaced their systems to possess certified EHR technology. For example, while 55 percent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

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

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

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

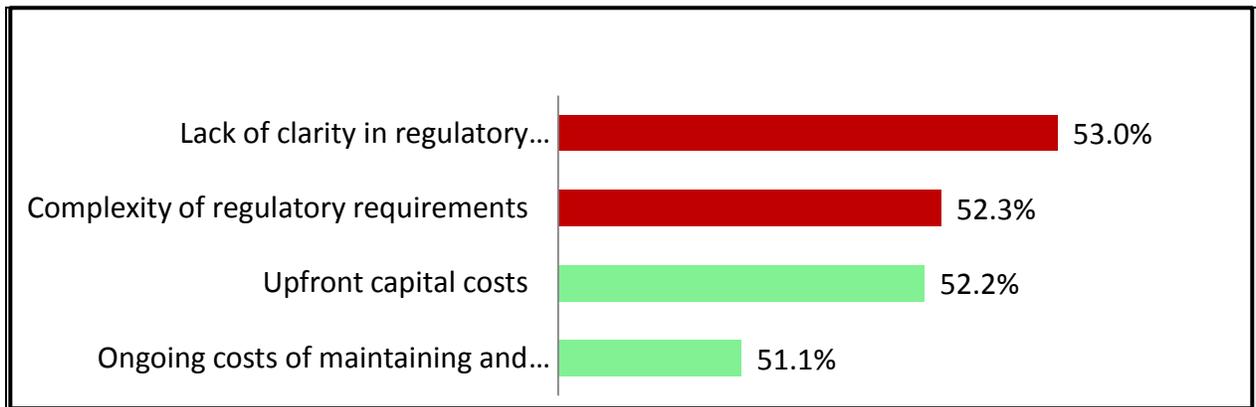
Chart 4. Percent of hospitals reporting they can meet each meaningful use **menu set** objective versus the percent reporting they both have certified EHR technology and can meet each objective



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

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

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



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