Regulatory ADVISORY
American Hospital Association™

October 1, 2012

CMS and ONC Final Rules on Stage 2 of Meaningful Use of EHRs

At a Glance

The Issue:

The Centers for Medicare & Medicaid Services (CMS) on September 4 published a 196-page final rule (www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-21050.pdf) defining Stage 2 of "meaningful use" of electronic health records (EHRs). At the same time, the Office of the National Coordinator (ONC) for Health Information Technology (IT) issued a 130-page final rule (www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf) that sets certification criteria, standards and implementation specifications for EHR technology beginning in fiscal year (FY) 2014 for hospitals and calendar year (CY) 2014 for physicians and other eligible professionals (EPs).

Taken together, these regulations raise the bar on EHR adoption requirements that hospitals and physicians must meet to continue to qualify for additional Medicare and Medicaid incentive payments that began in 2011, and to avoid significant payment penalties in 2015 and later years. The Stage 1 requirements are currently in place and effective through 2013.

The meaningful use requirements apply to hospitals paid under the inpatient prospective payment system (PPS) and critical access hospitals (CAHs). This advisory summarizes both the CMS and ONC final rules.

Our Take:

To address concerns raised by the AHA and others about the need for an orderly transition to Stage 2, CMS will delay the start of Stage 2 for one year, to October 1, 2013 for hospitals. In addition, CMS has adopted an optional one-quarter reporting period in 2014 for meaningful users in their second or later year of participation. This policy will provide an additional nine months of transition time.

CMS finalized a total of 22 hospital objectives for Stage 2, including seven new objectives. In Stage 2, hospitals will need to meet (or qualify for an exception to) each of 16 core objectives and three of six menu-set objectives. Hospitals also must electronically generate and report on 16 clinical quality measures from a menu of 29 using certified EHR technology. Both PPS hospitals and CAHs must meet these criteria. **The AHA is concerned that, taken together, the requirements raise the bar to a level that will be challenging for many hospitals to meet.**

CMS will impose Medicare payment penalties beginning in 2015 on hospitals (fiscal year) and physicians (calendar year). By statute, the reductions will be applied to the market-basket update for PPS hospitals, to cost-based reimbursement for CAHs, and to fee schedule payments for physicians. The Medicaid EHR incentive program has no penalties.

(*Continued*)

AT A GLANCE - CONTINUED

The AHA is disappointed that CMS has set an unrealistic date by which PPS hospitals must achieve meaningful use to avoid penalties. Specifically, CMS finalized its proposed policy to generally determine penalties using a reporting year that is two years in advance of the payment year, with exceptions for those in their first year of meaningful use. This approach will inappropriately accelerate when a hospital must meet meaningful use to avoid payment penalties and may, therefore, increase the share of hospitals that pay them. **However, the AHA is pleased that penalties for CAHs will be based on same-year performance.**

ONC will require **all** hospitals and EPs to upgrade to EHRs certified to the new "2014 Edition" criteria in 2014, regardless of their stage of meaningful use. This decision will increase the pressure on an already stressed health IT market. Starting in 2014, ONC will require that hospitals and EPs have EHRs certified only for the objectives they use to demonstrate meaningful use, rather than all objectives, as required today.

The many changes in each rule and the interactions between them paint a very complex picture, with requirements that differ depending on when a hospital first attests to meaningful use. Hospital leaders will need to be sure they understand how the requirements map to their individual implementation timelines.

What You Can Do:

- ✓ Share this advisory with your senior management team.
- ✓ Ask your chief information officer to incorporate the Stage 2 requirements into your plans to move forward with meaningful use.
- ✓ Discuss with your EHR vendors their plans to upgrade their products to the new certification requirements. Ask specific questions about their timeline for certification and your place in their queue for installations and upgrades.
- ✓ Ask your quality staff to evaluate the automated quality reporting requirements.
- ✓ Make sure your IT and medical records departments review the proposed data standards set out in the ONC certification rule.
- ✓ Participate in the 90-minute member calls that the AHA will hold to summarize the rules and answer your questions. The schedule is as follows:
  - Wednesday October 17 from 3:00 – 4:30 pm ET – Hospitals
  - Wednesday October 24 from 3:00 – 4:30 pm ET– Physicians

  AHA members can register for either or both of these calls at: http://www.surveymonkey.com/s/B2RYP5W.
- ✓ Additional resources on meaningful use can be found at http://www.aha.org/meaningfuluse.

A 51-page, in-depth examination of this issue follows.

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Table of Contents

BACKGROUND

The American Recovery and Reinvestment Act of 2009 (ARRA) authorized incentive programs under Medicare and Medicaid that began to pay bonuses to "meaningful users" of certified electronic health records (EHRs) in fiscal year (FY) 2011, and will phase-in Medicare penalties for those failing to meet "meaningful use" beginning in FY 2015. To be eligible for the incentives and avoid future payment penalties, hospitals and physicians must use EHRs that have been certified through a federal certification process established by the Office of the National Coordinator for Health Information Technology (ONC) to meet specific meaningful use and automated quality reporting requirements.

Stage 1 of meaningful use began in FY 2011 for hospitals. The two final regulations issued Sept. 4 change the program and raise the bar on compliance in Stage 2 of meaningful use, change the Stage 1 requirements for FY 2014 and later, and lay out how the Medicare penalties will be assessed. Specifically:

- the "meaningful use" rule (http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-21050.pdf) from the Centers for Medicare & Medicaid Services (CMS) sets out the requirements for provider use of certified EHRs; and
- the standards, implementation specifications and certification criteria rule (www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf) from ONC finalizes requirements for vendor products and EHR systems that hospitals and physicians self-develop for use by providers participating in the incentive program.

The rules do not change the payment formulas or the timing of payments, which are established in statute and described in the August 2010 AHA Regulatory Advisory on the Medicare and Medicaid EHR Incentive Programs (http://www.aha.org/advocacy-issues/tools-resources/advisory/2010/100826-regulatory-adv.pdf).

This advisory summarizes key elements of both of the final rules from CMS and ONC, including:

- timing and stages of meaningful use;
- the definition and requirements for demonstrating meaningful use in Stage 2;
- quality reporting requirements for Stage 2;
- changes to Stage 1 of meaningful use;
- implementation of payment penalties that begin in FY 2015 under the Medicare program for providers that fail to meet meaningful use;
- Medicaid-specific changes;
- changes to attestation, appeals and other CMS processes; and
- changes to the certification and standards requirements from ONC.

This advisory does not include information on incentive payments for qualifying Medicare Advantage Organizations.

CMS FINAL RULE ON STAGE 2 MEANINGFUL USE

Timing and Stages of Meaningful Use

Stage 1 of meaningful use began in FY 2011 for hospitals and critical access hospitals (CAHs); for physicians and other eligible professionals (EP), Stage 1 began in calendar year (CY) 2011. To address concerns about the need for an orderly transition, CMS delayed the start of Stage 2 to FY 2014 for hospitals and CY 2014 for physicians – one year later than previously expected. CMS also finalized a one-quarter reporting period in 2014 to facilitate the transition to a new version of certified EHRs and Stage 2. All hospitals and physicians will need to upgrade to ONC's newly finalized 2014 Edition of certified EHRs in 2014, regardless of stage.

Hospitals that first received meaningful use payments in FY 2011 will be able to receive incentives for Stage 1 compliance for three years (FYs 2011 through 2013). Those that start in 2012 or later will receive Stage 1 incentives for only two years.

When hospitals must start Stage 2 depends on when they first meet Stage 1 requirements (see Table 1). All hospitals and physicians will have two years at Stage 1 and Stage 2 (except for those that started in 2011, who will earn three years of incentives at Stage 1). However, CMS also finalized changes to the Stage 1 requirements, most of which are optional in 2013 but mandatory in 2014 (see page 13). CMS expects Stage 3 to start in FY 2016 but has not officially proposed Stage 3 requirements. If there is a Stage 4, CMS will include the years for Stage 4 in the Stage 3 proposed rule.

Table 1: Stages of Meaningful Use Criteria by Payment Year

First Payment Year	Payment Year (Fiscal Year for hospitals and CAHs; calendar year for EPs)										
	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
2011	Stage 1	Stage 1	Stage 1	Stage 2	Stage 2	Stage 3	Stage 3	TBD	TBD	TBD	TBD
2012		Stage 1	Stage 1	Stage 2	Stage 2	Stage 3	Stage 3	TBD	TBD	TBD	TBD
2013			Stage 1	Stage 1	Stage 2	Stage 2	Stage 3	Stage 3	TBD	TBD	TBD
2014				Stage 1	Stage 1	Stage 2	Stage 2	Stage 3	Stage 3	TBD	TBD
2015					Stage 1	Stage 1	Stage 2	Stage 2	Stage 3	Stage 3	TBD
2016						Stage 1	Stage 1	Stage 2	Stage 2	Stage 3	Stage 3
2017							Stage 1	Stage 1	Stage 2	Stage 2	Stage 3

Reporting Period. The meaningful use reporting period is variable. The first year of meaningful use attestation is based on a 90-day continuous reporting period that can start at any time, as long as it falls within the fiscal year for hospitals and calendar year for EPs. In FY 2014, hospitals in their second or later year of participation can either

report on a full year or choose a single quarter for reporting. The policy provides an additional nine-month window for transitioning to the 2014 edition of certified EHR technology and Stage 2. The selected quarter must be either:

- October 1 to December 31, 2013;
- January 1 to March 31, 2014;
- April 1 to June 30, 2014; or
- July1 to September 30, 2014.

For physicians, the one-quarter reporting option aligns with calendar year 2014. The optional one-quarter reporting period is available only in 2014. Outside of the first year of attestation and 2014, the meaningful use reporting period is a full year.

Definition of Meaningful Use for Stage 2

The ARRA set forward three requirements for hospitals and physicians to qualify for the EHR incentive programs:

- use of certified EHR technology;
- demonstration of meaningful use of the EHR; and
- clinical quality reporting using the EHR.

CMS finalized a new, stringent set of meaningful use criteria for Stage 2 that maintains the core and menu set objective approach. Stage 2 includes 22 hospital objectives, of which seven are new. In Stage 2 hospitals must use certified 2014 Edition EHRs to meet (or qualify for an exception to) each of 16 core objectives and three of six menu set objectives, for a total of 19 out of 22 objectives. CMS finalized its proposal to move the quality reporting requirements out of the meaningful use objectives, and make them a separate category.

The AHA is concerned that, taken as a whole, the final requirements for Stage 2 raise the bar very high, particularly given that, to date, relatively few providers have successfully attested to meaningful use in Stage 1. Hospitals will need to devote considerable resources to understanding the extensive changes from Stage 1 to Stage 2.

CMS regrouped and combined objectives from Stage 1 in ways that limit the total number of objectives in Stage 2, but not the performance requirements. Changes from Stage 1 to Stage 2 include:

- increasing performance thresholds and/or expanding definitions (such as increasing the Computerized Provider Order Entry (CPOE) requirement from 30 to 60 percent of medications and expanding the type of orders to also include 30 percent of laboratory orders and 30 percent of radiology orders);
- requiring most measures that were optional in Stage 1;
- combining related objectives; and
- adding seven new objectives.

The new objectives include two core objectives that all hospitals need to meet, and five in the menu set. The final two objectives (electronic notes and lab results) were not proposed for inclusion, but were the subject of comment. The new objectives are:

- Automatically tracking medications from order to administration using assistive technologies (such as bar coding) in conjunction with an electronic medication administration record (eMAR – Core);
- Providing patients the ability to view online, download and transmit information about a hospital admission (patient portal – Core) and tying performance to the share of patients that use this function;
- Making imaging results and information accessible through certified EHR technology (imaging – Menu);
- Recording patient family health history as structured data (Menu);
- Generating and transmitting permissible discharge prescriptions electronically (eRx – Menu);
- Recording electronic notes in patient records (Menu); and
- Providing structured electronic lab results from reference labs to physician offices using ONC standards, including LOINC (Menu).

None of the Stage 1 requirements was removed, although many changed form. Notable among the combined objectives is the removal of the problem list, medication list and medication-allergy list as separate objectives in favor of including them as mandatory data fields in both the new patient portal requirement, and the greatly expanded summary of care record requirement.

Table 2 (on page 7) lists the Stage 2 meaningful use objectives for hospitals. The table also includes the associated measures that will be reported to CMS, and notes about specific requirements, such as the data elements to be available through a patient portal, or in a care summary record. Given the many changes from Stage 1, Table 2 does not try to map the changes across stages. Selected objectives are discussed below.

Patient Portal. This objective includes two measures, one measuring hospital actions, the other measuring patient actions. Hospitals must ensure that at least 50 percent of patients have secure online access to an extensive set of information about a discharge from the inpatient or emergency department (ED) setting within 36 hours of discharge (see Table 2 for a list of information). In addition, hospitals must show that 5 percent or more of patients discharged from either the inpatient setting or ED have actually accessed the portal. Hospitals located in counties with limited broadband access can claim an exclusion. CMS lowered the performance requirement on the patient measure in response to comment, but did not remove it. **The AHA believes that it is unfair to base hospitals' success in meeting meaningful use on circumstances outside of their control.**

Summary of Care Record. In Stage 2, CMS greatly expands the scope of this Stage 1 objective and moves from a test to see if a care summary could be transmitted to actual exchange. In response to comments, CMS reduced the performance level for this

measure from 65 percent to 50 percent of transitions having a summary of care record sent to the next provider of care after a transition or referral. In addition, 10 percent of transitions must have a summary sent electronically. To reduce measurement burden, the agency also limited the objective requiring exchange with providers that have a different vendor from 10 percent to a single exchange. Table 2 includes the list of data elements required, as well as the definition of a transition of care.

Electronic Medication Administration Record (eMAR). CMS states that it introduced the use of eMAR directly into the core due to the proven safety benefits of this technology, but established a low performance threshold (10 percent of medication orders). Note that CMS defines eMAR to include use of "assistive technologies" such bar coding. As requested by the AHA, CMS provides an exception for hospitals with an average daily inpatient census of fewer than 10 patients in the previous calendar year.

CPOE. The CPOE requirement is greatly expanded in Stage 2, with an increase in the threshold for compliance from 30 percent to 60 percent of medication orders, as well as the addition of lab and radiology orders. CPOE is the only objective that specifies who must enter data into the EHR and when the entry must occur. The CPOE objective is currently limited to "any licensed healthcare professional who can enter orders into the medical record per state, local and professional guidelines to create the first record of the order." CMS notes that the originating provider (the provider whose judgment creates the order) must personally use the CPOE function, verbally communicate the order to someone else that will use the CPOE function, or give an electronic or written order that must not be retained in any way once the CPOE function has been utilized. In response to comments, CMS chose not to expand the CPOE requirement to include all non-licensed professionals, but did expand it to include "credentialed medical assistants," provided that credentialing is obtained from an organization other than the employing organization. CMS also will allow (but not require) providers to exclude standing orders from the CPOE measure calculation entirely, because they are predetermined for a given set of patient characteristics or a given procedure.

Meaningful Use Measures

Each meaningful use objective has an associated measure (or measures) to define what it means to meet the objective (see Table 2). Some measures require a percentage calculation, while others have a "yes/no" formulation. In many cases, CMS has increased the compliance level for the measures from Stage 1 to Stage 2. For instance, the threshold for recording demographics was increased from 50 percent of patients to 80 percent.

In Stage 2, all patient-based measures must be based on the total patient population. By comparison, in Stage 1, some measures were based on all patients, while other measures used only those with records in the EHR. CMS's rationale for this change is that by Stage 2 all providers using EHRs will have recorded all patients in the electronic record.

As with Stage 1, most measures are specified to include both inpatient and emergency departments (place of service (POS) 21 or 23). Hospitals may choose one of two ways

to include ED patients in their measures: all patients seen in the ED or only patients receiving observation services (whether admitted through the ED or an outpatient department).

Providers must use certified EHR technology to achieve the objectives, including use of any standards specified in the related standards, implementation specifications and certification criteria final rule from ONC. The final Stage 2 standards are discussed on page 32 of this advisory. In some areas, CMS has not identified a standard, but proposes to continue to require the use of structured data, rather than free text, in the EHR. For example, vital signs must be structured, but have no defined standards.

Table 2: Stage 2 Objectives and Measures for Eligible Hospitals and Critical Access Hospitals

STAGE 2 OBJECTIVES	MEASURES
Core Set: *Hospitals must achieve all of the following objectives and meet the required threshold. POS = Place of Service code.*	
Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed health care professional who can enter orders into the medical record per state, local and professional guidelines	More than 60 percent of medication, 30 percent of laboratory, and 30 percent of radiology orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE
Record the following demographics: • Preferred language • Sex • Race • Ethnicity • Date of birth • Date and preliminary cause of death in the event of mortality in the eligible hospital or CAH	More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have demographics recorded as structured data **Note:** Fields must be populated, but can include an indication that the data are not available.
Record and chart changes in vital signs: • Height/length • Weight • Blood pressure (age 3 and over) • Calculate and display BMI • Plot and display growth charts for patients 0-20 years, including BMI	More than 80 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data
Record smoking status for patients 13 years old or older	More than 80 percent of all unique patients 13 years old or older admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) during the EHR reporting period have smoking status recorded as structured data

STAGE 2 OBJECTIVES	MEASURES
Use clinical decision support to improve performance on high priority health conditions **Note:** The final rule contains significant details on clinical decision support that medical staff may want to review.	1. Implement five clinical decision support interventions related to four or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. Absent four clinical quality measures related to an eligible hospital or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions. It is suggested that one of the five clinical decision support interventions be related to improving healthcare efficiency 2. The eligible hospital or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period
Incorporate clinical lab-test results into certified EHR technology as structured data	More than 55 percent of all clinical lab test results ordered by authorized providers of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 or 23) during the EHR reporting period whose results are either in a positive/negative affirmation or numerical format are incorporated in certified EHR technology as structured data
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach	Generate at least one report listing patients of the eligible hospital or CAH with a specific condition.
Automatically track medications from order to administration using assistive technologies in conjunction with an electronic medication administration record (eMAR) - **NEW** **Note:** eMAR defined as "technology that automatically documents the administration of medication into certified EHR technology using electronic tracking sensors (for example, radio frequency identification (RFID)) or electronically readable tagging such as barcoding."	More than 10 percent of medication orders created by authorized providers of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period for which all doses are tracked using eMAR

STAGE 2 OBJECTIVES	MEASURES
Provide patients the ability to view online, download, and transmit information about a hospital admission - **NEW** **Note:** The following information must be available: patient name; admit and discharge date and location; reason for hospitalization; care team, including the attending provider and other providers of care; procedures performed during admission; current and past problem list; current medication list and medication history; current medication allergy list and medication allergy history; vital signs at discharge; all laboratory test results available at time of discharge; summary of care record for transitions of care or referrals to another provider; care plan field(s) including goals and instructions; discharge instructions for patient; demographics maintained by hospital (sex, race, ethnicity, date of birth, preferred language), and smoking status. To meet this measure, a provider can host a patient portal, contract with a vendor to host a patient portal, connect with an online personal health record (PHR) or use other arrangements, as long as the portal is certified.	1. More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH have their information available online within 36 hours of discharge 2. More than 5 percent of all patients (or their authorized representatives) who are discharged from the inpatient or emergency department (POS 21 or 23) of an eligible hospital or CAH view, download or transmit to a third party their information during the reporting period
Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient	More than 10 percent of all unique patients admitted to the eligible hospital's or CAH's inpatient or emergency departments (POS 21 or 23) are provided patient-specific education resources identified by certified EHR technology
The eligible hospital or CAH that receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation	The eligible hospital or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is admitted to the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23)

STAGE 2 OBJECTIVES	MEASURES
The eligible hospital or CAH that transitions their patient to another setting of care or provider of care or refers its patient to another provider of care provides a summary care record for each transition of care or referral **Note:** All summary of care documents used to meet this objective must include a value (which can be "none") for the fields of current problem list; current medication list; and current medication allergy list. The following fields must also be included, but may be blank if no information is known: patient name; procedures; encounter diagnosis; immunizations; laboratory test results; vital signs (height, weight, blood pressure, BMI); smoking status; functional status (including activities of daily living, cognitive and disability status); demographic information (preferred language, sex, race, ethnicity; date of birth); care plan field(s), including goals and instructions; care team (including the primary care provider of record and any additional known care team members beyond the referring or transitioning provider and the receiving provider); and discharge instructions. CMS defined transition in the proposed rule as "the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another," excluding a transition to home when there is no expectation of follow-up care by another provider. A transition within one setting of care does not qualify as a transition of care. Referral is defined as care "where one provider refers a patient to another, but the referring provider maintains its care of the patient as well." If the next provider of care has access to the same medical record as the provider in the first setting, the patient transition should not be included in the measure calculation, as there is no need for a summary of care.	1. The eligible hospital, or CAH that transitions or refers its patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals 2. The eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care provides a summary of care record for more than 10% of such transitions and referrals either – (a) electronically transmitted using certified EHR technology to a recipient or (b) where the recipient receives the summary of care record via exchange facilitated by an organization that is a Nationwide Health Information Network (NwHIN) Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the NwHIN 3. An eligible hospital or CAH must satisfy one of the two following criteria: (A) Conducts one or more successful electronic exchanges of a summary of care document, as part of which is counted in "measure 2" (for eligible hospitals and CAHs the measure at §495.6(l)(11)(ii)(B)) with a recipient who has EHR technology that was developed or designed by a different EHR technology developer than the sender's EHR technology certified to 45 CFR 170.314(b)(2) (B) Conducts one or more successful tests with the CMS designated test EHR during the EHR reporting period
Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic immunization data from certified EHR technology to an immunization registry or immunization information system for the entire EHR reporting period
Capability to submit electronic reportable laboratory results to public health agencies, except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic reportable laboratory results from certified EHR technology to public health agencies for the entire EHR reporting period

STAGE 2 OBJECTIVES	MEASURES
Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic syndromic surveillance data from certified EHR technology to a public health agency for the entire EHR reporting period
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data stored in certified EHR technology in accordance with requirements under 45 CFR 164.312 (a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the provider's risk management process
Menu Set: *Hospitals must achieve two of the following objectives and meet the required threshold*	
Record whether a patient 65 years old or older has an advance directive	More than 50 percent of all unique patients 65 years old or older admitted to the eligible hospital's or CAH's inpatient department (POS 21) during the EHR reporting period have an indication of an advance directive status recorded as structured data
Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through certified EHR technology – **NEW**	More than 10 percent of all tests whose result is one or more images ordered by an authorized provider of the eligible hospital or CAH for patients admitted to its inpatient or emergency department (POS 21 and 23) during the EHR reporting period are accessible through certified EHR technology
Record patient family health history as structured data – **NEW**	More than 20 percent of all unique patients admitted to the eligible hospital or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period have a structured data entry for one or more first-degree relatives.
Generate and transmit permissible discharge prescriptions electronically (eRx) – **NEW**	More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new, changed, and refilled prescriptions) are queried against a drug formulary and transmitted electronically using certified EHR technology
Record electronic notes in patient records – **NEW** **Note:** Electronic progress notes must be text-searchable. Nonsearchable notes do not qualify, but this does not mean that all of the content has to be character text. Drawings and other content can be included with searchable text notes under this measure.	Enter at least one electronic progress note created, edited and signed by an authorized provider of the eligible hospital's or CAH's inpatient or emergency department (POS 21 or 23) for more than 30 percent of unique patients admitted to the eligible hospital or CAH's inpatient or emergency department during the EHR reporting period
Provide structured electronic lab results to ambulatory providers – **NEW**	Hospital labs send structured electronic clinical lab results to the ordering provider for more than 20 percent of electronic lab orders received

Exclusions. CMS will continue to permit an eligible hospital or CAH to indicate that certain objectives/measures do not apply to them because, for example, they have no patients to which the measure applies. As in Stage 1, CMS will require attestation only for exclusions, but providers should maintain documentation to support their exclusions.

For core measures, an exclusion reduces the number of objectives required to demonstrate meaningful use. Beginning in 2014, an exclusion for a menu set objective will no longer count toward the number of menu set objectives needed to meet meaningful use. Providers will need to report on all relevant menu set items before reporting exclusions.

For hospitals and CAHs, the following seven objectives have specific exclusion criteria that are spelled out in the rule:

- Patient portal – exclusion for hospitals located in counties with limited broadband availability for households.
- Record smoking status – exclusion for hospitals with no patients aged 13 or older.
- ePrescribing of discharge prescriptions – exclusion for hospitals with no internal pharmacy or pharmacy within 25 miles that can accept electronic prescriptions.
- Record advance directive – exclusion for hospitals that admit no patients age 65 or older.
- Public health measures – All three of the public health measures (immunization registries, reportable lab results, and syndromic surveillance) benefit from the exclusions described below. An additional exclusion to the immunization registry requirement is provided for hospitals that do not provide immunizations for which data are collected.

Exclusions for Public Health Reporting. Exclusions for the three public health objectives will apply to hospitals that operate in a jurisdiction where no registry/public health agency is able do one or more of the following:

1. Receive the data according to the specified standards at the start of an EHR reporting period;
2. Provide timely information on their ability to receive data; or
3. Enroll an additional hospital for reporting due to capacity constraints.

The hospital must verify the capacities of the public health agency within the first 60 days of the applicable reporting period. In response to concerns about burden, CMS "anticipates developing a centralized repository" of information about the capability of public health agencies to receive the public health data. If the repository is developed, and a public health agency fails to provide information timely, the provider could claim the exclusion. CMS warns, however, that if it is unable to develop this centralized repository, providers will have to make the determination of public health agency capacity by working directly with public health agencies.

Privacy and Security. CMS finalized the objective to "protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities," with a slight difference to the associated measure. It now states that as part of the security and risk analysis providers include "addressing the encryption/security of data stored in certified EHR

technology in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3) [HIPAA]."

CMS insists that the objective and its associated measure do not change the HIPAA Security Rule requirements, or require anything more than the rule already requires. Rather by including this requirement as part of meaningful use, CMS "only emphasize[s] the importance of an EP or hospital including in its security risk analysis an assessment of the reasonableness and appropriateness of encrypting electronic protected health information as a means of securing it, and where it is not reasonable and appropriate, the adoption of an equivalent alternative measure."

For the purposes of this meaningful use measure, the security risk analysis would apply only to data created or maintained by certified EHR technology. Under meaningful use, the security risk analysis does not apply to data centers that are not part of the EHR, *although such data centers may be subject to the HIPAA security requirements found in the HIPAA regulation at 45 CFR 164.308(a)(1)*.

However, while emphasizing there is no difference between the meaningful use requirements and the HIPAA security rule obligations, CMS notes that the meaningful use requirement does necessitate that the security risk review be conducted *for each EHR reporting period* and any security updates and deficiencies that are identified be implemented or corrected in accordance with the provider's risk management process.

Notably, while CMS finalizes only one specific privacy and security objective, ONC includes multiple privacy and security criteria for the certification of EHR technology (see details on page 36).

Changes to Stage 1 of Meaningful Use. CMS also has finalized a number of changes to Stage 1 of meaningful use. Some changes are required for hospitals in FY 2013; others are optional. All changes would be required beginning in FY 2014 for hospitals demonstrating Stage 1 meaningful use, and in CY 2014 for EPs. In addition, ONC requires all providers to use EHRs certified to new requirements in 2014, regardless of stage.

CMS finalized the following changes to Stage 1:

- For CPOE, the denominator will change for medications and include all orders (rather than share of unique patients with a medication in the medication list). This change is optional in 2013 and required in 2014.

- For the Stage 1 public health objectives (immunizations, reportable lab results and syndromic surveillance), CMS has added "except where prohibited" to the regulation text, effective in 2013. CMS states that it made this change because the agency wants to encourage submission of electronic immunization data even where not required by state/local law.

- CMS removed the Stage 1 core objective of "capability to exchange key clinical information," effective in FY 2013, because the agency believes this objective has been "surprisingly difficult for providers to understand."

- Effective in FY 2014 for hospitals, CMS will replace Stage 1 hospital objectives relating to providing patients with electronic copies of their health information and discharge instructions upon request with the new (and required) "view online, download and transmit" objective for Stage 2. For EPs, the patient portal objective would replace the Stage 1 objective of providing patients with an electronic copy. Hospitals and physicians in Stage 1 would need to meet only the measure related to making the portal available, and not the measure related to the share of patients accessing the portal.

- Effective in FY 2014 for hospitals and CY 2014 for EPs, CMS will require providers in Stage 1 to report the same clinical quality measures as those in Stage 2 (see next section).

- For EPs, CMS proposes to modify the exclusion for the objective of record and chart changes in vital signs to allow an EP to split the exclusion and exclude blood pressure only or height/weight only, and change specified age limitations (optional in CY 2013 and required in CY 2014).

Reporting Clinical Quality Measures (CQMs)

CQMs. The ARRA requires that, for meaningful use, hospitals and EPs submit to the Department of Health and Human Services (HHS) information on CQMs, as determined by the Secretary. With respect to measure reporting, hospitals will be required to report 16 measures, out of a set of 29 available measures beginning in 2014. All 15 quality measures from Stage 1 were retained and are included in the set of 29 available measures.

In FY 2014, CMS attempts to align meaningful use quality reporting with quality measure requirements in other programs. The set of 29 measures overlaps in the following ways:

- Twenty-two overlap with the Medicare Inpatient Quality Reporting (IQR) program;
- Five overlap with the Hospital Value-Based Purchasing (HVBP) program;
- Two overlap with the Medicare Outpatient Quality Reporting (OQR) program;
- One is used by The Joint Commission (TJC); and
- Four are available for use in state Medicaid programs (state use).

CMS finalized its proposal to array the CQMs into the six domains that govern the National Quality Strategy (NQS).

Table 3 denotes the 29 CQMs available for FY 2014 reporting by hospitals and CAHs, sorted by domain. The exception is the Population and Public Health domain, which lacks CQMs. Hospitals are required to choose measures from a minimum of three NQS domains and report 16 measures. The 15 CQMs finalized for Stage 1 are included in

the CQMs available for reporting in 2014 and are found within four of the six NQS domains. The table notes the National Quality Forum (NQF) number, the measure title and the CMS quality programs that use the respective measure.

The domains are:

- Patient and Family Engagement. These CQMs reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level, as well as the population level, through greater involvement of patients and families in decision-making, self-care, activation and understanding of their health condition and its effective management (five measures).

- Clinical Processes/Effectiveness. These CQMs reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines (14 measures).

- Care Coordination. These CQMs demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers and families in order to improve appropriate and timely patient and care team communication (two measures).

- Patient Safety. These CQMs reflect the safe delivery of clinical services in both hospital and ambulatory settings and include processes that would reduce harm to patients and reduce burden of illness. These measures should enable longitudinal assessment of condition-specific, patient-focused episodes of care (six measures).

- Efficient Use of Healthcare Resources. These CQMs reflect efforts to significantly improve outcomes and reduce errors. These CQMs also impact and benefit a large number of patients and emphasize the use of evidence to best manage high priority conditions and determine appropriate use of health care resources (two measures).

- Population and Public Health. These CQMs reflect the use of clinical and preventive services and achieve improvements in the health of the population served (zero measures).

Table 3: Hospital CQMs for Reporting in Fiscal Year 2014 and Later Years

NQF Number	Measure Title	Use in other CMS Quality Programs
Stage 2 Measures for Patient and Family Engagement		
0495	Emergency Department (ED) – Median time from ED arrival to ED departure for admitted ED patients	IQR
0497	ED Throughput – Admit decision time to ED departure time for admitted patients	IQR
0440	Stroke - education	IQR
0375	Venous Thromboembolism (VTE) – Discharge Instructions	IQR
0338	Home Management Plan of Care (HMPC) document given to patient/caregiver	State use
Stage 2 Measures for Clinical Process/Effectiveness		
0435	Stroke – Discharged on anti-thrombotic therapy	IQR
0436	Stroke – Anticoagulation therapy for Atrial Fibrillation/Flutter	IQR
0437	Stroke – Thrombolytic Therapy	IQR
0438	Stroke – Antithrombotic therapy by end of hospital day two	IQR
0439	Stroke – Discharged on Statin Medication	IQR
0373	VTE – Patients with Anticoagulation Overlap Therapy	IQR
0374	VTE – Patients receiving unfractionated heparin (UFH) with dosages/platelet count by Protocol (or Nomogram)	IQR
0142	Acute myocardial infarction (AMI) – Aspirin prescribed at discharge for AMI	IQR
0469	PC – Elective delivery prior to 39 completed weeks gestation	TJC
0164	AMI – Fibrinolytic Therapy received within 30 minutes of hospital arrival	IQR, HVBP
0163	AMI – Primary PCI received within 90 minutes of hospital arrival	IQR, HVBP
0639	AMI – Statin prescribed at discharge	IQR
0480	Exclusive Breast Milk Feeding	State Use
1354	EHDI – Hearing screening prior to hospital discharge	State Use
Stage 2 Measures for Care Coordination		
0441	Stroke – Ischemic or hemorrhagic stroke – assessed for rehabilitation	IQR
0496	ED – Median time from ED arrival to ED departure for discharged ED patients	OQR
Stage 2 Measures for Patient Safety		
0371	VTE- VTE prophylaxis	IQR
0372	VTE – Intensive Care Unit (ICU) Vte prophylaxis	IQR
0376	VTE – Incidence of potentially preventable VTE	IQR
0527	SCIP-INF – Prophylactic antibiotic received within 1 hour prior to surgical incision	IQR, HVBP
0453	SCIP-INF – Urinary catheter removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD2)	OQR
0716	Healthy Term Newborn	State Use
Stage 2 Measures for Efficient Use of Healthcare Resources		
0147	PN – Initial antibiotic selection for community-acquired pneumonia in immunocompetent patients	IQR, HVBP
0528	SCIP-INF – Prophylactic antibiotic selection for surgical patients	IQR, HVBP

If CMS removes one or more CQMs between rulemakings, the number of CQMs that must be reported would be reduced by the number of CQMs removed. However, the final rule states providers not affected by removal of a CQM between rulemakings due to ability to report other CQMs are expected to continue to report the full number of required CQMs. CMS adds that the requirements that CQMs submitted cover at least three domains will remain unless all CQMs for a particular domain have been removed.

CMS will require hospitals and CAHs to use certified EHR technology to report the CQMs. The AHA is concerned that each hospital and CAH must verify that the 16 CQMs they select for reporting can be reported by their respective EHR. Under the ONC final rule, a certified EHR is not required to support all 29 measures, and the choice of CQMs to include is up to the vendor. Under this approach, each CQM measure is certifiable and a certified EHR could include any combination of certifiable CQMs. This flexibility places the burden on the hospital to ensure the certified technology utilized actually supports successful reporting of the CQMs selected for reporting.

Reporting Thresholds and Sampling. CMS finalized the case threshold policy for reporting of CQMs. The policy will be applicable for all hospitals in all stages of meaningful use beginning in 2014. Specifically, hospitals and CAHs will be exempt from reporting a CQM if they have five or fewer discharges per reporting quarter in 2014 or 20 or fewer discharges per year, as defined by that CQM's denominator. To be eligible for the exemption, hospitals must submit their aggregate population and sample size counts for Medicare and non-Medicare discharges for a CQM for the reporting period no later than the two-month submission period of Oct. 1 through Nov. 30 immediately following the reporting period. This information is required to be reported in the same manner it is reported for the IQR program. However, CMS also stated that hospitals and CAHs that are demonstrating meaningful use for the first time must submit their CQMs through attestation and will not be able to qualify for this exemption. **The AHA strongly supported a minimum case number threshold for quality measure reporting as it aligns with requirements of the IQR program and will work with CMS on implementation of this policy.**

CMS finalized the "sampling-all payer option" for data collection for patient-level data. CMS stated that this submission characteristic will include only patients that meet the denominator criteria of the CQMs that the hospital or CAH selects for reporting. Also, it will include only the data elements listed in the CQM. The AHA urged CMS to require data collection for a sample of patients across all payers. The agency noted that it expects to propose electronic algorithms for sampling in future rulemaking.

CMS will publish e-specifications for the final CQMs by early November 2012. The AHA is concerned that the many problems with the Stage 1 CQMs, such as mistakes in the e-specifications, and data requirements that go beyond the data available in the EHR, also will occur in CQMs that are reported in 2014 given the short timeframe between availability of e-specifications and their inclusion in certified products in 2013.

CQM Reporting Options. Hospitals in Year 1 of meaningful use must report their CQMs via attestation to CMS. In 2013, hospitals have the option to participate in the electronic reporting pilot as an alternative to the attestation.

Beginning in FY 2014, hospitals in their second or later year of meaningful use must submit CQM data electronically using the standards adopted by CMS. CMS offers two options for FY 2014 reporting of the quality measures for hospitals and CAHs (see Table 4).

Table 4: Hospital CQM Reporting Options in FY 2014 and Later

Option	Description of the Option	Data Required	Data Standard
Option 1	Submit the selected 16 CQMs on an aggregate basis through a CMS-designated transmission method using certified EHR technology	Aggregate data regardless of payer	Quality Reporting Data Architecture (QRDA) Category III format
Option 2	Submit the selected 16 CQMs on a patient-level basis in a manner similar to the 2012 Medicare EHR Incentive Program Electronic Reporting Pilot for Eligible Hospitals and CAHs using certified EHR technology; as long as the CQM data originates from certified EHR technology, it may be submitted directly from the hospital's certified EHR technology to CMS or through a data intermediary to CMS	Patient level data – sampling of all payers	Quality Reporting Data Architecture (QRDA) Category I format (release 2)

Option 2 is a continuation of a pilot program that CMS adopted in the CY 2012 outpatient PPS final rule.

Timing of Reporting for CQMs. Like reporting for meaningful use performance, the CQM reporting period varies with specific circumstances:

- For hospitals and CAHs in their first year of meaningful use, CMS requires the reporting of CQMs for a 90-day continuous period. Note, however, that if the first year of participation is FY 2014, the reporting period for hospitals must end by June 30, 2014 and data must be submitted to CMS by July 1, 2014 to avoid a penalty in 2015.
- In FY 2014 only, hospitals and CAHs beyond their first year reporting period for meaningful use have the option to report CQM data for one quarter of the fiscal year, as long as it covers the same quarter as their meaningful use reporting period. CQM data must be submitted within two months of the end of the fiscal year (by Nov. 30, 2014).

- In 2015 and later, the CQM reporting period will be a full year for hospitals and CAHs beyond their first year of meaningful use. Data must be submitted within two months of the end of the fiscal year (or by Nov. 30).

CMS anticipates that reporting will be electronic in FY 2014 and beyond, and the ONC rule provides specific standards for submission. However, attestation may be accepted if CMS lacks capacity to accept electronic submission. CMS expects to "align the submission frequency with the Hospital IQR program for electronic reporting of CQMs by hospitals."AHA will work with CMS to better understand the timing of reporting requirements across this and other CMS programs.

Medicare Payment Penalties

The final rule implements statutory Medicare payment penalties beginning in FY 2015 for PPS hospitals that fail to meet meaningful use. By law, the reductions are applied to PPS hospitals' market-basket update. The penalty is a 25 percent reduction to the market-basket update (before other cuts are applied) in FY 2015, 50 percent in FY 2016 and 75 percent in FY 2017 and beyond. The penalties for CAHs also begin in FY 2015, and are described below.

The AHA is disappointed that CMS has set an unrealistic date by which hospitals must achieve meaningful use to avoid penalties. Specifically, CMS finalized its proposed policy to generally determine penalties using a reporting year that is two years in advance of the payment year, with exceptions for those in their first year of meaningful use. For example, PPS hospitals will have to successfully attest in FY 2013 to avoid the FY 2015 penalty. The attestation must cover all of FY 2013 unless FY 2013 is the first year of demonstrating meaningful use, in which case a continuous 90-day EHR reporting period will apply. Even if a hospital successfully attested in FY 2011 or FY 2012, but not in FY 2013, it will still incur the penalties. For each year subsequent to FY 2015, the reporting period for the payment adjustment will continue to be two years before the payment period.

CMS finalized a one-time exception to this two-year look-back for those in their first year of meaningful use. For these hospitals, the look-back will be 15 months, rather than 24 months. For example, if a hospital has never before attested to meaningful use, CMS will allow it to avoid the FY 2015 penalty by attesting for a continuous 90-day reporting period that begins no later than April 3, 2014 and ends no later than June 30, 2014. The actual attestation must take place by July 1, 2014. The same timeline would also apply to subsequent years. This information is summarized in Table 5.

Table 5: Reporting Periods to Assess Payment Penalties for PPS Hospitals

Payment Year	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	FY 2017
Reporting Year for Incentive	FY 2012	FY 2013	FY 2014	FY 2015	FY 2016	n/a
Reporting Year for Penalty	n/a	n/a	n/a	FY 2013 or before July 1, 2014 if attesting for first time	FY 2014 or before July 1, 2015 if attesting for first time	FY 2015 or before July 1, 2016 if attesting for first time

CMS notes that meaningful user status will be tied to a hospital's CMS Certification Number (CCN). Thus, where a change of ownership has occurred and a new CCN is assigned due to the new owner's decision not to accept assignment of the prior provider agreement, CMS will not recognize a meaningful use determination that was established under the prior CCN for purposes of determining whether the payment adjustment applies. If the new owner does accept assignment of the prior provider agreement, CMS will recognize the demonstration of meaningful use under that CCN. Similarly, if hospital A is not a meaningful EHR user (for the applicable reporting period) and it absorbs hospital B, which was a meaningful EHR user, then the entire hospital will be subject to a penalty if hospital A's CCN is the surviving identifier.

Hardship Exceptions. CMS will grant exceptions to the penalties for certain hospitals through an application process. First, an exception could apply to a hospital that is located in an area without sufficient Internet access. This will be assessed for any 90-day period between the start of the year two years prior to the payment adjustment year through the application submission deadline of the year prior to the payment adjustment year. Applications for this exception must be submitted six months before the beginning of the penalty year (that is, by April 1 before the fiscal year to which the penalty would apply), although CMS encourages hospitals to file applications as early as possible.

A second exception applies to new hospitals for at least one full cost-reporting period after they accept their first Medicare-covered patient (the proposed rule had said simply "first patient"). For example, a hospital that accepted its first Medicare patient in March of 2015, but has a cost-reporting period from July 1 through June 30, would receive an exception from the payment adjustment for FY 2015 as well as for FY 2016. However, this hospital would need to demonstrate meaningful use for a continuous 90-day reporting period that ends no later than June 30, 2016, with attestation by July 1, 2016, to avoid being subject to the penalty in FY 2017. CMS emphasizes that this exception is not available to hospitals that have already been in operation in one form or another,

perhaps under a different owner or merely in a different location. CMS states that the following would not be considered "new" hospitals:

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

CMS did not finalize its proposal that a hospital that has been in operation for more than two years but has participated in the Medicare program for less than two years would not be considered new because of its decision to base the exception on when a hospital accepts its first Medicare patient.

Note that, despite CMS's stance regarding the CCN as the basis for the payment adjustment, the agency acknowledges that a CAH that becomes an inpatient PPS hospital would, of necessity, receive a new CCN. However, CMS would nevertheless allow the CAH to register its meaningful use designation obtained under its previous CCN in order to avoid being subject to penalties.

Finally, CMS will make an exception for hospitals under extreme circumstances. Such exceptions would be assessed on a case-by-case basis, with applications required no later than April 1 of the year prior to the penalty year. In the proposed rule, CMS had included the hospital's closing, a natural disaster destroying the EHR system, and the hospital's EHR vendor going out of business as potential examples of extreme circumstances. In the final rule, the agency notes two additional examples that will qualify as extreme circumstances: a hospital losing the certification for its certified EHR technology (complete or modular) either through revocation or because the vendor did not upgrade its technology to the latest requirements; and a hospital suffering severe financial distress resulting in a bankruptcy or restructuring of debt.

Two additional scenarios may fall under the exception for extreme circumstances: hospitals that determine they must switch EHR vendors to achieve meaningful use, and hospitals unable to meet meaningful use requirements because of failures on the part of EHR vendors. However, under these scenarios, the agency said that the granting of an exception would be highly dependent on individual circumstances and evaluation of, for example, whether it is truly necessary to switch vendors and whether the failures of the EHR vendor are both outside the norm of EHR implementation and beyond the control of the hospital.

In addition, CMS mentions a third scenario: hospitals that made a good faith effort to purchase certified EHR technology, but could not find a vendor willing to work with them. While the agency did not completely rule out the possibility that such a situation

could qualify for an extreme circumstances exception, it states it is "skeptical" it would. Hospitals would have to prove that their situation is extreme, out of the ordinary and truly beyond their control.

Penalties for CAHs. Statutory penalties also apply to CAHs that fail to meet meaningful use requirements. For CAHs, the penalties will reduce cost-based payments from 101 percent to 100.66 percent in FY 2015, 100.33 percent in FY 2016, and 100 percent in FY 2017 and beyond. CMS finalized its proposal to align the reporting year for determining CAH penalties with the payment year. CMS notes that the Medicare cost-report process will allow it to make the CAH reduction for the cost-reporting period that begins in the penalty year, with minimal disruptions to the CAH's cash flow and minimal administrative burden on Medicare contractors. For example, any CAH that is not a meaningful user in FY 2015 will incur penalties for its cost-reporting period that begins in FY 2015.

This means that CAHs must attest to meaningful use for all of FY 2015 (or, if a CAH is in its first year of demonstrating meaningful use, a continuous 90-day reporting period within FY 2015) to avoid penalties. CAHs are required to submit their attestations on meaningful use by Nov. 30 of the following fiscal year. Thus, if a CAH is attesting that it was a meaningful EHR user for FY 2015, the attestation must be submitted no later than Nov. 30, 2015. Such attestation (or lack thereof) will then affect interim payments to the CAH made after Dec. 1 of the applicable fiscal year and be reconciled during the cost-report settlement process.

As with other providers, CMS will make several exceptions for CAHs. It finalized its proposal to make an exception for CAHs with insufficient Internet connectivity, which would need to be demonstrated for any 90-day period within the cost-reporting period that begins prior to or during the payment adjustment year. CAHs must submit applications to their Medicare contractor by Nov. 30 of the fiscal year following the payment adjustment year (the same date by which the meaningful use attestation is due).

CMS also will make an exception for a new CAH for one year after it accepts its first Medicare-covered patient (the proposed rule had said simply "first patient"). For example, a CAH that is established in FY 2015 would be exempt from the penalty through its cost-reporting period ending at least one year after the CAH accepts its first Medicare-covered patient. If the CAH is established March 15, 2015, and its first cost-reporting period is less than 12 months (for example, from March 15 through June 30, 2015), the exception would exist for both the short cost-reporting period and the following 12-month cost-reporting period lasting from July 1, 2015 through June 30, 2016. However, the new CAH would be required to submit its attestation that it was a meaningful EHR user for FY 2016 no later than Nov. 30, 2016, in order to avoid being subject to the payment adjustment for the cost-reporting period that begins in FY 2016 (in the previous example from July 1, 2016 through June 30, 2017).

Finally, CMS will make an exception for CAHs with extreme circumstances. CMS is requiring CAHs to submit applications for an exception to their Medicare contractor by

Nov. 30 of the fiscal year following the payment adjustment year (the same date by which the meaningful use attestation is due).

Definition of Stage 2 Meaningful Use for Physicians and Other EPs

The Stage 2 meaningful use requirements for physicians and other EPs are similar to the requirement for hospitals. CMS delays the start of Stage 2 by one year, to CY 2014, and will allow EPs to have a one-quarter reporting period in 2014. This essentially provides EPs with an additional nine-month transition period to meet meaningful use Stage 2. There are slight differences, however, in some objectives and measures. Overall, EPs will need to meet (or qualify for an exclusion to) the 17 core and three of six menu objectives listed in Table 6. Thus, EPs must meet 20 of 23 objectives overall.

The changes in the EP objectives from Stage 1 to Stage 2 are numerous and involve increased thresholds, expanded definitions and new combinations of Stage 1 objectives. Like hospitals, EPs will need to use CPOE to enter 60 percent of medication, 30 percent of laboratory and 30 percent of radiology orders. In addition, EPs will be required to use e-prescribing for more than 50 percent (down from a proposed 65 percent) of all prescriptions.

In addition, the following seven new objectives have been added for EPs:

- Provide patients with the ability to view online, download and transmit their health information (Core);
- Use secure electronic messaging to communicate with patients on relevant health information (Core);
- Imaging results and information are accessible through certified EHR technology (Menu);
- Record patient family health history as structured data (Menu);
- Submit cancer cases to a public health central cancer registry (Menu);
- Submit specific cases to a specialized registry (Menu); and
- Record electronic notes in patient records (Menu).

We are disappointed that CMS adopted its proposal to make the performance of EPs contingent on the actions of others. Specifically, whether an EP meets the objective to provide a patient portal will be tied to the share of patients (5 percent, down from a proposed 10 percent) that have actually accessed it. Similarly, the secure messaging objective is tied to whether patients (and not EPs) are the senders.

Table 6: Stage 2 Objectives and Measures for Physicians & Other EPs

STAGE 2 OBJECTIVES	MEASURES
Core Set: *Physicians and other eligible professionals (EPs) must achieve all of the following objectives and meet the required thresholds.*	
Use computerized provider order entry (CPOE) for medication, laboratory and radiology orders directly entered by any licensed healthcare professional who can enter orders into the medical record per State, local and professional guidelines to create the first record of the order	More than 60 percent of medication orders, more than 30 percent of laboratory orders, and more than 30 percent of radiology orders created by the EP are recorded using CPOE.
Generate and transmit permissible prescriptions electronically (eRx)	More than 50 percent of all permissible prescriptions, or all prescriptions, written by the EP are queried for a drug formulary and transmitted electronically using certified EHR technology.
Record the following demographics • Preferred language • Sex • Race • Ethnicity • Date of Birth	More than 80 percent of all unique patients seen by the EP have demographics recorded as structured data
Record and chart changes in vital signs: • Height/length • Weight • Blood pressure (age 3 or over) • Calculate and display BMI • Plot and display growth charts for patients 0-20 years, including BMI	More than 80 percent of all unique patients seen by the EP have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data
Record smoking status for patients 13 years old or older	More than 80 percent of all unique patients 13 years old or older seen by the EP have smoking status recorded as structured data
Use clinical decision support to improve performance on high-priority health conditions	1. Implement 5 clinical decision support interventions related to 4 or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period. 2. The EP has enabled the functionality for drug-drug and drug-allergy interaction checks for the entre EHR reporting period.
Incorporate clinical lab-test results into certified EHR technology as structured data	More than 55 percent of all clinical lab test results ordered by the EP whose results are either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data
Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach	Generate at least one report listing patients of the EP with a specific condition
Use clinically relevant information to identify patients who should receive reminders for preventive/follow-up care and send these patients the reminder, per patient preference	More than 10 percent of all unique patients who have had two or more office visits with the EP within the 24 months prior to the beginning of the EHR reporting period were sent a reminder, per patient preference when available

STAGE 2 OBJECTIVES	MEASURES
Provide patients the ability to view online, download, and transmit their health information within 4 business days of the information being available to the EP - **NEW**	1. More than 50 percent of all unique patients seen by the EP are provided timely (within 4 business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information 2. More than 5 percent of all unique patients seen by the EP (or their authorized representatives) view, download , or transmit to a third party their health information
Provide clinical summaries for patients for each office visit	Clinical summaries provided to patients or patient-authorized representatives within 1 business day for more than 50 percent of office visits
Use certified EHR technology to identify patient-specific education resources and provide those resources to the patient	Patient-specific education resources identified by certified EHR technology are provided to patients for more than 10 percent of all unique patients with office visits seen by the EP
Use secure electronic messaging to communicate with patients on relevant health information - **NEW**	A secure message was sent using the electronic messaging function of certified EHR technology by more than 5 percent of unique patients (or their authorized representatives) seen by the EP during the EHR reporting period
The EP who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation	The EP performs medication reconciliation for more than 50 percent of all transitions of care in which the patient is transitioned into the care of the EP
The EP who transitions their patient to another setting of care or provider of care or refers their patient to another provider of care should provide summary care record for each transition of care or referral **Note:** The proposed rule defined transition as "the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another," excluding a transition to home when there is no expectation of follow-up care by another provider. A transition within one setting of care does not qualify as a transition of care. Referral is defined as care "where one provider refers a patient to another [provider], but the referring provider maintains their care of the patient as well."	1. The EP that transitions or refers his/her patient to another setting of care or provider of care provides a summary of care record for more than 50 percent of transitions of care and referrals 2. The EP that transitions or refers his/her patient to another setting of care or provider of care provides a summary of care record for more than 10 percent of such transitions and referrals <u>either:</u> - transmitted using certified EHR technology to a recipient; or - where the recipient receives the summary of care record via exchange facilitated by an organization that is a Nationwide Health Information Network Exchange participant or in a manner that is consistent with the governance mechanism ONC establishes for the Nationwide Health Information Network Exchange 3. The EP must satisfy one of the following: - Conducts one or more successful electronic exchanges of a summary of care record with a recipient using technology to receive the summary of care record that was designed by a different EHR developer than the sender's certified EHR technology; or - Conducts one or more successful tests with the CMS-designated test EHR during the EHR reporting period.

STAGE 2 OBJECTIVES	MEASURES
Capability to submit electronic data to immunization registries or immunization information systems except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic immunization data from certified EHR technology to an immunization registry or immunization information system for the entire EHR reporting period
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities	Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data stored in certified EHR technology in accordance with requirements under 45 CFR 164.312 (a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the EP's risk management process
Menu Set: *EPs must achieve 3 of the following objectives and meet the required threshold*	
Imaging results consisting of the image itself and any explanation or other accompanying information are accessible through certified EHR technology - **NEW**	More than 10 percent of all tests whose result is an image ordered by the EP during the EHR reporting period are accessible through certified EHR technology
Record patient family health history as structured data - **NEW**	More than 20 percent of all unique patients seen by the EP during the EHR reporting period have a structured data entry for one or more first-degree relatives
Capability to submit electronic syndromic surveillance data to public health agencies, except where prohibited, and in accordance with applicable law and practice	Successful ongoing submission of electronic syndromic surveillance data from certified EHR technology to a public health agency for the entire EHR reporting period
Capability to identify and report cancer cases to a public health central cancer registry, except where prohibited, and in accordance with applicable law and practice – **NEW**	Successful ongoing submission of cancer case information from certified EHR technology to a public health central cancer registry for the entire EHR reporting period
Capability to identify and report specific cases to a specialized registry (other than a cancer registry), except where prohibited, and in accordance with applicable law and practice – **NEW**	Successful ongoing submission of specific case information from certified EHR technology to a specialized registry for the entire EHR reporting period
Record electronic notes in patient records - **NEW**	Enter at least one electronic progress note created, edited, and signed by an EP for more than 30 percent of unique patients with at least one office visit during the EHR reporting period. The text of the electronic note must be text-searchable and may contain drawings and other content.

CQM Reporting for EPs

For quality reporting in CY 2013, EPs must submit data for the CQMs that were finalized in the Stage 1 final rule for CYs 2011 and 2012. As required by the Stage 1 final rule, EPs must report on three core or alternate core CQMs, and three additional CQMs.

Beginning in 2014, EPs must report the Stage 2 CQMs, even if they are still at Stage 1. EPs may choose one of two reporting options:

Option 1: Submit nine (down from a proposed 12) measures from a list of 64 CQMs with at least one measure from three of the six NQS domains (see http://www.aha.org/content/12/12stage2cqmtable.pdf for more information). Note that CMS identified two recommended core sets, for adults and children respectively, but does not require EPs to report the core sets.

Option 2: Submit and satisfactorily report CQMs under the Physician Quality Reporting System (PQRS) EHR reporting option. This option should reduce the reporting burden on EPs who participate in both programs.

CMS finalized its proposal to remove the following three EP measures from all stages of meaningful use beginning in CY 2014, as other CQMs are very similar or collect more precise data:

- NQF 0013 Hypertension - blood pressure;
- NQF 0027 Smoking and tobacco use cessation - medical assistance; and
- NQF 0084 Heart failure - warfarin therapy patients with atrial fibrillation.

The quality measures generally must be submitted two months immediately following the end of the EHR reporting period, or Jan. 1 through Feb. 28. As is the case for meaningful use attestation, the CQM reporting period varies:

- For EPs in their first year of Stage 1, the reporting period is any continuous 90-days in the calendar, with submission to CMS within two months of the end of the calendar year. For example, EPs who first demonstrated meaningful use in CY 2012 would have until Feb. 28, 2013 to report their CQM data.

- EPs beyond their first year of meaningful use in 2014 may submit either full calendar year data or one-quarter of data covering the identical period for which meaningful use objectives are submitted. This three-month reporting period option is available in 2014 only. Those EPs who choose to report CQMs through Option 2 would be subject to the reporting periods established for those programs. For example, for those EPs who choose to submit CQMs under the PQRS EHR, the reporting periods for the PQRS EHR reporting that fall within CY 2014 would apply.

- For EPs beyond their first year of meaningful use in 2015 and later, the CQM reporting period will be for the entire year.

Group Practice Reporting Option. For Stage 1, EPs were required to report CQMs on an individual basis. Beginning in 2014, CMS will allow two group reporting options:

Option 1: EPs participating in the Medicare Shared Savings Program or the Pioneer Accountable Care Organization (ACO) Model who use certified EHR technology to submit ACO CQMs will be considered to have satisfied their CQM reporting requirement as a group.

Option 2: EPs who satisfactorily report PQRS CQMs using certified EHR technology under the PQRS GPRO will be considered to have satisfied their CQM reporting requirement as a group.

Implementation of Medicare Penalties for EPs. In general, EPs who are not meaningful EHR users before CY 2015 will receive a reduction in their Medicare physician fee schedule payment amount. This penalty amount is 1 percent in CY 2015, 2 percent in CY 2016, and 3 percent for CY 2017 and beyond. By law, HHS will increase this penalty amount to 4 percent in 2018 and 5 percent in 2019 and beyond if the HHS Secretary determines that fewer than 75 percent of EPs are meaningful users of EHR technology. CMS will base the determination of the share of physicians that are meaningful users on the most recent calendar year for which the agency has sufficient data. The determination will exclude hospital-based physicians and those granted a hardship exception.

As with hospitals, CMS will base payment penalties for EPs on a reporting period two years prior to the payment year, with a one-time exception for those in their first year of meaningful use. This means that EPs will need to be meaningful EHR users in CY 2013 to avoid the CY 2015 payment penalties, unless they are first attesting to meaningful use in CY 2014. In this case, they will need to complete and attest to a 90-day continuous reporting period within the calendar year by Sept. 30, 2014, which means the 90-period would begin no later than July 3, 2014. However, attestation must occur on or before Oct. 1, 2014.

When assessing penalties, CMS will determine whether a physician was hospital-based in the reporting year for penalties. That is, two years prior to the payment year, with a one-time exception for those in their first year of meaningful use. In response to comments, CMS will allow certain hospital-based physicians who wish to be determined non-hospital-based to apply for EHR incentive payments. These EPs must demonstrate that they fund the acquisition, implementation and maintenance of certified EHR technology. To apply, the EP must provide documentation to CMS and actively seek a non-hospital-based determination.

EPs receiving first year Medicaid payments to support them as they "adopt, implement, and upgrade" to certified EHR technology but who have not yet achieved meaningful use in the reporting year will be subject to a payment penalty. However, those EPs who have been *deemed as meaningful users* under the Medicaid EHR Incentive Program also will be considered meaningful EHR users for the purposes of avoiding the Medicare payment penalty.

Hardship Exceptions. CMS finalizes with modification its three proposed hardship exceptions for EPs. The agency will examine these exceptions on a case-by-case basis based on an application from the EP (due by July 1 prior to the penalty year):

- Insufficient Internet access for any 90-day continuous period between the start of the two-year look-back period and July 1 of the year prior to the penalty year (the application date);

- Newly practicing EPs in their first two years; and
- Extreme circumstances such as unexpected closures, natural disaster, EHR vendor going out of business, EHR vendor not upgrading their certified EHR technology to the latest requirements, and bankruptcy.

In the proposed rule, the agency sought comment on whether additional exceptions were needed for certain specialty groups that may be exposed to penalties without the ability to receive incentives. In response to comments by AHA and others, CMS will allow a fourth exemption for EPs who lack direct interaction with patients (defined as lacking both face-to-face/telemedicine interactions with patients and the need to follow-up with patients). **CMS will deem EPs whose primary specialty is anesthesiology, radiology or pathology (as listed in PECOS six months prior to the first day of the year in which the payment adjustment would apply) as qualifying for this exception; thus, these EPs do not need to complete an exception application.**

Finally, CMS will allow a fifth exception for EPs who practice in multiple locations and can demonstrate inability to control the availability of certified EHR technology at one such practice location, or a combination of practice locations, and where the location(s) constitute more than 50 percent of their patient encounters.

Medicaid-Specific Changes for Hospitals and EPs

States will continue to run (at their option) the Medicaid EHR Incentive Programs in Stage 2. CMS will continue to allow states to petition CMS for approval of limited state-specific modifications to the meaningful use definition, particularly for public heath objectives and reporting to registries. Hospitals eligible for both Medicare and Medicaid will continue to be deemed meaningful users for Medicaid when they attest to Medicare. Therefore, hospitals that meet meaningful use criteria for Medicare will not have to meet state-specific criteria under Medicaid.

CMS finalized the following changes to the Medicaid EHR Incentive Program, which took effect with publication of the final rule.

Medicaid Hospital Incentive Payment Calculations. CMS finalized a revision allowing states to use, for the purpose of calculating the discharge-related amount and other determinations (such as inpatient bed days), the most recent continuous 12-month period for which data are available prior to the payment year. CMS specifies that if such 12-month period is a cost-reporting period, it should be one, single 12-month cost-reporting period (and not a consolidation of two, separate cost-reporting periods). If the date do not come from the cost report, CMS will rely on the state to ensure that it is appropriate, that the period is a continuous 12 months, and that the state is using the most recent available data. The change is not retroactive, and will affect only those hospitals that begin participation in FY 2013 or later.

CMS also finalized an amendment to the Medicaid incentive payment regulations to clarify that only acute-care discharges and bed-days are included in calculations of Medicaid EHR incentive payments, and not nursery days and discharges. The final rule

notes that neonatal intensive care unit days are considered acute inpatient services that should be included in the hospital incentive calculation.

In the Stage 1 regulations, CMS prohibited hospitals from participating in more than one state Medicaid program. In this rule, CMS clarifies that a hospital that changes from participating in one State Medicaid EHR Incentive Program to another may not receive more than the aggregate incentive amount calculated by the first state.

Eligibility Requirements for Children's Hospitals. CMS finalizes a revised definition of a children's hospital (for purposes of determining eligibility for Medicaid EHR incentives) to accommodate about 12 children's hospitals that do not have a CCN because they do not treat Medicare beneficiaries. CMS will provide an alternative number for purposes of enrollment in the Medicaid EHR Incentive Program to any separately certified hospital, either freestanding or hospital-within-hospital, which predominantly treats individuals under 21 years of age and does not have a CCN.

Net Average Allowable Costs of EHRs for EPs. CMS formalizes through rulemaking the guidance that was shared with State Medicaid Directors in a letter on April 8, 2011 (available at: http://www.cms.gov/smdl/downloads/SMD11002.pdf). In brief, as a result of the *Medicare and Medicaid Extenders Act of 2010*, EPs no longer need to document their personal 15 percent contribution to the purchase and maintenance of certified EHR technology. Instead their Medicaid incentive payment for adopting, implementing or upgrading certified EHR technology can simply be no more than 85 percent of the net average allowable cost determined by CMS (that is, $21,250 for first-year payments). This policy is already in effect.

Determining Physicians' and Other Professionals' Eligibility for the Medicaid EHR Incentive Program. CMS also finalized a number of changes to how states determine eligibility for the Medicaid EHR Incentive Program effective in 2013. There is no impact on patient volume calculations in 2011 and 2012. First, at least one of the clinical locations used for the calculation of an EP's Medicaid patient volume must have certified EHR technology to be eligible for incentive payments. EPs can base their eligibility on the patients seen in multiple locations; this provision would ensure that Medicaid patients benefit from the use of EHRs by EPs. CMS also finalized proposals to expand the definition of a Medicaid encounter to:

- Include any encounter with an individual receiving medical assistance under 1905(b), including Medicaid expansion populations (but not Children's Health Insurance Program, CHIP);
- Permit inclusion of patients on panels seen within 24 months (rather than 12);
- Include zero-pay Medicaid claims;
- Permit patient volume to be calculated using any representative, continuous 90-day period in either the preceding calendar year, as is currently permitted, or in the 12 months preceding the EP's attestation. With respect to EPs practicing predominantly at a federally qualified health center (FQHC) or rural health clinic (RHC), CMS made conforming changes to the calculation of patient volume for "needy individuals" (which include Medicaid, CHIP and uninsured patients).

CMS Operations and Appeals

Attestation. CMS retained the current mechanism for meaningful use attestation in Stage 2, where hospitals and EPs use a secure web portal at the end of the reporting period to report their meaningful use measures and list the certified EHR technology used. Beginning in 2014, the reporting of CQMs will be separate for those beyond their first year of meaningful use, and follow the methods discussed above (see page 12). Typically, attestation does imply certification by the individual or entity that the statements are correct, true and genuine. False attestation may have significant legal consequences.

Batch Reporting for EPs. CMS finalizes its proposal to allow groups of EPs to report each individual EP's core and menu measure data through a batch process beginning in CY 2014. This approach should be helpful to physician groups supported by hospitals. CMS defines a group as two or more EPs identified with unique National Provider Identifiers (NPIs) associated with a group practice identified under one Tax Identification Numbers (TIN). CMS will establish a file format and upload process for groups to submit individual attestation data for each Medicare EP in a group (including the stage of meaningful use the individual EP is in, numerator, denominator, exclusion and yes/no information for each measure of meaningful use). CMS notes that an EP who chooses the group reporting option would be required to include in such reporting core and menu objective information on all encounters where certified EHR technology is available, even if some encounters occurred at locations not associated with the EP's Medicare EHR Incentive Group.

Use of batch reporting would not change any eligibility factors for either Medicare or Medicaid, and each EP must meet the meaningful use criteria independently, and not via a group average. The batch reporting is only for attestation; EPs first need to individually register for the program (proxy registration is allowed). Payment would go to the tax ID number specified by the EP during registration, and not to the group submitting the batch report. Use of batch reporting for the Medicaid EHR Incentive Program is optional for states.

CMS sought public comment on a group reporting option that would allow a group to report measures for their EPs as a whole rather than broken out by individual EPs, but noted that additional policy development is needed before moving forward.

Public Health Reporting. For purposes of the public health measures, CMS expects that public health agencies will provide written communication (either paper or electronic) that hospitals and EPs did submit relevant public health data as required for meaningful use. These communications could then be used for attestation and in the event of an audit.

Audits. Under Stage 2, hospitals, CAHs and EPs must continue to keep documentation supporting their demonstration of meaningful use and use of a certified EHR for six years. CMS already conducts meaningful use audits for all hospitals that are eligible for Medicare incentives (regardless of their eligibility for Medicaid incentives). In the final rule, CMS confirmed that it will conduct audits of meaningful use

designation for approximately 150 hospitals that are eligible for only Medicaid incentives. States will remain responsible for auditing all other aspects of Medicaid incentives for hospitals. States also will be responsible for auditing all aspects of the Medicaid EHR Incentive Program for EPs.

Appeals. CMS had proposed new appeals processes for certain aspects of the program (eligibility, meaningful use and incentive payment). The agency concluded, however, that appeals are primarily procedural and do not need to be specified in regulation. CMS intends to issue guidance regarding types or categories of appeals and accompanying requirements at www.cms.gov/EHRIncentivePrograms. CMS also notes that there will not be reconsiderations of hardship exception or penalty determinations.

Impact Analysis. CMS revised its estimates upward and expects total incentive payments of $15.4 billion between 2014 to FY 2019. Of that, CMS estimates that hospitals should receive between $6.3 billion in Medicare and Medicaid incentives, net of penalties. CMS notes that these projections "are still very uncertain and actual future outcomes are likely to differ somewhat from these projections."

ONC RULE ON STANDARDS, CERTIFICATION CRITERIA AND IMPLEMENTATION SPECIFICATIONS

While the CMS rule governs requirements for providers to meet Stage 2 of meaningful use, the ONC rule includes the requirements for EHR developers (including vendors and hospitals with self-developed systems) that want to certify their EHR technology to support hospitals and EPs working to meeting meaningful use.

In the rule, ONC modified its definition of certified EHRs and puts forward a set of certification criteria, standards and implementation specifications that, for the most part, follow the Stage 2 meaningful use objectives laid out by CMS. However, the rule also includes several additional requirements, such as data export capabilities and specific capabilities to protect the privacy and security of health information.

This advisory does not fully address all of the technical material presented by ONC, but focuses on the issues that are most important to providers. Most importantly, CMS requires providers to "use the capability and standards" required for certification to achieve meaningful use. Beyond that overarching link, this advisory focuses on:

- the timing of certification;
- the definition of certified EHR technology; and
- the vocabulary, transport and other data standards that providers will need to use as part of meaningful use.

Hospitals and other providers in need of additional information, such as those seeking to certify self-developed EHR technology, should consult the final rule (www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-21050.pdf).

Timing of Certification

ONC finalized its proposal to tie certification of EHRs to a year, rather than to a stage of meaningful use. In particular, ONC refers to the current certification that supports Stage 1 of meaningful use as the "2011 Edition." The new certification is called the "2014 Edition." **The AHA is disappointed by this decision, which will lead to unnecessary upgrades and increased pressure on an already stressed health IT market.**

Under this approach, all providers must use EHRs certified to the new criteria in 2014, regardless of their stage of meaningful use (FY 2014 for hospitals; CY 2014 for EPs). For example, hospitals that first meet meaningful use Stage 1 in FY 2013 using the "2011 Edition" would need to upgrade to the "2014 Edition" in FY 2014, and meet the modified Stage 1 criteria described earlier. They will then need to complete the work needed to achieve Stage 2 in FY 2015. Providers are allowed to use EHRs certified to the "equivalent" 2014 Edition criteria before 2014 (FY for hospitals; CY for EPs), although it is unclear whether any will be available much before the start of FY 2014. ONC defines "equivalent" as capabilities at least equal to those previously adopted under the 2011 Edition rules.

Definition of Certified EHR Technology

In response to requests from the AHA and others, ONC changed its definition of "certified EHR technology" in a way that requires hospitals and EPs to have EHR technology to support only the objectives they use to achieve their stage of meaningful use. Today, providers must "possess" EHRs certified against all objectives, including those they have chosen to defer, or to which they qualify for an exclusion. The new definition will be effective in 2014 and does not apply to current EHR installations.

The new definition builds on the concept of a "Base EHR." Beginning in 2014, providers are required to have certified EHR technology to support all of the Base EHR capabilities, plus all core and menu set objectives the provider is using to achieve meaningful use. Providers will not be required to have certified EHR technology for objectives they choose to defer, or for which they qualify for an exclusion. A hospital may choose to defer three of the six items in the menu set, and may qualify for up to seven exclusions.

Despite the introduction of the term "Base EHR," ONC will continue to certify EHR products as either a complete EHR or an EHR module, as currently defined. Providers who choose to combine multiple EHR modules are responsible for ensuring that the modules work together and that, together, they meet all of the necessary certification criteria. Providers will continue to attest to using certified EHR technology to demonstrate meaningful use under the Medicare and Medicaid EHR Incentive Programs.

ONC made modifications to the specific elements it proposed to satisfy the Base EHR definition, including removal of three certification criteria (drug-drug, drug-allergy interaction check; vital signs; and view, download, transmit to a third party) and the addition of a data portability certification criterion (see Table 7).

Table 7: Final Capabilities of a Base EHR

Base EHR Capabilities	Certification Criteria (with regulatory reference)
Includes patient demographic and clinical health information, such as medical history and problem lists	Demographics § 170.314(a)(3) Problem List § 170.314(a)(5) Medication List § 170.314(a)(6) Medication Allergy List § 170.314(a)(7)
Has the capacity to provide clinical decision support	Clinical Decision Support § 170.314(a)(8)
Has the capacity to support physician order entry	Computerized Provider Order Entry § 170.314(a)(1)
Has the capacity to capture and query information relevant to health care quality	Clinical Quality Measures § 170.314(c)(1) through (3)
Has the capacity to exchange electronic health information with, and integrate such information from, other sources	Transitions of Care § 170.314(b)(1) and (2) Data Portability § 170.314(b)(7)
Has the capacity to protect the confidentiality, integrity, and availability of health information stored and exchanged	Privacy and Security § 170.314(d)(1) through (8)

Certification Criteria

The final rule includes 49 certification criteria, some of which are unchanged from previously finalized regulations. The certification criteria are organized into seven sections by type of function:

- clinical functions;
- care coordination functions;
- clinical quality measure functions;
- privacy and security functions;
- patient engagement;
- public health; and
- utilization.

The certification criteria to support the meaningful use objectives are included within the first six categories. The “utilization” category refers to other aspects of the EHR, including support for automated calculation of meaningful use measures and requirements to support safety-enhanced design.

Appendix A lists the final certification criteria applicable for meaningful use Stage 2 objectives and measures, by function. The certification criteria incorporate specific standards and implementation specifications through regulatory reference, some of which are described below. Please consult the final rule to analyze all of the proposed standards and implementation specifications.

Certification Requirements for CQMs. ONC finalized inclusion of the capacity to generate CQMs in the Base EHR, and clarified in the final rule the Base EHR must include certification to no fewer than the minimum number of CQMs that a provider must report. Note, however, that the Base EHR definition applies to the technology that a provider must have, and not certification requirements on the vendor. The finalized certification criteria for vendors require EHRs to be certified only for "each and every quality measure brought forward for certification." ONC does **not** require that certified EHRs be capable of generating all of the relevant CQMs finalized by CMS. The agency states: "We acknowledge that EHR technology developers get to choose the CQMs to which their EHR technology is certified and that those CQMs may not necessarily meet the needs of every EP, EH, or CAH." By contrast, CMS allows only CQMs calculated by certified EHR technology to count for meeting the meaningful use requirements for providers. **The AHA is disappointed in this policy and remains concerned that this limited certification requirement will result in EHRs that cannot report the full set of quality measures for providers, effectively limiting their ability to choose which measures to report.** This approach also could affect how EHR vendors market and price their CQM capabilities.

All EHRs certified to report the CQMs would need to be able to:

- Capture all of the data elements required to calculate CQMs, specifically the data elements specified in the Data Element Catalog, the repository of the data elements required for each individual CQM, and the supplemental data elements required for CQM data submission to CMS;
- Electronically incorporate all of the data elements necessary to calculate each of the CQMs that are included in the EHR technology (vendor choice);
- Electronically and correctly calculate each CQM that is included in the EHR technology (vendor choice); and
- Enable a user to electronically create for transmission CQM results in two different standard formats – QRDA category I and QRDA category III.

In the proposed rule, ONC sought comment on five approaches to data capture to address the gap between the quality data model definition of data and the EHR's capacity to capture data. The approaches ranged from a CQM-by-CQM data capture (capture data elements within each CQM) to a complete list of all unique data elements that would be required for data capture in order to calculate all CQMs. ONC's selection of the CQM-by-CQM data capture approach does not state why the Data Element Catalog repository was selected, how it was developed and how it will be managed in the future. Transparency and participation by all providers in the selection of the data elements included in the repository will be needed to ensure that the data elements actually provide a foundation for accurate and reliable CQMs.

Privacy and Security. ONC finalized nine privacy and security certification criteria, of which five are essentially unchanged from the proposed rule. One of these unchanged criteria, the criterion for accounting of disclosures, will continue to be *optional* in Stage 2. As ONC states, we "believe that alignment with an 'accounting of disclosures' final rule will provide the most certainty and useful functionality . . . while also mitigating any EHR technology development and implementation burdens that may accrue through compliance with potential multiple adopted versions of this certification criterion." ONC will wait for the final rule to be issued by the HHS' Office for Civil Rights before making any revisions to the meaningful use certification criterion for accounting of disclosures.

Additional criteria were finalized with specific differences from the proposed rule, including a criterion related to amendment of information in the CERHT; combined requirements for auditable events and audit reporting; and encryption. ONC included the certification criterion for amendment as part of the final Stage 2 rule to support HIPAA-covered entities' compliance with the existing privacy rule obligations relating to patients' requests to amend their protected health information. However, as ONC points out, there is no objective in the final CMS meaningful use rule expressly requiring the use of this capability, and hospitals and EPs do not need to demonstrate use of this capability in order to meet any meaningful use stage. ONC nevertheless "encourage[s] EPs, EHs, and CAHs to consider if this capability could make compliance with the requirements of the HIPAA Privacy Rule, particularly, 45 CFR § 164.526, more efficient."

Reporting Meaningful Use Measures. Certification requires EHRs to have the capacity to calculate the measures for all objectives they include. ONC finalized its proposal to add a more limited certification criterion to electronically record the numerator for each meaningful use objective with a percentage-based measure. This criterion would be applicable to EHR modules that might not have access to an accurate denominator. ONC did not finalize its proposal to add a new certification criterion that would address non-percentage-based measures, such as those that require providers to "implement" or "enable" a function due to comments regarding the complexities involved in creating those measures and implementing them in environments that use multiple systems.

Safety-enhanced Design. The 2014 standards rule includes certification criteria to introduce improvements in EHR technology design and safety, beginning with a focus on user-centered design (UCD). To demonstrate compliance with certification criteria, UCD must be applied to each capability of an EHR technology that is associated with the eight certification criteria, namely:

- CPOE;
- drug-drug and drug-allergy interaction checks;
- medication list;
- medication allergy list;
- clinical decision support;
- electronic medication administration record (eMAR);
- electronic prescribing; and

- clinical information reconciliation.

Also, the UCD certification criterion is only applicable where certification is sought for a capability. An EHR module is not required to be certified for every capability contained therein. ONC states that the certification criterion is a first step toward formal usability testing becoming part of the culture of EHR technology development, and clarified that, at a minimum, only lab-based summative testing will be necessary to be performed. ONC also noted, however, that nothing precludes field-testing and formative testing and encouraged EHR developers to do so. The AHA supported this set of proposed criteria as a good first step in shedding light on the usability and safety of certified EHR technology, and encouraged HHS to increase efforts across the department to develop and disseminate best practices in safe deployment and use of EHRs.

ONC was unable to publish the quality management document referenced in the Proposed Rule for 2014 standards and did not include an explicit requirement to use a specific quality management system (QMS) in the final rule. However, the 2014 edition of standards final rule includes a general QMS certification criterion intended to express that, for each capability included in EHR technology, and for which that capability's certification is sought, the use of a QMS in the development, testing, implementation and maintenance of that capability is identified. Any QMS may be used to meet the certification criterion. Also permitted is a designation that no QMS was used for a capability for which certification is requested.

ONC did not finalize its proposed certification criterion for reporting patient safety events according to the Agency for Healthcare Research and Quality (AHRQ) Common Formats.

Standards and Implementation Specifications

ONC finalized specific standards that fall into five categories:

- Transport standards, used to send data between parties;
- Functional standards, used for attributes such as accessibility of websites, retrieval of reference information, and the NQF quality data model;
- Content exchange standards, used to share clinical information such as clinical summaries and prescriptions;
- Vocabulary standards/code sets, including standardized nomenclatures, terminology, and code sets used to describe clinical problems and procedures, lab test results, medications, immunizations, and race and ethnicity; and
- Security Standards, such as encryption and decryption, access control and transmission security.

In some cases, ONC also finalized an "implementation specification" related to a specific standard. ONC defines implementation specifications as "specific requirements or instructions for implementing a standard." ONC defines a standard as "a technical, functional, or performance-based rule, condition, requirement, or specification that stipulates instructions, fields, codes data, materials, or actions."

These standards relate to meaningful use because, in some instances, the CMS meaningful use rule requires use of specific standards in order to be a meaningful user. The certification criteria require that vendor systems be able to support the standards, but hospitals and other providers will have to ensure that data are collected or shared in standardized formats. Examples of ONC-proposed standards that are incorporated into meaningful use objectives are described below. The full set of standards finalized by ONC is included in the rule (www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf).

Demographic Data. Recording of demographic data will require use of two separate standards:

- OMB Race and Ethnicity Categories listed in OMB Directive Number 15 – unchanged (these categories are explained in the recently-updated AHA/HRET Disparities Toolkit available at http://www.hretdisparities.org/); and
- Preferred language – new. ONC finalized use of an ISO standard 639-1:2002 to record patients' preferred language. This international standard contains more than 100 two-letter codes to represent languages spoken around the world.

Problem Lists. ONC finalized its proposal to require that structured problem lists incorporate only SNOMED-CT as a standard for problem lists beginning in FY 2014 for hospitals and CY 2014 for physicians. Therefore, hospitals and physicians will be required to use two different code sets for patient problems/diagnoses in their clinical record (SNOMED-CT) and their billing systems (ICD-10). **The AHA is concerned that given the challenges facing providers in moving to ICD-10, introducing a second mandatory standard for problem lists will carry significant additional burden to implement and create possible confusion for physicians asked to learn two new coding systems for the same type of information.**

Patient Portal. Beginning in FY 2014, CMS requires that hospitals provide patients the ability to view online, download and transmit information about a hospital admission within 36 hours of discharge. This requirement includes more than 20 types of information. The certification criteria speak to these data elements, as well as a patient-accessible audit log that provides information on who has used the portal, including the electronic health information affected by the action(s), and the date and time each action occurs.

To support this objective, certified EHRs will need to support the following standards, which hospitals would need to use to ensure that their portal is accessible; structure a summary document that can be both downloaded in "human readable form" and in an electronic document called a consolidated Clinical Document Architecture (CDA); format data elements as specified; and transmit data, including the CDA, to a party identified by the patient using specified exchange standards:

- 170.204(a) – Web Content Accessibility Guidelines (WCAG) 2.0, Level AA Conformance to ensure that the web portal is accessible to those with disabilities;

- § 170.205(a)(3) – HL7 Implementation Guide for CDA ® Release 2: IHE Health Story Consolidation as a content exchange standard for a clinical summary document;
- § 170.207(f) – OMB standards for the classification of federal data on race and ethnicity;
- § 170.207(g) – ISO 639-2 alpha-3 codes (limited) for recording preferred language;
- § 170.207(h) – smoking status types using SNOMED codes;
- § 170.207(a)(3) – IHTSDO SNOMED-CT® International Release July 2012 and US Extension to SNOMED-CT ® March 2012 Release for problem lists;
- § 170.207(i) – ICD-10-CM for encounter diagnoses;
- § 170.207(a)(2) – HCPCS and § 107.207(b)(2) CPT-4 or § 170.207(b)(3) - ICD-10-PCS for procedures;
- § 170.207(c)(2) – LOINC version 2.38 for laboratory results;
- § 170.207(d)(2) – RxNorm for medications;
- § 170.202(a) – ONC Applicability Statement for Secure Health Transport;
- §170.210(g) – synchronized clocks to create date and time stamps; and
- § 170.207(d)(2) – RxNorm for medication allergies.

Summary of Care Record. Like the patient portal, providing an electronic summary of care record on referrals and transitions of care incorporates a number of specific standards for how the data are coded (vocabulary standards), structured for exchange (content exchange standards) and transmitted (transport standard). While data do not need to be collected using these standards, they must be in these formats for exchange. This will require significant mapping of the data to these standards. The finalized vocabulary and context exchange standards are similar to those in the patient portal. In a change from the proposed rule, ONC finalized a single required transport standard (the Applicability Statement for Secure Health Transport) and outlined two optional certification approaches detailed in the rule.

Other Changes

Gap Certification. ONC finalized its proposal that EHR products would need to be re-certified only for those criteria that changed between the 2011 Edition and the 2014 Edition. ONC terms this “gap certification,” and identified the unchanged criteria in Table 3 of the final rule. The AHA believes gap certification will increase efficiency and limit upgrades to those functions that have changes due to regulatory changes.

Price Transparency. ONC sought comment on the value and feasibility of requiring certification bodies to ensure that EHR technology developers include clear pricing of the full cost of their certified products on their websites and in all marketing materials, communications, statements and other materials. While acknowledging the challenges raised by vendors, ONC finalized a certification requirement that brings a small amount of transparency to EHR pricing. Specifically, developers must notify hospitals and EPs of additional types of costs (not actual dollar amounts) that they would have to pay to implement their certified product. These are costs above the purchase price to acquire or upgrade EHR technology, such as monthly service fees or one-time or ongoing

interface development and configuration fees. As requested by the AHA, this requirement does not apply to hospitals or other providers that self-develop products that they do not market or sell.

Data Portability. ONC sought comment on whether the agency should adopt a certification criterion that focuses on the portability of data stored within certified EHR technology. After considering comments, the agency finalized a new data portability requirement that is part of the "Base EHR" definition. It requires vendors to enable a user to electronically create a set of care summaries for all patients that includes the most current clinical information about each patient, in the format required for transitions of care. The criterion outlines numerous data elements that must be included (see Appendix A for details). ONC notes that this is a starting point for data portability requirements.

NEXT STEPS

The AHA will continue to work with ONC and CMS to smooth implementation of the Medicare and Medicaid incentive programs. Both agencies have tip sheets and other materials on their websites at: http://www.healthit.gov/policy-researchers-implementers/meaningful-use-stage-2-0 and http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Stage_2.html.

Please share this advisory with your senior management team and ask your chief information officer (CIO) and clinical leaders to evaluate the requirements for Stage 2 in light of your current EHR implementation. Quality teams should review the quality reporting requirements, while medical records teams should evaluate the required vocabulary and other data standards (including race and ethnicity, preferred language, problem lists and smoking status). Your privacy and security staff also should review those portions of the rule. If you have not already done so, you or your CIO should discuss with your EHR vendors the products they intend to certify. Ask specifically about certification of the CQMs and your place in their implementation queue. Assess your need to supplement with additional certified EHR modules or self-certification to ensure that your system has been fully certified.

Member Calls. The AHA is hosting two member calls to review the final rules for hospital leaders and hospitals supporting physicians:

- Wednesday, October 17 from 3:00 to 4:30 p.m. ET – Hospitals
- Wednesday, October 24 from 3:00 to 4:30 p.m. ET – Physicians

AHA members can register for either of these calls at: http://www.surveymonkey.com/s/B2RYP5W.

Other Educational Materials. Members also can access a recording of a webinar with CMS staff at: www.aha.org/stage2webinar.

Watch for more educational materials on the AHA's meaningful use website at http://www.aha.org/meaningfuluse.

If you have questions, please contact Chantal Worzala, director of policy, at (202) 626-2313 or cworzala@aha.org.

Appendix A: Final 2014 Edition Certification Criteria

CLINICAL
A Complete EHR or EHR Module must include the capability to:
§170.314(a) Clinical
1. Computerized Provider Order Entry (CPOE) Enable a user to electronically record, change, and access the following order types, at a minimum: (i) Medications, (ii) Laboratory, and (iii) Radiology/imaging.
2. Drug-Drug, Drug-Allergy Interaction Checks (i) INTERVENTIONS. Before a medication order is completed and acted upon during CPOE, interventions must automatically and electronically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list. (ii) ADJUSTMENTS. (A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted. (B) Limit the ability to adjust severity levels to an identified set of users or available as a system administrative function.
3. Demographics (i) Enable a user to electronically record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth. (A) Enable race and ethnicity to be recorded in accordance with the OMB race and ethnicity vocabulary standard, specified in §170.207(f), and whether a patient declines to specify race and/or ethnicity. (B) Enable preferred language to be recorded in accordance with the ISO 639-2 alpha-3 codes vocabulary standard, specified in §170.207(g), and whether a patient declines to specify a preferred language. (ii) ***Inpatient setting only***. Enable a user to electronically record, change, and access preliminary cause of death in the event of a mortality.
4. Vital Signs, Body Mass Index, and Growth Charts (i) VITAL SIGNS. Enable a user to electronically record, change and access, at a minimum, a patient's height/length, weight, and blood pressure. Height/length, weight, and blood pressure must be recorded in numerical values only. (ii) CALCULATE BODY MASS INDEX. Automatically calculate and electronically display body mass index based on a patient's height and weight. (iii) ***Optional****:* PLOT AND DISPLAY GROWTH CHARTS. Plot and electronically display, upon request, growth charts for patients.
5. Problem List Enable a user to electronically record, change, and access a patient's problem list: (i) ***Ambulatory setting only:*** Over multiple encounters in accordance with, at a minimum, the version of the IHTSDO SNOMED CT® vocabulary standard, specified in §170.207(a)(3); or (ii) ***Inpatient setting only:*** For the duration of an entire hospitalization in accordance with, at a minimum, the version of the IHTSDO SNOMED CT® vocabulary standard, specified in §170.207(a)(3).
6. Medication List Enable a user to electronically record, change, and access a patient's active medication list as well as medication history: (i) ***Ambulatory setting***. Over multiple encounters; or (ii) ***Inpatient setting***. For the duration of an entire hospitalization.
7. Medication Allergy List Enable a user to electronically record, change, and access a patient's active medication allergy list as well as medication allergy: (i) ***Ambulatory setting***. Over multiple encounters; or (ii) ***Inpatient setting***. For the duration of an entire hospitalization.

8. Clinical Decision Support

(i) EVIDENCE-BASED DECISION SUPPORT INTERVENTIONS. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on the data elements included in each one or at least one combination of the following data: (A) Problem list; (B) Medication list; (C) Medication allergy list; (D) Demographics; (E) Laboratory tests and values/results; and (F) Vital signs.

(ii) LINKED REFERENTIAL CLINICAL DECISION SUPPORT

(A) EHR technology must be able to:

(1) Electronically identify for a user diagnostic and therapeutic reference information; or

(2) Electronically identify for a user diagnostic and therapeutic reference information in accordance with the Infobutton functional standard, and relevant implementation specification, specified at §170.204(b).

(B) For paragraph (A) above, EHR technology must be able to electronically identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the following data: (1) Problem list; (2) Medication list; (3) Medication allergy list; (4) Demographics; (5) Laboratory tests and values/results; and (6) Vital signs.

(iii) CONFIGURE CLINICAL DECISION SUPPORT.

(A) Enable interventions and reference resources specified in clauses (i) and (ii) immediately above to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.

(B) EHR technology must enable interventions to be electronically triggered:

(1) Based on the data elements specified in clause (i) immediately above.

(2) When a patient's medications, medication allergies, and problems are incorporated from a transition of care/referral summary received pursuant to transitions of care certification criteria. See §170.314 (b)(1)(iii) below.

(3) ***Ambulatory setting only***. When a patient's laboratory tests and values/results are incorporated pursuant to care coordination criterion for incorporating laboratory tests and values/results. See §170.314 (b)(5)(i)(A)(1) below.

(iv) AUTOMATICALLY AND ELECTRONICALLY INTERACT. Interventions triggered in accordance with clauses (i) through (iii) immediately above must automatically and electronically occur when a user is interacting with EHR technology.

(v) SOURCE ATTRIBUTES Enable a user to review the attributes as indicated for all clinical decision support resources:

(A) For evidence-based decision support interventions under clause (i) above:

(1) Bibliographic citation of the intervention (clinical research/guideline);

(2) Developer of the intervention (translation from clinical research/guideline);

(3) Funding source of the intervention development technical implementation; and

(4) Release and, if applicable, revision date(s) of the intervention or reference source.

(B) For linked referential clinical decision support in clause (ii) above and drug-drug, drug-allergy interaction checks in 170.314(a)(2), the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

9. Electronic Notes

Enable a user to electronically record, change, access, and search electronic notes.

10. Drug-Formulary Checks

EHR technology must automatically and electronically check whether a drug formulary (or preferred drug list) exists for a given patient and medication.

11. Smoking Status

Enable a user to electronically record, change, and access the smoking status of a patient in accordance with the vocabulary standard specified at §170.207(h) which lists SNOMED CT® codes for the following smoking status types: (i) current every day smoker; (ii) current some day

smoker; (iii) former smoker; (iv) never smoker; (v) smoker, current status unknown; (vi) unknown if ever smoked; (vii) heavy tobacco smoker; and (viii) light tobacco smoker.

12. Imaging

Electronically indicate to a user the availability of a patient's images and narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable electronic access to such images and narrative interpretations.

13. Family Health History

Enable a user to electronically record, change, and access a patient's family health history according to:
(i) at a minimum, the version of the SNOMED CT® vocabulary standard, specified in §170.207(a)(3); **or**
(ii) the HL7 Pedigree standard, specified in §170.207(j)

14. Patient List Creation

Enable a user to electronically and dynamically select, sort, access, and create patient lists by: date and time; and based on each one and at least one combination of the following data: (i) Problems, (ii) Medications, (iii) Medication allergies, (iv) Demographics, (v) Laboratory tests and values/results; and ***ambulatory setting only:*** (vi) Patient communication preferences.

15. Patient-Specific Education Resources

EHR technology must be able to electronically identify for a user patient-specific education resources based on data included in the patient's problem list, medication list, and laboratory tests and values/results:
(i) The Infobutton functional standard, and one of the implementation specifications, specified at §170.204(b); and
(ii) By any means (other than the Infobutton standard immediately above).

Inpatient setting only

16. Electronic Medication Administration Record (eMAR)

(i) In combination with an assistive technology that provides automated information on the five "rights" specified in (A) through (E) immediately below, enable a user to electronically verify the following before administering medication(s):

(A) Right patient. The patient to whom the medication is to be administered matches the medication to be administered.
(B) Right medication. The medication to be administered matches the medication ordered for the patient.
(C) Right dose. The dose of the medication to be administered matches the dose of the medication ordered for the patient.
(D) Right route. The route of medication delivery matches the route specified in the medication order.
(E) Right time. The time that the medication was ordered to be administered compared to the current time.

(ii) Right documentation. Electronically record the time and date in accordance with the protection standard for synchronized clocks specified in §170.210(g), and user identification when a medication is administered.

Inpatient setting only

17. Advance Directives

Enable a user to electronically record whether a patient has an advance directive.

CARE COORDINATION

1. Transitions of Care – Receive, Display, and Incorporate Transition of Care/Referral Summaries

(i) RECEIVE. EHR technology must be able to electronically receive transition of care/referral summaries in accordance with:

(A) The transport standard specified in §170.202(a).
(B) *Optional*. The transport standards specified in §170.202(a) and (b).
(C) *Optional*. The transport standards specified in §170.202(b) and (c).

(ii) DISPLAY. EHR technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following content exchange standards (and applicable implementation specifications) specified in: §170.205(a)(1), §170.205(a)(2), and §170.205(a)(3).

(iii) INCORPORATE. Upon receipt of a transition of care/referral summary formatted according to the content exchange standard adopted at §170.205(a)(3), EHR technology must be able to:

(A) Correct patient. Demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.
(B) Data incorporation. Electronically incorporate the following data expressed according to the specified vocabulary standard(s):
(1) Medications. At a minimum, the version of the standard specified in §170.207(d)(2);
(2) Problems. At a minimum, the version of the standard specified in §170.207(a)(3); and
(3) Medication allergies. At a minimum, the version of the standard specified in §170.207(d)(2).
(C) Section views. Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the content exchange standard adopted at § 170.205(a)(3).

2. Transitions of Care – Create and Transmit Transition of Care/Referral Summaries

(i) CREATE. Enable a user to electronically create a transition of care/referral summary formatted according to the content exchange standard at §170.205(a)(3) that includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(A) Encounter diagnoses. The vocabulary standard specified in §170.207(i) or, at a minimum, the version of the standard specified in §170.207(a)(3);
(B) Immunizations. The vocabulary standard specified in §170.207(e)(2);
(C) Cognitive status;
(D) Functional status;
(E) ***Ambulatory setting only***: The reason for the referral; and the referring or transitioning provider's name and office contact information.
(F) ***Inpatient setting only***: Discharge instructions.

(ii) TRANSMIT. Enable a user to electronically transmit the transition of care/referral summary created in clause (i) above in accordance with:

(A) The transport standard specified in § 170.202(a).
(B) *Optional*. The transport standards specified in § 170.202(a) and (b).
(C) *Optional*. The transport standards specified in § 170.202(b) and (c).

3. Electronic Prescribing

Enable a user to electronically create prescriptions and prescription-related information for electronic transmission in accordance with:
(i) The content exchange standard NCPDP SCRIPT, specified in §170.205(b)(2); and
(ii) At a minimum, the version of RxNorm vocabulary standard, specified in §170.207(d)(2).

4. Clinical Information Reconciliation

Enable a user to electronically reconcile the data that represent a patient's active medication, problem, and medication allergy list as follows. For each list type:
(i) Electronically and simultaneously display (i.e., in a single view) the data from at least two list

sources in a manner that allows a user to view the data and their attributes, which must include, at a minimum, the source and last modification date.

(ii) Enable a user to create a single reconciled list of medications, medication allergies, or problems.

(iii) Enable a user to review and validate the accuracy of a final set of data and, upon a user's confirmation, automatically update the list.

5. Incorporate Laboratory Tests and Values/Results

(i) RECEIVE RESULTS.

(A) ***Ambulatory setting only***:

(1) Electronically receive and incorporate clinical laboratory tests and values/results in accordance with the content exchange standard HL 7 2.5.1 Implementation Guide: S&I Framework Lab Results Interface specified in §170.205(j), and, at a minimum, LOINC® version 2.40 vocabulary standard, specified in §170.207(c)(2).

(2) Electronically display the tests and values/results received in human readable format.

(B) ***Inpatient setting only***:

Electronically receive clinical laboratory tests and values/results in a structured format and electronically display such tests and values/results in human readable format.

(ii) Electronically display all the information for a test report specified at 42 CFR 493.1291(c)(1) through (7):

(1) For positive patient identification, either the patient's name and ID number or a unique patient identifier and ID number. (2) The name and address of the laboratory location where the test was performed. (3) The test report date. (4) The test performed. (5) Specimen source, when appropriate. (6) The test result and, if applicable, the units of measurement or interpretation, or both. (7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

(iii) Electronically attribute, associate, or link a laboratory test and value/result with a laboratory order or patient record.

Inpatient setting only

6. Transmission of Electronic Laboratory Tests and Values/Results to Ambulatory Providers

EHR technology must be able to electronically create laboratory test reports for electronic transmission in accordance with:

(i) The content exchange standard HL 7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface specified in §170.205(j); and (ii) At a minimum, the LOINC® 2.40 vocabulary standard specified in §170.207(c)(2).

7. Data Portability

Enable a user to electronically create a set of export summaries for all patients in EHR technology formatted according to the content exchange standard adopted at § 170.205(a)(3) that represents the most current clinical information about each patient and includes, at a minimum, the Common MU Data Set and the following data expressed, where applicable, according to the specified standard(s):

(i) Encounter diagnoses. The vocabulary standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(3);

(ii) Immunizations. The vocabulary standard specified in § 170.207(e)(2);

(iii) Cognitive status;

(iv) Functional status; and

(v) ***Ambulatory setting only***: The reason for referral; and referring or transitioning provider's name and office contact information.

(vi) ***Inpatient setting only***: Discharge instructions.

CLINICAL QUALITY MEASURES

1. **Clinical Quality Measures – Capture and Export**

(i) CAPTURE. For each and every CQM for which the EHR technology is presented for certification, EHR technology must be able to electronically record all of the data identified in the functional standard specified in §170.204(c) (the Data Element Catalog) that would be necessary

to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of "patient reason," "system reason," or "medical reason."

(ii) EXPORT. EHR technology must be able to electronically export a data file formatted in accordance with the content exchange standards specified at §170.205(h) that includes all of the data captured for each and every CQM to which the EHR technology was certified under clause (i) above.

2. **Clinical Quality Measures – Import and Calculate**
(i) IMPORT. EHR technology must be able to electronically import a data file formatted in accordance with the content exchange standards specified at §170.205(h) and use such data to electronically calculate each and every CQM for which it is presented for certification, other than EHR technology presented for certification to all three CQM certification criteria adopted in paragraphs (c)(1) through (c)(3) of §170.314.
(ii) CALCULATE. EHR technology must be able to electronically calculate each and every CQM for which it is presented for certification.

3. **Clinical Quality Measures – Electronic Submission**
Enable a user to electronically create a data file for transmission of CQM data:
(i) In accordance with the content exchange standards specified at §170.205(h) and (k); and
(ii) That can be electronically accepted by CMS.

PRIVACY AND SECURITY

1. Authentication, Access Control, and Authorization
(i) Verify against a unique identifier(s) (e.g., username or number) that a person seeking access to electronic health information is the one claimed; and
(ii) Establish the type of access to electronic health information a user is permitted based on the unique identifier(s) provided in clause (i) above, and the actions the user is permitted to perform with the EHR technology.

2. Auditable Events and Tamper-Resistance
(i) RECORD ACTIONS. EHR technology must be able to:
(A) Record actions related to electronic health information in accordance with the protection standard specified in §170.210(e)(1);
(B) Record the audit log status (enabled or disabled) in accordance with the protection standard specified in §170.210(e)(2) unless it cannot be disabled by any user; and
(C) Record the encryption status (enabled or disabled) of electronic health information locally stored on end-user devices by EHR technology in accordance with the protection standard specified in §170.210(e)(3) unless the EHR technology prevents electronic health information from being locally stored on end-user devices (see (d)(7) below).

(ii) DEFAULT SETTING. EHR technology must be set by default to perform the capabilities:
(A) specified in clause (i)(A) above (record actions); and
(B) where applicable, specified in clause (i)(B) (record audit log status) or (i)(C) (record encryption status) , or both clauses (i)(B) and (i)(C).

(iii) WHEN DISABLING THE AUDIT LOG IS PERMITTED. For each capability specified in clauses (i)(A), (i)(B), and (i)(C) above, that EHR technology permits to be disabled, the ability to do so must be restricted to a limited set of identified users.

(iv) AUDIT LOG PROTECTION. Actions and statuses recorded in accordance with clause (i) above must not be capable of being changed, overwritten, or deleted by the EHR technology.

(v) DETECTION. EHR technology must be able to detect whether the audit log has been altered.

3. Audit Report(s)
Enable a user to create an audit report for a specific time period and to sort entries in the audit log according to each of the data specified in the protection standards at §170.210(e).

4. Amendments

Enable a user to electronically select the record affected by a patient's request for amendment and perform the capabilities specified in (i) **or** (ii) below:
(i) ACCEPTED AMENDMENT. For an accepted amendment, append the amendment to the affected record or include a link that indicates amendment's location.
(ii) DENIED AMENDMENT. For a denied amendment, at a minimum, append the request and denial of the request to the affected record or include a link that indicates this information's location.

5. Automatic Log-off
Prevent a user from gaining further access to an electronic session after a predetermined time of inactivity.

6. Emergency Access
Permit an identified set of users to access electronic health information during an emergency.

7. End-user Device Encryption
Clause (i) **or** (ii) below must be met to satisfy this certification criterion.
(i) EHR technology that is designed to locally store electronic health information on end-user devices must encrypt the electronic health information stored on such devices after use of EHR technology on those devices stops.
(A) Electronic health information that is stored must be encrypted in accordance with the protection standard specified in §170.210(a)(1).
(B) EHR technology must be set by default to perform this capability, and, unless this configuration cannot be disabled by any user, the ability to change the configuration must be restricted to a limited set of identified users.
(ii) EHR technology is designed to prevent electronic health information from being locally stored on end-user devices after use of EHR technology on those devices stops.

8. Integrity
(i) Create a message digest in accordance with the protection standard specified in §170.210(c).
(ii) Verify in accordance with the protection standard specified in §170.210(c) (i.e., a hashing algorithm with a security strength equal to or greater than SHA-1 as specified by NIST in FIPS PUB 180-3) upon receipt of electronically exchanged health information that such information has not been altered.

Optional

9. Accounting of Disclosures
Record disclosures made for treatment, payment, and health care operations in accordance with the protection standard specified in §170.210(d) (i.e., date, time, patient identification, user identification, and description of the disclosure must be recorded for disclosures for treatment, payment, and health care operations).

PATIENT ENGAGEMENT

1. View, Download, and Transmit to 3rd Party
(i) EHR technology must provide patients and their authorized representatives with an online means to view, download, and transmit to a 3rd party the data specified below. Access to these capabilities must be through a secure channel that ensures all content is encrypted and integrity-protected in accordance with NIST standard for encryption and hashing algorithms at §170.210(f):
(A) VIEW. Electronically view in accordance with the WCAG 2.0 functional standard adopted at §170.204(a), at a minimum, the following data elements:
(1) The Common MU Data Set (in their English (i.e., non-coded) representation if they associate with a vocabulary code set)
(2) ***Ambulatory setting only***. Provider's name and office contact information
(3) ***Inpatient setting only***. Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization
(B) DOWNLOAD.
(1) Electronically download an ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) in human readable format or formatted according to the CDA® content exchange standard adopted at §170.205(a)(3) that includes, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):
(i) ***Ambulatory setting only***. The Common MU Data Set, and the provider's name and

office contact information.
(ii) ***Inpatient setting only***. The Common MU Data Set; and the admission and discharge dates and locations, discharge instructions, and reason(s) for hospitalization.
(2) ***Inpatient setting only***. Electronically download transition of care/referral summaries created as a result of a transition of care (pursuant to capability expressed in certification criterion under 170.314(b)(2) described above).
(C) TRANSMIT TO THIRD PARTY.
(1) Electronically transmit the ambulatory summary or inpatient summary (as applicable to the EHR technology setting for which certification is requested) created in paragraph (e)(1)(i)(B)(1) above in accordance with the transport standard specified in §170.202(a) (i.e., ONC Applicability Statement for Secure Health Transport).
[new](2) ***Inpatient setting only***. Electronically transmit transition of care/referral summaries (as a result of a transition of care/referral) selected by the patient or authorized representative in accordance with the transport standard specified in §170.202(a).

(ii) Activity History Log

(A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) above, the following information must be recorded and made accessible to the patient:
(1) The action(s) [i.e., view, download, transmission] that occurred;
(2) The date and time each action occurs in accordance with the Synchronized Clocks protection standard specified at §170.210(g); and
(3) The user who took the action.
(B) EHR technology presented for certification may demonstrate compliance with (A) immediately above if it is also certified to the privacy and security certification criterion adopted at §170.314(d)(2) (Auditable events and tamper-resistance) and the information required to be recorded in (A) (immediately above) is accessible by the patient.

Ambulatory setting only

2. Clinical Summary

(i) CREATE. Enable a user to create a clinical summary for a patient in human readable format and formatted according to the content exchange standards adopted at §170.205(a)(3).
(ii) CUSTOMIZATION. Enable a user to customize the data included in the clinical summary.
(iii) MINIMUM DATA FROM WHICH TO SELECT. EHR technology must permit a user to select, at a minimum, the following data when creating a clinical summary:
(A) Common MU Data Set (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set).
(B) The provider's name and office contact information; date and location of visit; reason for visit; immunizations and/or medications administered during the visit; diagnostic tests pending; clinical instructions; future appointments; referrals to other providers; future scheduled tests; and recommended patient decision aids.

Ambulatory setting only

3. Secure Messaging

Enable a user to electronically send messages to, and receive messages from, a patient in a manner that ensures:
(i) Both the patient (or authorized representative) and EHR technology user are authenticated; and
(ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at §170.210(f) (i.e., any encryption and hashing algorithm identified by NIST as an approved security function in May 30, 2012 version of Annex A of FIPS Publication 140-2).

PUBLIC HEALTH

1. Immunization Information

Enable a user to electronically record, change, and access immunization information.

2. Transmission to Immunization Registries

EHR technology must be able to electronically create immunization information for electronic transmission in accordance with:
(i) The HL7 2.5.1 content exchange standard and the HL7 2.5.1 Implementation Guide for

Immunization Messaging Release 1.4, specified in §170.205(e)(3); and
(ii) At a minimum, the version of the HL7 Standard Code Set CVX-Vaccines Administered vocabulary standard specified in §170.207(e)(2).

3. Transmission to Public Health Agencies

EHR technology must be able to electronically create syndrome-based public health surveillance information for electronic transmission in accordance with:

(i) ***Ambulatory setting only***:

(A) The HL7 2.5.1 content exchange standard, specified in §170.205(d)(2).

(B) ***Optional***. The HL7 2.5.1 content exchange standard and implementation specifications specified in §170.205(d)(3) (i.e., the PHIN Messaging Guide for Syndromic Surveillance and Conformance Clarification).

(ii) ***Inpatient setting only***. The HL7 2.5.1 content exchange standard and implementation specifications specified in §170.205(d)(3) (described in clause (i)(B) immediately above).

Inpatient setting only

4. Transmission of Reportable Laboratory Tests and Values/Results

Enable a user to electronically create reportable laboratory tests and values/results for electronic transmission in accordance with:

(i) The HL7 2.5.1 content exchange standard and implementation specifications specified in §170.205(g) (i.e., the HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 1); and

(ii) At a minimum, the versions of the vocabulary standards IHTSDO SNOMED CT®, specified in §170.207(a)(3) and LOINC® version 2.40, specified in §170.207(c)(2).

Optional
Ambulatory setting only

5. Cancer Case Information

Enable a user to electronically record, change, and access cancer case information.

Optional
Ambulatory setting only

6. Transmission to Cancer Registries

EHR technology must be able to electronically create cancer case information for electronic transmission in accordance with:

(i) The HL7 CDA content exchange standard (and applicable implementation specifications) specified in §170.205(i); and

(ii) At a minimum, the versions of the vocabulary standards IHTSDO SNOMED CT®, specified in §170.207(a)(3) and LOINC® version 2.40, **s**pecified in §170.207(c)(2).

UTILIZATION

1. Automated Numerator Recording

For each meaningful use objective with a percentage-based measure, EHR technology must be able to create a report or file that enables a user to review the patients or actions that would make the patient or action eligible to be included in the measure's numerator. The information in the report or file created must be of sufficient detail such that it enables a user to match those patients or actions to meet the measure's denominator limitations when necessary to generate an accurate percentage.

2. Automated Measure Calculation

For each meaningful use objective with a percentage-based measure that is supported by a capability included in an EHR technology, electronically record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable meaningful use measure.

3. Safety-Enhanced Design

User-centered design (UCD) processes must be applied to each capability an EHR technology includes that is specified in the following certification criteria:

§170.314(a)(1): CPOE
§170.314(a)(2): Drug-drug, drug-allergy interaction checks
§170.314(a)(6): Medication list

	§170.314(a)(7): Medication allergy list §170.314(a)(8): Clinical decision support §170.314(a)(16): ***Inpatient setting only:*** Electronic medication administration record §170.314(b)(3): Electronic prescribing §170.314(b)(4): Clinical information reconciliation
4.	**Quality management system** For each capability that an EHR technology includes and for which that capability's certification is sought, the use of a Quality Management System (QMS) in the development, testing, implementation and maintenance of that capability must be identified. (i) If a single QMS was used for applicable capabilities, it would only need to be identified once. (ii) If different QMS were applied to specific capabilities, each QMS applied would need to be identified. This would include the application of a QMS to some capabilities and none to others. (iii) If no QMS was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.