American Hospital Association

Regulatory Advisory

November 3, 2015

Final Electronic Health Record Incentive Program Rules: Modifications 2015-2017, Stage 3 and 2015 Health IT Certification Criteria

At a Glance

At Issue:

The Centers for Medicare & Medicaid Services (CMS) on Oct. 16 published a final rule with comment for the Electronic Health Record (EHR) Incentive Program that makes modifications to meaningful use requirements in 2015 through 2017 and sets the start date for Stage 3 of the program as Jan. 1, 2018. Although this is a final rule, CMS seeks comment on the final policies for the Stage 3 objectives and measures and the EHR reporting period for Stage 3 in 2017 and subsequent years. Public comments received may be considered as CMS plans for the incorporation of meaningful use into implementation of the new physician payment models introduced by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and in future hospital payment rulemaking. The deadline for comments is 5:00 p.m. ET on Dec. 15.

At the same time, the Office of the National Coordinator (ONC) for Health Information Technology (IT) published a final rule for the 2015 Edition Health Information Technology Certification Criteria, 2015 Edition Base EHR Definition, and ONC Health IT Certification Program Modifications that sets certification criteria, standards and implementation specifications for EHR technology to support Stage 3, beginning in 2017.

This advisory contains highlights of both rules.

Our Take:

The AHA is pleased that CMS has released the long-awaited modification rule. Hospitals will have much-needed clarity to take steps to ensure they meet the revised requirements. However, the Stage 3 final rule is disappointing. It is simply too much too soon, as more than 60 percent of hospitals and about 90 percent of physicians have yet to attest to Stage 2.

What You Can Do:

- ✓ Share this advisory with your senior management team and ask your chief information officer and chief medical information officer to consider how the final rules affect your plans to move forward with meaningful use.
- ✓ Ask your quality staff to evaluate the policy finalizes for electronic quality reporting requirements.
- ✓ Make sure your IT and medical records departments review the final standards and certification criteria included in the ONC 2015 Edition certification rule.
- ✓ Consider submitting a comment letter to CMS using the instructions in this advisory.

Further Questions:

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FINAL ELECTRONIC HEALTH RECORD INCENTIVE PROGRAM RULES: MODIFICATIONS 2015-2017, STAGE 3 AND 2015 HEALTH IT CERTIFICATION CRITERIA

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BACKGROUND

The American Recovery and Reinvestment Act of 2009 (ARRA) authorized incentive payments to eligible hospitals (EHs), critical access hospitals (CAHs), eligible professionals (EPs) and Medicare Advantage (MA) organizations to promote the adoption and meaningful use of certified electronic health record (EHR) technology beginning in fiscal year (FY) 2011. To be eligible for the incentives and avoid payment penalties, EHs, CAHs and EPs must use EHRs certified through a process established by the Office of the National Coordinator (ONC) for Health Information Technology (IT).

The ARRA established three requirements for EHs, CAHs and EPs to qualify for the EHR Incentive Program:

- Use of certified EHR;
- Demonstration of meaningful use of the certified EHR; and
- Clinical quality reporting using the EHR.

FY 2016 is the last year for EHs and CAHs to receive incentive payments from Medicare. The Centers for Medicare & Medicaid Services (CMS) began phasing-in Medicare penalties for those failing to meet the requirements in FY 2015; the penalties do not sunset.

Stage 1 of meaningful use began in FY 2011 for EHs and CAHs. CMS created a phased approach to meaningful use, with Stage 1 requiring the use of the 2011 Edition certified EHR to meet an initial set of meaningful use requirements. In Stage 2, which began in FY 2014, CMS raised the bar on meaningful use requirements using the 2014 Edition certified EHR.

On March 30, CMS and ONC released two proposed rules that set the requirements and timelines for Stage 3 of meaningful use. CMS proposed that the Stage 3 definition of meaningful use would be the only definition of meaningful use for the EHR Incentive Program and would incorporate certain requirements and aspects of Stages 1 and 2. This meant that, for Stage 3, all providers would need to meet the same set of criteria for meaningful use, regardless of their level of participation in the program, thereby eliminating the varying phases of the EHR Incentive Program. The 2015 Edition certification criteria proposed by ONC would support providers in meeting Stage 3.

On April 15, CMS released a proposed rule to make modifications in 2015 through 2017 to the EHR Incentive Programs. The modifications rule advanced the concept that all EHs, CAHs and EPs would report on virtually the same objectives and measures beginning in 2015. The providers would continue to use their 2014 Edition certified EHR to meet the EHR Incentive Program modified requirements in 2015 through 2017.

This advisory summarizes key elements of the CMS and ONC final rules released Oct. 16, including:

- The timing and stages of meaningful use;
- The definition and requirements for demonstrating meaningful use in Stage 2 and Stage 3;
- Electronic clinical quality measure reporting policy for Stage 3;
- Medicaid-specific changes; and
- Changes to the certification criteria and standards requirements.

The final rules do not change the payment formulas or the timing of payments, which are established in statute and described in the August 2010 AHA advisory on the EHR Incentive Programs. This advisory does not include information on requirements for qualifying MA organizations.

In a multi-stakeholder meeting following the release of the meaningful use rule, CMS signaled that it is important for stakeholders to comment on certain provisions in the final rule that would support the transition to the Merit-Based Incentive Payment System (MIPS) that incorporates meaningful use and indicated that changes to hospital requirements could come through hospital payment rulemaking. Areas for comment include the:

- definition of the EHR reporting period in 2017 and subsequent years;
- objectives and measures for Stage 3 of the EHR Incentive Program;
- methods for demonstrating Stage 3 criteria of meaningful use for 2017 and subsequent years; and
- EHR reporting period and EHR reporting period for a payment adjustment year for first time meaningful users in Medicaid.

Additional information on the Medicare and Medicaid EHR Incentive Programs can be found at: http://www.aha.org/advocacy-issues/hit/meaningfuluse.shtml.

MODIFICATIONS TO MEANINGFUL USE IN 2015 TO 2017

Reporting Period

CMS finalizes a 90-day reporting period for all providers in 2015, as proposed. **The AHA has long advocated for this shorter reporting period and appreciates this change.** CMS also finalizes a change to the reporting period for EHs and CAHs from the fiscal year to the calendar year, aligning it with the reporting period for physicians and other EPs. The reporting periods are as follows:

- For 2015 only, CAHs and EHs will report on any continuous 90-day period between Oct. 1, 2014 and Dec. 31, 2015. EPs will report on any continuous 90-day period between Jan. 1 and Dec. 31, 2015.

- The reporting period will be a full calendar year in later years for those continuing their participation in the program, except for those providers that choose to attest to Stage 3 in 2017. They will have a 90-day reporting period.
- For new Medicare participants, CMS will allow a 90-day reporting period in 2016 and 2017, as recommended by the AHA. In 2018 and later, the reporting period will be a full calendar year for new participants.
- New Medicaid participants will continue to have a 90-day reporting period.

Attestation Deadlines

Because of the move to a calendar year reporting period for hospitals, CMS finalizes an attestation window of Jan. 4 to Feb. 29, 2016. The AHA had recommended that CMS begin attestation no later than Aug. 1, 2015. We remain concerned that this change will delay incentive payments for hospitals and could cause financial challenges. The agency notes that any CAH or EH that took advantage of an opportunity for first-time participants to attest in July and August of this year does not need to re-attest.

Timing of Stages

Under previous requirements, all providers entered the meaningful use program at Stage 1 and reported on Stage 1 requirements for at least two years before moving on to Stage 2. In this rule, CMS finalizes its proposal to require all providers to meet Stage 2 requirements in 2015, regardless of their history of previous participation in the program. As discussed further below, CMS also finalizes its proposal to give limited flexibility to providers meant to be at Stage 1 in 2015 under current rules. As recommended by the AHA, the agency extended some, but not all, of those flexibilities into 2016. In 2017 and later, however, CMS will require all providers to meet the same requirements, regardless of when they first enter the program. Table 1 summarizes the timing of stages.

Table 1. Stage of Meaningful Use Criteria by First Year of Hospital Program Participation

First Year as a meaningful user of certified EHR	Stage of Meaningful Use							
	FY 2011	FY 2012	FY 2013	FY 2014	FY/CY 2015	CY 2016	CY 2017	CY 2018
2011	1	1	1	2	Modified 2	Modified 2	Modified 2 or 3	3
2012		1	1	2	Modified 2	Modified 2	Modified 2 or 3	3
2013			1	1	Modified 2	Modified 2	Modified 2 or 3	3

First Year as a meaningful user of certified EHR	Stage of Meaningful Use							
	FY 2011	FY 2012	FY 2013	FY 2014	FY/CY 2015	CY 2016	CY 2017	CY 2018
2014				1	**Modified 2 with exceptions**	**Modified 2**	**Modified 2 or 3**	**3**
2015					**Modified 2 with exceptions**	**Modified 2 with exceptions**	**Modified 2 or 3**	**3**
2016						**Modified 2 with exceptions**	**Modified 2 or 3**	**3**
2017							**Modified 2 or 3**	**3**
2018 and thereafter								**3**

Note: *Items in bold denote places where the rule accelerates requirements on late entrants to the program. CMS states that a provider scheduled to participate in Stage 2 in the 2014 reporting period, who instead elected to demonstrate Stage 1 because of delays in availability of EHR technology certified to the 2014 Edition, is still considered a Stage 2 provider in 2014. In 2015, all such providers are considered to be participating in their second year of Stage 2.*

Modified Stage 2 Meaningful Use Requirements for Hospitals

CMS finalizes numerous changes to the meaningful use requirements with the intent to streamline the program and better align it with Stage 3. This section outlines the changes to the definition of meaningful use for CAHs and EHs. Items of particular interest to hospitals, such as the e-prescribing, health information exchange, patient portal, summary of care and public health reporting requirements are discussed in more detail. Table 2 lists all of the objectives and measures.

Modified Stage 2 Objectives. CMS finalizes its proposal that all EHs and CAHs report on the same nine objectives of meaningful use:

- Protect Patient Health Information
- Clinical Decision Support (CDS)
- Computerized Provider Order Entry (CPOE)
- Electronic Prescribing (eRx)
- Health Information Exchange
- Patient Specific Education
- Medication Reconciliation
- Patient Electronic Access (View, Download, Transmit)
- Public Health and Clinical Data Registry Reporting

Each objective has one or more measures associated with it. Only one objective – public health – would include flexibility in the measures required. The e-prescribing objective, which had been a menu item, is now required (see discussion below).

Removed Objectives. CMS removes the core and menu approach and will require providers to meet all objectives. Also, CMS finalizes the agency removal of numerous objectives from Stage 2 for EHs, CAHs and EPs that CMS believes are redundant, duplicative or topped out. Many of these items, however, will still be part of the meaningful use program because they are a fundamental piece of another objective. For example, CMS removes collection of problem lists as a separate objective, but problem lists would be expected to be available through the patient portal. CMS removes the following objectives and measures for hospitals:

- Record Demographics
- Record Vital Signs
- Record Smoking Status
- Structured Lab Results
- Patient List
- Summary of Care Measure 1-Any Method
- Summary of Care Measure 3-Test
- Electronic Medication Administration Record
- Advanced Directives (previously menu)
- Electronic Notes (previously menu)
- Imaging Results (previously menu)
- Family Health History (previously menu)
- Structure Labs to Ambulatory Providers (previously menu)

Modified Stage 2 for 2015 to 2017. Table 2 below lists the nine objectives and 16 measures that will apply to all hospitals and notes the type of exceptions available based on previous stage of meaningful use. After the table, changes of particular interest to hospitals are discussed.

Alternate Specifications and Exclusions. For 2015 only, CMS allows providers meant to be at Stage 1 under previous rules the option to attest to the Stage 1 objective and measure specifications for all of the objectives of meaningful use that it has retained. For example, EHs and CAHs previously meant to be at Stage 1 in 2015 would implement only one clinical decision support tool (Stage 1 requirement), rather than five (Stage 2 requirement) and report on only two public health measures, rather than three. For objectives that did not exist in Stage 1, these providers have an exclusion in 2015. For example, these providers have an exclusion for CPOE for lab and radiology, because Stage 1 does not have similar objectives. In 2016, Stage 1 EHs and CAHs will have exclusions for only those objectives that CMS deems to have a safety risk from rushed implementation, specifically CPOE for lab and radiology orders, and e-prescribing. For all EHs and CAHs, CMS will provide an exclusion to the e-prescribing measure in 2015 and 2016 if the hospital had not intended to pursue e-prescribing as a

menu option. Table 2 lists the alternate specifications and exclusions for 2015 and 2016.

The rule also outlines exclusions to certain measures similar to those previously finalized for specific Stage 2 objectives. For example, a provider in an area with insufficient broadband could be excluded from meeting the patient electronic access objective. Similarly, an EH or CAH may receive an exclusion from a public health reporting objective under certain circumstances described below.

Table 2. Hospital Meaningful Use Objectives and Measures for 2015 to 2017

Objective	**Measures**	**Exclusions and Alternate Specifications for Hospitals *Available in 2015 or 2016***
Protect electronic health information	Measure: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of electronic protected health information created or maintained in Certified EHR Technology in accordance with requirements in 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 EH's or CAH's risk management process.	None
Clinical decision support	Measure 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 EH's or CAH's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions. Measure 2: The EH or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	Measure 1: Hospitals previously meant to be at Stage 1 in 2015 implement one clinical decision support rule in 2015.
Computerized Provider Order Entry (CPOE)	Measure 1: More than 60 percent of medication orders created by authorized providers of the EH's or CAH's inpatient or emergency department place of service ((POS) 21 or 23)) during the EHR reporting period are recorded using CPOE. Measure 2: More than 30 percent of laboratory orders created by authorized providers of the EH's or CAH's inpatient or emergency	Measure 1: Hospitals previously meant to be at Stage 1 in 2015 meet threshold of 30 percent in 2015. They may count either: • 30 percent of all unique patients with at least one medication in their medication list, or • 30 percent of medication orders.

Objective	Measures	Exclusions and Alternate Specifications for Hospitals *Available in 2015 or 2016*
	department (POS 21 or 23) during the EHR reporting period are recorded using CPOE. Measure 3: More than 30 percent of radiology orders created by authorized providers of the EH's or CAH's inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	Measures 2 and 3. Hospitals previously meant to be at Stage 1 in 2015 or 2016 can claim an exclusion because Stage 1 did not have an equivalent measure.
e-Prescribing	Measure: More than 10 percent of hospital discharge medication orders for permissible prescriptions (for new, changed and refilled prescriptions) are queried for a drug formulary and transmitted electronically using Certified EHR Technology.	Hospitals previously meant to be at Stage 1 in 2015 or 2016 under current rules can claim an exclusion because Stage 1 did not have an equivalent measure. Hospitals at Stage 2 in 2015 or 2016 can claim an exclusion if they did not intend to select the Stage 2 e-prescribing of discharge medications menu objective in 2015.
Health information exchange	Measure: The EH or CAH that transitions or refers their patient to another setting of care or provider of care (1) uses Certified EHR Technology to create a summary of care record; and (2) electronically transmits such summary to a receiving provider for more than 10 percent of transitions of care and referrals.	Hospitals previously meant to be at Stage 1 in 2015 can claim an exclusion in 2015 because Stage 1 did not have an equivalent measure.
Patient-specific education	Measure: More than 10 percent of all unique patients admitted to the EH's or CAH's inpatient or emergency department (POS 21 or 23) are provided patient-specific education resources identified by Certified EHR Technology.	Hospitals previously meant to be at Stage 1 in 2015 can claim an exclusion in 2015 if they did not intend to select the Stage 1 patient-specific education menu objective.
Medication reconciliation	Measure: The EH or CAH performs medication reconciliation for more than 50 percent of transitions of care in which the patient is admitted to the EH's or CAH's inpatient or emergency department (POS 21 or 23).	Hospitals previously meant to be at Stage 1 in 2015 under current rules can claim an exclusion in 2015 if they did not intend to select the Stage 1 medication reconciliation menu objective.
Patient electronic access (view, download and transmit)	Measure 1: More than 50 percent of all patients who are discharged from the inpatient or emergency department (POS 21 or 23) of an EH or CAH are provided timely access to view online, download, and transmit to a third party their health information. EH/CAH Measure 2: For 2015 and 2016: At least 1 patient who is discharged from the	Measure 2: Hospitals previously meant to be at Stage 1 in 2015 can claim an exclusion in 2015 because Stage 1 did not have an equivalent measure. Note that these hospitals must still meet Measure 1.

Objective	Measures	Exclusions and Alternate Specifications for Hospitals *Available in 2015 or 2016*
	inpatient or emergency department (POS 21 or 23) of an EH or CAH (or patient-authorized representative) views, downloads, or transmits to a third party his or her health information during the EHR reporting period. For 2017: More than 5 percent of unique patients discharged from the inpatient or emergency department (POS 21 or 23) of an EH or CAH (or patient-authorized representative) view, download, or transmit to a third party their health information during the EHR reporting period.	
Public health EHs and CAHs must report on three of the four measure options.	Measure Option 1 – Immunization Registry Reporting: The EH or CAH is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system. Measure Option 2 – Syndromic Surveillance Reporting: The EH or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an emergency or urgent care department for EHs and CAHs (POS 23). Measure Option 3 – Specialized Registry Reporting: The EH or CAH is in active engagement with a public health agency to submit data to a specialized registry. Measure Option 4 – Electronic Reportable Laboratory Result Reporting: The EH or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.	EHs and CAHs previously meant to be at Stage 1 in 2015 must meet at least 2 measures in 2015.

Patient Engagement and View, Download and Transmit. In response to the concerns of hospitals and physicians, CMS finalizes less stringent requirements on patient engagement for 2015 to 2017. Under the final rule, the requirement to provide patients online access to their health information remains. However, the current requirement that 5 percent of patients use the patient portal is modified to at least one patient in 2015 and 2016. The threshold will increase back to more than 5 percent in 2017. **The AHA strongly advocated for this change and appreciates the increased flexibility.**

CMS finalizes an exclusion for this objective if a hospital is located in a county with limited broadband, defined as a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the Federal Communications Commission (FCC) on the first day of the EHR reporting period.

Health Information Exchange (formerly Summary of Care). CMS finalizes as proposed the new name and changed specifications for the transitions of care objective in prior meaningful use rules. First, CMS removes the current Stage 2 requirement that a summary of care document be sent for 50 percent of transitions and referrals (which could include fax and paper copies). Second, the agency keeps the requirement that the hospital or EP send the summary of care electronically for 10 percent of transitions and referrals. Third, CMS removes the requirement to send at least one summary of care record to a provider that uses a different EHR vendor. Finally, CMS removes any requirements on the specific methods used to electronically send the summary of care document, such as specifying the use of a certified EHR or the Direct protocol to do so. **The AHA appreciates the changes to this objective, which has been challenging for hospitals to meet.**

The final rule also discusses the data that must be included in the summary of care document. Specifically, all summary of care documents from hospitals **must** include current problem list, current medication list and current medication allergy list or an indication that there are none. In addition, the summary of care document must include the following information if the hospital knows it: patient name, procedures, encounter diagnosis, immunizations, laboratory test results, vital signs, smoking status, functional status, demographic information, care plan field, care team members and discharge instructions.

In response to stakeholder concerns about the volume of information included in the summary of care document, CMS recognizes that it may be beneficial for a hospital or other provider to limit lab results to a clinically relevant set. However, any provider that limits the results in the summary of care document must send the full results upon the request of the receiving provider or the patient.

e-Prescribing. CMS finalizes its proposal to make e-prescribing required for all hospitals, with the same threshold of 10 percent of hospital discharge medication orders for permissible prescriptions being queried against a drug formulary and transmitted electronically using a certified EHR. CMS also finalizes its proposed exclusion to this requirement for EHs and CAHs that did not intend to choose e-prescribing as a menu option in 2015 and extended it to 2016, as recommended by the AHA. EHs and CAHs meant to be at Stage 1 have a similar exclusion. All EHs and CAHs will be expected to meet the objective in 2017. CMS also finalizes an exclusion to this measure for any hospital that does not have an internal pharmacy that can accept electronic prescriptions and is not located within 10 miles of any pharmacy that access electronic prescriptions.

CMS states that it understands that intent or lack of intent may be difficult for a provider to document and will not require documentation that a provider did not plan to attest to a menu objective in order for the provider to claim the alternate exclusion.

Public Health Reporting. CMS finalizes only one additional measure option for public health reporting – Specialized Registry Reporting – which is a combination of the public health registries and clinical data registries proposed. CMS finalizes neither the addition of case reporting nor a change to the immunization registry reporting measure that would require bidirectional communication whereby hospitals both report to the registry and receive forecasts and other information from the registry. A total of four measures are finalized (see Table 2), of which hospitals must generally report on three (a hospital meant to be at Stage 1 in 2015 would report on two). If a hospital reports to more than one registry, they may each be counted toward meeting the requirement.

Additionally, CMS finalizes the concept of "active engagement" with public health, which includes:

- Registering to submit data within 60 days after the start of the EHR reporting period;
- Being in the process of testing and validating electronic submission of data; or
- Electronically submitting production data.

CMS finalizes that an exclusion for a measure would not count toward the total of three measures that must be met by a hospital. For example, if a hospital qualifies for an exclusion on one measure, the hospital would still need to meet three of the remaining measures. If a hospital qualifies for two exclusions, however, the hospital could meet the objective by meeting the remaining two measures. **The AHA remains concerned that this approach will increase burden on providers to identify and exhaust all public health and registry reporting options before benefiting from exclusions.**

The final public health reporting exclusions are:

- Measure 1 – Immunization registry reporting: The hospital does not administer any immunizations for the populations contained in their jurisdiction's immunization registry.
- Measure 2 – Syndromic surveillance reporting: The hospital does not have an emergency or urgent care department.
- Measure 3 – Specialized registry reporting: The hospital does not diagnose or directly treat any disease associated with or collect relevant data required by a specialized registry for which the EH or CAH is eligible.
- Measure 4 – Electronic reportable lab result reporting: The hospital does not perform or order lab tests that are reportable in their jurisdiction.

The final rule also includes exclusions for all of the public health measures if the EH or CAH operates in a jurisdiction where: (i) no public health department or registry for which the EH or CAH is eligible has declared readiness to receive the data; or (ii) no

public health department or registry can receive the data in the specific standards outlined in the certification criteria (please consult the final rule for more details).

After the publication of the rule, CMS released FAQ 12985 stating it will allow providers to claim an alternate exclusion for a measure if they did not intend to attest to the equivalent prior menu objective in 2015. EHs and CAHs previously meant to attest at Stage 1 must attest to at least 2 measures from the Public Health Reporting Objective measures 1-4, but may claim an alternate exclusion for up to any three of the measures. If alternative exclusions are claimed for three measures, then the provider must either attest to or meet the exclusion requirements for the remaining measure. EHs and CAHs scheduled to be at Stage 2 must attest to at least 3 measures from measures 1-4 and may claim an alternate exclusion for measure 3 (Specialized Registry Reporting Measure). The FAQ provides similar exclusions for EPs.

Use of Certified EHR Technology. CMS proposes no changes to the requirement that hospitals and EPs must use 2014 Edition Certified EHR Technology in 2015 and 2016. However, hospitals may use 2015 Edition Certified EHR Technology in 2017, and must use certain modules if they chose to attest to Stage 3, as discussed further below.

Meaningful Use Requirements for EPs

The requirements for EPs are similar to those for EHs and CAHs, but e-prescribing is listed separately from other types of CPOE. Additionally, CMS finalizes a slightly different policy for secure messaging than proposed. Specifically, EPs must demonstrate secure messaging capabilities in 2015, send at least one secure message to a patient (or patient-authorized representative) in 2016, and send secure messages to more than 5 percent of patients (or their authorized representative) in 2017.

Table 3 lists the final objectives measures applicable to EPs, as well as the exclusions and alternate specifications that will be available in 2015 only. We encourage you to consult the final rule for more detail on the EP requirements, including additional exclusions for specific objectives and measures available to EPs.

Definition of a Hospital-based EP. Under the meaningful use program, hospital-based EPs are not eligible for incentive payments or subject to payment penalties. The current definition considers EPs to be hospital-based if they furnish 90 percent or more of their covered professional services in sites (places) of service identified as an inpatient hospital (POS 21) or emergency room (POS 23) setting in the year preceding the payment year. CMS sought comment on whether additional POS codes or settings should be included in the definition of a hospital-based EP, and especially POS 22 for outpatient hospital settings, but did not finalize any changes to the definition. The agency states that it will continue to consider this issue in the future as it explores program requirements for new physician payment models.

Table 3. EP Meaningful Use Objectives and Measures for 2015 to 2017

Objective	Measures	Exclusions and Alternate Specifications for EPs *Available in 2015 and 2016*
Protect electronic health information	Measure: Conduct or review a security risk analysis in accordance with the requirements in 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of electronic protected health information created or maintained by Certified EHR Technology in accordance with requirements in 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.	None
Clinical decision support	Measure 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 EP's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions. Measure 2: The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	Measure 1: EPs previously required to be at Stage 1 in 2015 implement one clinical decision support rule in 2015.
Computerized Provider Order Entry (CPOE)	Measure 1: More than 60 percent of medication orders created by the EP during the EHR reporting period are recorded using CPOE. Measure 2: More than 30 percent of laboratory orders created by the EP during the EHR reporting period are recorded using CPOE. Measure 3: More than 30 percent of radiology orders created by the EP during the EHR reporting period are recorded using CPOE.	Measure 1: EPs previously required to be at Stage 1 in 2015 may meet a threshold of 30 percent in 2015. They may count either: • 30 percent of all unique patients with at least one medication in their medication list, or • 30 percent of medication orders. Measures 2 and 3. EPs previously required to be at Stage 1 in 2015 and 2016 can claim an exclusion because Stage 1 did not have an equivalent measure.

Objective	Measures	Exclusions and Alternate Specifications for EPs *Available in 2015 and 2016*
e-Prescribing	EP Measure: 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.	EPs previously required to be at Stage 1 in 2015 may meet a threshold of 40 percent in 2015.
Health information exchange	Measure: The EP that transitions or refers their patient to another setting of care or provider of care (1) uses Certified EHR Technology to create a summary of care record; and (2) electronically transmits such summary to a receiving provider for more than 10 percent of transitions of care and referrals.	EPs previously required to be at Stage 1 in 2015 can claim an exclusion in 2015 because Stage 1 did not have an equivalent measure.
Patient-specific education	EP Measure: 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 during the EHR reporting period.	EPs previously required to be at Stage 1 in 2015 can claim an exclusion in 2015 if they did not intend to select the Stage 1 patient-specific education menu objective.
Medication reconciliation	Measure: The EP performs medication reconciliation for more than 50 percent of transitions of care in which the patient is transitioned into the care of the EP.	EPs previously required to be at Stage 1 in 2015 can claim an exclusion in 2015 if they did not intend to select the Stage 1 medication reconciliation menu objective.
Patient electronic access (view, download and transmit)	Measure 1: More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely access to view online, download, and transmit to a third party their health information subject to the EP's discretion to withhold certain information. Measure 2: For 2015 and 2016: At least 1 patient seen by the EP during the EHR reporting period (or patient-authorized representative) views, downloads, or transmits to a third party his or her health information during the EHR reporting period. For 2017: More than 5 percent of unique patients seen by the EP during the EHR reporting period (or patient-authorized representative) views, downloads, or transmits their health information to a third party during the EHR reporting period.	Measure 2: EPs previously required to be at Stage 1 in 2015 can claim an exclusion in 2015 because Stage 1 did not have an equivalent measure. Note that these EPs must still meet Measure 1.

Objective	Measures	Exclusions and Alternate Specifications for EPs *Available in 2015 and 2016*
Secure messaging	For 2015: For an EHR reporting period in 2015, the capability for patients to send and receive a secure electronic message with the EP was fully enabled. For 2016: For at least one patient seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of Certified EHR Technology to the patient (or patient-authorized representative), or in response to a secure message sent by the patient (or patient-authorized representative) during the EHR reporting period. For 2016: For more than 5 percent of unique patients seen by the EP during the EHR reporting period, a secure message was sent using the electronic messaging function of Certified EHR Technology to the patient (or the patient-authorized representative), or in response to a secure message sent by the patient (or the patient-authorized representative) during the EHR reporting period.	EPs previously required to be at Stage 1 in 2015 can claim an exclusion because Stage 1 did not have an equivalent measure.
Public health EPs would need to report on two of the five measure options.	Measure 1 – Immunization Registry Reporting: The EP is in active engagement with a public health agency to submit immunization data. Measure 2 – Syndromic Surveillance Reporting: The EP is in active engagement with a public health agency to submit syndromic surveillance data. Measure 3 – Specialized Registry Reporting: The EP is in active engagement to submit data to a specialized registry.	Stage 1 eligible EPs must meet at least 1 measure in 2015.

Reporting Periods for Payment Penalties

The change from fiscal to calendar year reporting by hospitals also affects the reporting periods used to assess penalties, which will still be applied on a fiscal year basis. Because the penalties for hospitals vary across those paid under the inpatient prospective payment system (PPS) and CAHs, they are treated separately below.

Inpatient PPS Hospitals. Generally, CMS will base whether an inpatient PPS hospital receives a penalty in a given fiscal year on its meaningful use performance during the

calendar year that is two years earlier. For example, a penalty in FY 2018 will be based on performance in CY 2016. For FY 2017 only, CMS finalizes its proposal to use a 90-day reporting period from between Oct. 1, 2014 – Dec. 31, 2015 to avoid penalties. Otherwise, inpatient PPS hospitals continuing in the program must report on a full year of performance before the attestation deadline for that year. However, inpatient PPS hospitals that chose to report on Stage 3 in 2017 need only report on 90 days of performance to avoid penalties in 2019.

In general, inpatient PPS hospitals participating in meaningful use for the first time face different attestation deadlines to avoid penalties. Specifically:

- Those that first participate in 2015 will avoid payment penalties in FYs 2016 and 2017 if they successfully attest by Feb. 29, 2016.
- Those that first participate in 2016 must finish their 90-day reporting period within the first three quarters of the calendar year and complete their attestation by Oct. 1, 2016 to avoid a payment adjustment in FY 2017. To avoid a payment adjustment in FY 2018, those hospitals would need to complete their attestation by Feb. 28, 2017.
- Those that first participate in 2017 must finish their 90-day reporting period within the first three quarters of the calendar year and complete their attestation by Oct. 1, 2017 to avoid a payment adjustment in FY 2018. To avoid a payment adjustment in FY 2019, those hospitals would need to complete their attestation by Feb. 28, 2018.

For further details, readers are referred to Table 19 of the final rule.

Critical Access Hospitals. For CAHs, the penalties are based on same-year performance. Therefore, penalties in FY 2015 will be based on the 90-day performance in the FY/CY 2015 reporting period, with attestation completed by Feb. 29, 2016. Any penalties will be assessed through cost report reconciliation. In later years, CAHs continuing in the program must report on a full year of performance before the attestation deadline for that year. However, CAHs that chose to report on Stage 3 in 2017 need only report on 90 days of performance to avoid penalties.

CAHs that first participate in 2016 must finish their 90-day reporting period by the end of the calendar year and attest by Feb. 28, 2017 to avoid a payment penalty. Similarly, CAHs that first participate in 2017 must finish their 90-day reporting period by the end of the calendar year and attest by Feb. 28, 2018 to avoid a payment penalty.

For further details, readers are referred to Table 20 of the final rule.

STAGE 3 FINAL RULE

Definition of Meaningful Use for Stage 3

CMS confirms that Stage 3 will be the final stage in meaningful use and that no further stages will be developed. However, CMS states that, as circumstances warrant, it will consider changing objectives and measures under the EHR Incentive Program in future rulemaking due to changes in technology or clinical care standards associated with EHR technology. CMS also finalizes that the definition of certified EHR required by participants in the EHR Incentive Program will be determined by CMS and located in the EHR Incentive Program regulation.

Timing and Stages of Meaningful Use

CMS finalizes that Stage 3 be optional for providers in CY 2017 and required for all providers beginning in 2018, regardless of their stage of meaningful use in the preceding year (see Table 1 above). Either the 2014 or 2015 Edition certified EHR could be used in 2017. The 2015 Edition certified EHR will be required beginning with the 2018 reporting period.

Meaningful Use Stage 3 Objectives and Measures

CMS finalizes a set of eight objectives for all providers for Stage 3 in 2018. Limited variation would be permissible among the measures required of all EHs, CAHs and EPs. CMS states that the reduction in the number of objectives for Stage 3 is to focus on advanced use objectives that support clinical effectiveness, patient safety, patient engagement and care coordination.

The eight objectives are:

- Protect Patient Health Information
- Electronic Prescribing (eRx)
- Clinical Decision Support (CDS)
- Computerized Provider Order Entry (CPOE)
- Patient Electronic Access to Health Information
- Coordination of Care through Patient Engagement
- Health Information Exchange (HIE)
- Public Health and Clinical Data Registry Reporting

Stage 3 Requirements for EHs and CAHs

To meet the objectives of Stage 3 in 2018, CMS finalizes 21 measures that raise the modified Stage 2 thresholds and introduce new requirements and functionality, such as an application program interface (API) to facilitate providing the patient with access to his or her health information through a third-party application. Changes of particular note for EHs and CAHs are summarized below. Appendix A lists the Stage 3 objectives, measures and what changed from the Stage 3 proposed rule.

Protect Patient Health Information. CMS maintains the previous Stage 2 objective that providers protect electronic protected health information (ePHI) created or maintained by a certified EHR through the implementation of appropriate technical safeguards.

The measure requires conducting or reviewing a security risk analysis annually to assess whether the provider's technical, administrative and physical safeguards and risk management strategies are sufficient to reduce potential risks and vulnerabilities to the confidentiality, availability and integrity of ePHI. CMS will require security risk analysis and review:

- Upon installation of the certified EHR or upon upgrade to a new edition of certified EHR (the risk analysis could occur prior to the beginning of the first EHR reporting period); and
- During the EHR reporting period after the first EHR reporting period.

CMS references the guidance and other resources on security risk analysis provided by the Office for Civil Rights in support of the Health Insurance Portability and Accountability Act (HIPAA) Security Rule risk analysis requirement referenced by this objective.

eRx. CMS finalizes the requirement that prescribers practicing in EHs and CAHs generate and transmit permissible discharge prescriptions electronically for more than 25 percent of discharge medication orders in Stage 3. E-prescribing was made a mandatory objective in the final modification rule with a threshold of more than 10 percent of hospital discharge medication orders for permissible prescriptions (for new, changed and refilled prescriptions) being queried for a drug formulary and transmitted electronically using Certified EHR Technology. CMS finalizes that EPs continue the requirement to generate and transmit permissible prescriptions electronically with the threshold that more than 60 percent of all permissible prescriptions written by an EP are queried for a drug formulary and transmitted electronically.

CMS clarifies that the term "permissible prescriptions" includes all drugs meeting the definition of a prescription not listed as a controlled substance in Schedules II-V of the Controlled Substances Act. Given the variation in state law on electronic prescribing of controlled substances, CMS finalizes flexibility that will allow providers to include or exclude controlled substances in the denominator where inclusion of scheduled drugs is permitted and state law permits electronic prescription.

Exclusions available for eRx objective. CMS provides an exclusion for any EH or CAH that does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of the EH's or CAH's EHR reporting period.

CMS provides an exclusion for any EP who writes fewer than 100 permissible prescriptions during the EHR reporting period or any EP that does not have a pharmacy within its organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his/her EHR reporting period.

CDS. CMS finalizes the continuation of the objective to require EHs, CAHs and EPs implement CDS interventions focused on high-priority conditions. CMS states that providers should implement the CDS intervention at a relevant point in clinical workflows when the intervention can influence clinical decision making before diagnostic or treatment action is taken in response to the intervention.

Two measures are required to meet this objective. For measure number one, EHs, CAHs and EPs must implement five CDS interventions related to four or more clinical quality measures (CQMs) at a relevant point in patient care for the entire EHR reporting period. For the CDS and CQM pairings, CMS recommends that EHs, CAHs and EPs focus on the use of CQMs that are outcome measures rather than process measures. Absent four CQMs related to an eligible hospital, CAH or EP's scope of practice or patient population, the clinical decision support interventions must be related to high-priority health conditions. For measure number two, CMS finalizes that the EH, CAH or EP enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.

Exclusions available for CDS objective. CMS does not provide an exclusion for the CDS objective for EHs or CAHs. For EPs, CMS provides an exclusion for any EP who writes fewer than 100 medication orders during the EHR reporting period.

CPOE. CMS finalizes the CPOE objective that providers use a computer or mobile device to record and enter clinical orders in a structured format. It finalizes thresholds for the three measures required to meet this objective:

1. **Medication Orders:** CMS finalizes that 60 percent of all medication orders be recorded using CPOE. The modified Stage 2 measure threshold was 60 percent.
2. **Laboratory Orders:** CMS finalizes that 60 percent of all lab orders be recorded using CPOE. The modified Stage 2 threshold was 30 percent.
3. **Diagnostic Imaging Orders:** CMS finalizes that 60 percent of all diagnostic imaging orders be recorded using CPOE. The modified Stage 2 threshold was 30 percent for radiology imaging orders.

Exclusions available for CPOE objective. CMS does not present any CPOE exclusions for EHs or CAHs. For EPs, CMS an exclusion for each measure is available if an EP writes fewer than 100 of that order type during the EHR reporting period.

Patient Electronic Access. CMS finalizes continued use of patient portals to facilitate patients' ability to view, download or transmit (VDT) their health information electronically. CMS also finalizes an alternative functionality for Stage 3, known as application program interfaces (APIs). The API programming protocols installed in EHR software are intended to allow a provider to give patients the choice to access to their health information through a third-party application (app). In the final rule, CMS states that the provider must fully enable the API functionality such that any application chosen by a patient would enable the patient to gain access to their individual health information. The provider also must provide patients with detailed instructions on how to authenticate their access through the API, and provide supplemental information on the available apps that leverage the API. CMS expects that

providers will continue identity verification processes used to support VDT capabilities to ensure that a patient using an app has access to their health information. CMS also adds that the meaningful use objective requiring the conduct and review of a security risk analysis would include the certified API enabled as part of the provider's certified EHR.

CMS finalizes two measures to meet this objective. For measure one, CMS requires that patients or their authorized representatives be able to access their health information from a provider EH, CAH or EP by means of VDT or an ONC-certified API. Therefore, both VDT and the API functionality must be available to support patient choice in electronically accessing their health information. The Stage 3 threshold for measure one is more than 80 percent of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) or seen by the EP during the EHR reporting period, up from 50 percent threshold for patients to electronically access information by VDT in modified Stage 2. **The AHA recognizes the potential future use of APIs to facilitate information exchange. However, the standards to support the use of APIs are still under development and are not yet mature enough to be included as a requirement in regulation that providers must make available.**

For measure two of this objective, CMS finalizes that EHs, CAHs and EPs must use certified EHRs to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients. The modified Stage 2 threshold was 10 percent of unique patients are provided patient-specific resources identified by a certified EHR.

Exclusions available for patient electronic access objective. For measures one and two, CMS provides an exclusion for EHs and CAHs located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period. For EPs, CMS provides an exclusion from measure one and two if an EP does not have office visits during the EHR reporting period and if the EP conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability on the first day of the EHR reporting period.

Coordination of Care through Patient Engagement. CMS finalizes the objective to use certified EHRs to engage with patients or their authorized representatives in the coordination of care. The objective contains three measures. For measure one, CMS requires that more than 10 percent of unique patients discharged from an EH or CAH inpatient or emergency department (POS 21 or 23) or seen by an EP actively engage with the EHR and the patient engagement is facilitated by either VDT or an ONC-certified API or a combination of these options. For EHs, CAHs and EPs that choose to report Stage 3 in 2017, the threshold is more than 5 percent of unique patients. For the API option, CMS requires that EHs, CAHs and EPs must enable apps of the patient's choice that are configured to leverage the API functionality in the provider's certified EHR to retrieve their health information.

For measure two, CMS requires that for more than 25 percent of patients discharged from the EH or CAH inpatient or emergency department (POS 21 or 23) or seen by an EP during

the EHR reporting period, a secure message was sent using the electronic messaging function of the certified EHR between the patient, or the patient's authorized representative, and the EH, CAH or EP. CMS specifies that the secure message sent should contain relevant health information specific to the patient. For EH, CAHs and EPs that choose to report Stage 3 in 2017, the threshold is for more than 5 percent of unique patients, a secure message was sent.

For measure three, CMS requires that EHs, CAHs or EPs incorporate data in the certified EHR for more than 5 percent of patients discharged by the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) or seen by an EP during the EHR reporting period from non-clinical settings or data that is patient-generated. CMS states that many types of data would satisfy the measure, including social service data, data generated by a patient or a patient's authorized representative, advance directives, medical device data, home health monitoring data and fitness monitor data.

Exclusions available for care coordination through patient engagement objective. CMS provides exclusions for EHs, CAHs and EPs for measures one, two and three. Specifically, for EHs and CAHs, CMS provides an exclusion from measures one, two and three if the EH or CAH is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period. For EPs, CMS provides an exclusion from measures one, two and three if an EP does not have office visits during the EHR reporting period or if the EP conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability on the first day of the EHR reporting period.

CMS requires EHs, CAHs and EPs attest to the numerator and denominator for all three measures and must meet the threshold for two of the three measures in order to meet the requirements of the objective.

Collectively, the measures increase the options to facilitate patient engagement, the thresholds for patient engagement and the data types that could be incorporated in the certified EHR. **The AHA believes it is premature to impose requirements for provider use of technology functionality, such as APIs, before the standard is mature. Similarly, the standards to support the use of patient-generated data are still under development and are not yet mature enough to be included in regulation.**

HIE Supporting Transitions of Care. CMS finalizes a revision of the modified Stage 2 health information exchange objective to create a new HIE objective. Specifically, CMS will require an EH, CAH or EP to provide a summary of care record when transitioning or referring their patient to another setting of care, and retrieve a summary of care record upon the first patient encounter with a new patient. To meet the objective, CMS requires EHs, CAHs and EPs to use the common clinical data set (CCDS) specified by ONC in the final 2015 Edition certification rule, rather than the meaningful use data set from original Stage 2. The CCDS includes new information fields, such as the unique device identifier (UDI) for implantable medical devices. The CCDS is located in the 2015 Edition Certification final rule,

80 Fed Reg 200, pages 62697-62702.

For Stage 3, CMS finalizes three measures to support the objective. Measure one requires that, for more than 50 percent of transitions of care and referrals, the EH, CAH or EP create a summary of care record using their certified EHR and electronically exchange the summary of care record. **The AHA is concerned about increasing the threshold for summary of care documents sent electronically from 10 percent in Stage 2 to 50 percent for Stage 3, as providers are experiencing difficulties meeting the current threshold due to the lack of readiness on the part of clinicians to whom they would send the summary of care record. The AHA also is opposed to additional data collection in the CCDA, such as the UDI, to support the summary of care document when the EHR standard for the UDI data is immature.**

CMS finalizes the ability of providers to use discretion to determine the amount of information included in the summary of care record. CMS states that EHs, CAHs and EPs must maintain the ability to send a full set of all available lab results and clinical notes through an electronic transmission of a summary of care document. Additionally, providers must send all laboratory results and/or all clinical notes if the recipient of the summary of care record subsequently requests this additional information.

CMS finalizes that provider judgment should be used to determine the set of historical data included in a summary of care record. The summary of care record must contain a list of items believed to be pertinent and relevant to the patient's care, and the provider decides which items historically present on the problem list, medical history list or surgical history list are relevant given the clinical circumstances.

For measure two, CMS finalizes that, for more than 40 percent of transitions and referrals received and patient encounters in which the EH, CAH or EP has never before encountered the patient, a summary of care document received from another source is incorporated into the patient record in the EHR of the recipient EH, CAH or EP.

For measure three, CMS finalizes that the EH, CAH or EP recipient of the summary of care record from a transition or referral of a first encounter with a new patient perform a clinical information reconciliation for more than 80 percent of transitions or referrals received. The clinical information reconciliation must include the patient’s medications, medication allergies and current problem list.

Exclusions available for HIE supporting transitions of care objective. For measure one, CMS finalizes an exclusion that EHs and CAHs may exclude the measure if located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period. EPs may exclude the measure if he or she transfers a patient to another setting or refers a patient to another provider less than 100 times during the EHR reporting period, or if the EP conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability on the first day of the EHR reporting period.

For measure two, CMS finalizes an exclusion that EHs, CAHs and EPs may exclude the measure when the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient is fewer than 100 during the EHR reporting period. EHs and CAHs may exclude the measure if it is located in a county that does not have 50 percent or more of their housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period. EPs also may exclude the measure if the EP conducts 50 percent or more of his or her patient encounters in a county that does not have 50 percent or more of its housing units with 4Mbps broadband availability on the first day of the EHR reporting period.

For measure three, CMS finalizes an exclusion for any EH, CAH or EP for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period.

CMS finalizes that an EH, CAH or EP will meet this objective by attesting to the numerator and denominator for all three measures but will be required to successfully meet the threshold for two of the three measures.

Public Health Reporting. CMS finalizes the public health objective by expanding on the modified Stage 2 objective. For Stage 3, EHs and CAHs must meet four of six public health reporting measures and EPs must meet three of six public health measures. CMS continues the requirement that EHs, CAHs and EP are in "active engagement" when their certified EHR is used to submit data to a public health agency (PHA) or clinical data registry (CDR) in order to report the selected measure. CMS defines "active engagement" as:

- Completing registration to submit data with a PHA or CDR within 60 days after the start of the EHR reporting period;
- In the process of testing and validating electronic submission of data to a PHA or CDR; or
- Electronically submitting data generated through clinical processes involving patient care to a PHA or CDR.

CMS finalizes an exclusion from a public health and clinical data registry reporting measures if public health agencies and clinical data registries have not declared six months in advance of the start of the EHR reporting period their January 1 readiness for the upcoming reporting year.

CMS states that a centralized repository of national, state and local public health agency and clinical data readiness is expected to be available by the start of CY 2017. The centralized repository will include readiness updates for public health agencies and clinical data registries at the local, state and national level.

CMS finalizes the option for EHs, CAHs or EPs to report to more than one public health registry or more than one clinical data registry (see Table 4). Reporting to more than one

registry would count toward meeting the total number of required measures for this objective.

CMS states that the agency will work with ONC and the public health community and clinical specialty societies to develop ONC-certified electronic reporting standards as new registries are created.

Table 4. Public Health Reporting Objective and Measures

Measure	Maximum times a measure can be counted toward meeting the objective for an EH or CAH	Maximum times a measure can count toward meeting the objective for an EP
Measure 1 – Immunization Registry Reporting	1	1
Measure 2 – Syndromic Surveillance Reporting	1	1
Measure 3 – Case Reporting	1	1
Measure 4 – Public Health Registry Reporting	4	3
Measure 5 – Clinical Data Registry Reporting	4	3
Measure 6 – Electronic Reportable Laboratory Results	1	N/A

The final public health measures are:

Measure 1 – Immunization Registry Reporting. Active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS). CMS states that, by the time Stage 3 begins, the bi-directional components of immunization registry reporting will be ready. Therefore, the provider's health IT system may layer additional information on the immunization history, forecast and still successfully meet this measure.

Measure 2 – Syndromic Surveillance Reporting. Active engagement with a public health agency to submit syndromic surveillance data from a non-urgent care ambulatory setting for EPs, or an emergency or urgent care department for eligible hospitals and CAHs (POS 23). CMS states this measure is removed for EPs for Stage 3 with the exception of EPs who are practicing in urgent care settings. CMS finalizes the measure as proposed for EHs and

CAHs.

Measure 3 – Case Reporting. Active engagement with a public health agency to submit case reporting of reportable conditions. CMS states they believe that the standards will be mature and that jurisdictions will be able to accept these types of data by 2018.

Measure 4 – Public Health Registry Reporting. Active engagement with a public health agency to submit data to public health registries. CMS defines a public health registry as a registry that is administered by or on behalf of a local, state, territorial or national public health agency and which collects data for public health purposes. Although immunization registries are a type of public health registry, reporting to immunization registries will remain separate to maintain continuity with the previous EHR Incentive Program reporting requirements. CMS states that some public health jurisdictions began accepting electronic case reporting and prescription drug monitoring from specialized registries during the previous Stage 2 definition of meaningful use and could count for the purpose of reporting to this objective in Stage 3. However, CMS states in future years, as standards are developed and referenced in future ONC regulations, CMS may require further specialized registries to meet these future requirements under the ONC Health IT Certification Program.

Measure 5 – Clinical Data Registry Reporting. Active engagement to submit data to a clinical data registry. CMS defines a clinical data registry as a registry that is administered by or on behalf of a non-public health agency.

Measure 6 – Electronic Reportable Laboratory Result Reporting. Active engagement with a public health agency to submit electronic reportable laboratory results. This measure is not available for EPs.

Additional exclusions available for public health reporting objective. CMS finalizes specific exclusions to the public health reporting measures. CMS also finalizes the requirement that an EH, CAH or EP exhaust all possible measures before counting any specific measure as excluded. Examples of exclusions for immunization reporting include the lack of an available immunization registry. Examples of exclusions for syndromic surveillance, case reporting or public health registry reporting include the absence of treatment of a disease that is reportable to a disease system or registry, or the inability of a jurisdiction to accept electronic data in accordance with the certified EHR standards at the start of the EHR reporting period. EHs, CAHs and EPs that qualify for multiple exclusions for measures can meet the public health reporting objective by reporting on the remaining available measures.

Stage 3 Requirements for EPs

CMS finalizes Stage 3 requirements for EPs that are similar to those for EHs and CAHs. A point of variation is in the public health objective, where EPs will be required to meet three of the six measures. Variation is included in some of the exclusions available for measures in objectives two through eight. Appendix B lists the Stage 3 objectives, measures and exclusions for EPs.

Reporting Electronic Clinical Quality Measures (eCQMs)

CMS finalizes the change for EHs and CAHs to align the eCQM reporting period with the calendar year EHR reporting period. CMS also finalizes the continued requirement that in 2015 through 2017, EHs and CAHs report 16 eCQMs across at least three National Quality Strategy (NQS) domains and EPs report nine eCQMs across at least three NQS domains. For the Medicaid EHR Incentive Program, states will continue to determine whether and how eCQM reporting occurs and if attestation is permitted.

For 2015 only, all EHs, CAHs and EPs will report to any continuous 90-day period. Because of the shift from the fiscal year to the calendar year reporting period, EHs and CAHs may select any continuous 90-day period from Oct. 1, 2014 through Dec. 31, 2015 to report eCQMs via attestation using the EHR Incentive Program registration and attestation system. For 2016, EHs, CAHs and EPs, will report a full calendar year of eCQMs. For 2016, EHs and CAHs that chose to submit eCQMs electronically will have the option to report any four eCQMs for one calendar quarter, either Q3 or Q4, to meet the eCQM reporting requirement. This requirement aligns with the Hospital Inpatient Quality Reporting Program (IQR) requirement that hospitals participating in IQR in 2016 report any four eCQMs from Q3 or Q4 and electronically submit the data to CMS. eCQM reporting requirements for IQR in 2016 are located in the FY 2016 Hospital Inpatient Prospective Payment Systems Final Rule, 80 Fed Reg 158, pages 49692 - 49698. CMS also states that for 2015 through 2017, EHs, CAHs and EPs may electronically report eCQMs using the electronic reporting option.

For EHs, CAHs and EPs in 2017, CMS finalizes the proposal to require a full calendar year reporting eCQMs. However, EHs, CAHs and EPs demonstrating Stage 3 in 2017 and EHs, CAHs and EPs reporting in the Medicaid EHR Incentive Programs for the first time in 2017 will report eCQMs on a 90-day reporting period. For these EHs, CAHs and EPs, CMS states that the eCQM reporting period could be a different 90-day period than their EHR reporting period under Medicaid.

CMS finalizes the proposal that eCQMs must be electronically submitted where feasible in 2018 and subsequent years. Attestation to eCQMs would be an option in certain circumstances where electronic submission is not feasible. More information on the form and manner of reporting will be provided in future Medicare payment rulemaking.

CMS finalizes the elimination of the Quality Reporting Data Architecture Category-III (QRDA-III) option for EHs and CAHs to report aggregate level data to meet the eCQM requirements for the Medicare EHR Incentive Program. Submission of patient-level QRDA-I data to Medicare is the only available option. States retain the option to allow EHs and CAHs to report QRDA-III data for the Medicaid EHR Incentive Program. EPs retain the option to submit QRDA-I or QRDA-III data to CMS.

For the Medicaid EHR Incentive Program, CMS finalizes continuation of flexibility to allow the states to determine form and manner of reporting CQMs for their respective state Medicaid EHR Incentive Programs subject to CMS approval.

Medicaid-specific Changes

CMS finalizes the proposal to maintain under the Medicaid EHR Incentive Program a 90-day EHR reporting period for EHs and CAHs that are demonstrating meaningful use for the first time in CY 2018. Hospitals that are eligible under both Medicare and Medicaid and choose to attest for Medicare must complete an EHR reporting period for the full calendar year in 2018.

CMS finalizes the continuation of flexibility to states to create their own Medicaid measures for public health and clinical data registry reporting. States also will continue to have flexibility to specify the means of transmission of the data and otherwise change the public health agency reporting objective, as long as it does not require functionality greater than what is required for Stage 3 and included in the 2015 Edition certification final rule.

THE 2015 EDITION HEALTH INFORMATION TECHNOLOGY CERTIFICATION CRITERIA, 2015 EDITION BASE EHR DEFINITION, AND ONC HEALTH IT CERTIFICATION PROGRAM MODIFICATIONS

ONC Rule on Standards, Certification Criteria and Implementation Specifications

ONC released the final rule for the 2015 Edition Health Information Technology Certification Criteria (2015 Edition Certification). The final rule includes new and updated standards for health information technology modules (health IT modules) both required in the EHR Incentive Program and used in care and practice settings not included in the program. The rule includes standards for access and exchange of health information, including the use of application programming interfaces (API) capabilities. ONC removed the certified EHR definition for 2015 Edition certification stating that the definition of certified EHR is specific to the EHR Incentive Program and is determined by CMS. To meet the requirements of meaningful use Stage 3 specified by CMS, a provider will need technology certified to capabilities beyond the Base EHR definition. ONC provides guidance on the relationship between 2015 Edition certification and the certified EHR definition for Stage 3 meaningful use.

The rule also finalizes changes to the Health IT Certification Program with the goal of improving interoperability and providing greater disclosure about the certified products and surveillance requirements. ONC intends to use the revised certification program to certify both health IT modules that are used by participants in the EHR Incentive Program and those used in other care settings.

The AHA is concerned about the misalignment between the certification process for health IT modules and the requirement that providers use certified EHRs to meet meaningful use requirements. Experience has shown that requirements to use technology with immature standards create implementation challenges resulting in barriers to meeting regulatory mandates within required timeframes.

Definition Revisions in the 2015 Edition Rule

Base EHR Definition. ONC states that the 2015 Base EHR includes what the HITECH Act referred to as Qualified EHR and references a foundational set of certified capabilities that all EHs, CAHs and EPs need to adopt. Certified EHR, a definition adopted by CMS, will continue to point to the relevant Base EHR definition and other ONC certification criteria relevant to the EHR Incentive Program. The definition of the 2015 Edition Base EHR differs from the 2014 definition of Certified EHR, required for the EHR Incentive Program, in several ways.

First, the definition does not include privacy and security as a separate certification criteria within the Base EHR definition. Rather, ONC presents a privacy and security framework that maps individual privacy and security criteria to specific health IT modules. ONC states that the health IT developer is expected to apply the privacy and security criteria applicable to the respective health IT module capabilities in order to get the health IT module certified. ONC adds that purchaser of a health IT module will know exactly what privacy and security functionality the health IT module had to be tested against in order to be certified. The 2015 Edition Privacy and Security Certification Framework can be found in the 2015 Edition Certification final rule, 80 Fed Reg 200, page 62706.These changes make it more challenging for providers to understand the privacy and security protections in certified products.

Second, while the definition does include capability to record and export clinical quality measure information, it does not include the ability to import and calculate or to report clinical quality measure data. These capabilities were in the 2014 Edition. CMS, in future Hospital Inpatient Prospective Payment System and Physician Fee Schedule regulations, will determine requirements for these capabilities within the context of the certified EHR definition.

Third, the definition includes the 2015 Edition “implantable device list” certification.

Finally, the 2015 Base EHR includes three certification “Application Access” criteria supporting the use of APIs to support provider or patient access to information.

Certification Criteria

ONC finalizes changes that revise the functionality of the Base EHR, including three that are required for certified EHRs in the EHR Incentive Program.

Common Clinical Data Set (CCDS). ONC finalizes the renaming of the “Common Meaningful Use Data Set” as the “Common Clinical Data Set.” The CCDS is the information that must be available in the summary of care document exchanged in support of the meaningful use Stage 3 objective 7: Health Information Exchange Supporting Transitions of Care. The CCDS is located in the 2015 Edition Certification final rule, 80 Fed Reg 200, pages 62697-62702.

ONC finalizes updated and new standards for the 2015 Edition data fields included in the summary of care. New data fields included in CCDS are the unique device identifier(s) (UDI) for a patient's implantable device(s), smoking status and immunizations. ONC finalizes two certification criteria to support creation and receipt of a transition of care/referral summary: *Common Clinical Data Set Summary Record – Create* and *Common Clinical Data Set Summary Record – Receive*. Certified health IT modules must be able to create a transition of care/referral summary in accordance with C-CDA Release 2.1 (create) and both C-CDA Releases 1.1 and 2.1 (receive) standard.

Application Access to Common Clinical Data Set – Three Criteria. ONC finalizes three certification criteria to support the Stage 3 requirement that certified EHRs enable apps of the patient's choice that are configured to leverage the API functionality in the provider's certified EHR to retrieve their health information**:**

- **Support Patient Selection:** A means for the app to query for an identification (ID) or other token of a patient's record in order to subsequently execute data requests for that record.
- **Data Category Request:** The API must respond to requests for each of the data categories specified in the CCDS and return the full set of data for that data category.
- **All Data Request:** The API must respond to requests for all of the data included in the CCDS on which there is data for the patient and the return format with the patient's data is limited to patient's fully populated summary record formatted in accordance with the C-CDA version 2.0.

ONC did not name a standard for API functionality, stating that the certification criterion is the appropriate level of specificity given the ongoing development of API standards for health care, and ONC's interest in allowing a flexible approach without naming a specific standard. ONC stated an intention to adopt a standards-based approach for certification in the next appropriate rulemaking and also noted the existence of ongoing pilots of promising work.

ONC did not adopt a certification criterion for API to support registration of third-party applications as a means to establish security standards for APIs, stating applications should not be required to be approved in advance by the provider or the health IT developer before being allowed to access the API. ONC states that the privacy and security framework, as applicable to API criteria, requires certified health IT modules certified to be capable of:

- ensuring valid user credentials are presented;
- allowing the provider to authorize the user to view the patent's data;
- connecting the application through a trusted connection; and
- auditing access through the API.

ONC states that the health IT module must be certified to either approach 1 or approach 2 of the privacy and security framework (80 Fed Reg 200, page 62706) for the following security criteria: §170.315(d)(1) authentication, access control and authorization; §170.315(d)(9) trusted connection; and §170.315(d)(10) auditing actions on health information or § 170.315(d)(2) auditable events and tamper resistance.

ONC adds that they will consider a "sub-regulatory approach" to API testing and whether such an approach fits within the existing regulatory structure and leads to consistent and efficient testing and certification. **The AHA is concerned that the lack of a standard for APIs will limit the providers' ability to meet Stage 3 requirements and the absence of security requirements for the apps that will connect to EHRs will result in security vulnerabilities.**

Clinical Quality Measures. ONC finalizes one certification criterion in the Base EHR definition to support clinical quality measures. The health IT module must be able to record and export all of the data 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. The export functionality is expected to support the ability to export CQM data formatted to the Quality Reporting Document Architecture (QRDA) Category I Release 3 IG (both Volumes 1 and 2). ONC states that this criterion was included because they believe that the ability to export CQM data will serve two purposes. First, this functionality allows a provider or health system to view and verify their CQM results for quality improvement on a near real-time basis. Second, the export functionality gives providers the ability to export their results to multiple programs, such as those run by CMS, states and private payers. The 2014 Edition certified EHR does not provide users the ability to export QRDA Category I files "on demand." Users must submit requests for the health IT developer to assist or perform the export function on their behalf.

Two additional certification criteria are finalized in the 2015 Edition Certification and are required functionality for certified EHRs that support Stage 3: Clinical Quality Measures – Import and Calculate, and Clinical Quality Measures – Report.

Table 5 lists the Base EHR capabilities and the related certification criteria.

Table 5. Certification Criteria Required to Satisfy the 2015 Edition Base EHR Definition

Base EHR Capabilities	Certification Criteria
Includes patient demographic and clinical health information, such as medical history and problem lists	Demographics § 170.315(a)(5) Problem List § 170.315(a)(6) Medication List § 170.315(a)(7) Medication Allergy List § 170.315(a)(8) Smoking Status § 170.315(a)(11) Implantable Device List § 170.315(a)(14)
Capacity to provide clinical decision support	Clinical Decision Support § 170.315(a)(9)
Capacity to support physician order entry	Computerized Provider Order Entry § 170.315(a)(1), (2) or (3)

Base EHR Capabilities	Certification Criteria
Capacity to capture and query information relevant to health care quality	Clinical Quality Measures § 170.315(c)(1)
Capacity to exchange electronic health information with, and integrate such information from other sources	Transitions of Care § 170.315(b)(1), Data Export § 170.315(b)(6), Application Access to Common Clinical Data Set – Patient Selection §170.315(g)(7), Application Access to Common Clinical Data Set – Data Category Request §170.315(g)(8), Application Access to Common Clinical Data Set – All Data Request §170.315(g)(9), Direct Project § 170.315(h)(1) or Direct Project, Edge Protocol, and XDR/XDM § 170.315(h)(2)

Note: A "base EHR" is the term used by ONC that corresponds with the term defined in the HITECH Act as a "qualified EHR."

Gap Certification Eligibility for 2015 Edition Health IT Module Certification. The ONC gap certification policy focuses on the differences between certification criteria that are adopted through rulemaking at different points in time. ONC finalizes that health IT modules are to be presented for certification to the differences across the editions of certification criteria. "Unchanged" criteria are eligible for gap certification, and each of the ONC-ACBs has discretion over whether it will provide the option of gap certification.

Standards and Implementation Specifications

ONC finalizes a set of 19 new certification criteria for health IT certification to the 2015 Edition. Stage 3 requires use of an EHR certified to the following requirements, in addition to the 17 criteria in the 2015 Base EHR:

- **Implantable Device List.** ONC finalizes the requirement that the ability of health IT to exchange, record and allow a user to access a list of UDIs associated with a patient's implantable devices. Health IT modules certified to this criterion will be able to "parse" a UDI into its constituent components (or "identifiers") and make those accessible to the user. Separately, the health IT modules would be able to retrieve and provide a user with access to, if available, the optional "Device Description" attribute associated with a UDI in the FDA's Global Unique Device Identification Database (GUDID).

  ONC did not adopt any Automatic Identification and Data Capture (AIDC) requirements for UDIs, although it states that the UDIs should be captured using AIDC and should rarely if ever be manually entered. The implantable device list certification criterion is focused on baseline functionality necessary to ensure that, once recorded in a patient's electronic health record, UDIs can be exchanged among "downstream" health IT systems and accessed by clinicians wherever patients seek care. ONC

anticipates that users of certified health IT modules used in surgical settings will expect developers to include AIDC capabilities as a necessary complement to the baseline implantable device list functionality required by the criterion. **The AHA is concerned that without AIDC capabilities, hospitals may have to resort to manual entry of the UDI.**

- **Transmission to Immunization Registries.** ONC finalizes the criterion for certified EHR functionality needed for EHs, CAHs or EPs to be actively engaged with a public health agency to submit immunization data. The certification criterion requires the use of National Drug Codes for administered vaccines and requires the HL 7 immunization messages for vaccine administered (CVX) code set as the minimum standards code set for historical vaccines. When sending historical vaccines and the actual NDC code is not available, CVX codes can be sent as this method would be supported by health IT certified to this criterion.

- **Transmission to Public Health Agencies – Electronic Case Reporting.** ONC finalizes the criterion for certified EHR functionality needed for EH, CAH or EP to be actively engaged with a public health agency to submit case reporting of reportable conditions. The certification criterion requires support for the ability to electronically create case reporting information for electronic transmission in accordance with the IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation (Sept. 5, 2014) standard. ONC adds that the criterion requires the health IT module to demonstrate that it can create and send a constrained transition of care document to a public health agency, accept a URL in return, be able to direct end users to the URL, and adhere to the security requirements for the transmission of this information.

Criteria Required for All Health IT Modules Presented for Certification. ONC finalizes 12 safety-enhanced design (SED) certification criteria required for all health IT modules, down from the 17 in the proposed rule. Each SED criterion supports a specific capability, and SED user-centered design processes must have been applied in order satisfy this certification criterion. The 12 SED criteria support CPOE, drug-drug and drug-allergy interaction checks, demographics, problem list, medication list, medication allergy list, clinical decision support, implantable device list, clinical information reconciliation and incorporation, and ePrescribing.

Changes to the Health IT Certification Program

ONC proposes several changes to the certification program with the goal of making the program more transparent, open and accessible to more types of health IT.

Increased Information about Health IT Products. ONC finalizes the proposal to require ONC-ACBs to report an expanded set of information to ONC for inclusion in an open data file that would contain the Certified Health IT Product List (CHPL). The information publicly available in the open data CHPL will include information ONC-ACBs would be required to report in connection with a corrective action plan resulting from random in-the-field surveillance and reactive surveillance of certified products. ONC

also finalizes the proposal that ONC-ACBs retain records related to certification for "the life of the edition," plus an additional three years and make the certification records available to the Department of Health and Human Services upon request.

Transparency. ONC finalizes a revision of the principles of proper conduct (PoPC) to require ONC-ACBs to report an expanded set of information to ONC for inclusion in the open data file that will make up the ONC Certified Health IT Product List (CHPL). The final rule states that health IT developers must disclose a detailed description of information that could interfere with the ability of users to implement certified health IT in a manner consistent with the certification requirements. Examples cited include:

- Disclosure of additional costs or fees imposed by a developer, or any third-party from whom the developer obtains technology, to purchase, license, implement, maintain, upgrade, use or otherwise enable the use of health IT capabilities to which the technology is certified. Disclosure must describe factors that impact additional types of costs, including volume and usage, and costs associated with necessary interfaces. Disclosure can be accomplished by providing an abbreviated disclaimer with a hyperlink to the complete disclosure on the developer's website.
- Limitation on the use of any capability to which the technology is certified.
- Limitations that could prevent successful implementation, configuration, customization, maintenance, support or use of the capability to which the technology is certified.

ONC emphasizes that the developers are required to describe with particularity the nature, magnitude and extent of the known material limitations or types of costs, including those of which a developer should be aware are caused by a third party. ONC does not require that the vendor disclose the actual dollar amount, but the potential costs of the interface development and configuration.

The AHA appreciates the inclusion of disclosure requirements to mitigate possible surprises due to unexpected and additional costs beyond those associated with the adoption and implementation of capabilities certified as part of the provider's certified EHR.

Product Surveillance by ONC-ACBs. ONC finalizes a proposal that the ONC-ACBs must initiate surveillance in the field as necessary to assess whether a complete EHR or Health IT Module continues to conform to the requirements of its certification once the product has been implemented and is in use. The ONC-ACBs also must initiate surveillance in the field whenever it becomes aware of facts or circumstances that would cause a reasonable person to question if a complete EHR or health IT module continued to conform to its certification requirements. During each calendar year surveillance period, an ONC-ACB must conduct random surveillance on a minimum of two percent of the complete EHRs and health IT modules for which it has issued a certification. The surveillance must evaluate at one or more locations where the complete EHR and health IT module is implemented and in use. If non-conformance is

identified, the ONC-ACB must notify the developer and require the submission of a proposed corrective action plan to the ONC-ACB. The plan must include how affected and potentially affected users of the complete EHR or health IT module are notified and when the identified issues will be resolved. The ONC-ACB has authority to initiate suspension for complete EHR for health IT module if a proposed corrective action plan is not submitted, if submitted but is not approved, or initiate certification termination where the actions to reinstate a suspended certification are not completed. The contents of the ONC-ACB surveillance results will not include information that would identify the user or location subject to surveillance.

The AHA appreciates the inclusion of a plan for surveillance of certified products but is concerned about the transparency and utility of the plan to hospitals and CAHs.

Decertification of Health IT. In the proposed rule, ONC requested comment on the circumstances and processes that should be considered to establish new requirements for the ONC-ACBs to terminate certifications. In the final rule, ONC acknowledged comments received from stakeholders and stated that additional rulemaking would be necessary to implement any new decertification process. ONC will consider the comments as it determines whether a new regulatory process for health IT is necessary or if other steps could better support continued compliance of certified health IT with certification requirements.

NEXT STEPS

Please share this advisory with your senior management team. Ask your chief information officer to consider how the options in the proposed rule would affect your hospital's approach to meeting meaningful use.

The AHA will submit comments on the Stage 3 provisions of this final rule. We also encourage hospitals to submit their own comments to CMS before the deadline of Dec. 15 at 5 p.m. ET.

Comments may be filed through www.regulations.gov. Follow the "submit a comment" instructions and refer to file code CMS-3310 & 3311-FC. You also may submit written comments (one original and two copies) to the addresses below:

Via regular mail:
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-3311-P
P.O. Box 8013
Baltimore, MD 21244-8013

Via express or overnight mail:
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attn: CMS-3311-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, MD 21244-1850

FURTHER QUESTIONS

If you have questions or need more information, please contact Diane Jones, AHA senior associate director, at djones@aha.org or 202-626-2305.

Appendix A. Objectives and Measures for EHs and CAHs – Stage 3 in 2018

Objective	Measures	Major Changes from Proposed Stage 3 Rule
1. Protect electronic health information: Protect electronic protected health information (ePHI) created or maintained by the certified electronic health record technology (certified EHR) through the implementation of appropriate technical, administrative, and physical safeguards.	1. Conduct or review a security risk analysis per Health Information Portability and Accountability Act (HIPAA), including assessing the security (including encryption) of data created or maintained by certified EHR) in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.	None
2. Electronic prescribing: Eligible hospitals (EHs) and critical access hospitals (CAHs) must generate and transmit permissible discharge prescriptions electronically (eRx).	2. More than 25 percent of EH or CAH discharge medication orders for permissible prescriptions (new and changed) are queried for a drug formulary and transmitted electronically using certified EHR.	None
3. Clinical decision support (CDS): Implement CDS interventions focused on improving performance on high-priority health conditions.	3. Implement five clinical decision support interventions related to four or more clinical quality measures (CQMs) at a relevant point in patient care for the entire EHR reporting period. 4. Enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	None
4. Computerized Provider Order Entry (CPOE): Use CPOE for medication, laboratory, and diagnostic imaging orders.	5. CPOE for medication - More than 60 percent of medication orders created by authorized providers of the EH or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE. 6. CPOE for labs - More than 60 percent of laboratory orders created by the authorized providers of the EH or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	Proposed rule included an 80 percent threshold for medication orders. Thresholds for laboratory and diagnostic imaging orders are the same as proposed.

Objective	Measures	Major Changes from Proposed Stage 3 Rule
	7. CPOE for diagnostic imaging – More than 60 percent of diagnostic imaging orders created by the authorized providers of the EH or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period are recorded using CPOE.	
5. Patient electronic access to health information: Use the certified EHR functionality to provide patient access health information or patient-specific educational resources.	8. For more than 80 percent of unique patients, either: (i) the patient (or patient-authorized representative) is provided timely access to view online, download, and transmit their health information - and (ii) the provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's certified EHR. 9. Use certified EHR to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients.	First measure: no change to threshold but removed the reference to provision of the timely access within 24 hours of its availability to the provider. Change in the optionality for EH or CAH to select which of the two elements of the first measure to meet. Second measure: no change.
6. Coordination of Care through Patient Engagement: Use certified EHR functionality to engage with patients or their authorized representatives. EH and CAH must attest/report the numerators/denominators for all three measures and must meet thresholds for two out of three measures.	10. More than 10 percent of all unique patients (or their authorized representatives) discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23) actively engage with the electronic health record made accessible by the provider. Measure to be met by patient is one of the following (i) view, download, or transmit to a third parity their health information, (ii) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's certified a combination of (i) and (ii). 11. For more than 25 percent of all unique patients or patient's authorized	First measure: reduction in threshold from 25 percent of all unique patients in 2018 and the option to combine (i) and (ii).

Objective	Measures	Major Changes from Proposed Stage 3 Rule
	representative discharged from EH or CAH inpatient or emergency department (POS 21 or 23), certified EHR was used to send a secure message to the patient or used in response to a secure message sent by the patient. 12. Patient generated data or data from a non-clinical setting for more than 5 percent of all unique patients.	Second measure: reduction in the threshold from 35 percent of all unique patients for 2018. Third measure: reduction in the threshold from 15 percent of all unique patients.
7. Health information exchange: provide a summary of care record when transitioning or referring their patient to another setting of care, or retrieve a summary of care record upon the first patient encounter with a new patient. EH/CAH must attest/report the numerators/denominators for all three measures. Must meet threshold on two of three measures.	13. For more than 50 percent of transitions of care and referrals, a summary of care record is created and sent electronically. 14. For more than 40 percent of transitions and referrals received and patient encounters in which the provider has never before encountered the patient, incorporate into the patient's EHR an electronic summary of care document from a source other than the provider's EHR system. 15. For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EH, CAH or EP performs a clinical information reconciliation that includes medications, medication allergy, and current problem list.	None

Objective	Measures	Major Changes from Proposed Stage 3 Rule
8. Public health and clinical data registry reporting: EH or CAH is in active engagement with a public health agency (PHA) or clinical data repository (CDR) to submit electronic public health data in a meaningful way using certified EHR, except where prohibited and in accordance with applicable law. EHs and CAHs must attest/report on four measures. The registry measures may be counted more than once if multiple registries are supported.	16. Immunization registry reporting. The EH or CAH is in active engagement with a PHA to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS). 17. Syndromic surveillance reporting. The EH or CAH is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting. 18. Case reporting. The EH or CAH is in active engagement with a public health agency to submit case reporting of reportable conditions. 19. Public health registry reporting. The EH or CAH is in active engagement with a public health agency to submit data to public health registries. 20. Clinical data registry reporting. The EH or CAH is in active engagement to submit data to a clinical data registry. 21. Electronic reportable lab results. The EH or CAH is in active engagement with a public health agency to submit electronic reportable laboratory results.	None

Appendix B. Objectives and Measures for EPs – Stage 3 in 2018

Objective	Measures	EP Exclusions
1. Protect electronic health information: Protect electronic protected health information (ePHI) created or maintained by the certified electronic health record technology (certified EHR) through the implementation of appropriate technical, administrative, and physical safeguards.	1. Conduct or review a security risk analysis per Health Information Portability and Accountability Act (HIPAA), including assessing the security (including encryption) of data created or maintained by certified EHR in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.	None
2. Electronic prescribing: Eligible Professional (EPs) must generate and transmit permissible prescriptions electronically (eRx).	2. More than 60 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using certified EHR.	Any EP who: (1) writes fewer than 100 permissible prescriptions during the EHR reporting period; or (2) does not have a pharmacy within its organization and there are no pharmacies that accept electronic prescriptions within 10 miles of the EP's practice location at the start of his or her EHR reporting period.
3. Clinical decision support (CDS): Implement CDS interventions focused on improving performance on high-priority health conditions.	1. Implement five clinical decision support interventions related to four or more clinical quality measures (CQMs) at a relevant point in patient care for the entire EHR reporting period. 2. Enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.	Measure 2 only: Any EP who writes fewer than 100 medication orders during the EHR reporting period.
4. Computerized Provider Order Entry (CPOE): Use CPOE for medication, laboratory, and diagnostic imaging orders.	1. CPOE for medication - More than 60 percent of medication orders created by the EP during the EHR reporting period are recorded using CPOE.	Any EP who writes fewer than 100 medication orders (Measure 1), fewer than 100 laboratory orders (Measure 2) or fewer than 100 diagnostic imaging

Objective	Measures	EP Exclusions
	2. CPOE for labs - More than 60 percent of laboratory orders created by the EP during the EHR reporting period are recorded using CPOE. 3. CPOE for diagnostic imaging – More than 60 percent of diagnostic imaging orders created by the EP during the EHR reporting period are recorded using CPOE.	orders (Measure 3) during the EHR reporting period.
5. Patient electronic access to health information: Use the certified EHR functionality to provide patient access health information or patient-specific educational resources.	1. For more than 80 percent of unique patients, either: (i) the patient (or patient-authorized representative) is provided timely access to view online, download, and transmit their health information - **and** (ii) the provider ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the API in the provider's certified EHR. 2. Use certified EHR to identify patient-specific educational resources and provide electronic access to those materials to more than 35 percent of unique patients.	Measures 1 and 2. (1) An EP with no office visits during the EHR reporting period. (2) Any EP that conducts 50 percent or more of his or her patient encounters in a county (or any hospital located in a county) that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.
6. Coordination of Care through Patient Engagement: Use certified EHR functionality to engage with patients or their authorized representatives. EP must attest/report the numerators/denominators for all three measures and must meet thresholds for two out of three measures.	1. More than 10 percent of all unique patients (or their authorized representatives) seen by the EP actively engage with the electronic health record made accessible by the provider and either of the following (i) view, download, or transmit to a third parity their health information, (ii) access their health information through the use of an API that can be used by applications chosen by the patient and configured to the API in the provider's certified EHR or combination of (i) and (ii).	Measures 1, 2 and 3: Any EP who has no office visits during the reporting period and Any EP that conducts 50 percent or more of his or her patient encounters in a county (or any hospital located in a county) that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period.

Objective	Measures	EP Exclusions
	2. For more than 25 percent of all unique patients or patient's authorized representative seen by the EP, a secure message was sent using electronic messaging functionality of certified EHR. 3. Patient generated data or data from a non-clinical setting for more than 5 percent of all unique patients.	
7. Health information exchange: EP provides a summary of care record when transitioning or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition or referral or upon the first patient encounter with a new patient, and incorporates summary of care information from other providers into their HER using the functions of certified EHR. EP must attest/report the numerators/denominators for all three measures. Must meet threshold on two of three measures.	1. For more than 50 percent of transitions of care and referrals, the EP that transitions or refers their patient to another setting of care or provider of care: (1) creates a summary of care record using the certified EHR; and (2) electronically exchanges the summary of care record. 2. For more than 40 percent of transitions or referrals received and patient encounters in which the EP has never before encountered the patient, the EP incorporates into the patient's EHR an electronic summary of care document. 3. For more than 80 percent of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, the EP performs clinical information reconciliation. The EP must implement clinical information reconciliation for two of the following three clinical information sets: medication, medication allergy, and current problem list.	Measure 1. (1) An EP who transfers a patient to another setting or refers a patient to another provider less than 100 times during the EHR reporting period. (2) Any EP that conducts 50 percent or more of his or her patient encounters in a county (or any hospital located in a county) that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from the FCC at the start of the EHR reporting period. Measure 2. (1) Any EP for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period. (2) Any EP that conducts 50 percent or more of his or her patient encounters in a county (or any hospital located in a county) that does not have 50 percent or more of its housing units with 4Mbps broadband availability according to the latest information available from

Objective	Measures	EP Exclusions
		the FCC at the start of the EHR reporting period. Measure 3. Any EP for whom the total of transitions or referrals received and patient encounters in which the provider has never before encountered the patient, is fewer than 100 during the EHR reporting period.
8. Public health and clinical data registry reporting: EP is in active engagement with a public health agency (PHA) or clinical data repository (CDR) to submit electronic public health data in a meaningful way using certified EHR, except where prohibited and in accordance with applicable law. EPs must attest/report on two measures. The registry measures may be counted more than once if multiple registries are available.	1. Immunization registry reporting. The EP is in active engagement with a PHA to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS). 2. Syndromic surveillance reporting. The EP is in active engagement with a public health agency to submit syndromic surveillance data from an urgent care setting. 3. Case reporting. The EP is in active engagement with a public health agency to submit case reporting of reportable conditions. 4. Public health registry reporting. The EP is in active engagement with a public health agency to submit data to public health registries. 5. Clinical data registry reporting. The EP is in active engagement to submit data to a clinical data registry.	Measures 1-5. The EP operates in a jurisdiction for which no registry or public health agency is capable of accepting the specific standards required to meet the certified EHR definition at the start of the EHR reporting period; or (b) operates in a jurisdiction where no registry or public health department has declared readiness to receive data as of 6 months prior to the start of the EHR reporting period. Measure 1. The EP (1) does not administer any immunizations to any of the populations for which data is collected by their jurisdiction’s registry or public health department during the EHR reporting period. Measure 2. The EP is not in a category of providers from which ambulatory syndromic surveillance data is collected by their jurisdiction's syndromic surveillance system.

Objective	Measures	EP Exclusions
		Measure 3. The EP does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system during the EHR reporting period. Measure 4. The EP does not diagnose or directly treat any disease or condition associated with a public health registry in their jurisdiction during the EHR reporting period. Measure 5. The EP does not diagnose or directly treat any disease or condition associated with a clinical data registry in their jurisdiction during the EHR reporting period.

Appendix C. 2015 Edition Certification Criteria to Support Stage 3

CFR Citation	Name of Certification Criterion	Inclusion in 2015 Edition Base Electronic Health Record (EHR) Definition	Relationship to the Certified EHR Definition and Stage 3 Objectives
§ 170.315 (a)(1)	Computerized Provider Order Entry (CPOE) - Medications	Included	CPOE Objective
§ 170.315 (a)(2)	CPOE - Laboratory	Included	CPOE Objective
§ 170.315 (a)(3)	CPOE - Diagnostic Imaging	Included	CPOE Objective
§ 170.315 (a)(4)	Drug-Drug, Drug-Allergy Interaction Checks for CPOE	Not Included	Clinical Decision Support Objective
§ 170.315 (a)(5)	Demographics	Included	No relationship beyond Base EHR definition
§ 170.315 (a)(6)	Problem List	Included	No relationship beyond Base EHR definition
§ 170.315 (a)(7)	Medication List	Included	No relationship beyond Base EHR definition
§ 170.315 (a)(8)	Medication Allergy List	Included	No relationship beyond Base EHR definition
§ 170.315 (a)(9)	Clinical Decision Support (CDS)	Included	CDS Objective
§ 170.315 (a)(10)	Drug Formulary and Preferred Drug List Checks	Not Included	Electronic Prescribing Objective
§ 170.315 (a)(11)	Smoking Status	Included	No relationship beyond Base EHR definition
§ 170.315 (a)(12)	Family Health History	Not Included	Certified EHR
§ 170.315 (a)(13)	Patient-specific Education Resources	Not Included	Patient Electronic Access to Health Information Objective
§ 170.315 (a)(14)	Implantable Device List	Included	No relationship beyond Base EHR definition

CFR Citation	Name of Certification Criterion	Inclusion in 2015 Edition Base Electronic Health Record (EHR) Definition	Relationship to the Certified EHR Definition and Stage 3 Objectives
§ 170.315 (b)(1)	Transitions of Care	Included	Health Information Exchange Objective
§ 170.315 (b)(2)	Clinical Information Reconciliation and Incorporation	Not Included	Health Information Exchange Objective
§ 170.315 (b)(3)	Electronic Prescribing	Not Included	Electronic Prescribing Objective
§ 170.315 (b)(6)	Data Export	Included	No relationship beyond Base EHR definition
§ 170.315 (c)(1)	Clinical Quality Measures - record & export	Included	Certified EHR
§ 170.315 (c)(2)	Clinical Quality Measures – import & calculate	Not Included	To be addressed in Hospital IPPS and PFS rulemaking
§ 170.315 (c)(3)	Clinical Quality Measures - report	Not Included	To be addressed in Hospital IPPS and PFS rulemaking
§ 170.315 (e)(1)	View, Download Transmit to Third Party	Not Included	Patient Electronic Access to Health Information Objective and Coordination of Care Objective
§ 170.315 (e)(2)	Secure Messaging	Not Included	Coordination of Care Objective
§ 170.315 (e)(3)	Patient Health Information Capture	Not Included	Certified EHR Coordination of Care Objective
§ 170.315 (f)(1)	Transmission to Immunization Registries	Not Included	Public Health Reporting Objective
§ 170.315 (f)(2)	Transmission to Public Health Agencies – syndromic surveillance	Not Included	Public Health Reporting Objective
§ 170.315 (f)(3)	Transmission to Public Health Agencies – reportable lab tests and values/results	Not Included	Public Health Reporting Objective
§ 170.315 (f)(4)	Transmission to Cancer Registries	Not Included	Public Health Reporting Objective

CFR Citation	Name of Certification Criterion	Inclusion in 2015 Edition Base Electronic Health Record (EHR) Definition	Relationship to the Certified EHR Definition and Stage 3 Objectives
§ 170.315 (f)(5)	Transmission to Public Health Agencies – case reporting	Not Included	Public Health Reporting Objective
§ 170.315 (f)(6)	Transmission to Public Health Agencies – anti-microbial use and resistance reporting	Not Included	Public Health Reporting Objective
§ 170.315 (f)(7)	Transmission to Public Health Agencies – health care surveys	Not Included	Public Health Reporting Objective
§ 170.315 (g)(1)	Automated Numerator Recording	Not Included	Certified EHR
§ 170.315 (g)(2)	Automated Measure Calculation	Not Included	Certified EHR
§ 170.315 (g)(7)	Application Access –Patient Selection	Included	Certified EHR Patient Electronic Access Health Information Electronic Objective and Coordination of Care Objective
§ 170.315 (g)(8)	Application Access – Data Category Request	Included	Certified EHR Patient Electronic Access Health Information Electronic Objective and Coordination of Care Objective
§ 170.315 (g)(9)	Application Access – All Data Request	Included	Certified EHR Patient Electronic Access Health Information Electronic Objective and Coordination of Care Objective
§ 170.315 (h)(1)	Direct Project	Included	No relationship beyond Base EHR definition
§ 170.315 (h)(2)	Direct Project, Edge Protocol, XDR/XDM	Included	No relationship beyond Base EHR definition

Note: In the EHR Incentive Program final rules, CMS finalizes the proposal to place the "Certified EHR" definition within the Stage 3 rule. In the 2015 Edition certification final rule, ONC identifies the 2015 Edition certification criteria associated with the EHR Incentive Programs Stage 3 as finalized in the EHR Incentive Program Stage 3 and Modifications final rule.