PROPOSED RULES ON STAGE 3 OF MEANINGFUL USE OF EHRs

AT A GLANCE

At Issue:
The Centers for Medicare & Medicaid Services (CMS) on March 30 published the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 proposed rule defining Stage 3 of “meaningful use” of electronic health records (EHRs). At the same time, the Office of the National Coordinator (ONC) for Health Information Technology (IT) issued a proposed 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 beginning in 2017. Taken together, these regulations raise the bar on EHR adoption requirements that hospitals and physicians must meet to avoid significant payment penalties. This advisory contains highlights of both rules. Comments are due May 29 for both rules.

Additionally, CMS on April 15 published a separate proposed rule that would modify the reporting period for the Medicare and Medicaid EHR Incentive Programs in 2015 from a 365-day to a 90-day period aligned with the calendar year and provide additional flexibilities. The rule also would remove some measures that have reached widespread adoption. However, the rule also proposes a significant number of other changes to the program in the middle of the program year. Watch for a separate advisory on the rule modifying meaningful use in 2015 to 2017. Comments are due June 15.

Our Take:
While we are pleased about the proposed 90-day period in the April 15 rule, the AHA is very concerned that the proposed Stage 3 requirements would raise the bar too high without first addressing the challenges with meeting existing program thresholds, such as those related to the patient portal, transitions of care and electronic quality reporting.

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 proposed rules would affect your plans to move forward with meaningful use.

✓ Ask your quality staff to evaluate the proposed change in policy for quality reporting requirements.

✓ Make sure your information technology and medical records departments review the proposed data standards set forward in the ONC certification rule.

Further Questions:
Please contact Diane Jones, AHA senior associate director, at djones@aha.org or 202-626-2305.
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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 (certified EHR) 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). FY 2016 is the last year for EHs and CAHs to receive incentive payments from Medicare. CMS began phasing-in Medicare penalties for those failing to meet the meaningful use program requirements in FY 2015; the penalties do not sunset.

Stage 1 of meaningful use began in FY 2011 for EHs and CAHs. Stage 2 began in FY 2014. On March 30, the Centers for Medicare & Medicaid Services (CMS) and ONC released two proposed rules that set the requirements and timelines for Stage 3 of meaningful use. This advisory summarizes key elements of the proposed rules, including:

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

The proposed 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 Medicare and Medicaid EHR Incentive Programs. This advisory does not include information on incentive payments for qualifying MA organizations.

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

THE MEDICARE AND MEDICAID PROGRAMS; EHR INCENTIVE PROGRAM- STAGE 3 PROPOSED RULE

Definition of Meaningful Use for Stage 3
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.

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, CMS raised the bar on meaningful use requirements using the 2014 Edition certified EHR. CMS proposes 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 means 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 certified EHR proposed by ONC would support providers in meeting Stage 3.

CMS adds 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.

**Timing and Stages of Meaningful Use**

CMS proposes 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 below). Either the 2014 Edition certified EHR or 2015 Edition could be used in 2017. The 2015 Edition certified EHR would be required beginning with the 2018 reporting period.

<table>
<thead>
<tr>
<th>First Year as a meaningful user of certified EHR</th>
<th>Stage of Meaningful Use</th>
</tr>
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<tbody>
<tr>
<td>2011</td>
<td>1</td>
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<tr>
<td>2012</td>
<td>1</td>
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<tr>
<td>2013</td>
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<td>2014</td>
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<td>2015</td>
<td>1</td>
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<tr>
<td>2016</td>
<td>1</td>
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<tr>
<td>2017</td>
<td>1, 2 or 3</td>
</tr>
<tr>
<td>2018 and thereafter</td>
<td></td>
</tr>
</tbody>
</table>

Explanatory Note: 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, despite the alternate demonstration of meaningful use. In 2015, all such providers are considered to be participating in their second year of Stage 2.

**Meaningful Use Stage 3 Objectives and Measures**

CMS proposes to create a single set of eight objectives for all providers for Stage 3, eliminating the use of core and menu objectives. Limited variation would be permissible among the measures required of EHs, CAHs and EPs.

CMS proposes to consolidate the 16 core and three menu objectives required for hospitals in Stage 2 in the objectives and measures for Stage 3. CMS notes that some of the objectives and measures included in Stages 1 and 2 involved EHR functions that are required by the statutory definition of “certified EHR technology,” which a provider must use to demonstrate meaningful use. The agency...
states that the objectives and measures proposed for Stage 3 would include uses of these EHR functions in a more advanced form.

The eight proposed 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

To meet the objectives in Stage 3, CMS proposes 21 measures that raise 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, while the full set of measures is in Appendix A.

**Protect Patient Health Information.** CMS proposes to maintain the previously finalized 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. CMS proposes the addition of the terms “administrative and physical safeguards” to the objective.

The proposed 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 proposes to 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
- At least once per EHR reporting period in subsequent years.

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 proposes to require 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 a menu objective in Stage 2 and the threshold was 10 percent. CMS proposes that EPs continue the requirement to generate and transmit permissible prescriptions electronically, but would raise the threshold to more than 80 percent of all permissible prescriptions written by an EP are queried for a drug formulary and transmitted electronically.

CMS proposes that prescribers practicing in a state where controlled substances may be electronically prescribed may include these prescriptions in the numerator and denominator for calculating the percent, but must do so across all patients and across all allowable schedules for the duration of the EHR reporting period.
Exclusions available for eRx objective. For EHs and CAHs, CMS proposes an exclusion if the EH or CAH does not have an internal pharmacy that can accept electronic prescriptions and there are no pharmacies within 10 miles that accept electronic prescriptions at the start of its EHR reporting period. CMS maintains the exclusion for EPs who write fewer than 100 permissible prescriptions during the EHR reporting period.

CDS. CMS proposes to continue the Stage 2 objective that EHs, CAHs and EPs implement clinical decision support (CDS) interventions focused on high-priority conditions. CMS clarifies 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. For measure number two, CMS proposes 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 propose an exclusion for EHs or CAHs for either measure. For EPs, CMS proposes an exclusion for measure two if an EP writes fewer than 100 medication orders during the EHR reporting period.

CPOE. CMS proposes to maintain the computerized provider order entry (CPOE) objective that providers use a computer or mobile device to record and enter clinical orders in a structured format. It proposes to expand the objective to include diagnostic imaging, a broader category than radiology imaging, and proposes to increase the thresholds for the three measures required to meet this objective:

1. Medication Orders: CMS proposes that 80 percent of all medication orders be recorded using CPOE. The Stage 2 measure threshold was 60 percent.
2. Laboratory Orders: CMS proposes that 60 percent of all lab orders be recorded using CPOE. The Stage 2 threshold was 30 percent.
3. Diagnostic Imaging Orders: CMS proposes that 60 percent of all diagnostic imaging orders be recorded using CPOE. The Stage 2 threshold was 30 percent for radiology imaging orders.

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

Patient Electronic Access. CMS proposes to continue the use of patient portals to facilitate patients’ ability to view, download or transmit (VDT) their health information electronically. CMS also proposes 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). If a provider elects to implement an API, the provider would need to fully enable the API functionality, provide patients with detailed instructions on how to authenticate the app, and provide supplemental information on the app that leverages the API. CMS proposes that two measures are required to meet this objective.
For measure one of this objective, CMS proposes the use of VDT and an ONC-certified API to facilitate patient electronic access. Specifically, CMS proposes that patients or their authorized representatives are able to access their health information within 24 hours of its availability from a provider EH, CAH or EP by means of VDT or an ONC-certified API. CMS also seeks public comment on alternatives to this proposal – whether providers must offer VDT and ONC-certified API functionality; VDT or ONC-certified API functionality; or just ONC-certified API functionality. The Stage 3 threshold for measure one would be 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 in 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 in regulation.

For measure two of this objective, CMS proposes 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 Stage 2 threshold was 10 percent of unique patients.

**Exclusions available for patient electronic access objective.** CMS proposes to continue the exclusion offered in Stage 2 that any EH, CAH or EP is excused from measure one if it is located in a county with limited broadband availability, 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) at the start of the EHR reporting period. CMS also proposes an additional exclusion for any EP who has no office visits during the EHR reporting period.

**Coordination of Care through Patient Engagement.** CMS proposes to create a new 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 proposes that more than 25 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. For the API option, CMS proposes that EH, CAHs and EPs must attest that they have enabled an API and that at least one app which leverages the API is available to patients or the patient-authorized representative to retrieve health information from the EHs, CAHs or EPs certified EHR.

For measure two, CMS proposes that for more than 35 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 sent using the electronic messaging function of the certified EHR must be used for the communication 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 measure three, CMS proposes that EHs, CAHs or EPs incorporate data in the certified EHR for more than 15 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 proposes that a non-clinical setting shall be defined as a setting with any provider who is not an EH, CAH or EP as defined for the Medicare and Medicaid EHR Incentive Programs and where the care provider does not have shared access to the EH, CAH or EP certified EHR. Patient-generated data may have many sources, including data from wearable devices, patient self-monitored data or social service data. CMS seeks comment on whether this measure should be proposed for EHs and CAHs or only for EPs.
Exclusions available for care coordination through patient engagement objective. CMS proposes an exclusion for EHs, CAHs and EPs that is applicable to measures one, two and three. Specifically, CMS proposes that any EH or CAH that is located in a county with limited broadband availability, as defined above is excluded from the measure. CMS also proposes an exclusion for any EP who has no office visits during the EHR reporting period.

CMS proposes that EHs, CAHs and EPs must 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 is concerned that raising the VDT threshold to 25 percent is too high given that the majority of providers have not yet met Stage 2 objectives. While important, electronic patient engagement has been one of the most challenging objectives to meet because it holds providers responsible for the actions of others outside of their control. We are concerned that the standards to support the use of ONC-certified APIs and patient-generated data are still under development and are not yet mature enough to be included in regulation.

HIE Supporting Transitions of Care. CMS proposes to revise the Stage 2 objective to create a new HIE objective requiring an EH, CAH or EP to provide a summary of care record when transitioning or referring their patient to another setting of care, and retrieving a summary of care record upon the first patient encounter with a new patient. To meet the Stage 3 objective, CMS proposes to require EHs, CAHs and EPs to use the common clinical data set (CCDS) specified by ONC in the proposed 2015 Edition certification rule, rather than the meaningful use data set from Stage 2. The CCDS includes new information fields, such as the unique device identifier (UDI) for implantable medical devices.

For Stage 3, CMS proposes three measures to support the objective. Measure one proposes that, for more than 50 percent of transitions of care and referrals, the EH, CAH or EP create a summary of care record 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.

CMS proposes to offer provider discretion regarding the circumstances and cases where the EH, CAH or EP may limit the information included in the summary of care record to the clinically relevant laboratory test results, clinical notes, problem lists and the care plan. CMS acknowledges prior stakeholder comments that this flexibility would be beneficial but adds that it would be incumbent on the providers to define and develop in partnership with their health IT developers the approaches that best fit organizational needs and specific patient populations. CMS states that EHs, CAHs and EPs must have a certified EHR that can send all labs or clinical notes if the recipient of the summary of care record subsequently requests this additional information.

CMS also proposes to allow provider discretion on the set of historical data to include in a summary of care record. CMS encourages providers to send a list of items believed to be pertinent and relevant to the patient’s care, rather than a list of all problems, whether active or resolved, that have ever populated the problem list. CMS adds that a provider can use judgment to decide 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 proposes 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 proposes 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 health information exchange supporting transitions of care objective. CMS proposes an exclusion for EHs, CAHs and EPs that is applicable to measures one, two and three. Specifically, CMS proposes an exclusion for any EH, CAH or EP that is located in a county with limited broadband availability as defined above.

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

CMS proposes that to meet this objective, an EH, CAH or EP must attest to the numerator and denominator for all three measures but will only be required to successfully meet the threshold for two of the three proposed measures.

Public Health Reporting. In Stage 3, EHs and CAHs would need to meet four of six public health reporting measures and EPs would need to meet three of six public health measures. CMS proposes in Stage 3 to use the term “active engagement” to describe the requirement that an EH, CAH or EP use certified EHRs to submit data to a public health agency (PHA) or clinical data registry (CDR) in order to report the selected measure. Active engagement replaces the Stage 2 requirement for “ongoing submission.” CMS includes three options to demonstrate “active engagement:"

- 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 proposes to distinguish between reporting to a PHA and a CDR. An EH, CAH or EP would be permitted to report to more than one public health registry, such as reporting to both the National Hospital Care Survey and the National Healthcare Safety Network registry. Reporting to more than one registry would count toward meeting the total number of required measures for this objective. Also, an EH, CAH or EP would be permitted to report to more than one clinical data registry (see Table 2).

In Stage 2, the term “specialized registry” was used to include both registry reporting to public health agencies and clinical data registries but CMS proposes to separate them in Stage 3. CMS also proposes a new measure in the public health reporting objective: case reporting of reportable conditions to a PHA. CMS states that the electronic collection of “reportable conditions,” as defined by the state, territorial, and local PHAs, will improve the ability to monitor disease trends and support the management of outbreaks.
Table 2. Public Health Reporting Objective and Measures

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

Exclusions available for public health reporting reporting objective. CMS proposes specific exclusions to the public health reporting measures. However, the agency proposes to require 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.

Reporting Electronic Clinical Quality Measures (eCQMs)
The rule proposes many changes to electronic clinical quality measure (eCQM) reporting requirements for meaningful use in Stage 3, including a change to the reporting period, the format of reporting and version of the eCQMs reported. Importantly, CMS proposes to require electronic submission of eCQMs in CY 2018. The AHA is concerned about setting a specific date for required electronic eCQM submission. Additional work is necessary to improve the feasible, reliable and accurate use of EHRs for eCQM reporting.

CMS proposes to require EHs and CAHs to report eCQMs on a calendar basis beginning in calendar year (CY) 2017. CMS also proposes to require a full year of reporting and require the submission of quality data on a quarterly basis. A limited exception would be available for eCQM reporting in the Medicaid EHR Incentive Program.

To report eCQMs in 2017, CMS proposes to allow different versions of certified EHRs to be used to report eCQMs and the meaningful use measures. Specifically, the proposal would allow EHs, CAHs and EPs to use the 2015 Edition certified EHRs to report eCQMs and the 2014 Edition certified EHRs.
to report the meaningful use objectives and measures; or to allow EHs, CAHs and EPs to use 2015 Edition EHRs to report meaningful use objectives and measures and use 2014 Edition EHRs to report eCQMs in 2017.

Providers submitting eCQMs via attestation in 2017 could use the version of the eCQM specifications for which their EHR was certified. Providers submitting eCQMs electronically must use the most recent version of the electronic specifications that will be released by CMS in 2016. CMS acknowledges that this would impose a new task on EHR vendors to make annual updates to their products to support the annual electronic specifications updates of eCQMs. CMS states that attestation to eCQMs would be an option in 2018 only in circumstances where electronic reporting is not feasible due to circumstances such as a data submission system failure, natural disaster or certification issue outside the control of the provider.

CMS proposes to eliminate the Quality Reporting Data Architecture Category-III (QRDA-III) option for EHs and CAHs to report aggregate level data for the Medicare EHR Incentive Program. Submission of patient-level QRDA-I data to Medicare would be required. States would have the option to allow EHs and CAHs to report QRDA-III data for the Medicaid EHR Incentive Program. EPs will retain the option to submit QRDA-I or QRDA-III data to CMS.

Additionally, CMS proposes some changes to eCQMs in this rule (Electronic Health Record Incentive Program-Stage 3) and some changes in the FY 2016 Inpatient Prospective Payment System (PPS) proposed rule. In the inpatient PPS rule, CMS states that it intends to expand the set of eCQMs available for reporting under the EHR Incentive Programs in CY 2017 and subsequent years and will engage stakeholders for input. With respect to the versions of the electronic specifications that support electronic reporting of eCQMs, CMS encourages EHR developers to test any updates, including changes to the eCQMs and changes to CMS reporting requirements based on the CMS QRDA implementation guide, on an annual basis. CMS seeks comment on an appropriate frequency for requiring retesting and recertification of EHRs to the most updated versions of CQMs and most recent “form and manner” of reporting required for both the Hospital Inpatient Quality Reporting Program and EHR Incentive Program. Additional insight on the eCQMs reported by EPs will be included in the proposed Physician Fee Schedule rule. **We are concerned that CMS is proposing to adopt a date certain for electronic submission of eCQMs while proposing in a separate rule additional changes to eCQM reporting.**

**Medicaid-specific Changes**

CMS proposes to maintain under the Medicaid EHR Incentive Program a 90-day EHR reporting period for EHs, CAHs and EPs that are demonstrating meaningful use for the first time in CY 2017. 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 2017.

CMS proposes to give states the flexibility to create their own Medicaid measures for public health and clinical data registry reporting. States also would 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 proposed rule.

**CMS Operations**

CMS proposes that EHs, CAHs and EPs would submit their meaningful use data for the applicable objectives and measures of meaningful use in 2017 and subsequent years in the two months following the close of the EHR reporting period, with an attestation deadline of the last day of February.

*American Hospital Association*
CMS proposes to potentially publish performance and participation data on the Stage 3 objectives and measures in a manner comparable to the publication of performance with quality programs.

CMS proposes no change to the hardship exceptions previously finalized. For EHs and CAHs, CMS proposes to change the reporting periods subject to review for implementation of penalties from the fiscal to calendar years, reflecting the change in reporting periods. For example, for CAHs, CMS proposes that the EHR reporting period that would be subject to review for consideration of a payment adjustment would be the full 2017 calendar year, rather than a full 2017 fiscal year.

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
The ONC proposed rule on 2015 Edition Health Information Technology Certification Criteria (2015 Edition rule) includes new and updated content and vocabulary standards that support the structured recording by health information technology modules (HIT modules) required in the EHR Incentive Program and in care and practice settings not included in the EHR Incentive Program. The rule includes proposals to facilitate access and exchange of health information by including API capabilities in the 2015 Edition Base EHR definition which ONC maps to statutory requirements. To meet the requirements of meaningful use set forward by CMS, a provider will need an EHR certified to capabilities beyond the Base EHR definition. The APIs available as part of the EHR are intended to allow a provider to give patients the choice to access to their health information through third-party apps.

ONC also proposes changes to the Health IT Certification Program with the goal of improving interoperability and providing greater disclosure about the certified products and surveillance requirements. The revised certification program also is intended to support the certification of health IT modules that are used by participants in the EHR Incentive Program and other care settings.

The AHA is concerned that the 2015 Edition Certification Criteria includes immature standards. Experience to date indicates that such immature standards create implementation challenges for providers and create barriers to meeting program requirements within the program timeframe.

Definition Revisions in the 2015 Edition Rule
Certified EHR Definition. ONC proposes to cease using the term “certified EHR technology” in its certification regulation and to refer to certified products as “Health IT modules.” ONC states that certified EHR technology is a term specific to the CMS EHR Incentive Program. ONC adds that the change aligns with the approach throughout the proposed rule to make the ONC Health IT Certification Program more open and accessible to other types of health IT beyond EHR technology required for inclusion in the EHR Incentive Program. The CMS definition of certified EHR in the EHR Incentive Program Stage 3 proposed rule refers to the Base EHR definition, which defines the minimal functions required for an EHR and the certification criteria promulgated by ONC that refer to additional functionality required for a certified EHR.

Base EHR Definition. ONC proposes the use of the term “2015 Edition Base EHR” and to rename the current Base EHR as the “2014 Edition Base EHR.” The definition of the 2015 Edition Base EHR
differs from the 2014 definition in several ways:

- Does not include privacy and security capabilities and certification criteria. Privacy and security criteria are addressed in a newly proposed health IT module certification criterion.
- Includes capabilities to record and export clinical quality measure data, not the capabilities to import, calculate and report clinical quality measure data.
- Includes the “smoking status” certification criterion.
- Includes the 2015 Edition “implantable device list” certification as patient demographic and clinical health information data.
- Includes the 2015 Edition “application access to Common Clinical Data Set” certification criterion.

**Certification Criteria**

ONC proposes several changes in the certification criteria for the 2015 Edition. The table in Appendix B includes the certification criteria included in the 2015 Edition Certification Criteria and indicates if the certification criteria are included in the Base EHR, are required for the EHR Incentive Program, and support a specific meaningful use objective.

**Common Clinical Data Set (CCDS).** ONC proposes to redefine the “Common Meaningful Use Data Set” and rename it the “Common Clinical Data Set.” The CCDS will contain the updated and new standards for the 2015 Edition data fields included in a summary of care. The new data fields are the unique device identifier (UDI) of a patient’s implantable device(s), smoking status and immunizations. ONC proposes to adopt the Food and Drug Administration’s (FDA) definitions of UDI, implantable device and device identifier in the 2015 Edition certification rule. ONC states that, with this information, providers can accurately identify a patient’s implantable devices and prevent adverse events resulting from misidentification or non-identification of the device and its associated safety characteristics (such as MRI compatibility and latex content). ONC adds that health IT also could be leveraged in conjunction with automated identification and data capture (AIDC) or other technologies to streamline the capture and exchange of UDIs and associated data for patients’ devices. It adds that, as UDIs become ubiquitous, UDI capabilities in health IT could facilitate better post-market surveillance of devices, better and more accurate reporting of device-related events, and more effective corrective and preventive action in response to device recalls and alerts.

ONC proposes that the current care plan fields, including goals and instructions, be replaced with fields for the “assessment and plan of treatment,” “goals” and “health concerns.” ONC proposes that APIs have access to the CCDS to capture and query information. All EHRs, CAHs and EPs would have to adopt a health IT module that is certified to these criteria.

**Vocabulary Standards.** ONC proposes the inclusion of updated and new vocabulary standards in the CCDS for 2015 Edition certification:

- Health Level 7 (HL7) Version 3 for sex;
- “Race & Ethnicity – Centers for Disease Control and Prevention (CDC)” code system and the Office of Management and Budget (OMB) standard for race and ethnicity;
- Tags for Identifying Languages – Request for Comment (RFC) 5646 for preferred language;
- The September 2014 Release of the U.S. Edition of Systemized Nomenclature of Medical Clinical Terms (SNOMED CT®) for problems and procedures;
Clinical Quality Measures. ONC proposes that the Base EHR include the capability to record and export CQM data. The capabilities to import, calculate and report CQM data would not be included.

ONC also proposes additional changes for eCQM certification in FY 2016 inpatient PPS proposed rule. In that rule, ONC proposes four options that would specify the electronic data form used to submit electronic clinical quality measures:

1. The July 2012 QRDA Category-I Implementation Guide (currently supported by 2014 Edition EHRs);
2. The July 2012 QRDA Category I Implementation Guide with the September 2014 Errata;
3. QRDA-like standards for individual patient-level reports based on the anticipated Quality Improvement and Clinical Knowledge (QUICK) Fast Health Interoperability Resources (FHIR)-based Draft Standard for Trial Use; and
4. The next release of the QRDA Category I Implementation Guide (under development).

For the Medicaid EHR Incentive Program, states will continue to be responsible for determining whether and how electronic reporting of CQMs occurs or if reporting through attestation is allowed.

The AHA opposes the inclusion in regulation of proposals for standards or implementation guidance that has not been tested and is not mature for widespread use.

Privacy and Security. ONC proposes that the privacy and security certification criteria for a health IT module will depend on the functional area of the module. The health IT vendor would be required to identify the privacy and security certification criteria that would be applicable based on the capabilities included in the health IT module. The vendor would have to meet one of three approaches in order to receive certification:

- The module’s system documentation and certification testing indicate it meets the criteria;
- The module has implemented an interface that enables external services necessary to meet the criteria; or
- The module’s documentation indicates that it is not required to meet the criteria.

ONC states that this new approach would eliminate EH, CAH and EP responsibility to ensure that they have technology certified to all the necessary privacy and security criteria.

Data Segmentation Criteria. ONC proposes to adopt two new certification criteria that focus on the capability to track the sending and receipt of individually identifiable health information that is protected by rules that are more privacy-restrictive than the HIPAA Privacy Rule. The sensitive health information certification proposals would use the data segmentation for privacy implementation guide to indicate that the information being sent is subject to additional restrictions so that the recipient can
properly handle the electronically transmitted sensitive health information.

Criteria Proposed as Required for All Health IT Modules Presented for Certification. ONC proposes that safety-enhanced design (SED) and quality management system (QMS) certification criteria are required for all health IT modules. For the safety-enhanced design certification criteria, ONC proposes 17 SED certification criteria, of which seven are new in the 2015 Edition. Each SED criterion supports a specific capability, and SED user-centered design processes must have been applied in order satisfy this certification criterion. ONC proposes that health IT modules will not be permitted to receive certification without being subject to a QMS. ONC also proposes to require health IT developers to either use a recognized QMS or illustrate how the QMS they used maps to one or more QMSs established by the federal government or a standards developing organization.

Certification Criteria Required in Meaningful Use but not a 2015 Edition Certification Requirement. ONC proposes that ONC Authorized Certification Bodies (ONC-ACBs) will not be required to certify Health IT modules to the automated numerator recording and the automated measure calculation criteria included in meaningful use. However, EHs, CAHs and EPs are required to have health IT certified to meet these criteria for the proposed Stage 3 EHR Incentive Program.

The table below lists the base EHR capabilities and the required certification criteria to support the capabilities.

### Table 3. Certification Criteria Required to Satisfy the 2015 Edition Base EHR Definition

<table>
<thead>
<tr>
<th>Base EHR Capabilities</th>
<th>Certification Criteria</th>
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</thead>
</table>
| Includes patient demographic and clinical health information, such as medical history and problem lists | Demographics § 170.315(a)(5)  
Problem List § 170.315(a)(7)  
Medication List § 170.315(a)(8)  
Medication Allergy List § 170.315(a)(9)  
Smoking Status § 170.315(a)(12)  
Implantable Device List § 170.315(a)(20) |
| Capacity to provide clinical decision support                                         | Clinical Decision Support § 170.315(a)(10)                                             |
| Capacity to support physician order entry                                             | Computerized Provider Order Entry § 170.315(a)(1), (2) or (3)                           |
| 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 Portability § 170.315(b)(6)  
Application Access to Common Clinical Data Set §170.315(g)(7)  
Direct Project § 170.315(h)(1) or Direct Project, Edge Protocol, and XDR/XDM § 170.315(h)(2) |

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 proposes 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 proposes several new certification criteria for the 2015 Edition, including:

- **CPOE:** To accommodate the split of the 2014 criterion, ONC proposes three separate criteria by order type (medications, laboratory and diagnostic imaging). ONC seeks comment on whether a health IT module should (for purposes of testing and certification) include the capability to include any or all of the following in a transmitted order: secondary diagnosis codes, reasons for order, comment fields for the ordering provider and other data elements.

- **Vital Signs:** ONC proposes to expand the types of vital signs for recording; require each type of vital sign to have a specific LOINC® code attributed to it; require that The Unified Code of Units of Measure, Revision 1.9, Oct 23, 2013 (“UCUM Version 1.9”) be used to record vital sign measurements; and require that certain metadata accompany each vital sign, including date, time and measuring or authoring type source.

- **Electronic Prescribing:** ONC proposes to require receipt and response for additional transactions or segments (Change, Refill and Cancel Prescription; Fill Status; and Medication History); require directions for medication use transmitted as e-prescriptions to be codified in a structured format; and limit e-prescriptions to the metric unit standard only.

- **CDS:** ONC proposes to adopt an updated Infobutton standard and two updated implementation guides to require certification only to the Infobutton standard (and associated guide); and to require the ability to record users’ actions in response to CDS interventions.

- **Family Health History:** ONC proposes to adopt two family health history certification criteria (Family Health History and Family Health History-Pedigree), both of which are revised.

- **Patient-specific Education Resources:** ONC proposes to remove the requirement to identify resources electronically based on “laboratory values/results,” and to clarify resources must be identified electronically using Infobutton and another method that does not rely on Infobutton.

- **Transition of Care (ToC):** ONC proposes to expand on the 2014 Edition optional criterion with an updated consolidated clinical document architecture (C-CDA) standard and to require the capability to detect valid and invalid C-CDA documents.

- **View, Download, Transmit (VDT):** ONC proposes to revise the criterion to clarify that this capability is patient-facing and for patients to use; to include the CCDS and diagnostic imaging reports; to require that the same API capabilities applicable to the CCDS apply to this criterion; to include the addressee of an ambulatory or inpatient summary; to provide patient laboratory test reports; and for the view capability to be compliant with Web Content Accessibility Guidelines (WCAG) 2.0 Level A.

- **Clinical Summary:** ONC does not propose a 2015 Edition clinical summary certification criterion; it believes the capabilities under the VDT criterion adequately support proposals of the EHR Incentive Programs.
• **Transmission to Immunization Registries**: ONC proposes to adopt an updated implementation guide, require National Drug Codes for recording administered vaccines, require CVX codes for historical vaccines, and require that a health IT module display an immunization history and forecast from an immunization registry.

• **Safety-enhanced Design**: ONC proposes to add criteria for error prevention and to clarify compliance requirements for data elements in National Institute of Standards and Technology Interagency/Internal Report (NISTIR) 7742.

**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 proposes 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). ONC proposes to require API functionality of the information to facilitate access. ONC proposes to require that ONC-ACBs obtain a monthly report from vendors on all adaptations and updates, including changes to user-facing aspects, made to the certified health IT module. The reports on product updates would not be made available on the CHPL. ONC also proposes that ONC-ACBs retain records related to certification for six years and make the certification records available to other Department of Health and Human Services agencies.

**Vendor Transparency.** ONC proposes to revise the principles of proper conduct in order to require disclosure of additional costs to the provider in order to use the functionality of the certified Health IT module. Examples include the disclosure of separate “one-time” and/or “ongoing” interface development and configuration fees to establish connectivity between a certified Health IT module and a public health authority, or a “one-time” fee charged to integrate the certified health IT with a hospital's other certified technology or a health information exchange. In these instances, ONC does not propose that the vendor disclose the actual dollar amount, but the potential costs of the interface development and configuration. ONC also proposes that vendors disclose in detail any limitations on the certified health IT module. The examples of limitations include additional licensing fees or upgrades, limitations on use of the health IT module’s data generated or limits on customization or 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.**

**Additional Requirements for Product Surveillance by ONC-ACBs.** ONC proposes to build on existing surveillance responsibilities of ONC-ACBs by specifying requirements and procedures for in-the-field surveillance requirements of certified products, through unscheduled inspections of products in use and through greater scrutiny applied to products that are the subject of complaints. ONC proposes to require the ONC-ACBs to report on complaints received concerning certified health IT to the National Coordinator. ONC recognizes that the assessment of certified products in the field would require ONC-ACBs to employ different methodologies than those used in a controlled testing and certification environment. However, ONC states that the ONC-ACBs should be able to effectively assess certified capabilities in the field using other remote methods that would not involve in-person site visits.
Decertification of Health IT. ONC seeks comment on the circumstances and processes that should be considered to establish new requirements for the ONC-ACBs to terminate certifications.

**NEXT STEPS**

Please share this advisory with your senior management team and ask your chief information officer (CIO), chief medical information officer and clinical leaders to evaluate the proposed requirements for Stage 3 in light of your current EHR implementation. Quality and clinical analytics teams should review the proposed quality reporting policy changes, while medical records teams and privacy and security staff should evaluate the proposed data standards (including race and ethnicity, preferred language, social, psychological and behavioral data, and the problem list). If you have not already done so, your CIO should discuss with your EHR vendors what products they intend to certify and assess your need to supplement with additional certified EHR modules or self-certification to ensure that your system has been fully certified.

The AHA recommends that members submit comments to CMS and ONC on their respective proposed rules by the deadline of **May 29, 2015**. Comments may be submitted electronically at www.regulations.gov. Follow the “submit a comment” instructions and refer to file code CMS-3310-P for the CMS rule and RIN 0991-AB93 for the ONC rule. 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
P.O. Box 8013,
Baltimore, MD 21244-8013

Via overnight or express mail:
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3310-P
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

Via regular, overnight or express mail:
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Attention: 2015 Edition Health IT Certification Criteria Proposed Rule
Hubert H. Humphrey Building
Suite 729D
200 Independence Ave, S.W.
Washington, D.C. 20201
**FURTHER QUESTIONS**

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

<table>
<thead>
<tr>
<th>Objective</th>
<th>Measures</th>
<th>Optionality</th>
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<tbody>
<tr>
<td>Protect patient 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.</td>
<td>1. Conduct or review a security risk analysis per Health Information Portability and Accountability Act (HIPAA) (assessing the security of data stored in certified EHR), implementing security updates as necessary, and correcting identified security deficiencies as part of the provider’s risk management process.</td>
<td>None</td>
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<tr>
<td>Electronic prescribing: Eligible hospitals (EHs) and critical access hospitals (CAHs) must generate and transmit permissible discharge prescriptions electronically (eRx). Eligible professionals (EPs) must generate and transmit permissible prescriptions electronically.</td>
<td>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. More than 80 percent of all permissible prescriptions written by the EP are queried for a drug formulary and transmitted electronically using certified EHR. Menu objective in Stage 2 with threshold of 10 percent.</td>
<td>None</td>
</tr>
<tr>
<td>Clinical decision support (CDS): Implement CDS interventions focused on improving performance on high-priority health conditions.</td>
<td>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.</td>
<td>None</td>
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<td></td>
<td>4. Enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.</td>
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</tr>
<tr>
<td>Computerized Provider Order Entry (CPOE): Use CPOE for medication, laboratory, and diagnostic imaging orders.</td>
<td>5. CPOE for medication - More than 80 percent of medication orders created by authorized providers of the EH or CAH inpatient or emergency department (POS 21 or 23) or by the EP during the EHR reporting period are recorded using CPOE. Stage 2 was 60 percent.</td>
<td>None</td>
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<tr>
<td>Objective</td>
<td>Measures</td>
<td>Optionality</td>
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<tr>
<td>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) or by the EP during the EHR reporting period are recorded using CPOE. 60 percent of orders. Stage 2 was 30 percent.</td>
<td>None</td>
<td></td>
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<tr>
<td>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) or by the EP during the EHR reporting period are recorded using CPOE. 60 percent of orders. Stage 2 was 30 percent.</td>
<td>None</td>
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<tr>
<td>Patient electronic access to health information: Use the certified EHR functionality to provide patient access health information or patient-specific educational resources.</td>
<td>8. For more than 80 percent of unique patients, either: (i) the patient (or patient-authorized representative) is provided access to view online, download, and transmit their health information within 24 hours of its availability of the provider - or (ii) the patient (or patient-authorized representative) is provided access to an ONC-certified application program interface (API) that can be used by 3rd-party applications or devices. Stage 2 threshold was 50 percent.</td>
<td>None</td>
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<td></td>
<td>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. Stage 2 threshold was 10 percent.</td>
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<tr>
<td><strong>Objective</strong></td>
<td><strong>Measures</strong></td>
<td><strong>Optionality</strong></td>
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<td>Coordination of Care through Patient Engagement: Use certified EHR functionality to engage with patients or their authorized representatives</td>
<td>10. More than 25 percent of all unique patients actively engage with the EHR made accessible by the provider. Measure may be met by (i) more than 25 percent of patients view, download, or transmit to a third party their health information, or (ii) more than 25 percent of unique patients access health information using an API. Stage 2 threshold was 5 percent.</td>
<td>Attest/Report the numerators/denominators for all three measures. Must meet threshold on 2 of 3 measures.</td>
</tr>
<tr>
<td></td>
<td>11. For more than 35 percent of all unique patients or patient’s authorized representative discharged from EH or CAH inpatient or emergency department (POS 21 or 23) or seen by the EP, certified EHR was used to send a secure message to the patient or used in response to a secure message sent by the patient.</td>
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<td>12. Patient generated data or data from a non-clinical setting for more than 15 percent of all unique patients.</td>
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<tr>
<td>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.</td>
<td>13. For more than 50 percent of transitions of care and referrals, a summary of care record is created and sent electronically. Stage 2 threshold was 50 percent for creation of summary of care record and 10 percent for electronic exchange.</td>
<td>Attest/Report the numerators/denominators for all three measures. Must meet threshold on 2 of 3 measures.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
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<tr>
<td>Objective</td>
<td>Measures</td>
<td>Optionality</td>
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<tr>
<td>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.</td>
<td>Public health and clinical data registry reporting: EH, CAH or EP is in active engagement with a public health agency (PHA) or clinical data repository (CDR) to submit electronic public health data.</td>
<td>EHS and CAHs must attest/report on 4 measures. EPs must attest/report on 3 measures. The registry measures may be counted more than once if multiple registries are supported.</td>
</tr>
</tbody>
</table>
### Appendix B – Proposed Certification Criteria to Support Stage 3

<table>
<thead>
<tr>
<th>Proposed CFR Citation</th>
<th>Name of Certification Criterion</th>
<th>Proposed Inclusion 2015 Edition Base Electronic Health Record (EHR) Definition</th>
<th>Relationship to the Proposed Certified EHR Definition and to the Proposed Stage 3 Objectives</th>
</tr>
</thead>
<tbody>
<tr>
<td>§ 170.315 (a)(1)</td>
<td>Computerized Provider Order Entry (CPOE) - Medications</td>
<td>Included</td>
<td>CPOE Objective</td>
</tr>
<tr>
<td>§ 170.315 (a)(2)</td>
<td>CPOE - Laboratory</td>
<td>Included</td>
<td>CPOE Objective</td>
</tr>
<tr>
<td>§ 170.315 (a)(3)</td>
<td>CPOE - Diagnostic Imaging</td>
<td>Included</td>
<td>CPOE Objective</td>
</tr>
<tr>
<td>§ 170.315 (a)(4)</td>
<td>Drug-Drug, Drug-Allergy Interaction Checks for CPOE</td>
<td>Not Included</td>
<td>Clinical Decision Support Objective</td>
</tr>
<tr>
<td>§ 170.315 (a)(5)</td>
<td>Demographics</td>
<td>Included</td>
<td>No relationship beyond Base EHR definition</td>
</tr>
<tr>
<td>§ 170.315 (a)(7)</td>
<td>Problem List</td>
<td>Included</td>
<td>No relationship beyond Base EHR definition</td>
</tr>
<tr>
<td>§ 170.315 (a)(8)</td>
<td>Medication List</td>
<td>Included</td>
<td>No relationship beyond Base EHR definition</td>
</tr>
<tr>
<td>§ 170.315 (a)(9)</td>
<td>Medication Allergy List</td>
<td>Included</td>
<td>No relationship beyond Base EHR definition</td>
</tr>
<tr>
<td>§ 170.315 (a)(10)</td>
<td>Clinical Decision Support (CDS)</td>
<td>Included</td>
<td>CDS Objective</td>
</tr>
<tr>
<td>§ 170.315 (a)(11)</td>
<td>Drug Formulary and Preferred Drug List Checks</td>
<td>Not Included</td>
<td>Electronic Prescribing Objective</td>
</tr>
<tr>
<td>§ 170.315 (a)(12)</td>
<td>Smoking Status</td>
<td>Included</td>
<td>No relationship beyond Base EHR definition</td>
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<tr>
<td>§ 170.315 (a)(14)</td>
<td>Family Health History</td>
<td>Not Included</td>
<td>Certified EHR</td>
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<tr>
<td>§ 170.315 (a)(15)</td>
<td>Family Health History - Pedigree</td>
<td>Not Included</td>
<td>Certified EHR</td>
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<tr>
<td>§ 170.315 (a)(17)</td>
<td>Patient-specific Education Resources</td>
<td>Not Included</td>
<td>Patient Electronic Access to Health Information Objective</td>
</tr>
<tr>
<td>§ 170.315 (a)(19)</td>
<td>Patient Health Information Capture</td>
<td>Not Included</td>
<td>Certified EHR Coordination of Care Objective</td>
</tr>
<tr>
<td>Proposed CFR Citation</td>
<td>Name of Certification Criterion</td>
<td>Proposed Inclusion 2015 Edition Base Electronic Health Record (EHR) Definition</td>
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<tr>
<td>§ 170.315 (a)(20)</td>
<td>Implantable Device List</td>
<td>Included</td>
<td>No relationship beyond Base EHR definition</td>
</tr>
<tr>
<td>§ 170.315 (b)(1)</td>
<td>Transitions of Care</td>
<td>Included</td>
<td>Health Information Exchange Objective</td>
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<tr>
<td>§ 170.315 (b)(2)</td>
<td>Clinical Information Reconciliation and Incorporation</td>
<td>Not Included</td>
<td>Health Information Exchange Objective</td>
</tr>
<tr>
<td>§ 170.315 (b)(1)</td>
<td>Electronic Prescribing</td>
<td>Not Included</td>
<td>Electronic Prescribing Objective</td>
</tr>
<tr>
<td>§ 170.315 (b)(3)</td>
<td>Data Portability</td>
<td>Included</td>
<td>No relationship beyond Base EHR definition</td>
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<tr>
<td>§ 170.315 (c)(1)</td>
<td>Clinical Quality Measures - record &amp; export</td>
<td>Included</td>
<td>Certified EHR</td>
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<tr>
<td>§ 170.315 (e)(1)</td>
<td>View, Download Transmit to Third Party</td>
<td>Not Included</td>
<td>Patient Electronic Access to Health Information Objective and Coordination of Care Objective</td>
</tr>
<tr>
<td>§ 170.315 (e)(2)</td>
<td>Secure Messaging</td>
<td>Not Included</td>
<td>Coordination of Care Objective</td>
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<tr>
<td>§ 170.315 (f)(1)</td>
<td>Transmission to Immunization Registries</td>
<td>Not Included</td>
<td>Public Health Reporting Objective</td>
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<tr>
<td>§ 170.315 (f)(2)</td>
<td>Transmission to Public Health Agencies – syndromic surveillance</td>
<td>Not Included</td>
<td>Public Health Reporting Objective</td>
</tr>
<tr>
<td>§ 170.315 (f)(3)</td>
<td>Transmission to Public Health Agencies – reportable lab tests and values/results</td>
<td>Not Included</td>
<td>Public Health Reporting Objective</td>
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<tr>
<td>§ 170.315 (f)(4)</td>
<td>Transmission to Cancer Registries</td>
<td>Not Included</td>
<td>Public Health Reporting Objective</td>
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<tr>
<td>§ 170.315 (f)(5)</td>
<td>Transmission to Public Health Agencies – case reporting</td>
<td>Not Included</td>
<td>Public Health Reporting Objective</td>
</tr>
<tr>
<td>§ 170.315 (f)(6)</td>
<td>Transmission to Public Health Agencies – anti-microbial use and resistance reporting</td>
<td>Not Included</td>
<td>Public Health Reporting Objective</td>
</tr>
<tr>
<td>Proposed CFR Citation</td>
<td>Name of Certification Criterion</td>
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<tr>
<td>§ 170.315 (f)(7)</td>
<td>Transmission to Public Health Agencies – health care surveys</td>
<td>Not Included</td>
<td>Public Health Reporting Objective</td>
</tr>
<tr>
<td>§ 170.315 (g)(1)</td>
<td>Automated Numerator Recording</td>
<td>Not Included</td>
<td>Certified EHR</td>
</tr>
<tr>
<td>§ 170.315 (g)(2)</td>
<td>Automated Measure Calculation</td>
<td>Not Included</td>
<td>Certified EHR</td>
</tr>
<tr>
<td>§ 170.315 (g)(7)</td>
<td>Application Access to Common Clinical Data Set</td>
<td>Included</td>
<td>Patient Electronic Access Health Information Electronic Objective and Coordination of Care Objective</td>
</tr>
<tr>
<td>§ 170.315 (h)(1)</td>
<td>Direct Project</td>
<td>Included</td>
<td>No relationship beyond Base EHR definition</td>
</tr>
<tr>
<td>§ 170.315 (h)(2)</td>
<td>Direct Project, Edge Protocol, XDR/XDM</td>
<td>Included</td>
<td>No relationship beyond Base EHR definition</td>
</tr>
</tbody>
</table>

Note: CMS proposes to require the criteria labeled “Certified EHR” as part of meaningful use. However, these criteria do not support a specific objective of meaningful use.