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CMS Makes Significant Changes to Stage 2 Meaningful Use and Finalizes Stage 3

On October 16, 2015, the Centers for Medicare & Medicaid Services (CMS) published a final rule (Final Rule) that streamlines Stage 2 and finalizes Stage 3 of the Medicare and Medicaid electronic health record (EHR) Incentive Programs (Meaningful Use Programs). The Final Rule also shortens the EHR reporting period in 2015 to 90 days and eliminates Stage 1. Providers scheduled to satisfy Stage 1 must instead meet the requirements of a modified Stage 2 (Modified Stage 2), which contains fewer objectives than the current Stage 2 and eliminates the optional menu objectives. Importantly, CMS provides a number of exclusions for Stage 1 providers in 2015 to ease the transition to this newly Modified Stage 2. Modified Stage 2 is effective for EHR reporting periods in 2015 through 2017. CMS treats 2017 as a transition year and permits providers to demonstrate either Modified Stage 2 or Stage 3. Beginning in 2018, Stage 3 will become mandatory, and all providers will be required to attest to a single set of eight objectives. The Final Rule includes a comment period to address future years of the Meaningful Use Programs through additional rule making. Comments are due to CMS by December 15, 2015.

EHR REPORTING PERIOD

Providers participating in the Meaningful Use Programs must meet certain objectives and measures during their respective "EHR reporting periods" to become a "meaningful user" of certified EHR technology (CEHRT). Currently, the EHR reporting period for eligible hospitals (EHs) and critical access hospitals (CAHs) is based on the federal fiscal year. The EHR reporting period for eligible professionals (EPs) is based on the calendar year. Under the Final Rule, all EPs, EHs, and CAHs (collectively, Providers) have a 90-day EHR reporting period in 2015. EPs may select any 90-day period between January 1, 2015, and December 31, 2015, while EHs and CAHs may choose any 90-day period between October 1, 2014, and December 31, 2015. Similarly, in 2016, Providers who demonstrate meaningful use for the first time will have a 90-day EHR reporting period. All other Providers will be required to satisfy meaningful use for the entire calendar year. Beginning in 2017, the EHR reporting period will be a full calendar year for all Providers attesting to Modified Stage 2. However, if the EP or EH is participating in the Medicaid Meaningful Use Program for the first time, the Provider will have a 90-day EHR reporting period. Providers attesting to Stage 3 in 2017 will also have a 90-day EHR reporting period.

PAYMENT ADJUSTMENT YEAR

The Final Rule similarly revises the attestation deadline for purposes of determining a Provider's downward payment adjustment. For a 2015 EHR reporting period, Providers must attest to meaningful

use by February 29, 2016. Thereafter, Providers with a full calendar year EHR reporting period generally must attest by the end of February of the year following the EHR reporting period to avoid a payment adjustment in the year that is two years from the EHR reporting period. Providers demonstrating meaningful use for the first time before 2018 generally must attest by October 1 of the EHR reporting period to avoid a payment adjustment in the following year and must attest again by the end of February of the year following the EHR reporting period to avoid a payment adjustment two years from the EHR reporting period year. For example, an EP demonstrating meaningful use for the first time in 2016 must attest by October 1, 2016, to avoid a payment adjustment in 2017. The EP must attest again by February 28, 2017, to avoid a payment adjustment in 2018.

MEANINGFUL USE OBJECTIVES AND MEASURES

Under the Meaningful Use Programs, Providers must use CEHRT to demonstrate the meaningful use objectives and measures. Prior to the Final Rule, Stages 1 and 2 required Providers to meet as many as 20 objectives, with a number of objectives requiring satisfaction of multiple measures. Of these objectives, Providers were required to satisfy a core set of objectives and were then able to choose the remaining objectives from a menu-style list. With the Final Rule, CMS attempts to ease Providers' reporting obligations by removing objectives that are redundant, or are no longer useful because less advanced measures have become more widespread.

Modified Stage 2 Objectives and Measures

To transition Providers from Stage 2 to the single set of objectives under Stage 3, CMS created a Modified Stage 2. Providers are no longer able to choose from a menu of objectives. Instead, EPs are required to satisfy ten objectives, and EHs and CAHs are required to satisfy nine. CMS retained most of the core objectives from Stage 2; added several previously optional menu objectives as mandatory; and removed redundant, duplicative, and topped-out objectives. Modified Stage 2 contains limited exceptions to accommodate Providers who have made efforts to satisfy Stage 1 or the prior version of Stage 2 in 2015. An overview of the objectives and measures are described below.

- **Objective 1: Protect Patient Health Information**. Providers must implement appropriate technical capabilities to protect electronic protected health information (ePHI) created or received by CEHRT. To satisfy this objective, Providers must conduct or review a security risk analysis in accordance with HIPAA and correct any identified deficiencies.

- **Objective 2: Clinical Decision Support**. Providers must use clinical decision support (CDS) to improve high-priority health conditions. To meet this objective, they are required to satisfy two measures. First, Providers must implement five CDS interventions related to at least four clinical quality measures (CQMs). If a Provider cannot identify four relevant CQMs, the CDS interventions must be related to high-priority health conditions. CMS permits Provider flexibility in identifying high-priority health conditions; however, the conditions must be identified prior to the start of the EHR reporting period. Providers scheduled to demonstrate Stage 1 in 2015 may satisfy an alternative to this first measure by implementing and tracking one CDS rule relevant to the Provider's specialty or a high-priority condition. The second measure requires Providers to enable their CEHRTs' drug-drug and drug-allergy interaction checks throughout the applicable EHR reporting period.

- **Objective 3: Computerized Provider Order Entry (CPOE)**. This objective requires Providers to enter medication, laboratory, and radiology orders using CPOE. EPs and authorized providers of an EH or CAH must use CPOE for over 60 percent of their medication orders and over 30 percent of their laboratory and radiology orders to satisfy this objective. EPs who write fewer than 100 orders during the EHR reporting period for any of the above may claim an exclusion from this measure.

  The Final Rule creates alternate measures and an exclusion for Providers scheduled to demonstrate Stage 1 in 2015 or 2016. Stage 1 Providers may satisfy the medication orders

measure by using CPOE to enter at least one medication order for over 30 percent of their patients (inpatient and emergency department patients for EHs and CAHs) who have at least one medication prescription. These Providers may also claim an exclusion in 2015 and 2016 for the measures related to laboratory and radiology orders. Providers that qualify for an exclusion from an objective or measure are not required to meet the particular objective or measure.

- **Objective 4: Electronic Prescribing**. EPs must query a drug formulary and transmit through CEHRT more than 50 percent of permissible prescriptions written by the EP. EHs and CAHs must query a drug formulary and transmit through CEHRT more than 10 percent of their hospital discharge medication orders. EPs can claim an exclusion from this objective if they write fewer than 100 prescriptions in the EHR reporting period, and all Providers may claim an exclusion if no pharmacies within a 10 mile radius accept electronic prescriptions.

  EPs who are in Stage 1 in 2015 are required to do the above for only 40 percent of their permissible prescriptions. An EH or CAH can claim an exclusion from this objective if it was scheduled to demonstrate Stage 1 in 2015 or 2016, or if it was scheduled to demonstrate Stage 2 in 2015 or 2016 and did not intend to select the electronic prescribing option from the menu options.

- **Objective 5: Health Information Exchange (formerly "Summary of Care")**. This objective requires Providers to provide a summary of care record for patients referred or transitioned to another care setting or provider. To meet this objective, Providers are required to create the summary of care record using CEHRT and to electronically transmit the care summary for more than 10 percent of referrals and transitions of care. EPs who refer or transmit a patient to another provider or care setting fewer than 100 times during the EHR reporting period may claim an exclusion from this objective. Furthermore, Providers scheduled to demonstrate Stage 1 in 2015 may claim an exclusion from this objective for the 2015 EHR reporting period.

- **Objective 6: Patient-Specific Education**. To satisfy this objective, EPs must provide clinically relevant, patient-specific education resources identified by the CEHRT to more than 10 percent of patients for an office visit. EPs with no office visits during an EHR reporting period may claim an exclusion from this objective. EHs and CAHs must provide such educational resources to more than 10 percent of patients admitted to their inpatient or emergency departments. Providers scheduled to demonstrate Stage 1 in 2015 may claim an exclusion from this objective if they did not plan to select it as one of their menu objectives.

- **Objective 7: Medication Reconciliation**. Under this objective, Providers who receive a patient from another provider or care setting, or believe an encounter is relevant, must perform a medication reconciliation for more than half of such transitions of care. EPs who do not receive any transitions of care during the EHR reporting period may claim an exclusion from this objective. Additionally, all Providers may claim an exclusion if they were scheduled for Stage 1 in 2015 and were not planning to select the medication reconciliation menu objective.

- **Objective 8: Patient Electronic Access**. EPs must provide their patients with the ability to view online, download, and transmit to third parties (VDT) their health information within four days of such information becoming available to the EP. EHs and CAHs must provide patients with VDT capability within 36 hours of discharge from the hospital. The Final Rule specifies the information that must be made available to patients and includes information such as the patient's current and past problem list, laboratory test results, and medication allergies.

  To meet this objective, Providers must satisfy two objectives or one objective and one exclusion. First, they must timely provide more than half of their patients (for EHs and CAHs, more than half of inpatient and emergency department discharges) with VDT access to their health information. Second, for EHR reporting periods in 2015 and 2016, at least one of the Provider's patients seen during the reporting period (for EHs and CAHs, at least one inpatient or emergency department discharge) must view, download, or transmit to a third party his or her health information. In 2017, this threshold is raised to 5 percent of patients or discharges

respectively. An EP can claim an exclusion from the second measure if it does not order or create the specific health information required to be made available to patients. An EP can also claim an exclusion from the second measure if it conducts more than half of its patient encounters in a county with limited access to high-speed Internet. An EH or CAH may claim an exclusion if it is located in such a county. All Providers may claim an exclusion from the second measure if they are scheduled to demonstrate Stage 1 in 2015.

- **Objective 9: Secure Electronic Messaging**. This objective applies only to EPs. It requires EPs to use secure electronic messaging to communicate with patients concerning relevant health information. EPs must meet an increasingly stringent threshold each year from 2015 through 2017 to satisfy the objective. For an EHR reporting period in 2015, EPs can satisfy the objective by fully enabling the capability for patients to send and receive electronic messages during the EHR reporting period. In 2016, EPs must send an electronic message using the CEHRT's secure messaging function to at least one patient during the EHR reporting period. In 2017, EPs must use CEHRT to send an electronic message to 5 percent of patients. EPs can claim an exclusion from this objective if they (1) have no office visits during the EHR reporting period, (2) conduct over half of their patient encounters in a county with limited high-speed Internet access, or (3) were scheduled to demonstrate Stage 1 in 2015.

- **Objective 10: Public Health Reporting**. This objective requires Providers to be in "active engagement" with a public health agency (PHA) to submit electronic public health data to that agency using CEHRT. A Provider may demonstrate "active engagement" in one of three ways. The Provider may (1) register to submit data with a PHA within 60 days after the start of the EHR reporting period, (2) test and validate the electronic submission of data to a PHA and respond within 30 days of a request from a PHA, or (3) electronically submit production data to a PHA.

  There are four measures associated with this objective: (1) immunization registry reporting, (2) syndromic surveillance reporting, (3) specialized registry reporting, and (4) electronic reportable laboratory result reporting. EPs musts meet at least two of the first three measures, and EHs and CAHs must meet at least three of the first four measures. EPs scheduled to demonstrate Stage 1 in 2015 are only required to satisfy one measure, and EHs and CAHs scheduled for Stage 1 in 2015 must only meet two measures. Specialized registry reporting may be counted as more than one measure if the Provider reports to more than one specialized registry.

  Each of the above measures allows a Provider to satisfy certain criteria to qualify for an exclusion from such measure. If the Provider qualifies for an exclusion, it does not count as a successfully attested measure; however, if one or fewer measures (in the case of an EP) or two or fewer measures (for an EH or CAH) are available after qualification for exclusions, the Provider may satisfy the objective by attesting to the remaining number of measures.

Stage 3 Objectives and Measures

The Final Rule establishes the Stage 3 objectives and associated measures, most of which are similar to the Modified Stage 2 objectives and measures but with higher thresholds and additional obligations. Providers may begin Stage 3 in 2017, but all Providers must transition to Stage 3 by 2018. Below is an overview of the Stage 3 objectives and measures:

- **Objective 1: Protect Patient Health Information**. Stage 3 maintains the Modified Stage 2 objective requiring Providers to protect ePHI. The Stage 3 objective, however, is broader and requires Providers to implement appropriate technical, administrative, and physical safeguards to protect ePHI. To meet this objective, as in Modified Stage 2, Providers are required to conduct or review a security risk analysis that assesses the risks associated with ePHI created or maintained in CEHRT. The risk analysis must be performed upon installation of or upgrade to a CEHRT and at least once during each EHR reporting period.

- **Objective 2: Electronic Prescribing**. This Stage 3 objective builds on the corresponding Modified Stage 2 objective. It requires EPs to generate and transmit prescriptions electronically and EHs and CAHs to generate and electronically transmit medication discharge orders for permissible prescriptions. To satisfy this objective, more than 60 percent of an EP's prescriptions, or 25 percent of an EH's or CAH's discharge medication orders for permissible prescriptions, must be queried for a drug formulary and transmitted electronically using CEHRT. Stage 3 retains the Modified Stage 2 exclusions to this measure for EPs that infrequently write prescriptions and for Providers located more than 10 miles from a pharmacy that accepts electronic prescriptions.

- **Objective 3: Clinical Decision Support**. Stage 3 retains the Modified Stage 2 objective requiring Providers to implement CDS interventions in CEHRT to improve their performance on high-priority health conditions. The measures that Providers must satisfy are identical to those of Modified Stage 2.

- **Objective 4: Computerized Provider Order Entry**. This objective is retained from Modified Stage 2 with some changes. Stage 3 expands the types of orders that may be entered using CPOE by replacing Modified Stage 2's radiology orders with the broader category of diagnostic imaging, which includes radiology, ultrasound, magnetic resonance, and computed tomography orders. To satisfy this objective, EPs and authorized providers of an EH or CAH must use CPOE for more than 60 percent of their medication, laboratory, and diagnostic orders. Stage 3 retains the Modified Stage 2 exclusions to this measure for Providers that infrequently issue the relevant types of orders.

- **Objective 5: Patient Electronic Access to Health Information**. Under this objective, Providers must give patients timely electronic access to their health information. Each EP must make available to patients their health information within 48 hours of it becoming available to the EP, while EHs and CAHs must do so within 36 hours. Providers must meet two measures to satisfy this objective. The first measure requires more than 80 percent of patients seen by an EP or discharged from an EH or CAH inpatient or emergency department to be provided VDT access to their health information. Notably, the Final Rule allows Providers to satisfy this objective using application programming interfaces (APIs), and Providers are no longer required to purchase and install a separate patient portal.

  The second measure for Objective 5 requires Providers to use clinically relevant information from their CEHRTs to provide 35 percent of their respective patients electronic access to patient-specific educational resources. The Final Rule provides an exclusion from this second measure for Providers located in a county with limited access to high-speed Internet and to EPs who have no office visits during an EHR reporting period.

- **Objective 6: Coordination of Care through Patient Engagement**. This objective obligates Providers to use their CEHRTs to engage with patients about their care. Providers must attest to each of the following three measures but are only required to meet the threshold for any two of the three. The first measure depends on patient action and requires more than 10 percent of patients to "actively engage" with their EHR made available by the Provider. This threshold is 5 percent for Providers attesting to Stage 3 in 2017. Patients may actively engage with the EHR by either (1) viewing, downloading, or transmitting to a third party their health information, (2) accessing their health information in the Provider's CEHRT through an API, or (3) any combination of (1) and (2).

  The second measure requires Providers to send or respond to a patient's secure message using their CEHRT's electronic messaging function for more than 25 percent of patients. Providers demonstrating Stage 3 in 2017 may satisfy this measure by sending an electronic message to 5 percent of patients. Messages sent between Providers using CEHRT count toward fulfillment of this measure as long as the patient has the ability to actively participate in the conversation between Providers.

  The third measure requires Providers to incorporate into their CEHRTs data from a nonclinical

setting or data generated by patients for more than 5 percent of their patients. Nonclinical-setting data includes data from physical therapists, nutritionists, psychologists, home health care providers, and care providers in settings where the care provider does not have access to the Provider's CEHRT. Patient-generated health data is data resulting from patient self-monitoring.

- **Objective 7: Health Information Exchange**. Stage 3 expands on the Modified Stage 2 health information exchange requirement. Providers are required to supply a summary of care record when transitioning or referring patients to another setting of care, to retrieve a summary of care record upon the first encounter with a new patient, and to incorporate summary of care information from other providers into a patient's EHR using CEHRT. Transitions or referrals must be between Providers with different Meaningful Use Program billing identities to count toward this objective.

  Providers are required to attest to each of the following three measures but are only required to meet the threshold for two. First, Providers must create a summary of care record using CEHRT and electronically exchange such record for more than 50 percent of the Provider's transitions of care or referrals. Second, Providers must incorporate an electronic summary of care document into a patient's EHR for more than 40 percent of transitions or referrals received and new patient encounters. Last, Providers must perform a clinical information reconciliation for more than 80 percent of transitions or referrals received and new patient encounters. Providers are required to reconcile the patient's medication, medication allergies, and current problem list.

  The Final Rule also establishes exclusions from the above measures for Providers who infrequently see new patients or make or receive referrals or transitions of care and for Providers located in areas with limited access to high-speed Internet (for measures one and two only).

- **Objective 8: Public Health and Clinical Data Registry Reporting**. Modified Stage 2 requires that Providers actively engage with a PHA. Stage 3 builds upon this objective to require that Providers actively engage with a PHA or a clinical data registry (CDR) by submitting electronic public health data to such agency or registry using CEHRT. The Final Rule establishes the following six measures for Objective 8: (1) immunization registry reporting, (2) syndromic surveillance reporting, (3) case reporting for reportable conditions, (4) public health registry reporting, (5) CDR reporting, and (6) electronic reportable laboratory results. EPs must meet any combination of two of the first five measures, and EHs and CAHs must meet any combination of four of the six measures. Public health registry and CDR reporting may be counted as more than one measure if the Provider reports to more than one public health registry or CDR.

  CMS also created several exclusions to these measures. As in Modified Stage 2, if the Provider qualifies for an exclusion, it does not count as satisfying the measure. If, however, there is one or fewer measures (in the case of an EP) or three or fewer measures (for an EH or CAH) available after qualification for exclusions, the Provider may satisfy the objective by attesting to the remaining number of measures.

MEANINGFUL USE IN 2017

In the Final Rule, CMS treats 2017 as a transition year and allows Providers flexibility in meeting the Meaningful Use Programs' requirements. Providers may repeat a year at their current Meaningful Use Program stage or move up to the next stage. Providers are not permitted to revert to a prior stage. Providers demonstrating Stage 3 in 2017 may use 2015 Edition CEHRT or a combination of 2014 and 2015 Edition CEHRT as long as the 2015 Edition CEHRT has the capability to meet the Stage 3 objectives. Providers have the option to use 2014 Edition CEHRT in 2017 and to demonstrate the Modified Stage 2 objectives and measures. A Provider that uses 2014 Edition CEHRT, however, is not

able to attest to the Stage 3 objectives and measures.

Beginning in 2017, CMS will also decouple the use of CEHRT for CQM reporting from the use of CEHRT for satisfying the Meaningful Use Programs' objectives and measures. This will allow a Provider to report CQMs using either 2014 or 2015 Edition CEHRT, regardless of which edition the Provider uses to demonstrate meaningful use.

REPORTING CQMs

As part of the Meaningful Use Programs, Providers must report certain CQMs established by CMS. In connection with the revised 2015 EHR reporting period, the Final Rule establishes the CQM reporting period in 2015 as any continuous 90-day period from January 1 through December 31 for EPs and from October 1, 2014, through December 31, 2015, for EHs and CAHs. The CQM reporting period reverts to the full calendar year in 2016.

In Stage 3, CMS maintains its requirement that Providers report certain CQMs. As noted above, Stage 3 requires a uniform EHR reporting period of one calendar year for all Providers. Similarly, the Final Rule requires that Providers report CQMs based on a full calendar year, starting with calendar year 2017; however, the CQM reporting period for a Medicaid Provider demonstrating meaningful use for the first time in 2017 is a 90-day period within the calendar year, which may be different than the Provider's EHR reporting period. Beginning in 2018, all Providers participating in the Medicare Meaningful Use Program must submit CQMs electronically unless electronic reporting is not feasible. Each state may continue to determine the appropriate method for submission of CQMs for Providers participating in the Medicaid Meaningful Use Program.

CONCLUSION

The Final Rule contains a variety of changes to the Meaningful Use Programs designed to ease the burden on Providers and to encourage widespread adoption and use of EHRs. CMS has created a shortened EHR reporting period for 2015, eliminated Stage 1, and created Modified Stage 2 and Stage 3, each of which reduce the total number of objectives that Providers must satisfy. CMS appears open to further adjustment to the Meaningful Use Programs. Industry stakeholders are encouraged to submit their comments on the Final Rule by December 15, 2015.

If you have any questions, please contact a member of Robinson+Cole's Health Law Group:

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