ROPES & GRAY ALERT

Digital Health ▪ Health Care

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CMS and ONC Issue Final Rules for EHR Advancement

On October 6, 2015, the U.S. Department of Human Health and Services ("HHS") released two final rules related to the Medicare and Medicaid Electronic Health Record Incentive Programs (collectively, the "EHR Incentive Program"), the Health Information Technology ("HIT") Certification Criteria, and the HIT Certification Program. One HHS official commented that the final rules are meant to eliminate unnecessary requirements; to simplify and increase flexibility for those requirements that remain; and to focus on interoperability, information exchange, and patient engagement.

1. Stage 3 EHR Incentive Program Final Rule

The HHS Centers for Medicare and Medicaid Services ("CMS") issued the first of the two final rules; the "Stage 3 EHR Final Rule."[1] This rule finalizes the regulations governing Stage 3 of the EHR Incentive Program (optional in 2017 and fully effective in 2018) and amends the existing regulations for Stage 2 (effective for 2015 through 2017) to decrease the reporting burden on eligible providers ("EPs"), eligible hospitals ("EHs"), and critical access hospitals ("CAHs").

The Stage 3 EHR Final Rule specifically implements a number of EHR Incentive Program changes, including:

- consolidating the number of Stage 2 meaningful use reporting objectives for EPs, EHs and CAHs;
- identifying reporting objectives for Stage 3 meaningful use while delaying implementation of Stage 3 until 2018;
- adopting more flexible reporting periods through 2017;
- aligning attestation of meaningful use compliance to the calendar year for all EHR Incentive Program participants; and
- lowering a controversial patient electronic access standard in 2015 and 2016 to require only one unique patient access or transmit their health information using the EHR system.

CMS included a 60-day comment period to facilitate feedback on, among other things, the rule's requirements related to the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), enacted on April 16, 2015, which established the Merit-Based Incentive Payment System ("MIPS") that will incorporate meaningful use.

Consolidation of Stage 2 Meaningful Use Reporting Objectives

The Stage 3 EHR Final Rule consolidates the Stage 2 meaningful use reporting objectives and also transitions Stage 1 and Stage 2 meaningful use participants into a single, modified Stage 2. EHR Incentive Program participants who are scheduled to demonstrate only Stage 1 meaningful use will have alternate exclusions or specifications (with lower burdens) under some of the modified Stage 2 objectives.

The new consolidated Stage 2 for EPs includes 10 objectives (including 1 public health objective), as opposed to 20 objectives under the current Stage 2 structure. The consolidated objectives for EPs between 2015 and 2017 now include: (1) protect patient health information; (2) clinical decision support; (3) computerized provider order entry;

[1] The full title of CMS's Stage 3 EHR Incentive Program Final Rule is: *Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 through 2017.*

(4) electronic prescribing; (5) health information exchange; (6) patient-specific education; (7) medication reconciliation; (8) patient electronic access; (9) secure messaging; and (10) public health.

For EHs and CAHs, the new consolidated Stage 2 includes 9 objectives (including 1 public health objective), as opposed to 19 objectives under the current Stage 2 structure. The consolidated objectives for EHs and CAHs between 2015 and 2017 include the same objectives as for EPs, with the exception of the secure messaging objective.

Stage 3 Meaningful Use Reporting Objectives

The Stage 3 EHR Final Rule also establishes the reporting objectives for Stage 3. Stage 3 will include 8 objectives for EPs, EHs and CAHs. They are: (1) protect patient health information; (2) electronic prescribing; (3) clinical decision support; (4) computerized provider order entry; (5) patient electronic access; (6) coordination of care through patient engagement; (7) health information exchange; and (8) public health and clinical data registry reporting.

Additionally, the Stage 3 EHR Final Rule makes the Stage 3 meaningful use requirements optional for 2017. This means that EPs, EHs and CAHs may choose to attest to the Stage 3 meaningful use requirements in 2017, but are not required to do so until calendar year 2018. This additional time benefits the EHR Incentive Program participants and provides developers with additional time to create improved technologies for health care entities and patients.

Decrease in Measurement Period for Reporting

In the Stage 3 EHR Final Rule, CMS recognizes that many EHR Incentive Program participants may struggle to show meaningful use over an entire 365-day period in 2015 and, as a result, allows EPs, EHs and CAHs to report on their use of EHRs for any continuous 90-day period. It also transitions EHs and CAHs from an October 1 – September 31 reporting period to a calendar year reporting period to align them with EPs. Therefore, for calendar year 2015, EPs may show meaningful use over any continuous 90-day period between January 1, 2015 and December 31, 2015, and EHs and CAHs may show meaningful use over any continuous 90-day period between October 1, 2014 and December 31, 2015. These changes mean that incentive payments available to EHs and CAHs will be delayed as the attestation portal for all entities will not open until January 4, 2016 (remaining open through February 29, 2016), as opposed to October 1, 2015.

Lowering the Patient Electronic Access Standard

In response to industry concerns, the Stage 3 EHR Final Rule lowers the patient electronic access standard. Originally, starting in Stage 2 in 2015, EPs, EHs and CAHs would have been required to show that more than five percent (5%) of unique patients during the EHR reporting period viewed, downloaded, or transmitted their health information to a third party using the EHR system. That requirement for 2015 and 2016 has been reduced so that only one unique patient is required to view, download or transmit his or her health information during the EHR reporting periods. In 2017 (regardless of whether the participant is attesting to Stage 2 or Stage 3), this requirement increases to five percent (5%) of unique patients, and in 2018, it again increases to 10 percent (10%) of unique patients.

Potentially More Changes Ahead

Two factors in particular have led many commentators to believe that more changes are in store for the Stage 3 meaningful use requirements. First, CMS noted that, after it had published the preceding proposed rule, MACRA was enacted, which phases out the downward payment adjustment for providers that do not attest to meaningful use after 2018. Instead, providers will be reimbursed through a MIPS, which will take into consideration the provider's EHR usage. As a result of these significant changes, this final rule includes the aforementioned 60-day comment period, which suggests future modifications may be incorporated into the rule.

Additionally, there was significant pressure from Congress for CMS to delay issuing the Stage 3 final rule. Immediately after the release of the Stage 3 EHR Final Rule, the Chairman of the Senate Committee on Health,

Education, Labor and Pensions underscored the importance of getting Stage 3 right, believing that Stage 2 was not a success, stating "[o]nly about 12 percent of doctors and 40 percent of hospitals have been able to comply with Stage 2."

2. 2015 Edition Final Rule

Concurrent with CMS's issuance of the Stage 3 EHR Final Rule, the HHS Office of the National Coordinator for Health Information Technology ("ONC") issued another final rule; the "2015 Edition Final Rule."[2] This rule modifies the definition of Certified Electronic Health Record Technology ("CEHRT") for 2015 and expands the HIT Certification Program to apply to other types of HIT by adding new certifications.

ONC released the 2015 Edition Final Rule, which establishes:

- a new Base EHR definition for 2015 (which is part of the CEHRT definition);
- new certification criteria designed to align with and support Stage 3 of the EHR Incentive Program;
- a publicly available Certified Health IT Product List to improve health care providers' purchasing decisions and facilitate new technologies; and
- an expanded Health IT Certification Program, designed to make the program open and accessible to more types of HIT and HIT that supports various care and practice settings.

These changes aim to increase interoperability, which has significant congressional and industry support.

New CEHRT Definition and Modified Criteria

Significantly, the 2015 Edition Final Rule adopted a new "2015 Definition" of the Base EHR. The 2015 Definition incorporates new criteria intended to align with the requirements of Stage 3 of the EHR Incentive Program and omits several clinical quality measure ("CQM") capabilities that were required under the 2014 Definition. The 2015 Edition Final Rule incorporates the 2015 Definition, but also retains these CQM capabilities within the CEHRT definition under the EHR Incentive Program, in effect binding participants to both the new 2015 Definition criteria as well as those that were required under the 2014 Definition.

The 2015 Definition specifically (1) removes privacy and security capabilities and certification criteria (now required under Health IT Program criteria); (2) removes certain CQM capabilities to import, calculate and report to CMS; (3) includes new patient demographic and clinical health information data certification criteria (such as "smoking status" and "implantable device list"); (4) expands the existing application programming interface ("API") certification criteria to three available criteria that support capture and query of relevant health care quality information, as well as integration of information from other sources; (5) requires API certification criteria that demonstrate the ability to respond to data requests for specific categories and demographic data referenced in the Common Clinical Data Set; (6) incorporates new Common Clinical Data Set (formerly "Common MU Data Set") code and criteria; and (7) incorporates 2015 certification criteria corresponding to criteria referenced in the 2014 Base EHR definition.

Expansion of HIT Certification Program

The 2015 Edition Final Rule also added several new certifications available to different HIT providers, such as health information service providers and health information exchanges. Further, instead of embedding criteria within definitions, the 2015 Edition Final Rule aligns with requirements of particular HIT certifications sought by the participant. It also changes the terminology of programs and technology, notably changing terms "EHR" and "EHR Technology" to "Health IT."

[2] The full title of ONC's 2015 Edition Final Rule is: *2015 Edition HIT Certification Criteria, 2015 Edition Base EHR Definition, and ONC HIT Certification Program Modifications*.

Under the 2015 Edition Final Rule, ONC realigned the HIT Certification Program in several ways, including: (1) ONC-Authorized Certification Bodies ("ONC-ACBs") can no longer certify to the new "Meaningful Use Measurements"; however, these standards will continue to apply under CMS's CEHRT definition; (2) new, simpler privacy and security certification frameworks, contingent only on the specific type of certification sought by the technology provider; (3) expanded and revised Principles of Proper Conduct for ONC-ACBs, including additional disclosure requirements; and (4) new certification programs for long-term, post-acute care, behavioral health and pediatrics.

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Ropes & Gray will continue to monitor regulatory developments in this area. If you have any questions, please contact any member of Ropes & Gray's digital health or health care practices or your usual Ropes & Gray advisor.