The Meaningful Use Stage 2 Final Rule: Overview and Outlook

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Introduction

On August 23, 2012, the Centers for Medicare and Medicaid Services (CMS) published a final rule on the Stage 2 Meaningful Use criteria that eligible professionals (EPs), eligible hospitals and critical access hospitals (CAHs) must meet to qualify as meaningful users of electronic health records (EHRs) and receive incentive payments under the Medicare and Medicaid programs.5 This final rule builds upon the Stage 2 proposed rule, released on March 7, 2012.6 The Stage 2 final rule also revises certain Stage 1 criteria, which were finalized in the July 28, 2010 final rule.7 Stage 1 of the incentive program, designed to encourage providers to move key clinical data into an electronic format, was focused on establishing the functionalities of a certified EHR system to allow for quality improvement and exchange of health information.8 With the final rule, CMS continues its careful, incremental approach to continuing this transitional process and strikes a balance between stakeholders calling for Stage 2 to require demonstrated improvements in care as a result of EHR use and those seeking more flexibility in the rules, with incentives simply to acquire EHR technology. Stage 2 also increases expectations for more robust health information exchange, allowing information to follow the patient through care transitions and referrals.9

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A number of the changes CMS made from Stage 1 to Stage 2 reflect the need to reduce the burden of meeting the meaningful use criteria on EPs, eligible hospitals and CAHs. This can be seen through the delay of the Stage 2 requirements until 2014 from the 2013 deadline set in the Stage 1 final rule. The final rule also attempts to ease administrative burdens and reduce duplicative work by aligning the reporting of meaningful use measures with other federal programs that require quality reporting. CMS seeks to give states flexibility in the Medicaid incentive program with the choice of public health measures and whether a measure is in the core or menu objective. CMS realized that separating the clinical quality measures from the meaningful use objectives and measures caused unnecessary confusion. Therefore, the final rule eliminates the reporting of clinical quality measures as a core objective and instead incorporates it into the definition of a meaningful EHR user.

Many of the finalized sections of the regulation also focus on providing patients access to their health information and sharing health information across providers. For example, the Stage 2 final rule replaces a Stage 1 measure: providing patients with an electronic copy of their health record to giving patients the ability to view online, download or transmit their health information. Under the final Stage 2 rule, the provider must only provide a summary of care records for referred or transferred patients. This was reduced from the proposed rule, requiring maintenance of an up-to-date problem list, medication list, and allergy list, which shows the need to balance the need for increased electronic health information sharing and burdens on health care entities.

**Overview of HITECH Act**

The American Recovery and Reinvestment Act of 2009 (ARRA) directed the adoption and meaningful use of health information technology (HIT) as a national policy priority. Within ARRA, the Health Information Technology for Economic and Clinical Health (HITECH) Act established a legal framework for advancing HIT adoption and use. It also amended the Social Security Act to create financial incentives in the Medicare and Medicaid programs to encourage qualifying health care professionals and hospitals to become meaningful users of certified electronic health record (EHR) technology (CEHRT).

The HITECH Act authorizes the payment of financial incentives to eligible health care professionals who participate in Medicare and Medicaid and who are meaningful users of

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14 Id.
17 Id.
19 Public Health Service Act § 3000 et seq. [42 U.S.C. § 201 et seq.] (as added by ARRA § 13101). The term “HITECH Act” refers collectively to ARRA’s Title XIII (“Health Information Technology”) of Division A and Title IV (“Medicare and Medicaid Health Information Technology; Miscellaneous Medicare Provisions”) of Division B.
20 Social Security Act § 1903 (a)(3)(F) [42 U.S.C. § 1396b et seq.] (as added by ARRA § 4201(a)(1)).
certified EHR technology.\textsuperscript{21} While Medicare incentives are limited to reimbursements for providers who can demonstrate meaningful use, Medicaid incentive payments are available to cover costs incurred by qualified providers and hospitals related to “adopting, implementing, or upgrading” (AIU) certified EHRs,\textsuperscript{22} in addition to bonus payments (for up to five years) for providers who “demonstrate meaningful use of certified EHR technology.”\textsuperscript{23} CMS decided to implement the meaningful use program in three stages: Stage 1 meaningful use criteria primarily address the capture of health information;\textsuperscript{24} Stage 2 meaningful use criteria are intended to expand upon the initial criteria to include more robust requirements for health information exchange;\textsuperscript{25} and Stage 3 meaningful use criteria, to be proposed by the end of 2013, would make the measure of meaningful use more robust by adding criteria that focus on quality, safety and efficiency improvements, decision support for national high priority conditions, patient access to self-management tools, and access to comprehensive patient data and improving population health.\textsuperscript{26}

The Government Accountability Office (GAO) estimates that up to $30 billion in EHR incentive payments are available under program, covering all three stages from 2011 through 2019.\textsuperscript{27} CMS reports that as of July 2012, more than $6 billion in Medicare and Medicaid incentive payments have been made to 132,511 physicians and hospitals that demonstrated meaningful use of EHRs in Stage 1 of the program.\textsuperscript{28}

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\textbf{Stage 2 Final Rule}
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Changes to Stage 1 of the Program

The Stage 2 final rule makes some modifications to the Stage 1 final rule, which will apply to providers already participating in Stage 1 and those beginning the program in the future. First, as noted above, the Stage 2 final rule codifies the delay in implementation of the Stage 2 objectives until 2014.\textsuperscript{29} CMS noted in the final rule that a majority of commenters asserted that the existing timeline was not feasible and would lead to a large number of providers being unable to meet Stage 2 of meaningful use by 2013.\textsuperscript{30} In response, CMS finalized the delay for Stage 2 until 2014, and will give providers a 3 month reporting period for EHR attestation rather than a

\begin{thebibliography}{9}
\bibitem{21} Social Security Act § 1848(a)(1)(A)(i) [42 U.S.C. §1395w-4 et seq.] (as added by ARRA § 4101(a)) (Medicare incentive program); Social Security Act § 1903 (a)(3)(F) [42 U.S.C. § 1396b et seq.] (as added by ARRA § 4201(a)(1)) (Medicaid incentive program).
\bibitem{22} Social Security Act § 1903(t)(6)(C)(i)(I) [42 U.S.C §1396b et seq.] (as added by ARRA §4201(a)(2)).
\bibitem{23} Social Security Act § 1903(t)(6)(C)(i)(II) [42 U.S.C §1396b et seq.] (as added by ARRA §4201(a)(2)).
\bibitem{24} 75 Fed. Reg. 44314, 44566 (to be codified at 42 C.F.R § 495.6).
\bibitem{25} 75 Fed. Reg. 44314, 44321-22.
\bibitem{26} 75 Fed. Reg. 44314, 44322.
\bibitem{27} United States Government Accountability Office, Report to Congressional Committees, “Electronic Health Records: First Year of CMS’s Incentive Programs Shows Opportunities to Improve Processes to Verify Providers Met Requirements.” GAO-12-481. Available at: \url{http://www.gao.gov/assets/600/590538.pdf}
\bibitem{29} Stage 2 Final Rule, 77 Fed. Reg. 53971.
\bibitem{30} Id.
\end{thebibliography}
full year. According to the final rule, the shorter EHR reporting period will allow vendors enough time to upgrade the certified EHR technology and allow providers to implement it.32

Second, the final rule gives an alternate measure for Computerized Provider Order Entry (CPOE) that requires 30% of medication orders to be created using CPOE to meet Stage 1 objectives.33 For Stage 2, the threshold level of CPOE is finalized at 60% of medication orders created by providers in an eligible hospital or CAH’s inpatient or emergency department.34 More than 30% of the laboratory and radiology orders created by providers in an eligible hospital’s or CAH’s inpatient or emergency department must be recorded by CPOE under the final rule.35 Stage 2 also expands the Stage 1 rule by allowing credentialed medical assistants and EPs to enter the orders under the final rule.36

Third, the Stage 2 final rule increases the threshold for electronic prescribing from 40% in Stage 1 to 50% for Stage 2.37 The rule exempts controlled substances and over-the-counter medications from being counted in the total number of prescriptions written.38 The final rule also exempts providers who do not have a pharmacy within their organization or a pharmacy that accepts electronic prescriptions within 10 miles of the practice location from the electronic prescription objective in Stages 1.39

Additionally, the final rule no longer requires the exchange of key clinical information as an objective to meet Stage 1.40 The Stage 2 final rule requires a provider who transfers or refers a patient to another care provider to provide a summary of care record for that patient for each transition or referral.41 The final rule also addresses the electronic exchange of health information for patients who are transferred from one provider to another through three measures.42 The final rule includes two additional components to the summary of care record requirements: 1) Record care plan fields, including goals for at least 10% of care transitions; 2) Record team member, including primary care practitioner for at least 10% of patients.43 The Stage 2 final rule also includes specific information to be contained in the summary of care record. Specifically, CMS lowers the threshold in the proposed rule of 65% to 50% of transitions that the EP, eligible hospital or CAH that transitions or refers their patient must provide a summary of care record for.44 The Stage 2 final rule also includes a second measure that meets the objective if the EP, eligible hospital or CAH that transitions or refers their patient to another care setting or provider electronically submits a summary of care record using a certified EHR or the recipient receives the summary of care record through an exchange

33 Stage 2 Final Rule, 77 Fed. Reg. 53975; 53985-86.
35 Id.
36 Id.
44 Id.
facilitated by a third party for more than 10% of transitions of care and referrals. The third measure included by CMS is that an EP, eligible hospital or CAH must either conduct an electronic exchange of summary of care documents with an EHR system that is different from its own, demonstrating interoperability, or conduct one or more successful tests with CMS’ designated test EHR through the EHR reporting period.

Stage 2 Meaningful Use Objectives and Measures

In order to achieve meaningful use, a provider or entity must satisfy a requisite number of core objectives and a specified number of menu objectives. Both the core and menu objectives must: 1) improve quality safety, efficiency and reduce health disparities; 2) engage patients and their families in their care; 3) improve care coordination; 4) improve population and public health; and 5) maintain privacy and security of health information. Participants of the meaningful use program are required to meet the core objectives while they are able to choose which menu objectives to meet. CMS has retained the same core and menu structure to qualify for the EHR incentive payment for EPs, eligible hospitals, and CAHs. The final rule requires EPs to satisfy (or qualify for an exclusion of) 17 core objectives and 3 out of 6 menu objectives. Eligible hospitals and CAHs must meet or qualify for an exclusion of 16 core objectives and 3 out of 6 menu objectives. A majority of the Stage 1 core and menu objectives have been retained for Stage 2, while the final rule also added new core and menu objectives for Stage 2. Some of the Stage 1 objectives that were not retained for Stage 2 include the objective for testing the capability to exchange key clinical information. The final rule also combines some of the Stage 1 objectives for Stage 2. For example, the objectives of maintaining an up-to-date problem list, active medication list, and active allergy list are combined into the objective of providing a summary of care record for each care transition or referral for Stage 2. In addition, the Stage 2 final rule changes the menu set exclusions policy for Stage 1 so that starting in 2014, qualifying for an exclusion from a menu set item will not reduce the number of menu set objectives that an EP or hospital must meet to demonstrate Stage 1 meaningful use.

CMS also increased the threshold level for successful reporting of demographic data (including preferred language, sex, race, ethnicity, date of birth, date and preliminary cause of death).
death in the event of mortality in the eligible hospital or CAH) for an EP, eligible hospital’s or CAH’s inpatient or emergency department to more than 80% in Stage 2 from 50% in Stage 1.\textsuperscript{56}

The Stage 2 final rule also strengthens patient engagement and patient access to health information. Stage 2 requires that the threshold level for a clinical summary is 50% of office visits, and that for the clinical summary to meet the requirement, they must be available within one business day.\textsuperscript{57} The final rule also clarifies the information required to be a part of the clinical summary or noted as unavailable.\textsuperscript{58} In addition, the proposed Stage 2 objective of providing patients with the ability to view online, download, and transmit their health information within four days replaces the Stage 1 core measure of providing patients with the an electronic copy of their health information or the menu objective of providing patients with timely electronic access to their health information.\textsuperscript{59} The final rule thus makes the ability to view online, download, and transmit health information a core objective for Stage 2.\textsuperscript{60} This objective is satisfied when more than 50% of all unique patients seen by the EP during the EHR reporting period are provided electronic access to their health information within four business days after the information is available to the EP, and when more than 5% of all unique patients seen by the EP during the EHR reporting period view, download, or transmit their health information to a third party.\textsuperscript{61} There were a number of comments about whether the EP can control whether a patient accesses his or her health information, but the final rule took that into account by lowering the threshold from 10% in the proposed rule to 5% in the final rule.\textsuperscript{62} Finally, the Stage 2 final rule adds another core objective for EPs. The rule calls for secure electronic communication between the provider and the patient for 5% of patients in order to foster greater patient engagement.\textsuperscript{63}

The final rule also sets forth the specific information that is required to be available to the patients electronically.\textsuperscript{64} The Stage 2 final rule on clinically relevant patient-specific education materials maintains that clinically relevant patient-specific education materials identified by the certified EHR must be provided to patients for 10% of all office visits by the EP and for more than 10% of unique patients admitted to an eligible hospital or CAH’s inpatient or emergency department.\textsuperscript{65}

**Modifications to the Medicaid EHR Incentive Program**

The final rule expands the definition of a patient encounter under the Medicaid EHR program to include individuals enrolled in a Title XXI-funded Medicaid expansion encounter.\textsuperscript{66}

\textsuperscript{56} Stage 2 Final Rule, 77 F Fed. Reg. 53993.
\textsuperscript{57} Stage 2 Final Rule, 77 Fed. Reg. 53999-54002.
\textsuperscript{58} Stage 2 Final Rule, 77 Fed. Reg. 54001-54002.
\textsuperscript{60} Stage 2 Final Rule, 77 Fed. Reg. 54007.
\textsuperscript{61} Stage 2 Final Rule, 77 Fed. Reg. 54007-54011.
\textsuperscript{62} Id.
\textsuperscript{64} Stage 2 Final Rule, 77 Fed. Reg. 54005-06.
\textsuperscript{65} Id.
\textsuperscript{66} Stage 2 Final Rule, 77 Fed. Reg. 53971.
Notably, CMS also made 12 children’s hospitals eligible to participate in the Medicaid EHR incentive program starting payment year 2013.67

Mandatory Public Health Objectives

The final rule states that to meet the requirements for Stage 2 meaningful use, actual patient data must be submitted.68 In order to encourage reporting to a public health authority, the final rule takes into account that different states may have unique reporting requirements, so CMS has retained the language of “in accordance to, “ and also retains language that provides an exception to the reporting requirement when prohibited by law.69 CMS included as part of the Stage 2 final rule the capability to successfully submit data electronically to immunization registries or other information systems for the entire EHR reporting period as a core objective for EPs, eligible hospitals and CAHs, with certain exclusions.70 Other core measures finalized by CMS include the ability to successfully submit electronic reportable laboratory results to public health agencies,71 the capability to electronically submit syndromic surveillance data to public health agencies,72 the ability to report cancer cases electronically to the state cancer registry,73 for the entire EHR reporting period for EPs, eligible hospitals, and CAHs. Another notable core measure CMS finalized is the automatic tracking of medications from order to administration with an electronic medication administration record (eMAR) for more than 10% of medication orders for EPs, eligible hospital or CAH’s inpatient or emergency department.74

Clinical Quality Measures Reporting

The Medicare and Medicaid EHR incentive programs require EPs, eligible hospitals, and CAHs to report on specified clinical quality measures (CQMs).75 The final rule for Stage 2 maintains that the reporting periods for EPs, eligible hospitals and CAHs will be the same as those for the EHR reporting periods for the meaningful use objectives and measures.76 The final rule includes processes for electronic submission of CQM data for EPs, eligible hospitals, and CAHs, which is intended to reduce the administrative burden of quality reporting.77 More specifically, CMS seeks to align quality measurement and reporting among the various CMS programs, such as Medicare, state Medicaid rules, Physician Quality Reporting System, the Children’s Health Insurance Program Reauthorization Act, Accountable Care Organizations, dual eligibles demonstrations, and other Affordable Care Act measures in order to make it easier for providers and entities to coordinate meaningful use with other reporting programs.78 CMS

67 Id.
78 Id.
lists the CQMs that have been finalized for Medicare and Medicaid EPs for Stage 2 to start in 2014.79

The rule requires EPs to submit nine core CQMs from three different National Quality Strategy domains out of a list of 64 CQMs across six domains.80 The six domains are based on the National Quality Strategy’s 6 priority areas, such as 1) patient and family engagement; 2) patient safety; 3) care coordination; 4) population and public health; 5) efficient use of health care resources; 6) clinical processes/effectiveness.81 For the adult population, CMS’ final rule emphasizes controlling blood pressure, and includes behavioral health, dental care, long-term care, special needs populations, and care coordination.82 CMS also recommends a core set of nine CQMs for pediatric populations.83 Eligible hospitals and CAHs must submit 16 CQMs from three National Quality Strategy domains out of 29 CQMs across six domains.84

In terms of reporting, the Stage 2 final rule requires EPs, eligible hospitals, and CAHs participating in the Medicare EHR incentive program participating in their first year of the meaningful use program must submit their CQM data through attestation.85 Those beyond the first year must submit the CQM data through a CMS approved method.86 For payment adjustments, the EHR reporting periods will begin and end prior to the year of the payment adjustment.87 For example, for EPs who become meaningful users for the first time in 2014, CMS finalized that the EHR reporting period for the 2015 payment adjustment would be the same EHR reporting period that applies in order to receive the incentive for payment year 2013.88 CMS also included an exception for EPs who never successfully attested to meaningful use prior to 2014.89 Because it would be their first year of demonstrating meaningful use, for the 2015 payment adjustment, CMS will allow a continuous 90-day reporting period that begins in 2014 and that ends at least 3 months before the end of CY 2014.90 This payment adjustment period is similar for eligible hospitals and CAHs.91 According to the HITECH Act, the HHS Secretary may grant exemptions from the payment adjustments in 2015 on a case-by-case basis, if the Secretary determines that compliance with the meaningful use requirements will pose significant burden on the provider.92 Key exceptions the final rule addresses are hardship due to limited Internet connectivity or exceptions based on extreme circumstances. However, an exception may not be granted for more than five years.93 These exceptions apply in most cases to both EPs and eligible hospitals and CAHs.94

89 Id.
93 Id.
ONC Final Rule

The Office of the National Coordinator for Health Information Technology also released its final rule for certification and standards for electronic health records on August 23, 2012. The rule emphasizes ONC’s emphasis on reducing regulatory burdens, improving patient safety, enhanced patient engagement, and increased EHR interoperability. The final rule revises the definition of certified EHR technology needed to meet meaningful use. Therefore, ONC allows providers in the EHR reporting period before 2014, to choose and customize their EHR technology to what works best for their practices and patients by adopting EHR technology certified to 2011 standards, 2014 standards, or a mix of the two. Furthermore, the final rule calls for greater privacy and security protections, greater interoperability with other EHR systems, data portability, a certification standard for patient safety, and three additional CQMs. The final rule also emphasizes increased flexibility and reduced administrative burdens. All of these goals are consistent with the CMS final rule.

Conclusion

The Stage 2 final rule allows health care providers to transition EHR use to foster greater patient engagement and care coordination among providers. With the final rule, CMS has taken steps to lower the burden on providers by delaying the implementation of Stage 2 meaningful use requirements and by streamlining the quality reporting process. In addition, the final rule encourages patients to engage in their own health care by providing electronic access to health information and adding the ability to transmit their information to other providers who are part of their care teams. Significantly, the Stage 2 final rule encourages greater information sharing by making various public health reporting objectives mandatory.

The EHR incentive program has the power to drive improvement throughout the health care system. Currently, one of every nine Medicare eligible physicians and professionals are meaningful users of EHRs. 42 percent of all eligible hospitals have received an incentive payment for either demonstration of meaningful use or, in the case of Medicaid providers, or to adopt, implement or update their systems. For the Medicaid program, 17 states are open for registration for the incentive program, and Medicaid incentives have been paid to 2,400 physicians and hospitals so far.

98 Id.
100 Id.
102 “CMS EHR Payments Surpass $5B” GovernmenthealthIT.
As EPs, eligible hospitals and CAHs move toward meeting Stage 2, policymakers have begun exploring possible requirements for Stage 3, which will be proposed in late 2013 or 2014. Stage 3 is set to go into effect in 2016 for EPs, eligible hospitals, and CAHs. The Stage 3 rule will focus on improving outcomes, such as improving patient safety, improved health outcomes, better decision support for high priority health conditions, better patient access to self-management tools, and more patient-centered health information exchange. Stage 3 will also address those items that CMS declined to address in Stage 2, such as recording of disability status and gender or sexual identity and adding a historical problem list to a patient’s medical history. Finally, the Stage 3 rule will build on Stage 2, by increasing the thresholds for the core objectives, and achieving the final goal of improved health outcomes.

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106 Id.