

“What keeps you up at night?”

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CMS and ONC issue final rules on HITECH incentives for meaningful use of electronic health records

By Scott D. Patterson

SUMMARY

HHS has just published two complex new Final Rules specifying what hospitals, doctors, and other eligible providers need to do to qualify for Medicare and Medicaid incentives for "meaningful use" of electronic health records (EHR) technology. This Alert discusses key provisions of the new rules.

On July 28, 2010, the HHS Centers for Medicare & Medicaid Services ("CMS") published its Final Rule (<http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf>) ("EHR Rule") governing the electronic health record ("EHR") incentive program created by the 2009 HITECH Act. On the same day, the HHS Office of the National Coordinator for Health Information Technology ("ONC") issued a companion Final Rule (<http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf>) ("EHR Certification Rule"), effective August 27, 2010, specifying technical standards, implementation criteria, and certification programs for EHR technology.

The EHR Rule made numerous changes to CMS's initial proposal in response to thousands of comments. Most modifications reflected HHS's recognition of the significant barriers to full EHR adoption in the limited time between now and 2011, and will make it easier for providers to qualify for incentives. For Stage 1, CMS also eliminated proposed objectives relating to checking insurance eligibility and submitting payment claims.

For previous Saul Ewing Alerts on elements of the HITECH Act, click on the following links:

Health Law Practice Group Alert - July 27, 2010

(http://www.saul.com/common/publications/pdf_2711.pdf)

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BASIC ELEMENTS OF THE EHR RULE

The EHR Rule specifies what eligible healthcare providers must do to demonstrate Stage 1 “meaningful use” of certified EHR technology to qualify for Medicare/Medicaid incentives beginning in 2011. CMS declined to finalize all criteria for Stage 2 and Stage 3 “meaningful use.” However, the Rule does establish some preliminary Stage 2 requirements, and the background material issued with the Rule provides additional guidance for future stages. Stage 2 updates are expected to be issued by the end of 2011, and Stage 3 updates are expected by the end of 2013.

In a major accommodation, CMS agreed to establish two tiers of Stage 1 objectives: a “core” set and a “menu” set, rather than requiring providers to meet all objectives. Providers must demonstrate compliance with all core objectives, but only five of the menu objectives (§495.6).¹ If an objective does not apply (e.g., an objective relating to patients over 65 if no patients over 65 were treated during the relevant year), the provider can satisfy the test by meeting a reduced number of remaining objectives (§495.6(a)(2), (b)(2)). Stages 2 and 3 will require higher levels of achievement and satisfaction of additional objectives. Each objective is associated with one of five “health outcomes policy priorities” that CMS believed the HITECH Act was designed to promote: (1) improving quality, safety, and efficiency and reducing health disparities; (2) engaging patients and their families in healthcare; (3) improving care coordination; (4) improving population and public health; and (5) ensuring adequate privacy and security protections for personal health information. At least one of the “menu” choices must be an objective associated with improving population and public health.

Medicaid-eligible hospitals and eligible professionals (EPs) are given an additional accommodation – they are only required to “adopt, implement, or upgrade certified EHR technology” during the

first payment year, and do not actually need to meet the Stage 1 meaningful use objectives until the second payment year (§§495.6(a)(3), (b)(3); 495.8).

“Meaningful use” requires providers to use “certified” EHRs in order to qualify for incentives. The EHR Certification Rule spells out the detailed requirements that “Complete EHRs” and “EHR Modules” must meet in order to be qualified for certification. For now, certification of specific products will be carried out under HHS’s temporary certification program published on June 24, 2010, 45 CFR Part 170, Subpart D. (which can be viewed at <http://edocket.access.gpo.gov/2010/pdf/2010-14999.pdf>)

States may establish alternative “meaningful use” criteria under their Medicaid programs, but are prohibited from establishing stricter criteria that would disqualify a provider who has satisfied all of the federal “meaningful use” criteria for purposes of Stage 1 Medicare incentive eligibility (§495.4, definition of “Meaningful EHR User”; 495.332(f)(2)(ii)).

ELIGIBILITY

A full description of Medicare/Medicaid eligibility criteria is beyond the scope of this Alert, but in general, both Medicare and Medicaid incentives are available to acute care and critical access hospitals, and Medicaid incentives are also available to children’s hospitals and cancer hospitals. Both Medicare and Medicaid incentives are available to non-hospital-based physicians² and healthcare professionals, although the two programs define non-physician “eligible professionals” differently.³

To be eligible for Medicaid incentives, at least 10 percent of an acute care hospital’s patient volume or 30 percent of a profession-

1. All section references are to Title 42 of the Code of Federal Regulations (CFR).
2. “Hospital based” means furnishing 90 percent of covered professional services in a hospital inpatient or emergency room setting during the preceding year (§495.4).
3. For Medicare incentives, eligible professionals are doctors of medicine, osteopathy, dental surgery or medicine, podiatric medicine, or chiropractors (§495.100); for Medicaid incentives, they are physicians, dentists, certified nurse midwives, nurse practitioners, and physician assistants practicing in FQHCs or RHCs led by physician assistants (§495.304(b)).

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al's patient volume must be individuals receiving Medicaid (reduced to 20 percent for pediatricians.) To avoid double-dipping, eligible professionals who are eligible for incentives under both Medicare and Medicaid must choose one program, although they can switch once, retroactive to the first payment year (§495.10(e)).

CERTIFIED EHRs AND EHR MODULES

Under the EHR Certification Rule, EHRs or combinations of EHR Modules must fully satisfy defined standards for exchanges of patient records and e-prescription information, submission of immunization data and lab results, and quality reporting (§170.205) in order to qualify for certification. They must conform to specified vocabulary standards (§170.207) and security standards (§170.210), and must provide dozens of listed functional capabilities (§§170.302, 304, 306), such as performing drug interaction checks, calculating body-mass index, generating patient lists sorted by specific problems, encrypting data for exchange, facilitating computerized physician order entry (CPOE), and implementing automated clinical decision support rules.

Unfortunately, according to the American Medical Association's July 20, 2010 comments on the final EHR Rule. “There is no EHR in the market today that does all of the things required for physicians to successfully meet Stage 1 meaningful use criteria.” (The comment does note that CMS and ONC expect that situation to change by the fall of 2010.)

INCENTIVE AMOUNTS

The EHR Rule establishes a complicated set of formulas and rules for calculating incentive payments. Incentives are capped for each payment year, for an aggregate maximum of \$44,000 for most eligible professionals (§495.102). For hospitals, the cap is calculated based on the volume of inpatient discharges (§495.104). For hospitals whose first payment year is 2011, 2012, or 2013, the maximum range is from \$2,000,000 to \$6,370,200 per year. That annual amount is reduced to 75 percent for the second year, 50 percent for the third year, and 25 percent for the fourth year. Hospitals that start in 2014 begin at the 75 percent cap and are

eligible for only three years of payments, and those that start in 2015 begin at the 50 percent cap and are eligible for only two years. The goal is to motivate providers to start implementing their EHR systems sooner rather than later. One significant complication for some health systems is that “eligible hospitals” are counted based on CMS Certification Numbers (“CCNs”), so that multi-hospital health systems using a single CCN will only qualify for one incentive, not one per facility (§§495.4, 495.104); CMS retained this definition in the face of multiple negative comments characterizing it as arbitrary.

Critical access hospitals that become meaningful users receive a different incentive under the Medicare fee for service program: reimbursement of a share of their purchase costs for qualifying EHR hardware and software (§495.106(b)).

TIMETABLE AND PAYMENTS

The EHR Rule (§§495.102, 495.104) clarifies how quickly providers must attain each stage of meaningful use to receive incentive payments, and, in the case of Medicare, to receive full payment for services rendered after calendar year 2014. To obtain the earliest possible benefits, providers must implement systems during 2011.

As a practical matter, hospitals that want to qualify for 2011 Medicare incentives will need to have all Stage 1 capabilities in place and operational by July 1, 2011, and eligible professionals will need to reach that point by October 1, 2011, because 90 days of “meaningful use” are required to qualify for incentives in the first payment year. (Subsequent payment years require a full 12 months of utilization.)

Providers that start late can still earn incentives, but, in the case of Medicare, will lose out permanently on the incentives available for earlier years. CMS has not yet decided what stages need to be achieved in 2015 and beyond, but in any event incentive payments will not be available after 2016 for Medicare and after 2021 for Medicaid. Importantly, CMS has emphasized that the HITECH Act does not authorize the provision of partial incentive payments, so payments will be made on an “all or nothing” basis depending

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upon meaningful use compliance for the payment period in question.

The table below reflects the Medicare incentive payment timeline (dollar amounts shown below are those for eligible professionals.) The Medicaid timeline is more complicated, because compliance years under the Medicaid portion of the program do not need to be consecutive (§495.4, definition of “First, second, third, fourth, fifth, or sixth payment years”)⁴, and, as noted above, Medicaid providers can qualify for the first year of incentives by implementing systems without actually achieving Stage 1 objectives until the second year.

Payment Year	2011	2012	2013	2014	2015
1st Payment Year ↓					
2011	Stage 1 EP Max \$18,000	Stage 1 EP Max \$12,000	Stage 2 EP Max \$8,000	Stage 2 EP Max \$4,000	TBD EP Max \$2,000
2012		Stage 1 EP Max \$18,000	Stage 1 EP Max \$12,000	Stage 2 EP Max \$8,000	TBD EP Max \$4,000
2013			Stage 1 EP Max \$15,000	Stage 1 EP Max \$12,000	TBD EP Max \$8,000
2014				Stage 1 EP Max \$15,000	TBD
2015					TBD

MEANINGFUL USE: CORE OBJECTIVES (§495.6(A), (D), (F))

45 CFR §495.6 spells out core objectives for hospitals and professionals, with related measures. The list below necessarily omits critical percentages and other measurement details that determine whether an objective has actually been met. For instance, the “eligible professional” objective for use of CPOE (§495.6(d)(1)) does not require that all medication orders, or even a percentage of all orders be entered through CPOE: it requires only that 30 percent of the professional’s patients receiving medications have a single CPOE order apiece. (This percentage increases to 60 percent of patients in Stage 2.) Certain objectives are not

measured against all patient records but only against patients whose records are maintained in EHRs (§495.6(c)).

STAGE 1 CORE OBJECTIVES FOR ELIGIBLE PROFESSIONALS (§495.6(A), (D)):

- Use CPOE
- Implement drug-drug and drug-allergy medication checks
- Maintain an up-to-date problem list
- Generate and transmit electronic prescriptions
- Maintain active medication and medication allergy lists
- Record demographic information
- Record and chart changes in height, weight, blood pressure, and body mass index
- Record smoking status for patients 13 and older
- Report ambulatory clinical quality measures
- Implement one clinical decision support rule
- Provide patients with a copy of their health information and clinical summaries of their office visits
- Perform at least one test of the EHR system’s ability to exchange key clinical information
- Do a security risk analysis and implement security as necessary

STAGE 1 CORE OBJECTIVES FOR HOSPITALS (§495.6(F))

The core objectives for hospitals are mostly the same as for eligible professionals, but with certain differences in measurements and percentages. “Generate and transmit electronic prescriptions” is not included. Hospitals are to report hospital rather than ambulatory clinical quality measures, and to provide patients with a copy of discharge instructions rather than summaries of office visits.

MEANINGFUL USE - MENU OBJECTIVES (§495.6(E), (G))

As noted above, during Stage 1, eligible professionals and hospitals can pick five objectives from the “menu” set of objectives.

4. For hospitals, however, starting with FY 2017, incentive payments relating to the Medicaid program must be made in consecutive years (§495.4).

Again, the actual measurement is typically less demanding than the general statement of the objective would suggest. For instance, the “patient reminder” menu objective (§495.6(e)(4)) only requires that 10 percent of patients age 65 and older or 5 and younger be sent an appropriate reminder. At least one of the selected objectives must be associated with “improving population and public health” (the three objectives tagged as “PH” in the bullet points below).

STAGE 1 MENU OBJECTIVES FOR ELIGIBLE PROFESSIONALS (§§495.6(E))

- Implement drug-formulary checks
- Incorporate clinical lab-test results into EHR as structured data
- Generate lists of patients by specific conditions
- Send patient reminders for preventive/followup care
- Provide patients with timely electronic access to their health information
- Use EHR technology to identify patient-specific education resources
- Perform medication reconciliation for care transitioned from another provider
- Provide a summary care record for transitions to another provider
- Perform at least one test of the system’s ability to submit data to immunization registries
- Perform at least one test of the system’s ability to provide electronic syndromic surveillance data to agencies

STAGE 1 MENU OBJECTIVES FOR HOSPITALS (§495.6(G))

As with the core objectives, the menu objectives for hospitals are mostly the same as for professionals, with limited differences in some measurements. Additional menu objectives are:

- Record an “indication of advance directive status” for patients 65 and older.
- Perform at least one test of the system’s ability to provide electronic submission of reportable lab results to public health agencies

CONCLUSION

The new EHR Rule and EHR Certification Rule, together with the establishment of a temporary EHR certification program, have been drafted with precision, and should give providers the certainty they need to move forward with implementation of their EHR systems and programs. The use of a “staged” approach by CMS and ONC should address many providers’ concerns regarding: technology product limitations/capabilities; ability of third parties (such as laboratories and pharmacies) to engage in electronic exchanges; and metrics/qualifications for receipt of incentive payments.

The commentaries accompanying these Rules and their predecessors, and the focus on outcomes, demonstrate that HHS recognizes that EHRs are merely means to an end. System implementation is only the first step down a long road to a world in which patients have comprehensive access to their health histories and providers have the tools to better understand their patients’ needs and to improve the quality of the care they deliver.

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