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CMS AND ONC FINAL REGULATIONS DEFINE MEANINGFUL USE AND SET STANDARDS FOR ELECTRONIC HEALTH RECORD INCENTIVE PROGRAM

The Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) today announced two complementary final rules to implement the electronic health records (EHR) incentive program under the Health Information Technology for Economic and Clinical Health (HITECH) Act.

Enacted as part of the American Recovery and Reinvestment Act (ARRA) of 2009, the HITECH Act supports the adoption of electronic health records by providing financial incentives under Medicare and Medicaid to hospitals and eligible professionals who implement and demonstrate “meaningful use” certified EHR technology. The CMS regulations announced today specify the objectives that providers must achieve in payment years 2011 and 2012 to qualify for incentive payments; the ONC regulations specify the technical capabilities that EHR technology must have to be certified and to support providers in achieving the “meaningful use” objectives.

The final CMS rule:

- Specifies initial criteria that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet to demonstrate meaningful use and qualify for incentive payments.
- Includes both “core” criteria that all providers must meet to qualify for payments, while also allowing provider choice among a “menu set” of additional criteria.
- Outlines a phased approach to implement the requirements for demonstrating meaningful use. This approach initially establishes criteria for meaningful use based on currently available technological capabilities and providers’ practice experience. CMS will establish graduated criteria for demonstrating meaningful use through future rulemaking, consistent with anticipated developments in technology and providers’ capabilities.

The CMS rule finalizes a Notice of Proposed Rulemaking published on Jan 13, 2010.

The final ONC rule:

- Sets initial standards, implementation specifications, and certification criteria for EHR technology under the incentive program.
- Coordinates the standards required of EHR systems with the meaningful use requirements for eligible professionals and hospitals

- With these standards in place, providers can be assured that the certified EHR technology they adopt is capable of performing the required functions to comply with CMS' meaningful use requirements and other administrative requirements of the Medicare and Medicaid EHR incentive programs.

ONC's standards and certification criteria final rule completes the adoption of an initial set of standards, implementation specifications and certification criteria that was begun with publication of ONC's on Jan. 13, 2010.

Timetable for Implementation

The HITECH Act states that payments for Medicare providers may begin no sooner than October 2010 for eligible hospitals and January 2011 for EPs. The final rule aligns the Medicare and Medicaid program start dates. Key steps in the implementation timeline include:

- ONC began accepting applications from entities that seek approval as an ONC-Authorized Testing and Certification Body (ONC-ATCB) on July 1, 2010.
- ONC projects that certified EHR software will be available for purchase by hospitals and eligible professionals by fall, 2010
- Registration by both EPs and eligible hospitals with CMS for the EHR incentive program will begin in January 2011. Registration for both the Medicare and Medicaid incentive programs will occur at one virtual location, managed by CMS.
- For the Medicare program, attestations may be made starting in April 2011 for both EPs and eligible hospitals.
- Medicare EHR incentive payments will begin in mid May 2011.
- States will be initiating their incentive programs on a rolling basis, subject to CMS approval of the State Medicaid HIT plan, which details how each State will implement and oversee its incentive program.

The "Meaningful Use" Model

By focusing on the effective use of EHRs with certain capabilities, the HITECH Act makes clear that the adoption of records is not a goal in itself: it is the use of EHRs to achieve health and efficiency goals that matters. HITECH's incentives and assistance programs seek to improve the health of Americans and the performance of their health care system through "meaningful use" of EHRs to achieve five health care goals:

- To improve the quality, safety, and efficiency of care while reducing disparities;
- To engage patients and families in their care;
- To promote public and population health;
- To improve care coordination; and
- To promote the privacy and security of EHRs.

In the context of the EHR incentive programs, “demonstrating meaningful use” is the key to receiving the incentive payments. It means meeting a series of objectives that make use of EHRs’ potential and related to the improvement of quality, efficiency and patient safety in the healthcare system through the use of certified EHR technology.

Coordinated Approach to Support EHR Adoption

CMS’ and ONC’s final rules complement two other rules that were recently issued. On June 24, 2010, ONC published a final rule to establish a temporary certification program for health information technology. And on July 8, 2010, the Office for Civil Rights announced a proposed rule that would strengthen and expand privacy, security, and enforcement protections under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Together the four rules are key components of the regulatory structure needed to administer the EHR incentive program and to meet the goals of the HITECH Act:

- The assurance of privacy protections is fundamental to the success of EHR adoption. The refinements and expansions of HIPAA provisions announced July 8 form an important base for EHR acceptance and use.
- The temporary certification process published June 24 establishes a process through which organizations can be approved as certifying entities to which vendors may submit their EHR systems for review and certification.
- The ONC rule announced today identifies the technical standards which must be met in the certification process, and coordinates those requirements with the meaningful use objectives.
- Finally, the CMS rule announced today establishes guidelines and requirements on achieving meaningful use in clinical settings and qualifying for incentive payments based on this meaningful use.

Key Provisions of the Final Rule

CMS's final meaningful use rule incorporates changes from the proposed rule on meaningful use that are designed to make the requirements more readily achievable while meeting the goals of the HITECH Act. For Stage 1, which begins in 2011, the criteria for meaningful use focus on electronically capturing health information in a coded format, using that information to track key clinical conditions, communicating that information for care coordination purposes, and initiating the reporting of clinical quality measures and public health information.

The final rule reflects significant changes to the proposed rule while retaining the intent and structure of the incentive programs. Key provisions in the final rule include:

- For Stage 1, CMS's proposed rule called on physicians and other eligible professionals to meet 25 objectives (23 for hospitals) in reporting their meaningful use of EHRs. The final rule divides the objectives into a "core" group of required objectives and a "menu set" of procedures from which providers can choose. This "two track" approach ensures that the most basic elements of meaningful EHR use will be met by all providers qualifying for incentive payments, while at the same time allowing latitude in other areas to reflect providers' varying needs and their individual paths to full EHR use.
- In line with recommendations of the Health Information Technology Policy Committee, the final rule includes the objective of providing patient-specific educational resources for both EPs and eligible hospitals and the objective of recording advance directives for eligible hospitals.
- With respect to defining hospital-based physicians, the final rule conforms to the Continuing Extension Act of 2010. That law addressed provider concerns about hospital-based providers in ambulatory settings being unable to qualify for incentive payments by defining a hospital-based EP as performing substantially all of his or her services in an inpatient hospital setting or emergency room only.
- The rule makes final a proposed rule definition that would make individual payments to eligible hospitals identified by their individual CMS Certification Number. The final rule retains the proposed definition of an eligible hospital because that is most consistent with policy precedents in how Medicare has historically applied the statutory definition of a "subsection (d)" hospital under other hospital payment regulations.
- Under Medicaid, the final rule includes critical access hospitals (CAHs) in the definition of acute care hospital for the purpose of incentive program eligibility.
- The final rule's economic analysis estimates that incentive payments under Medicare and Medicaid EHR programs for 2011 through 2019 will range from \$9.7 billion to \$27.4 billion.

Development of the Rules

CMS and ONC worked closely to develop the two rules and received input from hundreds of technical subject matters experts, health care providers, consumers, and other key stakeholders. Numerous public meetings to solicit public comment were held by three Federal advisory committees: the National Committee on Vital and Health Statistics (NCVHS), the HIT Policy Committee (HITPC), and the HIT Standards Committee (HITSC). HITSC presented its final recommendations to the National Coordinator in August 2009.

CMS published its proposed rule on Jan. 13, 2010. The agency actively solicited comments on its proposal and received more than 2,000 submissions by the close of the 60-day comment period. These comments, along with the input from advisory groups and outreach activities, were given careful consideration in developing the regulations announced today.

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