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CMS and ONC Issue Regulations Proposing a Definition of ‘Meaningful Use’ and Setting Standards for Electronic Health Record Incentive Program

Public Encouraged to Comment on New Regulations

The Centers for Medicare & Medicare Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) encourage public comment on two regulations issued today that lay a foundation for improving quality, efficiency and safety through meaningful use of certified electronic health record (EHR) technology. The regulations will help implement the EHR incentive programs enacted under the American Recovery and Reinvestment Act of 2009 (Recovery Act).

A proposed rule issued by CMS outlines proposed provisions governing the EHR incentive programs, including defining the central concept of “meaningful use” of EHR technology. An interim final regulation (IFR) issued by ONC sets initial standards, implementation specifications, and certification criteria for EHR technology. Both regulations are open to public comment.

“Widespread adoption of electronic health records holds great promise for improving health care quality, efficiency, and patient safety,” said, National Coordinator for Health Information Technology David Blumenthal, M.D., M.P.P. “The Recovery Act’s financial incentives demonstrate Congress’ and the Administration’s commitment to help providers adopt and make meaningful use of EHR technology so they can give better care and their patients’ experience of care will improve. Over time, we believe the EHR incentive program under Medicare and Medicaid will accelerate and facilitate health information technology adoption by more individual providers and organizations throughout the health care system.”

“These regulations are closely linked,” said Charlene Frizzera, CMS acting administrator. “CMS’s proposed regulation would define and specify how to demonstrate ‘meaningful use’ of EHR technology, which is a prerequisite for receiving the Medicare incentive payments. Our rule also outlines the proposed payment methodologies for the Medicare and Medicaid EHR incentive programs. ONC’s regulation sets forth the standards and specifications that will enhance the interoperability, functionality, utility and security of health information technology.”

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CMS and ONC worked closely to develop the two rules and received input from hundreds of technical subject matters experts, health care providers, 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 Health IT Policy Committee (HITPC), and the Health IT Standards Committee (HITSC). HITSC presented its final recommendations to the National Coordinator in August 2009. These recommendations, along with all other input were considered to help inform the development of the regulations announced today.

The IFR issued by ONC describes the standards that must be met by certified EHR technology to exchange healthcare information among providers and between providers and patients. This initial set of standards begins to define a common language to ensure accurate and secure health information exchange across different EHR systems. The IFR describes standard formats for clinical summaries and prescriptions; standard terms to describe clinical problems, procedures, laboratory tests, medications and allergies; and standards for the secure transportation of this information using the Internet.

The IFR calls for the industry to standardize the way in which EHR information is exchanged between organizations, and sets forth criteria required for an EHR technology to be certified. These standards will support meaningful use and data exchange among providers who must use certified EHR technology to qualify for the Medicare and Medicaid incentives.

Under the statute, HHS is required to adopt an initial set of standards for EHR technology by Dec. 31, 2009. The IFR will go into effect 30 days after publication, with an opportunity for public comment and refinement over the next 60 days. A final rule will be issued in 2010. "We strongly encourage stakeholders to provide comments on these standards and specifications," Dr. Blumenthal said.

The Recovery Act established programs to provide incentive payments to eligible professionals and eligible hospitals participating in Medicare and Medicaid that adopt and make "meaningful use" of certified EHR technology. Incentive payments may begin as soon as October 2010 to eligible hospitals. Incentive payments to other eligible providers may begin in January 2011.

The proposed rule would define the term "meaningful EHR user" as an eligible professional or eligible hospital that, during the specified reporting period, demonstrates meaningful use of certified EHR technology in a form and manner consistent with certain objectives and measures presented in the regulation. These objectives and measures would include use of certified EHR technology in a manner that improves quality, safety, and efficiency of health care delivery, reduces health care disparities, engages patients and families, improves care coordination, improves population and public health, and ensures adequate privacy and security protections for personal health information.

The proposed rule would define meaningful use for the Medicare EHR incentive programs. It proposes one definition that would apply to eligible professionals participating in the Medicare fee-for-service and the Medicare Advantage EHR incentive programs as well as a proposed definition that would apply to eligible hospitals and critical access hospitals. These definitions also would serve as the minimum standard for eligible professionals and eligible hospitals participating in the Medicaid EHR incentive program. The rule proposes that states could request CMS approval to implement additional meaningful use measures, as appropriate, but could not request approval of fewer or less rigorous meaningful use measures than required by the rule.

This rule proposes a phased approach to implement the proposed requirements for demonstrating meaningful use. This approach would initially establish reasonable criteria for meaningful use based on currently available technological capabilities and providers' practice experience. CMS will establish stricter and more extensive criteria for demonstrating meaningful use over time, as anticipated developments in technology and providers' capabilities occur.

CMS provides a 60-day comment period on the proposed rule. "The definition and requirements for demonstrating meaningful use of EHR technology are proposals. CMS welcomes and will give serious consideration to comments that improve our proposal while achieving the goals Congress established for the EHR incentive programs," Frizzera said.

The CMS proposed rule and fact sheets, may be viewed at http://www.cms.hhs.gov/Recovery/11_HealthIT.asp

ONC's interim final rule may be viewed at <http://healthit.hhs.gov/standardsandcertification>. In early 2010 ONC intends to issue a notice of proposed rulemaking related to the certification of health information technology

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