CMS Proposes Rule for Electronic Health Record Standards and Specifications

By Craig A. Conway, J.D., LL.M. (Health Law)
caconway@central.uh.edu

Although it is not receiving as much attention as a companion regulation released the same day, the Office of the National Coordinator for Health Information Technology (ONC), released an interim final rule for public comment on standards and specification criteria for electronic health records (EHR) systems that must be met in order for physicians, hospitals, and other healthcare providers to receive Medicare and Medicaid incentive payments starting later this year or early 2011. The incentive programs are part of the American Recovery and Reinvestment Act (ARRA), enacted in early 2009 in an effort to stimulate the nation’s economy. The interim final rule describes the standards that must be met by certified EHR technology to exchange healthcare information among providers and between providers and patients. The rule also includes 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 such information using the Internet. On December 30, 2009, CMS, in a related announcement, released a second set of regulations aimed at defining “meaningful use” criteria governing the EHR programs. Both sets of rules were published in the Federal Register on January 13, 2009, and will be open for public comments for a 60-day period.

Background

The health information technology (HIT) provisions of the ARRA are found primarily in Title IV of the legislation, known as the Health Information Technology for Economic
and Clinical Health Act (HITECH).\footnote{See Centers for Medicare & Medicaid Servs., Fact Sheets: Details For: Medicare and Medicaid Health Information Technology: Title IV of the American Recovery and Reinvestment Act, June 16, 2009, http://www.cms.hhs.gov/apps/media/press/factsheet.asp?Counter=3466&intNumPerPage.} Pursuant to the HITECH Act, physicians and hospitals that implement the “meaningful use” of certified EHR technology during calendar years 2010 to 2014 will be eligible to receive higher Medicare and Medicaid incentive payments.\footnote{Id.; see also Ron Scott, \textit{ARRA Provides Incentives for “Meaningful Use” of Electronic Health Records 14:5 UPDATE ON HEALTH} at *3 (May 2009).} Those that do not implement such technology may be hit with penalties. Regardless, a technology and standards foundation must first be laid to ensure that the proper coordination, communication and compatibility between healthcare providers and the federal Medicare and Medicaid programs is achieved when exchanging healthcare information and data. Under the HITECH Act, CMS administers the EHR programs while the ONC has responsibility for developing the standards and implementing the specifications and certification criteria for EHR technology.

The CMS and ONC rules intertwine in that providers must “meaningfully use” their EHRs, but the systems themselves must be “qualified” under a definition in the ARRA and “certified” against criteria established through federal rulemaking by a certification organization “recognized” by the ONC.\footnote{Joseph Conn, \textit{Certification Details for “Meaningful” EHRs Still Unknown}, MODERN HEALTHCARE.COM, Jan. 11, 2010, http://www.modernhealthcare.com/article/20100111/REG/301119980.} A rule has yet to be written covering how certification bodies will be selected and “recognized.”\footnote{Id.}

The Medicare EHR programs provide incentive payments to eligible professionals, eligible hospitals, and critical access hospitals that are meaningful users of certified EHRs. Incentive payments would be made to qualifying Medicare Advantage organizations for the meaningful use of certified EHR technology by their affiliated eligible professionals. The Medicaid EHR incentive program provides incentive payments to eligible professionals and hospitals for efforts to adopt, implement or upgrade certified EHR technology or for meaningful use in the first year and for meaningful use for up to another five years.\footnote{Centers for Medicare and Medicaid Servs., \textit{Health Information Technology}, http://www.cms.hhs.gov/Recovery/11__HealthIT.asp (last accessed Jan. 14, 2010).}

**Overview of the Interim Final Rule (IFR)**

The ONC established the following goals to guide its approach to adopting the standards, implementation specifications, and certification criteria within the IFR:

- promote interoperability and where necessary be specific about certain content exchange and vocabulary standards to establish a path forward toward semantic interoperability;
- support the evolution and timely maintenance of adopted standards;
- promote technical innovation using adopted standards;
- encourage participation and adoption by all vendors, including small businesses;
• keep implementation costs as low as reasonably possible;
• consider best practices, experiences, policies, frameworks, and the input of the HIT Policy Committee and HIT Standards Committee in current and future standards;
• enable mechanisms such as the Nationwide Health Information Network (NHIN) to serve as a test-bed for innovation and as an open-source reference implementation of best practices; and
• to the extent possible, adopt standards that are modular and not interdependent.\textsuperscript{10}

The certification criteria adopted in the interim final rule set forth the standards and requirements that certified EHR technology will need to include in order to, at a minimum, support the meaningful achievement of the proposed meaningful use Stage 1 criteria beginning in 2011. \textit{See Health Law Perspectives article: Some Tout CMS’ Proposed “Meaningful Use” Definition for Use of Electronic Health Records As Too Ambitious} for an explanation of the three proposed stages to implement EHR technology.

\textit{Eligible Professional}

Under the Medicare incentive program, an eligible professional is a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of optometry, or a chiropractor, who is legally authorized to practice under state law.\textsuperscript{11} Hospital-based eligible professionals who furnish substantially all their services in a “hospital setting” are not eligible for incentive payments and are defined as an one who furnishes 90 percent or more of his/her allowed services in a hospital, including all hospital inpatient, outpatient, and emergency department settings.\textsuperscript{12} A qualifying eligible professional can receive EHR incentive payments for up to five years with payments beginning as early as 2011. In general, the maximum amount of total incentive payments that he or she can receive under the Medicare program is $44,000.\textsuperscript{13} An eligible professional who predominantly furnishes services in a geographic Health Professional Shortage Area is eligible for a 10 percent increase in the maximum incentive payment amount.\textsuperscript{14} And even if an eligible professional meets the requirements for both the Medicare and Medicaid incentive programs, he or she may participate in only one program and must designate the program in which they would like to participate. CMS proposes that, after

\textsuperscript{12} \textit{Id.}
\textsuperscript{13} \textit{Id.} (In general, a qualifying eligible professional can receive an annual incentive payment as high as $18,000 if their first payment year is 2011 or 2012. Otherwise, the annual incentive payment limits in the first, second, third, fourth, and fifth years are $15,000, $12,000, $8,000, $4,000, and $2,000 respectively.)
\textsuperscript{14} \textit{Id.} (The maximum amount of total incentive payments that such an eligible professional can receive under the Medicare program is $48,400.)
the initial designation, eligible professionals be allowed to change their program selection only once during payment years 2012 through 2014.\textsuperscript{15}

\textit{Eligible Hospital}

An eligible hospital must be located in one of the 50 states or the District of Columbia and be paid under the hospital inpatient prospective payment system.\textsuperscript{16} Unlike eligible professionals, eligible hospitals can qualify to receive payments from both the Medicare and Medicaid EHR incentive programs. A qualifying hospital is an eligible hospital that demonstrates meaningful use for the EHR reporting period during a payment year.\textsuperscript{17} Eligible hospitals may qualify to receive incentive payments for up to four years beginning in 2011. The last year for which an eligible hospital can begin receiving incentive payments for meaningful EHR use is 2015.\textsuperscript{18}

\textbf{Conclusion}

According to a 2009 survey conducted by the Centers for Disease Control and Prevention, four of every 10 office-based physicians use electronic health records.\textsuperscript{19} Thus only 40 percent of current physicians have a basic framework for upgrading to the required technology in order to receive incentive payments. The remaining 60 percent will be required to invest significant capital to convert current data capture systems to electronic formats. This initial cost may financially hit those physicians hard. Any meaningful incentive payments they receive thereafter may not be so meaningful for months to come. However, some companies are offering physician practices and other providers interest-free or low-interest loans to absorb some of the cost.\textsuperscript{20} For additional information on CMS’ proposed definition of “meaningful use” of EHR technology, see Health Law Perspectives article: Some Tout CMS’ Proposed “Meaningful Use” Definition for Use of Electronic Health Records As Too Ambitious.

\textbf{Health Law Perspectives (January 2010)}
Health Law & Policy Institute
University of Houston Law Center
http://www.law.uh.edu/healthlaw/perspectives/homepage.asp

The opinions, beliefs and viewpoints expressed by the various Health Law Perspectives authors on this web site do not necessarily reflect the opinions, beliefs, viewpoints, or official policies of the Health Law & Policy Institute. The Health Law & Policy Institute is part of the University of Houston Law Center. It is guided by an advisory board consisting of leading academicians, health law practitioners, representatives of area institutions, and public officials. A primary mission of the

\textsuperscript{15} Id.
\textsuperscript{16} Id.
\textsuperscript{17} Id. (A Payment Year is a Federal Fiscal Year).
\textsuperscript{18} Id.
Institute is to provide policy analysis for members of the Texas Legislature and health and human service agencies in state government.