Health Care Alert: HHS Issues Final Rules to Support Meaningful Use of Electronic Health Records

On July 28, 2010 the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) in the US Department of Health & Human Services (HHS) published two complementary final rules to implement the electronic health records (EHR) incentive program under the Health Information Technology for Economic and Clinical Health Act (HITECH Act). The CMS rule may be found at http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf, and the ONC rule may be found at http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf. Enacted as part of the American Recovery and Reinvestment Act of 2009 (ARRA), the HITECH Act supports the adoption of EHRs by providing financial incentives under Medicare and Medicaid to hospitals and eligible professionals (EPs) who implement and demonstrate "meaningful use" of certified EHR technology. The CMS regulations specify the objectives that providers must achieve in 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. EPs may receive as much as $44,000 under Medicare and $63,750 under Medicaid, and hospitals may receive in excess of $2 million for implementation and meaningful use of certified EHRs under both Medicare and Medicaid.

Highlights of the CMS Final Rule

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• Specifies initial criteria that EPs, eligible hospitals and critical access hospitals (CAHs) must meet to demonstrate meaningful use and qualify for incentive payments. Under Medicare, EPs are doctors of medicine or osteopathy, doctors of dental surgery or medicine, doctors of podiatric medicine, doctors of optometry, or chiropractors. Under Medicaid, EPs are physicians, dentists, certified nurse-midwives, nurse practitioners or physician assistants practicing in a Federally Qualified Health Center led by a physician assistant or a rural health clinic that is led by a physician assistant.

• 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.

• For Stage 1, CMS’ 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.

• Defines hospital-based EPs as those who perform substantially all of their services in an inpatient hospital setting or emergency room only, thus expanding the availability of incentive payments to EPs who provide services in hospital-based ambulatory settings.

• Retains the proposed definition of an eligible hospital. Because the incentive program will pay each eligible hospital a base payment amount of $2 million plus a per-discharge amount, one implication of the definition is that multi-campus hospital systems using one Medicare provider number will be recognized under the incentive program as a single eligible hospital that qualifies for a single base payment amount. Multi-campus hospital systems with multiple Medicare provider numbers will receive multiple base payments.

• Under Medicaid, the final rule includes CAHs in the definition of acute care hospital for the purpose of incentive program eligibility.
• Estimates that incentive payments under Medicare and Medicaid EHR programs for 2011 through 2019 will range from $9.7 billion to $27.4 billion.

**Highlights of the ONC Final 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.
• Provides assurance that the adopted certified EHR technology will comply with the meaningful use requirements of the Medicare and Medicaid EHR incentive programs.

**Timetable for Implementation**

Payments for Medicare providers may begin no sooner than October 2010 for eligible hospitals and January 2011 for EPs. The final CMS rule aligns the start dates for the Medicare and Medicaid incentive programs. Following are key steps in the implementation timeline:

• On July 1, 2010 ONC began accepting applications from entities seeking approval as an ONC- Authorized Testing and Certification Body.
• By the fall of 2010 ONC projects that certified EHR software will be available for purchase by hospitals and EPs.
• Beginning in January 2011 both EPs and eligible hospitals may register with CMS for the EHR incentive program.
• Starting in April 2011 both EPs and eligible hospitals may make attestations for the Medicare program.
• In mid-May 2011 Medicare EHR incentive payments will begin.

States will initiate 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. More information on the EHR incentive program may be found at [http://www.cms.gov/EHRIncentivePrograms](http://www.cms.gov/EHRIncentivePrograms).

**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. The temporary certification program establishes a process by which organizations can be approved as
certifying entities for vendors to submit their EHR systems for review and certification. Additionally, on July 8, 2010 the HHS 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). For more information on the proposed HIPAA rules see "HHS Proposes Significant Changes to HIPAA Privacy and Security Rules — Part One of a Three-Part Series." 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.

What Are Key Changes Under the Final Rules?

CMS’ final meaningful use rule incorporates changes from the proposed rule on meaningful use that are designed to make the requirements more readily achievable. 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.

Squire Sanders lawyers have significant experience in health information technology, including the structuring of arrangements between physicians and hospitals to achieve meaningful use of EHRs and obtaining incentive payments. We routinely advise clients on matters related to health information technology. We continue to monitor the implementation of these rules and are available to assist clients in structuring arrangements to achieve meaningful use including registration with CMS and preparation of the required attestations.

The contents of this update are not intended to serve as legal advice related to individual situations or as legal opinions concerning such situations. Counsel should be consulted for legal planning and advice.

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