Recently, the Department of Health and Human Services (DHHS) released the final rule for the first two years (2011 and 2012) of the multiyear incentive program related to support of providers in deploying electronic health records (EHRs). The final rule is divided into two groups: a set of core objectives that constitute a starting point for meaningful use of EHRs, and a separate menu of additional important activities from which providers will choose several to implement in the first two years. This rule is a core requirement for healthcare providers to become eligible for payment under the Medicare and Medicaid EHR incentive programs.

Overview
The Health Information Technology for Economic and Clinical Health Act (HITECH Act) was signed into law on Feb. 17, 2009 as part of the American Recovery and Reinvestment Act (ARRA) of 2009. The ARRA is a $787 billion stimulus package with heavy investments in science, energy, healthcare, and technology. Of the $787 billion, more than $180 billion has been set aside for healthcare-related spending, with the intent of creating compelling financial incentives for physicians and hospitals to adopt EHRs during the next five years.

The funding for the EHR implementation will be administered through Medicare and Medicaid via incentive payments for hospitals and healthcare professionals that implement compliant EHR systems. Hospitals are eligible to receive up to four years of financial incentive payments under Medicare and up to six years of incentive payments under Medicaid beginning on Oct. 1, 2010. Eligible physicians can receive up to $44,000 during five years under Medicare or $63,750 during six years under Medicaid, beginning on Jan. 1, 2011.

What Does It Mean?
These steps to "meaningful use" may seem like a heavy lift. However, the new rules clearly provide for the ability of providers to leverage numerous projects that may already be in process, including Health Information Exchange (HIE) initiatives, Regional Extension Center (REC) grants, and Beacon Community grants which are designed to help providers meet the goal of achieving "meaningful use."

Along with considerable health IT funding, "meaningful use" will be phased in during the next several years in three stages.

- **Stage 1** will primarily be collecting electronic health data in coded formats
- **Stage 2** will implement structured data exchange and continuous quality improvement
- **Stage 3** focuses on advanced decision support and population health

An important consideration for both providers and hospitals is the payment schedule developed under the ARRA program. The incentive is clearly to engage the healthcare community sooner rather than later in adopting "meaningful use" and to promote a nationwide acceleration in the use of health information technology (HIT). Furthermore, the payment incentive program is intended to take providers and hospitals through all three stages of adoption. The three stages will use the following general criteria:

- **Stage 1**: Data Capture and Sharing — the goal is to electronically capture data in coded format as well as report health information usable for tracking key clinical conditions.
- **Stage 2**: Advanced Clinical Processes — the goal is to guide and support care processes and care coordination through the exchange of information in the most structured format possible, such as the electronic transmission of orders entered using computerized provider order entry (CPOE) and the electronic transmission of diagnostic test results (e.g., blood tests, microbiology, urinalysis, pathology tests, radiology, cardiac imaging, nuclear medicine tests, pulmonary function tests, and other such data needed to diagnose and treat disease).

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Stage 3: Improved Outcomes — the goal is to achieve improved performance through the effective adoption and use of care processes as well as advance key health system outcomes. In addition, at this stage, the goal is to promote further improvements in quality, safety, and efficiency by focusing on decision support for national high-priority conditions, patient access to self-management tools, improving access to comprehensive patient data, and improving population health.

Defining Meaningful Use

In December 2009, the Office of the National Coordinator for Health IT (ONCHIT), an office within Health and Human Services (HHS) that oversees health information technology policy and implementation and also provides recommendations to the Secretary, announced a notice for proposed rulemaking (NPRM) to define “meaningful use,” which is a key element in providing incentive payments for EHR technology. This NPRM was published January 13 with the initial set of standards, certification criteria, and implementation specifications for Stage 1 of the EHR incentive program. The proposed rule in January proposed criteria with 23 objectives for hospitals and 25 objectives for eligible professionals that needed to be met in order for providers and organizations to meet the “meaningful use” criteria. The new, final regulations represent a smaller subset of 15 core objectives for eligible professionals and 14 core objectives for hospitals.

There is also a separate “menu” of 10 additional activities. Professionals and hospitals can choose five of those to implement in the first two years and the remainder could be deferred to Stage 2. Achievement levels in the criteria have also been reduced. For example, in the proposed rule, eligible professionals had to prescribe 75 percent of their prescriptions electronically. The number has now been reduced to 40 percent.

The following are the final rules released by ONCHIT for defining “meaningful use” as the core set of objectives for Stage 1 Criteria:

- Record demographics (50 percent requirement)
- Record and chart changes in vital signs (50 percent of all unique patients age 2 and older admitted to the eligible hospital, record blood pressure and BMI; additionally, plot growth chart for children age 2 to 20)
- Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT (80 percent of all unique patients admitted have at least one entry or an indication of “none” recorded as structured data)
- Maintain active medication list (80 percent requirement)
- Maintain active medication allergy list (80 percent requirement)
- Record smoking status for patients 13 years old or older (50 percent requirement)
- Eligible professionals must provide patient with clinical summary for each visit (clinical summaries provided to patients for more than 50 percent for all office visits within three business days)
- Eligible hospitals must provide electronic copy of discharge instructions on request (50 percent of patients discharged from the inpatient or emergency department for patients that request it)
- On request, provide patients with electronic copy of their health information (50 percent of patients must receive electronic copy within three days)
- Generate and transmit permissible prescriptions electronically — eRx (40 percent requirement, does not apply to hospitals)
- Use CPOE for all order types (30 percent for patients with at least one medication ordered through CPOE)
- Implement drug-drug and drug-allergy interaction checks (functionality is enabled for these checks for the entire reporting period)
- Implement capability to electronically exchange key clinical information among providers and patient authorized entities (perform at least one test of EHR’s capacity to exchange information)
- Implement one clinical decision support rule and ability to track compliance with the rule (one clinical decision support rule implemented)
- Protect electronic health information maintained using certified EHR technology through the implementation of appropriate technical capabilities (conduct or review a security risk analysis in accordance with the requirements and implement security updates as necessary)
- Report clinical quality measures to CMS or states (for 2011, provide aggregate numerator and denominator through attestation; for 2012, electronically submit measures)

Menu Set

In addition to the core set, ONCHIT is proposing that a “menu set” of activities also be included as part of Stage 1 meaningful use criteria. Professionals and hospitals would “select” five elements from this list for meeting the requirements of meaningful use. This allows a degree of customization for providers and hospitals so that they can work to not only meet meaningful use requirements but also the objectives of their individual practices. Specifically, the menu criteria include:

- Implement drug-formulary checks (generate at least one report for entire reporting period)
- Incorporate clinical lab-test results into EHR as structured data (40 percent requirement)
• Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, and outreach (generate at least one report)
• Use EHR to identify patient-specific education resources and provide to patient (10 percent requirement)
• Perform medication reconciliation at relevant encounters and at each transition of care (50 percent requirement)
• Provide summary care record for each transition of care and referral (50 percent requirement)
• Submit electronic data to immunization registries and actual submission where required and accepted (perform at least one test)
• Submit electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice (perform at least one test)

Additional Choices for hospitals and critical access hospitals:
• Record advance medical directives for patients 65 and older (50 percent requirement)
• Submission of reportable lab results to public health agencies (perform at least one test)

Additional Choices for eligible professionals:
• Send reminders to patients for preventative and follow-up care (20 percent requirement for patients 65 and older or 5 years and younger)
• Provide patients with electronic access to their health information, including laboratory results, problem list, medication list, and medication allergies (10 percent requirement within 4 days)

The rule is available to view and download on the Federal Register’s Public Inspection Desk (http://www.ofr.gov/OFRUpload/OFRData/2010-17207_PI.pdf).

Certification/Adoption Interim Rule
On June 24, the ONCHIT issued a final rule to establish a temporary certification program for EHR technology that is a core requirement for providers who seek to qualify to receive incentive payments under the ARRA as a part of the HITECH Act. This temporary certification program establishes processes that organizations will need to follow in order to be authorized by the National Coordinator to test and certify EHR technology.

ONCHIT established the following goals to guide its approach to adopting the standards, implementation specifications, and certification criteria within the final rule:

• Promote interoperability through the use of standards 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 for implementation of best practices.

Security and Privacy Proposed Rule
On July 8, the Department of HHS’s Office for Civil Rights (OCR) released a proposed rule to modify and strengthen provisions of the HIPAA privacy, security, and enforcement rules. The enforcement rule covers the HIPAA administrative simplification, privacy, security, and breach notification rules. Provisions of the rule include:

• Make requirements under the privacy and security rules applicable to business associates in the same manner they presently apply to covered entities. Under the proposed rule, patient safety organizations now are defined as business associates.
• Require business associates to obtain “satisfactory assurances” from subcontractors that they will comply with applicable requirements of the privacy and security rules. Existing contracts between business associates and subcontractors can be grandfathered for up to one year beyond the rule’s compliance date.
• Restrict marketing activities by redefining “marketing,” which will limit health-related communications that may be considered “health care operations.” The proposed rule would require covered entities receiving payment for making certain communications to obtain authorization from individuals before making the communications.
• Define uses and disclosures of protected health information for which individual authorization is required, such as the sale of personal health information (PHI). In the proposed rule, OCR asks for additional public comment on uses and disclosures of PHI for research purposes.
• Require recipients of fundraising communications with a clear and conspicuous opportunity to opt out of receiving future communications, making clear that opting out will not affect future treatment of the individual.
• Require notice of privacy practices to include a description of the uses and disclosures of protected health information that require an authorization.
• Enable individuals to request restriction of disclosures of PHI, unless otherwise required by law, if the restriction applies solely to a service fully paid out-of-pocket.
• Strengthen the right of individuals to obtain their EHRs.
• Increase civil money penalties for violations of requirements to protect the privacy and security of protected health information, with fines of up to $1.5 million in a single calendar year for violations of the same requirement.
• Define “reasonable cause,” “reasonable diligence,” and “willful neglect,” the definitions of which are the basis for setting monetary penalty amounts.

• Outline the responsibilities of covered entities during complaint investigations and compliance reviews.


Conclusion
Taking advantage of Medicare and Medicaid incentive payments to implement EHRs is intended to foster improved prevention and management of chronic diseases, reduction of medication errors, and manage other healthcare disparities which will transform healthcare delivery and lower healthcare costs. The implementation of these systems will also serve as a foundation for efforts to amplify the effectiveness of healthcare services by supporting a host of new reimbursement models. While considerable discussion is underway on the exact focus of these new models of care delivery, it is anticipated that the modification of reimbursement methodologies will reward more organized, coordinated, and efficient care.

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