January 18, 2010

To our friends and clients:

Dechert’s Health Law Practice monitors developments related to healthcare reform and periodically issues a Dechert Healthcare Reform Update. Each Update provides the latest information on efforts by the Obama administration and Congress to reform healthcare.

**New Rules for the HITECH Electronic Health Records Incentive Program and “Meaningful Use”**

Under the HITECH Act within the American Recovery and Reinvestment Act of 2009, a provider or hospital must demonstrate “meaningful use” of certified electronic health record (“EHR”) technology in order to receive Medicare and Medicaid incentive payments. On January 13, 2010, the Centers for Medicare and Medicaid Services (“CMS”) and the Office of the National Coordinator for Health Information Technology (“ONC”) each published rules relating to EHR incentives, standards, and certification, including the definition of “meaningful use.”

The two rules are closely linked. To qualify for incentives, an eligible provider (“EP”) or hospital must both adopt certified EHR technology and demonstrate meaningful use of this technology. The CMS proposed rule outlines provisions governing EHR incentive programs, including defining “meaningful use” of EHR technology. Meaningful use involves more than just adopting an EHR system. Providers must use the technology in a manner consistent with certain objectives and measures set forth in the regulations.

The interim final rule issued by ONC sets initial standards, implementation specifications, and certification criteria to enhance the interoperability, functionality, utility, and security of health information technology and to support its meaningful use. Both rules are quite complex and are open for public comment.

**Meaningful Use**

The CMS proposed rule includes a phased approach to implementing requirements for demonstrating meaningful use. Under Stage 1, an EP or hospital requesting incentive payments will be considered a meaningful user of EHR during a specified period if it meets a number of criteria focusing on:

- Capturing health information in coded format;
- Using the information to track key clinical conditions and communicate for care purposes;
- Implementing clinical decision support tools; and
- Reporting clinical quality measures and public health information to relevant government officials.
Some specified criteria/measures apply to both EPs and hospitals, while some are separate criteria applicable to either EPs or hospitals. For each criterion, the regulations list an objective and a means of measuring how the EP or hospital can meet that objective. For example, one objective for EPs and hospitals is to maintain an active medication allergy list. The measure for this objective is that at least 80% of all unique patients seen by the EP or admitted to the hospital have at least one drug allergy entry (or an indication of “none” if the patient has no medication allergies) recorded as structured data. For Stage 1, which begins in 2011, CMS proposes 25 objectives/measures for EPs and 23 objectives/measures for eligible hospitals that must be met to be deemed a meaningful EHR user. In 2011, all of the results for all objectives/measures, including clinical quality measures, would be reported by EPs and hospitals to CMS, or for Medicaid EPs (depending on which program they choose to seek incentive payments from) and hospitals to the states, through an attestation process.

EPs and hospitals that begin the process of meeting the meaningful-use criteria early will have more time to accomplish each objective/measure. In other words, the longer an EP or hospital waits to implement an EHR system, the quicker the EP or hospital will need to move through the stages to continue receiving incentive payments.

In Stage 2, the meaningful-use criteria (not yet published) are expected to encourage the use of health IT for continuous quality improvement at the point of care and the exchange of information in the most structured format possible, such as electronic transmission of orders entered using computerized provider order entry and electronic transmission of diagnostic test results. Stage 3 is expected to focus on promoting improvements in quality, safety, and efficiency, focusing on decision support for national high priority conditions, patient access to self management tools, access to comprehensive patient data, and improving population health.

Certified EHR Technology

A “Qualified EHR” is an electronic record of health-related information on an individual that:

■ Includes patient demographic and clinical health information such as medical history and problem lists;

■ Provides clinical decision support;

■ Supports computerized physician order entry (“CPOE”);

■ Captures and queries information relevant to health care quality; and

■ Exchanges electronic health information with, and integrates such information from, other sources.

“Certified EHR Technology” means a complete EHR or a combination of EHR Modules, each of which:

■ Meet the requirements included in the definition of a Qualified EHR; and

■ Has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary.

An EHR Module is any service, component, or combination thereof that can meet the requirements of at least one certification criterion. Examples of such Modules include a clinical decision support rules engine, and a quality measure reporting service or software program. The published standards, implementation specifications, and certification criteria apply to complete EHRs, as well as EHR Modules and the testing and certification of such complete EHRs and Modules. Under the complete EHR approach, an EP or hospital would implement an entire system knowing that all criteria has been certified in a single system.
Otherwise, if they purchase a variety of EHR modules, then the EP or hospital is responsible for ensuring that the combinations of EHR modules collectively satisfy all the criteria specified in the rule.

The certification criteria are designed to support the various measures for meaningful use specified in the CMS rule and described above, so that the EP or hospital acquiring EHR technology has the technological capabilities to become a meaningful user and to track and report its use automatically and electronically. The criteria address 21 functional areas generally applicable to all EHRs, nine of those areas focusing on ambulatory EHR, and five areas relating to inpatient EHRs. The standards are broken down into the following four general areas: vocabulary standards; content exchange standards; transport standards (for communication between systems); and privacy and security standards. The rules do not create new technology standards, but adopt existing standards, specifications, and protocols promulgated by the technology industry generally.

As noted above, the certification criteria include standards and implementation specifications relating to protecting the privacy and security of health information, but they do not guarantee compliance with the HIPAA privacy and security rules. This rule takes effect 30 days after publication. ONC is working on a proposed rule addressing the process by which EHR technology may be certified using the certification criteria listed in the interim final rule and described above.

Incentive Payments

An EP or hospital must meet all of the applicable criteria referenced above to receive incentive payments. Incentive payments may be available to certain users as early as 2010 under the Medicaid program, while payments under the Medicare program may not be forthcoming until 2011. Incentive payments to EPs will be based on a calendar year, while payments to hospitals will be based on a fiscal year. Under the Medicare program, payment adjustments (penalties) will be assessed to EPs and hospitals who have not met the criteria for meaningful EHR use by 2015.

Eligibility

EPs and hospitals may qualify for incentive payments from either a Medicare or Medicaid incentive payment program, or both. EPs that qualify for both the Medicare (Fee For Service or Medical Advantage) and Medicaid programs have a dilemma, since EPs can participate in only one incentive program, and may change to the other program only once. However, hospitals may participate in the Medicare and Medicaid incentive programs simultaneously. EPs and hospitals that participate in the Medicaid incentive program, but who care for patients in multiple states, may participate in only one state Medicaid incentive program.

Eligible Providers

Under the Medicare program, incentives payments to EPs are available for "physicians" only. Physicians, for these purposes are limited to: doctors of medicine; doctors of osteopathy; dental surgeons; doctors of dental medicine; podiatrists; optometrists; and chiropractors. In contrast, under the Medicaid program, incentive payments to EPs are available to a broader range of professionals, including: physicians; dentists; certified nurse midwives; nurse practitioners; and physician assistants practicing in a federally qualified health center, or rural health clinic led by a physician assistant, provided these professionals have a Medicaid patient volume of more than 30% with a certain exception for pediatricians who only need 20% Medicaid patient volume in order to qualify.

Under both programs, “hospital-based” providers are excluded from participation. A hospital-based provider is an individual who provides substantially all (at least 90%) of his or her covered professional services in an inpatient or outpatient hospital setting, utilizing the equipment and facilities of the hospital. Medicaid providers practicing predominantly in a federally qualified health center or a rural health clinic are not subject to the hospital-based exclusion.
Eligible Hospitals

Under the Medicare program, eligible hospitals are “subsection (d) hospitals” that are paid under the hospital inpatient prospective payment system. Subsection (d) hospitals are hospitals located in the 50 states or the District of Columbia, but not Puerto Rico or the territories. Hospitals and hospital units that are excluded from participation are psychiatric, rehabilitation, long-term care, children’s, and cancer hospitals. Under the Medicaid program, only acute care hospitals, with 10% Medicaid volume, and children’s hospitals, with no volume requirement, qualify for the incentive program.

In addition to subsection (d) hospitals, critical access hospitals also qualify for incentive payments, provided they are meaningful users of certified EHR technology during an EHR reporting period for a cost reporting period beginning during a payment year after fiscal year 2010, but before fiscal year 2016.

Payments

Under the Medicare program, EPs who are meaningful EHR users during the relevant EHR reporting period are entitled to an incentive payment amount, subject to an annual limit, for up to five years. There is a phased reduction in payment limits for EPs that first demonstrate meaningful use of certified EHR technology after 2013. An EP that does not qualify to receive an EHR-related incentive payment prior to 2015 will not receive any of these incentive payments. These limits are increased by 10% for EPs that predominantly furnish services in a Health Professional Shortage Area or “HPSA.”

Under the Medicare program, hospitals may qualify for financial incentive payments for only four consecutive years, but unlike payments to EPs, the payments are not capped. However, incentive payments decrease annually after the first year. The formula for calculation of incentive payments under the Medicare program is:

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\text{Incentive Amount} = [\text{Initial Amount}] \times [\text{Medicare Share}] \times [\text{Transition Factor}].
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Factors included in this calculation are based on a hospital’s cost report data for: inpatient days; discharges; and charity care, among others. Hospitals that fail to qualify as meaningful users before fiscal year 2016 will be subject to reductions to their annual Medicare payments.

Under the Medicaid program, payment for EPs equals 85% of “net average allowable costs.” The net average allowable costs are capped by statute and are equal to $25,000 in the first year, and $10,000 for each of five subsequent years (with certain exceptions). Thus, the maximum incentive payment an EP could receive from Medicaid equals $63,750, over a period of six years. EPs must begin receiving incentive payments no later than calendar year 2016.

Medicaid incentive payments for hospitals are largely based on the methodology applied to Medicare incentive payments. The Medicaid incentive amount is calculated only once as an aggregate four-year total. There are no penalties for hospitals under the Medicaid incentive program.

Under the Medicaid program, in the first year, both EPs and hospitals do not have to show “meaningful use,” but must begin adopting, implementing, or upgrading certified EHR technology to be eligible for the first Medicaid incentive. After the first year, incentive payments will require compliance with the meaningful use standard.
For More Information

If you have questions regarding the information in this update, please contact the Dechert attorney with whom you regularly work, or any of the attorneys listed.

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