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Health IT Regulations Taking Shape Rules Beginning to Clarify Qualification for \$19 Billion in Stimulus Funding

Part-way through a rule-making and standard-setting process that has already lasted almost a full year, the medical profession and technology industry are now getting a sense of what it will take to access the approximately \$19 billion in federal stimulus dollars and what kind of opportunities this will stimulate in this already booming market. Two federal government agencies issued draft rules in recent weeks that are geared to easing compliance into a system that will have increasingly strict requirements as the process evolves.

Background

One of the much-trumpeted, but stretched-out provisions of The American Recovery and Reinvestment Act of 2009 (the "Recovery Act") provides a series of dramatic opportunities for medical practices that treat Medicaid/Medicare patients and technology entities on the front edge of health information technology.

The crux of these rules is the implementation of electronic health records ("EHR"), a new name for an expanded data set of what used to be known as electronic medical records, designed in accordance with the federal requirements. The government's expectation is that widespread use of EHR will lead to significant systemic efficiencies.

To speed EHR adoption, in the hope of reducing systemic costs, the federal government has adopted a carrot and stick approach for Medicare and Medicaid providers. The government will provide subsidies of \$19 billion from 2011-2016 for medical practices that become meaningful users of EHR before January 1, 2014, and will impose reduced payment schedules for those that do not adopt EHR by 2016.

Subsidies -- What Practices Qualify?

Because the Recovery Act subsidies are being provided through Medicaid and Medicare programs, these subsidies are only available to practices and hospitals that provide Medicare fee-for-service, Medicaid, and Medicare Advantage services. For these "in-system" providers, payments are first available for practices that are "meaningful users" of EHR technology in 2011.

The Centers for Medicare and Medicaid Services issued a proposed rule on December 30, 2009 (the "Draft CMS Rule"), that sets forth a three-stage process for what will constitute meaningful use, with lesser standards in place for 2011 and increasing requirements in later years. While Stage 1 is well developed (although potentially subject to revision when the final rule is approved in the upcoming weeks), the requirements of Stages 2 and 3 are still being developed and these regulations are expected later in 2010. The Draft CMS Rule anticipates changes before a final rule is proposed early in the second quarter of 2010.

Most public comments, and experts that have looked at implementation of EHR systems, have indicated that the \$44,000 per physician subsidies are a significant but incomplete subsidy for EHR implementation. Depending on the scale of the practice and the software purchased, the \$44,000 will likely cover between one-tenth and one-third of the hardware, software, and connectivity costs. While the costs are significant, the efficiencies, both for the system and the practices, are generally expected to allow a strong return on practitioner's unsubsidized further investments.

How About Doctors Who Have Already Invested in Modern Systems?

Practitioners who already qualify as meaningful users, provided that the EHR system meets the certification criteria, will receive the incentive payments so long as they continue their meaningful use.

Becoming a Meaningful User

To be a "meaningful user" in 2011, providers will have to capture health information in a specific coded format; use that information to track key clinical conditions; use and communicate the information for care coordination, and begin the process of reporting clinical quality measures and public health information. The Draft CMS Rule contains 25 measures that would define objective use covering the entire range of interfaces.

A sample of these 25 requirements requires that the following be done electronically:

- transmission of at least 75% of eligible prescriptions electronically
- recording blood pressure and body mass index for 80% of patients seen
- recording smoking status for 80% of patients over age 13
- implementation of five clinical decision support rules
- checking insurance eligibility for at least 80% of patients
- testing as required by local authorities and reporting of public health information

The Draft CMS Rule is explicit that CMS anticipates increasing these thresholds in Stages 2 and 3, as the available technology infrastructure improves. The policy intention is to move towards 100 percent use of EHR in every mandated category.

What are the Deadlines?

The amount of the subsidy that a qualified user of EHR receives will depend on when it becomes a meaningful user. Each physician is eligible for the lesser of (i) the capped amount under the chart below or (ii) 75 percent of the physician's Medicare Part B billings for the given year. (Similar, but different, provisions apply for Medicare Advantage and Medicaid providers.)

First Meaningful Use by the Doctor	2011 Payment	2012 Payment	2013 Payment	2014 Payment	2015 Payment	2016 Payment
2011	\$18,000	\$12,000	\$8,000	\$4,000	\$2,000	\$0
2012		\$18,000	\$12,000	\$8,000	\$4,000	\$2,000
2013			\$15,000	\$12,000	\$8,000	\$4,000
2014				\$12,000	\$8,000	\$4,000

The Draft CMS Rule defines meaningful use for 2011 to be 90 continuous days. Thus, a practice that comes online by October 3, 2011 qualifies for the 2011 subsidy. The rule is not as forgiving for later years in that the Draft CMS Rule defines meaningful use for 2012 and thereafter to require a full year's participation. If this rule holds, the full \$44,000 per physician subsidy will only be available to those who become meaningful users by January 1, 2012, and no subsidies would be available to physicians who become meaningful users after January 1, 2014.

The verification process will also change. Under the Draft CMS Rule, for 2011, medical practices will be able to self-certify their meaningful use. However, for 2012 and thereafter, CMS intends to require submission of certain EHR information before it will pay the incentives.

What Will the System Look Like?

While private industry is building, or in many cases, retrofitting proprietary systems, EHR systems will have to comply with a detailed set of standards that will be promulgated by the Office of the National Coordinator for Health Information Technology ("ONCHIT"), an office established by executive order signed by President George W. Bush and formalized and funded with \$2 billion in the Recovery Act. ONCHIT is responsible not only for establishing the interoperability standards, but promoting innovation, adoption, and assisting with implementation.

On January 13, 2010, ONCHIT issued an interim final rule (the "Draft ONCHIT Rule") to provide guidance to the industry while the formal rulemaking process to establish its permanent priorities and implement the technical standards for technology interoperability. When finalized, the Draft ONCHIT Rule will almost certainly be the basis. The Draft ONCHIT Rule adopts a high level set of standards

designed to largely reflect those most commonly used in the industry today. It also sets forth the process to establish standards that will provide greater details in the future to promote enhanced interoperability.

The standards used borrow heavily from the current standards established and/or promoted by the government's National Institute of Standards and Technology, the non-profit Health Level 7, and the international association Integrating the Healthcare Enterprise. The standards also utilize certain current nomenclature and classification systems, including drawing significant content from SNOMED CT, ICD-9 and 10, X12, LOINC, NCPDP, and RxNorm.

Operationally, the new requirements are both creating tremendous opportunities and challenges for technology companies and practices. In what is clearly a market-driven decision, the leading "EMR" system providers have announced that they will be retrofitting their systems to meet the ONCHIT standards once they are finalized. However, not all providers have specified whether they are including conformity for current customers or whether there will be a subsequent charge where allowed by underlying contracts. Any system or software purchase going forward should include a requirement of continuing compliance with ONCHIT requirements and future enhanced requirements under the Health Insurance Portability and Accountability Act.

Who is Weighing In?

The window for comments will remain open until March 15 on the ONCHIT Rule. It is anticipated that significant comments will be forthcoming from the Health IT industry, medical associations, hospitals and individual practitioners. Comments can be submitted online at www.regulations.gov.

If you would like more information about this issue, contact [Kevin Greenberg](#) or any member of Flaster/Greenberg's [Healthcare Practice Group](#).