HIT Perspectives
Perspectives and Updates on Health Information Technology
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HIT Legislation

Now We Know: Feds Issue Regulations on Meaningful Use of Qualified EHRs

By Ed Daniels, Contributing Editor

The wait is over. On July 13, the federal government issued new regulations showing how hospitals and physicians can establish that they have meaningfully used "qualified" electronic health records (EHRs) to be eligible for hefty federal incentive payments.

The guidance came in two parts. The Centers for Medicare and Medicaid Services (CMS) issued a final rule defining meaningful use (MU) objectives and criteria. The Office of the National Coordinator (ONC) issued a final rule describing required standards and certification criteria for EHR technology. We applaud both entities for listening to the numerous comments that were received and issuing thoughtful new rules in a very short timeframe.

These regulations are important on a number of levels. First, they establish basic qualifications for incentive payments totaling up to $27 billion over 10 years that will be available under Medicare and Medicaid to health care providers demonstrating MU of certified EHRs. That equates to more than $4 million per hospital and as much as $44,000 (through Medicare) and $63,750 (through Medicaid) per clinician. Second, the ONC rule lays the foundation for ensuring that EHR technology will be in sync with the MU criteria. Third, the new rules provide the framework to which vendors must adhere in order to stay in business. Finally, these rules will help ensure that providers can buy with confidence and that certified EHR systems, when used appropriately, will qualify them for incentive bonuses.

There is a lot of detail in these two rules and much to digest. Point-of-Care Partners (POPC) is working closely with clients to develop in-depth analyses and action plans. In this issue of *HIT Perspectives*, we offer some high-level observations that our readers will find useful. This article focuses on the content of the new rules. Others provide insight about what they mean to select market segments and ePrescribing, in particular.

So, what's in the new rules and what has changed?

Meaningful use objectives. The CMS draft proposal included roughly 2 dozen mandatory and intensively measured objectives that both hospitals and clinicians would need to meet to demonstrate MU. Reacting to substantial industry push-back during the comment period, its final rule now offers flexibility and a phased approach. This means that the Stage 1 criteria set forth in the new rule apply to 2011 and 2012, the first 2 years of the program. MU requirements for Stages 2 and 3 will be covered in subsequent rule making over the next few years.

The final rule also offers flexibility in a mix-and-match approach to achieve the Stage 1 objectives. There is a core set of mandatory objectives plus a "menu set" of 10 optional objectives from which providers can choose any five to implement in 2011–2012. These are summarized in the table below. It is noteworthy for our readers that eligibility checking is no longer a requirement, at least for now. Formulary checking was dropped as a mandatory requirement and has slipped into the menu set.

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The bar was lowered. The CMS draft proposal had an all-or-nothing approach with fairly rigorous requirements that were viewed as unattainable for many hospitals and clinicians. These have been ratcheted way down in the final rule. For example, only a single measure will need to be enacted to meet the clinical decision support requirement, down from five measures. Clinicians and hospitals now need only to perform at least one test of their certified EHR capacity to electronically exchange key clinical information. Other measures, such as use of CPOE to electronically send results to a lab or diagnostic imaging center, were deferred to forthcoming Stage 2 and 3 requirements.

Changes in provider eligibility criteria. CMS' final rule expands eligibility criteria for the hospital setting. A hospital-based eligible professional is now defined as a provider who performs nearly all services in an inpatient hospital setting or emergency department. The rule also expands the definition of acute care hospital to include designated critical access hospitals.

Certification and standards. At the same time the final MU regulations were issued, ONC released the "Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology." This 228-page document (http://www.ofr.gov/OFRUpload/OFRData/2010-17210_PI.pdf) defines the criteria for certifying EHRs and modules. The new standards are very closely aligned with final MU Stage 1 objectives and measures. In fact, the document contains tables showing how the final rules are associated with each MU objective and measure.

The certification standards include:

- Content standards (things like which patient summary record standard to use, which electronic prescribing standard and standards for quality reporting).
- Vocabulary standards (including standards for procedures, laboratory test results, medications and immunizations).
- Privacy and security (including transport standards, encryption standards and standards relating to who did what to specific data elements when).

While this is useful and we know what will be required, the real emphasis will be on getting testing and certification up and running. Organizations, including consortia, may immediately apply to become testing and/or certification entities. According to ONC, the goal is to have these entities approved by the end of the summer, which—given that we're in the middle of summer already—will be no mean feat. So far, 30 entities have asked for applications. Sixteen have submitted applications, including the Drummond Group and the Certification Commission for Health IT (CCHIT). CCHIT was not afforded special treatment and will have to apply as essentially a new entity. CCHIT-certified EHRs are not grandfathered in, even though there was an appeal for this in the public comments.

Hopefully, the certification bodies can be recognized quickly and testing can begin. The government aims to have certification bodies in place and testing beginning in the fall. We hope this will be the case. In addition, the new regulations came out just in time so that purchasers can learn the facts and get into purchase mode.

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That would be a good thing because of great confusion in the marketplace. For example, a new survey of 850 health care providers from across the nation found that two-thirds of respondents consider certification of their electronic health records to be very important, though they are uncertain of specific certification requirements. According to the 2010 U.S. Ambulatory Electronic Health Records Certification Study conducted by CapSite, 69% of respondents did not know that organizations other than CCHIT may be accredited to certify ambulatory EHRs. In addition, 52% believed CCHIT certification is needed to receive federal Medicare and Medicaid incentives to purchase EHRs.

The long and short of all this is the final regulations issued represent improvements over the draft proposal issued earlier this year. We hope the federal government can quickly vet certification and/or testing entities, and that certified products can be in physician offices sometime in early Q4. We believe the MU and certification regulations will really jump start EHR adoption. Drop us a line and let us perform a custom analysis of the regulations to explain how they may impact your company.

Summary of Meaningful Use Objectives, 2011-2012
Mandatory (Core Set) Objectives for Clinicians and Hospitals. Must Use Certified EHR.
Record patient demographics (sex, race, ethnicity, date of birth, preferred language; hospitals also must record date and preliminary cause of death in the event of mortality)
Maintain an up-to-date problem list of current and active diagnoses
Maintain an active medications list
Maintain an active medication allergy list
Record smoking status for patients 13 and older
Use computerized physician order entry
For clinicians, generate and transmit “permissible” prescriptions electronically (does not apply to hospitals; only refers to ambulatory prescriptions for controlled substances that can be transmitted electronically according to requirements of the Drug Enforcement Agency’s (DEA) proposed rule dated January 13, 2010)
Report selected clinical quality measures to CMS and/or states
Implement one decision support rule
Provide patients with an electronic copy of their health information upon request
Provide clinical summaries/discharge instructions for patients with each office visit (clinicians only)
Have capability to exchange key clinical information among providers and patient-authorized entities
Protect privacy and security of electronic health information that is created and/or received

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Optional (Menu Set) Objectives. Clinicians and Hospitals Must Use Certified EHR and Select Five to Report On in 2011-2012
Implement drug formulary
Record advance directives for elderly patients (hospitals only)
Generate lists of patients by specific conditions to use for quality improvement, disparity reductions, research or outreach
Incorporate clinical lab results into EHR as structured data
Send reminders to patients (as per their preferences) for preventive/follow-up care (clinicians only)
Provide patients with timely electronic access to their health information (clinicians only)
Identify patient-specific educational resources and provide them as appropriate
Perform medication reconciliation
Submit electronic data to immunization registries
Electronically submit syndromic surveillance data to public health agencies, in keeping with federal and state requirements
Submit required lab results electronically to public health agencies, in keeping with federal and state requirements (hospitals only)

Source: Point-of-Care Partners, July 2010. Details on the criteria and measures to achieve meaningful use are in Table 2 of the regulations, which can be accessed at http://www.ofr.gov/OFRUpload/OFRData/2010-17207_PI.pdf

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What Does Meaningful Use Mean to Stakeholders?

By Kurt Andrews, PhD and Tony Schueth

The federal government's new meaningful use (MU) regulations will surely change the health care landscape. The expectation is that MU will become a means of transforming health care from a system based on fee-for-service to a quality-based system dependent on metrics, outcomes and pay-for-performance. As a result, MU also will significantly affect various stakeholder groups. Point-of-Care Partners (POCP) is creating detailed analyses, strategic plans and business objectives for our clients in response to the regulations' requirements. Below are some brief examples of how we think the new MU regulations will affect major stakeholder groups. We note that there are portions relevant to all stakeholders in each section; for example, personal health records have relevance to patients as well as to Pharma, health plans and physicians.

Pharma. We expect that meaningful use will affect pharmaceutical companies in several key ways. The first is MU use will affect brand sales. As mentioned earlier in this issue of *HIT Perspectives*, MU undoubtedly will increase ePrescribing, which will boost overall prescription volume, including brands. As a byproduct, brand representation in ePrescribing systems and electronic health records (EHRs) could become more significant for pharma. How drugs are listed in the ePrescribing process -− alphabetically by manufacturer, brand, generic name or price point – could advantage certain manufacturers and their brands and disadvantage others. Second, with MU and ePrescribing will come increased use of formulary in the ePrescribing process (eFormularies). Strategic positioning will be needed for pharma to benefit from the increased use of eFormularies and compliance with them. In addition, eFormularies and other measures are parts of medication management, a more holistic process that will receive greater-than-ever emphasis in the inpatient and outpatient settings. Third, MU is also about clinical quality management and clinical decision support, which are placing even greater emphasis on quality and the reliance on health information technology for data tracking and reporting, and providing the evidence to ensure optimal prescription therapy for the patient, condition and time, even if a generic alternative is available. Finally, MU places additional demands on prescribers and will likely cause changes in the way practitioners act with patients as well at the business level by driving practice consolidation. This could impact sales and marketing activities by pharmaceutical companies.

Health plans. Health plans have a number of key issues and challenges baked into the MU regulations. Quality reporting is one. Not only do health plans have inherent enlightened self-interest in improving quality and how it is reported, they will be able to build on the MU requirements for their own quality improvement, value-based purchasing and pay-for-performance programs. In fact, private payers typically follow Medicare's lead in payment and data-reporting requirements, so health plans must quickly align their own programs with the MU requirements. Use of eFormularies is another area of major interest to health plans, which are likely to benefit from eFormulary compliance. This means that plans must work with vendors to ensure that their formularies are available, accurate and up-to-date. Finally, plans and other payers will want to ensure that their provider networks are implementing and using EHRs that are certified for MU.

Pharmacies. Meaningful use is reinforcing change in the pharmacy. Increased ePrescribing will put new demands on pharmacy systems and workflows, including a pharmacy's ability to receive and process the flood of new ePrescriptions that will be on the way. Additionally, pharmacies are being increasingly pressured to provide origin code (already mandated in Medicare Part D) as well as fill status. It is quite possible that health plans will either put pressure on non-cooperating pharmacies or discontinue using them if they do not provide this information.

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Health Information Exchanges (HIEs). MU requirements involving HIEs are minimal in 2011-2012 − only one electronic exchange of information is required for a provider to qualify for this criterion. That said, HIE use will accelerate rapidly in 2013 when MU sets much higher thresholds for electronic data exchange. This places HIEs in the middle of helping clinicians and hospitals achieve their MU requirements for exchanging data. Examples include exchanging data among the usual set of stakeholders and with patients, as well as facilitating public and population health reporting requirements. Because of the regulations' aggressive timetable, HIEs will need to ramp up quickly to satisfy the needs of providers, pharmacies and health plans.

Patients. While we're at it, let's not forget about patients—the ultimate reason why manufacturers, health plans and HIEs are in business. Meaningful use is also about enabling patients, and the MU regulations include several requirements aimed at getting patients more involved with their health and healthcare decisions. We believe that mandating patient access to their electronic health records will increase the use of personal health records and mobile health technologies. This, in turn, will lay the foundation for a new electronic communication channel with patients that can be leveraged to encourage adherence to medication therapies and provide patient education .

Point-of Care Partners has the tools, experts, experience and track record to help you successfully navigate the dizzying transformational change in MU, health reform, technology adoption and incentive payments. Let us help you keep pace and make sense of it all in a way that works for you and your environment. Call us or drop us a line.

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eMedication Management

Meaningful Use and ePrescribing

ByTony Schueth, Editor-in-Chief

As expected, ePrescribing and many related functionalities retained places of prominence in the newly released federal regulations that define meaningful use (MU) and detail technical standards that must be used to qualify electronic health records (EHRs) for certification and users for incentive bonuses. Overviews of these rules are in the first article of this issue of *HIT Perspectives*. As mentioned there, the government listened to industry commenters and created regulations that are flexible.

According to the new rules, Medicare and Medicaid providers that have qualified EHRs can ePrescribe using some familiar standards. First, there are two choices for transaction standards: the National Council for Prescription Drug Programs (NCPDP) Prescriber/Pharmacist Interface SCRIPT standard, Implementation Guide Version 8, Release 1 (Version 8.1) October 2005 or NCPDP SCRIPT Standard, Implementation Guide, Version 10.6. In terms of vocabularies for medications, there also is flexibility.

The certification rule allows any source vocabulary that is included in RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine. In terms of minimal functionality, qualified systems must have capabilities that we believe are part and parcel of ePrescribing: the ability to maintain a medication list, perform drug-drug and drug-allergy checks and generate and transmit “permissible” ePrescriptions. Optional functionalities, for now, include the ability to conduct drug formulary checks and to transmit controlled substances. Prescription eligibility is no longer required.

Once they have a qualified EHR system that can perform the required functions, practitioners have to show they are using them, based on specific criteria in the regulations – and the bar is pretty low. For drug-drug and drug-allergy checks, all a physician has to do is attest to the government that the functionalities have been *enabled*. The same goes for formulary checking, although the provider must have access to at least one internal or external drug formulary for the entire EHR reporting period. In terms of ePrescribing, providers only have to send 40% of their prescriptions electronically.

We should note that there is confusion about whether ePrescribing of controlled substances is part of MU. It is our understanding that controlled substances will not be included in the 40% of prescriptions transmitted calculation. The rationale provided by the Centers for Medicare and Medicaid Services (CMS) is that the Drug Enforcement Agency (DEA) requirements permitting ePrescribing of controlled substances were not finalized when the MU rules were first published. We hope the federal government will issue a technical correction to the MU regulation so the requirements will be in sync with the most recent DEA rule (which, incidentally, is different in several major ways than its January 2010 counterpart).

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What does all this mean for adoption? Point-of-Care Partners (POCP) is advising clients that the new regulations should help stimulate adoption of EHRs in physician practices. That is due to the very minimal criteria for clinicians to demonstrate MU. This, in turn, should help get small and solo practices off the fence and into purchase mode, though we remain concerned that far too many will still delay purchase to see how things shake out.

The lowered quality-reporting bar should also help practitioners feel more comfortable with the MU requirements and closer to making a buy decision. Finally, the publication of the new rules should light a fire under vendors and get them to create products that can be certified right away.
To be sure, the current absence of named certifying bodies is a barrier to adoption, but that should be rectified in the near future, according to government sources. In the meantime, one school of thought is that this will push the market to the “blue chip” technology vendors, especially those offering financial guarantees that their products will be MU certified when official MU certification is available.

All in all, we believe the regulations will be another shot in the arm for ePrescribing and EHRs. However, a lot of details must still be sorted out. POCP is here to help.

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ePrescribing in the News

By David Green and Mihir Patel, PharmD

As mentioned in the last issue of *HIT Perspectives*, the news of ePrescribing's "death" has been greatly exaggerated. That sentiment may have come from some associating ePrescribing with a stand-alone product and not functionality. Our view of ePrescribing is that, as functionality, it is alive, well and growing, supported once again by new data.

Surescripts just released its state-by-state analysis of ePrescribing adoption and use for 2007-2009, which is available on its Web site (www.Surescripts.com). This is a very robust data set with state-by-state drill-down capability. Included are state statistics for prescription benefit requests, prescription volume routed electronically, estimated responses to medication history requests, percentage of physicians routing prescriptions electronically by year end and percentage of patients with available prescription benefit information.

The data also are a precursor to Surescripts' SafeRx Awards, which are announced in the fall. Based on last year's criteria, which focus on ePrescription volume as a percentage of total prescriptions eligible to be transmitted electronically, Massachusetts and Rhode Island would remain the top two states with 32% and 28%, respectively. Michigan would dip from third to fourth with 20% volume of ePrescriptions. Minnesota would jump to third with 21% of prescriptions that could be transmitted electronically, likely due to the state's ePrescribing mandates. The reminder of the top 10 generally would stay the same.

Last year, however, Surescripts announced that the criteria would be different this year, with weight being given to eligibility-informed formulary and medication history. We've done some analysis and have a sense of how this will shake out; however, we're not doing the calculations or giving the awards, so we'll refrain from making any predictions. What we will note is that there is likely to be a shake-up among awardees.

Meanwhile, "explosive" growth in ePrescribing in upstate New York is predicted in a new report from Excellus BlueCross and BlueShield. According to this report, electronic prescribing in upstate New York increased from 12% in 2009 to 17% in the first quarter of 2010, representing 3.6 million new and renewed prescriptions on an annual basis. This number is expected to grow significantly, spurred in part by the federal meaningful use adoption incentives discussed earlier in this issue of *HIT Perspectives.* The report finds that more than 2 million adverse drug events could be avoided in upstate New York if all physicians in the region switched to ePrescribing and that ePrescribing could increase the use of generics, thus reducing health care spend in that market.

According to Excellus, raising the generic fill rate by just 1% could reduce health care spending in upstate New York alone by more than $64 million annually. In addition, its analysis of the upstate New York data suggests that ePrescribing holds the potential to annually prevent 35 deaths, 160 permanent disabilities, 400 hospitalizations and 3,000 physician office visits.

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There's adoption and then there's use. A new national study from the Center for Studying Health System Change (HSC) has some mixed reviews of ePrescribing use. Researchers found that among physicians with ePrescribing capabilities, about a quarter used the technology only occasionally or not at all. Moreover, fewer than 60% of those physicians had access to three advanced features—identifying potential drug interactions, obtaining formulary information and transmitting prescriptions to pharmacies electronically—and less than a quarter of those routinely used all three features Researchers also found that physicians in practices using electronic medical records exclusively were much more likely to report routine use of ePrescribing than those physicians with stand-alone ePrescribing systems. Other gaps in adoption and routine use of ePrescribing also exist, most notably between physicians in larger and smaller practices. We believe this latter finding is not unexpected, given that larger practices tend to be the early adopters and have had more experience in using ePrescribing systems.

That said, this study generally mirrors our practical experience with ePrescribing. We have only two concerns. First, "ePrescribing" and "electronic health record" are not well defined, so we suspect that adoption may be on the high side and lack of use of certain features may be negatively skewed. We are also concerned about when it was done, which was before the Medicare Improvements in Patients and Providers Act of 2008 started having full impact.

To be sure, things are in transition and now adopters have to settle in and use the equipment. This can take some time. However, we now have data demonstrating that ePrescribing is alive and well, despite the turbulent environment of market consolidation and shake-out now occurring.