Health Reform and HIT

Meaningful Use: What's Next?

By Tony Schueth, Editor-in-Chief

The Federal government is mulling over the several thousand comments it received in response to its Notice of Proposed Rule Making (NPRM) on requirements for what constitutes "meaningful" of electronic medical records for ARRA purposes. Even though some things are obviously in a holding pattern, there are some things we DO know at this time and can make some educated guesses about.

We know there are two-dozen or so proposed requirements for meaningful use. We think they can be put into four big buckets: health information exchange; ePrescribing; personal health records (PHRs) and electronic medical records (EMRs); and some concerning clinical decision support (CDS). We believe the latter two could be huge market differentiation factors. Vendors that can build a better CDS mousetrap will have a major leg up in the market place. Those than can better integrate a PHR into their EMR also will create significant market traction.

According to the buzz at HIMSS, EMR sales may be slowing down. But we believe that won't be the case for vendors with a large, existing customer base, which can be used as a springboard for EMR aftermarket opportunities. Not all vendors have such a built-in aftermarket channel or can leverage it. Those that can will meet or exceed their revenue targets.

Overall, POCP expects market activity to continue its steady upward pace in the near future, despite the uncertainties up to this point surrounding health reform, meaningful use and certification. Now that legislation has passed and regulations have been issued, the dust will be settling sooner rather than later. POCP can make sense of it all with our custom market and landscape analyses.

HIT Strategy & Management Consultants

EHR Certification

Feds Issue New Rule to Select EHR Certification Bodies

In the middle of the flurry around meaningful use, one major question has been left hanging: Who will certify the electronic health records (EHRs) that providers will need to qualify for their ARRA incentive payments? A partial answer was provided with the March 10 publication of a proposed rule that establishes two certification programs—one temporary and one permanent--to certify and test complete EHRs, EHR modules or both. The rule was issued by the Office of the National Coordinator (ONC) and rounds out the government's initial suite of regulations to implement the "meaningful use" provisions of ARRA.

The first proposed program creates a temporary certification process under which the National Coordinator would authorize organizations to test and certify EHRs, EHR modules or both. Testing and certification are separate concepts. Testing is whether an EHR can meet specific, predefined measurable, quantitative requirements as put forth by the government. Certification is the assessment and assertion that, after analysis, the EHR has met all the applicable criteria <u>and</u> has agreed to abide by policies, rules, etc.

During the temporary phase, ONC serves as the accreditation body, which will approve applications, conduct oversight, and revoke approval for violations. EHR testing and certification will be combined and performed by one or more organizations known as ONC-Authorized Testing and Certification Bodies (ONC-ATCBs). In addition to other requirements, they must demonstrate proficiency to test impatient and ambulatory EHRs using test methods developed by the National Institute for Standards and Technology (NIST) (see related story below). Testing can be done at the ATCB and at developers' sites, users' sites, or remotely.

ONC believes that having the two functions combined this will speed up the process for the first stage. Selection is expected to begin in Q2 of 2010, and ONC-ATCBs will be in business through Q1 of 2012, when the permanent certification program is established and ONC has authorized at least one certification body. ONC expects that at least three organizations will be named, and the Certification Commission for Health Information Technology is expected to be one of them.

For the permanent, the rule proposes a separate process that splits accreditation and testing authorities and activities. A single accreditation body for certified products will be approved by ONC, aka an ONC-Approved Accreditor or ONC-AA. In addition accrediting certifying bodies and other requirements, it will conduct "surveillance activities." These include evaluating and reevaluating previously certified EHR technology to determine if it functions acceptably in the field and submitting an annual surveillance plan to ONC.

Organizations interested in serving as an ONC-ACB (Authorized Certification Body) would first have to be accredited by the ONC-AA and then could apply to ONC for designation as an ONC-ACB. NIST's National Voluntary Laboratory Accreditation Program (NVLAP) will accredit testing labs and determine their competency. ONC-ACBs would only be permitted to accept test results from NVLAP-accredited testing laboratories when evaluating EHR technology for certification.

ONC believes it will take between 8 and 16 months to implement the permanent certification program, and its goal is to have ONC-ACBs authorized under this program by or before the beginning of calendar year 2012 (later in the proposed rule, ONC notes the possibility that they could be authorized as soon as late 2011). ONC estimates that there will be no more than 6 applicants for ONC-ACB status.

It is possible that the permanent program could ultimately include the testing and certification of other types and aspects of HIT, such as personal health records and networks designed for the electronic exchange of health information.   ONC invites comment on the need for additional HIT certification, as well as on a range of issues.

The proposed rule—including selection processes, selection criteria and other potential requirements--may be viewed at http://edocket.access.gpo.gov/2010/pdf/2010-4991.pdf. Comments are due on April 9, 2010 (30 days) for the temporary program and May 10, 2010 (60 days) for the Permanent Program. While two certification programs are described in this proposed rule, ONC anticipates issuing separate final rules for each of the programs.

We are closely monitoring this key infrastructure process. Stay tuned or give us a call and let us give you a customized update.

EHR Standards

NIST Issues Guidance on EHR Standards Testing

The National Institute of Standards and Technology (NIST) published draft versions of testing methods aimed at ensuring that vendor EHR offerings will meet government-defined technical requirements and standards for sharing health information. POCP is monitoring this closely as the outcomes will affect EHR markets and related ePrescribing functionalities--how vendor offerings will change or adapt to comply, what vendors will drop out of the market in response, and how this will affect EHR adoption trends in various market segments.

Ultimately, the test methods will be used in a laboratory environment to certify that EHRs, EHR modules or both are compliant with government-issued criteria to meet ARRA's meaningful use requirements. In collaboration with ONC, NIST is developing the conformance test methods (test procedures, test data, and test tools) to ensure compliance with the meaningful use technical requirements and standards.

The newly issued guidance covers the first of four groups of testing methods: recording and modifying patient problem, medication and allergy lists, as well as conducting computerized provider order entry, and recording and updating vital signs and smoking status.

NIST seeks public feedback on the test methods, even as they are rolled out on an incremental basis. The test methods are based on ONC's Interim Final Rule (IFR) published in the Federal Register on January 13, 2010. Users will find draft test procedures under Draft Test Procedures. Finalized test procedures are found under Finalized Test Procedures. Feedback on test procedures can be sent to hit-tst-fdbk@nist.gov. Additional details are on the NIST website at http://xw2k.nist.gov/healthcare

eMedication Management

ePrescribing Posts Big Gains in 2009

By David S. Green, Senior Editor

Surescripts released its annual ePrescribing progress report, and—as expected—the numbers of prescribers and transactions showed major gains in 2009. Prescribers routing prescriptions electronically more than doubled to 156,000, so that roughly a quarter of eligible prescribers are now on board with ePrescribing. E-prescriptions jumped from 68 million in 2008 to 191 million in 2009. Last year there were 303 million electronic requests for benefit information, more than triple 2008's tally. Electronic medication history requests more than quadrupled, up from more than 16 million in 2008 to 81 million in 2009.

Also in 2009, approximately 85 percent of community pharmacies U.S. were connected to Surescripts for prescription routing and six of the largest mail order pharmacies were able to receive prescriptions electronically. By Surescripts' reckoning, about 23 percent of electronic medical record (EMR) systems were deployed for all three of its ePrescribing services at the end of 2009, compared with about 57 percent of stand-alone ePrescribing software.

We believe several key drivers have come into play. Probably the biggest are the Federal government's financial adoption and use incentives. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) provides positive incentives for practitioners who use ePrescribing in 2009 and through 2013. It gives qualified e-Prescribers a two percent bonus above certain threshold of Part B charges in 2009 and 2010, and one percent in 2011 and 2012. In addition, the American Recovery and Reinvestment Act (ARRA) give incentives to physicians and hospitals to invest in and become "meaningful users" of EHR technology, which must have ePrescribing capability. The most lucrative incentives are available to early adopters and current users of EHR systems. That is because the incentives are greatest for 2011 and 2012 and they allow physicians to max out to $44,000 in Medicare bonus payments. And let's not forget about the significantly higher incentives that could be in store for Medicaid practitioners. An estimated 15% (about 45,000) of office-based physicians and 99% of health center physicians could qualify for as much as $63,750 under ARRA's Medicaid incentives.

We understand that physicians can participate in both MIPPA ePrescribing and the ARRA incentive programs. Regardless of whether you do the math for each program individually or for them together, it adds up to tens of thousands of reasons to adopt-- and adopt sooner rather than later.

Another driver for the significant increase in transactions is the early adoption of ePrescribing systems by large clinics and health systems. They are best positioned to immediately benefit from incentives available from the federal government, states and some private payers. Solo-, small- and medium-sized physician practices are still lagging behind the adoption curve. And of course, now that controlled substances can be e-Prescribed, we expect a surge in market activity. Let us help you analyze your ePrescribing business opportunities and put together customized projections for your products and your markets.