The “Big One” Hits: New Regulations Will Radically Change the HIT Landscape

By Tony Schueth, Editor-in-Chief

If you live in a state that’s prone to hurricanes, like I do, you take note when you hear a “big one” is on the way. If the definition of meaningful use and EHR certification were hurricanes, they’d be Category 5 as big as they get on the Saffer-Simpson Scale. We’re now left to assess the impact.

Taken together, the two new regulations form the foundation of how eligible prescribers and hospitals will be able to receive up to $27.3 billion in incentive payments stemming from the American Reinvestment and Recovery Act of 2009 (ARRA), some of which can begin in 2011. The good news is that this isn’t an unfunded mandate, like the Health Insurance Portability and Accountability Act (HIPAA). However, like HIPAA, it changes health care -- profoundly.

To achieve these incentives, eligible prescribers and hospitals must demonstrate “meaningful use” of certified EHRs as specified by 20+ criteria that are tied to five national health priorities. These in turn have numerous associated goals and objectives. The requirements will ramp up in three stages for 2011, 2013 and 2015, although the new rules only deal with what’s required for stage 1 in 2011. The two rules will work hand-in-glove to launch an iterative process for advancing adoption of EHRs.

The certification criteria were issued as an Interim Final Rule with Comment (IFC) that becomes effective on or around February 12, 2010. Although this basically makes the criteria effective immediately, because of vendor development cycles and the time required to implement or upgrade, the government may change the base rule in response to any comments it receives during the comment period. A Notice of Proposed Rule Making (NPRM) on the process and entities for certifying EHR technologies is expected in the near future.

The meaningful use criteria were promulgated in an NPRM, which is basically a draft rule that often contains trial policy and implementation balloons. We understand a flood of comments are expected by the March 15, 2010 deadline, and the government will use these comments to adjust specific requirements in the final rule. We suspect there will be numerous changes, which should be issued in late spring. These rules are just the first of a series that will evolve to become more expansive and specific as the health care industry evolves to stages 2 and 3 of EHR meaningful use.

The result will be massive and spur ongoing changes in the industry and among various stakeholders in relatively short timeframes —or at least much more compressed timetables than for traditional implementations. Some stakeholders will be affected more than others.

While POCP can develop detailed overview and impact analyses, here are selected highlights that different organizations should consider.

**Vendors:** Many EHR vendors will be challenged to bring products to market in time to enable users to qualify for 2011 incentives. They will need “all hands on deck” to upgrade software and implementation programs to help customers meet meaningful use requirements because eligible prescribers and hospitals must have their systems up and running by October 2011. Individual certification of EHR modules should foster the development of clinical decision support (CDS) “plug-ins” based on an open, standards-based architecture. In addition, most EHR implementations today do not allow patients to electronically access health information stored in a provider’s system. This imposes a significant demand on vendors to offer patient access to applications that are secure and flexible enough for providers to control who has access to what data. Hence, EHR developers are likely to be motivated more than ever to develop the infrastructure needed to engage patients in their care management. The stage is set for EHR system innovations that promote the detection of medication adherence problems and patient self-management of medication therapies.
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Payers: It has already been openly stated that meaningful use of EHRs will be the vehicle to transform health care delivery in this country. For most payers, near-term impacts will be around increases in electronic prescriptions and provision of electronic formularies. Payers may also notice increased participation in P4P and other quality programs due to the loosely aligned nature of their internal programs with meaningful use. Once payers have assessed the short-term situation, it will be time to assess longer term implications of meaningful use. Payers may want to consider augmenting current federal incentives to encourage increased use of desired systems and functionality. -Stage 2 criteria are scheduled for development by fall 2011. Because there will be an increased emphasis on quality, payers will need to think more about the transformation of health care as meaningful use dangles the vision of a patient-centered medical home model replacing the traditional fee-for-service model. Those payers wishing to have an influence must plan their input on such things as quality metrics soon.

Standards organizations: More work will need to be done by the standards development organizations HL7 and ASTM, among others, both in the short term and as requirements ramp up through 2015. For example, the HL7 clinical document architecture and ASTM continuity of care record standards are incorporated, as we expected, for patient summary records, with the intent to evolve a more precise standard in the future. Implementation specifications to foster the use of standards are brief in this IFC, suggesting that most are not yet ready for broad adoption. In addition, no references to implementation guides exist within the IFC, highlighting a major chasm between availability of certified EHR technologies and best practices for deployment that will need to eventually be filled.

Physicians: Adoption of an EHR is very disruptive to the office practice, often taking a year or more to fully implement while reducing the capacity of the office. In many offices not currently using an EHR, this will be one of several factors that will likely lead to later adoption. The tight adoption deadlines and dribbling out of incentive payments over time make it very possible that meaningful use will further increase the divide between the “haves” and “have nots,” meaning it will be much easier for those with systems up and running to achieve meaningful use sooner rather than later. Furthermore, those that have been on the fence may not be able to adopt fast enough to realize the maximum incentive payments. And, because there are separate incentives for hospitals, physicians who are deemed “hospital based” are not eligible to receive meaningful use incentives. This may have the unintended consequence of excluding physicians practicing in outpatient centers and clinics merely because their office or clinic is located in a facility owned by a hospital.

Pharmaceutical manufacturers: The new world of meaningful use presents both threats and opportunities for pharma, a group that has been minimally engaged up until this point. Since up to 75% of all prescribers will be writing prescriptions electronically by the time the incentives end in 2015 and ePrescribing has been shown to increase formulary compliance, market share increases for generics and brands with solid formulary positions will likely occur. Interestingly, overall brand volume may increase as electronic prescribing has been associated with an increase in volume. Encouraging the utilization of more longitudinal medication histories (e.g., claims based), could present opportunities to encourage adherence to medication therapies, benefitting not just pharma but patients, payers, providers and society as a whole. In addition, EHRs are viewed as the vehicle to transform health care and the emphasis on quality will change current practices and make outcomes even more important. There will also be opportunities and challenges associated with possible alliances with payers, health systems and vendors. Finally, funding is available within ARRA for comparative effectiveness studies.

Let us know how we can help you understand the impact the new federal regulations will have on your business, your environment and your industry. We are here to help.
A State of the Function: What does ARRA mean for ePrescribing?

While some people think of ePrescribing as an industry unto itself, we have always considered it a function of health information technology (HIT). In the marketplace, we see ePrescribing in free-standing systems or as part of a clinical system, such as an electronic health record (EHR).

Though it’s been around for decades, ePrescribing got a boost in 2003 with the passage of the landmark legislation that created Medicare Part D. It didn’t mandate ePrescribing, but required providers prescribing electronically to adhere to certain standards.

Some physicians took the leap into EHRs while others opted for the free-standing systems, with lower costs and less impact on workflow and implementation. Then, with the passage of the Medicare Improvement in Patients and Providers Act of 2008 (MIPPA), adoption of the free-standing systems increased and EHRs started upgrading their ePrescribing functionality.

While there’s no “hockey stick,” adoption is growing at a steady pace. According to Surescripts, roughly a quarter of physicians are prescribing electronically and last year nearly 15% of prescriptions that could be transmitted electronically flowed in that manner. By the end of 2012, we expect more than half of eligible prescriptions to be electronic.

The latest driver is the American Recovery and Reinvestment Act of 2009 (ARRA). As cited in the article above, this landmark legislation was passed with detailed statutory and implementation requirements. It provides an economic shot in the arm to hospitals, clinics and practitioners aimed at spurring adoption of EHRs. But what exactly does this mean for ePrescribing?

Well, ePrescribing is a key functionality that providers must have — and use ☑ to qualify for the ARRA bonus incentives in the early years and to keep from having their reimbursements reduced in later years. Of the approximately 26 criteria, eight include some component of ePrescribing.

Prescribers must use a certified EHR. This could be a full EHR or part of a combination of “EHR modules.” Free-standing systems must therefore evolve to become a full EHR or combine with other modules, such as disease registries or lab order systems. Two companies – Zix and iScribe – have decided all of this is too much.

We think they won’t be alone. Others will evolve to be full EHRs. For a while now, some have supplied the embedded ePrescribing function within a full EHR. Those EHRs will have to evolve to meet “meaningful use” requirements. Some will choose not to. There will be mergers. There will be acquisitions. In a word, there will be change.

For some time now, we have been looking not at ePrescribing but “eMedication management,” borrowing from a model that Rand’s Doug Bell, MD, PhD, introduced in a landmark study in 2003. He looked at the continuum of prescribing -> transmitting -> dispensing -> administering -> monitoring. This model will be relevant long after we have 100% of prescriptions flowing electronically. We already know there are associated challenges and opportunities.

Flowing from Dr. Bell’s model, we’ve been doing a great deal of thinking and work around interactions and contraindications; treatment guidelines and messaging; therapy management; adherence, compliance and persistence; medication reconciliation; and safety surveillance. We guess we’re just comfortable being pioneers.

When we present to clients or at a conference, we show our value model. On one axis is complexity and investment and on the other is measureable value. We have two buckets: one is cost and efficiency and the other quality and safety. Free-standing systems can get us well up the axis in the cost and efficiency bucket and, while they have definite flaws in quality and safety benefits, we see substantial jumps in the integration between ePrescribing and other EHR functionality (i.e. drug-to-lab or -diagnosis alerts, evidence-based guidelines). These lead to future cost savings in the form of reduced hospitalization, fewer adverse drug events and higher quality of life.

There’s still a lot to do in eMedication Management. Let us know if you’d like to learn more about our models or chat about where things are going.
POCP News

Mihir Patel joins Point-of-Care Partners

Mihir Patel, PharmD, an experienced pharmacy professional with more than 10 years’ experience in both the managed care and retail settings, recently joined Point-of-Care Partners. He will be working with our pharmacy, pharmaceutical manufacturer and pharmacy benefit management clients, as well as on initiatives.

“I met Mihir in 2006 during the Rand, MMA pilot, the New Jersey ePrescribing Action Coalition (NJEPAC), and he always impressed me as the kind of person we would want as part of the POCP team,” said Tony Schueth, CEO and managing partner. “He’s intelligent, experienced, thorough and very good with clients. I’m delighted to have another clinician, practicing pharmacist and talented executive on our team!”

Dr. Patel joined POCP in September 2009. Recent engagements include assessing state and federal long-term care regulations and their impact on ePrescribing, co-managing the creation of ePrescribing and HIT training modules for a large global pharmaceutical company, co-authoring a government health care agency-sponsored tool set that will assist retail pharmacies in incorporating ePrescribing into their practice, and conducting market research on ePrescribing with managed care executives for a large health care concern.

Prior to joining Point-of-Care Partners, Mihir was a clinical program manager at MedImpact Healthcare Systems, where he provided clinical consultations with clients to help lower net costs while maintaining high clinical quality. Strategic recommendations included benefit design and formulary performance suggestions, facilitation of clinical drug information, pharmacy and therapeutics (P&T) committee participation, recommendations for rational drug formulary positioning, online system edits and restrictions, ongoing clinical product evaluations, and recommendations regarding client pharmacy benefit expenditures and utilization. He also prepared, implemented, and maintained drug use evaluation/review and quality initiative programs to meet plan, Health Employer Data and Information Set and National Committee for Quality Assurance guidelines.

Prior to joining MedImpact, Dr. Patel spent five years with Horizon Blue Cross Blue Shield of New Jersey, holding various clinical and business development positions. He was responsible for managing its electronic health record (EHR) program, assessing health information technology tools, and participating in state-level discussions regarding privacy and security for a statewide health information exchange. In addition, he coordinated pharmaceutical industry partnerships to support pharmacy and disease management initiatives, managed Horizon’s medical cost ratio by implementing programs to increase the generic dispensing rate, and supported sales and account management teams by providing client-specific analysis and recommendations regarding plan design changes. Dr. Patel also oversaw member and physician-based communications, the corporate pharmacy Web site, request for proposal/information responses, as well as collaborations with industry and academic researchers to assess the impact of EHRs, generic sampling, adherence and compliance programs.

Dr. Patel is a registered and practicing pharmacist, having graduated with a bachelor of science degree in pharmacy and doctor of pharmacy from Ernest Mario School of Pharmacy at Rutgers.