



Implementing the DEA Rule May Be More Challenging Than Anticipated

By Tony Schueth, Editor-in-Chief

On June 1, ePrescribing of controlled substances was permitted by a regulation recently promulgated by the Drug Enforcement Administration (DEA). Now that this is legal, provided a number of restrictions are met, both the government and health care industry have high hopes that this will spur ePrescribing adoption and ultimately improve patient safety and reduce costs of care.

But, as always, the devil is in the details. Based on our consulting work across the country and in particular as project manager for the Southeastern Michigan ePrescribing Initiative (SEMI), we are hearing that implementation may not be as quick and easy as anticipated by the DEA. Concerns fall into several buckets:

- **Confusion in the marketplace.** ePrescribing of controlled substances is so new that many providers have no idea what this means, how it works or how it fits in the recent federal incentives available through funding from the American Recovery and Reinvestment Act of 2009 (ARRA). Recognizing that outreach is needed, the DEA recently sent a letter to providers announcing legality of ePrescribing of controlled substances and providing a high-level overview of what is entailed. Unfortunately, many providers didn't read the letter carefully. We hear they've been firing off ePrescriptions for controlled substances that didn't meet the DEA's very specific requirements. In turn, pharmacies have received the ePrescriptions but not filled them because they are not technically legal. Furthermore, pharmacies have then had to go back to the prescribers and explain what has happened and why, which has left a bad taste in everyone's mouth. The unintended consequences are dissatisfaction, confusion and more paperwork. We've heard from numerous practitioners who intend to keep using paper prescriptions or printing out prescriptions from their electronic systems, wet signing them and handing them to patients to deliver to the pharmacy. With scenarios like these being repeated across the country, the implementation of ePrescribing of controlled substances feels like one step forward and two steps backward.
- **Technological challenges.** In the May issue of *HIT Perspectives*, we explained how the ePrescribing community was not ready to immediately create products that can meet the rigorous DEA requirements. We believe that is still the case and is likely to be for some time, which is causing providers to delay purchasing decisions. And while we are still waiting to see if the DEA will make any changes in response to the latest round of comments it received, we note that there are still problems with some technical features that are likely to survive. Biometrics, for example, is one category of authentication technology that can be used. However, they are not always 100% fail safe and system lockouts can occur. The SCRIPT standard still needs to be tweaked to meet the DEA requirements. Although the industry is working to address these issues, they contribute to market confusion and create barriers to adoption.
- **Certification of systems.** There is not yet a certification body for ePrescribing systems that meets the DEA requirements. This may change now that the federal government has issued regulatory guidance for selection of entities to certify that electronic health records (EHRs) meet the ARRA meaningful use criteria. Presumably, the EHR offerings approved will have ePrescribing functionality that also meets the DEA requirements. According to a recent phone discussion with federal officials, certification bodies are likely to be approved this summer by the Office of the National Coordinator and should be up and running this fall. For more information about the government's certification process and regulations, go to <http://healthit.hhs.gov/certification>.

The Certification Commission for Health Information Technology (CCHIT) is likely to continue in this role. We wonder if Surescripts is considering expanding its rigorous internal vetting processes to certify for meaningful use and the DEA requirements, though it is noteworthy that the DEA stated publicly – in its regulations – that it did not perceive Surescripts as an unbiased third party. Whether it's Surescripts, eRx Network/Emdeon or Relay Health, we're not sure we understand this concern; after all, pharmacists are looking at these intermediaries today to provide them with legal prescriptions from a licensed prescriber. In our view, it would be more efficient to have certification entities that are already providing this service also certify for controlled substances.





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Regardless of who steps up and when, the lack of certification bodies remains a large void that results in confusion for providers. We continuously hear that providers want to know which systems have the "Good Housekeeping seal." They cannot make meaningful system comparisons for purchase decisions until that happens on a large scale, which of course depends on which certification bodies get approved and when. It is a circular problem that is not likely to be resolved for some time.

- **Authentication of providers.** In order to meet the DEA requirements, providers must get identity proofed by registering with approved third-party authentication entities, such as credential service providers (CSPs), that have been approved by a federal authority. As we noted previously in *HIT Perspectives*, there has not been a rush for such entities to be created or get approved. Further, there is no apparent process for doing so, which is a disincentive for those that may consider becoming an authentication body. We also hear that the lack of identity-proofing entities is a real sticking point among physicians. Not only do they take umbrage at the implications behind their use, but providers could not ePrescribe controlled substances if they wanted to because identity-proofing entities are virtually nonexistent. This again serves as a disincentive for adoption.
- **Additional pharmacy requirements.** To dispense controlled substances, pharmacists have to receive, store and possibly digitally sign for the drug before storing it, the latter depending on their relationship with network. If a pharmacy decides it wants to accept digitally signed prescriptions from prescribers, it needs a way to authenticate digital signatures. This requires major coordination. The DEA opened the door to these two scenarios and pharmacies will need to decide in which they want to participate, and this will impact what their system has to be able to do. This will potentially affect pharmacy relationships with vendors. Also, there is the issue of assigning access to their systems that is similar to what the prescribers have to do.

To be sure, we are entering a new world and all implementations are fraught with bumps and bruises. We hope that the issues described above will be resolved sooner than later and that the comfort level for ePrescribers of controlled substances will increase exponentially in the near future.





Personal Health Records

Will Vendors Take a Short- or Long-Term View of Personal Health Management?

By Tony Schueth and Ed Daniels

Once the next “big thing” in health information technology (HIT), personal health record (PHR) adoption has been slow and spotty, so our clients want to know: Is the PHR dead? We think not. With respect to Mark Twain, the rumors of the death of the PHR have been greatly exaggerated.

Like so much in health care these days, we need to look at the American Recovery and Reinvestment Act of 2009 (ARRA), specifically the meaningful use (MU) requirements where there is an underlying emphasis on promoting patient-centric care and having patients become active participants in their health care. PHRs are not strictly required in MU stage 1 because EMR vendor can get away with simply providing patients with Web access to a “safe” subset of clinical data. But MU stage 2 is likely to be another matter. The HIT Policy Committee — the government’s multidisciplinary advisory group — is advocating that “self-management tools” be incorporated in MU stage 2 or possibly stage 3. We believe their recommendations will survive the next round of government rulemaking.

So, for the EMR company, it comes down to short-term (checking off the list) or longer-term (developing a PHR infrastructure upon which to build). Which choice will they make? As with any question our clients ask, it depends on a number of factors, such as what else is in the pipeline, expected level of effort, resources, costs structure and pricing. We know this, though: inevitably a personal health management platform will be needed to achieve the MU self-management criteria proposed by the HIT Policy Committee.

Why is the HIT Policy Committee emphasizing self management? Self-management makes the most sense for the chronically ill, the segment of our population that costs the most. The construct is all about enhancing patients’ knowledge of their health, providing skills to manage it and building self-confidence in that ability. A large body of literature exists on this topic, suggesting the need for a longitudinal view of patients’ progress and not limiting access to certain clinical measures that might be found in an electronic medical record (EMR). For example, to achieve the self-management goals, patients will need to track their diets, adhere to their exercise regimens and monitor their vital signs from their homes. It is clear that PHRs will be needed to support these functions.

To be sure, PHRs have faced a number of challenges. There have been technical issues with getting accurate patient information and keeping it updated. Interoperability has been challenging because of less than comprehensive messaging standards and data formats. There have been questions about the business model. And there remain questions about privacy and security.

That hasn’t stopped Microsoft and Google. In entering the PHR world, both seemed convinced that health care consumers wanted to take control of their own information. Both have placed bets that an independent platform would be preferred over one supplied by employers or insurers, where users might experience discrimination based on their supposedly confidential health information. While we’re not there yet -- Forrester Research survey in late 2009 of more than 5,200 consumers found that while almost a third of respondents had some form of PHR, the vast majority was using the PHR supplied by their health insurer – it’s worth acknowledging the strategic bets of two “800 lb gorillas.”

Whether it’s a boost to the independent platform or an extension of the insurer’s, we believe an assist to adoption will come from pairing mobile health (mHealth) apps with PHRs. This new technology will use a proven mass-market distribution model, the “app store,” to allow users to download PHR apps that are specifically designed to meet the needs of each different group of users. According to a Microsoft executive interviewed in *HealthData Management*, Microsoft is already seeing the opportunities with this business model. To date, there are 135 health care applications written for its HealthVault, running the gamut from a consumer app that helps triathletes monitor their training and diet to software for managing chronic diseases. While the latter can be a boon to helping chronically ill patients manage their care, uptake may be stakeholder dependent. For example, the elderly are unlikely to be early and widespread adopters of mHealth/PHR apps.





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The trick will be how to connect these sexy iPhone, iPad and Android user interfaces to secure legacy sources of data, protecting privacy but exuding excitement. This will require developers to converge data in real time using workable standards and interoperable platforms. Looking at the PHR track record, it seems unlikely for fully functional and secure apps to be available anytime soon. But, within 5 years, we believe people will have their own health record across providers and fitness/rehab facilities, accessible via the Internet and mobile devices with intelligent evidence and non-evidence-based agents that will help us identify diagnostic and therapeutic options. On the mobile side, in June, Apple's app store passed the 5 billion download mark. Where there is a market, there is a way to service it!

POCP believes that ARRA and mHealth are among the many revolutionary aspects of health care. We know that 2011 will see even bigger and more dramatic advances. We are closely tracking the opportunities and threats associated with this fast-paced and volatile environment. In fact, a key member of our team, Michael Solomon, is the leader of the Health Information and Management Systems Society (HIMSS) PHR Workgroup. Let us help you determine how today's health care revolution will impact your company.





Electronic Health Records

The Allscripts/Eclipsys Merger: Harbinger of Things to Come

By Tony Schueth

The health information technology (HIT) industry was rocked by the announcement of the \$1.3 billion acquisition of Eclipsys Corporation by rival Allscripts-Misys Healthcare Solutions. The result: a combined client base to include 180,000 physicians, 1,500 hospitals and 10,000 post-acute organizations. In short, a new giant is born.

We at Point-of-Care Partners (POCP) were not surprised for a number of reasons. First, well, we hear things, some of which we are either not at liberty to repeat or choose not to because sometimes things don't work out. Furthermore, we have been waiting for a major merger and expecting that it to be a harbinger of things to come. That is because the normal shakeout that occurs at this point in any industry has not yet occurred in the HIT world.

We believe this shakeout is beginning to occur and could accelerate with a vengeance. Why? There are hundreds of electronic medical record (EMR) and ePrescribing companies in the market today. Not all have the functionality that will be needed to meet the stringent requirements being set forth under the provisions of the American Recovery and Reinvestment Act of 2009 (ARRA), evolving federal privacy and security rules or payers' quality and/or reimbursement requirements. Not all can — or will want to — survive in this new world. They will disappear sooner rather than later. Some will be targeted in make or buy decisions by larger, stronger players. Others will flounder and become easy pickings for opportunistic and visionary competitors.

Niche markets will be created. Executives of companies in and around this market need to have a strategic vision, but also need to make sure that they are positioned to respond tactically to opportunities and threats. Mergers and acquisitions will occur with little warning and major market consolidation will be the ultimate result.

Having said that, we're going to hedge our prediction by making some observations. (Hey, this is basically an opinion piece with no subscription fee, so we can do what we want.) Should the Committee for Medicare and Medicaid Services (CMS) back down on full meaningful use, it's possible that some of the drivers could be diluted. Furthermore, some of the surviving EMRs could let the weaker ones just go out of business instead of effectively acquiring the client. After all, there is still a sale around getting the practice or client to upgrade.

What will this merger mean for various stakeholders? Let's look at three.

- **Health plans.** Market consolidation will result in a smaller number of more dominant entities having greater capacity to help plans achieve their clinical quality goals. This means plans will need more targeted approaches to collaborating with technology vendors. However, technology vendors may be less willing to partner since development of new plan-oriented functionality will compete with their other priorities, such as platform migrations. In addition, mergers such as that between Allscripts/Eclipsys, will allow plans to work with one vendor that has access to physicians across the care continuum from inpatient admissions to outpatient and ambulatory care. Merged companies will argue that working with a single vendor will allow a plan to send a clear, consistent message across multiple care delivery channels, but buyers beware.
- **Pharma.** Consolidation of the market means there will be fewer but far more dominant entities that can influence physicians. This can be a double-edged sword for Pharma. On one hand, it can present larger opportunities for promoting and representing branded products, after the dust settles on system integration and platform consolidation. On the other hand, Pharma will need to carefully consider how to work with these larger and more significant companies, which will want to lead rather than follow.





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- **Physicians.** Consolidation of the market may help physicians choose a vendor as the confusion over the numerous vendor choices decreases. In addition, the larger, more dominant entities may help physicians more quickly meet meaningful use requirements. As technology vendors consolidate and their product lines merge, physicians may have access to technology that has a similar look and feel from the inpatient hospital setting to outpatient office setting, which may help increase utilization of the technology. In addition, vendors may well be willing to create channels so that data can be shared across their platforms and technologies, which may result in a mini-HIE (health information exchange) and may help them achieve meaningful use. Physicians may also benefit by being able to share data with other users of the same technology without setting up connectivity through an HIE.

If you need help sorting through the implications of the impending wave of mergers and consolidations in the HIT industry, contact us.

