DrFirst

The Evolving Landscape for Electronic Prescribing of Controlled Substances (EPCS) – An Industry Briefing

Table of Contents

Understanding the Benefits, Opportunities and Challenges of EPCS

There is an epidemic of addiction, abuse and diversion of controlled substances in this country and worldwide. Since 90% of all physicians write prescriptions for controlled substances, this industry briefing is designed to provide meaningful data and up-to-date resources to assist physicians and members of the healthcare industry understand the benefits of electronic prescribing of controlled substances (EPCS), while also addressing some common misconceptions which have unnecessarily hindered adoption. In addition, we will discuss compliance of controls and processes, and the standards enforced for EPCS in order to achieve full compliance with the relevant EPCS components.

EPCS delivers many of the same patient safety measures that traditional e-prescribing offers. As a fully electronic platform, it helps reduce the errors inherent in the paper-based process, such as illegible handwriting, misinterpreted abbreviations and unclear dosages. Similarly, EPCS technology can be configured with a medication reconciliation module, allowing providers to capture and view more complete prescription histories at the point of care, which can further reduce the likelihood of an adverse drug event. And when real-time patient clinical decision support information is combined with transparent drug pricing models, clinicians can select both the most therapeutically appropriate medications for the patient and the most cost-effective.[2]

This paper draws upon interviews and data from highly respected physicians who have extensive experience in e-prescribing and EPCS as well as industry experts in security processes.

Background and Introduction

EPCS was made legal at the national level in 2010 by the Drug Enforcement Agency (DEA) following years of deliberations on exactly what new requirements would be added to eRx to assure that this class of drugs would not be abused or diverted for illegal use. DEA regulations were modified to allow the use of EPCS, inclusive of Schedule II to Schedule V and provide the federal regulatory framework by which this process will be governed. The rule gives prescribers the option for, but does not mandate, the use of e-prescribing for controlled substances.

When the DEA published its Interim Final Rule (IFR) on EPCS, it created a number of questions and concerns for state regulatory bodies. Many of the concerns centered on whether software providers were meeting, or could meet, the technical and administrative requirements outlined by the DEA.

Since that time, e-prescribing, EHR, and pharmacy practice management application software vendors have devoted significant resources to two of the main technical requirements. First, completing the EPCS certification process, as required by the DEA in 21 CFR 1311.300 Application Provider Requirements—Third-party Audits or Certifications; and secondly, attest to its compliance with all EPCS aspects of 21 CFR - 1300, 1304, 1306 and 1311, and having a written copy of the vendor's third-party audit or certification.

The remaining technical requirement revolves around electronic authentication, or what is referred to as "identity proofing." The National Institute of Standards and Technology (NIST), in special publication 800-63-1, defines electronic authentication as "the process of establishing confidence in user identities electronically presented to an information system."[3]

The identity proofing process, essentially a form of credentialing, is required for physicians in order to provide yet another layer of security and authentication.

As of this writing, 40 states have made EPCS legal, although some states still do not allow for e-prescribing of Schedule II drugs, since each state has the authority to modify prescription practices within its jurisdiction over and above the DEA regulations. However, e-prescribing networks such as Surescripts do operate in all 50 states and have created a highly secure network infrastructure. Vendors such as DrFirst have developed compliant systems that meet all of the DEA's requirements as well as the Surescripts strict certification processes. DrFirst was the first company to electronically transmit prescriptions for controlled substances under a DEA waiver. Now major pharmacy chains such as Rite-Aid, Walgreens and CVS have the ability to accept electronic prescriptions for controlled substances in any state where it is legal. Other pharmacy chains are almost certain to follow. Presently there are more than 13,000 pharmacies accepting EPCS, and that number is increasing rapidly.

In short, essentially all of the elements are in place to allow physicians to start e-prescribing of controlled substances. The remaining regulatory barriers to adoption are being actively addressed and resolved on a state by state basis.

Interview: Peter N. Kaufman, MD

In an effort to further inform the discussion, we asked Peter N. Kaufman, MD, a practicing physician and a highly regarded expert on EPCS, to provide an overview of the benefits for physicians, the identity proofing process and what the future looks like for EPCS.

Dr. Kaufman has lectured nationally on computers in medicine, electronic medical records, the Internet and medical practice, and high-tech medicine. He is a board-certified gastroenterologist and continues to practice medicine approximately 15 hours per week for a gastroenterology practice in Bethesda, Maryland. Dr. Kaufman participates in multiple national organizations promoting standards in healthcare, including the Physicians EHR Coalition (Secretary/Executive Board), CCHIT (Stand-alone eRx Workgroup), HIMSS (eRx Workgroup), NCPDP (Workgroup 11), and the AMA (Delegate from the American Gastroenterological Association).

He also serves as the Chief Medical Officer at DrFirst, with the primary goal of prioritizing provider needs first and secondly modernizing the continuum-of-care across the nation through connected healthcare communities.

What are the benefits of EPCS for a physician?

The reason a doctor would want to use EPCS is that most doctors, about 90%, write prescriptions for controlled substances. The estimate is that approximately 11% of all prescriptions are for controlled substances. Many doctors are moving to e-prescribing, and it is certainly easier to have one system—and one workflow—for prescribing than to have multiple systems. In addition, when you prescribe electronically it automatically creates an electronic record. In some states you must maintain duplicate or triplicate paper records. In many doctor's offices those paper records may or may not make it into the patient's chart, or the record is also not always easily found. It is often quite difficult to perform a search on those paper records.

The third benefit for doctors with regard to controlled substances is the ability to link into their state's prescription monitoring database. This allows the prescriber to know if the patient has received a prescription for a controlled substance from other doctors and when those

prescriptions were written. Now this link to the state databases is not currently in wide use yet, however I expect that to become much more wide spread in the near future.

Another benefit of e-prescribing for controlled substances is the same for e-prescribing in general. Specifically, the prescriptions are legible, they are checked for clinical alerts such as drug-to-drug and drug-to-allergy interactions, pregnancy, breast feeding, dosing, duplicate therapy and issues of that nature. Again with e-prescribing, the doctor has access to the patients' formulary information and there's a convenience factor for the patient. The patient only has to go to the pharmacy once and therefore is more likely to be adherent.

The last benefit is that we believe electronic prescribing of controlled substances will significantly reduce fraud and abuse. For example, it's a lot easier to steal a prescription pad and fake a signature than it is to get into this extremely secure system.

How does the "identity proofing" process work?

The identity proofing process is accomplished over the Internet, and it is based on verifying identities using a combination of identity element verification (such as name, address, Social Security number, and date of birth), knowledge-based authentication (interactive questions designed to ensure an individual is who they claim to be), and verification of account information (generally a financial instrument such as a credit card number). The majority of doctors—approximately 85%—are able to complete the process entirely online.

With that said, there are a number of initiatives underway to utilize equitable measures in identity risk assessment, such that within a year at most, we should see completion rates of identity proofing up at around 98% or 99%. Another aspect of the security is the issuance of a hard token which is a small fob that can be carried on your keychain. For doctors who don't want one more thing to carry around, there are also "soft" tokens which can be generated by a smart phone app.

What are your thoughts on the future of e-prescribing of controlled substances?

In the fairly near future, I expect that we will see EPCS being legally authorized in the few remaining states that still do not allow EPCS. There will be many more pharmacies able to

accept e-prescriptions for controlled substances. Today, Rite-Aid and Walgreens have activated EPCS in all states where it is legal. CVS, the nation's largest pharmacy chain, is rolling out EPCS on a state by state basis, currently amounting to approximately four states, but obviously many more to come. I also expect improved identity proofing that is faster and more efficient. For example, DrFirst is setting up an alternate process to assist doctors who have some difficulty getting through the online identity proofing process.

I also expect to see individual state prescription drug monitoring programs working in conjunction with controlled substance e-prescribing systems. This will make it much easier to control, monitor and reduce drug diversion and abuse into a much smaller pool. Substance abuse of controlled substances is a major problem in this country and an issue that the DEA is very concerned about. For example, in the state of New York, real-time prescription monitoring has been mandated by the I-STOP legislation and will be required of all New York physicians by the end of 2014. Many states are likely to follow suit and require real-time monitoring as a first line of defense against prescription drug diversion.

So the technology solution is available today and the barriers to adoption are falling away. For example, DrFirst is making our EPCS Gold product available to all of our software partners and associates to integrate into their EHR systems or use it as a stand-alone EPCS solution. We've invested the time, resources and effort to meet all of the DEA's stringent requirements and undertake extensive auditing so other software solutions providers do not have to go through the expensive and time consuming process of DEA certification.

Physician Concerns

Physicians have voiced concern over one aspect of the certification process, specifically the identity proofing process. We asked Michelle Soble-Lernor, the Chief Pharmacy Officer at DrFirst, to describe this concern. "The identity proofing process is managed by Experian. However, some doctors are uncomfortable providing or confirming personal financial information over the Internet. Everyone knows not to provide credit card or financial information over the Internet unless you are absolutely certain your information will be secure. That's just ingrained in all of us now. That hesitation is one of

the issues that contribute to the approximate 15% failure rate on first attempts to complete the Experian identity proofing process."

A key to alleviating these concerns is the ongoing education process to user communities. As online services and capabilities expand, so too will use of personal information in verifying identities. Users are more likely to feel comfortable in the provision of information online if they 1) trust that the application is secure and 2) that the information is being used with a purpose specific to the application and not for residual applications, such as marketing.

Interview: Tom Sullivan, MD

Tom Sullivan, MD joined DrFirst in 2004, just after completing his term as President of the Massachusetts Medical Society. He is known throughout the healthcare industry as the father of the Continuity of Care Record ("CCR") and a leader on the future of healthcare technology. He is assisting DrFirst in ensuring that DrFirst's flagship e-prescribing product, Rcopia®, continues to add the functionality necessary to maintain its leadership position both in electronic prescribing and in the channel of communication between various sectors of the healthcare community and the physician. Dr. Sullivan is nationally active in organized medical groups, and is a past Co-Chair of the Physicians EHR Consortium, and both a delegate to the American Medical Association (AMA) and a member of their Council on Medical Service. He is also the Chair of the Healthcare Workgroup, helping the US Department of Commerce achieve the goals of their National Strategy for Trusted Identities in Cyberspace (NSTIC).

Can you describe the history of DrFirst's work to achieve a solution for EPCS?

This dates back to the company's founding in the 2000. Pharmacies, pharmaceutical companies and health plans all recognized the clear return on investment for e-prescribing. So once we started that and it became successful the next question was – Why can't you do the same thing with controlled substances? In some ways it was a pragmatic challenge in terms of identifying the issues and hurdles that needed to be overcome. One of the major issues was communicating and collaborating with the Drug Enforcement Agency (DEA). They were

extremely concerned about security and identity proofing. Even back then, the DEA realized better than anyone, there was a growing problem of drug abuse and illegal diversion.

However, unlike other agencies within the federal government, such as HHS, CMS and others who are focused on a range of issues concerning quality of healthcare, the DEA has a very singular and narrow focus. Their mission is stopping drug abuse and illegal diversion. Since their main concern was security, they proposed a series of security requirements that were so difficult that no one was even interested in pursuing a solution. However, our company's founder, Jim Chen, had an extensive background in Internet security, having worked on the early development of VPN's or Virtual Private Networks. He became very interested in this problem, and it was also a natural extension of what we were doing in e-prescribing which also requires security, privacy and other Internet security elements.

At that time, I was the president of the Massachusetts Medical Society and I had an opportunity to testify about the value of e-prescribing in front of the Massachusetts House, the Senate and the governor's office. Mitt Romney was the governor at that time, and I met with one of his Cabinet members.

The end result was that we were able to obtain a grant from Agency for Healthcare Research and Quality (AHRQ), and we conducted the very first pilot project on EPCS. It was a 3-year pilot project that was conducted under the auspices of the Massachusetts Department of Public Health, controlled substances division.

We had a DEA waiver to electronically prescribe controlled substances in western Massachusetts and share the results so everyone could learn from the experience. The study was published in 2011 in the Journal of the American Medical Informatics Association by Brandeis University.

Our leadership in EPCS was the result of a confluence of the right people from our organization, Jim Chen, Dr. Peter Kaufman and others. Secondly, we were willing to take the risk and devote the significant time and resources to conducting this first ever pilot project and study.

I serve on a number of national committees and we are still leading the way in terms of making EPCS more efficient. We are actively working with state regulatory bodies as well as federal agencies to educate, inform and even offer technical solutions. We see tremendous efficiency in having a fully electronic system for prescribing all drugs. And that efficiency will drive down costs along with reducing errors and promoting more patient safety in our healthcare system.

There are many other practical benefits, but from a larger perspective we have very inefficient systems in healthcare. Part of that is driven by regulatory issues, and we all understand the need for the correct balance. However, we envision that universal adoption of e-prescribing for all drugs can resolve many of the remaining aspects of the inefficiencies in the "big picture" pharmaco-economic and patient safety system—and that's a worthwhile goal.

Why is e-prescribing of controlled substances so important?

It's incredibly important because there is a huge epidemic of drug abuse and illegal diversion in this country. Twenty years ago most people who were diverting drugs were getting their prescriptions illegally from stolen or forged and altered paper prescriptions. Today, most of the diversion and drug abuse comes from legitimate doctors writing legitimate prescriptions. Just as a single example, we are seeing it with teenagers who sustain an injury playing sports. They receive a prescription for a narcotic, sometimes more than they need and they can become addicted if not properly monitored. Or a family member receives a prescription and they only take a few of the pills in the bottle. Then, an adolescent or other person decides to experiment with the rest of the pills and they can also become addicted that way.

However, the issue affects all age groups, and it's a major societal problem. The inefficiencies and problems with paper based systems and records widen the open door, allowing the practice of doctor shopping to occur.

Another reason is that there's a huge problem with workflow and inefficiency in healthcare. Over the past ten years, we have acquired plenty of experience with e-prescribing of non-controlled substances. With EPCS, the question is why not make the workflow smoother for the prescribers, have better and more timely audit trails, make it safer for patients, easier for pharmacists and help the law enforcement officials carry out their mandates.

Of course, there's some training involved for doctors and there are some obstacles still to overcome. There's an adoption curve as with any new technology. E-prescribing of non-controlled substances has reached what I would call a tipping point in that adoption curve and EPCS will follow a similar trajectory and reach the same point fairly soon. The benefits of EPCS simply far outweigh the obstacles.

What's Next: EPCS in 2013 and Beyond

During 2012, electronic prescribing of controlled substances adoption recognized significant growth, expanding from a handful of pharmacies to what is now more than 13,000, accounting for nearly 18% of all U.S. pharmacies. Physician adoption is accelerating as well. All signs indicate that the industry has grown past the launch stage, and is now rapidly progressing toward widespread use. If electronic prescribing of controlled substances continues to mirror the adoption pattern of e-prescribing, the next two years will see EPCS becoming a mainstream practice among physicians who recognize the benefits of workflow efficiencies, drug diversion protection, and patient safety benefits of controlled substance e-prescribing.

About DrFirst

DrFirst pioneers software solutions and services designed to optimize healthcare provider access to patient information, improve the doctor's clinical view of the patient at the time of care, and enable more effective, efficient administration and collaboration across a patient's circle of caregivers. Our growth is driven by a commitment to innovation and reliability across a wide array of service areas, including Medication History and e-Prescribing, Secure Messaging and Clinical Data Sharing, and Patient Behavioral Education and Medication Adherence. We are a Surescripts Gold Certified provider, and have the #1-ranked Standalone e-Prescribing Software as rated by Black Book Rankings. We are proud of our track record of service to 40,000 providers and over 270 EMR/EHR/HIS vendors nationwide. For more information please visit www.drfirst.com.

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Footnotes

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