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A Planning Guide for Electronic Prescriptions for Controlled Substances (EPCS)

The Federal Drug Enforcement Administration (DEA) regulates prescriptions of controlled substances that have risks for abuse. For healthcare organizations that want to implement ePrescribing for all medications, the need to use manual processes for controlled substances can delay overall ePrescribing adoption.

In June of 2010, the DEA issued an interim final rule allowing electronic prescriptions for controlled substances (in Schedules II-V). Meeting the DEA requirements requires significant effort on the part of the Surescripts prescription network, software vendors for electronic medical records, ePrescribing and retail pharmacy systems, and care providers themselves. As of today, electronic prescriptions for controlled substances are still in the earliest phases of adoption. And in some states, the board of pharmacy still restricts EPCS in spite of the DEA ruling.

This paper offers guidance for healthcare organizations that are planning for or evaluating their options for ePrescribing for controlled substances. Much of this information is dependent on specific organizational factors such as the state you are located in, the software vendor you use, and the status of the retail pharmacies in your area.

THE REGULATORY BACKGROUND

When it comes to ePrescribing, healthcare providers in the U.S. have to conform to two different sets of regulations:

- The DEA regulations (as stated in the final rule 21 CFR 1311)
- The state board of pharmacy regulations for the state in which they practice

Unfortunately, these two sets of regulations don't always match. The DEA allows the option for electronic prescriptions of controlled substances, while the state board of pharmacy may only allow it for certain schedules and may impose other requirements. States cannot be less restrictive than the DEA requirements, only more restrictive.

DEA Regulations for EPCS

DEA regulations are designed to aid the federal government in law enforcement objectives, not necessarily to streamline medical workflows. Their primary objectives include:

- Reducing the potential diversion of controlled substances
- Establishing non-repudiation for prescriptions of controlled substances

The DEA EPCS regulations offer care providers the option of ePrescribing controlled substances if they meet the stated requirements. ePrescribing is by no means mandatory, and any prescriptions must abide by state pharmacy regulations as well. The DEA EPCS regulations only apply to prescriptions sent to retail pharmacies, not inpatient medication orders.

The DEA EPCS rule requires EMR/ePrescribing and pharmacy software vendors to upgrade their systems and undergo a third-party audit for EPCS compliance. In addition, both EMR/ePrescribing software and pharmacy software must gain Surescripts certification.

For care providers to support EPCS they must:

- Use systems that have been certified and audited as being EPCS-compliant by third-party auditors
- Acquire signing credentials (identity proofing)
- Use approved authentication technologies to electronically sign electronic prescriptions

For more details and common questions, see the DEA Office of Diversion control web page at http://www.deadiversion.usdoj.gov/ecomm/e_rx/index.html

State Board of Pharmacy Regulations

On a state-by-state basis, individual pharmacy boards may allow or restrict ePrescribing for controlled substances:

- Some states allow ePrescribing for Schedule II-V controlled substances
- Some states allow ePrescribing only for Schedule III-V controlled substances, not Schedule II
- Some states have not made clear rulings on ePrescribing for controlled substances

Note that the current situation is still in transition as more states are clarifying or changing their ePrescribing

requirements based on the changes the DEA introduced in 2010. Also, the state of Ohio has its own two-factor authentication requirements for non-controlled substance electronic prescriptions, predating the DEA ruling.

The best source of information for your own state is your state's board of pharmacy. Surescripts also maintains information on a state-by-state basis.

REASONS FOR ADOPTING EPCS

For healthcare organizations adopting electronic medical records, ePrescribing is a natural progression in terms of moving processes and workflow online. ePrescribing for all medications offers several benefits, including:

- Reduced medication errors
- Reduced office call volume for refills
- A more complete prescription history in the medical record
- Reduced wait times for patients at the pharmacy
- Improved medication adherence
- Reduced pharmacy call-backs
- No need to stock state specific ePrescribing paper

The Center for Medicare and Medicaid Services (CMS) introduced an ePrescribing incentive program in 2009 to support the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Under this program care providers can receive up to 2% reimbursement for ePrescribing. Penalties for not ePrescribing started in 2012 and unless providers can prove they are exempt, reductions in their Medicare reimbursement of 1% will apply.

ARRA/HITECH introduced Meaningful Use in 2009 that also has an ePrescribing incentive. Stage 1 requires 40% of eligible prescriptions to be sent electronically; Stage 2 is proposing to increase this to 50% and has an optional requirement to ePrescribe at discharge. The final Stage 2 rule is not expected until August 2012. Also, many states have incentive programs for ePrescribing: the Surescripts site has a list by state of available incentive programs.

Controlled substances have always been the special case and it's important to note that neither incentive program on ePrescribing require EPCS. In fact, prescriptions for controlled substances are exempt from penalties in the MIPPA program. However, for healthcare organizations that write a large number of prescriptions for Schedule II-V controlled substances, the need to use manual processes for these prescriptions and this can be a barrier to overall ePrescribing adoption. As long as physicians need to use paper processes for the majority of their prescriptions, they are less likely to adopt ePrescribing.

By enabling EPCS, healthcare organizations can eliminate barriers to ePrescribing in general and improve overall adoption. Adding ePrescribing for controlled substances has other benefits as well:

- Improving the office workflow by reducing the number of manual forms and steps
- Reducing the paper burden of maintaining prescription records
- Reducing prescription forgery
- Reducing cost of stocking state-specific prescription paper and dedicated printers to print prescriptions

FIVE QUESTIONS TO ASK BEFORE ADOPTING EPCS

Before starting down the path to EPCS, healthcare providers should ask themselves the following questions:

1. Does your state board of pharmacy currently allow EPCS, and for which scheduled medications? Depending on your state and practice, it might make sense to wait.

2. Do the pharmacies in your area support EPCS? You can check with Surescripts to find pharmacies in your area.

3. Is your EMR system EPCS certified? If so, which two-factor authentication credentials does it support? (As of this writing, many of the major EMR systems are in the process of certification.) If not, will you need to upgrade your EMR software, and does the vendor charge extra for EPCS functionality?

4. Is ePrescribing widely adopted in your organization? If not, why not? If you are having problems with ePrescribing adoption in general, you may need to solve those problems before adding controlled substances with their special requirements.

5. If you build it, will they come? How many controlled substance prescriptions do your physicians write per month? Will the physicians who will benefit most from EPCS go through the credentialing process?

If you are ready to move ahead, it's a good idea to do a test pilot for EPCS before committing across a larger practice.

WHAT IT NEEDS TO KNOW

From an IT perspective, you must address planning and technical issues before adopting EPCS.

The Software Requirements

You have to use software that is audited and certified for EPCS. Many of the large Electronic Medical Record systems and ePrescribing vendors are still in the process of completing their upgrades and certifications.

Check with your own software provider to see where they are in this process. Before actually deploying EPCS, you will need a letter of attestation from your software vendor that their systems have passed an EPCS audit.

The Authentication Issue

The DEA requires two-factor authentication for signing controlled substance prescriptions. The factors must include two of the three following authentication modalities:

- Something you know (password, key, security question)
- Something you have (PKI smartcard, keyfob token): Devices must meet FIPS 140-2 level 1 requirements or better
- Something you are (biometric): Devices must meet FIPS-201 Personal Identity Verification (PIV) requirements

For example, a keyfob token and password would work as they combine two different modalities: something you have and something you know.

Note that the DEA does not specify what kind of biometrics you can use (fingerprint, iris scan). However, to meet the FIPS requirement the technology must have a false match rate of less than 1 in 1000. Most of the built-in fingerprint readers on laptops are not FIPS-201 compliant.

The DEA regulations do not support authentication factors and technologies that are widely used in healthcare today, including:

- Tap-and-go proximity cards
- Out-of-band factors, including one-time-passwords sent through text messages
- Built-in fingerprint readers on most laptops

If you already have strong authentication measures in place for login authentication and non-controlled prescription signatures, or if you are looking at authentication technologies for your EMR, you have to balance the need to support EPCS with cost, ease-of-use and adoption. You can choose DEA-compliant methods for all authentications (including logins), or only for those individuals or workstations that write a large number of controlled substance prescriptions.

For example, the 'tap-and-go' nature of proximity cards is very successful in hospital environments, giving care providers rapid, no-click access to medical records as they change locations. Since few of the care providers in the hospital environment write prescriptions for retail pharmacies on their rounds, you may not want to compromise their efficiency for the smaller number of controlled substance prescriptions.

Identity Proofing and Registration

Once you have ePrescribing software that's been audited and certified, and have put in place supported two-factor authentication technologies, the last responsibility for your organization or prescribers is mostly a matter of process:

- Individual care providers using their own DEA numbers need to go through an identity proofing process to get their EPCS signing credentials. If they are using their own DEA number, they need to use a federally approved Credential Service Provider (CSP) or certificate authority (CA).
- Care providers in healthcare organizations like hospitals can use the institutional DEA number if it is combined with a unique "internal code" assigned to that prescriber. In this case, the practitioner gets EPCS signing credentials from the hospital credentialing office.

Care providers must then register their authentication credentials and request EPCS privileges.

In addition, healthcare organizations must train care providers appropriately on using the EPCS signing technologies and processes:

- Any security breaches, including a lost or stolen token, must be reported within one business day.
- If an electronic prescription is unsuccessful, the replacement process must indicate that the original electronic attempt was sent unsuccessfully to the pharmacy.

IMPRIVATA AND EPCS

A large number of hospitals, clinics and physician practices throughout the U.S. use Imprivata OneSign for single sign-on (SSO) with strong authentication, for both authentication to the healthcare environment and electronic prescriptions.

Imprivata OneSign supports a wide range of authentication factors, including FIPS-compliant authentication technologies such as hard and soft tokens and fingerprint biometrics.

Imprivata is working closely with many of the leading EMR vendors to integrate OneSign with EPCS capabilities into their products. However, the prescribing system itself must be EPCS certified – not Imprivata OneSign. Imprivata OneSign can help EMR and ePrescribing vendors support the two-factor authentication technologies required by the regulations.

If you are using or considering proximity cards with Imprivata OneSign today, you will want to consider how to best balance the needs of EPCS with overall workflow and adoption in your environment.

- Determine which authentication methods your EMR vendor will be certified to use for EPCS. For example, some EMR vendors are only certified for one-time-password (keyfob) tokens – a technology that many care providers may resist adopting for all authentication.
- Identify within each area or workstation the number of EPCS that will be completed each day.
- Identify for each area or workstation the number of times users authenticate and use that workstation for patient information access.
- Compare the two numbers; you should optimize the workstation/area for whichever usage is higher, keeping in mind that only a fraction of clinical users will require EPCS.

For example, it may make sense to support proximity card authentication everywhere on the inpatient side and in some clinics, deploy FIPS-compliant fingerprint readers for the clinics that write many controlled substance prescriptions, and then issue OTP tokens to prescribers on the inpatient side who occasionally need to do EPCS from the patient rooms during discharge.

SUMMARY

There are many compelling reasons for implementing ePrescribing for controlled substances, including streamlined workflows and better overall ePrescribing adoption. But no two situations are exactly alike; healthcare organizations vary in the number of controlled prescriptions they write, the regulations of their state boards of pharmacy, and the willingness of prescribing physicians to adopt new technologies.

With many of the major EMR vendors in the process of upgrading and certifying their solutions for EPCS, and with many states now allowing these prescriptions, the industry is reaching a tipping point where EPCS will become attractive for a growing number of prescribing organizations.

By carefully examining your own organizational and technology requirements, you can put the foundation in place to support EPCS while at the same time enhancing your care providers' workflows.

ABOUT IMPRIVATA

With more than 2 million users and 900 healthcare customers, Imprivata is the #1 provider of secure access solutions for healthcare. By strengthening user authentication, streamlining application access and simplifying compliance reporting across multiple computing environments, customers realize improved workflows, increased security and compliance with government regulations.

Imprivata has received numerous product awards and top review ratings from leading industry publications and analysts, including a Strong Positive rating in Gartner's 2011 Marketscope for ESSO, the #1 ranking in the KLAS SSO Performance report and the #1 rating in 2010 Best in KLAS and Category Leaders report. Headquartered in Lexington, Mass., Imprivata partners with over 200 resellers and serves the access security needs of customers around the world. For more information, please visit www.imprivata.com or follow us on Twitter at @Imprivata.

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