



Update on Industry Progress in Implementing Electronic Prescribing for Controlled Substances

To: State Boards of Pharmacy
State Controlled Substance Agencies
State and National Pharmacy Organizations

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It has now been two years since the Drug Enforcement Administration (DEA) published its interim final rule (IFR) on electronic prescribing for controlled substances (EPCS). Surescripts, as the primary e-prescribing network in the U.S., has worked with the physician and pharmacy application vendors that connect to its network to ensure that EPCS is implemented in the ambulatory healthcare setting in a way that is fully compliant with the DEA's EPCS rules. The time is now approaching when EPCS will begin to be utilized by prescribers and pharmacies connected to the Surescripts network, so it seems like an appropriate occasion to provide an update on the network's EPCS progress to interested stakeholders. Given that Surescripts has started to receive questions from the field with respect to its EPCS plans and progress, a question and answer format has been chosen as a vehicle to share this information.

Question: What must be done in order for a physician electronic health record application vendor or pharmacy practice management application vendor to be able to connect its users to the Surescripts network for EPCS communications?

Answer: The first step is that the vendor must study the extensive technical requirements made by the DEA in its EPCS interim final rule and then work through the software development process necessary to meet said requirements. It is Surescripts' experience that this effort typically takes vendors several months to finish.

Once the development process is concluded, the vendor must:

- (1) Successfully complete the Surescripts EPCS certification process, which is in addition to the basic Surescripts certification process that is required in order for a vendor to connect to the network for general e-prescribing purposes,
- (2) Submit to Surescripts documentation satisfactory to Surescripts in form and substance confirming the successful completion of the vendor's third-party audit

or certification as required by the DEA in § CFR 1311.300 Application Provider Requirements–Third-party Audits or Certifications, and

(3) Fill out, sign, and submit to Surescripts a form attesting to the vendor's compliance with all EPCS aspects of 21 CFR § 1300, 1304, 1306, and 1311 in addition to a copy of the vendor's third-party audit or certification.

Upon complying with all of these requirements, a physician or pharmacy application vendor is permitted to connect its end users to the Surescripts network for EPCS purposes.

Question: What companies are available in the industry to conduct the Part 1311 third-party audits required by the DEA's EPCS IFR?

Answer: Surescripts does not recommend any companies to its network participants as being able to conduct Part 1311 EPCS audits. This said, Surescripts has been informed by some of its network participants that they are using the following companies for their EPCS audits:

- Assurance Concepts
- BDO
- Brightline
- Chief Security
- Deloitte
- KPMG
- NetSPI
- Price Waterhouse Coopers

These companies are understood to belong in one or more of the categories of entities recognized by the DEA in its EPCS IFR as being able to perform Part 1311 EPCS audits: SysTrust, WebTrust, SAS 70 and/or Certified Information System Auditors. In addition, it should be noted that in October 2011, the DEA specifically approved InfoGard Laboratories as another company capable of conducting Part 1311 EPCS audits.

Again, Surescripts has chosen to not recommend or endorse any of these specific companies over another, and this list should not be considered to be comprehensive. It is simply meant to share examples of the types of firms that are offering Part 1311 EPCS audit services in the industry.

Question: Have any physician or pharmacy application vendors completed the process of becoming certified and audited to connect to the Surescripts network for EPCS purposes?

Answer: Yes, as of the date of this memo, the following application vendors have completed the necessary development, certification, and audit processes and have been allowed to connect to the Surescripts network for EPCS purposes:

- Physician application vendors
 - DrFirst
 - NewCrop
 - NextGen
 - RxNT

- Pharmacy application vendors (or chains that have developed their own applications)
 - Cerner Etreby
 - Rite Aid
 - SUPERVALU
 - Walgreens

There are a number of additional vendors in the offing to be added to these lists in the near future.

Question: Does Surescripts plan to publish the names of vendors that have completed the necessary processes and have been allowed to connect to the Surescripts network for EPCS purposes?

Answer: Yes, it is Surescripts' intent to post the names of application vendors that have been approved for EPCS purposes on its web site in the future. In addition, if individual prescribers or pharmacists want to know if their own applications have been audited and found to be in compliance with the DEA's EPCS IFR, all they need do is ask their vendor for documentation of its audit. The DEA's EPCS IFR requires application vendors to give documentation of their Part 1311 EPCS audits to their current and potential customers upon request.

Question: Have any DEA-compliant electronic prescriptions for controlled substances been transmitted across the Surescripts network?

Answer: Yes, a modest number of EPCSs have been transmitted across the Surescripts network in states in which it is permitted.

Question: In which states is Surescripts allowing EPCS transactions to flow at this time?

Answer: As states align their rules with those of the DEA, Surescripts will allow prescriber vendors, prescribers, pharmacy vendors, and pharmacies to transmit and receive EPCSs in those locales. As of this date, prescribers registered in eight states have issued DEA-compliant EPCSs: California, District of Columbia, Massachusetts, Maryland, Michigan, Texas, Virginia, and Washington. Surescripts prescriber and pharmacy network participants provide services in all fifty states and DC, so Surescripts eventually will be deploying EPCS nationwide once permitted in all locales.

Question: Is Surescripts doing anything to facilitate the EPCS process that is not required of it by the DEA in its EPCS IFR?

Answer: Yes, Surescripts is offering the following value-added services and/or making the following additional requirements that are not required of intermediaries by the DEA's EPCS IFR:

- Surescripts requires all application vendors to prove that they have completed their Part 1311 EPCS audits as required by the DEA prior to being activated for EPCS transactions on the Surescripts network.
- Pharmacy directories in prescriber applications are required to indicate which pharmacies are enabled to receive EPCSs, and prescribers are only able to send EPCSs to those pharmacies.
- Physician directories in pharmacy applications are required to indicate which prescribers are using applications that have been certified and audited for EPCS purposes.
- Surescripts is digitally signing all EPCSs that have the "Signature Indicator" flag so as to augment transaction traceability, and it has encouraged all other intermediaries to do the same.
- Surescripts is monitoring compliance with EPCS rules, e.g., reminding network participants that EPCS procedures must be followed for state controlled drugs such as tramadol and that schedule II drugs should not be electronically prescribed in states in which it is not yet permitted.
- In instances in which an EPCS crosses a state line, Surescripts requires that both the transmitting prescriber and the receiving pharmacy be in compliance

with both the DEA's EPCS IFR and the controlled substance rules of the state in which the prescriber or pharmacy is located. For example, Surescripts does not allow a prescriber in a state in which EPCS is legal to transmit an EPCS to a pharmacy in a state in which EPCS is not yet permitted.

Question: If one has additional questions about the implementation of EPCS processes on the Surescripts network, to whom should they pose their questions?

Answer: Individuals who have additional questions about EPCS processes not answered in this memo can send an email to ken.whitemore@surescripts.com and said questions will be triaged and replied to in a timely fashion.

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