



Second Update Regarding Industry Progress in Implementing Electronic Prescribing for Controlled Substances (EPCS)

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

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It has been four years since the Drug Enforcement Administration (DEA) published its interim final rule (IFR) allowing electronic prescribing for controlled substances (EPCS). Over the past four years, Surescripts, as the primary network facilitating e-prescribing in the U.S., has worked with the pharmacy and prescriber 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.

Surescripts published an update similar to this two years ago and distributed it to the pharmacy community with the goal of answering the questions that were being asked most frequently about EPCS by a variety of stakeholders, both within and without the industry. Given that Surescripts continues to receive general and technical questions from the field with respect to the adoption and utilization of EPCS processes, this second update seems appropriate, and a question and answer format is being used again as a vehicle to share such information. We hope you find this information useful.

Question: How can prescribers and pharmacists confirm that EPCS is legal according to the DEA?

Answer: This might seem to be an unusual question, but Surescripts continues to receive reports of both pharmacists and prescribers not believing that EPCS is a legal practice. The best resource for confirming the legality of EPCS is the section of the DEA website that discusses the issue at: http://www.deadiversion.usdoj.gov/ecomm/e_rx/index.html

At this website, the following highly recommended FAQs can be found:

- General: http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/faq.htm
- Pharmacies: http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/pharmacies.htm
- Prescribers: http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/practitioners.htm

Of course, in addition to the DEA's rules, one must also comply with state rules when choosing to engage in EPCS communications. At this writing, 49 states and the District of Columbia allow EPCS, and the remaining state is in the process of adopting enabling legislation. It is assumed that the readers of this update will be aware of and will understand the rules regarding EPCS in their respective states.

Question: How can pharmacists be assured that EPCSs transmitted through the Surescripts network are compliant with DEA's EPCS rules?

Answer: Surescripts is committed to full compliance with the DEA's EPCS IFR. The Surescripts network adheres strictly to the sections within the DEA's EPCS rule that place requirements on intermediary networks. Surescripts also requires that pharmacy and prescriber application vendors that would like to connect to its network for EPCS purposes prove that they have successfully completed a Part 1311 EPCS audit as required by the DEA prior to being activated for EPCS transactions on the Surescripts network. This is accomplished by insisting that all such application vendors submit a copy of their successful EPCS audit reports to Surescripts, both at their initial activation and on a biennial basis as is required by the DEA. Further, it should be noted that the DEA's EPCS IFR makes very rigorous requirements on prescribers and their application vendors, which include prescriber identity proofing according to Federal security standards, issuance and use of highly secure two-factor authentication credentials to sign EPCSs, and extensive application audit trails. Finally, Surescripts requires that pharmacies and pharmacy system application vendors display an indication to pharmacists to confirm to them that the EPCS that they are viewing is in fact DEA EPCS IFR compliant.

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

Answer: The first step is that the application vendor must study the extensive technical requirements made by the DEA in its EPCS IFR and then work through the software development process necessary to meet said requirements. It is Surescripts' experience that this effort typically takes a minimum of several months to complete.

Once the development process is concluded, the application vendor must:

- (1) Successfully complete the Surescripts EPCS certification process, which is in addition to the basic Surescripts certification that is required in order for an application 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 application 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 application vendor's compliance with all EPCS aspects of 21 CFR § 1300, 1304, 1306, and 1311 along with a copy of the application vendor's third-party audit or certification.

These procedures are designed to confirm and document that all application vendors connecting to the Surescripts network have met all of the applicable DEA EPCS IFR requirements, thereby ensuring that EPCS communications on the Surescripts network are legal. It is only upon complying with all of these requirements that a pharmacy or prescriber application vendor is permitted to connect its end users to the Surescripts network for EPCS purposes.

Question: Do pharmacy or prescriber applications need to be approved, audited or certified by the DEA prior to their use to receive or transmit EPCSs?

Answer: This is a commonly misunderstood aspect of the DEA's EPCS IFR. The answer is no, the DEA itself does not approve, audit or certify any pharmacy or prescriber applications for EPCS purposes. What the DEA does do in the EPCS IFR is identify the types of entities that the agency recognizes as being capable of conducting what are commonly referred to as Part 1311 EPCS audits. These audits are mandated by the DEA's EPCS IFR, and it is the responsibility of pharmacy and prescriber application vendors to identify and contract with such entities in order to have their EPCS audits performed.

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

Answer: In Surescripts' experience, the types of entities that are allowed to conduct third-party Part 1311 EPCS audits is probably the least understood aspect of the DEA's EPCS IFR. To review, here is an excerpt from the DEA's EPCS IFR that specifies what types of entities are recognized as being able to conduct such audits:

- (b) The third-party audit must be conducted by one of the following:
 - (1) A person qualified to conduct a SysTrust, WebTrust, or SAS 70 audit.
 - (2) A Certified Information System Auditor who performs compliance audits as a regular ongoing business activity.
- (c) An audit for installed applications must address processing integrity and determine that the application meets the requirements of this part.
- (d) An audit for application service providers must address processing integrity and physical security and determine that the application meets the requirements of this part.
- (e) If a certifying organization whose certification process has been approved by DEA verifies and certifies that an electronic prescription or pharmacy application meets the requirements of this part, certification by that organization may be used as an alternative to the audit requirements of paragraphs (b) through (d) of this section

Surescripts does not recommend any entities to its network participants as being able to conduct Part 1311 EPCS audits. This said, Surescripts has been informed by its network participants that they have used many different entities for such audits. The following entities have been reported to Surescripts as belonging to the first two DEA EPCS IFR categories mentioned in sections (b)(1) and (b)(2) above, and they have therefore been employed by pharmacy and prescriber application vendors to conduct such audits:

- A-lign CPAs
- Assurance Concepts
- BDO USA, LLP
- Brightline
- Chief Security Officers, LLC
- Coalfire Systems, Inc.
- ComplySmart, LLC
- Deloitte & Touche, LLP
- Electronic Healthcare Network Accreditation Commission (EHNAC)
- KPMG
- McGladrey, LLP
- NetSPI
- Paladion Inc.
- Price Waterhouse Coopers
- Roosa CPA, LLC
- Schneider Downs & Company, Inc.
- SunGard Availability Service
- Weaver & Tidwell, LLP

In addition, since the publication of the agency's EPCS IFR, the DEA has identified six entities pursuant to the third EPCS IFR category, which is in section (e) above. These entities have all applied directly to the DEA to be recognized as being able to conduct Part 1311 EPCS audits, and they all have been approved to do so:

- ComplySmart, LLC
- Drummond Group Inc
- EHNAC (approved for this category by the DEA on 12/03/2014)
- Global Sage Group, LLC
- iBeta, LLC
- InfoGard Laboratories

It is important to note that the DEA does not list entities in the first two categories on its website, but the agency does list entities in the third category on its website as industry stakeholders otherwise would not know who they are.

To reiterate, Surescripts has chosen not to recommend or endorse any of these specific entities over another, and the first list should not be considered to be comprehensive. It is simply meant to share examples of the types of entities that are offering Part 1311 EPCS audit services in the industry. Surescripts does, however, recommend that application vendors interview several potential Part 1311 EPCS auditors prior to engagement, because it has been reported to Surescripts that services offered and fees charged by these entities vary dramatically.

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

Answer: Yes, Surescripts posts the names of application vendors that have been certified and audited as being able to engage in EPCS transactions at the following links on its website:

- Pharmacies and pharmacy application vendors: <http://surescripts.com/epcscertified>
- Prescriber application vendors: <http://surescripts.com/epcscertifiedehr>

In addition to these resources, if individual pharmacists or prescribers want to confirm that 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 application vendor for a copy of its audit report. The DEA's EPCS IFR requires application vendors to give documentation of their Part 1311 EPCS audit reports to their current and potential customers upon request.

Question: To what extent have DEA-compliant EPCSs been transmitted across the Surescripts network?

Answer: Since the first legal EPCS transmission took place on the Surescripts network in August 2011, approximately 1.8 million new EPCSs and 60,000 refill responses have traversed the Surescripts network. (Note that refill responses must meet DEA EPCS IFR requirements and are treated as new prescriptions by pharmacies.)

Question: In which states have EPCS transactions been transmitted and received via the Surescripts network since August 2011?

Answer: EPCS transactions have been transmitted by prescribers and received by pharmacies in all states except Montana.

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 implementing the following additional requirements that are not included in the DEA's EPCS IFR:

- As mentioned above, Surescripts requires all application vendors to prove that they have successfully 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.
- Prescriber directories in pharmacy applications are required to indicate which prescribers are using applications that have been certified and audited for EPCS purposes.
- As an added security feature, Surescripts is digitally signing all EPCSs that include the “Signature Indicator” flag so as to augment transaction traceability.
- Surescripts is monitoring compliance with EPCS rules, e.g., reminding network participants that EPCS procedures must be followed for state controlled drugs 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: To whom should additional questions about the implementation of EPCS on the Surescripts network be posed?

Answer: More information about EPCS is available on the Surescripts website at: <http://www.surescripts.com/epcs>. Individuals who have additional questions about EPCS processes not answered in this memo or on the Surescripts website can send an email to ken.whittemore@surescripts.com and said questions will be triaged and replied to in a timely fashion.

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