

A Live Online Town Hall Brought to You by



Electronic Prescribing of Controlled Substances (EPCS)

Frequently Asked Questions

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General Questions

- *When did EPCS become legal?*

In terms of federal law, the DEA's Interim Final Rule (IFR) on Electronic Prescriptions for Controlled Substances went into effect on June 1, 2010. This Rule laid out all of the security criteria and operational requirements for DEA-registered prescribers to issue electronic prescriptions for Schedule II, III, IV and V drugs to DEA-registered pharmacies using certified EPCS software solutions.

Other DEA regulations related to prescribing and dispensing of controlled substances, as well as regulations for changing prescriptions, remain unchanged and are in effect as before.

Many states also have laws that relate to prescribing or dispensing controlled substances. Other states have not addressed EPCS and therefore will have to enact laws and/or regulations in order to allow prescribers and pharmacies to use this technology.

- *When will EPCS become operational?*

While the DEA Rule permitting EPCS went into effect on June 1, 2010, it did not become operational. Certification and auditing requirements are still in development. Industry estimates indicate that EPCS will become an operational reality by early 2011, but that is just an approximation based on where the industry currently stands.

- *Is EPCS mandatory for prescribers? For pharmacies?*

EPCS is completely voluntary and optional for prescribers and for pharmacies.

- *Under federal law, can a provider electronically prescribe all controlled substance drugs?*

Yes, as long as both the prescriber and the pharmacy are DEA registrants and certified to electronically prescribe (21 CFR 1311.125, 21 CFR 1311.130). Under the new DEA regulations the prescribing practitioner can electronically prescribe all Schedule II, III, IV and V controlled substances. In certain circumstances additional information is required for a subset of prescriptions:

- Extension data is required for providers prescribing under institutional DEA numbers.
- The special DEA identification number is required for providers approved to prescribe Schedule III, IV and V controlled substances for maintenance or detoxification treatment.
- Under the DEA Rule, there is a 30-day maximum prescription limit for an electronically prescribed Schedule II drug. All other provisions remain the same as for written Schedule II prescriptions.

- Certain prescriptions require additional notes when transmitted as a paper prescription. These continue to require special notes electronically.

- *Are there any other changes to DEA policies as a result of the new regulations?*

No. All DEA regulations related to prescribing and dispensing of controlled substances, as well as regulations for changing prescriptions, remain unchanged and are in effect as before.

- *Are there any other laws in place that I need to be aware of as I embark on EPCS?*

Yes. Many states have laws that relate to prescribing or dispensing controlled substances. Other states have not addressed EPCS and therefore will have to enact laws and/or regulations in order to allow prescribers and pharmacies to use this technology.

- *How will prescribers know which pharmacies are certified to receive and dispense EPCS?*

Just as **ePrescribing applications** currently have an indicator to show which pharmacies participate in general ePrescribing, we understand that the industry expectation is that each ePrescribing vendor is likely to have an indicator designating pharmacies certified to receive and dispense EPCS. For example, with the DrFirst Rcopia application a red "C" follows the name of authorized EPCS pharmacies.

- *Will ePrescriptions transmitted for controlled substances count in the calculation of Meaningful Use or MIPPA reimbursement incentives?*

The algorithms used to calculate Medicaid and Medicare incentive payments under the Medicare Improvements for Patients and Providers Act of 2008 ("MIPPA") and HITECH-Meaningful Use were finalized before the DEA's IFR on EPCS went into effect. As such, EPCS are not included in the calculation as it currently stands. We understand that this is likely to be addressed in 2011.

- *Under the new DEA regulations who is eligible to participate in EPCS?*

DEA-registered prescribers are eligible to electronically prescribe controlled substances and DEA-registered pharmacies are eligible to dispense those prescriptions. However, there are operational and security measures that must be in place to do so, including the successful completion of a third party audit of prescriber and pharmacy software applications. More information related to this timeline should be available soon from third party vendors offering to provide these services. (21 CFR 1300.03)

- *What happens if a **prescriber** sends an electronic prescription for a controlled substance to a pharmacy and it does not go through? (21 CFR 1311.170)*

The **prescribing application vendor** is required to notify the **prescriber** if an electronic prescription for a controlled substance has not been delivered to the pharmacy.

To address this situation:

- For a Schedule III, IV, or V medications: if the electronic transaction fails the **prescriber** will print the prescription, manually sign it, and either fax it directly to the pharmacy where the electronic prescription was sent or give it to the patient. This copy must indicate that the prescription was originally transmitted electronically and include the date and time of the transmission, the name of the intended pharmacy, and the fact that the transmission failed.
- For Schedule II prescriptions: **prescribers** will have to revert to the traditional hard copy format with the same additional information.
- *Can an EPCS be printed after digital signature and transmission?*

Yes, as long as it is labeled "Copy only – not valid for dispensing."
(21 CFR 1311.170(c))

- *Can written prescriptions be used during any system failure?*

Yes. The provider always has the option of issuing a handwritten or printed and signed hard copy of a controlled substance prescription.

- *Can an electronic prescription be recalled after it has been sent?*

Most **prescribing applications** have a "void" or "cancel" feature that will send a message to the pharmacy that the prescribing practitioner no longer wishes the prescription to be filled. Of course, if the patient has already picked up the prescription this will be of limited benefit.

- *Does the **pharmacist** still need a manually-signed prescription for controlled substances in addition to an electronic prescription?*

No. Electronic prescriptions that meet the regulations of the interim final rule are considered legal signatures of the prescription. (21 CFR 1306.21, 21 CFR 1311.135)

- *What happens when a **prescriber** electronically transmits a prescription for a controlled substance but also gives the patient a hard copy?*

The **pharmacy** is required to make sure the prescription is only filled once and the other is marked as void. (21 CFR 1311.200)

- If a patient presents the paper prescription at the pharmacy to which the original prescription was transmitted, the **pharmacist** is required to check to ensure the electronic prescription was not dispensed and mark one of the prescriptions as void.
- If the paper prescription is presented at a pharmacy other than the one to which the original prescription was transmitted, the **pharmacist** is required to contact the pharmacy to which the prescription was originally transmitted

to ensure the electronic prescription was not dispensed. One of the prescriptions must be marked void.

Current DEA regulations about paper prescriptions continue to apply. In order to dispense the medication under a paper prescription the **prescriber** is required to manually sign the prescription. (21 CFR 1306.05)

- *How do physician assistants and advance practice nurses include the name of their supervising physician in an electronic prescription for a controlled substance?*

The **prescribing application** must provide this information within the context of the prescription for advance practice nurses and physician assistants. If this cannot be done by the prescribing application, these providers may enter the name of their supervising physician into appropriate fields as long as it becomes part of the digitally signed prescription.

- *What is identity proofing?*

In order to ePrescribe controlled substances DEA-registered prescribers must go through a process to prove his or her identity, or **identity proofing** during which the prescriber proves they are who they say they are. Afterward, the prescriber receives certification and a **two-factor authentication** device to apply that certification electronically. Identity proofing occurs only once, when EPCS is first implemented, or as new prescribing staff come on board.

At the time an EPCS is transmitted to the pharmacy, the **prescribing application** attaches either a digital signature or a validation that two-factor authentication was used to digitally sign the prescription, providing assurance that the prescription originates from an authorized DEA-registered prescriber. (21 CFR 1311.115)

- *What is two-factor authentication?*

During identity proofing, DEA-registered prescribers receive two unique elements to use during the transmission of an EPCS to validate that the prescription is coming from an authorized DEA-registered prescriber. (21 CFR 1311.115)

- Two-factor authentication includes two of the following factors:
 - Something you know — a password, PIN, etc.
 - Something you have — a tangible physical object possessed by the individual prescriber (e.g. a cryptographic key stored on a PDA, cell phone, smart-card, USB memory stick, one-time use password generating device, etc.)
 - Something you are — a biometric identifier like a retinal scan or a fingerprint

The DEA is requiring the physical object used for authentication be a different device than is used to ePrescribe. For example, a one-time password token could be generated on a mobile phone, but then the prescriber would need to use a different device to ePrescribe. A hard token is considered a separate device from the computer into which it's plugged.

- *What is a hard token?*

A hard token (PKI token) is a small hardware device frequently used as one of the two factors required to digitally sign an EPCS. Two-factor authentication is required to verify that you are a DEA-authorized prescriber. A hard token is often used in conjunction with a password to meet the threshold of two-factor authentication. (21 CFR 1311)

The hard token is generally about the size of a “thumb” drive and has a microprocessor with a small amount of memory. When inserted into the USB port of a computer, it provides a very high level of security for messages sent from that computer.

It may be helpful to know that there are two kinds of hard token.

- One-time-password (OTP) tokens will work on any device. They have a 6-digit code that changes once per minute. The prescriber enters the 6-digit code along with their PIN to meet the requirements for two-factor authentication. The problem with OTP is that the prescriber has to look at it and enter the code each time he/she signs a controlled drug prescription, along with his/her PIN.
- PKI tokens have other security functions built in and only require that the prescriber enter a PIN to sign a controlled drug prescription.

- *Are hard tokens compatible with PDAs and Macintosh computers?*

This will vary from application to application. Providers are encouraged to work with their application providers to ensure their hard token is compatible with their computer and operating system. Some tokens will work only with Windows PCs, while others will work with both PCs and Macintosh computers.

- *How will the pharmacists know if the controlled substance ePrescription is legitimate?*

In order to ePrescribe controlled substances DEA-registered providers must go through a process of proving their identity, or identity proofing (as explained above). Identity proofing gives the prescriber a two-factor authentication device or system to use in the course of each EPCS to prove that this prescriber is who he or she says they are and to validate him or herself to the system in a way that cannot be repudiated. (21 CFR 1311)

At the time an EPCS is transmitted to the pharmacy, the **prescribing application** attaches either a digital signature or a validation that the prescription was digitally signed using two-factor authentication.

- *Does the DEA require that an electronic prescription be signed and transmitted simultaneously?*

No. The DEA states that EPCS should be transmitted as soon as possible after signing. (21 CFR 1311.170(a))

- *Can I support DEA electronic prescribing requirements using the current NCPDP SCRIPT 8.1?*

Yes, the version of NCPDP SCRIPT (8.1) currently in use will be able to support the DEA requirements with some modifications. Your **vendor** will be able to give you more information about the timeline for these modifications for your application.

- *Can I support DEA electronic prescribing requirements using NCPDP SCRIPT 10.6?*

The use of NCPDP SCRIPT 10.6 can begin, however as the CMS regulation approving SCRIPT 10.6 was only recently published, the industry will need time to prepare. Coordination with industry partners is necessary to verify switches/networks and pharmacies are able to accept NCPDP SCRIPT 10.6. Consult your trading partners for the timeline.

- *Who crafted the changes for the NCPDP SCRIPT 8.1 and 10.6 for DEA requirements? Do they have industry consensus?*

Yes. The changes were created by a subgroup of the industry that worked on possible solutions. They presented the recommendation to the larger NCPDP Work Group for approval in August 2010.

- *Where do I obtain more information on the NCPDP SCRIPT Standard?*

See the NCPDP SCRIPT Implementation Recommendations document available to members http://www.ncdp.org/members/members_download.aspx

Questions for Pharmacists to ask Pharmacy Application Vendors

- 1) *Has this software been certified by a DEA-approved third party auditor or certification organization to verify that the application meets all DEA specifications for EPCS? (21 CFR 1311.300)*
- 2) *DEA regulations require that pharmacy applications store all EPCS electronically for at least two years and backup files daily. (21 CFR 1311.205(b)(18); 1311.305) Will my records be archived at another location to prevent the loss of records in the event of natural disasters, fires, or system failures?*
- 3) *When can I begin using the NCPDP SCRIPT 8.1 to support the DEA requirements?*
- 4) *When can I begin using the NCPDP SCRIPT 10.6 to support the DEA requirements?*

Why do I need to ask my Pharmacy Application Vendor these questions?

- 1) *Has this software been certified by a DEA-approved third party auditor or certification organization to verify that the application meets all DEA specifications for EPCS? (21 CFR 1311.300)*

There are some requirements that the Rule specifies must be met. As the certification/audit process comes to fruition adjustments are likely to be made and more requirements may arise. According to known requirements set forth in the Rule:

- This certification/audit will verify that the software can:
 - Digitally sign and archive the controlled substance prescription; or import and archive the record that the last intermediary digitally signed; or accept, validate and archive the digital signature as received from the prescriber;
 - Electronically accept and store all of the information and annotation that the DEA requires to document the dispensing of a prescription;
 - Allow the pharmacy to limit access to specific individuals or roles for the annotation, alteration (to the extent that alteration is permitted by DEA regulations), or deletion of controlled substance prescription information;
 - Have an internal audit trail that:
 - Documents whenever a prescription is received, altered, annotated, or deleted; and,
 - Documents date and time of event, type of event, identity of person completing action, and outcome of event.
 - Documents any changes in access controls.
 - Conduct an internal audit that identifies any potential security problems daily and, if a problem is identified, generates a report for review by the pharmacy.

- 2) *DEA regulations require that pharmacy applications store all EPCS electronically for at least two years and backup files daily. (21 CFR 1311.205(b)(18); 1311.305) Will my records be archived at another location to prevent the loss of records in the event of natural disasters, fires, or system failures?*

This is probably not required but it is recommended.

- 3) *When can I begin using the NCPDP SCRIPT 8.1 to support the DEA requirements?*

The version of NCPDP SCRIPT (8.1) currently in use should be able to support the DEA requirements with some modifications. Your **vendor** will be able to give you more information about the timeline for these modifications for your application.

- 4) *When can I begin using the NCPDP SCRIPT 10.6 to support the DEA requirements?*

The use of NCPDP SCRIPT 10.6 can begin, however as the CMS regulation approving SCRIPT 10.6 was only recently published, the industry will need time to prepare. Coordination with industry partners is necessary to verify switches/networks and pharmacies are able to accept NCPDP SCRIPT 10.6. Consult your trading partners for the timeline.

For the Pharmacist: Getting Started with EPCS

- **Pharmacist requirements:**
 - Select an application that has successfully completed the required third party audit or certification to verify that the pharmacy application to be used for EPCS is in compliance with DEA regulations
 - Set role-based access controls
 - Receive, process, dispense and archive prescriptions
 - Make all annotations to EPCS electronically
 - Review daily audit reports
- *Obtain a copy of the report that verifies the application meets all DEA requirements for EPCS. (21 CFR 1311.300)*

Pharmacies are required to have a copy of this report on file. The pharmacy cannot receive electronic prescriptions for controlled substances or dispense controlled substances resulting from an electronic prescription until the third party audit or certification report is received.

- *Set appropriate access controls (either by individual or by role) on your pharmacy application so that pharmacy staff have the appropriate access to annotate, alter or delete controlled substance prescription information.*

There has been no change in the DEA regulations about which staff can perform these functions. This requirement simply states that the software must be programmed to limit technological access to this functionality in accordance with the existing regulations. (21 CFR 1311.120)

All annotations to EPCS must be made electronically. (21 CFR 1311.120)

- *The pharmacy application is required to run a daily audit of EPCS to identify potential security incidents and then generate a report of any problems.*
 - If a problem report is generated then the administrator of the access controls must investigate the problem and determine whether the issuance or records of controlled substance prescriptions has been or could have been compromised.
 - If the determination is made that the system has been compromised then the incident must be reported to the DEA and to the pharmacy application vendor within one business day. (CR CFR 1311.150)
 - In general, reportable incidents are those where there has been a successful attack on the application or other incidents where someone has gained unauthorized access. (21 CFR 1311/150)

- *During the transmission of an EPCS the content of the prescription cannot be altered. The same laws and regulations that apply to changing a paper prescription govern changes a pharmacy can make to an electronic prescription. (21 CFR 1311.120)*

The regulations for making changes to Schedules III, IV, and V prescriptions have not changed. **Pharmacists** may add or change the patient's address upon verification, and modify the dosage form, drug strength, drug quantity, directions for use, or issue date only after consultation with the prescribing practitioner; this must then be noted on the prescription. The patient's name, prescriber's signature, and the drug prescribed (except for generic substitution permitted by state law) cannot be changed. Any other laws prohibiting changes to prescriptions for controlled substances must also be followed.

- An EPCS can be printed after digital signature and transmission as long as it is labeled "Copy only – not valid for dispensing." (21 CFR 1311.170(c))

Questions for Prescribers to ask Prescribing Application Vendors:

- 1) *Has this software been certified by a qualified third party auditor or DEA-approved certification organization to verify the application meets all DEA specifications for EPCS? (21 CFR 1311.300)*
- 2) *How does this software indicate which pharmacies are certified to receive and dispense EPCS?*
- 3) *DEA regulations require that physician applications store all EPCS electronically for at least two years and backup files daily. Will my records be archived at another location to prevent the loss of records in the event of natural disasters, fires, or system failures?*
- 4) *Which Credential Service Provider (CSP), Certification Authority (CA), or Federal Bridge Certification Authority (FBCA) should I use to secure identity proofing for my office that is interoperable with this application?*
- 5) *The prescribing application vendor is required to notify the prescriber if an electronic prescription for a controlled substance has not been delivered to the pharmacy. How will I be notified? (21 CFR 1311.170(b))*
- 6) *For this software application, how do physician assistants and advance practice nurses include the name of their supervising physician in an EPCS?*

Why do I need to ask my Prescribing Application Vendor these questions?

- 1) *Has this software been certified by a qualified third party auditor or DEA-approved certification organization to verify the application meets all DEA specifications for EPCS? (21 CFR 1311.300)*

There are some requirements that the Rule specifies must be met. As the certification/audit process comes to fruition adjustments are likely to be made and more requirements may arise. According to known requirements:

- This certification/audit will verify that:
 - Each EPCS will display (21 CFR 1311.120(b)(9)):
 - Date of issuance
 - Patient name
 - Drug name, strength, form, quantity prescribed, directions for use
 - Name, address, DEA registration number of practitioner
 - Other information as applicable
 - The application will generate a log of a practitioner's EPCS.
 - Automatically generate a log of a practitioner's EPCS during the previous calendar month and provide this log to the practitioner no more than seven calendar days after the end of the month.
 - Upon request, generate a log of a practitioner's EPCS for a provider-specified period of time and provide this log to the practitioner.

- Logs are sortable by patient name, drug name and date of issuance.
- That the application stores a practitioner's archived EPCS for at least two years. (21 CFR 1311.120(b)(27))
- That the application creates an audit trail.
 - Track the creation, alteration, indication of readiness for signing, transmission, or deletion on an EPCS as well as notification of failed transmission.
 - Track the date and time of event, identity of person completing action, and outcome of event.
 - Conduct an internal audit that identifies any potential security problems daily and generate a report for review by the practitioner if a problem is identified.
 - Identify changes in access control(21 CFR 1311.120(b)(23))

2) *How does this software indicate which pharmacies are certified to receive and dispense EPCS?*

Just like **ePrescribing applications** currently have an indicator to show which pharmacies participate in general ePrescribing, the industry expectation is that each ePrescribing vendor is likely to have an indicator designating pharmacies certified to receive and dispense EPCS. For example, with the DrFirst Rcopia application a red "C" follows the name of authorized EPCS pharmacies.

3) *DEA regulations require that physician applications store all EPCS electronically for at least two years and backup files daily. Will my records be archived at another location to prevent the loss of records in the event of natural disasters, fires, or system failures?*

This is probably not required but it is recommended.

4) *Which Credential Service Provider (CSP), Certification Authority (CA), or Federal Bridge Certification Authority (FBCA) should I use to secure **identity proofing** for my office that is interoperable with this application?*

- **Prescribers** should consult with their **prescribing application vendor** for guidance on identity proofing organizations that issue **two-factor authentication credentials** that are compatible with their particular software application.
 - For a practice, identity proofing can be accomplished with an in-person visit from a Credential Service Provider (CSP) or Certification Authority (CA) or remotely.
 - Communications between the CSP/CA and prescriber must utilize two of the following three channels of communication (e.g. mail, telephone, email, etc.). The practitioner must submit identity proofing information to the CSP/CA. This will include but not be limited to various forms of identification, including government issued identification.

- Institutional practitioners have the option of using a slightly different method. Specifically, the Medical Staff Office of a hospital or medical center (with a credentialed DEA-registered provider) may act as a “trusted agent” of a CA/CSP and provide the necessary documentation to allow the issuance of authentication credentials. (21 CFR 1311.110)
- During identity proofing, DEA-registered prescribers are certified and receive two unique elements, known as two-factor authentication, to apply that certification to the ePrescribing system. During every EPCS transmission this two-factor authentication validates that the prescription is coming from that certified prescriber.
 - Two-factor authentication includes two of the following factors (21 CFR 1311.115):
 - Something you know — a password, PIN, etc.
 - Something you have — a tangible physical object possessed by the individual prescriber (e.g. a cryptographic key stored on a PDA, cell phone, smart-card, USB memory stick, one-time use password generating device, etc.)
 - Something you are — a biometric identifier like a retinal scan or a fingerprint)

The DEA is requiring the physical object used for authentication be a different device than is used to ePrescribe. (21 CFR 1311.115) For example, a one-time password token could be generated on a mobile phone, but then the prescriber would need to use a different device to ePrescribe. A hard token is considered a separate device from the computer into which it's plugged.

- 5) *The **prescribing application vendor** is required to notify the **prescriber** if an electronic prescription for a controlled substance has not been delivered to the pharmacy. How will I be notified? (21 CFR 1311.170(b))*

In the normal course of business, it will be important to know how the vendor plans to notify you about any failure in the transmission of an EPCS.

- 6) *For this software application, how do physician assistants and advance practice nurses include the name of their supervising physician in an EPCS?*

The **prescribing application** must provide this information within the context of the prescription for advance practice nurses and physician assistants. If this cannot be done by the prescribing application, these providers may enter the name of their supervising physician into the appropriate fields so long as it becomes part of the digitally signed prescription. (21 CFR 1311.135)

For the Prescriber: Getting Started with EPCS

- **Prescriber requirements:**
 - Select an application that has successfully completed a required third party audit and is certified as being in compliance with DEA regulations pertaining to electronic prescriptions for controlled substances.
 - Undergo the required identity proofing
 - Set role-based access controls for prescribers in the practice
 - Sign and transmit prescriptions
- *The **prescribing application vendor** must provide a copy of the report that verifies that the application meets all DEA requirements for EPCS to each prescriber before the **prescriber** can transmit EPCS. (21 CFR 1311.300)*

Prescribers are required to have a copy of this report on file. The prescriber cannot transmit electronic prescriptions for controlled substances until this audit or certification report is in hand. (21 CFR 1311.102)

- *In order to ePrescribe controlled substances DEA-registered prescribers must go through a process known as **identity proofing** which gives the prescriber two unique elements known as **two-factor authentication**.*

At the time an EPCS is transmitted to the pharmacy, the **prescribing application** attaches either a digital signature or a validation that two-factor authentication was used to digitally sign the prescriber, providing assurance that the prescription originates from an authorized DEA-registered prescriber. (21 CFR 1311.115)

- Identity proofing occurs when EPCS is first implemented and as new prescribing staff come on board.
- The credentialing information/tools must be retained only by the prescriber and not shared by any other person.
- Prescribers should consult with their prescribing application vendor for guidance on identity proofing organizations that issue two-factor authentication credentials that are compatible with their particular software application.
 - For a practice, identity proofing can be accomplished with an in-person visit from a Credential Service Provider (CSP) or Certification Authority (CA) or via remote identity proofing.
 - Communications between the CSP/CA and prescriber must utilize two of the following three channels of communication (e.g. mail, telephone, email, etc.). The practitioner must submit identity proofing information to the CSP/CA. This will include but not be limited to various forms of identification, including government issued identification.
 - Institutional practitioners can use this method or a slightly different method specific to their needs. Specifically, the Medical Staff Office of a hospital or medical center, which has already credentialed a DEA-registered provider, may act as a "trusted agent" of a CA/CSP and provide the necessary documentation to allow the issuance of an authentication credential to the provider by either the CA/CSP or another entity within the organization. (21 CFR 1311.110)

- **Two-factor authentication:** *During identity proofing, DEA-registered prescribers are certified and receive two unique elements, known as two-factor authentication, to apply that certification to the ePrescribing system. During every EPCS transmission this two-factor authentication validates that the prescription is coming from that certified prescriber.*
 - Two-factor authentication includes two of the following factors:
 - Something you know — a password, PIN, etc.
 - Something you have — a tangible physical object possessed by the individual prescriber (e.g. a cryptographic key stored on a PDA, cell phone, smart-card, USB memory stick, one-time use password generating device, etc.)
 - Something you are — a biometric identifier like a retinal scan or a fingerprint (21 CFR 1311.115)

The DEA is requiring the physical object used for authentication be a different device than is used to ePrescribe. For example, a one-time password token could be generated on a mobile phone, but then the prescriber would need to use a different device to ePrescribe. A hard token is considered a separate device from the computer into which it's plugged.

- *Once identity proofing has been completed, and two-factor authentication credentials have been issued to the appropriate prescribers, the practice must set up logical **access controls**. (21 CFR 1311.120)*
 - In an independent practice, a DEA-registered prescriber (with a two-factor authentication credential) and one other staff member will be designated to manage access control to the EPCS application. Together, these two individuals assign the role-based access for the other registrants in the practice, assuring that only those authorized to prescribe controlled substances have access to that functionality.
 - For institutional practitioners, two individuals will be assigned by the institutional registrant to perform this function. They must work in a part of the organization separate from the body responsible for identity proofing. These two individuals assign role-based or name-based access for individual practitioners authorized to electronically prescribe controlled substances.
- *What is the **prescriber's** responsibility if a hard token is lost, stolen or compromised or if the application protocol is otherwise compromised?*

In this circumstance a **prescriber** is required to notify the individuals designated to assign access controls for their practice or facility. (21 CFR 1311.125)

- *Under what circumstances would a **prescriber's** access to EPCS functionality be terminated?*

Permission to sign controlled substance prescriptions must be revoked on the date any of the following is discovered (21 CFR 1311.125(d), 1311.130(d)):

- A hard token or any other authentication factor is lost, stolen, or compromised; access terminated immediately upon receiving notification from the individual practitioner
 - DEA registration expires, unless it has been renewed
 - DEA registration terminated, revoked, or suspended
 - Individual practitioner is no longer authorized to use the electronic prescription application (e.g. the practitioner leaves the practice)
- *What happens if a prescriber sends an electronic prescription for a controlled substance to a pharmacy and it does not go through? (21 CFR 1311.170)*

The **prescribing application vendor** is required to notify the **prescriber** if an electronic prescription for a controlled substance has not been delivered to the pharmacy.

To address this situation:

- For Schedule III, IV, or V medications: the **prescriber** will print the prescription, manually sign it, and either fax it directly to the pharmacy where the electronic prescription was sent or give it to the patient. This copy must indicate that the prescription was originally transmitted electronically and include the date and time of the transmission, the name of the intended pharmacy, and the fact that the transmission failed.
 - For Schedule II prescriptions: the prescriber will have to revert to the traditional hard copy format with the same additional information.
- *Can an EPCS be printed after digital signature and transmission?*

Yes, as long as it is labeled "Copy only – not valid for dispensing."
(21 CFR 1311.170(c))

- *What happens when a **prescriber** electronically transmits a prescription for a controlled substance but also gives the patient a hard copy?*

The pharmacy is required to make sure the prescription is only filled once and the other is marked as void.

- If a patient presents the paper prescription at the pharmacy to which the original prescription was transmitted, the **pharmacist** is required to check to ensure the electronic prescription was not dispensed and mark one of the prescriptions as void. (21 CFR 1311.200)
- If the paper prescription is presented at a pharmacy other than the one to which the original prescription was transmitted, the **pharmacist** is required to contact the pharmacy to which the prescription was originally transmitted to ensure the electronic prescription was not dispensed. One of the prescriptions must be marked void. (21 CFR 1311.200)

Current DEA regulations about paper prescriptions continue to apply. In order to dispense the medication under a paper prescription the **prescriber** is required to manually sign the prescription.

- *Can written prescriptions be used during any system failure?*

Yes. The provider always has the option of issuing a hand written or printed and signed hard copy of a controlled substance prescription. It is recommended that the prescription be issued on tamper-resistant prescription pads.

- *Can an electronic prescription be recalled after it has been sent?*

Most prescribing applications have a "void" or "cancel" feature that will send a message to the pharmacy that the prescribing practitioner no longer wishes the prescription to be filled. Of course, if the patient has already picked up the prescription this will be of limited benefit. (Federal Register, Vol. 75, No. 61, Rules and Regulations page 16239)

If the **pharmacy application** does not support an electronic cancellation, the prescriber's designated staff should contact the pharmacy to cancel the prescription manually (e.g., via phone, etc.).

- *The **prescribing application** is required to run a daily audit of EPCS to identify potential security incidents and then generate a report of any auditable events. (21 CFR 1311.150)*
 - If an auditable event is identified then an individual designated to set logical access controls must investigate the problem and determine whether the issuance or records of controlled substance prescriptions has been or could have been compromised.
 - If the determination is made that the system has been compromised then the incident must be reported to the DEA and to the **prescribing application vendor** within one business day.
 - In general, reportable incidents are those where there has been a successful attack on the application or other incidents where someone has gained unauthorized access.
- *Under federal law, a provider can electronically prescribe all controlled substance drugs, presuming the other DEA security and operational requirements have been met. (21 CFR 1306.21)*

Under the new DEA regulations the **prescribing practitioner** can electronically prescribe all Schedule II, III, IV and V controlled substances. In certain circumstances additional information is required for a subset of prescriptions:

- Extension data is required for providers prescribing under institutional DEA numbers.
- The special DEA identification number is required for providers approved to prescribe Schedule III, IV and V controlled substances for maintenance or detoxification treatment.

- Under the DEA Rule, there is a 30-day maximum prescription limit for any electronically prescribed Schedule II drug. Some prescribers may choose to send multiple prescriptions on the same day in order to provide a 90-day supply for the patient. Under these circumstances, the prescriber must include the dates before which the two future prescriptions may not be filled and be in compliance with established parameters for written Schedule II prescriptions.
- Certain prescriptions require additional notes when transmitted as a paper prescription. These continue to require special notes electronically.

For the Pharmacy Application Vendor: Getting Started with EPCS

- *In order to be able to process an EPCS, a **pharmacy application** must be certified by a DEA-approved third party auditor, Certified Information System Auditor, or independent certification organization to verify that the application to be used to process EPCS is in compliance with DEA regulations. (21 CFR 1311.300)*

There are some requirements that the Rule specifies must be met. As the certification/audit process comes to fruition adjustments are likely to be made and more requirements may arise. According to known requirements:

- This certification/audit will verify that the software can:
 - Digitally sign and archive the controlled substance prescription; or import and archive the record that the last intermediary digitally signed; or accept, validate and archive the digital signature as received from the prescriber;
 - Electronically accept and store all of the information and annotation that the DEA requires to document the dispensing of a prescription;
 - Allow the pharmacy to limit access to specific individuals or roles for the annotation, alteration (to the extent that alteration is permitted by DEA regulations), or deletion of controlled substance prescription information;
 - Have an internal audit trail that:
 - Documents whenever a prescription is received, altered, annotated, or deleted;
 - Documents date and time of event, type of event, identity of person completing action, and outcome of event;
 - Documents changes in access control settings
 - Conduct an internal audit that identifies any potential security problems daily and generate a report for review by the pharmacy if a problem is identified;
 - Documents changes made in access control settings.
- DEA-identified resources for application certification/audit:
 - WebTrust, SysTrust, SAS 70 (21 CFR 1311.300(b)(1))
 - Certified Information System Auditor (21 CFR 1311.300(b)(2))
 - Independent certification organization approved by DEA (21 CFR 1311.300(e))
- Audit/certification must be conducted:
 - Before the application can be used to create, sign, transmit or process prescriptions. (21 CFR 1311.300(a)(1))
 - Whenever functionality related to controlled substance prescription requirements is altered or every two years, whichever comes first. (21 CFR 1311.300(a)(2))

The auditor/certifying authority will then issue a report to application provider. The DEA anticipates that the audit/certification report will be made available on application

web sites. [Ferritto, DEA presentation to NGA State Alliance for eHealth.](#)

- The **pharmacy application vendor** must provide a copy of the report that verifies the application meets all DEA requirements for EPCS to each pharmacy before the **pharmacy** can accept EPCS. (21 CFR 1311.300)

Pharmacies are required to have a copy of this report on file. The pharmacy cannot receive electronic prescriptions for controlled substances or dispense controlled substances resulting from an electronic prescription until this audit or certification report is in hand.

- The **pharmacy application** is required to run a daily audit of EPCS to identify potential security incidents and then generate a report of any problems (21 CFR 1311.150)
 - If a problem report is generated then the **administrator of the access controls** must investigate the problem and determine whether the issuance or records of controlled substance prescriptions has been or could have been compromised.
 - If the determination is made that the system has been compromised then the **pharmacy** must be reported to the DEA and to the **pharmacy vendor** within one business day.
 - In general, reportable incidents are those where there has been a successful attack on the application or other incidents where someone has gained unauthorized access.

For the Prescribing Application Vendor: Getting Started with EPCS

- Each **prescribing application** must be certified by a DEA-approved, third party auditor, Certified Information Systems Auditor, or independent organization to verify that the application meets all DEA specifications for EPCS. (21 CFR 1311.300)

There are some requirements that the Rule specifies must be met. As the certification/audit process comes to fruition adjustments are likely to be made and more requirements may arise. According to known requirements:

- This certification/audit will verify that:
 - Each EPCS will display(21 CFR 1311.120(b)(27)):
 - Date of issuance
 - Patient name
 - Drug name, strength, form, quantity prescribed, directions for use
 - Name, address, DEA registration number of practitioner
 - Other information as applicable (21 CFR 1311.120(b)(9))
 - The application will generate a log of a practitioner's EPCS.
 - Automatically generate a log of a practitioner's EPCS during the previous calendar month and provide this log to the practitioner no more than seven calendar days after the end of the month.
 - Upon request, generate a log of a practitioner's EPCS for a provider-specified period of time and provide this log to the practitioner.
 - Logs are sortable by patient name, drug name and date of issuance.
 - That the application stores a practitioner's archived EPCS for at least two years.
 - That the application creates an audit trail.
 - Track the creation, alteration, indication of readiness for signing, transmission, or deletion on an EPCS as well as notification of failed transmission.
 - Track the date and time of event, identity of person completing action, and outcome of event.
- DEA-identified resources for application certification/audit:
 - WebTrust, SysTrust, SAS 70 (21 CFR 1311.300(b)(1))
 - Certified Information System Auditor (21 CFR 1311.300(b)(2))
 - Independent certification organization approved by DEA (21 CFR 1311.300(e))
- Audit/certification must be conducted:
 - Before the application is used to create, sign, transmit or process prescriptions. (21 CFR 1311.300(a)(1))
 - Whenever functionality related to controlled substance prescription requirements is altered or every two years, whichever comes first. (21 CFR 1311.300(a)(2))

Then the auditor/certifying authority will issue a report to application provider. The DEA anticipates that the audit/certification report will be made available on application web sites. [Ferrito, DEA presentation to NGA State Alliance for eHealth.](#)

- *What happens if a **prescriber** sends an electronic prescription for a controlled substance to a pharmacy and it does not go through? (21 CFR 1311.170)*

The **prescribing application vendor** is required to notify the **prescriber** if an electronic prescription for a controlled substance has not been delivered to the pharmacy.

To address this situation:

- For a Schedule III, IV, or V medications: the **prescriber** will print the prescription, manually sign it, and either fax it directly to the pharmacy where the electronic prescription was sent or give it to the patient. This copy must indicate that the prescription was originally transmitted electronically and include the date and time of the transmission, the name of the intended pharmacy, and the fact that the transmission failed.
- For Schedule II prescriptions: the **prescriber** will have to revert to the traditional hard copy format with the same additional information.

For the Intermediary: Getting Started with EPCS

- **Intermediary** role:
 - To assist the physician and pharmacy vendors and providers with controls and services to meet the requirements of the DEA Rule. While the intermediaries do not have any specific requirements, some of the optional services that can be performed include:
 - Provider validation
 - Prescription validation (controlled v. non-controlled)
 - Version control to allow systems running different versions or formats to communicate
 - Digitally sign the prescription
- During the transmission of an EPCS the content of the prescription cannot be altered. The specific contents that cannot be altered include the full name and address of the patient, drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the practitioner. While these must not be altered during transmission the information could be reformatted. (21 CFR 1306.08)
- While the contents of the electronic prescription cannot be altered, the data may be converted from one software version to another between the electronic prescription application and the pharmacy application; conversion includes altering the structure of fields or machine language so that the receiving pharmacy application can read the prescription and import the data. (21 CFR 1311.150)
- Depending on the technological software, the electronic format may vary, but the prescription must remain electronic. Conversion to fax is not permitted. (21 CFR 1311.170(f))

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