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**I-STOP and e-Prescribing of Controlled Substances (EPCS) in New York State
Frequently Asked Questions**

THE INFORMATION CONTAINED IN THIS DOCUMENT IS SPECIFIC TO NEW YORK STATE ONLY.

1.1 BACKGROUND – LEGALITY OF EPCS AND REQUIREMENTS OF I-STOP*

Q. Is electronic prescribing of controlled substances currently legal?
A. Yes. Electronic prescribing of controlled substances, known as EPCS, became legal when the United States Drug Enforcement Administration's (DEA) interim final rule ("IFR") went into effect on June 1, 2010. The IFR allows health care professionals with prescribing privileges (prescribers) the option to sign and transmit prescriptions for controlled substances electronically and for pharmacies to receive, dispense and archive these electronic prescriptions. However, the IFR outlines stringent requirements that Electronic Health Record (EHR)/e-prescribing systems, prescribers and pharmacies must meet in order to legally transmit, receive or facilitate the transmission of EPCS. Further, states can impose requirements that are more stringent than those outlined in the IFR, such as not allowing EPCS in their state.

Q. What is I-STOP?
A. The Internet System for Tracking Over-Prescribing Act, known as I-STOP, was signed by NY Governor Andrew M. Cuomo in June 2012. This act, implemented to curb prescription drug related abuse, created a number of laws that impact prescribers, pharmacies and EHR/e-prescribing vendors operating in New York State.

Q. How is I-STOP related to EPCS?
A. One of I-STOP's most significant, and now time-sensitive, laws for prescribers is that as of March 27, 2016, **ALL** prescriptions in New York are required to be **electronically** transmitted to pharmacies via compliant EHR/e-prescribing tools.

Q. Does I-STOP require anything other than electronic prescribing?
A. I-STOP seeks to reduce substance abuse and drug diversion in several ways. Note, each component has a different effective date. These other components include:
  1. Regulations that require a prescriber to consult the State's Prescription Drug Monitoring program (PMP) database prior to prescribing or dispensing a schedule II-IV controlled substance. Each prescriber and authorized designee(s) must set up an individual Health Commerce System (HCS) account to access the PMP. For additional details visit:
     https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/
  2. The reclassification of several controlled substances (e.g., hydrocodone and all products containing hydrocodone reclassified to Schedule II). For additional details visit:
     https://www.health.ny.gov/professionals/narcotic/laws_and_regulations/
  3. The creation of the Prescription Pain Medication Awareness Program. For additional details visit:

https://www.oasas.ny.gov/StopRxMisuse/ISTOP.cfm

4. A requirement that the Department of Health establish a consumer program for the safe disposal of controlled substances.

Q. How does I-STOP change what is being done now?
A. Following the passage of the I-STOP act, New York State implemented many new laws to deal with various facets of the prescribing, maintenance and disposal of controlled substances. The state legalized EPCS on March 27, 2013, but imposed additional requirements for EPCS on top of those outlined in the Rule. Further, the New York regulations include a provision that as of two years from March 27, 2013, **ALL** prescriptions in New York must be electronically transmitted to pharmacies. In February 2015, the New York State legislature passed a bill to delay the impact and enforcement of I-STOP for one calendar year. The current effective date for the mandate is **March 27, 2016**.

Q. Is EPCS legal in all states?
A. All 50 states have now passed rules allowing EPCS, however, Vermont does not allow electronic prescriptions for Schedule II drugs. Missouri, the last state to adopt rules, is expected to begin permitting EPCS in July 2015, 30 days after the new rule is published in the Missouri register. For more information on where EPCS is legal, please refer to: http://surescripts.com/products-and-services/medication-network-services/e-prescribing-of-controlled-substances.

Q. Are there any exceptions to the requirement that ALL prescriptions in New York be electronically transmitted by March 27, 2016?
A. Yes. Exceptions to the mandate for electronic prescriptions are outlined *in* New York Education Law Article 137 §6810. In brief, the exemptions apply to the following:

- Veterinarians
- Prescribers with waivers from the Commissioner of Health, for certain hardship reasons for a specified period of time, not to exceed one year
- Situations where electronic prescribing is not available due to a temporary electrical or technical failure
- If a prescriber feels that the electronic transmission requirement will hinder a patient's ability to obtain their medication in a timely manner, thus resulting in adverse consequences for the patient's health. If the prescription is for a controlled substance, the quantity cannot exceed a five-day supply.
- If the location of the dispensing pharmacy is out of state

Q. Should prescribers keep prescription forms after March 27, 2016?
A. Yes. It may be necessary to write a prescription on the Official New York State Prescription forms in the event of an electrical/technical failure or other allowed exception.

Q. Can prescribers be penalized for non-compliance?
A. Yes. **Willful non-compliance** is considered a violation of NY Public Health Law 12-b. Non-compliance carries penalties including but not limited to, a fine of up to $2,000, imprisonment or both.
http://law.onecle.com/new-york/public-health/PBH012-B_12-B.html

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Q. The mandate for electronic prescribing of controlled and non-controlled substances goes into effect on March 27, 2016, but other components of the bill are already in effect. Why?
A. New York Education Law Article 137 §6810 requires that all prescriptions be transmitted electronically two years from the Department of Health's establishing regulations for EPCS. Those regulations will be effective on March 27, 2016.

Q. Where can I get more information?
A. There are many sources for additional information. For information on the DEA's interim final ruling, please refer to:
http://www.deadiversion.usdoj.gov/21cfr/cfr/2111cfrt.htm

For information on the I-STOP Act, please refer to:
http://assembly.state.ny.us/leg/?default_fld=&bn=S07637&term=2011&Summary=Y&Actions=Y&Votes=Y&Memo=Y&Text=Y

For information on the NY State Department of Health's rules on electronic prescribing, please refer to:
https://www.health.ny.gov/professionals/narcotic/electronic_prescribing/

For information on the I-STOP prescription monitoring program, please refer to:
https://www.health.ny.gov/professionals/narcotic/prescription_monitoring/

For additional information on EPCS and certified vendors, please refer to:
www.surescripts.com/epcs

For FAQs from the New York State Department of Health Bureau of Narcotic Enforcement (BNE), please refer to:
https://www.health.ny.gov/professionals/narcotic/electronic_prescribing/docs/epcs_faqs.pdf

1.2 DEFINITIONS: E-PRESCRIBING BASICS

Q. What is an electronic or electronically-transmitted prescription?
A. Section 3302 Article 33 New York Public Health Law defines a prescription to include an "electronic" prescription. It further defines an electronic prescription as a prescription issued with an electronic signature and transmitted by electronic means in accordance with the appropriate regulations.

The Centers for Medicare & Medicaid Services (CMS) defines e-prescribing as a prescriber's ability to electronically send an accurate, error-free and understandable prescription directly to a pharmacy from the point-of-care -- and notes it is an important element in improving the quality of patient care.

For more information on how the State of NY defines electronic prescriptions, please refer to:
http://www.op.nysed.gov/prof/pharm/pharmelectrans.htm

Q. Is a facsimile (fax) prescription considered an electronic prescription?
A. No. New York Public Health Law Section 3302 Article 33 specifically excludes a fax from the definition of an electronic prescription. Further, the same section indicates that a faxed prescription requires a manual signature, which is not the same as an electronic signature. For more information please visit:
http://www.health.ny.gov/regulations/public_health_law/article/33/docs/33.pdf

Q. What is an electronic signature?
A. New York Public health law, section 3302 Article 33 defines an electronic signature as "an electronic sound, symbol, or process, attached to or logically associated with an electronic record and executed or adopted by a person with the intent to sign the record, in accordance with regulations of the commissioner and the commissioner of education."

Q. How is an electronic prescription for a controlled substance signed?
A. The prescriber uses the two-factor credential (discussed in section 1.4) to sign the prescription electronically. Completing the two-factor authentication protocol validates the prescriber's identity and verifies the prescriber as the user writing the electronic prescription. This is considered to be the equivalent of a physical signature.

1.3 COMPLIANCE: WHAT ARE THE REQUIREMENTS TO ELECTRONICALLY PRESCRIBE CONTROLLED SUBSTANCES LEGALLY IN NEW YORK?

Q. If a prescriber uses an EHR or e-prescribing system for electronic prescribing as well as for printing prescriptions for some controlled substances, can the prescriber use that system to e-prescribe controlled substances?
A. No, the DEA regulations outline very specific requirements that must be met by the EHR/e-prescribing product, the prescriber and the pharmacy before a controlled substance prescription can legally be transmitted electronically. This means that before a prescriber uses an EHR or e-prescribing system for controlled substances, that system must comply with legal requirements and the prescriber's practice must have been upgraded to the compliant version. Additionally, New York State imposes additional requirements for prescribers and pharmacies to follow.

Q. What are the requirements for EHR/e-prescribing vendors?
A. Every EHR/e-prescribing vendor should refer to the DEA regulations for specific requirements. Additionally, the EHR vendor typically works with Surescripts to ensure the software version is certified to transmit across the Surescripts network. What is critical for New York prescribers to know is that in order to legally e-prescribe controlled substances they must use software that is specifically certified for EPCS. This software certification, referred to as the "1311 audit," is available through appropriately credentialed auditors or DEA-certified approved organizations. A prescriber cannot

legally e-prescribe controlled substances on a system that has not completed the 1311 audit/certification.

For more information on e-prescribing vendor requirements, please refer to: http://www.deadiversion.usdoj.gov/21cfr/cfr/1311/subpart_c100.htm

Q. What role does Surescripts play in EPCS?
A. Surescripts connects prescriber, pharmacy and payor applications through their health information network. To be included in the Surescripts network, vendors must complete a certification process, ensuring that their system meets the high standards of Surescripts and the National Council for Prescription Drug Programs (NCPDP). For EPCS, each vendor must complete the DEA audit process and then go through an additional Surescripts' certification to join their network.

For more information on Surescripts, please refer to: http://surescripts.com/products-and-services/medication-network-services/e-prescribing-of-controlled-substances

Q. How will a prescriber know if his/her software application is compliant?
A. To determine the compliance status of the software application, a prescriber should request a copy of the audit or certification report from the vendor. The vendor's 1311 auditor or certifying organization will issue a report that states whether the application complies with the DEA's requirements and whether there are any limitations on its use for controlled substance prescriptions. The EHR or e-prescribing vendor is required to provide a copy of the audit report to prescribers or pharmacies upon request. This will allow them to determine the application's compliance status. Prescribers in New York State should obtain a copy of their software's audit report and save it in the event the Department of Health requests to inspect it.

Q: What are the DEA requirements for a pharmacy?
A. Pharmacies should refer to the DEA regulations for details on their respective requirements, but, in brief, to consider electronic prescriptions for controlled substances to be valid, the pharmacy must:
- Receive said prescriptions via an electronic prescribing computer application that is certified for EPCS,
- Register the certified electronic prescribing computer application with the New York State Department of Health's BNE,
- Create access controls, set up an e-prescribing audit process and adhere to all record keeping requirements outlined in the regulations
- Submit controlled substance dispensing data to the BNE, using the American Society for Automation in Pharmacy (ASAP) format Version 4.2 or greater (specific to pharmacies in New York)

For additional details on DEA regulations for pharmacies, please refer to: http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.html

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Q. What does the DEA require individual prescribers to do to legally e-prescribe controlled substances?

A. In brief, the prescriber must:
- Verify that the system (and the specific version in use) is certified for EPCS and obtain a copy of the audit report
- Complete the identity proofing requirement
- Obtain a dual authentication device or process
- Set up access controls within the practice
- Adhere to digital signature and audit requirements

For detailed and specific information regarding the regulations outlined in the DEA's interim final rule, please refer to:

http://www.deadiversion.usdoj.gov/21cfr/cfr/2111cfrt.htm
http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/practitioners.htm

Q. Are there additional requirements for prescribers in New York?
A. Yes. The BNE requires each individual prescriber who intends to write electronic prescriptions for controlled substances to register the certified EPCS software with the BNE. This task must be completed *by each individual prescriber* as opposed to the software vendor for each location where the prescriber practices that uses a different software application. Prior to registering the EPCS software with the BNE, the prescriber must complete identity proofing and the two-factor authentication set-up for each practice site.

For more information on the BNE registration process, please refer to:
https://www.health.ny.gov/professionals/narcotic/electronic_prescribing/practitioner_epcs_form_instructions.htm
https://www.health.ny.gov/professionals/narcotic/electronic_prescribing/ropes.htm
https://www.health.ny.gov/forms/doh-5121.pdf

Q: Once the prescriber has registered his/her software with the BNE, does he/she have to re-register at a later date?
A: Yes, the prescriber must re-register with the BNE:
- At least **every two years** or when the DEA requires a new third party audit of the software (whichever occurs first)
- If the prescriber's software version is upgraded
- If the prescriber implements a new (certified) software application

Q. Are the processes for identity proofing, dual authentication and setting access controls the same for individual prescribers and "institutional prescribers" (i.e., prescribers employed by or working in hospitals or clinics)?
A. No, there are key differences. The DEA distinguishes between individual and institutional prescribers. The DEA allows institutional prescribers who are registered

with the DEA to carry out identity proofing through the institution's credentialing office if they choose. However, if they elect this option they must do it in person. It cannot be done remotely. Institutional prescribers can also issue two factor authentication credentials from their institution or obtain them from a DEA-authorized third party, which impacts how the individual practitioner proceeds. The process for setting access controls must be completed by another department within the institution.

For more information on identity proofing, two factor authentication and setting access controls for the institutional practitioner, please refer to:
http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/practitioners.htm#institutional

1.4 GETTING STARTED - WHERE DO I BEGIN?

Q. I don't have an EHR or an e-prescribing system and I write prescriptions for controlled substances. What do I do now?
A. You need to purchase an EHR or stand-alone e-prescribing system that is certified for EPCS, meaning that all the federal requirements for legally-prescribing controlled substances have been met by the software vendor for the system. Once your new system is implemented, you must commit to e-prescribing and build it into your workflow.

As a starting point, you can go to the Surescripts website at www.surescripts.com/epcs to search for e-prescribing vendors who are certified for EPCS. You will need to decide which option is right for your practice – a full EHR system or a stand-alone e-prescribing system. Typically, stand-alone e-prescribing applications are less expensive, faster and easier to implement than a complete EHR and some meet meaningful use requirements. However, these systems do not necessarily have the level of functionality that exists in an EHR system.

You can visit the following websites for help in determining whether an EHR or a stand-alone e-prescribing system is right for your practice, and which system will better meet your needs:

http://nyehealth.org/for-healthcare-providers/
http://nyehealth.org/for-healthcare-providers/choosing-a-vendor/
http://www.nycreach.org/
http://healthit.ahrq.gov/health-it-tools-and-resources/implementation-toolsets-e-prescribing (See tool on vendor assessments)
http://www.nationalerx.com/

Q. I never write prescriptions for controlled substances. Do I have to do anything?
A. The law in New York requires that as of March 27, 2016, **all prescriptions** must be transmitted electronically. If you do not write any prescriptions for controlled substances, you must still transmit your prescriptions electronically; however, your EHR or e-prescribing system does not have to be certified for EPCS. Surescripts certifies vendors

for other functionalities that their systems offer, which confirms the systems' reliability for the prescriber. To learn more about the various software systems certified by Surescripts and see what they are certified to do, please visit: http://surescripts.com/network-connections/mns/prescriber-software

Q. I currently e-prescribe. How do I know whether I can use my current system to e-prescribe controlled substances?
A. Contact your EHR/e-prescribing vendor to ask if it is certified for EPCS. You will need to clarify whether your specific software version is certified, and, if not, when the vendor anticipates releasing a system upgrade that's certified. If your system is not ready for EPCS certification and the expected timing for certification doesn't align with the timeline to which you're required to adhere, then you will need to consider changing your software. You may have to upgrade to another version of the software that includes this functionality or you may need to consider a new vendor all together. If your tool is certified for EPCS, you should request a copy of the audit report from the vendor.

Q. What if my EHR or e-prescribing system is not certified to support EPCS?
A. If your system is not currently certified for EPCS and you prefer to remain with this tool, you should request information on the vendor's timeline for certification and system upgrade releases. Some important questions to ask are:
- Have they started the 1311 audit process? If so, when do they expect to complete it and what are they basing this estimate on? (Has the auditor told them the anticipated completion date?) Have they started the Surescripts certification process?
- When do they expect to release an EPCS-certified product? What's the process and lead time for implementation?

Based on these answers, you will need to determine whether there is sufficient time for you to wait for your vendor to complete their certification. You may need to consider adopting a different application if your vendor doesn't plan to certify their application or they cannot complete certification in time for you to implement before the deadline.

Q. If my system can be upgraded to a version that is capable of supporting EPCS, what's my next step?
A. Contact your vendor. Tell the vendor that you want EPCS functionality in your system. Your account representative should be able to tell you how to proceed with a system upgrade or conversion to a different version. Clarify the costs, timeframes and steps involved. You should plan to do the following:
1. **Request a copy of your vendor's 1311 audit report or certification**. This is the document that shows the results of your vendor's audit or certification and verifies the vendor's compliance with DEA regulations. In New York, you should retain a copy in the event the Department of Health requests to see it.

2. **Complete the identity proofing process**. Identity proofing is the process, required by the DEA, by which a prescriber is uniquely identified and proves they are who they say they are. This is required to ensure that only appropriate prescribers have

the necessary access to authorize and transmit electronic prescriptions using a software application.

Individual practitioners may complete identity proofing remotely. Your vendor can provide guidance on how to do this. The vendor may direct you to a third party company, where you will be asked a number of personal questions that only you would know the answers to. This process, and the questions asked, is very similar to the process of obtaining a credit report from an outside company.

3. **Two factor authentication:** The DEA requires two-factor authentication to prove that the provider is who they say they are and that they're authorized to digitally sign an electronic prescription for a controlled substance. Two factor authentication requires two out of following:
   - Something you have in your possession (hard token)—this can be something like a key fob token, a debit card, etc.
   - Something you know (e.g., password, PIN)
   - Something you are (e.g., biometrics such as fingerprint, retinal scan)

   Your EHR or e-prescribing vendor will direct you to a source that can provide you with two factor authentication credentials that are supported by their EPCS-enabled application.

4. **Set access controls**: Your practice will need to set access controls so that only legally authorized individuals can sign electronic controlled substance prescriptions.

5. **Register your certified EPCS system with the BNE.**

Q. How long will it take to complete the identify proofing and two factor authentication?
A. This depends on your vendor's process and the two authenticators will be used. It is recommended that you begin this work as soon as possible and discuss anticipated timeframes for completing all the steps with your vendor.

Q: How will I know if the pharmacies my patients use are certified to dispense controlled substances from electronically transmitted prescriptions?
A. In many certified systems there is an indicator in the e-prescribing dashboard that identifies which pharmacies in the directory are enabled for EPCS. Currently, all CVS/pharmacy™, CVS Caremark Specialty Pharmacy and CVS Caremark Mail Service Pharmacy are certified and actively dispensing controlled substances from electronic prescriptions. To ensure your system provides you with the most up-to-date pharmacy information, you should confirm that your directory is set to update monthly. Depending on the system, updating your directory may be a manual process or a preference setting that you can select. Speak with your vendor about how to conduct directory updates on your specific system.

Today, many retail pharmacies can accept electronic prescriptions and are enabled for and actively dispensing EPCS. You can go to the Surescripts' state pharmacy

enablement page to view which pharmacies are certified for EPCS and e-prescribing. Simply enter a ZIP code to view e-prescribing and EPCS-enabled pharmacies in and around that ZIP area. To find a pharmacy in your EHR/e-prescribing tool's directory, simply search by the name, address, ZIP code or NCPDP number.

To visit the Surescripts state pharmacy enablement map, please go to: http://surescripts.com/products-and-services/medication-network-services/e-prescribing-of-controlled-substances

Q. How much will it cost to become certified and/or adopt a new EHR/e-prescribing system that is certified for EPCS?
A. The price of purchasing or upgrading to an EHR or e-prescribing system that is certified for EPCS will vary by system. Although there is no additional transaction cost to the prescriber to transmit an electronic prescription for a controlled substance, there may be additional monthly charges for EPCS functionality, a one-time set up fee or other related costs. You should contact your vendor for information on all fees associated with implementing a system capable of EPCS.

Q. I work at a hospital or clinic and write discharge prescriptions for controlled substances. How should I proceed?
A. You should check with the administration at the hospital or clinic where you work to confirm that the institution's software application is certified for EPCS and for guidance on how they will manage EPCS there. Because the DEA distinguishes between an individual prescriber and an institutional prescriber, the institutional prescriber will likely have protocols in place for how identity proofing, dual authentication and setting access controls are carried out.

However, the penalties for non-compliance with I-STOP are incumbent upon individual prescribers. If your facility's EHR or e-prescribing system does *not* support EPCS, you cannot use paper prescriptions without running the risk of penalties due to non-compliance.

For more information on how the DEA classifies individual providers versus institutional providers, please refer to:
http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/practitioners.htm#individual
http://www.deadiversion.usdoj.gov/ecomm/e_rx/faq/practitioners.htm#institutional

1.5 WORKING WITH PATIENTS

Q. What should I tell my patients if they want a paper prescription?
A. Many patients will not be familiar with the I-STOP requirement mandating the electronic transmission of all prescriptions in New York. You or your office staff should take time to explain this to your patients. This is an excellent opportunity to help them understand the benefits of electronic prescribing and to reinforce the importance of taking their medication as prescribed.

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The following steps may help facilitate discussions with your patients:

- Create a handout that explains your practice's move to e-prescribing and the benefits to your patients
- Put up signs in your office that alert your patients to your new status as a certified e-prescriber
- Create a handout that is a similar size to a prescription that lets your patients know that you transmitted their prescription electronically to their preferred pharmacy. Be sure to communicate that the handout is for information only and is not an actual prescription

Q. My patient wants a prescription for a controlled substance to be sent to a neighborhood pharmacy, but that pharmacy isn't EPCS enabled.
A. An electronic prescription for a controlled substance is only considered legal and valid if it is transmitted via a certified e-prescribing system, by an authorized prescriber, to a pharmacy system certified for EPCS. If a pharmacy is not certified for EPCS, it is not legal to transmit a prescription for a controlled substance to that location. You will need to explain this to the patient and work with the patient to find another pharmacy that is EPCS certified. The Surescripts pharmacy enablement tool could be a helpful tool to identify other pharmacies in the area that are enabled to receive EPCS.

The only applicable exception in this case would be if you felt the patient's inability to obtain the medication in a timely manner will have potential adverse consequences for the patient's health. In this instance, the prescriber can issue a written prescription for five days. In this situation, a prescriber should carefully document the record. However, it's important to note that e-prescribing can significantly reduce the time between when a prescriber writes a prescription and when a patient starts taking the prescribed medication. It also decreases the chance of the patient not filling the prescription.