



## The following Q&A is based on Act 96 of 2018 and applicable federal requirements

### **Q: What is electronic prescribing of controlled substances (EPCS)?**

A: EPCS requires a prescriber to electronically send an accurate, error-free and understandable prescription for a Schedule II-V controlled substance from his or her office directly to a pharmacy.

### **Q: Is a fax of a prescription considered an electronic prescription?**

A: No. A prescription generated on an electronic system and printed or transmitted through fax is not considered an electronic prescription per Act 96.

### **Q: What are the specific controlled substances that are required to be reported to the Prescription Drug Monitoring Program (PDMP) system administered by the Department?**

A: As of January 1, 2017, all Schedule II-V dispensed prescriptions must be reported to the PDMP no later than the close of the subsequent business day.

### **Q: Is EPCS mandatory for practitioners in Pennsylvania?**

A: Yes. EPCS is mandatory as of October 24, 2019, for all practitioners, not including veterinarians, to issue electronic prescriptions for Schedule II-V controlled substances. Act 96, passed into law on October 24, 2018, mandates the use of EPCS to help fight the current opioid epidemic. Health care clinicians need up-to-date tools and technology that support appropriate prescribing of prescription opioids. EPCS can help minimize medication errors for patients and reduce prescription forgery, diversion and theft in Pennsylvania.

### **Q: Why will EPCS be mandatory?**

A: Act 96 legislation was passed into law on October 24, 2018 and took effect on October 24, 2019. In order to help combat the current opioid epidemic, health care clinicians need up-to-date tools and technology that support appropriate prescribing of prescription opioids. EPCS has the potential to minimize medication errors for patients, and reduce prescription forgery, diversion, and theft in Pennsylvania.



**Q: Are there any statutory exceptions to mandatory EPCS?**

A: Yes. Electronic prescribing is not required if the prescription is issued:

1. by a veterinarian;
2. under circumstances when an electronic prescription is not available to be issued or received due to a temporary technological or electrical failure, and, in the instance of a temporary technological failure, a practitioner shall, within seventy-two hours, seek to correct any cause for the failure that is reasonably within his or her control;
3. by a practitioner and dispensed by a pharmacy located outside this Commonwealth;
4. by a practitioner who or health care facility that does not have either of the following:
  - i. Internet access, or
  - ii. An electronic health record system;
5. by a practitioner treating a patient in an emergency department or a health care facility under circumstances when the practitioner reasonably determines that electronically prescribing a controlled substance would be impractical for the patient to obtain the controlled substance prescribed by electronic prescription or would cause an untimely delay resulting in an adverse impact on the patient's medical condition;
6. for a patient enrolled in a hospice program or for a patient residing in a nursing home or residential health care facility;
7. for controlled substance compounded prescriptions and prescriptions containing certain elements required by the Federal Food and Drug Administration or any other governmental agency that are not able to be accomplished with electronic prescribing;
8. pursuant to an established and valid collaborative practice agreement between a practitioner and a pharmacist, a standing order or a drug research protocol;
9. in an emergency situation pursuant to Federal or State law and regulations of the department;
10. under circumstances where the pharmacy that receives the prescription is not set up to process electronic prescriptions; or
11. for controlled substances that are not required to be reported to the Prescription Drug Monitoring Program system administered by the department.



**Q: If a practitioner has internet access but does not have an electronic health record system, do they do they need to electronically prescribe controlled substances as required in Act 96 of 2018?**

A: The Department of Health will not take action against a practitioner if the practitioner has internet access but the practitioner does not have an electronic health record system. Under this circumstance, a practitioner is not required to apply for a hardship exemption and is therefore not required to e-prescribe.

**Q: If a practitioner does not have internet access but has an electronic health record system, do they need to electronically prescribe controlled substances as required in Act 96 of 2018?**

A: The Department of Health will not take action against a practitioner if the practitioner has an electronic health record system, but the practitioner does not have internet access. Under this circumstance, a practitioner is not required to apply for a hardship exemption and is therefore not required to e-prescribe.

**Q: If a practitioner or health care facility does not meet the statutory exceptions and is unable to meet the requirements of Act 96 by the effective date, what can they do?**

A: A practitioner or health care facility that does not meet a statutory exception to the electronic prescribing requirements and is unable to timely comply with the electronic prescribing requirements may apply for temporary exemption from the requirements based upon economic hardship, technical limitations or exceptional circumstances.

Temporary exemptions are being accepted before the effective date of the act and while the department works to promulgate regulations. These temporary exemptions are subject to approval by the department and preliminary in nature, pending final publishing of regulations as stated in Section 11 (b.6) of the act. To file for a temporary exemption, please fill out [this form](#).

**Q: How will I know if my temporary exemption was approved?**

A: You will be notified of the department's determination by email. Please allow a minimum of 5 business days to process your request. This timeframe may vary based on the volume of applications received and time to process and review all application requests. You will be contacted directly if additional information is needed to process your application.

**Q: How long will my temporary exemption be valid?**

A: The temporary exemption will expire one year from the date of approval from the Department or when regulations are published per Section 11(b.6) of the act, whichever occurs first. The exemption may be renewed annually upon request by the practitioner and subject to the department's review and approval.



**Q: Are dispensers required to verify that one of the exceptions or exemptions exists if they receive a non-electronically prescribed prescription for a controlled substance?**

A: No. A dispenser that receives a written, oral, or faxed prescription is not required to verify that the prescription falls under one of the exceptions or exemptions in Act 96. A dispenser is authorized to continue to dispense medications from otherwise valid written, oral, or faxed prescriptions.

**Q: Are there penalties for practitioners who do not comply with Act 96?**

A: A practitioner who violates this act is subject to administrative penalties as follows:

1. \$100 per violation for the first through 10th violations
2. \$250 per violation for the 11th and any subsequent violations
3. The maximum cumulative fine per calendar year cannot exceed \$5,000.

**Q: Will Act 96 violations be reported to the appropriate licensing board?**

A: No. [Act 96](#) specifically states that the assessment of administrative penalty shall not be reported by the Department of Health to the practitioner's appropriate licensing board and shall not be considered disciplinary action. The practitioner is not required to self-report the violation to the appropriate licensing board.

**Q: Will the Department of Health issue regulations regarding Act 96?**

A: Yes. [Act 96](#) requires the Department of Health to promulgate regulations within 180 days of the effective date of the act.

**Q: Does a practitioner have to consult the Prescription Drug Monitoring Program (PDMP) registry when electronically prescribing?**

A: Yes. The practitioner must consult the PDMP prior to prescribing a Schedule II-V controlled substance regardless of how the prescription is issued. Please refer to the [PA PDMP FAQ for prescribers](#) regarding these requirements.

**Q: How does a dispenser annotate an electronic prescription?**

A: Dispensers should consult their software vendor or corporate headquarters for guidance to ensure annotation meets all federal requirements. The process of annotating a prescription may vary based on the software used.

**Q: Is it mandatory for pharmacies to receive electronic prescriptions for controlled substances?**

A: No. However, as of October 24, 2019, it is mandatory for practitioners, with some exceptions, to issue electronic prescriptions for controlled substances.





**Q: Where do I find the software that will allow a practitioner to electronically prescribe controlled substances?**

A: The Department of Health does not endorse or provide a specific EPCS software for practitioners to use. You may research different options on the internet, speak to your professional colleagues or professional associations that you are associated with to determine what options are available. You may also wish to contact your current Electronic Health Record (EHR) software application provider, if you are currently using an EHR.

**Q: What should I do if I am notified that the security of my certified EPCS software application is noncompliant with federal requirements?**

A: If you are notified that your EPCS software application no longer meets federal security requirements, you must update your software to come into compliance and you may not use your current software to process electronic prescriptions for controlled substances until your software is in compliance with the federal DEA requirements.

**Q: What should I do if my credentials used to sign electronic prescriptions have been lost, stolen or compromised?**

A: You should contact your EPCS software provider immediately and notify the DEA.

**Q: What should I do if I suspect or am notified of a security breach with my certified EPCS software application?**

A: If there has been a security breach, you may not process electronic prescriptions for controlled substances. You should contact your EPCS software provider immediately, file a complaint with the [PA Office of Attorney General](#), and notify the DEA.

**Q: How do I know if my software has been certified to process electronic prescriptions for controlled substances?**

A: Please contact your software vendor, they should be able to provide you with this information.

**Q: I currently electronically prescribe non-controlled substances. Are there any additional steps I need to complete in order to electronically prescribe controlled substances?**

A: Yes. First, the software you currently use must meet all the federal security requirements for EPCS, which can be found on the [Drug Enforcement Agency's \(DEA\) web page](#). **Note that federal security requirements include a third-party audit or DEA certification of the software.** Second, you must complete the identity proofing process as defined in the federal requirements. Third, you must obtain a two-factor authentication as defined in the federal requirements.



**Q: Can practitioners electronically prescribe controlled substances before it becomes mandated?**

A: Yes, as long as all federal security requirements are met for EPCS.

**Q: If only five days or less of a controlled substance is prescribed, does the prescription need to be transmitted electronically?**

A: Yes. Any amount of controlled substances being prescribed must be transmitted electronically, unless the practitioner meets one of the exceptions.

**Q: Can a practitioner who prescribes controlled substances electronically from multiple practice sites change the practice site address on the prescribing software or choose from multiple practices site addresses within the software?**

A: Practitioners should speak to their EPCS software vendor regarding the functionality around practice site addresses.

**Q: Will practitioners be required to electronically prescribe non-prescription items, including durable medical equipment?**

A: No, Act 96 requirements for electronic prescribing apply to Schedule II to V medications.

**Q: If a third-party payor requires a prescription for payment of non-prescription items, including durable medical equipment, can it be electronically prescribed?**

A: Consult with your electronic prescribing software vendor to ascertain if the e-prescribing software is capable of transmitting these items correctly. If not, a written prescription, manually signed, is permissible for non-prescription items, including durable medical equipment, that a payor requires for payment.

**Q: Can a Physician Assistant electronically prescribe controlled and non-controlled substances?**

A: Yes. For more information, please visit: <http://pspa.net/governmental-affairs/sbm-regulations/>

**Q: Can a practitioner electronically prescribe using a facility DEA number?**

A: Yes. The existing regulations in [Title 49](#), pertaining to the prescribing and dispensing of medications, are still applicable with electronic prescribing.



**Q: Is the phrase “Authorization for Emergency Dispensing” required on the follow-up prescription for an emergency oral prescription for a schedule II controlled substance?**

A: Yes. Please refer to [Title 28 § 25.45](#).

**Q: If a pharmacy does not dispense controlled substances, does their computer system have to be certified to meet the DEA security standards?**

A: No. Computer systems only need to be certified that they meet the DEA security standards if they will be used to dispense controlled substances.

**Q: What are the accepted software requirements for EPCS?**

A: The software must meet all federal security requirements for electronic prescribing of controlled substances (EPCS) which can be found on the Drug Enforcement Agency’s (DEA) [web page](#). Note that federal security requirements include a third-party audit or DEA certification of the software.

1. You must complete the identity proofing process as defined in the federal requirements.
2. you must obtain a two-factor authentication as defined in the federal requirements.

**Q: If a practitioner is granted temporary exemption from electronic prescribing, are they required to indicate in the patient’s health record that an oral or written prescription was issued?**

A: No.

**Q: Can practitioners electronically prescribe multiple Schedule II prescriptions to a patient for the same controlled substance to be dispensed on different dates?**

A: Yes.





## The following answers are provided as interim guidance until regulations are formalized by the Pennsylvania Department of Health, pursuant to Act 96 of 2018.

### *Information is subject to change.*

**Q: How are practitioners defined?**

A: A person who is lawfully authorized to prescribe, dispense or administer a controlled substance, other drug, or device in the course of professional practice or research in the Commonwealth of Pennsylvania. The term does not include a veterinarian.

**Q: What are the definitions for, administer, dispense, prescribe and prescription?**

A: "Administer" means the direct introduction of or the application of a drug into or on the body of a patient by injection, inhalation, ingestion or any other means and, where required by law, shall occur only pursuant to a medical order. (PA. Pharmacy Act, section 2-16 added June 29, 2002, P.L.673, No.102)

"Dispense" or "dispensing" means the delivery or preparation of a prescription or non-prescription drug pursuant to the lawful order of a practitioner including packaging, labeling, or compounding necessary to prepare such item for that delivery for subsequent administration to or use by a patient or other individual entitled to receive the drug. (PA Controlled Substances, Drugs, Device, and Cosmetic Act of 1972, P.L. 233, No. 64., Section 2)

"Prescribe" means the issuance of a prescription by a duly licensed medical practitioner authorized by law to prescribe drugs. (See "prescription").

"Prescription" means a written or oral order issued by a duly licensed medical practitioner in the course of his or her professional practice for a controlled substance which is dispensed for use by a consumer. PA. (Pharmacy Act, Section 2-8 added June 29, 2002, P.L.673, No.102)

**Q: What is a controlled substance?**

A: A drug, substance or immediate precursor included in the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, or the Controlled Substances Act (Public Law 91-513, 84 Stat. 1236). [DEA: List of controlled substances in alphabetic order \(PDF\)](#)

**Q: What is a temporary technological or electrical failure?**

A: A temporary technological or electrical failure is defined as any failure of a computer system, application or device, or the loss of electrical power to that system, application or device, or any other service interruption to a computer system, application or device in a manner that reasonably prevents a practitioner from utilizing his or her certified electronic prescribing application to transmit an electronic prescription for a controlled substance in accordance with this act and federal requirements.

**Q: What should practitioners do if they experience a temporary technological or electrical failure?**

A: Act 96 requires a practitioner to correct any cause for the failure that is reasonably within the practitioner's control within 72 hours. It is recommended that during any time a practitioner is unable to electronically prescribe due to a temporary technological or electrical failure, the practitioner note in the patient's medical record the reason for issuing a prescription via an alternative method. Practitioners and health care facilities should also consider developing policies for tracking these instances and the steps taken to correct the temporary technological or electrical failure in the event that the Department of Health or other governmental entity investigates these instances.

**Q: What should a practitioner do if a patient intends to have a prescription dispensed outside of the commonwealth?**

A: It is not mandated that a practitioner verify or follow-up with a pharmacy to ensure that the patient filled a prescription outside the commonwealth. If a practitioner issues a written prescription via alternative method due to an exception, the practitioner should note this reason in the patient's medical record.

**Q: In a case where any statutory exception or temporary exemption applies, what kind of prescription paper is acceptable for use?**

A: The Centers for Medicare & Medicaid Services (CMS) requires all written prescriptions for outpatient drugs prescribed to a Medicaid beneficiary to be on paper that meets all three baseline characteristics of tamper-resistant pads. [Click here](#) for more information.



**Q: Will practitioners be required to issue electronic prescriptions for compounds containing a controlled substance element?**

A: Yes. Except in cases where the compounds containing a controlled substance cannot be electronically prescribed due to limitations of the industry accepted data standards.

**Q: What is a collaborative practice agreement between a practitioner and a pharmacist?**

A: The regulations concerning collaborative management of drug therapy went into effect in August 2015. See Title 49 chapter 27. Specifically, sections 27.301 and 27.302 address management of drug therapy in institutional and non-institutional settings, respectively. The collaborative agreement must be maintained on the premises of the pharmacy and the practitioner for review during inspection by or upon request of the Department of Health.

**Q: What classifies as a standing order?**

A: A standing order is an instruction or prescribed procedure in force permanently or until changed or canceled; especially any of the rules for the guidance and government of parliamentary procedure which endure through successive sessions until vacated or repealed. Standing orders usually name the condition and prescribe the action to be taken in caring for the patient, including the dosage and route of administration for a drug or the schedule for the administration of a therapeutic procedure. Standing orders are commonly used in intensive care units, coronary care units, and emergency departments.

**Q: What classifies as drug research protocol?**

A: A drug research protocol is a precise and detailed plan for the study of a biomedical problem or for a regimen of therapy; an explicit, detailed plan of an experiment, procedure, or test. A research protocol clearly and plainly provides an overview of a proposed study in order to satisfy an organization's guidelines for protecting the safety of human subjects who might be impacted by the work. Research protocols are typically submitted to Institutional Review Boards (IRBs) within universities and research centers.

**Q: What is classifies as an “emergency situation” pursuant to Federal or State law and regulations of the board?**

A: A situation which, in a prescriber’s good faith professional judgment, creates an immediate threat of serious risk to the life or physical health of the patient.

**Q: What should a practitioner do if a patient’s pharmacy is not set up to process electronic prescriptions?**

A: The practitioner must notate this information in the patient’s medical record.



**Q: Are there additional exemptions?**

A: Currently there are none; however, the department may grant additional exemptions beyond the exemptions provided for in subsections (a) and (b), subject to the act of June 25, 1982 (P.L.633, No.181), known as the "Regulatory Review Act.

**Q: What are the practitioner and dispenser responsibilities when transmission of an electronic prescription for a controlled substance fails?**

A: The practitioner may issue a written or oral prescription as a replacement of the original electronic prescription that failed. The practitioner shall document within the medical record that electronic transmission failed.

**Q: Are there any exceptions to Act 96 requirements when practitioners dispense or administer controlled substances directly to patients?**

A: Yes. In cases when practitioners dispense or administer directly to the patient they are exempt from [Act 96](#) requirements. See previous question regarding definitions of prescribe, administer, and dispense.

Subject to change



**Q: Certain elements may be changed or added to a controlled substance prescription by a dispenser with practitioner authorization. If a prescription is sent electronically that requires information to be added or changed, how should the information be added to the electronic prescription?**

A: Federal law requires the following elements: Prescriber's name, prescriber's DEA number, prescriber's address, patient's name, patient's address, date, drug name, drug strength, dosage form, quantity prescribed, direction for use, and prescriber's signature. Federal law does not allow any changes to be made to a schedule II substance. However, under federal law, changes to most elements can be made orally for schedule III-V.

Information added/changed on an electronic prescription must be annotated and maintained electronically. Dispensers should consult their software vendor or corporate headquarters for guidance to ensure annotation meets all federal requirements. The process of annotating a prescription may vary based on the software used.

When a prescription prepared by a practitioner is incomplete, the practitioner may orally furnish the missing information to the pharmacist and authorize him or her to enter the missing information on the prescription. The pharmacist shall write the date he or she received the oral authorization on the prescription and shall affix his or her signature. This procedure shall not apply to unsigned or undated prescriptions or where the name and/or quantity of the controlled substance is not specified or where the name of the ultimate user is missing. The pharmacist is not required to obtain authorization from the practitioner to enter the patient's address, sex or age if the pharmacist obtains this information through a good-faith effort.

**Q: Can a Pennsylvania dispenser legally accept an out-of-state electronic prescription for a controlled substance?**

A: Yes. It is prudent on the part of the pharmacist to verify the authenticity of any controlled substance prescription presented to them.

**Q: Can EPCS prescriptions be transferred between pharmacies?**

A: Yes. Prescriptions may be transferred in accordance with the Pharmacy Act (63 P. S. § § 390-1—390-13).

**Q: Can an agent or employee of the prescriber create or prepare an electronic prescription?**

A: Under federal law an agent may prepare a prescription for a prescriber but only the prescriber can sign.



**Q: Can an agent or employee of the prescriber electronically sign an electronic prescription?**

A: No. Only individuals licensed to prescribe may review and sign the prescription.

**Q: Can an agent or employee of the prescriber transmit an electronic prescription to the pharmacy?**

A: The signing and transmission of an electronic prescription are two distinct actions. Only the practitioner may review and electronically sign the prescription. Once signed, an agent or employee of the practitioner may transmit the prescription on behalf of the practitioner. The act of transmission must be independent of the review and signature process.

**Q: Can a pharmacy accept an electronic prescription as a follow-up to an oral prescription?**

A: Yes. A pharmacy may accept an electronic prescription as a follow-up to an oral prescription. It is incumbent on the pharmacist to know the limitations of their software application and if it can accurately accept and archive an electronic follow-up prescription. If the software application cannot do this, a paper prescription is necessary and permissible. This should be communicated to the practitioner at the time the prescription is called in, and the need for the follow-up is discussed.

**Q: Which exceptions need to be documented in the patient record?**

A: Practitioners must document in the patient record when unable to electronically prescribe in any of the following scenarios:

1. Under circumstances when an electronic prescription is not available due to a temporary technological or electrical failure;
2. By a practitioner treating a patient in an emergency department or health care facility under circumstances when the practitioner reasonable determines that electronically prescribing a controlled substance would be impractical for the patient to obtain the controlled substance prescribed by the electronic prescription or would cause an untimely delay resulting in an adverse impact on the patient's medical condition;
3. Under circumstances where the pharmacy that receives the prescription is not set up to process electronic prescriptions.