# PENNSYLVANIA ACT 96
# MANDATORY ELECTRONIC CONTROLLED SUBSTANCE PRESCRIPTIONS

## SUMMARY & IMPLEMENTATION GUIDELINES

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## INTRODUCTION

Act 96 of 2018 significantly amended the Pennsylvania Drug Device and Cosmetic Act ("Drug Act") to require all health care practitioners writing prescriptions for controlled substances in Pennsylvania to submit their prescriptions electronically to the pharmacy. The term "practitioner" means (a) a physician, and (b) a CRNP or Physician Assistant who has prescriptive authority approved by the applicable state licensing board.

## EFFECTIVE DATE

Act 96 takes effect on **October 24, 2019**. As of October 24, 2019, controlled substance prescriptions issued on paper will no longer be permissible in Pennsylvania with certain exceptions listed on page 5.

## DEPARTMENT OF HEALTH REGULATIONS

Several sections of Act 96 address the requirement of the Department of Health to publish regulations to implement provisions of Act 96. As of this writing, these regulations have not been published. This means that information which may be necessary for a practice to fully implement Act 96 requirements is not currently available. PAOrtho will monitor the Pennsylvania Bulletin and other means of communication for any published regulations and advise PAOrtho members accordingly.

## MANDATORY ELECTRONIC PRESCRIPTIONS FOR SCHEDULE II – V CONTROLLED SUBSTANCES

Pennsylvania's Drug Act has been amended by Act 96 to state as follows:

> **Except when dispensed or administered directly to the patient** by a practitioner or his authorized agent, other than a pharmacist to an ultimate user, **no controlled substance in Schedule II shall be dispensed without an electronic prescription** of a practitioner

Act 96 also amended Section 11(b) of the Drug Act to apply the same rule to Schedule III, IV and V controlled substances.

Therefore, **beginning October 24, 2019, all prescriptions for Schedule II through V controlled substances cannot be dispensed without an electronic prescription**.

**IF YOU PRESENTLY PRESCRIBE** SCHEDULE II THROUGH V CONTROLLED SUBSTANCES ELECTRONICALLY AND COMPLY WITH DEA REQUIREMENTS TO DO SO, **SKIP TO PAGE 5 "Exceptions to the New Requirement".**

**IF YOU DO NOT PRESENTLY PRESCRIBE S**CHEDULE II THROUGH V CONTROLLED SUBSTANCES ELECTRONICALLY, **READ ON.**

## NECESSARY IMPLEMENTATION MEASURES

Act 96 requires all electronic prescription computer applications to meet the requirements in the DEA (US Drug Enforcement Administration) regulations at 21 C.F.R. §1311.120. Those regulations are summarized in more detail below.

To ensure each orthopaedic practice is prepared for the October 24, 2019 implementation date, the following steps should be taken.

For a practitioner to transmit prescriptions for controlled substances electronically, the DEA requires that the practitioner submit "identity proofing" information to a credentialed service practitioner ("CSP") or certification authority ("CA"). The CSP or CA must then issue two pieces of information used to generate or activate the authentication credential using two channels. This process is commonly referred to as Two-Factor Authentication ("2FA").

**Step 1** – Contact all the EHR (electronic health record company) providers through which your physicians and extenders currently E-prescribe. Work with the third party (the CSP or CA referenced above) ***that each EHR has chosen*** to verify the identity of each provider. Common examples are IdenTrust or Imprivada. The CSP or CA will provide a "digital certificate" for each provider. There will be a waiting period before validation of a provider's identity.

**Step 2** – Depending on the EHR's choice, each provider will need to establish a 2FA process utilizing a method such as a smart phone application or USB token. Either method will require steps to set up.

The DEA mandates the generation of two reports: 1) Audit Report for the administrator; and 2) Controlled Substance Prescription Report for the practitioner.

**Step 3** – DAILY AUDIT REPORT - The EHR must run an Audit Report at the end each day to search for any Auditable Events as listed in the DEA regulations. The six Auditable Events are:

a) **Attempted unauthorized access to the electronic prescription application, or successful unauthorized access where the determination of such is feasible**.

b) Attempted unauthorized **modification or destruction of any information or records, or successful unauthorized modification or destruction of any information or records where the determination of such is feasible**.

c) Interference with application operations of the prescription application.

d) Any setting of or change to logical access controls related to the issuance of controlled substance prescriptions.

e) Attempted or successful interference with audit trail functions.

f) For application service providers, attempted or successful creation, modification, or destruction of controlled substance prescriptions or logical access controls related to controlled substance prescriptions by any agent or employee of the application service provider.

The electronic prescription application must analyze the audit trail at least **once every calendar day and generate an incident report that identifies each Auditable Event**.

Any person designated to set logical access controls must determine whether any identified auditable event represents a security incident that compromised or could have compromised the integrity of the prescription records. Any such incidents must be reported to the electronic prescription application provider and to the DEA within one business day.

A point person and a backup point person must review the report daily. Any potential issues must be communicated to the EHR and the DEA.

**Step 4** – MONTHLY CONTROLLED SUBSTANCE PRESCRIPTION REPORT - The EHR must run a Controlled Substance Prescription Report at the end of each month and provide it to the provider. A process to verify that the report has been reviewed must be established. For example, some systems will provide the report the same way it returns labs to the provider by requiring the provider "sign off" as confirmation the report was reviewed.

## ITEMS TO NOTE UNDER DEA REGULATIONS

The following compliance issues under DEA regulations must be followed:

- If an attempt to electronically prescribe a prescription fails to transmit, the prescription can be printed but must include a statement on the printed script that indicates the transmission failed, to which pharmacy it was attempted to be sent, and the date and time it was sent.

- A prescription for a controlled substance **initiated electronically** may not be printed first then transmitted electronically. A prescription for a controlled substance may be transmitted electronically then printed but must include "Copy – Not for Dispensing" –OR– "Pharmacy Didn't Receive Script" on the printed script indicating the transmission failed, to which pharmacy it was attempted to be sent, and the date and time it was sent.

- A prescription for a controlled substance **which has been printed** may not be electronically prescribed. If a script is printed but needs to be electronically prescribed, it must be reordered or a new one created.

- Only the prescribing practitioner may sign and transmit electronic prescriptions for controlled substances. Therefore, all practitioners using EPCS must set up a Script Queue.

- The 2FA process must occur for every controlled substance transmitted electronically. Only one controlled substance may be sent at a time unless transmitting multiple prescriptions for one patient.

## ADDITIONAL DEA ELECTRONIC PRESCRIPTION APPLICATION REQUIREMENTS

Act 96 incorporates several sets of DEA regulations that must be followed in order to comply with Act 96. In addition to the T2FA and Reporting requirements summarized above, DEA regulations require the following:

1. The e-prescription (eRx) must link each prescriber, by name, to at least one DEA registration number.

2. The eRx must be capable of setting the logical access controls to limit permissions to make sure the prescription is ready for signing and execute logical access controls.

3. If a practitioner has more than one DEA number, the eRx application must require the practitioner or his agent to select the DEA registration number to be included on the prescription.

4. The eRx application must present for the practitioner's review and approval all the following data for each controlled substance prescription:

    - The date of issuance;
    - The full name of the patient;
    - The drug name;
    - The dosage strength and form, quantity prescribed and directions for use;
    - The number of refills authorized;
    - The earliest date on which the pharmacy may fill each prescription; and
    - The name, address and DEA registration number of the prescribing practitioner.

5. If a practitioner seeks to prescribe more than one controlled substance at one time for a patient, the eRx application may allow the practitioner to sign multiple prescriptions for that patient at one time using a single invocation of the 2FA protocol.

6. The eRx application must not allow alteration of any of the information required to be on the prescription.

7. The eRx application must not allow transmission of a prescription that has been printed.

## EXCEPTIONS TO THE NEW REQUIREMENT

Act 96 creates 11 different exceptions to the mandatory electronic controlled substance prescription obligation. The electronic prescription requirement does not apply 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**, a practitioner must, within 72 hours, seek to correct any cause for the failure that is reasonably within his or her control. Act 96 defines "temporary technological or electronic failure" to mean:

   > Any **failure of a computer system**, application or device, where 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.

3. By a practitioner and dispensed by a pharmacy located **outside of Pennsylvania**.

4. By a practitioner or a facility that **does not either have internet access or an electronic health records system**.

5. By a practitioner treating a patient in an **emergency department** or a health care facility if the practitioner reasonably determines that electronically prescribing a controlled substance would be **impractical** for the patient or would cause an **untimely delay resulting in an adverse impact on the patient's medical condition**.

6. For a patient in a hospice program, nursing home or residential health care facility.

7. For controlled substance compounded prescriptions.

8. Pursuant to a Collaborative Practice Agreement between a practitioner and a pharmacist, a standing order or a drug research protocol.

9. In an emergency situation defined by federal or state law.

10. Where the pharmacy that receives the prescription is not set up to process electronic prescriptions.

11. For controlled substances that are not required to be reported to the PDMP.

## A FAX IS NOT AN ELECTRONIC PRESCRIPTION

Act 96 created new §11(b.2) of the Drug Act, and states as follows:

> A prescription generated on an electronic system and **printed or transmitted via facsimile is not an electronic prescription**.

Therefore, faxes do not count as electronic prescriptions.

## PRESCRIBER RESPONSIBILITIES

Act 96 states that practitioners are subject to the responsibilities described in 21 C.F.R. §1311.102.

Under these DEA regulations, the practitioner must retain sole possession of the hard token and must not share the password or other knowledge factor, or biometric information, with any other person.

Also, if the practitioner is notified by a pharmacy that an eRx was not successfully delivered, he must ensure that any paper or oral prescription issued as a replacement of the original eRx indicates that the prescription was originally transmitted electronically to a particular pharmacy and that the transmission failed.

## SANCTIONS

Act 96 imposes the following sanctions on any provider who fails to comply with the electronic controlled substance prescription obligations summarized above, as follows:

1. A penalty of $100 will be imposed for the first through 10$^{th}$ violations.

2. A penalty of $250 for each subsequent violation after the 10$^{th}$ violation will be imposed.

3. There is a maximum fine of $5,000 per calendar year.

4. Violations will “reset” and will not carry over to subsequent calendar years.

5. Any fines imposed by the Department of Health for violating the electronic controlled substance prescription requirement will **not be reported by the Department of Health to the practitioner’s licensing board**.

6. Violations of Act 96 will **not be considered a disciplinary action or need to be reported by the practitioner as a violation to the practitioner’s licensing board**.

Therefore, non-compliance with the Act will cost physicians and extenders money but will not result in any licensure disciplinary action.

## EXEMPTION REQUEST

If a physician or extender is unable to timely comply with the electronic prescribing requirements, the provider may petition the Department of Health for an exemption from the requirements based upon economic hardship, technical limitations or exceptional circumstances.

The Department of Health is also required to publish regulations to implement this section. Any exemptions will be allowed for up to one year and can be renewed annually upon request subject to the Department of Health's approval.

## OTHER INFORMATION

LINKS TO DEA REGULATIONS

The full text of the DEA regulations relating to Practitioner Responsibilities and Electronic Prescription Application Requirements summarized above are accessible in the following links:

Practitioner Responsibilities

Electronic Prescription Application Requirements

PAOrtho members should review the foregoing and make sure all physicians and extenders who prescribe controlled substances are aware of these requirements.

PAOrtho will provide additional updates as more information becomes available.

Please email marisa@paorthosociety.org with questions or concerns.