E-Prescribing of Controlled Substances Forum
Sponsored by

Arizona Association of Health Plans

AzAHP

Arizona Association of Health Plans

The Arizona Association of Health Plans represents the private half of the public-private partnership that makes the AHCCCS program one of the most successful managed care programs in the Nation. AzAHP is proud to partner with Arizona Health-e Connections, advancing innovation and collaboration, to support our providers across the State of Arizona.

- Bridgeway
- Care1st
- Health Arizona Health Net
- Mercy Care MIHS

- Phoenix Health Plan
- Scan
- The UA Health Plans
- UnitedHealthcare Community Plan

Speaker Biography

Jeff Hull is a registered pharmacist with more than 30 years of experience in the industry. Jeff recently managed the physician engagement program within a premier pharmacy benefit manager. In this time, he helped expand the use of e-Prescribing to the company's pharmacy by more than 300 percent across the country.

In addition to consulting, he also works as an independent pharmacist, and has worked in chain drug store and mail order pharmacy settings as well. He has 15 years of experience in project and change management. He is currently pursuing a master's degree in health informatics. Jeff is a member of these pharmacy-related organizations: APhA, HIMSS, AHIMA, OPA (Ohio Pharmacists Association).

The e-Prescribing and EPCS Landscape

ePrescribing Statistics

- **Prescription Benefit**: Prescription Benefit information responses increased 33% in 2012.

- **Medication History**: Medication history use increased 48% in 2011. Nearly half of patient visits generated an electronically delivered medication history in 2011.

- **Prescription Routing**: 44% of prescriptions dispensed were e-prescribed in 2012. A record 788 million prescriptions were routed electronically in 2012, up 38% from 2011. {AZ eRx rate = 50%}

- **Prescribers**: By the end of 2012, 489,000 prescribers routed prescriptions electronically, up from 390,000 in 2011. This represents 69% of all office-based prescribers. {AZ prescribers electronically routing = 63%}

- **Community and Mail Order Pharmacists**: 93% of community pharmacies (including 85% of Independent Pharmacies) and 10 mail order pharmacies in the United States were connected for prescription routing in 2012.

- **Payers/PBMs**: Provided access to 255 million member records (patient lives) from participating health plans in 2012 for prescription benefit and medication history information.

Source: Surescripts

Let's Eliminate some *Confusion*

1. Is EPCS Legal?

2. What does AZ Pharmacy law allow?

3. What is an 'electronic Rx'?

4. What is required for ME to do EPCS?

EPCS is LEGAL in Arizona

DEA's Interim Final Rule for Electronic Prescriptions for Controlled Substances was published on March 31, 2010 at 75 FR 16236-16319 and became effective on June 1, 2010.

News

CHAPTER 184
HOUSE BILL 2369

CONTROLLED SUBSTANCES IN SCHEDULES II, III, IV AND V MAY BE DISPENSED AS ELECTRONICALLY TRANSMITTED PRESCRIPTIONS IF THE PRESCRIBING MEDICAL PRACTITIONER IS ALL OF THE FOLLOWING:

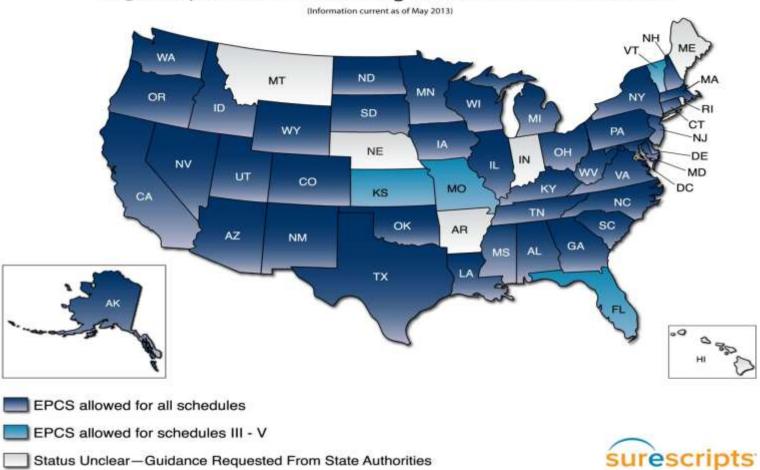1. PROPERLY REGISTERED BY THE UNITED STATES DRUG ENFORCEMENT ADMINISTRATION.
2. LICENSED IN GOOD STANDING IN THE UNITED STATES JURISDICTION IN WHICH THE MEDICAL PRACTITIONER PRACTICES.
3. AUTHORIZED TO ISSUE SUCH PRESCRIPTIONS IN THE JURISDICTION IN WHICH THE MEDICAL PRACTITIONER IS LICENSED.

National Map of EPCS readiness by State

Regulatory Status: E-Prescribing of Controlled Substances

(Information current as of May 2013)

EPCS allowed for all schedules

EPCS allowed for schedules III - V

Status Unclear—Guidance Requested From State Authorities

surescripts

EPCS is LEGAL in Arizona

ARIZONA REVISED STATUTES

ARTICLE 4. PROFESSIONAL PRACTICES
R4-23-407. PRESCRIPTION REQUIREMENTS

<u>Electronic transmission of a prescription order from a medical practitioner to a pharmacy</u>

2. For electronic transmission of a Schedule II, III, IV, or V controlled substance prescription order, the medical practitioner and pharmacy shall ensure that the transmission <u>complies with any security or other requirements of federal law.</u>
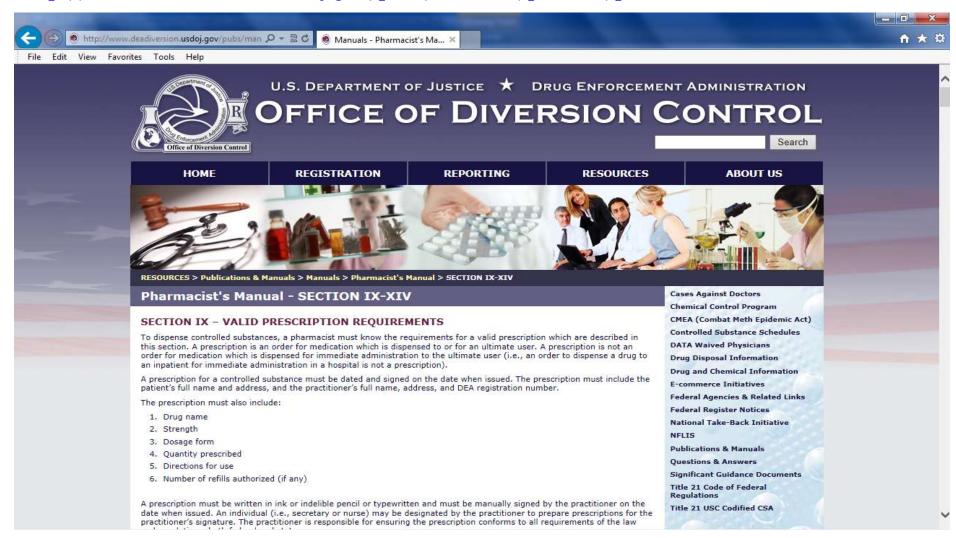
R4-23-407. Prescription Requirements

F. **Electronic transmission of a prescription order from a medical practitioner to a pharmacy**.

1. Unless otherwise prohibited by law, a medical practitioner or medical practitioner's agent may transmit a prescription order by electronic means, **directly** or **through an intermediary**, including an E-prescribing network, to the dispensing pharmacy as specified in A.R.S. § 32-1968.

2. For electronic transmission of a Schedule II, III, IV, or V controlled substance prescription order, the medical practitioner and pharmacy shall ensure that the transmission **complies with** any security or other requirements of federal law.

3. The medical practitioner and pharmacy shall ensure that all electronic transmissions comply with all the security requirements of state or federal law related to the privacy of **protected health information**.

4. In addition to the information required to be included on a prescription order as specified in A.R.S. § 32-1968, an electronically transmitted prescription order shall include:

> a. The **date of transmission**; and

> b. If the **individual transmitting the prescription** is not the medical practitioner, the name of the medical practitioner's authorized agent who transmits the prescription order.

5. A pharmacy receiving an electronically transmitted prescription order shall **maintain** the prescription order as specified in A.R.S. § 32-1964.

6. A medical practitioner or medical practitioner's agent shall transmit an electronic prescription order **only** to the pharmacy of the **patient's choice**

http://azsos.gov/public_services/Title_04/4-23.htm#Article_4

An Informational Outline of the Controlled Substances Act Revised 2010

http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_content.htm#9

This manual has been prepared by the Drug Enforcement Administration, Office of Diversion Control, as a guide to assist pharmacists in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the pharmacy profession.

Section IX – Valid Prescription Requirements

Electronic Prescriptions

On March 31, 2010 the DEA published in the Federal Register an interim final rule *Electronic Prescriptions for Controlled Substances* which became effective June 1, 2010. The rule revises DEA regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions. These regulations are an addition to, not a replacement of, the existing rules.

Persons who wish to dispense controlled substances using electronic prescriptions must select software that meets the requirements of this rule. As of June 1, 2010, only those electronic pharmacy applications that comply with all of DEA's requirements as set forth in 21 C.F.R. § 1311 may be used by DEA-registered pharmacies to electronically receive and archive controlled substances prescriptions and dispense controlled substances based on those prescriptions.

A registered pharmacy may process electronic prescriptions for controlled substances only if the following conditions are met:

   -The pharmacy uses a pharmacy application that meets all of the applicable requirements of 21 C.F.R. § 1311, and

   -The prescription is otherwise in conformity with the requirements of the CSA and 21 C.F.R. § 1311.

Section IX – Valid Prescription Requirements

A pharmacy cannot process electronic prescriptions for controlled substances until its pharmacy application provider obtains a third party audit or certification review that determines that the application complies with DEA's requirements and the application provider provides the audit/certification report to the pharmacy.

The audit report the pharmacy will receive from the pharmacy application provider will indicate if the application is capable of importing, displaying, and storing DEA-required prescription information accurately and consistently. If the third-party auditor or certification organization finds that a pharmacy application does not accurately and consistently import, store, and display the information related to the name, address, and registration number of the practitioner, patient name and address, and prescription information (drug name, strength, quantity, directions for use), the indication of signing, and the number of refills, the pharmacy must not accept electronic prescriptions for the controlled substance

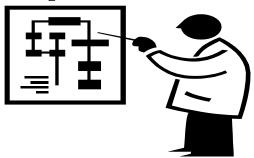# Section IX – Valid Prescription Requirements

The pharmacy must determine which employees are authorized to enter information regarding the dispensing of controlled substance prescriptions and annotate or alter records of these prescriptions (to the extent such alterations are permitted under DEA regulations). The pharmacy must ensure that logical access controls in the pharmacy application are set so that only such employees are granted access to perform these functions.

When a pharmacist fills a prescription in a manner that would require, under 21 C.F.R. § 1306, the pharmacist to make notation on the prescription if the prescription were a paper prescription, the pharmacist must make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record or linked files. When a prescription is received electronically, the prescription and all required annotations must be stored electronically.

Benefits of EPCS to Prescribers and Pharmacies

Creates <u>one workflow</u> for all electronic prescriptions

Reduces fraud and abuse by preventing forgeries and stolen Rx pads

Condenses recordkeeping for patients' prescription history

Eliminates illegible hand-written Rx's and decreases adverse drug events

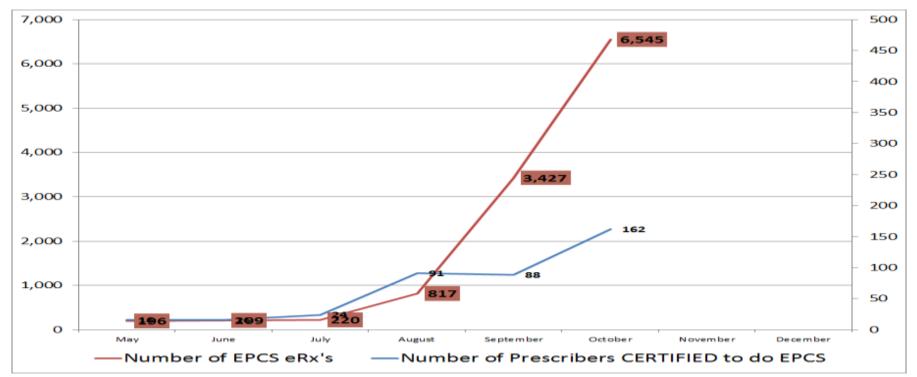# Understanding the Arizona market for EPCS & e-Prescribing

POINT-OF-CARE PARTNERS

HIT Strategy & Management Consultants

Current Statistics for EPCS Prescribers
(as of 10/31/13)

2013	Number of Prescribers CERTIFIED to do EPCS	Number of Prescribers who have DONE EPCS	Number of EPCS eRx's	Number of Pharmacies EPCS enabled
May	16		196	n/a
June	16		209	263
July	24		220	263
August	91	37	817	404
September	88	47	3,427	407
October	162	55	6,545	411

Pharmacy Readiness

- Pharmacies must also be certified to accept EPCS Rx's
- Walgreens & CVS both now accept EPCS Rx's
- Fry's, Safeway and Wal-Mart plan to be by EOY

#	Name	# of Stores
1	Walgreens Drug Store	250
2	CVS/pharmacy	136
3	FRYS PHARMACY	119
4	SAFEWAY	98
5	Wal-Mart Neighborhood Market/Pharmacy	97
6	TARGET PHARMACY	47
7	OSCO DRUG/PHARMACY	35
8	Bashas' United Drug	30
9	Costco Pharmacy	17
10	Sam's Club Pharmacy	15
11	KMART	12
		856

Prescriber eRx & EHR technology vendors

The following prescriber software vendors have products that have achieved Surescripts certification and completed their third-party audits for e-prescribing of controlled substances:

- Allscripts ePrescribe

- Cerner Corporation

- DrFirst*

- Epic

- NewCrop*

- NextGen

- RxNT

* Additional EHR solutions are able to transmit EPCS transactions over the Surescripts network through their use of DrFirst and NewCrop as the e-prescribing application

EPCS Requirements for EHRs

All applications involved in the EPCS process must meet specific security requirements to prevent diversion, fraud, and abuse. The software they use meets the DEA's requirements set forth in the IFR.

This is done in one of two ways:

Third Party Audit: The first is for the application provider to undergo a third party audit to ensure software compliance with the IFR. This must be   performed by an appropriately credentialed auditor:

- The third party audit may be conducted by a person qualified to perform a WebTrust, SysTrust, or SAS 70 audit.
- The audit may be conducted by a Certified Information System Auditor who performs compliance audits as regular ongoing business activity.

Certification: The second option is for the application to be certified by a DEA Approved Certifying Organization.

DEA-ACO's and their EPCS certification processes are reviewed and approved by the DEA. ACO certification of an application signifies that the application is compliant with the DEA EPCS Rule as expressed in the IFR.

Prescriber Prescription Logs

➢ Electronic prescription applications must generate a log of all controlled substances prescriptions issued by a practitioner during previous calendar month and provide log to practitioner no later than seven calendar days after the month (21 CFR 1311.120(b)(27)(i))

➢ Application must be capable of generating a log of all controlled substance prescriptions issued by a practitioner for a period specified by the practitioner upon request; information must span at least previous two years (21 CFR 1311.120(b)(27)(ii))

➢ All logs generated must be archived; logs must be readable (21 CFR 1311.120(b)(iii), (iv))

➢ Logs sortable by patient name, drug name, and date of issuance (21 CFR 1311.120(b)(27)(v))

EPCS Set-up Steps for Prescribers

1. Contact your EHR and ask if they are certified to do EPCS
   a) If yes, proceed to step 2
   b) If no, then you cannot do EPCS until they are certified

2. Complete Identity Proofing requirement

3. Set up Access Controls

4. Obtain Dual Authentication device or process

5. Adhere to digital signature and audit requirements

To find out more about certification for EPCS or which vendors are certified, you can also visit the Surescripts website:
http://www.surescripts.com/about-e-prescribing/e-prescribing-of-controlled-substances

Identity Proofing

➤ What is it?

  ➤ The process by which a credential service provider or certification authority validates sufficient information to uniquely identify a person

  ➤ Necessary to verify that a person is who he claims to be

➢ What does two-factor authentication mean?

➢ Proves the prescriber is authorized to digitally sign an electronic prescription for a controlled substance by using <u>two of the following:</u>

- Something you have (hard token)
- Something you know (password, PIN)
- Something you are (biometric)

POSSIBLE TYPES OF HARD TOKENS

Cryptokey & One-time password generator

EPCS Set-up Steps for Pharmacies

1. Contact your Pharmacy System vendor and ask if they are certified to do EPCS
   a) If yes, proceed to step 2
   b) If no, then you cannot accept EPCS Rx's until they are certified

2. Set up Access Controls

3. Create an eRx Audit process

4. Adhere to record-keeping requirements

To find out more about Pharmacy Requirements for EPCS, visit the DEA website: http://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/index.html

Pharmacy Overview

➢ Application provider makes audit/certification report available to pharmacies using or considering use of application (21 CFR 1311.300(f))

➢ Pharmacies may only process electronic controlled substances prescriptions using applications which have been determined to meet DEA's requirements (21 CFR 1311.200(a), (b); 1311.300(g)

➢ Pharmacy receives prescription, archives all records for two years

Pharmacy Access Controls

➤ Access controls ensure that only individuals authorized to enter information regarding dispensing and annotate or alter (where permissible) prescription information are allowed to do so (21 CFR 1311.200(e))

➤ Pharmacy sets access controls to ensure only authorized persons can annotate, alter (where permissible), delete prescriptions (21 CFR 1311.205(b)(1), (2))

Receipt of Prescriptions

➤ Pharmacy receives prescription which has been digitally signed by last intermediary (21 CFR 1311.205(b)(3); 1311.210(a), (b)) OR

➤ Pharmacy receives prescriptions and digitally signs upon receipt (21 CFR 1311.205(b)(3), (4); 1311.210(a)) OR

➤ Pharmacy receives prescription signed with practitioner's digital certificate (21 CFR 1311.205(b)(3), (5); 1311.210(c))

Pharmacy Annotations, Records

➤ All annotations must be electronic (21 CFR 1311.200(f))

➤ Prescriptions can be retrieved by practitioner name, patient name, drug name, date dispensed; sortable (21 CFR 1311.205(b)(11), (12))

➤ Pharmacy records must be backed up daily (21 CFR 1311.205(b)(17))

➤ All records must be retained electronically (21 CFR 1311.205(b)(18); 1311.305)

Audit Trails

- A record showing who has accessed an application and what operations the user performed during a given period (21 CFR 1300.03)

- Practitioner: application tracks creation, alteration, indication of readiness for signing, signing, transmission, or deletion of a controlled substance prescription; notification of failed transmission (21 CFR 1311.120(b)(23))

- Pharmacy: application Tracks receipt, annotation, alteration, deletion of controlled substance prescriptions (21 CFR 1311.205(b)(13)(i))

Audit Trails

- Setting of, or changes to, access controls (21 CFR 1311.120(b)(23)(ii); 1311.205(b)(13)(ii))

- Other auditable events (21 CFR 1311.120(b)(23)(iv); 1311.150(a); 1311.205(b)(13)(iii); 1311.215(a))

- Date and time of event, type of event, identity of person, outcome of event (success or failure) (21 CFR 1311.120(b)(24); 1311.205(b)(14))

Reporting Security Incidents

➢ Electronic Prescription and pharmacy applications must conduct internal audits to determine whether security incidents have occurred (21 CFR 1311.150; 1311.215)

➢ Automated function; generates a report for human review

➢ If person reviewing report determines that incident has occurred, reports incident to application provider and DEA (21 CFR 1311.150(c); 1311.215(c))

Best Practices for Pharmacists
Getting the most from e-prescribing

1. Inform local physicians that you are enabled to accept prescriptions electronically, and that you can start sending renewal authorization requests immediately.

2. Educate your entire staff about electronic prescribing and how it works within your pharmacy management software.

3. Identify a staff member to become your local expert on your pharmacy's electronic prescribing ability.

4. Take full advantage of managing renewal authorization requests electronically.

5. If you do not receive a prompt response from a physician for a prescription renewal authorization request you've sent electronically, please do not resend another request for the same prescription within 24 hours.

6. Communicate with practices that you believe are sending problematic e-prescriptions to your pharmacy.

7. Report issues with e-prescriptions that are causing you concern.

8. Communicate prescription fill-time expectations to local physicians and their staffs, as well as patients.

9. Ensure that information in your pharmacy system about local prescribers is up-to-date.

10. Turn over every leaf before turning away a patient.

AzHeC Programs & Initiatives

Arizona Health-e Connection
Advancing health and wellness through information technology

HIT

HIE

REC – Helping Arizona providers meet their health IT goals

Policy development – leading legislative efforts

HIE Marketplace – viable HIE solutions for providers

eRx Initiative – increasing adoption

HINAz Provider Outreach – Recruitment & Enrollment

HIT & HIE Stakeholder Engagement – committees, online forums, etc.

Consumer Outreach - education, awareness & engagement

AzHeC eRx Goals

By end of 2013, aim to achieve the following:

- **70%** of all Arizona prescription electronically routed to pharmacies

- **60%** of Arizona prescribers routing prescriptions electronically

- **100%** of Arizona pharmacies with e-prescribing capabilities

EPCS Prescriber Incentive Program

- Arizona prescribers that meet specific requirements may be eligible to receive a $200 reimbursement.
- A maximum of 125 awards will be given out on a first come first served basis to those who qualify.
- Individual prescribers **MUST**:
  - Currently use an EPCS certified system.
  - Have completed the identity proofing process for two factor authentication and provide a copy of the receipt.
  - Intend to continue to use EPCS for the next three years.
  - Complete the verification form on the AzHeC website, with all accurate and qualifying information.

> **To apply for the incentive program visit:**
> **http://www.azhec.org/?page=EPCS**

Questions?

www.pocp.com