



PDX, Inc.

Independent Accountant's Report

**For Compliance of the Enterprise Pharmacy System and the PDX
Classic Pharmacy System with the Electronic Prescriptions for
Controlled Substances Final Rule as of August 31, 2013**



C O N T E N T S

	Page
INDEPENDENT ACCOUNTANT’S REPORT	1
MANAGEMENT’S ASSERTION	2
DESCRIPTION OF PDX’S PHARMACY MANAGEMENT APPLICATION SYSTEM	4
INTRODUCTION TO EPCS REQUIREMENTS.....	5
APPENDIX A	8

INDEPENDENT ACCOUNTANT'S REPORT

To the Board of Directors:

We have examined management's assertion, included in the accompanying "Compliance of the Enterprise Pharmacy System and the PDX Classic Pharmacy System with the Electronic Prescriptions for Controlled Substances Final Rule as of August 31, 2013", that PDX, Inc's ("PDX") Enterprise Pharmacy System and PDX Classic Pharmacy System complied with the *Code of Federal Regulations* Title 21, *Food and Drugs*, Parts 1300, 1304, 1306, and 1311, "Electronic Prescriptions for Controlled Substances; Final Rule," established by the Drug Enforcement Administration (DEA) of the U.S. Department of Justice (Pharmacy Management Criteria (PMA) criteria) as of August 31, 2013. Management is responsible for PDX's compliance with those requirements. Our responsibility is to express an opinion on management's assertion about compliance of the Enterprise Pharmacy System and PDX Classic Pharmacy System based on our examination. We have determined the following per 1311.300(h)(i):

- (1) The Enterprise Pharmacy and PDX Classic Pharmacy systems meets the requirements in 1306.05(a), which indicates that the prescription was signed as required by 1311.205(b)(6), and the number of refills as required by 1306.22 of this chapter, can be consistently and accurately imported, stored, and displayed.
- (2) The pharmacy application accepts Emdeon's (the intermediary's) verification of prescriptions with the practitioner's digital signature through a digital signature flag and the intermediary is responsible for importing, storing, and verifying the digital signature on behalf of the Enterprise Pharmacy and PDX Classic Pharmacy Systems.

Our examination was conducted in accordance with attestation standards established by the American Institute of Certified Public Accountants and, accordingly, included examining, on a test basis, evidence about PDX's compliance with those requirements and performing such other procedures as we considered necessary in the circumstances. We believe that our examination provides a reasonable basis for our opinion. Our examination does not provide a legal determination on PDX's compliance with specified requirements.

Because of the nature of the applications, our procedures only extended to the capabilities of release versions 2505.010 and 4.7.03.003 of the Enterprise Pharmacy and PDX Classic Pharmacy Systems respectively, in the PDX test environment. Users must apply the necessary updates and security features to the software in the on-premise versions hosted within their environments. Our procedures did not extend to the on-premise, production versions hosted in user's environments.

In our opinion, the Enterprise Pharmacy and PDX Classic Pharmacy systems complied, in all material respects, with the aforementioned requirements as of August 31, 2013.

This report is intended solely for the information and use of PDX, user entities of PDX's Enterprise Pharmacy System and PDX Classic Pharmacy System, independent auditors and practitioners providing services to such user entities, and regulators and is not intended to be and should not be used by anyone other than these specified parties.

Weaver and Tidwell, L.L.P.

Weaver and Tidwell, L.L.P.
Dallas, TX
September 13, 2013

MANAGEMENT OF PDX INC.'S ASSERTION REGARDING COMPLIANCE OF THE ENTERPRISE PHARMACY SYSTEM AND THE PDX CLASSIC PHARMACY SYSTEM WITH THE ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES FINAL RULE AS OF AUGUST 31, 2013

It is our belief to the best of our knowledge that the Enterprise Pharmacy System and the PDX Classic Pharmacy System comply with the Pharmacy Management Application criteria specified in 21 CFR parts 1300, 1304, 1306, 1311 (collectively "the criteria") as of August 31, 2013, and are supported by the IT General Controls we deemed to be necessary. The criteria are included in Appendix A of the attached description.

Our assertion is supported by our internal evaluation of the compliance of the Enterprise Pharmacy System and the PDX Classic Pharmacy System with the criteria. During this evaluation, management determined that the following criteria were not applicable to the Enterprise Pharmacy System and the PDX Classic Pharmacy System at the time of this report due to mitigating controls in place or the use of a third party:

- 1311.205(b)(13) The pharmacy application maintains an audit trail of all actions related to the following:
 - (i) The deletion of a controlled substance prescription.
- 1311.205(b)(3) The pharmacy application digitally signs and archives a prescription on receipt or be capable of receiving and archiving a digitally signed record.
- 1311.205(b)(4) For pharmacy applications that digitally sign prescription records upon receipt, the digital signature functionality meets the following requirements:
 - (i) The cryptographic module used to digitally sign the data elements required by part 1306 of this chapter is at least FIPS 140-21 Security Level 1 validated.
 - (ii) The digital signature application and hash function complies with FIPS 186-32 and FIPS 180-3.3
 - (iii) The pharmacy application's private key is stored encrypted on a FIPS 140-2 Security Level 1 or higher validated cryptographic module using a FIPS-approved encryption algorithm.
 - (iv) For software implementations, when the signing module is deactivated, the pharmacy application clears the plain text password from the application memory to prevent the unauthorized access to, or use of, the private key.
 - (v) The pharmacy application has a time application that is within five minutes of the official National Institute of Standards and Technology time source.
- 1311.205(b)(5) The pharmacy application verifies a practitioner's digital signature (if the pharmacy application accepts prescriptions that were digitally signed with an individual practitioner's private key and transmitted with the digital signature).
- 1311.210(c) If a pharmacy receives a digitally signed prescription that includes the individual practitioner's digital signature, the pharmacy application:
 - (1) Verifies the digital signature as provided in FIPS 1863, as incorporated by reference in § 1311.08.
 - (2) Checks the validity of the certificate holder's digital certificate by checking the certificate revocation list. The pharmacy may cache the CRL until it expires.
 - (3) Archives the digitally signed record. The pharmacy record retains an indication that the prescription was verified upon receipt. No additional digital signature is required.

- 1311.145(a) An individual practitioner who has obtained a digital certificate as provided in §1311.105 may digitally sign a controlled substance prescription using the private key associated with his digital certificate.
- 1311.145(b) The electronic prescription application must require the individual practitioner to complete a two-factor authentication protocol as specified in §1311.140(a)(4) to use his private key.
- 1311.145(c) The electronic prescription application must digitally sign at least all information required under part 1306 of this chapter.
- 1311.145(d) The electronic prescription application must electronically archive the digitally signed record.
- 1311.145(e) A prescription that is digitally signed with a practitioner's private key may be transmitted to a pharmacy without the digital signature.
- 1311.145(f) If the electronic prescription is transmitted without the digital signature, the electronic prescription application checks the certificate revocation list of the certification authority that issued the practitioner's digital certificate. If the digital certificate is not valid, the electronic prescription application does not transmit the prescription. The certificate revocation list may be cached until the certification authority issues a new certificate revocation list.
- 1311.145(g) When the individual practitioner digitally signs a controlled substance prescription with the private key associated with his own digital certificate obtained as provided under § 1311.105, the electronic prescription application is not required to digitally sign the prescription using the application's private key.

The attached description of services summarizes those aspects of the Enterprise Pharmacy System and the PDX Classic Pharmacy System covered by our assertion.

DESCRIPTION OF PDX, INC.'S PHARMACY MANAGEMENT APPLICATIONS AND RELATED SERVICES

Company Overview

Located in Fort Worth, Texas, National Health Systems, Inc., was founded in 1978 with PDX, Inc. being founded in 1985. The more than 400 employees provide customers with key products from electronic healthcare records to accounts receivable solutions. Almost 10,000 pharmacies across the U.S. benefit from technologies provided by PDX® and affiliates Rx.com® and NHIN®. PDX continues to build on its 25+ year commitment to excellence in retail pharmacy and patient care. Its single-source, integrated solution is unmatched by any other single provider or group of technology providers. It features the fast, intuitive, and advanced Enterprise Pharmacy System—already the choice of 21 chains and one major managed care plan; the portable, interoperable Rx.com Electronic Pharmacy Record which contains almost two billion prescriptions and 90 million patients; industry-leading accounts receivable services from Absolute^{AR}; store-based mail order and central fill services from Rx.com; pharmaceutical manufacturer performance programs from Rx.com Manufacturer Services; and more.

Description of the Pharmacy Management Applications and the IT Environment

Pharmacy software and services including pharmacy management systems used by 10,000 pharmacies in the U.S., a national portable, interoperable Electronic Pharmacy Record, pharmacy data services, accounts receivable submission and reconciliation, store-based mail order and central prescription fulfillment services, electronic prescriptions, and pharmaceutical manufacturer programs provided to retail pharmacy including drug store chains, mass merchants, supermarket chains, and independent pharmacies.

PDX Enterprise Pharmacy System

An advanced and intuitive pharmacy system, EPS features two implementations—advanced Workflow, ideal for pharmacies that want to streamline processes and balance work across stores and call centers and RapidFill™, perfect for pharmacies needing a solution that impacts efficiency without significantly altering in-store processes.

With RapidFill, EPS runs like a traditional pharmacy system, in that users can perform many of the required prescription filling steps at one location/station and with a maximum aggregation of those steps. RapidFill is ideal for pharmacies that have low-volume filling or reduced staff.

With Workflow, EPS dispenses tasks to users one-at-a-time, based on their roles. Workflow assigns the right task to the right person at the right time, creating a prescription filling process with more steps than RapidFill, but with arguably more accuracy in a higher volume environment. Workflow is ideal for pharmacies that have high-volume filling and numerous staff to fulfill the roles.

The infrastructure required to support the EPS application includes:

- Oracle 10g or later server
- A supported version of Redhat, AIX, or SUSE operating systems
- Internet Explorer 8 - release 8.0.6001.18702 or greater

In addition, security features of the application, version 2505.010 include:

- Role based security must be enabled
- Biometric device - Digital Persona DP OneTouch version 1.3.0.671 or greater or,
- Digital Persona Integrator Gold 4500 Reader

The application allows for the backing up of data daily using the backup features within the application however it is ultimately the responsibility of the client to establish backup schedules and procedures to configure the backup of prescription records.

PDX supports an EPS store server running in a virtualized environment. With respect to the System being operated in virtual environments (VMware, Hyper-V, Citrix, etc.) and/or when a customer is employing the available direct read-only database access to the Enterprise Pharmacy System's embedded database, as well as access to the database diagnostics pack, prior to requesting assistance from PDX for a System error or performance issue, the customer will apply reasonable efforts to diagnose whether the virtual environment is the cause of the System error.

EPS uses an embedded Oracle database, which is configured to automatically back up data, by writing backup files to the customer's system's file system. It is recommended to periodically off-load these files to an off-site location, or to an external hard drive. Adequate off-site storage, as well as network infrastructure to support this periodic off-loading of backup files is the responsibility of the customer. If the customer's server is running Linux, EPS can be configured to automatically back up data to an external hard drive.

PDX offers an optional Turnkey Solution: a standard server model PDX selects that comes pre-loaded with EPS. This option provides the convenience of a ready-to-go system, but provides standardized, optimized, and low-cost hardware that PDX thoroughly tests.

PDX Classic Pharmacy System

The PDX Pharmacy System is a software solution for chain pharmacies and high-volume independents. PDX addresses the requirements of high volume prescription filling and the pressing demands of third party processing. Over 10,000 retail drug stores have used PDX software technology to fill, bill, and track prescriptions.

PDX Classic is highly customizable and offers a wide range of functions, such as basic prescription filling, third party claim submissions and reconciliation, and thorough reporting. The PDX Pharmacy System is also integrated with the Electronic Pharmacy Record (EPR).

PDX Classic release 4.7.03.003 is configured to meet customer needs while providing scalability and flexible. The application server can run on the following: SLES 8, SLES 9, SLES 10, SLES 11, Red Hat 4, AIX 5.x, or AIX 6.x.

The application allows for the backing up of data daily using the backup features within the application however it is ultimately the responsibility of the client to establish backup schedules and procedures to configure the backup of prescription records.

INTRODUCTION TO EPCS REQUIREMENTS

In June, 2010, the U.S. Drug Enforcement Administration (DEA) promulgated an Interim Final Rule (IFR) governing the electronic prescribing of controlled substances (EPCS). The IFR spells out the terms and conditions for electronically creating, transmitting, and processing prescriptions for federally controlled substances (CS) (Schedules II thru V) and applies to all entities involved with the transmission workflow, including:

- Providers
- Pharmacies
- Prescribing Application Vendors
- Pharmacy Application Vendors
- Intermediaries

The Drug Enforcement Administration (DEA) revised its 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 in addition to, not a replacement of, the existing rules. The regulations provide pharmacies, hospitals, and practitioners with the ability to use modern technology for controlled substance prescriptions while maintaining the closed

system of controls on controlled substances dispensing; additionally, the regulations will reduce paperwork for DEA registrants who dispense controlled substances and have the potential to reduce prescription forgery. The regulations will also have the potential to reduce the number of prescription errors caused by illegible handwriting and misunderstood oral prescriptions. Moreover, they will help both pharmacies and hospitals to integrate prescription records into other medical records more directly, which may increase efficiency, and potentially reduce the amount of time patients spend waiting to have their prescriptions filled.

The detailed EPCS requirements are listed in Appendix A.

Criteria Not Applicable

The following criteria are currently not applicable for both the EPS and PDX Classic applications:

1. **Audit Trail of Deletions** - 1311.205(b)(13) – The requirement for audit trail of deletion of a controlled substance prescription is not applicable due to the manner in which requirement 1311.205(b)(18) was designed and implemented in the PDX applications. The pharmacy applications retain all archived records electronically for at least two years from the date of their receipt or creation and prevents deletion of any records.
2. **Digital Signature Related Criteria** - 1311.205(b)(3-5), 1311.210(c), 1311.145(a-g) – The requirements for the pharmacy application verification of digital signatures is not applicable due to the use of the third party intermediary, Emdeon. The verification and storage of digital signatures occurs in the Emdeon system with the digital signature flag and XML wrapper being transmitted to the pharmacy applications.

Emdeon

In order to electronically create or process a prescription for a controlled substance, the provider and/or pharmacy must use an application that has successfully completed a compliance audit conducted by an independent third party qualified to complete this task. Using certified software applications, providers are required to employ two-factor authentication to create and sign the CS prescription. With respect to signing the prescription, providers may use a private key (hard token) issued to them by a federal certification authority; a public or device key (hard token) that uses a one-time password and the digital signature of the prescribing application; or a biometric to authenticate the prescription prior to transmission. Most prescribing applications are initially going to use the hard token options. All CS prescriptions created in this manner must be transmitted to the pharmacies through an intermediary such as Emdeon.

The IFR provides for two options with respect to transmitting the CS prescription to the pharmacy. The first option (Option 1) pertains to a process where a private key is used by the provider while the second (Option 2) applies to processes in which the provider uses a public or “device” key which has the application’s digital signature. In Option 2, the digital signature of the application is not affixed to the CS prescription but is archived in the patient’s record with the prescription. An indicator, confirming the authority of the prescriber to create and transmit the prescription is affixed to the record before transmission and remains with the transmission serving as a confirmation to the pharmacy application and the pharmacist that the EPCS is valid.

Emdeon is the third party intermediary that provides the PMAs the digital signature verification function. Emdeon eRx Network is an electronic prescribing (ePrescribing) network owned and operated by Emdeon. Emdeon eRx Network gives pharmacies and prescribers a common method of connecting through a fast, secure, and reliable network that is a part of Emdeon’s health information interchange, which currently performs more than 6.4 billion health information exchanges per year.

Emdeon provides ePrescribing solutions and serves as a gateway to all ePrescribing pharmacies and prescribers nationwide. Certified partnerships with all major ePrescribing prescriber networks affords Emdeon with direct electronic connectivity to more than 200,000 prescribers.

Emdeon eRx Network supports the National Council for Prescription Drug Programs (NCPDP) standards. NCPDP is the organization that creates and maintains the voluntary communication standards for the pharmacy sector of the healthcare industry.

The DEA allows the transaction to be signed by a public key issued to the prescribing application vendor and stored within the prescriber's electronic record system.

The provider's personal or private signature is not required and will not be sent in the transaction. However, attached to the transaction is an indicator that signifies the prescription was signed by the prescribing practitioner. Emdeon's interpretation of the IFR is such that the pharmacy application is required to digitally sign the controlled substance (CS) prescription upon receipt if the pharmacy application is capable (Store Signed). If the pharmacy application cannot create a digital signature, the pharmacy application can elect for their intermediary (Emdeon) to sign the transaction on the pharmacy's behalf (Emdeon signed).

Appendix A

The following table lists the pharmacy management application (PMA) criteria excerpted from the *Code of Federal Regulations* (CFR) Title 21, *Food and Drugs*, Parts 1300, 1304, 1306, and 1311, “Electronic Prescriptions for Controlled Substances; Final Rule, “ established by the DEA.

Pharmacy Management Application Criteria
1311.205(b) The pharmacy application must meet the following requirements:
<p>1311.205(b)(1) The pharmacy application is capable of setting logical access controls to limit access for the following functions:</p> <ul style="list-style-type: none"> i) Annotation, alteration, or deletion of prescription information. ii) Setting and changing the logical access controls.
1311.205(b)(2) Logical access controls are set by individual user name or role.
1311.205(b)(3) The pharmacy application digitally signs and archives a prescription on receipt or be capable of receiving and archiving a digitally signed record.
<p>1311.205(b)(4) For pharmacy applications that digitally sign prescription records upon receipt, the digital signature functionality meets the following requirements:</p> <ul style="list-style-type: none"> (i) The cryptographic module used to digitally sign the data elements required by part 1306 of this chapter is at least FIPS 140-21 Security Level 1 validated. (ii) The digital signature application and hash function complies with FIPS 186-32 and FIPS 180-3.3 (iii) The pharmacy application's private key is stored encrypted on a FIPS 140-2 Security Level 1 or higher validated cryptographic module using a FIPS-approved encryption algorithm. (iv) For software implementations, when the signing module is deactivated, the pharmacy application clears the plain text password from the application memory to prevent the unauthorized access to, or use of, the private key. (v) The pharmacy application has a time application that is within five minutes of the official National Institute of Standards and Technology time source.
1311.205(b)(5) The pharmacy application verifies a practitioner's digital signature (if the pharmacy application accepts prescriptions that were digitally signed with an individual practitioner's private key and transmitted with the digital signature).
<p>1311.205(b)(6) If the prescription received by the pharmacy application has not been digitally signed by the practitioner and transmitted with the digital signature, the pharmacy application either:</p> <ul style="list-style-type: none"> (i) Verifies that the practitioner signed the prescription by checking the data field that indicates the prescription was signed; or (ii) Displays the field for the pharmacist's verification.
1311.205(b)(7) The pharmacy application reads and retains the full DEA number including the specific internal code number assigned to individual practitioners authorized to prescribe controlled substances by the hospital or other institution, as provided in § 1301.22(c).
1311.205(b)(8) The pharmacy application reads and stores, and is capable of displaying, all information required by part 1306 of this chapter.

1311.205(b)(9) The pharmacy application reads and stores in full the information required under § 1306.05(a) of this chapter. The pharmacy application either verifies that such information is present or displays the information for the pharmacist's verification.

Section 1306.05 Manner of issuance of prescriptions:

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner.

1311.205(b)(10) The pharmacy application provides for the following information to be added or linked to each electronic controlled substance prescription record for each dispensing:

- (i) Number of units or volume of drug dispensed.
- (ii) Date dispensed.
- (iii) Name or initials of the person who dispensed the prescription.

1311.205(b)(11) The pharmacy application is capable of retrieving controlled substance prescriptions by practitioner name, patient name, drug name, and date dispensed.

1311.205(b)(12) The pharmacy application allows downloading of prescription data into a database or spreadsheet that is readable and sortable.

1311.205(b)(13) The pharmacy application maintains an audit trail of all actions related to the following:(i) The receipt, annotation, alteration, or deletion of a controlled substance prescription.(ii) Any setting or changing of logical access control permissions related to the dispensing of controlled substance prescriptions.(iii) Auditable events as specified in § 1311.215 (see section 1311.215 Internal Audit Trail).

1311.205(b)(14) The pharmacy application records within each audit record the following information:

- (i) The date and time of the event.
- (ii) The type of event.
- (iii) The identity of the person taking the action, where applicable.
- (iv) The outcome of the event (success or failure).

1311.205(b)(15) The pharmacy application conducts internal audits and generates reports on any of the events specified in § 1311.215 (see section 1311.215 Internal Audit Trail) in a format that is readable by the pharmacist. Such an internal audit may be automated and need not require human intervention to be conducted.

1311.205(b)(16) The pharmacy application protects the stored audit records from unauthorized deletion. The pharmacy application shall prevent modifications to the audit records.

1311.205(b)(17) The pharmacy application backs up the controlled substance prescription records daily.

1311.205(b)(18) The pharmacy application retains all archived records electronically for at least two years from the date of their receipt or creation and comply with all other requirements of § 1311.305 (see section 1311.305 Record Keeping).

1311.210 Archiving the initial record.

1311.210(a) Except as provided in paragraph (c) of this section, a copy of each electronic controlled substance prescription record that a pharmacy receives is digitally signed by one of the following:

- (1) The last intermediary transmitting the record to the pharmacy immediately prior to transmission to the pharmacy.
- (2) The first pharmacy application that receives the electronic prescription immediately upon receipt.

<p>1311.210(b) If the last intermediary digitally signs the record, it forwards the digitally signed copy to the pharmacy.</p>
<p>1311.210(c) If a pharmacy receives a digitally signed prescription that includes the individual practitioner's digital signature, the pharmacy application:</p> <ol style="list-style-type: none"> (1) Verifies the digital signature as provided in FIPS 1863, as incorporated by reference in § 1311.08. (2) Checks the validity of the certificate holder's digital certificate by checking the certificate revocation list. The pharmacy may cache the CRL until it expires. (3) Archives the digitally signed record. The pharmacy record retains an indication that the prescription was verified upon receipt. No additional digital signature is required.
<p>1311.215 Internal audit trail.</p>
<p>1311.215(a) The pharmacy application provider establishes and implements a list of auditable events. The auditable events, at a minimum, includes the following:</p> <ol style="list-style-type: none"> (1) Attempted unauthorized access to the pharmacy application, or successful unauthorized access to the pharmacy application where the determination of such is feasible. (2) Attempted or successful unauthorized modification or destruction of any information or records required by this part, or successful unauthorized modification or destruction of any information or records required by this part where the determination of such is feasible. (3) Interference with application operations of the pharmacy application. (4) Any setting of or change to logical access controls related to the dispensing of controlled substance prescriptions. (5) Attempted or successful interference with audit trail functions. (6) For application service providers, attempted or successful annotation, alteration, 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.
<p>1311.215(b) The pharmacy application analyzes the audit trail at least once every calendar day and generates an incident report that identifies each auditable event.</p>
<p>1311.305 Recordkeeping.</p>
<p>1311.305(a) If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription are retained electronically.</p>
<p>1311.305(b) Records required by this subpart are maintained electronically for two years from the date of their creation or receipt. This record retention requirement shall not pre-empt any longer period of retention which may be required now or in the future, by any other Federal or State law or regulation, applicable to practitioners, pharmacists, or pharmacies.</p>
<p>1311.305(c) Records regarding controlled substances prescriptions are readily retrievable from all other records. Electronic records are easily readable or easily rendered into a format that a person can read.</p>
<p>1311.305(d) Records required by this part must be made available to the Administration upon request.</p>
<p>1311.305(e) If an application service provider ceases to provide an electronic prescription application or an electronic pharmacy application or if a registrant ceases to use an application service provider, the application service provider must transfer any records subject to this part to the registrant in a format that the registrant's applications are capable of retrieving, displaying, and printing in a readable format.</p>
<p>1311.305(f) If a registrant changes application providers, the registrant must ensure that any records subject to this part are migrated to the new application or are stored in a format that can be retrieved, displayed, and printed in a readable format.</p>
<p>1311.305(g) If a registrant transfers its electronic prescription files to another registrant, both registrants must ensure that the records are migrated to the new application or are stored in a format that can be retrieved, displayed, and printed in a readable format.</p>
<p>1311.305(h) Digitally signed prescription records must be transferred or migrated with the digital signature.</p>

1311.145 Digitally signing the prescription with the individual practitioner's private key.
1311.145(a) An individual practitioner who has obtained a digital certificate as provided in §1311.105 may digitally sign a controlled substance prescription using the private key associated with his digital certificate.
1311.145(b) The electronic prescription application must require the individual practitioner to complete a two-factor authentication protocol as specified in §1311.140(a)(4) to use his private key.
1311.145(c) The electronic prescription application must digitally sign at least all information required under part 1306 of this chapter.
1311.145(d) The electronic prescription application must electronically archive the digitally signed record.
1311.145(e) A prescription that is digitally signed with a practitioner's private key may be transmitted to a pharmacy without the digital signature.
1311.145(f) If the electronic prescription is transmitted without the digital signature, the electronic prescription application checks the certificate revocation list of the certification authority that issued the practitioner's digital certificate. If the digital certificate is not valid, the electronic prescription application does not transmit the prescription. The certificate revocation list may be cached until the certification authority issues a new certificate revocation list.
1311.145(g) When the individual practitioner digitally signs a controlled substance prescription with the private key associated with his own digital certificate obtained as provided under § 1311.105, the electronic prescription application is not required to digitally sign the prescription using the application's private key.