QS/1 Electronic Prescriptions for Controlled Substances (EPCS)

Customer Implementation Guide

History of Revisions

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1 ELECTRONIC PRESCRIBING

1.1 Introduction

This document examines the Code of Federal Regulations (CFR), Part 1311 Digital Certificates, Subpart C – Electronic Prescriptions and the effect of this code on prescription processing functionality in QS/1 Pharmacy Management Systems. This code addresses the compliance requirements that must be met by pharmacy application providers to process Schedule II, III, IV and V controlled substance prescriptions electronically. For reference purposes, the CFR mandate is listed in red at the end of each section outlining compliance requirements. For purposes of this document, and all future references to electronic prescriptions, the term Electronic Prescriptions for Controlled Substances, EPCS, is used.

1.2 What is EPCS?

EPCS is electronic communication between prescribers and pharmacies to generate, transmit and fill prescriptions for Schedule II, III, IV and V controlled substance prescriptions. Pharmacies dispensing these prescriptions must use an EPCS application that is certified by a DEA approved entity. Before a software application can be used for electronic prescriptions for controlled substances, it must be reviewed and determined by a third party to meet all requirements of CFR, Part 1311 (referenced in 1.1 Introduction). After meeting all the requirements and receiving certification from the third party, the certification report must be available to any prescriber or pharmacy that uses the software application. These requirements minimize the potential for controlled substance diversion.

1.3 Pharmacy Application EPCS Security Compliance

QS/1 Pharmacy Management Systems pharmacist/technician security access flags for processing Schedule II, III, IV and V controlled substances include the following options:

- Prescription Access
    - Edit Profiled/Refill Prescriptions
        - All Classes
            - Update Brand Drug
            - Update Generic Drug
            - Update Pricing Plan
        - Class 2-5 Rx's
            - Update Refills Authorized/Remaining
            - Update Qty Authorized
            - Update Qty Dispensed
            - Update Qty Remaining
        - ePrescription Access
            - Deactivate/Delete
            - Reactivate ePrescription
            - Void ePrescription
- Transaction Access
    - Update
        - Update Original/Refill/Last Date
        - Update RPh/Tech
        - Update Qty Dispensed
        - Update Remaining Fields

User ID and Password is required for Prescription and Transaction Record field changes. The default setting for security access flags is N (character systems) and unchecked (GUI systems).

Set Up Security Access in NRx and PrimeCare (GUI)

1. Access NRx or PrimeCare GUI.
2. Click **Store Control**.
3. Select Security Access and click **Manage Employees**. The Manage Employees scan displays.
4. Select the group (Pharmacists or Technicians) and then select the Employee Record to update. The Employee Detail window displays.
5. Complete General Information and Identifiers.
6. Under Security Access Flags, complete General Security Rights and Pharmacist/Technician Security Rights for the Prescription Access and Transaction Access options noted above.
7. Click **Save**.

Set up Security Access in PrimeCare (Character)

1. Access PrimeCare.
2. Press **F11**, Security Access Codes.
3. Type User ID and Password; press **Enter**.
4. Press **F1**, Access Codes and the Pharmacist Passwords and Initials scan displays. Press **F10** to toggle between Pharmacist and Technician scans.
5. To set prescription processing privileges for a pharmacist or technician, type the number corresponding to that employee and press **Enter**. The Security Access screen displays.
6. Tab to the function titles corresponding to Transaction Update and Prescription Record/Edit Profile & Refill. Type **Y** or **N** to set access.
7. Open each of the options (Transaction Update and Prescription Record) and type **Y** or **N** for each individual function.
8. Press **F1** to save.

Set up Security Access in RxCare Plus

1. Access RxCare Plus.
2. Type **G**, Security Access codes; press **Enter**.
3. Type User ID and Password; press **Enter**.
4. Type **A**, Security Access and press **Enter**. The Pharmacist Password and Initials scan displays. Press **F10** to toggle between Pharmacist and Technician scans.
5. To set prescription processing privileges for a pharmacist or technician, select the corresponding number from the scan and press **Enter**.
6. Tab to the function titles corresponding to Transaction Update and Prescription Record/Edit Profile & Refill. Type **Y** or **N** to set access.
7. Open each of the options (Transaction Update and Prescription Record) and type **Y** or **N** for each individual function.
8. Press **F1** to save.

QS/1 Pharmacy Management Systems Store Control Options for processing Schedule II, III, IV and V controlled substances should include the following for EPCS compliance:

If the Store Control/Store Level Options/Rx Filling Option Controlled Substance Processing is Y/Checked, the following must be set in Store Control/Security Access/Security Options:

- Password Expiration Days: Must be 90 days or less.
- Maximum Login Attempts: Must be five (5) or less.
- Minimum Password Length: Must be eight (8) or more.
- Require Special Characters: Check this field.
- Require Upper/Lower Case: Check this field.

The same password may not be reused within six (6) changes of the password.

If the above requirements are not met at login the system displays an error message with the following information:

- Password must be a minimum of 8 characters.
- Password must include 1 special character.
- Password must include upper/lower case characters.
- Reusing a password used in last six password setups is not allowed.

Part 1311 Digital Certificates
Subpart C – Electronic Prescriptions Reference:

1311.205(b)(1)(i) The pharmacy application must be capable of setting logical access controls to limit access for the following functions:
(i) Annotation, alteration, or deletion of prescription information

1.4 EPCS Digital Signatures

QS/1 software systems are developed using the industry standard application program interface, OpenSSL FIPS Object Module, which meets FIPS Standards 140-2 Security Level 1, 180-3 (Message Digests) and 186-3 (Digital Signature and Asymmetric Key Generation).

QS/1 Pharmacy Management Systems have a Store Control/Store Level Option, Controlled Substance Processing, to support the pharmacist's verification of the prescriber's electronic signature. When a new ePrescription or refill response with a digital signature is selected, the Prescriber's Service Level on the Prescriber Record/Electronic Rx screen is checked. If the level is Controlled Substance (EPCS) = No, a warning screen displays with the options to Accept, Cancel or Void.

The status of electronic signature verification for new and refill responses displays on the New Electronic Prescription Information screen. If the signature is not verified, a warning screen displays with the options to Accept, Cancel or Void.

- Accept: Click Accept and the system prompts for User ID and Password. When the employee is verified as a pharmacist, the system saves the Employee ID and ePrescription Status as Accepted-Signature Verified. A confirmation screen displays.

- Cancel: If Cancel is selected, the warning screen closes and the previous screen displays. Any changes to the ePrescription Record are recorded in the ePrescription Security Journal File. Refer to 1.7 Internal Audits and Reports.

- Void: Click Void and the system prompts for the User ID and Password. When the employee security access is verified, the system saves the ePrescription Status as

Voided-Unverified Signature. A confirmation displays. When an ePrescription Record is voided, it may not be undone.

A new prescription or refill response ePrescription can be voided from the Mail scan. This functionality is used for duplicate prescriptions or prescriptions with unverified signatures. When void is selected, the change is recorded in the ePrescription Security Journal File.

Set the Store Control Flag in NRx and PrimeCare GUI

1. Access NRx or PrimeCare GUI.
2. Click **Store Control**, **Store Level Options**.
3. The Store Level Options/Systems window displays.
4. Click **Rx Filling** on the vertical icon bar.
5. Check **Controlled Substance Processing** under Electronic Information Options.
6. Click **Save**.

Set the Store Control Flag in RxCare Plus

1. Access RxCare Plus
2. Type **A**, Store Information; press **Enter**.
3. Type User ID and Password; press **Enter**.
4. Type **1**, Identification; press **Enter**.
5. Press **F2** to scroll to Pharmacy Options.
6. Tab to the field to the right of Rx Filling Options and press **Enter**.
7. Select **Electronic Prescribing Options**.
8. Type **Y** in the Controlled Substance Processing field.

Set the Store Control Flag in PrimeCare (Character)

1. Access PrimeCare.
2. Press **F9**, System Management.
3. Type User ID and Password; press **Enter**.
4. Press **F8**, Store Identification; press **Enter**.
5. Press **F2** to scroll to Pharmacy Options.
6. Tab to the field to the right of Rx Filling Options and press **Enter**.
7. Select **Electronic Prescribing Options**.
8. Type **Y** in the Controlled Substance Processing field.

Part 1311 Digital Certificates
Subpart C – Electronic Prescriptions Reference:

1311.205(b)(4)(i-iv) For pharmacy applications that digitally sign prescription records upon receipt, the digital signature functionality must meet the following requirements:

> (i) The cryptographic module used to digitally sign the data elements required by part 1306 of this chapter must be at least FIPS 140-2 Security Level 1 validated. FIPS 180-2 is incorporated by reference in §1311.08.
>
> (ii) The digital signature application and hash function must comply with FIPS 186-3 and FIPS 180-3, as incorporated by reference in §1311.08.
>
> (iii) The pharmacy application's private key must be stored encrypted on a FIPS 140-2 Security Level 1 or higher validated cryptographic module using a FIPS-approved encryption algorithm. FIPS 1140-2 is incorporated by reference in §1311.08.

(iv) For software implementations, when the signing module is deactivated, the pharmacy application must clear the plain text password from the application memory to prevent the unauthorized access to, or use of, the private key.

1.5 Standard Time Verification

QS/1 Pharmacy Management Systems add a Coordinated Universal Time (UTC) stamp to all electronic prescription data records. The use of the UTC stamp ensures that the receiver of a message knows the time regardless of the time zone. The format of the date/time fields in the XML schema is CCYY-MM-DDTHH:MM:SS.FZ, For example 2010-01-01T16:09:04.5Z, where 16:09:04.5Z would be 16 hours, 09 minutes, 04 seconds, 5 fractional seconds, and Z to denote UTC time. The fractional seconds are optional. For simple date fields that do not include the time portion the format is: CCYY-MM-DD.

Part 1311 Digital Certificates
Subpart C – Electronic Prescriptions Reference:

1311.205 (b)(4)(v) The pharmacy application must have a time application that is within five minutes of the official National Institute of Standards and Technology time source.

1.6 Data Export Template

QS/1 Pharmacy Management Systems offer a Custom Data Export module to copy data from system databases into third-party spreadsheets or other database applications for analysis and reporting. Fields exported through data export may be edited if using the file type Comma Delimited ASCII. Character, packed numeric, date and time fields can be edited.

The pharmacy systems also offer a customized report generator to create reports using virtually all data elements contained in the system files. There are several pre-defined reports in the system. The option to change data in these existing reports, save the reports and add them to a report scheduler is available. The pharmacy systems enable the compilation of prescription, third party, patient, prescriber and drug reports with built-in templates. Any customized report is available as a Custom Data Export.

Custom Data Export templates can be stored on the QS/1 Customer Support Web Site with the option to export report templates to the site to share, or import templates from the site into your system.

Create a Custom Data Export in NRx or PrimeCare GUI

1. Access NRx or PrimeCare GUI.
2. Click **System Utilities**, **Data Export**. Select **New** or **Saved**.

   New: Follow the same process as when creating a new customized report. Use Set Export Options to direct the export to the desired output.

   Saved: Type the report name in the Find field on the Saved Custom Report Scan. Double-click the report name or press the corresponding function key to select a specific report. Complete the Select and Sort Options. Use Set Export Options to direct the report to the desired output.

3. If new was selected, the Pharmacy File Selection screen displays.

4. Double-click the file to use for the export. The fields for the selected file display. To use data from a field, highlight that field and click **Add**.
5. When all fields are selected, click **Ok**. The Export Filtering Options screen displays.
6. Complete the filtering options screen to determine data to print for the export. Click **Next**. The Change Exported Fields screen displays.
7. Select the field to export by highlighting the field name and clicking **Add**. When all the fields to export are added, click **Ok**. The Set Export Options screen displays.
8. Use the definitions below to set export options:

   Title for this Export: Type a title for the export.

   Save Path: Type the path to use to save the export file. To export to a hard drive, type the drive letter followed by :\ and then the file name.

   Save File Type: Default is Comma Delimited ACSII. Select a valid entry from the drop-down list.

   Save to Server?: Check to export the file to the hard drive on the server.

   Include Field Names: Check to include the field names on the first record.

   Totals Only: Check to print totals only.

   Use Store ID: Check to print the Store ID on the report.

   Beginning Tr Nbr: This option displays if the primary input file is the Rx Transaction file. If a transaction number is entered, the system does not export transactions prior to that number.

9. Click **Finish** when the export options are complete. The option to save the data export displays. Click **Yes** or **No**.
10. The number of records written to the export displays. Click **Ok**.

Create a Custom Data Export in RxCare Plus

1. Access RxCare Plus.
2. Type **C**, General Reports; press **Enter**.
3. Type User ID and Password; press **Enter**.
4. Type **D**, Customized Report Generator; press **Enter**.
5. Type **E**, Generate a Data Export; press **Enter**. The Export File Selection displays.
6. Type the corresponding number of the file needed, or press **Enter** to view more selections. Select Options display.
7. Complete the data selection and press **Esc**. Complete the Select Option screen to determine which data to print for the export. Verify entries are correct.
8. Tab to the Type in Options prompt and type **SA** to save. NOTE: Each Select, Export and Data screen must be saved individually. Press **Enter** to access the Export Choice screen.
9. Complete the export options. Tab to the Type in Options prompt and type **SA** to save. Press **Enter**. A Custom Export Request Data Export Options screen displays.
10. Use the definitions below to set export options:

Title: Type a title for the export (up to 35 characters).

Path: Type the path to use to save the export file. To export to a hard drive, type the drive letter followed by :\ and then the file name.

Type: Default is Comma Delimited ACSII. Other valid entries are: dBase, WordPerfect, Foxpro, Lotus 123, Microsoft Word, Colon Delimited ASCII. Press **F6** to change values.

Write to Server?: Type **YES** to export the file to the hard drive. Type **NO** to export the file to the client.

Use Field Names: Type **YES** to include the field names on the first record.

Totals only: Type **YES** to print totals only, omitting details.

Use Store ID: Type **YES** to use the Store ID in the report.

Beginning Tr Nbr: This option displays if the primary input file is the Rx Transaction file. If a transaction number is entered, the system does not export transactions prior to that number.

11. Tab to the Type in Options prompt and type **SA** to save.

Create a Custom Data Export in PrimeCare (Character)

1. Access PrimeCare.
2. Press **F4**, General Reports; press **Enter**.
3. Type User ID and Password; press **Enter**.
4. Press **F4**, Customized Report Generator; press **Enter**.
5. Press **F5**, Generate a Data Export. The Export File Selection displays.
6. Type the corresponding number of the file needed, or press **Enter** to view more selections. Select Options display.
7. Complete the data selection and press **Esc**. Complete the Select Option screen to determine which data to print for the export. Verify entries are correct.
8. Tab to the Type in Options prompt and type **SA** to save. NOTE: Each Select, Export and Data screen must be saved individually. Press **Enter** to access the Export Choice screen.
9. Complete the export options. Tab to the Type in Options prompt and type **SA** to save. Press **Enter**. A Custom Export Request Data Export Options screen displays.
10. Use the definitions below to set export options:

Title: Type a title for the export (up to 35 characters).

Path: Type the path to use to save the export file. To export to a hard drive, type the drive letter followed by :\ and then the file name.

Type: Default is Comma Delimited ACSII. Other valid entries are: dBase, WordPerfect, Foxpro, Lotus 123, Microsoft Word, Colon Delimited ASCII. Press **F6** to change values.

Write to Server?: Type **YES** to export the file to the hard drive. Type **NO** to export the file to the client.

Use Field Names: Type **YES** to include the field names on the first record.

Totals only: Type **YES** to print totals only, omitting details.

Use Store ID: Type **YES** to use the Store ID in the report.

Beginning Tr Nbr: This option displays if the primary input file is the Rx Transaction file. If a transaction number is entered, the system does not export transactions prior to that number.

11. Tab to the Type in Options prompt and type **SA** to save.

Part 1311 Digital Certificates
Subpart C – Electronic Prescriptions Reference:

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

1.7 Internal Audits and Reports

QS/1 Pharmacy Management Systems track and log (date and time and type of event) the following auditable events:

(1) Attempted access to the system with an invalid password. The following login error displays:

Login process failed for the following reason(s):
Primary User password is incorrect.
Primary login reserved for pharmacist accounts.

(2) Attempted access to the system with an invalid user ID. The following login error displays:

Login process failed for the following reason(s):
Primary user account not found.
Primary login reserved for pharmacist accounts.

(3) Attempted modifications/erasures to files. The following errors display:

XXXXRPH Access Denied for Void
XXXXRPH Access Denied for Update

The Security Journal option is used to log changes to selected files. When this option is set up, the system logs changes every 30 seconds. Changes to the selected files can be printed in a customized report which displays the task, date, time, user ID and the before and after changes to the file. Journals are available for Patient, Doctor, Drug, Prescription, Transaction, Employee and ePrescription files.

The ePrescription Security Journal records the data as it is received from the prescriber and logs when the prescription is accepted, processed, voided or transferred. The e-Prescription

Security Journal File Control Options are File and Description, in addition to Log File?, Updates?, Log New?, and All Fields?.

EPCS regulations recommend the analysis of the auditable events once every calendar day. To provide a report of these events, Security Journals can be added to the QS/1 Report Scheduler and set to run at a specific time during each 24-hour period. EPCS regulations also recommend that only specific employee(s) be set up with the security access to run these reports.

The Employee Security Journal records changes to all editable fields, password updates and resets and login attempts and failures. Password information does not display on screen or print in the Security Journal Report. The Employee Security Journal option is available as a data export and custom report option. The Employee Security Journal in File Maintenance includes a warning message with the Purge function – *check with State for the required time frame for maintaining records*.

Pharmacy system files are retained for a minimum period of two years from the date last filled or according to state laws if greater than two years. Files included are: Prescription, Transaction, Employee, Audit, ePrescription Data and Prescriber. It is recommended that these files be backed up on a nightly basis.

Set Up Security Journals in NRx or PrimeCare GUI

1. Access NRx or PrimeCare GUI.
2. Click **Store Control**.
3. Select **Security Access** and click **Security Journals**. The Security Journal Control Options display.
4. Complete the Control Options using the following definitions:
    - Next File: This field is used to alphabetically select files in the system. For example, type **R** and press **Enter** to display all files beginning with that letter.
    - File: this column lists all files in the system. Click **Next** to scroll through the files.
    - Description: Describes the file listed to the left.
    - Log File: Check this box to log changes to the file.
    - Updated: Check this box to log changes to existing records.
    - New?: Check this box to log new records added to the file.
    - All Fields?: Check this box to log changes to all fields in the file. Leave blank to select individual fields and then click the magnifying glass to the left of the file name to display individual fields. Check Log? to log changes for individual fields.
5. Security Journals can be added to the Report Scheduler and run for the following reports. To access the Security Journal Change Logs for the files listed below, click the Security Journal icon on that record's tool bar.
    - Patient
    - Patient Insurance
    - Doctor
    - Drug
    - Inventory
    - Prescription
    - Transaction
    - Employee
6. Click **Save**.

Set Up Security Journals in RxCare Plus

1. Access RxCare Plus.
2. Type **G**, Security Access Codes.
3. Type User ID and Password; press **Enter**.
4. Type **E**, Security Journals; press **Enter**. The Security Journals Control Options screen displays.
5. Complete the Control Options using the following definitions:
   - Next File: This field is used to alphabetically select files in the system. For example, type **R** and press **Enter** to display all files beginning with that letter.
   - File: This column lists all files in the system. Press **F2** to scroll through the files.
   - Description: Describes the file listed to the left.
   - Log File: Type **Y** in this box to log changes to the file.
   - Updated: Type **Y** in this box to log changes to existing records.
   - New?: Type **Y** in this box to log new records added to the file.
   - All Fields?: Type **Y** in this box to log changes to all fields in the file. Leave blank to select individual fields and then click the magnifying glass to the left of the file name to display individual fields. Type **Y** in the Log? option to log changes for individual fields.
6. Security Journals can be added to the Report Scheduler and run for the following reports. To access the Security Journal Change Logs for the files listed below, click the Security Journal icon on that record's tool bar.
   - Patient
   - Patient Insurance
   - Doctor
   - Drug
   - Inventory
   - Prescription
   - Transaction
   - Employee
7. Press **F1** to save.

Set Up Security Journals in PrimeCare (Character)

1. Access PrimeCare.
2. Press **F11**, Security Access Codes.
3. Type User ID and Password; press **Enter**.
4. Press **F5**, Security Journals. The Security Journal Control Options display.
5. Complete the Control Options using the following definitions:
   - Next File: This field is used to alphabetically select files in the system. For example, type **R** and press **Enter** to display all files beginning with that letter.
   - File: This column lists all files in the system. Press **F2** to scroll through the files.
   - Description: Describes the file listed to the left.
   - Log File: Type **Y** in this box to log changes to the file.
   - Updated: Type **Y** in this box to log changes to existing records.
   - New?: Type **Y** in this box to log new records added to the file.
   - All Fields?: Type **Y** in this box to log changes to all fields in the file. Leave blank to select individual fields and then click the magnifying glass to the left of the file name to display individual fields. Type **Y** in the Log? option to log changes for individual fields.
6. Security Journals can be added to the Report Scheduler and run for the following reports. To access the Security Journal Change Logs for the files listed below, click the Security Journal icon on that record's tool bar.
   - Patient
   - Patient Insurance

- Doctor
- Drug
- Inventory
- Prescription
- Transaction
- Employee

7. Press **F1** to save.

Part 1311 Digital Certificates
Subpart C – Electronic Prescriptions Reference:

1311.205(b) The pharmacy application must meet the following requirements:

(15) The pharmacy application must conduct internal audits and generate reports on any of the events specified in §1311.215 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.

(16) The pharmacy application must protect the stored audit records from unauthorized deletion. The pharmacy application shall prevent modifications to the audit records.

(17) The pharmacy application must back up the controlled substance prescription records daily.

(18) The pharmacy application must retain 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.

1311.215 Internal audit trail.

(a) The pharmacy application provider must establish and implement a list of auditable events. The auditable events must, at a minimum, include the following:

(1) Attempted unauthorized access to the pharmacy application, or 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.

(b) The pharmacy application must analyze the audit trail at least once every calendar day and generate an incident report that identifies each auditable event.

(c) The pharmacy must determine whether any identified auditable event represents a security incident that compromised or could have compromised the integrity of prescription records. Any such incidents must be reported to the pharmacy application service provider, if applicable, and the Administration within one business day.

Section 1304.03 Persons required to keep records and file reports.

(h) A person is required to keep the records and file the reports specified in §1304.06 part 1311 if they are either of the following:

(1) An electronic prescription application provider.

(2) An electronic pharmacy application provider.

Section 1304.06 Records and reports for electronic prescriptions.

(d) A registrant and application service provider must retain a copy of any security incident report filed with the Administration pursuant to §§ 1311.150 and 1311.215.

(e) An electronic prescription or pharmacy application provider must retain third party audit or certification reports as required by § 1311.300.

(f) An application provider must retain a copy of any notification to the Administration regarding an adverse audit or certification report filed with the Administration on problems identified by the third-party audit or certification as required by § 1311.300.

1.8 EPCS Recordkeeping

Pharmacy management system files are retained for a minimum period of two years. Files included are: Prescription, Transaction, Employee, Audit, e-Prescription Data and Prescriber. These files reside in an e-Data file which has the security safeguards as outlined in 1.7 Internal Audits and Reports.

The prescriptions and transactions associated with the e-Prescribing of controlled substances are tracked via the Rx/Transaction Change Log. This ensures that all e-Prescribing data is protected. The Rx Audit File cannot be purged prior to two years of the current date during File Maintenance. Employees with Administrator = Y and Security Access = Y can bypass the two year restriction for purging the files. If the restriction is bypassed, the system displays a warning message to check with the State for the mandated time frame for keeping the file.

Part 1311 Digital Certificates
Subpart C – Electronic Prescriptions Reference:

1311.305 Recordkeeping

(a) If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.

(b) Records required by this subpart must be 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.

(c) Records regarding controlled substances prescriptions must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read.

(d) Records required by this part must be made available to the Administration upon request.

(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.

(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.

(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.

(h) Digitally signed prescription records must be transferred or migrated with the digital signature.

1.9 Prescriber Database for LexisNexis®

Implementation of Prescriber Database for LexisNexis updates for QS/1 Prescriber Record fields account for information mandated by Surescripts and Change Healthcare directories, including prescriber downloads and pharmacy updates. The updates supply information needed for claims submission, e-Prescribing and Federal sanctions and are part of Clinical Update Database Services.

Fields Updated via LexisNexis in QS/1 Pharmacy Management Systems

Prescriber Record/General Information Screen

- Prescriber Last Name: 35 alpha/numeric positions
- Prescriber First Name: 35 alpha/numeric positions
- Prescriber Middle Name: 35 alpha/numeric positions
- Prescriber Address Line 1: 35 alpha/numeric positions
- Prescriber Address Line 2: 35 alpha/numeric positions
- Practice Name: 35 alpha/numeric positions
- NADEAN (Narcotics Addiction DEA Number): Nine alpha/numeric positions
- State: Two alpha/numeric positions. State associated with NADEAN

Prescriber Record/Additional Information Screen

- Credential: Ten alpha/numeric position for the prescriber's credentials (examples: ARN = Advanced Registered Nurse, CCFP = Certificate of the College of Family Practice).
- Auth for Schedule 2, 3, 4, 5: Check each class of drug the prescriber can dispense. If the prescriber is not authorized for a drug class and tries to prescribe that class, the system displays the message *Prescriber Not Authorized for Schedule 2, 3, 4 or 5.*
- Sanctions: Federal sanctions levied against the prescriber. Start Date = MM/DD/CCYY. End Date = MM/DD/CCYY. Board and Action = 50 alpha/numeric character fields for the board issuing the sanction and the action taken.
- CTP (Certificate to Prescribe): LexisNexis updates with a Y (checked) if the State License Number is for a nurse practitioner in Ohio. Otherwise, the field is blank.
- DPS (Department of Public Safety): LexisNexis updates this field (up to 15 alpha/numeric characters) for the state of Texas. Otherwise, the field is blank.

  Click the Notes icon on the Prescriber Record/Additional Information screen to display the Prescriber Record/Notes screen.

Prescriber Record/Electronic Rx Screen

- Service Levels/New Rx: Sent from the prescriber to the pharmacy as a new prescription. Default = checked (Y).
- Service Levels/Refill Request: Sent from the pharmacy to the prescriber to request a refill. Default = checked (Y).
- Service Levels/Controlled Substance (EPCS): Authorization for the prescriber to send electronic Rx information. Default = unchecked (N).

System Utilities/Data Updates/Electronic Data Updates/Set Up Prescriber Options Screen

- Update Practice Name: Default = unchecked (N). When checked (Y), the practice name on the Prescriber Record is updated (up to 35 positions).
- Update Prescriber DEA: Default = unchecked (N). When checked (Y), the following fields on the Prescriber Record are updated:
  - Prescriber DEA#: First nine positions in the DEA field, then additional positions in the DEA Suffix field up to 11 positions.
  - DEA Expiration Date
  - DEA Schedule (2, 3, 4, 5)
- Update Prescriber NADEAN: Default = unchecked (N). When checked (Y), the prescriber NADEAN is updated (up to nine positions).
- Update Prescriber State License#: Default = unchecked (N). When checked (Y), the following fields on the Prescriber Record are updated:
  - Prescriber State License#: Up to 25 positions
  - Prescriber State License Expiration Date
  - State Issuing License: Two positions
  - Prescriber State License Type: Up to three positions
  - Prescriber CTP: One position
- Update Prescriber DPS: Default = unchecked. When checked (Y), the Prescriber DPS is updated (up to 15 positions).
- Update Prescriber Credential: Default = unchecked. When checked (Y), the Prescriber Credential is updated (up to 10 positions).
- Update Prescriber Sanctions: Default = unchecked. When checked (Y), the following fields on the Prescriber Record are updated. When checked (Y) and Sanction information is NOT received, the system automatically clears these fields.
  - Sanction Start Date
  - Sanction End Date
  - Board Description: Up to 50 positions
  - Action Description: Up to 50 positions
- Update e-Prescribing Identifiers: When this field is checked (Y), the following Prescriber Record electronic prescribing information is updated:
  - New Rx
  - Refill Request
  - Rx Change
  - Rx Fill
  - Cancel Rx
  - Medication History
  - Eligibility
  - Census
  - Controlled Substance (EPCS)
- Preferred e-Prescribing Vendor: Update for vendors include:
  - No Preference: Update Level 1 ID# and Level Three ID# with the first vendor received.
  - Change Healthcare: Update Level 1 ID# and Level Three ID# with information received for Change Healthcare. Level 1 ID Qualifier is normally C for clinic.
  - Surescripts: Update Level 1 ID# and Level Three ID# with information received for Surescripts. Level 1 ID Qualifier is normally D for prescriber (Doctor).

How to Update the Prescriber Record

To update the Prescriber Record, click **Request Info** on the main title bar on the Prescriber Record. Electronic Prescriber Information displays. Click **Update Prescriber** to populate the Prescriber Record with the electronic information shown in bold. If the information is returned and more than one prescriber match is made, the Prescriber Updates Scan displays. Select the correct prescriber from the scan to update that prescriber's information.

Electronic Refill Requests

The Electronic Refill Request option from the Rx Summary screen displays the message, *Prescriber Does Not Accept Electronic Refill Request*, if the prescriber does not accept electronic refill requests.

Labels

Prescriber Record fields are available as label routine options.

Reports

Prescriber Record fields are available as Report Select, Sort, Print and Export Options.

Security Journals

Prescriber Record fields are available in Doctor Security Journals.

Price Plan

Price Plan error messages display if the prescriber is not authorized to dispense Schedule 2, 3, 4 or 5 drugs, or if there are sanctions against the prescriber.

The system automatically checks the Drug Record to determine the Drug Class and the Prescriber Record to confirm the prescriber's authorization for that class. The system automatically checks the Prescriber Record for Sanctions when filling or refilling prescriptions. If the Sanction Start Date is earlier than the current system date, and the End Date is blank or a future date, an error message displays.

