ADL Data Systems
Optimum Order Entry
and
Financials

DEA EPCS
Certification Test Report

Prepared for
ADL Data Systems
9 Skyline Drive
Hawthorne, NY 10532-2146

Version 1.0

Report #190917-iBetaCTR-v1.0

Trace to Standards
21 CFR Parts 1300, 1304, 1306, 1311

Test Results in this report apply to the EPCS signing application system configuration tested. Testing of EPCS applications that have been modified may or may not produce the same test results. This report shall not be reproduced, except in full.

iBeta Quality Assurance is approved for DEA-EPCS Application Testing

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v1.0	Final report for re-certification	*Todd Prebynski*	*Adam Sisneros*	*17 September 2019*

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1 Executive Summary

This report contains the results, conclusions and recommendations of the iBeta Quality Assurance assessment for certification of the DEA EPCS compliant Optimum Financials Version EPCS 1.04 and Order Entry Version EPCS 1.04 from ADL Data Systems. Re-Certification functional testing was performed from 5 September 2019 to 10 September 2019 and validated the applicable requirements of 21 CFR Part 1311 for an application used for the Electronic Prescription of Controlled Substances System (EPCS) are met.

iBeta certifies that Optimum Financials Version EPCS 1.04 and Order Entry Version EPCS 1.04 meet the requirements of 21 CFR Part 1311 as applicable and other applicable requirements contained in Parts 1300, 1304, and 1306. This system meets the requirements to be used for EPCS for a prescription signing system.

This report is provided to ADL Data Systems for distribution and is available for distribution by iBeta at the written request of ADL Data Systems. The report will be delivered to the DEA in accordance with the iBeta approval letter and will be maintained within iBeta SharePoint document system for 2 years after the date printed on the cover of this report.

1.1 *System Identification*

The ADL Data System application certified and documented within this Final Report is for the Order Entry modules with a version of Non-RO: 201908.01, RO: 2017-09-01 dev DEA as released as EPCS Version 1.04 and Optimum Financials Version OFU 39.00 released as EPCS 1.04 exclusively.

The ADL Data System application is a prescription signing application and ADL Data Systems is an application provider. The ADL Data System application does not support the following functionality and was neither tested nor certified against the corresponding DEA EPCS regulations:

- Detoxification or maintenance treatments per 1306.05
- Institutional Practitioners per 1306.05, 1311.110, 1311.120 and 1311.130
- Biometrics as one of the two-factor authenticators per 1311.116
- Prescribing more than one controlled substance at one time for a single patient per 1311.120

1.2 *Disclosure*

This report consists of the entire disclosure of assessment and test results made between the independent test organization, iBeta Quality Assurance LLC and the vendor.

iBeta worked with the vendor to find means to test the application for the requirements of the regulations. Data from test runs was not necessarily recorded and is not reported, though portions of it may have been provided to the vendor to clarify discrepancies prior to the final test. As detailed in the report, data was provided for functional reasons and not in a way allowing the vendor to tune the system.

iBeta tested the application as described in the System Identification section of this report. iBeta believes this information is sufficient to allow end point users to verify that the application they are implementing is the same application that iBeta has certified. The vendor, ADL Data Systems, is aware that the certification expires two years from the date listed on this report, or if the application is modified, whichever comes first [21 CFR 1311.300(e)(2)]. It is the end point user's responsibility to verify that they are using the certified version.

Information and data not disclosed to the vendor or any party outside of the testing lab includes:

- Design documents leading to test case templates
- Test case templates and as-run test cases

2 Introduction

This report is generated to document iBeta Quality Assurance assessment and testing of an EPCS Prescriber application as per 21 CFR 1311.300(e).

Testing was conducted at iBeta Quality Assurance facility in Aurora, Colorado via GoToMeeting for access to the application for testing. Screen shots were captured and uploaded into the test cases as test steps were validated.

Certification testing was performed in compliance with the requirements of 21 CFR Parts 1300, 1304, 1306 and 1311. The test record included all test executions and reviews. All test executions and reviews included the record

of requirements that were satisfactorily and unsatisfactorily completed, deficiencies noted, reports to ADL Data Systems, software application resolutions, validations of resolutions and documentation of incorporation of resolutions into the EPCS system.

iBeta Quality Assurance, a limited liability company, is located in Aurora, Colorado. The company is a full service software testing laboratory providing Quality Assurance and Software Testing for the business and interactive entertainment communities.

2.1 *Internal Documentation*

The documents identified below are iBeta internal documents used in certification testing.

Table 1 Internal Documents

Version #	Title	Abbreviation	Date
Rev 01	Agreement for EPCS Re-Certification Testing Services	Contract	7/25/19
	iBeta Non-Disclosure Agreement	NDA	11/14/13
iBeta	Independent Test Lab Procedures		
Form A	DEA EPCS Certification Report Template		9/27/12
Form A	DEA-EPCS Assessment Procedure		9/26/12
Form A	DEA-EPCS-TestCase-Template		3/19/12
iBeta	Project Documents		
Rev 01	Discrepancy Report – ADL Data Systems		1/6/15
Rev 01	DEA-EPCS Requirement for ADL Prescriber Re-Certification		9/25/17
Rev 01	DEA EPCS ADL Prescriber Regression Test Cases		9/25/17

2.2 *External Documentation*

The documents identified below are external resources used in certification testing.

Table 2 External Documents

Version #	Title	Abbreviation	Date	Author (Org.)
NIST Handbook 150 2006 Edition	NVLAP System Testing	NIST 150	February 2006	National Voluntary Lab Accreditation Program
NIST Handbook 150-25	NVLAP Biometric System Testing	NIST 150-25		National Voluntary Lab Accreditation Program
31 Mar, 2010	21 CFR Parts 1300, 1304, 1306 and 1311		31 Mar, 2010	DEA Office of Diversion Control
19 Oct, 2011	Docket No. DEA-360 Clarification and Notification		19 Oct, 2011	DEA Office of Diversion Control
1	Guide for Assessing the Security Controls in Federal Information Systems and Organizations	NIST SP 800-53A Or SP800-53A	June, 2010	NIST

2.3 *Technical Documents*

The Technical Documents submitted for this certification test effort are listed in Section 3 System Identification.

2.4 *Test Report Contents*

The contents of this Test Report include:

- Section 1: The Introduction - identifies the scope of certification testing.
- Section 2: The Certification Test Background identifies the process for certification testing.
- Section 3: The System Identification identifies the system configuration including hardware, software and the technical documentation.

- Section 4: The System Overview identifies the overall design and functionality of EPCS system.
- Section 5: The Certification Review and Test Results are the methods and results of the testing effort.
- Section 6: The certification statement of the EPCS system.

Test Operations, Findings and Data Analysis are in the appendices.

- Appendix A: Security Assessment Results for DEA-EPCS Conformance
- Appendix B: Test Cases (bound separately)

3 Re-Certification Test Background

The prescriber application submitted for certification had been certified for DEA EPCS previously so a regression review and analysis of all of the regulations was conducted.

As part of their application for Re- Certification Testing, ADL Data Systems reconfirmed their initial responses to the iBeta questionnaire as a baseline for the functionality of the prescriber application being submitted for re-certification. These responses limited the scope of the re-certification assessment in that the re-certification candidate does not support:

- Prescribing for detoxification or maintenance treatments per 1306.05(b)
- Institutional Practitioners per 1306.05(g) & (h), 1311.110, 1311.120(b)(1)(ii), 1311.130
- Biometrics as one of the two-factor authentication per 1311.116
- Prescribing more than one controlled substance at one time for a particular patient per 1311.120(b)(13)

3.1 *Terms and Definitions*

The Terms and Definitions identified below are used in this test report.

Table 3 Terms and Definitions

Term	Abbreviation	Definition
Authentication	Auth	The process whereby a claimant provides evidence to a system that the claimant is in fact the person claimed and not an imposter.
Conformance Test Suite	CTS	A test program utilized to provide data such as biometric data to the IUT and automatically obtain results (such as a similarity score) in response to a particular challenge.
Drug Enforcement Agency	DEA	United States Department of Justice Drug Enforcement Agency
Electronic Prescription of Controlled Substances	EPCS	Program allowing physicians and their agents to electronically transmit prescriptions to a dispensary such as a pharmacy.
Factor		In authentication, one of the pieces of evidence that is used to support the identity claim of the claimant.
Filling Application	FA	An application used to fill an electronic prescription or an application that acts as an intermediary between the signing application and the location where the electronic prescription is filled or dispensed.
Independent Test Lab	ITL	Lab accredited by NVLAP
National Voluntary Laboratory Accreditation Program	NVLAP	Part of NIST that provides third-party accreditation to testing and calibration laboratories.
Not Applicable	NA	A regulation that has been assessed as not applicable to the prescriber application being submitted for DEA EPCS Certification.
Not Testable	NT	A regulation or sub-set of the regulations that are not testable.
Pharmacy Application		A Filling Application specifically performing functions for a pharmacy.
System under test	SUT	The computer system of hardware and software on which the implementation under test operates
Signing Application	SA	The application used by the practitioner to apply a digital signature to the electronic prescription.
Tested Elsewhere	TE	A regulation that has been assessed to apply to the prescriber application but is being tested within

Term	Abbreviation	Definition
		another regulation.
Vendor		System/application manufacturer

3.2 *DEA-EPCS Certification*

Under 21 CFR 1300, 1304, 1306 and 1311, the DEA Office of Diversion Control specifies and regulates the operation of Electronic Prescription of Controlled Substances (EPCS). The regulations require an independent third-party to review and test the application and validate that it meets the requirements in 21 CFR 1311 and elsewhere as referenced.

3.2.1 Definition of Test Cases

The test criteria were defined as the regulations that applied to the re-certification candidate. As none of the functionality related to EPCS had been modified (as confirmed by review of the differences in the source code between the last certified version and the certification candidate), iBeta selected a regression test suite for the re-certification test effort.

The DEA EPCS regulations, as originally translated into test cases to validate functionally each regulation in the initial certification test effort, were reviewed during the identification of the regression test suite. In the cases where a regulation could not be validated through a functional test case, a static test case was defined to verify the regulation. As the ADL EPCS Policy and Procedure Guide had been updated, the static test case of document review was fully regressed.

Seven functional regression test cases where identified and executed. The test cases are provided as Appendix B to this report and summarized as follows:

- Test Case 1 – Digital Signature
- Test Case 2 – Audit Log
- Test Case 3 – Prescription Content
- Test Case 5 – Two-Factor Authentication
- Test Case 6 – Archive
- Test Case 7 – Access Control
- Test Case 8 – Miscellaneous: includes 90-Day Supply for Schedule II and Monthly Reporting

The security aspects of the application were assessed using 21 CFR 1311 requirements as guidelines along with the DEA Clarification dated 19-October-2011 to include “processing integrity” utilizing NIST SP800-53A as a guideline.

3.2.2 Test Environment Setup

The test environment was controlled and maintained by ADL Data Systems and accessed by iBeta via GoToMeeting only. iBeta captured screen shots of the application under test to record the configuration tested. Throughout the testing, iBeta requested and was provided the XML in the SCRIP 10.6 format for review.

3.2.3 Test Execution

Functional regression test execution was conducted from 5 September 2019 through 10 September 2019. The summary results are listed in Appendix A.

3.2.3.1 *Deviations and Exclusions*

Any deviations from or exclusions to the test method are documented, technically justified, authorized and accepted by the customer and are documented as such in Appendix A.

There were no deviations or omissions from the standards.

4 System Identification

The System Identification stipulates the ADL Data Systems Optimum Financials Version EPCS 1.04 and Order Entry Version EPCS 1.04 submitted for certification and the hardware, software and the documentation used in testing.

4.1 *Submitted System Identification*

Table 4 System Name and Version

System Name	Version
Optimum Financials	EPCS 1.04
Order Entry	EPCS 1.04

4.2 *System Test Environment*

The test environment was the ADL Data Systems Quality Assurance test environment. The documentation provided throughout the test effort is delineated below.

Table 5 ADL Data Systems Documentation

File Name	Document Date	Date Received
Key Registration Steps.pdf		9/23/14
Aarons DEA Certification Document_rev1.pdf	9/1/14	9/23/14
Professionals Module Prescriber Update_rev1.pdf		9/23/14
Time_Synchronization_External_Source_rev1.pdf		9/23/14
Emergency Medication Supply_rev1.pdf		9/23/14
Aarons DEA Certification Document_highlight(1).docx		10/1/14
Emergency Medication Supply.docx		10/1/14
Setting_system_to_fips.doc		10/1/14
dea_test_steps.doc		11/10/14
FIPS 140-2.pdf		11/10/14
adding_a_professional_REV1.pdf		11/10/14
Key Registration Steps_REV1.pdf		11/10/14
EPCS Policy and Procedure Guide.pdf	12/11/14	12/11/14
RFP Responses KS ADL Nov2 2012 1 2_Physical Security pg3.pdf		12/17/14
Contract ADL 6 2013_Backups and Restoreds.pdf - Appendix A Service Schedule No. [1]		12/17/14
EPCS Policy and Procedure Guide.pdf	8/29/17	9/5/17

Table 6 Other Software, Hardware and Materials

Material	Material Description	Use in the Biometrics System
Other		
Multiple desktop and laptop PCs	A variety of PCs running Microsoft operating systems	Supplied by iBeta: Preparation, management and recording of test plans, test cases, reviews and results
Repository servers	Separate servers for storage of test documents and source code, running industry standards operating systems, security and back up utilities	Supplied by iBeta: Documents are maintained on a secure network server. Source code is maintained on a separate data disk on a restricted server
Microsoft Office 2010	Excel and Word software and document templates	Supplied by iBeta: The software used to create and record test plans, test cases, reviews and results
SharePoint 2010	Test documentation repository	Supplied by iBeta: Vendor document and test documentation repository and configuration management tool
Other standard business application software	Internet browsers, PDF viewers email	Supplied by iBeta: Industry standard tools to support testing, business and project implementation

4.3 *Order Entry Component Capabilities*

The Order Entry component provides the physician with the function to create, update and sign electronic Physician Orders. This component is expanded to allow for electronic prescribing of controlled substances in accordance with the 21 Part 1311 regulations. The current released component provided managed patient status, real-time order entry, electronically created and signed orders, and ease of use through order templates.

4.4 *Financials Component Capabilities*

The Financials component controls the access control for the prescriber. By requiring roles based access and two-factor authentication, the component meets the regulations for establishing the access control required for electronic prescribing of controlled substances.

5 Certification Review and Test Results

The results and evaluations of the assessment tests are identified below. Detailed data regarding the Acceptance/Rejection criteria, reviews and tests are found in the appendices.

- Appendix A identifies all certification test results for Security Assessment Testing
- Appendix B provides the Test Cases as executed

5.1 *Limitations*

The results and conclusions of this report are limited to the specific certification candidate applications and versions described below.

It is the responsibility of the vendor to provide the laboratory with systems and devices which are representative of those systems and devices produced for the consumer.

These results represent usage of falsification testing methodology. Testing can only demonstrate non-conformity, i.e., if errors are found, non-conformance of the System-Under-Test (SUT) shall be proven, but the absence of errors does not necessarily imply the converse. These results are intended to provide a reasonable level of confidence and practical assurance that the SUT conforms to the standard. Use of these results will not guarantee conformity of an implementation to the standard; that normally would require exhaustive testing, which is impractical for both technical and economic reasons.

5.2 *DEA EPCS Review*

5.2.1 Optimum Financials Version EPCS 1.04 Component Results

The Access Control regulations addressed and tested in Test Case 7 were validated successfully. There were neither deviations from the standard test method nor any test setup that varied from the standard protocol. All of the functionality for EPCS contained within the Optimum Financials component was validated.

5.2.1.1 *Exceptions*

For the Access Control functions provided by the Optimum Financials component, Institutional Practitioners (per 1306.05(g) & (h), 1311.110, 1311.120(b)(1)(ii), and 1311.130) were not supported and are excluded from this certification.

The data supporting this review are found in Appendix A.

5.2.2 Order Entry Version EPCS 1.04 Component Results

The Order Entry component regulations were addressed and tested within 6 functional regression test cases and one verification test case. All test cases were successfully executed. There were neither deviations from the standard test method nor any test setup that varied from the standard protocol. All of the functionality for EPCS contained within the Order Entry component was validated and/or verified.

5.2.2.1 *Exceptions*

For the Order Entry functions within this component, three functions were not supported and are excluded from this certification:

- Prescribing for detoxification or maintenance treatments per 1306.05(b)

- Biometrics as one of the two-factor authentication per 1311.116
- Prescribing of more than one controlled substance at one time for a particular patient per 1311.120(b)(13)

The data supporting this review are found in Appendix A.

6 Opinions & Recommendations

6.1 *Recommendations*

iBeta Quality Assurance has completed the testing of ADL Data Systems Optimum Financials Version EPCS 1.04 and Order Entry Version EPCS 1.04. In our opinion the acceptance requirements of 21 CFR 1311 have been met.

Table 7 contains a summary of the 21 CFR 1311 requirements that were found to be in compliance with the regulation.

Table 7 Summary of Requirements

Requirement	Description	Approved
1311.05	Standards for technologies for electronic transmission of orders.	☑
1311.100	General.	☑
1311.102	Practitioner responsibilities	☑
1311.105	Requirements for obtaining an authentication credential—Individual practitioners.	☑
1311.110	Requirements for obtaining an authentication credential—Individual practitioners eligible to use an electronic prescription application of an institutional practitioner.	☑
1311.115	Additional requirements for two-factor authentication.	☑
1311.116	Additional requirements for biometrics – not applicable.	☑
1311.120	Electronic prescription application requirements.	☑
1311.125	Requirements for establishing logical access control—Individual practitioner.	☑
1311.130	Requirements for establishing logical access control—Institutional practitioner – not applicable.	☑
1311.135	Requirements for creating a controlled substance prescription.	☑
1311.140	Requirements for signing a controlled substance prescription.	☑
1311.145	Digitally signing the prescription with the individual practitioner's private key	☑
1311.150	Additional requirements for internal application audits.	☑
1311.170	Transmission requirements.	☑
1311.200	Pharmacy responsibilities – not applicable.	☑
1311.205	Pharmacy application requirements – not applicable.	☑
1311.210	Archiving the initial record.	☑
1311.215	Internal audit trail.	☑
1311.300	Application provider requirements—Third-party audits or certifications.	☑
1311.305	Recordkeeping.	☑
1311	Clarification 19 October 2011	☑

iBeta Quality Assurance certifies ADL Data Systems Optimum Financials Version EPCS 1.04 and Order Entry Version EPCS 1.04 as a prescriber system for EPCS.

6.1.1 Limitations

As described in section 5.1 Limitations, iBeta has tested what it believes to be a representative sample of the commercially available system and used the appropriate test methods to test conformance to the standards. Device or system behavior which falls outside of the scope of testing is not certified.

6.1.2 Exceptions

The ADL Data System application does not support the following functionality and was neither tested nor certified against the corresponding DEA EPCS regulations:

- Detoxification or maintenance treatments per 1306.05
- Institutional Practitioners per 1306.05, 1311.110, 1311.120 and 1311.130

- Biometrics as one of the two-factor authenticators per 1311.116
- Prescribing more than one controlled substance at one time for a single patient per 1311.120

6.2 *Opinions*

Based upon the testing conducted and the exceptions documented herein, iBeta Quality Assurance certifies ADL Data Systems Optimum Financials Version EPCS 1.04 and Order Entry Version EPCS 1.04 as a prescriber system for EPCS.

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7 APPENDICES: TEST OPERATION, FINDINGS & DATA ANALYSIS

Appendix A: Security Assessment Results for DEA-EPCS Conformance

Below is the DEA-EPCS assessment matrix for the Signing Agent (Physician) based upon the Department of Justice Drug Enforcement Administration 21 CFR Parts 1300, 1304, 1306, and 1311 [Docket No. DEA–218I] Electronic Prescriptions for Controlled Substances.

Result	Result Definition	Total	Regression
Pass	Regulation has been assessed as being met during the Certification.	170	95
Fail	Regulation has not been assessed as being met by the design, documentation, or demonstration of the prescriber application during Certification.	0	0
NT	Not Testable: This regulation or sub-set of the regulations is not testable.	27	0
NA	Not Application: This regulation has been assessed as not applicable to the prescriber application being submitted for DEA EPCS Certification.	22	0
TE	Test Elsewhere: This regulation has been assessed to apply to the prescriber application but is being tested within another regulation.	64	0
Total Regulations for Certification		283	95

21 CFR Part	Sub-section	Regulation statement	Assessment or test action	Test Case	Result	Comments for Certification
Security Assessment, Electronic Prescription for Controlled Substances, All						
1304.04 Maintenance of records and inventories.						
1304.04	(b)	All registrants that are authorized to maintain a central recordkeeping system under paragraph (a) of this section shall be subject to the following conditions:	As below (1-4)		TE	
1304.04	(b)(1)	The records to be maintained at the central record location shall not include executed order forms and inventories, which shall be maintained at each registered location.	Validate as applicable		NA	
1304.06 Records and reports for electronic prescriptions.						

1304.06	(a)	As required by § 1311.120 of this chapter, a practitioner who issues electronic prescriptions for controlled substances must use an electronic prescription application that retains the following information:	As below (1-2)		TE	
1304.06	(a)(1)	The digitally signed record of the information specified in part 1306 of this chapter.	Verify that the digitally signed record exists	TC2 Step 1	Pass	
1304.06	(a)(2)	The internal audit trail and any auditable event identified by the internal audit as required by § 1311.150 of this chapter.	Verify that records of auditable events exist	TC2 Step 1	Pass	
1304.06	(b)	An institutional practitioner must retain a record of identity proofing and issuance of the two-factor authentication credential, where applicable, as required by § 1311.110 of this chapter.	Outside the scope of the Signing Application.		NT	
1304.06	(c)	As required by § 1311.205 of this chapter, a pharmacy that processes electronic prescriptions for controlled substances must use an application that retains the following:	Not a testable requirement of the Signing Application		NT	
1304.06	(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 of this chapter.	Validated as part of 1311.150 and 1311.215 as documented in this final report	TC DR	Pass	
1304.06	(e)	An electronic prescription or pharmacy application provider must retain third party audit or certification reports as required by § 1311.300 of this chapter.	Validated as part of 1311.300 and as documented in this final report	TC DR	Pass	
1304.06	(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 of this chapter.	Validated as part of 1311.300 and as documented in this final report	TC DR	Pass	
1304.06	(g)	Unless otherwise specified, records and reports must be retained for two years.	Validated records and reports are retained for two years	TC DR	Pass	
1304.11 Inventory requirements.						
1304.11			There are no electronic prescription specific requirements for inventory		NT	
1304.21 General requirements for continuing records.						
Part 1306						
1306.01-1306.03						
1306.03 Persons entitled to issue prescriptions.						
			There are no electronic prescription specific requirements for 1306.01 thru 1306.03		NT	

1306.05 Manner of issuance of prescriptions.						
1306.05	(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.	as below		TE	
			Dated	TC3 Step 1	Pass	
			Signed	TC3 Step 2	Pass	
			Day when issued	TC3 Step 3	Pass	
			full name and address of patient	TC3 Step 4	Pass	
			drug name	TC3 Step 5	Pass	
			strength	TC3 Step 6	Pass	
			dosage form	TC3 Step 7	Pass	
			quantity prescribed	TC3 Step 8	Pass	
			directions for use	TC3 Step 9	Pass	
			name, address and registration number of practitioner	TC3 Step 10	Pass	
1306.05	(b)	A prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for “detoxification treatment” or “maintenance treatment” must include the identification number issued by the Administrator under §1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of §1301.28(e) of this chapter.	The Signing Application has the capability to include this information or documentation that it is not capable		NA	ADL does not prescribe for detox treatments so this regulation is not applicable.
1306.05	(c)	Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription.	Signing Application documents capability to support requirement	TC8 Step 12	Pass	Only Schedule III Xyrem is prescribed.
1306.05	(e)	Electronic prescriptions shall be created and signed using an application that meets the requirements of part 1311 of this chapter.	Tested in 1311, 1311.140(a)(5)		TE	

1306.05	(g)	An individual practitioner exempted from registration under §1301.22(c) of this chapter shall include on all prescriptions issued by him the registration number of the hospital or other institution and the special internal code number assigned to him by the hospital or other institution as provided in §1301.22(c) of this chapter, in lieu of the registration number of the practitioner required by this section. Each paper prescription shall have the name of the practitioner stamped, typed, or handprinted on it, as well as the signature of the practitioner.	The Signing Application has the capability to include this information or documentation that it is not capable		NA	ADL does not support institutional practitioners.
1306.05	(h)	An official exempted from registration under §1301.23(a) of this chapter must include on all prescriptions issued by him his branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and his service identification number, in lieu of the registration number of the practitioner required by this section. The service identification number for a Public Health Service employee is his Social Security identification number. Each paper prescription shall have the name of the officer stamped, typed, or handprinted on it, as well as the signature of the officer.	The Signing Application has the capability to include this information or documentation that it is not capable		NA	ADL does not support branches of service or agencies.
1306.08 Electronic prescriptions.						
1306.08			There are no requirements for a Signing Application beyond those tested in 1311		NT	
1306.11 Requirement of prescription						
1306.11	(d)(4)	(d)(4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 1306.05, **the prescription shall have written on its face ''Authorization for Emergency Dispensing,'' and the date of the oral order**. ...	Validate capability to support: For electronic prescriptions, the prescriber must send a prescription to the pharmacy. If electronic, the physician must include a note that includes that this is the "Authorization for Emergency Dispensing" and the date of the oral order.	TC8 Step 1	Pass	
1306.12 Refilling prescriptions; issuance of multiple prescriptions.						
1306.12	(b)	An individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a Schedule II controlled substance provided the following conditions are met:	The Signing Application has the capability to sign multiple prescriptions authorizing the patient to receive up to a 90-day supply of Schedule II controlled substances, or documents otherwise	TC8 Step 9	Pass	

1306.12	(b)(1)(i)	Each separate prescription is issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice;	As above, not a specific requirement of electronic prescriptions		TE	
1306.12	(b)(1)(ii)	The individual practitioner provides written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription;	As above, not a specific requirement of electronic prescriptions		TE	
1306.12	(b)(1)(iii)	The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse;	As above, not a specific requirement of electronic prescriptions		TE	
1306.12	(b)(1)(iv)	The issuance of multiple prescriptions as described in this section is permissible under the applicable state laws; and	As above, not a specific requirement of electronic prescriptions		TE	
1306.12	(b)(1)(v)	The individual practitioner complies fully with all other applicable requirements under the Act and these regulations as well as any additional requirements under state law.	as above, not a specific requirement of electronic prescriptions		TE	
1306.12	(b)(2)	Nothing in this paragraph (b) shall be construed as mandating or encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing Schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.	as above, not a specific requirement of electronic prescriptions		TE	
1306.15 Provision of prescription information between retail pharmacies and central fill pharmacies for prescriptions of Schedule II controlled substances.						
1306.15			1306.15 is not applicable to the Signing Application		NT	
PART 1311—REQUIREMENTS FOR ELECTRONIC ORDERS AND PRESCRIPTIONS						
1311.100	(a)	This subpart addresses the requirements that must be met to issue and process Schedule II, III, IV, and V controlled substance prescriptions electronically.	As tested elsewhere		TE	
1311.100	(b)	A practitioner may issue a prescription for a Schedule II, III, IV, or V controlled substance electronically if all of the following conditions are met:	Not a testable requirement for the Signing Application		NT	
1311.100	(b)(1)	The practitioner is registered as an individual practitioner or exempt from the requirement of registration under part 1301 of this chapter and is authorized under the registration or exemption to dispense the controlled substance;	Not a testable requirement for the Signing Application		NT	

1311.100	(b)(2)	The practitioner uses an electronic prescription application that meets all of the applicable requirements of this subpart; and	Not a testable requirement for the Signing Application		NT	
1311.100	(b)(3)	The prescription is otherwise in conformity with the requirements of the Act and this chapter.	As tested elsewhere		TE	
1311.100	(c)	An electronic prescription for a Schedule II, III, IV, or V controlled substance created using an electronic prescription application that does not meet the requirements of this subpart is not a valid prescription, as that term is defined in §1300.03 of this chapter.	As tested elsewhere		TE	
1311.100	(d)	A controlled substance prescription created using an electronic prescription application that meets the requirements of this subpart is not a valid prescription if any of the functions required under this subpart were disabled when the prescription was indicated as ready for signature and signed.	As tested elsewhere test functionality cannot be disabled to sign a prescription.		TE	
1311.100	(f)	Nothing in this part alters the responsibilities of the practitioner and pharmacy, specified in part 1306 of this chapter, to ensure the validity of a controlled substance prescription.	As tested elsewhere		TE	
1311.102	Practitioner responsibilities					
1311.102	(a)	The practitioner must retain sole possession of the hard token, where applicable, and must not share the password or other knowledge factor, or biometric information, with any other person. The practitioner must not allow any other person to use the token or enter the knowledge factor or other identification means to sign prescriptions for controlled substances. Failure by the practitioner to secure the hard token, knowledge factor, or biometric information may provide a basis for revocation or suspension of registration pursuant to section 304(a)(4) of the Act (21 U.S.C. 824(a)(4)).	Procedures and awareness exist.	TC DR	Pass	
1311.102	(b)	The practitioner must notify the individuals designated under §1311.125 or §1311.130 within one business day of discovery that the hard token has been lost, stolen, or compromised or the authentication protocol has been otherwise compromised. A practitioner who fails to comply with this provision may be held responsible for any controlled substance prescriptions written using his two-factor authentication credential.	Procedures and awareness exist.	TC DR	Pass	

1311.102	(c)	If the practitioner is notified by an intermediary or pharmacy that an electronic prescription was not successfully delivered, as provided in §1311.170, he must ensure that any paper or oral prescription (where permitted) issued as a replacement of the original electronic prescription indicates that the prescription was originally transmitted electronically to a particular pharmacy and that the transmission failed.	Procedures and awareness exist.	TC DR	Pass	
1311.102	(d)	Before initially using an electronic prescription application to sign and transmit controlled substance prescriptions, the practitioner must determine that the third-party auditor or certification organization has found that the electronic prescription application records, stores, and transmits the following accurately and consistently:	Procedures and awareness exist.	TC DR	Pass	
1311.102	(d)(1)	The information required for a prescription under §1306.05(a) of this chapter.	Procedures and awareness exist.	TC DR	Pass	
1311.102	(d)(2)	The indication of signing as required by §1311.120(b)(17) or the digital signature created by the practitioner's private key.	Procedures and awareness exist.	TC DR	Pass	
1311.102	(d)(3)	The number of refills as required by §1306.22 of this chapter.	Procedures and awareness exist.	TC DR	Pass	
1311.102	(e)	If the third-party auditor or certification organization has found that an electronic prescription application does not accurately and consistently record, store, and transmit other information required for prescriptions under this chapter, the practitioner must not create, sign, and transmit electronic prescriptions for controlled substances that are subject to the additional information requirements.	Procedures and awareness exist.	TC DR	Pass	
1311.102	(f)	The practitioner must not use the electronic prescription application to sign and transmit electronic controlled substance prescriptions if any of the functions of the application required by this subpart have been disabled or appear to be functioning improperly.	Procedures and awareness exist.	TC DR	Pass	
1311.102	(g)	If an electronic prescription application provider notifies an individual practitioner that a third-party audit or certification report indicates that the application or the application provider no longer meets the requirements of this part or notifies him that the application provider has identified an issue that makes the application non-compliant, the practitioner must do the following:	Procedures and awareness exist.	TC DR	Pass	
1311.102	(g)(1)	Immediately cease to issue electronic controlled substance prescriptions using the application.	Procedures and awareness exist.	TC DR	Pass	

1311.102	(g)(2)	Ensure, for an installed electronic prescription application at an individual practitioner's practice, that the individuals designated under §1311.125 terminate access for signing controlled substance prescriptions.	Procedures and awareness exist.	TC DR	Pass	
1311.102	(h)	If an electronic prescription application provider notifies an institutional practitioner that a third-party audit or certification report indicates that the application or the application provider no longer meets the requirements of this part or notifies it that the application provider has identified an issue that makes the application non-compliant, the institutional practitioner must ensure that the individuals designated under §1311.130 terminate access for signing controlled substance prescriptions.	Procedures and awareness exist.		NA	ADL does not support institutional practitioners
1311.102	(i)	An individual practitioner or institutional practitioner that receives a notification that the electronic prescription application is not in compliance with the requirements of this part must not use the application to issue electronic controlled substance prescriptions until it is notified that the application is again compliant and all relevant updates to the application have been installed.	Procedures and awareness exist.	TC DR	Pass	
1311.102	(j)	The practitioner must notify both the individuals designated under §1311.125 or §1311.130 and the Administration within one business day of discovery that one or more prescriptions that were issued under a DEA registration held by that practitioner were prescriptions the practitioner had not signed or were not consistent with the prescriptions he signed.	Procedures and awareness exist.	TC DR	Pass	
1311.102	(k)	The practitioner has the same responsibilities when issuing prescriptions for controlled substances via electronic means as when issuing a paper or oral prescription. Nothing in this subpart relieves a practitioner of his responsibility to dispense controlled substances only for a legitimate medical purpose while acting in the usual course of his professional practice. If an agent enters information at the practitioner's direction prior to the practitioner reviewing and approving the information and signing and authorizing the transmission of that information, the practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations.	Procedures and awareness exist.	TC DR	Pass	
1311.105	Requirements for obtaining an authentication credential—Individual practitioners.					

1311.105		Requirements for obtaining an authentication credential—Individual practitioners.	These requirements are imposed on the practitioner by the provider and outside of the scope of system certification or installed system audit		NT	
1311.105	(a)	An individual practitioner must obtain a two-factor authentication credential from one of the following:	Tested below		TE	
1311.105	(a)(1)	A credential service provider that has been approved by the General Services Administration Office of Technology Strategy/Division of Identity Management to conduct identity proofing that meets the requirements of Assurance Level 3 or above as specified in NIST SP 800–63–1 as incorporated by reference in §1311.08.	Procedures and awareness exist.	TC DR	Pass	
1311.105	(a)(2)	For digital certificates, a certification authority that is cross-certified with the Federal Bridge certification authority and that operates at a Federal Bridge Certification Authority basic assurance level or above.	As above, not directly tested		TE	
1311.105	(b)	The practitioner must submit identity proofing information to the credential service provider or certification authority as specified by the credential service provider or certification authority.	As above, not directly tested		TE	
1311.105	(c)	The credential service provider or certification authority must issue the authentication credential using two channels (e.g., e-mail, mail, or telephone call). If one of the factors used in the authentication protocol is a biometric, or if the practitioner has a hard token that is being enabled to sign controlled substances prescriptions, the credential service provider or certification authority must issue two pieces of information used to generate or activate the authentication credential using two channels.	As above, not directly tested		TE	
1311.110	Requirements for obtaining an authentication credential—Individual practitioners eligible to use an electronic prescription application of an institutional practitioner.					
1311.110	(a)	For any registrant or person exempted from the requirement of registration under §1301.22(c) of this chapter who is eligible to use the institutional practitioner's electronic prescription application to sign prescriptions for controlled substances, the entity within a DEA-registered institutional practitioner that grants that individual practitioner privileges at the institutional practitioner (e.g., a hospital credentialing office) may conduct identity proofing and authorize the issuance of the authentication credential. That entity must do the following:	As tested below		TE	

1311.110	(a)(1)	Ensure that photographic identification issued by the Federal Government or a State government matches the person presenting the identification.	Validate procedures and awareness	TC DR	Pass	
1311.110	(a)(2)	Ensure that the individual practitioner's State authorization to practice and, where applicable, State authorization to prescribe controlled substances, is current and in good standing.	Validate procedures and awareness	TC DR	Pass	
1311.110	(a)(3)	Either ensure that the individual practitioner's DEA registration is current and in good standing or ensure that the institutional practitioner has granted the individual practitioner exempt from the requirement of registration under §1301.22 of this chapter privileges to prescribe controlled substances using the institutional practitioner's DEA registration number.	Validate procedures and awareness	TC DR	Pass	
1311.110	(a)(4)	If the individual practitioner is an employee of a health care facility that is operated by the Department of Veterans Affairs, confirm that the individual practitioner has been duly appointed to practice at that facility by the Secretary of the Department of Veterans Affairs pursuant to 38 U.S.C. 7401–7408.	Validate procedures and awareness	TC DR	Pass	
1311.110	(a)(5)	If the individual practitioner is working at a health care facility operated by the Department of Veterans Affairs on a contractual basis pursuant to 38 U.S.C. 8153 and, in the performance of his duties, prescribes controlled substances, confirm that the individual practitioner meets the criteria for eligibility for appointment under 38 U.S.C. 7401–7408 and is prescribing controlled substances under the registration of such facility.	Validate procedures and awareness	TC DR	Pass	
1311.110	(b)	An institutional practitioner that elects to conduct identity proofing must provide authorization to issue the authentication credentials to a separate entity within the institutional practitioner or to an outside credential Service provider or certification authority that meets the requirements of §1311.105(a).	Validate procedures and awareness		NA	ADL does not support institutional practitioners
1311.110	(c)	When an institutional practitioner is conducting identity proofing and submitting information to a credential service provider or certification authority to authorize the issuance of authentication credentials, the institutional practitioner must meet any requirements that the credential service provider or certification authority imposes on entities that serve as trusted agents.	Validate procedures and awareness		NA	ADL does not support institutional practitioners

1311.110	(d)	An institutional practitioner that elects to conduct identity proofing and authorize the issuance of the authentication credential as provided in paragraphs (a) through (c) of this section must do so in a manner consistent with the institutional practitioner's general obligation to maintain effective controls against diversion. Failure to meet this obligation may result in remedial action consistent with §1301.36 of this chapter.	Validate procedures and awareness		NA	ADL does not support institutional practitioners
1311.110	(e)	An institutional practitioner that elects to conduct identity proofing must retain a record of the identity-proofing. An institutional practitioner that elects to issue the two-factor authentication credential must retain a record of the issuance of the credential.	Validate procedures and awareness		NA	ADL does not support institutional practitioners
1311.115	Additional requirements for two-factor authentication.					
1311.115	(a)	To sign a controlled substance prescription, the electronic prescription application must require the practitioner to authenticate to the application using an authentication protocol that uses two of the following three factors:	Validate 2 factors of the 3 below:	TC5 Step 2	Pass	
1311.115	(a)(1)	Something only the practitioner knows, such as a password or response to a challenge question.	choose 2, validated above	TC5 Step 3	Pass	
1311.115	(a)(2)	Something the practitioner is, biometric data such as a fingerprint or iris scan.	choose 2, validated above		NA	ADL does not use biometrics.
1311.115	(a)(3)	Something the practitioner has, a device (hard token) separate from the computer to which the practitioner is gaining access.	choose 2, validated above	TC5 Step 4	Pass	
1311.115	(b)	If one factor is a hard token, it must be separate from the computer to which it is gaining access and must meet at least the criteria of FIPS 140–2 Security Level 1, as incorporated by reference in §1311.08, for cryptographic modules or one-time-password devices.	For hard tokens, the token is FIPS 140-2 Level 1 certified	TC5 Step 5	Pass	
			The token is FIPS 140-2 Level 1 certified	TC5 Step 6	Pass	
			The token is separate from the computer to which it is gaining access	TC5 Step 7	Pass	
1311.115	(c)	If one factor is a biometric, the biometric subsystem must comply with the requirements of §1311.116.			NA	System does not use biometrics; regulation is not applicable.
1311.116	Additional requirements for biometrics.					
1311.116		Electronic prescription application requirements.			NA	System does not use biometrics; regulation is not applicable.

1311.120	Electronic prescription application requirements.					
1311.120	(a)	A practitioner may only use an electronic prescription application that meets the requirements in paragraph (b) of this section to issue electronic controlled substance prescriptions.	Requirements of the application are tested below (b)(1)-(b)(28)		TE	
1311.120	(b)	The electronic prescription application must meet the requirements of this subpart including the following:	Requirements of the application are tested below (b)(1)-(b)(28)		TE	
1311.120	(b)(1)	The electronic prescription application must do the following:	As below		TE	
1311.120	(b)(1)(i)	Link each registrant, by name, to at least one DEA registration number.	Test each individual requirement, as below	TC8 Step 9	TE	
1311.120	(b)(1)(ii)	Link each practitioner exempt from registration under §1301.22(c) of this chapter to the institutional practitioner's DEA registration number and the specific internal code number required under §1301.22(c)(5) of this chapter.	As stated		NA	ADL does not support institutional practitioners
1311.120	(b)(2)	The electronic prescription application must be capable of the setting of logical access controls to limit permissions for the following functions:	As below		TE	
1311.120	(b)(2)(i)	Indication that a prescription is ready for signing and signing controlled substance prescriptions.	as stated	TC7 Step 1	Pass	
1311.120	(b)(2)(ii)	Creating, updating, and executing the logical access controls for the functions specified in paragraph (b)(2)(i) of this section.	as stated	TC7 Step 2	Pass	
1311.120	(b)(3)	Logical access controls must be set by individual user name or role. If the application sets logical access control by role, it must not allow an individual to be assigned the role of registrant unless that individual is linked to at least one DEA registration number as provided in paragraph (b)(1) of this section.	as stated	TC7 Step 3	Pass	
1311.120	(b)(4)	The application must require that the setting and changing of logical access controls specified under paragraph (b)(2) of this section involve the actions of two individuals as specified in §§1311.125 or 1311.130. Except for institutional practitioners, a practitioner authorized to sign controlled substance prescriptions must approve logical access control entries.	as stated	TC7 Step 4	Pass	
1311.120	(b)(5)	The electronic prescription application must accept two-factor authentication that meets the requirements of §1311.115 and require its use for signing controlled substance prescriptions and for approving data that set or change logical access controls related to reviewing and signing controlled substance prescriptions.	as stated	TC5 Step 8	Pass	

1311.120	(b)(6)	The electronic prescription application must be capable of recording all of the applicable information required in part 1306 of this chapter for the controlled substance prescription.	As stated	TC5 Step 8	Pass	
1311.120	(b)(7)	If a practitioner has more than one DEA registration number, the electronic prescription application must require the practitioner or his agent to select the DEA registration number to be included on the prescription.	As stated, see also 1306.05		NA	ADL does not support multiple DEA numbers
1311.120	(b)(8)	The electronic prescription application must have a time application that is within five minutes of the official National Institute of Standards and Technology time source.	As stated, see www.time.gov	TC8 Step 4	Pass	
1311.120	(b)(9)	The electronic prescription application must present for the practitioner's review and approval all of the following data for each controlled substance prescription:	as below		TE	
1311.120	(b)(9)(i)	The date of issuance.	as stated	TC3 Step 13	Pass	
1311.120	(b)(9)(ii)	The full name of the patient.	as stated	TC3 Step 14	Pass	
1311.120	(b)(9)(iii)	The drug name.	as stated	TC3 Step 15	Pass	
1311.120	(b)(9)(iv)	The dosage strength and form, quantity prescribed, and directions for use.	as stated	TC3 Step 16	Pass	
1311.120	(b)(9)(v)	The number of refills authorized, if applicable, for prescriptions for Schedule III, IV, and V controlled substances.	as stated	TC3 Step 17	Pass	
1311.120	(b)(9)(vi)	For prescriptions written in accordance with the requirements of §1306.12(b) of this chapter, the earliest date on which a pharmacy may fill each prescription.	as stated	TC3 Step 18	Pass	
1311.120	(b)(9)(vii)	The name, address, and DEA registration number of the prescribing practitioner.	as stated	TC3 Step 19	Pass	
1311.120	(b)(9)(viii)	The statement required under §1311.140(a)(3).	as stated	TC3 Step 20	Pass	
1311.120	(b)(10)	The electronic prescription application must require the prescribing practitioner to indicate that each controlled substance prescription is ready for signing. The electronic prescription application must not permit alteration of the DEA elements after the practitioner has indicated that a controlled substance prescription is ready to be signed without requiring another review and indication of readiness for signing. Any controlled substance prescription not indicated as ready to be signed shall not be signed or transmitted.	as stated	TC5 Step 9	Pass	

1311.120	(b)(11)	While the information required by paragraph (b)(9) of this section and the statement required by §1311.140(a)(3) remain displayed, the electronic prescription application must prompt the prescribing practitioner to authenticate to the application, using two-factor authentication, as specified in §1311.140(a)(4), which will constitute the signing of the prescription by the practitioner for purposes of §1306.05(a) and (e) of this chapter.	as stated	TC5 Step 10	Pass	
1311.120	(b)(12)	The electronic prescription application must not permit a practitioner other than the prescribing practitioner whose DEA number (or institutional practitioner DEA number and extension data for the individual practitioner) is listed on the prescription as the prescribing practitioner and who has indicated that the prescription is ready to be signed to sign the prescription.	as stated	TC5 Step 11	Pass	
1311.120	(b)(13)	Where a practitioner seeks to prescribe more than one controlled substance at one time for a particular patient, the electronic prescription application may allow the practitioner to sign multiple prescriptions for a single patient at one time using a single invocation of the two-factor authentication protocol provided the following has occurred: The practitioner has individually indicated that each controlled substance prescription is ready to be signed while the information required by paragraph (b)(9) of this section for each such prescription is displayed along with the statement required by §1311.140(a)(3).	As below		NA	ADL system does not prescribe multiple prescriptions for a patient - one at a time so this is not applicable.
	(b)(14)	The electronic prescription application must time and date stamp the prescription when the signing function is used.	As stated	TC1 Step 8	Pass	
1311.120	(b)(15)	When the practitioner uses his two-factor authentication credential as specified in §1311.140(a)(4), the electronic prescription application must digitally sign at least the information required by part 1306 of this chapter and electronically archive the digitally signed record. If the practitioner signs the prescription with his own private key, as provided in §1311.145, the electronic prescription application must electronically archive a copy of the digitally signed record, but need not apply the application's digital signature to the record.	As stated, see also 1311.55(b)(8)	TC1 Step 9	Pass	
1311.120	(b)(16)	The digital signature functionality must meet the following requirements:	As below		TE	
1311.120	(b)(16)(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 140–2 is incorporated by reference in §1311.08.	at the above link, verify that the digital signature (186-3) and hash (180-3) are certified and being used to generate the signature(s)	TC1 Step 10	Pass	

1311.120	(b)(16)(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.	at the above link, validate that the private key is maintained by such a certified module	TC1 Step 11	Pass	
1311.120	(b)(16)(iii)	The electronic prescription 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 140–2 is incorporated by reference in §1311.08.	Code review or otherwise generate a test case.	TC1 Step 12	Pass	
1311.120	(b)(16)(iv)	For software implementations, when the signing module is deactivated, the application must clear the plain text password from the application memory to prevent the unauthorized access to, or use of, the private key.	as stated	TC10 Step 1	Pass	
1311.120	(b)(17)	Unless the digital signature created by an individual practitioner's private key is being transmitted to the pharmacy with the prescription, the electronic prescription application must include in the data file transmitted an indication that the prescription was signed by the prescribing practitioner.	Validate all methods of signature documented	TC1 Step 13	Pass	
1311.120	(b)(18)	The electronic prescription application must not transmit a controlled substance prescription unless the signing function described in §1311.140(a)(4) has been used.	Validate all methods of signature documented	TC1 Step 14	Pass	
1311.120	(b)(19)	The electronic prescription application must not allow alteration of any of the information required by part 1306 of this chapter after the prescription has been digitally signed. Any alteration of the information required by part 1306 of this chapter after the prescription is digitally signed must cancel the prescription.	Attempt to alter the prescription and verify it is no longer signed if alteration is possible.	TC1 Step 15	Pass	
1311.120	(b)(20)	The electronic prescription application must not allow transmission of a prescription that has been printed.	See also section 1306 Verify that once printed, prescription cannot be transmitted	TC8 Step 5	Pass	
1311.120	(b)(21)	The electronic prescription application must allow printing of a prescription after transmission only if the printed prescription is clearly labeled as a copy not for dispensing. The electronic prescription application may allow printing of prescription information if clearly labeled as being for informational purposes. The electronic prescription application may transfer such prescription information to medical records.	As stated	TC8 Step 6	Pass	

1311.120	(b)(22)	If the transmission of an electronic prescription fails, the electronic prescription application may print the prescription. The prescription must indicate that it was originally transmitted electronically to, and provide the name of, a specific pharmacy, the date and time of transmission, and that the electronic transmission failed.	As stated, attempt to fail transmission and then print	TC9 Step 1	Pass	
1311.120	(b)(23)	The electronic prescription application must maintain an audit trail of all actions related to the following:	Verify audit trail as below	TC2 Step 3	Pass	
1311.120	(b)(23)(i)	The creation, alteration, indication of readiness for signing, signing, transmission, or deletion of a controlled substance prescription.	Validate as below, audit trail contains	TC2 Step 4	Pass	
			prescription readiness	TC2 Step 5	Pass	
			prescription signing	TC2 Step 6	Pass	
			prescription transmission	TC2 Step 7	Pass	
			prescription deletion	TC2 Step 8	Pass	
1311.120	(b)(23)(ii)	Any setting or changing of logical access control permissions related to the issuance of controlled substance prescriptions.	As stated	TC2 Step 9	Pass	
1311.120	(b)(23)(iii)	Notification of a failed transmission.	As stated	TC2 Step 10	Pass	
1311.120	(b)(23)(iv)	Auditable events as specified in §1311.150.	As stated	TC2 Step 11	Pass	
1311.120	(b)(24)	The electronic prescription application must record within each audit record the following information:	As below, (b)(24)(i)-(iv)		TE	
1311.120	(b)(24)(i)	The date and time of the event.	As stated	TC2 Step 12	Pass	
1311.120	(b)(24)(ii)	The type of event.	As stated	TC2 Step 13	Pass	
1311.120	(b)(24)(iii)	The identity of the person taking the action, where applicable.	As stated	TC2 Step 14	Pass	
1311.120	(b)(24)(iv)	The outcome of the event (success or failure).	As stated	TC2 Step 15	Pass	
1311.120	(b)(25)	The electronic prescription application must conduct internal audits and generate reports on any of the events specified in §1311.150 in a format that is readable by the practitioner. Such internal audits may be automated and need not require human intervention to be conducted.	As stated	TC2 Step 16	Pass	
1311.120	(b)(26)	The electronic prescription application must protect the stored audit records from unauthorized deletion. The electronic prescription application shall prevent modifications to the audit records.	See also 1311.150	TC 2 Step 17	Pass	

1311.120	(b)(27)	The electronic prescription application must do the following:	Tested below		TE	
1311.120	(b)(27)(i)	Generate a log of all controlled substance prescriptions issued by a practitioner during the previous calendar month and provide the log to the practitioner no later than seven calendar days after that month.	Verify that the application generates the logs per the regulation.	TC DR	Pass	
1311.120	(b)(27)(ii)	Be capable of generating a log of all controlled substance prescriptions issued by a practitioner for a period specified by the practitioner upon request. Prescription information available from which to generate the log must span at least the previous two years.	As stated	TC2 Step 18	Pass	
1311.120	(b)(27)(iii)	Archive all logs generated.	As stated	TC6 Step 1	Pass	
1311.120	(b)(27)(iv)	Ensure that all logs are easily readable or easily rendered into a format that a person can read.	As stated	TC2 Step 19	Pass	
1311.120	(b)(27)(v)	Ensure that all logs are sortable by patient name, drug name, and date of issuance of the prescription.	As below.		TE	
			patient name	TC2 Step 20	Pass	
			drug name	TC2 Step 21	Pass	
			date of issuance	TC2 Step 22	Pass	
			Verify procedures and process to retain for two years.	TC2 Step 23	Pass	
1311.120	(b)(28)	Where the electronic prescription application is required by this part to archive or otherwise maintain records, it must retain such records electronically for two years from the date of the record's creation and comply with all other requirements of §1311.305.	Verify capability	TC2 Step 24	Pass	
1311.125	Requirements for establishing logical access control—Individual practitioner.					
1311.125	(a)	At each registered location where one or more individual practitioners wish to use an electronic prescription application meeting the requirements of this subpart to issue controlled substance prescriptions, the registrant(s) must designate at least two individuals to manage access control to the application. At least one of the designated individuals must be a registrant who is authorized to issue controlled substance prescriptions and who has obtained a two-factor authentication credential as provided in §1311.105.	Verify that the Signing Application can support this requirement. I.e requires at least one registrant	TC7 Step 5	Pass	

1311.125	(b)	At least one of the individuals designated under paragraph (a) of this section must verify that the DEA registration and State authorization(s) to practice and, where applicable, State authorization(s) to dispense controlled substances of each registrant being granted permission to sign electronic prescriptions for controlled substances are current and in good standing.	Not a testable requirement of the Signing Application		NT	
1311.125	(c)	After one individual designated under paragraph (a) of this section enters data that grants permission for individual practitioners to have access to the prescription functions that indicate readiness for signature and signing or revokes such authorization, a second individual designated under paragraph (a) of this section must use his two-factor authentication credential to satisfy the logical access controls. The second individual must be a DEA registrant.	Signing Application has the capability to support this operation	TC7 Step 6	Pass	
1311.125	(d)	A registrant's permission to indicate that controlled substances prescriptions are ready to be signed and to sign controlled substance prescriptions must be revoked whenever any of the following occurs, on the date the occurrence is discovered:	Signing Application has the capability to support this operation	TC7 Step 7	Pass	
1311.125	(d)(1)	A hard token or any other authentication factor required by the two-factor authentication protocol is lost, stolen, or compromised. Such access must be terminated immediately upon receiving notification from the individual practitioner.	Signing Application has the capability to support this operation	TC7 Step 8	Pass	
1311.125	(d)(2)	The individual practitioner's DEA registration expires, unless the registration has been renewed.	Signing Application has the capability to support this operation	TC 7 Step 9	Pass	
1311.125	(d)(3)	The individual practitioner's DEA registration is terminated, revoked, or suspended.	Signing Application has the capability to support this operation	TC7 Step 10	Pass	
1311.125	(d)(4)	The individual practitioner is no longer authorized to use the electronic prescription application (e.g., when the individual practitioner leaves the practice).	Signing Application has the capability to support this operation	TC 7 Step 11	Pass	
1311.130	Requirements for establishing logical access control—Institutional practitioner.					
1311.130	(a)-(d)(4)	(a) The entity within an institutional practitioner that conducts the identity proofing under § 1311.110 must develop a list of individual practitioners who are permitted to use the institutional practitioner's electronic prescription application to indicate that controlled substances prescriptions are ready to be signed and to sign controlled substance prescriptions. The list must be approved by two individuals. (b) After the list is approved, it must be sent to a separate	Institutional Requirements, Not testable requirements for the Signing Application		NA	ADL does not support institutional practitioners

		entity within the institutional practitioner that enters permissions for logical access controls into the application. The institutional practitioner must authorize at least two individuals or a role filled by at least two individuals to enter the logical access control data. One individual in the separate entity must authenticate to the application and enter the data to grant permissions to individual practitioners to indicate that controlled substances prescriptions are ready to be signed and to sign controlled substance prescriptions. A second individual must authenticate to the application to execute the logical access controls. (c) The institutional practitioner must retain a record of the individuals or roles that are authorized to conduct identity proofing and logical access control data entry and execution. (d) Permission to indicate that controlled substances prescriptions are ready to be signed and to sign controlled substance prescriptions must be revoked whenever any of the following occurs, on the date the occurrence is discovered: (1) An individual practitioner's hard token or any other authentication factor required by the practitioner's two-factor authentication protocol is lost, stolen, or compromised. Such access must be terminated immediately upon receiving notification from the individual practitioner. (2) The institutional practitioner's or, where applicable, individual practitioner's DEA registration expires, unless the registration has been renewed. (3) The institutional practitioner's or, where applicable, individual practitioner's DEA registration is terminated, revoked, or suspended. (4) An individual practitioner is no longer authorized to use the institutional practitioner's electronic prescription application (e.g., when the individual practitioner is no longer associated with the institutional practitioner.)				
1311.135	Requirements for creating a controlled substance prescription.					
1311.135	(a)	The electronic prescription application may allow the registrant or his agent to enter data for a controlled substance prescription, provided that only the registrant may sign the prescription in accordance with §§1311.120(b)(11) and 1311.140.	Tested below		TE	

			may allow the registrant or his agent to enter data for a controlled substance prescription	TC7 Step 12	Pass	
			provided that only the registrant may sign the prescription in accordance with §§1311.120(b)(11) and 1311.140.	TC7 Step 13	Pass	
1311.135	(b)	If a practitioner holds multiple DEA registrations, the practitioner or his agent must select the appropriate registration number for the prescription being issued in accordance with the requirements of §1301.12 of this chapter.	As tested in 1311.120(b)(11) and 1311.140		NA	ADL does not support multiple DEA numbers
1311.135	(c)	If required by State law, a supervisor's name and DEA number may be listed on a prescription, provided the prescription clearly indicates who is the supervisor and who is the prescribing practitioner.	Test as stated, or validate documentation states that supervisor name cannot be entered (and application cannot be used in states requiring supervisor name)	TC8 Step 10	Pass	
			Functionality and capability documented	TC DR	Pass	
1311.140	Requirements for signing a controlled substance prescription.					
1311.140	(a)	For a practitioner to sign an electronic prescription for a controlled substance the following must occur:	As below		TE	
1311.140	(a)(1)	The practitioner must access a list of one or more controlled substance prescriptions for a single patient. The list must display the information required by §1311.120(b)(9).	As below		TE	
1311.140	(a)(2)	The practitioner must indicate the prescriptions that are ready to be signed.	See also 1311.120(b)(9)	TC5 Step 12	Pass	
1311.140	(a)(3)	While the prescription information required in §1311.120(b)(9) is displayed, the following statement or its substantial equivalent is displayed: “By completing the two-factor authentication protocol at this time, you are legally signing the prescription(s) and authorizing the transmission of the above information to the pharmacy for dispensing. The two-factor authentication protocol may only be completed by the practitioner whose name and DEA registration number appear above.”	As below	TC5 Step 13	Pass	
1311.140	(a)(4)	While the prescription information required in §1311.120(b)(9) and the statement required by paragraph (a)(3) of this section remain displayed, the practitioner must be prompted to complete the two-factor authentication protocol.	As stated	TC5 Step 14	Pass	

1311.140	(a)(5)	The completion by the practitioner of the two-factor authentication protocol in the manner provided in paragraph (a)(4) of this section will constitute the signing of the prescription by the practitioner for purposes of §1306.05(a) and (e) of this chapter.	As stated	TC5 Step 15	Pass	
1311.140	(a)(6)	Except as provided under §1311.145, the practitioner's completion of the two-factor authentication protocol must cause the application to digitally sign and electronically archive the information required under part 1306 of this chapter.	Completion of 2-factor auth causes digital signature of prescription(s)	TC1 Step 16	Pass	
1311.140	(b)	The electronic prescription application must clearly label as the signing function the function that prompts the practitioner to execute the two-factor authentication protocol using his credential.	As stated	TC5 Step 16	Pass	
1311.140	(c)	Any prescription not signed in the manner required by this section shall not be transmitted.	Attempt to transmit an unsigned prescription.	TC8 Step 7	Pass	
1311.145	Digitally signing the prescription with the individual practitioner's private key					
1311.145	(a)	(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.	Functionality is implied by other testing		NT	
1311.145	(b)	(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.	Verify that the digital signature requires two-factor authentication	TC1 Step 19	Pass	
1311.145	(c)	(c) The electronic prescription application must digitally sign at least all information required under part 1306 of this chapter.	As tested below.		TE	
1306.05	(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.	validate that the following information is signed by the application using the application or practitioner private key	TC1 Step 18	Pass	
			Dated	TC3 Step 21	Pass	
			Signed	TC3 Step 22	Pass	
			Day when issued	TC3 Step 23	Pass	

			full name and address of patient	TC3 Step 24	Pass	
			drug name	TC3 Step 25	Pass	
			strength	TC3 Step 26	Pass	
			dosage form	TC3 Step 27	Pass	
			quantity prescribed	TC3 Step 28	Pass	
			directions for use	TC3 Step 29	Pass	
			name, address and registration number of practitioner	TC3 Step 30	Pass	
1306.05	(b)	(b) A prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for "detoxification treatment" or "maintenance treatment" must include the identification number issued by the Administrator under §1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of §1301.28(e) of this chapter.	good faith exception of 1301.28(e) or ID number		NA	Confirmed that the system does not support this regulation - Not Applicable.
1306.05	(c)	(c) Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription.	Verify medical need if GHB	TC8 Step 12	Pass	Only Schedule III Xyrem is prescribed.
1311.145	(d)	The electronic prescription application must electronically archive the digitally signed record.	As stated	TC6 Step 2	Pass	ADL is signing with an encipherment certificate.
1311.145	(e)	(e) A prescription that is digitally signed with a practitioner's private key may be transmitted to a pharmacy without the digital signature.	Verify that if the digital signature is not included, the signed record contains a the field indicating that the prescription was signed	TC1 Step 19	Pass	
1311.145	(f)	(f) If the electronic prescription is transmitted without the digital signature, the electronic prescription application must check 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 must not transmit the prescription. The certificate revocation list may be cached until the certification authority issues a new certificate revocation list.	Delete CRL, validate CRL is acquired prior to transmission, if possible use a certificate that has been revoked	TC1 Step 20 TC10 Step 2	Pass	

1311.145	(g)	(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.	Verify that the application is digitally signing the prescription with either the practitioners' or the applications' private key.	TC1 Step 21	Pass	
1311.150	Additional requirements for internal application audits.					
1311.150	(a)	(a) The application provider must establish and implement a list of auditable events. Auditable events must, at a minimum, include the following:	As below (1)-(6)		TE	
1311.150	(a)(1)	(1) Attempted unauthorized access to the electronic prescription application, or successful unauthorized access where the determination of such is feasible.	Documentation review and Verify	TC2 Step 26	Pass	
1311.150	(a)(2)	(2) Attempted 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.	Documentation review and Verify	TC2 Step 27	Pass	
1311.150	(a)(3)	(3) Interference with application operations of the prescription application.	Documentation review and Verify	TC2 Step 28	Pass	
1311.150	(a)(4)	(4) Any setting of or change to logical access controls related to the issuance of controlled substance prescriptions.	Documentation review and Verify	TC2 Step 29	Pass	
1311.150	(a)(5)	(5) Attempted or successful interference with audit trail functions.	Documentation review and Verify	TC2 Step 30	Pass	
1311.150	(a)(6)	(6) For application service providers, attempted or successful creation, modification, or destruction of controlled substance prescriptions or logical access controls related to controlled substance prescriptions by any agent or employee of the application service provider.	Documentation review and Verify	TC2 Step 31	Pass	
1311.150	(b)	(b) The electronic prescription application must analyze the audit trail at least once every calendar day and generate an incident report that identifies each auditable event.	Verify	TC2 Step 32	Pass	
1311.150	(c)	(c) Any person designated to set logical access controls under §§1311.125 or 1311.130 must determine whether any identified auditable event represents a security incident that compromised or could have compromised the integrity of the prescription records. Any such incidents must be reported to the electronic prescription application provider and the Administration within one business day.	As supported by the signing application.	TC2 Step 33	Pass	
1311.170	Transmission requirements.					

1311.170	(a)	(a) The electronic prescription application must transmit the electronic prescription as soon as possible after signature by the practitioner.	Verify that the application transmits the prescription within five minutes when possible	TC9 Step 2	Pass	
		&	Verify that if the application is not connected, transmission occurs within five minutes when the connection is available.	TC9 Step 3	Pass	
1311.170	(b)	The electronic prescription application may print a prescription that has been transmitted only if an intermediary or the designated pharmacy notifies a practitioner that an electronic prescription was not successfully delivered to the designated pharmacy. If this occurs, the electronic prescription application may print the prescription for the practitioner's manual signature. The printed prescription must include information noting that the prescription was originally transmitted electronically to [name of the specific pharmacy] on [date/time] and that transmission failed.	Verify functionality	TC8 Step 8	Pass	
1311.170	(c)	The electronic prescription application may print copies of the transmitted prescription if they are clearly labeled: "Copy only—not valid for dispensing." Data on the prescription may be electronically transferred to medical records, and a list of prescriptions written may be printed for patients if the list indicates that it is for informational purposes only and not for dispensing.	Verify functionality	TC8 Step 8	Pass	
1311.170	(d)	The electronic prescription application must not allow the transmission of an electronic prescription if an original prescription was printed prior to attempted transmission.	Verify functionality	TC8 Step 8	Pass	
1311.170	(e)	The contents of the prescription required by part 1306 of this chapter must not be altered during transmission between the practitioner and pharmacy. Any change to the content during transmission, including truncation or removal of data, will render the electronic prescription invalid. The electronic prescription data may be converted from one software version to another between the electronic prescription application and the pharmacy application; conversion includes altering the structure of fields or machine language so that the receiving pharmacy application can read the prescription and import the data.	The digitally signed portion of the transmission is tested elsewhere [ref 1311.145(c)]	TC9 Step 4	Pass	

1311.170	(f)	(f) An electronic prescription must be transmitted from the practitioner to the pharmacy in its electronic form. At no time may an intermediary convert an electronic prescription to another form (e.g., facsimile) for transmission.	Verify that an electronic prescription cannot be converted to another valid (i.e not a copy or not marked as unfillable) form without invalidating the electronic form.	TC DR	Pass	ADL is using Prescriber's Connection as an intermediary.
1311.210	Archiving the initial record.					
1311.210	(a)(1)	The last intermediary transmitting the record to the pharmacy must digitally sign the prescription immediately prior to transmission to the pharmacy.	As applicable to intermediary applications	TC1 Step 22	Pass	ADL Data Systems does transmit both directly to pharmacies and to PrescribersConnection intermediary. In both cases, Optimus digitally signs the prescription immediately prior to transmission.
1311.210	(b)	If the last intermediary digitally signs the record, it must forward the digitally signed copy to the pharmacy.	As applicable if there is an intermediary capability in the signing application	TC1 Step 23	Pass	
1311.300	Application provider requirements—Third-party audits or certifications.					
1311.300	(a)	Except as provided in paragraph (e) of this section, the application provider of an electronic prescription application or a pharmacy application must have a third-party audit of the application that determines that the application meets the requirements of this part at each of the following times:	Tested below		TE	
1311.300	(a)(1)	Before the application may be used to create, sign, transmit, or process controlled substance prescriptions.	Capabilities as tested below		TE	
1311.300	(a)(2)	Whenever a functionality related to controlled substance prescription requirements is altered or every two years, whichever occurs first.	Certification Report contains the statement and the date when the certification expires	TC DR	Pass	
1311.300	(b)	The third-party audit must be conducted by one of the following:	Tested below		TE	
1311.300	(b)(1)	A person qualified to conduct a SysTrust, WebTrust, or SAS 70 audit.	Applicable only for on-site audit of uncertified applications		NT	
1311.300	(b)(2)	A Certified Information System Auditor who performs compliance audits as a regular ongoing business activity.	Applicable only for on-site audit of uncertified applications Affirm one of (1) OR (2) is performs audit	TC DR	Pass	
1311.300	(c)	An audit for installed applications must address processing integrity and determine that the application meets the requirements of this part.	Tested elsewhere.		TE	

1311.300	(d)	An audit for application service providers must address processing integrity and physical security and determine that the application meets the requirements of this part.	Verify the physical security procedures are in-place and sufficient for the hosting service.	TC DR	Pass	
1311.300	(e)	If a certifying organization whose certification process has been approved by DEA verifies and certifies that an electronic prescription or pharmacy application meets the requirements of this part, certification by that organization may be used as an alternative to the audit requirements of paragraphs (b) through (d) of this section, provided that the certification that determines that the application meets the requirements of this part occurs at each of the following times:	iBeta is a certifying organization whose certification process has been approved by the DEA.		NT	
1311.300	(e)(1)	Before the application may be used to create, sign, transmit, or process controlled substance prescriptions.	As tested below		TE	
1311.300	(e)(2)	Whenever a functionality related to controlled substance prescription requirements is altered or every two years, whichever occurs first.	Certification Report contains the statement and the date when the certification expires	TC DR	Pass	
		&	Processes and Procedures of application provider require recertification of modified applications prior to shipment to customers	TC DR	Pass	
1311.300	(f)	The application provider must make the audit or certification report available to any practitioner or pharmacy that uses the application or is considering use of the application. The electronic prescription or pharmacy application provider must retain the most recent audit or certification results and retain the results of any other audits or certifications of the application completed within the previous two years.	Validate processes and procedures	TC DR	Pass	
1311.300	(g)	Except as provided in paragraphs (h) and (i) of this section, if the third-party auditor or certification organization finds that the application does not meet one or more of the requirements of this part, the application must not be used to create, sign, transmit, or process electronic controlled substance prescriptions. The application provider must notify registrants within five business days of the issuance of the audit or certification report that they should not use the application for controlled substance prescriptions. The application provider must also notify the Administration of the adverse audit or certification report and provide the report to the Administration within one business day of issuance.	Processes and Procedures of application provider	TC DR	Pass	

1311.300	(h)	For electronic prescription applications, the third-party auditor or certification organization must make the following determinations:	As applicable, below (1)-(2)		TE	
1311.300	(h)(1)	If the information required in §1306.05(a) of this chapter, the indication that the prescription was signed as required by §1311.120(b)(17) or the digital signature created by the practitioner's private key, if transmitted, and the number of refills as required by §1306.22 of this chapter, cannot be consistently and accurately recorded, stored, and transmitted, the third-party auditor or certification organization must indicate that the application does not meet the requirements of this part.	As tested in 1306.05(a), 1311.120(b)(17) and 1306.22		TE	
1311.300	(h)(2)	If other information required under this chapter cannot be consistently and accurately recorded, stored, and transmitted, the third-party auditor or certification organization must indicate that the application has failed to meet the requirements for the specific information and should not be used to create, sign, and transmit prescriptions that require the additional information.	As tested elsewhere, all signing application requirements must be met.		TE	
11.302 Additional application provider requirements.						
1311.302	(a)	If an application provider identifies or is made aware of any issue with its application that make the application non-compliant with the requirements of this part, the application provider must notify practitioners or pharmacies that use the application as soon as feasible, but no later than five business days after discovery, that the application should not be used to issue or process electronic controlled substance prescriptions.	Processes and Procedures exist	TC DR	Pass	
			iBeta's report contains a disclaimer that this requirement is outside of the scope of its testing, but processes of application provider were audited		Pass	
1311.302	(b)	When providing practitioners or pharmacies with updates to any issue that makes the application non-compliant with the requirements of this part, the application provider must indicate that the updates must be installed before the practitioner or pharmacy may use the application to issue or process electronic controlled substance prescriptions.	Processes and Procedures exist	TC DR	Pass	

			iBeta's report contains a disclaimer that this requirement is outside of the scope of its testing, but processes of application provider were audited		Pass	
1311.305	Recordkeeping.					
1311.305	(a)	If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.	Signing Application retains all records electronically	TC2 Step 34	Pass	
1311.305	(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.	Signing Application retains all records electronically for two years	TC DR	Pass	
1311.305	(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.	As stated	TC2 Step 35	Pass	
1311.305	(d)	Records required by this part must be made available to the Administration upon request.	Capability tested above		TE	
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.	Document Review	TC DR	Pass	
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.	Document Review	TC DR	Pass	
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.	Document Review	TC DR	Pass	
1311.305	(h)	Digitally signed prescription records must be transferred or migrated with the digital signature.	Test capability	TC6 Step 3	Pass	

1311	Clarification 19 October 2011					
		EPCS applications must address security to prevent insider threats and outsider attacks on any system. Careful review by an independent, qualified third-party of the "processing integrity" of any application is required to determine whether an application or application service provider has adequate protection against the range of potential security threats.	Referred to above as "Clarif. 2011OCT19" this requirement is tested above as a refinement		TE	