2014

DEA 1311.205 Compliance Report for Pharmacy Application Providers as of January 3, 2014

ScriptPro®

ASSURANCE CONCEPTS

A SKODA MINOTTI ADVISORY FIRM

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SECTION 1: Independent Auditors Report on Applying Agreed-Upon Procedures

To Management of ScriptPro, LLC:

We have performed the procedures described below, which were agreed to by ScriptPro, LLC ("ScriptPro" or the "Company"), solely to assist in the identification of Compliance Assessment for DEA Part 1311.205 controls that were in place as of January 3, 2014, as set forth in the accompanying Schedule A. The maintenance of these controls is solely the responsibility of ScriptPro. Consequently, we make no representation regarding the sufficiency of the controls as a whole for ScriptPro as described below either for the purpose for which this report has been requested or for any other purpose.

The controls and associated findings are as follows:

1. Compared ScriptPro's controls implemented in the pharmacy application ScriptPro SP Central Pharmacy Management System Build Series 12 to applicable controls specified by the DEA Part 1311.205 pharmacy application requirements. Reviewed application operations and processes to verify that controls were in place and operating as of January 3, 2014 (SECTION 3: Schedule B | DEA Part 1311.205 Testing Matrices).
   No exceptions were found as a result of this comparison.
2. Reviewed ScriptPro's controls implemented in the information security environment for the production system of ScriptPro's electronic prescription application services. Reviewed information security controls and processes to verify that controls were in place and operating as of January 3, 2014 (SECTION 3: Schedule B | DEA Part 1311.205 Testing Matrices).
   No exceptions were found as a result of this comparison.

We were not engaged to and did not conduct an examination, the objective of which would be the expression of an opinion on the controls set forth in the accompanying Schedule A. Accordingly, we do not express such an opinion. Had we performed additional procedures, other matters might have come to our attention that would have been reported.

The description of controls at ScriptPro is as of January 3, 2014, and any projection of such information to the future is subject to the risk that, because of change, the description may no longer portray the controls in existence. The potential effectiveness of specific controls at ScriptPro is subject to inherent limitations and, accordingly, errors or fraud may occur and not be detected. Furthermore, the projection of any conclusions, based on our findings, to future periods is subject to the risk that changes may alter the validity of such conclusions.

We did not perform procedures to determine the operating effectiveness of controls for any period. Accordingly, we express no opinion on the operating effectiveness of any aspects of ScriptPro controls, individually or in the aggregate.

This report is intended solely for the information of potential customer, existing customers, regulatory agencies and use by the management of ScriptPro and is not intended to be and should not be used by anyone other than these specified parties.

January 8, 2014

SECTION 2: ScriptPro Pharmacy Application System Description

Company Overview and Services Provided

ScriptPro located in Mission Kansas and founded in 1994, develops, provides and supports state-of-the-art, robotics-based pharmacy management, workflow and telepharmacy systems. ScriptPro is dedicated to helping pharmacies lower operating costs, reduce dispensing errors and maximize customer satisfaction. ScriptPro technology helps pharmacies operate efficiently, safely, and profitably so they can make the maximum contribution to the healthcare system.

ScriptPro is the industry and world leader in pharmacy automation. We develop and provide pharmacy solutions that address 100% of the prescription fulfillment process. We are dedicated to producing pharmacy software and technology to advance the pharmacy industry. To achieve these goals we placed a high priority on our relationships with employees, customers and vendors. We have a group of talented, motivated and loyal individuals who constitute a vibrant team. We value character and trustworthiness and cultivate a work environment that is conducive to creativity and excellence.

Information Systems Overview

ScriptPro's information systems were built to facilitate the electronic dispensing of controlled substances used by a DEA registrant. Information systems contain prescription and dispensing information required by DEA regulations, digitally sign records of the prescription that is sent to the pharmacy, and maintain an internal audit trail of required auditable events. ScriptPro's information systems fully reside at their clients premises and never transmit pharmacy data through the ScriptPro network..

ScriptPro is a custom developed application that healthcare providers utilize to dispense electronic prescriptions for controlled substances. It resides at the Pharmacies, and prescriptions are routed from SureScripts to Rx Linc (an intermediary), and then to ScriptPro's instances located at physical pharmacies. The prescription application then validates the prescription for required fields, and only accepts prescriptions with a Signature Indicator ("SI") flag. Once confirmed, the system then transmits the prescription to the designated pharmacy. ScriptPro's prescription application uses the mail box function from Rx Linc for the delivery of their electronic prescriptions to the individual pharmacies from SureScripts through Rx Linc. ScriptPro remotely manages and supports the Pharmacy Applications that are installed locally at each pharmacy customer location.

Scope and Summary of Report

This report describes the control structure under the guidance of DEA Part 1311.205 for ScriptPro as it relates to application and information security standards for their Electronic Pharmacy Application Services at their Mission, Kansas facility. It is intended to assist ScriptPro's customers and potential customers in determining the adequacy of ScriptPro's internal controls. The scope of this assessment included the evaluation of the DEA Part 1311.205 Pharmacy Application Requirements as it applies to ScriptPro's pharmacy software and processing integrity the supporting managed services system. "SECTION 3: Schedule A | DEA Part 1311.205" is the criteria used for as requirements for the pharmacy application and "SECTION 3: Schedule B | DEA Part 1311.205 Testing Matrices" of this report describes the procedures performed to verify ScriptPro's application features of their on-premise pharmacy software services.

SECTION 2: ScriptPro Pharmacy Application System Description

Pharmacies are required to adhere to requirements described in DEA Part 1311.200; this information can be access via http://www.deadiversion.usdoj.gov/21cfr/cfr/1311/subpart_c100.htm#200. Although ScriptPro provides pharmacy application requirements to their customers described in DEA 1311.205 and throughout the remainder of this report, pharmacies still have requirements to be evaluated under DEA 1311.200. Additionally, there are certain parts of the application services provided to pharmacies that ScriptPro alone is not able to provide by itself, which users of the system are required to assess the User Control Considerations defined Throughout Section 3 of this report.

SECTION 3: Schedule A | DEA Part 1311.205 Testing Matrices

DEA 1311.205 pharmacy applications control specifications:

Sec. 1311.205 Pharmacy Application Requirements are specified by the DEA and are required to be met, where applicable, to the system under review. The pharmacy application was evaluated for the following control specifications referenced in (a) and (b) 1 through 18:

(a) The pharmacy may only use a pharmacy application that meets the requirements in paragraph (b) of this section to process electronic controlled substance prescriptions.

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

(1) The pharmacy application must be capable of setting logical access controls to limit access for the following functions:

(i) Annotation, alteration, or deletion of prescription information.

(ii) Setting and changing the logical access controls.

(2) Logical access controls must be set by individual user name or role.

(3) The pharmacy application must digitally sign and archive a prescription on receipt or be capable of receiving and archiving a digitally signed record.

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

(i) The cryptographic module used to digitally sign the data elements required by part 1306 of this chapter must be at least FIPS 140–2 Security Level 1 validated. FIPS 140–2 is incorporated by reference in §1311.08.

(ii) The digital signature application and hash function must comply with FIPS 186–3 and FIPS 180–3, as incorporated by reference in §1311.08.

(iii) The pharmacy application's private key must be stored encrypted on a FIPS 140–2 Security Level 1 or higher validated cryptographic module using a FIPS-approved encryption algorithm. FIPS 140–2 is incorporated by reference in §1311.08.

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

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

(5) The pharmacy application must verify a practitioner's digital signature (if the pharmacy application accepts prescriptions that were digitally signed with an individual practitioner's private key and transmitted with the digital signature).

(6) If the prescription received by the pharmacy application has not been digitally signed by the practitioner and transmitted with the digital signature, the pharmacy application must either:

(i) Verify that the practitioner signed the prescription by checking the data field that indicates the prescription was signed; or

(ii) Display the field for the pharmacist's verification.

(7) The pharmacy application must read and retain the full DEA number including the specific internal code number assigned to individual practitioners authorized to prescribe controlled substances by the hospital or other institution as provided in §1301.22(c) of this chapter.

(8) The pharmacy application must read and store, and be capable of displaying, all information required by part 1306 of this chapter.

(9) The pharmacy application must read and store in full the information required under §1306.05(a) of this chapter. The pharmacy application must either verify that such information is present or must display the information for the pharmacist's verification.

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

(i) Number of units or volume of drug dispensed.

(ii) Date dispensed.

(iii) Name or initials of the person who dispensed the prescription.

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

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

(13) The pharmacy application must maintain an audit trail of all actions related to the following:

(i) The receipt, annotation, alteration, or deletion of a controlled substance prescription.

(ii) Any setting or changing of logical access control permissions related to the dispensing of controlled substance prescriptions.

(iii) Auditable events as specified in **§1311.215**.

(14) The pharmacy application must record within each audit record the following information:

(i) The date and time of the event.

(ii) The type of event.

(iii) The identity of the person taking the action, where applicable.

(iv) The outcome of the event (success or failure).

(15) The pharmacy application must conduct internal audits and generate reports on any of the events specified in **§1311.215** in a format that is readable by the pharmacist. Such an internal audit may be automated and need not require human intervention to be conducted.

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

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

(18) The pharmacy application must retain all archived records electronically for at least two years from the date of their receipt or creation and comply with all other requirements of **§1311.305**

User Control Considerations:

- Users of the pharmacy applications are responsible to verify all prescription information fields received when filling prescriptions.

SECTION 3: Schedule A | DEA Part 1311.205 Testing Matrices

Information Security controls implemented by ScriptPro

Review the procedures of ScriptPro to remotely support their on premise pharmacy application services. These controls are implemented and performed by ScriptPro. The following controls were identified:

- ScriptPro's customer account access is controlled through the Technical Support User Management (TSUM).
- IT access requests are authorized prior to granting access to production systems.
- TSUM accounts and passwords are changed across all systems upon termination of personnel with access to TSUM.
- Annual security training is provided to ScriptPro personnel.

User Control Considerations:

- Users of the pharmacy applications are responsible to issue new or changes to existing application accounts.
- Users of the pharmacy application are required to maintain the security of their account and password.
- Users of the pharmacy application are required to maintain security of their own premise systems, network and hardware.
- Users of the pharmacy application are required to restrict logical access to their own internal networks.

SECTION 3: Schedule B | DEA Part 1311.205 Testing Matrices

Electronic Pharmacy Application

Control Objective 1: Control activities provide reasonable assurance that the electronic prescription application Software Version ScriptPro SP Central Pharmacy Management System Build Series 12 (application) that processes the dispensing of received electronic prescriptions for controlled substances (EPCS) used by dispensing agents retains prescription and dispensing information required by DEA Part 1311.205.

#	Control Activity Specified by DEA Part 1311.205	Procedures Performed by the Independent Accountant	Results
1.1	(1) The pharmacy application must be capable of setting logical access controls to limit access for the following functions: (i) Annotation, alteration, or deletion of prescription information. (ii) Setting and changing the logical access controls.	Inspected the pharmacy application to verify that the application was capable of user security to enforce the following permissions: ➢ Annotation ➢ Alteration ➢ Deletion of prescription information ➢ User security administration	No relevant exceptions noted.
1.2	(2) Logical access controls must be set by individual user name or role.	Inspected the pharmacy application to verify that during user account creation, the application only permitted the assignment of a role during user creation. The application requires roles to be assigned to user accounts, and individual screen permission can be modified for user accounts.	No relevant exceptions noted.
1.3	(3) The pharmacy application must digitally sign and archive a prescription on receipt or be capable of receiving and archiving a digitally signed record.	Observed the application received a valid, digitally signed signature, and verified that the application rejected the script. ScriptPro Pharmacy Application only accepts scripts with a Signature Indicator flag and verified digital signature were signed upon receipt.	No relevant exceptions noted.

SECTION 3: Schedule B | DEA Part 1311.205 Testing Matrices

#	Control Activity Specified by DEA Part 1311.205	Procedures Performed by the Independent Accountant	Results
1.4	(4) For pharmacy applications that digitally sign prescription records upon receipt, the digital signature functionality must meet the following requirements: (i) The cryptographic module used to digitally sign the data elements required by part 1306 of this chapter must be at least FIPS 140–2 Security Level 1 validated. FIPS 140–2 is incorporated by reference in §1311.08. (ii) The digital signature application and hash function must comply with FIPS 186–3 and FIPS 180–3, as incorporated by reference in §1311.08. (iii) The pharmacy application's private key must be stored encrypted on a FIPS 140–2 Security Level 1 or higher validated cryptographic module using a FIPS-approved encryption algorithm. FIPS 140–2 is incorporated by reference in §1311.08. (iv) For software implementations, when the signing module is deactivated, the pharmacy application must clear the plain text password from the application memory to prevent the unauthorized access to, or use of, the private key. (v) The pharmacy application must have a time application that is within five minutes of the official National Institute of Standards and Technology time source.	Inspected the digitally signed records and the cryptographic module and signing configurations to verify that the signing module was FIPS 140-2 or higher compliant and utilized SHA-1 hashing which is FIPS 180-3 compliant. Inquired of management to verify that the no plain text passwords were used or stored in memory and inspected the pharmacy time configuration to ensure it was peered with NTP for time synchronization.	No relevant exceptions noted.
1.5	(5) The pharmacy application must verify a practitioner's digital signature (if the pharmacy application accepts prescriptions that were digitally signed with an individual practitioner's private key and transmitted with the digital signature).	N/A, ScriptPro does not accept digitally signed records with the practitioner's private key. Verified that digitally signed records were rejected upon receipt.	No relevant exceptions noted.

SECTION 3: Schedule B | DEA Part 1311.205 Testing Matrices

#	Control Activity Specified by DEA Part 1311.205	Procedures Performed by the Independent Accountant	Results
1.6	(6) If the prescription received by the pharmacy application has not been digitally signed by the practitioner and transmitted with the digital signature, the pharmacy application must either: (i) Verify that the practitioner signed the prescription by checking the data field that indicates the prescription was signed; or (ii) Display the field for the pharmacist's verification.	Inspected prescriptions sent through the application with no digital signature to verify that the application checked for the signature indicator flag to verify the prescription was signed. Inspected prescriptions sent through the application with no digital signature and no signature indicator field to verify that prescriptions received with no digital signature or a signature indicator flag were rejected.	No relevant exceptions noted.
1.7	(7) The pharmacy application must read and retain the full DEA number including the specific internal code number assigned to individual practitioners authorized to prescribe controlled substances by the hospital or other institution as provided in §1301.22(c) of this chapter.	Inspected prescriptions sent through the application to verify that the full DEA number and other internal codes were captured with the prescription.	No relevant exceptions noted.
1.8	(8) The pharmacy application must read and store, and be capable of displaying, all information required by part 1306 of this chapter.	Inspected the pharmacy application to verify that for each prescription the following was capable of being displayed and stored: ➢ full name and address of the patient ➢ the drug name, strength dosage form ➢ quantity prescribed ➢ directions for use ➢ name, address and registration number of the practitioner ➢ Transfers record the name of pharmacist and date of transfer	No relevant exceptions noted.
1.9	(9) The pharmacy application must read and store in full the information required under §1306.05(a) of this chapter. The pharmacy application must either verify that such information is present or must display the information for the pharmacist's verification.	Inspected the pharmacy application to verify that prescription information received, stored and displayed was available for the pharmacist's verification as follows: ➢ full name and address of the patient ➢ the drug name, strength dosage form ➢ quantity prescribed ➢ directions for use ➢ name, address and registration number of the practitioner	No relevant exceptions noted.
1.10	(10) The pharmacy application must provide for the following information to be added or linked to each electronic controlled substance prescription record for each dispensing: (i) Number of units or volume of drug dispensed. (ii) Date dispensed. (iii) Name or initials of the person who dispensed the prescription.	Inspected the pharmacy application and a sample of dispensed prescriptions via the dispense log to verify that the following was linked in read only logs to the dispensed prescription records: - Description (included the type of drug and the number of units or volume dispensed) - Date/Time that drug was dispensed by the pharmacy user - User (unique identifier for person that dispensed the prescription)	No relevant exceptions noted.

SECTION 3: Schedule B | DEA Part 1311.205 Testing Matrices

#	Control Activity Specified by DEA Part 1311.205	Procedures Performed by the Independent Accountant	Results
1.11	(11) The pharmacy application must be capable of retrieving controlled substance prescriptions by practitioner name, patient name, drug name, and date dispensed.	Inspected the pharmacy application search and reporting features to verify that a query and retrieval was capable for each of the following attributes: ➢ practitioner name ➢ patient name ➢ drug name ➢ date dispensed	No relevant exceptions noted.
1.12	(12) The pharmacy application must allow downloading of prescription data into a database or spreadsheet that is readable and sortable.	Observed the application's report export functionality to verify that reports were exportable to a .csv file.	No relevant exceptions noted.
1.13	(13) The pharmacy application must maintain an audit trail of all actions related to the following: (i) The receipt, annotation, alteration, or deletion of a controlled substance prescription. (ii) Any setting or changing of logical access control permissions related to the dispensing of controlled substance prescriptions. (iii) Auditable events as specified in §1311.215.	Inspected the audit trail logs for a sample of prescriptions in the application to verify that the following were available, where applicable: ➢ the receipt, annotation, alteration, or deletion of a controlled substance prescription. ➢ any setting or changing of logical access control permissions related to the dispensing of controlled substance prescriptions. ➢ Auditable events as specified in 1311.215.	No relevant exceptions noted.
1.14	(14) The pharmacy application must record within each audit record the following information: (i) The date and time of the event. (ii) The type of event. (iii) The identity of the person taking the action, where applicable. (iv) The outcome of the event (success or failure).	Inspected the audit logs for a sample of transactions in the application to verify that the following were recorded, where applicable: ➢ the date and time of the event. ➢ the type of event. ➢ the identity of the person taking the action, where applicable. ➢ the outcome of the event (success or failure).	No relevant exceptions noted.
1.15	(15) The pharmacy application must conduct internal audits and generate reports on any of the events specified in §1311.215 in a format that is readable by the pharmacist. Such an internal audit may be automated and need not require human intervention to be conducted.	Inspected the audit reports to verify that daily reports were available and auditable events listed in 1311.215 applicable to the pharmacy application were presented in a readable structure.	No relevant exceptions noted.
1.16	(16) The pharmacy application must protect the stored audit records from unauthorized deletion. The pharmacy application shall prevent modifications to the audit records.	Inspected the pharmacy application and audit records to verify that audit records were read only through the application user interface.	No relevant exceptions noted.

SECTION 3: Schedule B | DEA Part 1311.205 Testing Matrices

#	Control Activity Specified by DEA Part 1311.205	Procedures Performed by the Independent Accountant	Results
1.17	(17) The pharmacy application must back up the controlled substance prescription records daily.	Inspected the backup configuration and logs of completed backups to verify that the controlled substance prescription records were backed up daily.	No relevant exceptions noted.
1.18	(18) The pharmacy application must retain all archived records electronically for at least two years from the date of their receipt or creation and comply with all other requirements of §1311.305.	Inspected the pharmacy application prescription records requirement settings and verified that the records were configured to be stored and / or archived for a minimum of 24 months.	No relevant exceptions noted.

Information Security

Control Objective 2: Control activities provide reasonable assurance that logical access to critical systems and data is restricted to authorized individuals.

#	Control Activity	Testing Procedures and Results	Results
2.1	ScriptPro's customer account access is controlled through the Technical Support User Management (TSUM).	Inquired of the Systems Administrator to verify that access to customer accounts was restricted via TSUM and limited to authorized system administrators.	No relevant exceptions noted.
2.2	IT access requests are authorized prior to granting access to production systems.	Inquired of the Systems Administrator to verify that an approved IT access request was authorized prior to granting access to production systems. Verified that the customer service information assurance team approves new access requests.	No relevant exceptions noted.
2.3	TSUM accounts and passwords are changed across all systems upon termination of personnel with access to TSUM.	Verified that TSUM accounts were changed upon termination of a TSUM user.	No relevant exceptions noted.
2.4	Annual security training is provided to ScriptPro personnel.	Inquired of the Systems Administrator to verify that annual security trainings were in place.	No relevant exceptions noted.