CAREPOINT, INC.

CPERX APPLICATION VERSION 1.0
THIRD PARTY AUDIT ON COMPLIANCE WITH
UNITED STATES' DRUG ENFORCEMENT ADMINISTRATION, TITLE 21,
CODE OF FEDERAL REGULATIONS, CHAPTER II, PART 1311

OCTOBER 5, 2012

Attestation and Compliance Services

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Section I

Certified Information Systems Auditor's Report on Compliance

October 5, 2012

To Whom It May Concern:

BrightLine CPAs & Associates, Inc. ("BrightLine") has completed an independent third party assessment of the CarePoint CpERx Application version 1.0 (the "Application") for controlled substances administered by CarePoint, Inc. (the "Application Provider"). The objective of our assessment was to determine whether the Application was capable of performing the relevant and requisite functions set forth in the United States Department of Justice Drug Enforcement Administration's requirements for pharmacy applications for controlled substances as defined in Title 21 of the Code of Federal Regulations, Parts 1306 and 1311 (the "Regulation") and dated April 1, 2010. These relevant and requisite functions are provided in section 2 (the "Applicable Compliance Requirements") of this document.

As of October 5, 2012, we have determined that the Application accurately and consistently imported, stored, and displayed (i) the information required for a prescription by §1306.05(a), (ii) the number of refills as required by §1306.22, and (iii) the indication that the prescription was signed by a practitioner's digital signature as required by §1311.205(b)(6). Additionally, we have determined that the Application accepts prescriptions with the practitioner's digital signature and does import, store, and verify the practitioner's digital signature.

Our assessment is a determination of the Application's capability to perform the relevant and requisite functions set forth in the Regulation as of October 5, 2012. Our determination should not be projected to later dates given the risk that changes, or the failure to make needed changes, may alter the validity of the determinations described herein. Our assessment was not intended to detect errors or fraud that may have occurred during the course of our assessment.

Although our organization is a licensed CPA firm, we did not conduct our assessment in accordance with attestation standards established by the American Institute of Certified Public Accountants. Furthermore, we are not a law firm or an accredited independent certification organization, as defined by §1311.300(e) of the Regulation, and therefore, our assessment is not a legal determination of compliance with the Regulation or a certification of compliance as defined by the Regulation. This third party assessment was conducted by a team of Certified Information Systems Auditors who perform compliance audits as a regular ongoing business activity, and as such, were qualified to conduct this assessment per §1311.300(b) of the Regulation.

The sufficiency of the requirements is solely the responsibility of the United States Department of Justice Drug Enforcement Administration. Consequently, we make no representation regarding the sufficiency of the requirements of the Regulation either for the purpose for which this report has been requested or for any other purpose.

This report is intended solely for use by the management of the Application Provider and the current and prospective users of the Application.

Ryan J. Buckner, Certified Information Systems Auditor
Principal

Section 2

Applicable Compliance Requirements

PART 1311.205

Applicable Pharmacy Application Requirements

Point No.	DEA Regulatory Reference	DEA Regulatory Requirement
1.	1311.205 (b) (1) (i)	The pharmacy application must be capable of setting logical access controls to limit access for the following function: (i) Annotation, alteration, or deletion of prescription information.
2.	1311.205 (b) (1) (ii)	The pharmacy application must be capable of setting logical access controls to limit access for the following function: (ii) Setting and changing the logical access controls.
3.	1311.205 (b) (2)	Logical access controls must be set by individual user name or role.
4.	1311.205 (b) (3)	The pharmacy application must digitally sign and archive a prescription on receipt or be capable of receiving and archiving a digitally signed record.
5.	1311.205 (b) (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.	1311.205 (b) (6) (i)	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
7.	1311.205 (b) (6) (ii)	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: (ii) Display the field for the pharmacist's verification.
8.	1311.205 (b) (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.
9.	1311.205 (b) (8)	The pharmacy application must read and store, and be capable of displaying, all information required by part 1306 of this chapter.
10.	1311.205 (b) (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.
11.	1311.205 (b) (10) (i)	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.
12.	1311.205 (b) (10) (ii)	The pharmacy application must provide for the following information to be added or linked to each electronic controlled substance prescription record for each dispensing: (ii) Date dispensed.

Point No.	DEA Regulatory Reference	DEA Regulatory Requirement
13.	1311.205 (b) (10) (iii)	The pharmacy application must provide for the following information to be added or linked to each electronic controlled substance prescription record for each dispensing: (iii) Name or initials of the person who dispensed the prescription.
14.	1311.205 (b) (11)	The pharmacy application must be capable of retrieving controlled substance prescriptions by practitioner name, patient name, drug name, and date dispensed.
15.	1311.205 (b) (12)	The pharmacy application must allow downloading of prescription data into a database or spreadsheet that is readable and sortable.
16.	1311.205 (b) (13) (i)	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.
17.	1311.205 (b) (13) (ii)	The pharmacy application must maintain an audit trail of all actions related to the following: (ii) Any setting or changing of logical access control permissions related to the dispensing of controlled substance prescriptions.
18.	1311.205 (b) (13) (iii)	The pharmacy application must maintain an audit trail of all actions related to the following: (iii) Auditable events as specified in §1311.215.
19.	1311.205 (b) (14) (i)	The pharmacy application must record within each audit record the following information: (i) The date and time of the event.
20.	1311.205 (b) (14) (ii)	The pharmacy application must record within each audit record the following information: (ii) The type of event.
21.	1311.205 (b) (14) (iii)	The pharmacy application must record within each audit record the following information: (iii) The identity of the person taking the action, where applicable.
22.	1311.205 (b) (14) (iv)	The pharmacy application must record within each audit record the following information: (iv) The outcome of the event (success or failure).
23.	1311.205 (b) (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.
24.	1311.205 (b) (16)	The pharmacy application must protect the stored audit records from unauthorized deletion. The pharmacy application shall prevent modifications to the audit records.
25.	1311.205 (b) (17)	The pharmacy application must back up the controlled substance prescription records daily.
26.	1311.205 (b) (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.

Non-applicable Pharmacy Application Requirements

Pursuant to 1311.205(b)(3) of the Regulation, the Carepoint CpERx Application Version 1.0 (the "Application") has been designed to only receive and archive digitally signed records. The Application does not perform digital signature functions and is not required to meet the following requirements:

Point No.	DEA Regulatory Reference	DEA Regulatory Requirement
1.	1311.205 (b) (4) (i)	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.
2.	1311.205 (b) (4) (ii)	(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.
3.	1311.205 (b) (4) (iii)	(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.
4.	1311.205 (b) (4) (iv)	(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.
5.	1311.205 (b) (4) (v)	(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.