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InstantDx, LLC

OnCallData Version 5.0

21 CFR EPCS Certification Report

January 24, 2023

Prepared by Drummond Group

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Certification Summary

Overview

Drummond Group has reviewed InstantDx's application (OnCallData 5.0) against 21 CFR 1311 federal rule using the Drummond Group Certification Process submitted to and approved by DEA in July 2012.

During the audit, which was renewed on January 24, 2023 the implementation of these requirements underwent a thorough review by a Drummond Group test proctor to determine if the application satisfactorily met these requirements. All requirements are reviewed in order to make this determination.

During the audit, Drummond Group's responsibility was to review and collect evidence of the application as it would be used by a practice as required by 21 CFR 1311. This included reviewing user creation, logical access controls for users, granting of signing privilege, creation of prescriptions, marking prescriptions ready to sign, signing prescriptions, two-factor authentication, transmission of prescriptions, audit trails, reporting, printing of prescriptions, and export capability of prescription data.

InstantDx the organization and its management, is responsible for ensuring these requirements are in compliance. Furthermore, as stipulated by the federal rule, the practice must also ensure it follows all procedures according to 21 CFR 1311. Drummond Group's audit does not make a legal determination on InstantDx's certification to 21 CFR 1311 (and related 1300, 1304, and 1306) rules.

Processing Integrity

In addition to application requirements, 21 CFR 1311.300(d) requires that a review for application service providers address processing integrity and physical security.

InstantDx has completed the Drummond Group Security Survey and provided detailed information regarding the processing integrity and physical security of the environment which is hosting the EPCS application. Drummond Group has reviewed the answers to the survey and it is their opinion that the security controls described and attested to therein, including, a secure data center, regular vulnerability assessments and thorough security policies, represent sufficient controls to meet the processing integrity and physical security requirements.

Qualification and Results

Drummond Group's review is not intended to be a quality assurance review. The intent of the review is to make an assessment of the application against the requirements of 21 CFR 1311 and assess whether the application met the requirements.

Drummond Group's review has assessed that InstantDx has made the necessary modifications to their application mentioned above to comply with the intent of 21 CFR Part 1311 (and 1300, 1304, 1306 by reference).

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Use of this Certification Report

This certification report is intended for use by InstantDx to demonstrate its application has undergone a review by an approved DEA certification organization as required by DEA EPCS Final Rule (Interim).

Findings

The table below shows the requirements that were part of the review. The following table is sorted by 21 CFR part 1311 requirements. The requirements found in parts 1304 and 1306 are satisfied by 1311 and therefore omitted. See www.deadiversion.usdoj.gov/fed_regs/rules/2010/fr0331.pdf for full requirement information. Redundant requirements within 1311 have been omitted from this table.

See Next Page for Prescriber Requirements

21 CFR 1311	Requirement Description
1311.105	Requirements for obtaining an authentication credential
1311.110	Requirements for obtaining an authentication credential
1311.115	Practitioner Two Factor Authentication Additional Requirements
1311.116	Practitioner Biometrics Requirements
1311.120(b).1	Practitioner User Identification
1311.120(b).2	Practitioner Logical Controls
1311.120(b).3	Practitioner Logical Controls Role Based
1311.120(b).4	Practitioner Logical Controls Two Individuals
1311.120(b).5	Practitioner Signing Two Factor Authentication
1311.120(b).6	Practitioner Prescription Information
1311.120(b).7	Practitioner Information-Two DEA Numbers
1311.120(b).8	Practitioner NIST Time
1311.120(b).9	Prescription Information
1311.120(b).10	Ready to Sign
1311.120(b).11	Signing of Prescription
1311.120(b).12	DEA Number of Signer
1311.120(b).13	Batch Signing
1311.120(b).14	Practitioner Signing Time Stamp
1311.120(b).15	Digitally Signing the Prescription
1311.120(b).16	Digital Signature Requirements
1311.120(b).17	Indication of Signing
1311.120(b).18	Transmitting Unsigned Prescription
1311.120(b).19	Alteration of Information
1311.120(b).20	Transmission of Printed Prescription
1311.120(b).21	Printing Prescriptions after transmission
1311.120(b).22	Failed Transmission
1311.120(b).23	Audit Trail
1311.120(b).24	Audit Records
1311.120(b).25	Internal Audit Reports
1311.120(b).26	Audit Record Protection
1311.120(b).27	Prescriptions Issued Report
1311.120(b).28	Two Year Retention
1311.125	Establishing logical access control
1311.135	Agent Support, Supervisor Name
1311.140	Signing Prescriptions
1311.145	Practitioner Individual Digital Certificate
1311.150	Practitioner Auditable Event List
1311.170(a)	Transmission Requirements
1311.170(e)	No Alteration During Transmission
1311.302	Notification to Practitioners
1311.305	Data Migration (record export)
1306.12	Schedule II prescriptions
1306.22	Schedule III & IV Prescriptions
1306.22	Pharmacy Refill Requests (information)
1306.12(a)	Schedule II Refill Requests
1306.22(a)	Schedule III & IV Refill Requests
1311.215	ASP Processing Integrity
1311.300€	EPCS Module requirements

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About Drummond Group

Drummond Group is a global software test and certification lab that serves a wide range of vertical industries. In healthcare, Drummond Group tests and certifies Controlled Substance Ordering Systems (CSOS), Electronic Prescription of Controlled Substances (EPCS) software and processes, and Electronic Health Records (EHRs) – designating the trusted test lab as the only third-party certifier of all three initiatives designed to move the industry toward a digital future. Founded in 1999, and accredited for the Office of the National Coordinator HIT Certification Program as an Authorized Certification Body (ACB) and an Authorized Test Lab (ATL), Drummond Group continues to build upon its deep experience and expertise necessary to deliver reliable and cost-effective services. For more information, please visit http://www.drummondgroup.com or email EPCS@drummondgroup.com.