Certification Summary

Overview

Drummond Group has reviewed the MedQuest Pharmacy, Inc. application (eMedPlus v. 3.5) against 21 CFR 1311 federal rule using the Drummond Group Certification Process submitted to and approved by DEA in July 2012.

During the review, which was completed on March 27, 2018 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.

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, receipt of prescriptions, prescription dispensing, audit trails, reporting, and export capability of prescription data.

MedQuest Pharmacy, Inc., 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.

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.

MedQuest Pharmacy, Inc. 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.

It is Drummond Group's opinion that MedQuest Pharmacy, Inc. 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).

Use of this Certification Report

This certification report is intended for use by MedQuest Pharmacy, Inc. to demonstrate it has undergone a review of its application by a certification organization with an approved DEA certification process 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. 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.

21 CFR 1311	Requirement Description
1311.205(b).1	Access Controls
1311.205(b).2	Access Control Scheme
1311.205(b).3	Pharmacy Prescription Sign & Archive
1311.205(b).4.i-iv	Pharmacy Signature Requirements
1311.205(b).4.v	Pharmacy NIST Time Application
1311.205(b).5	Digital Signature Verification
1311.205(b).6	Signed Flag Verification
1311.205(b).7	DEA Number Retention
1311.205(b).8	Pharmacy Prescription Information Display
1311.205(b).9	Pharmacy Prescription Information Storage
1311.205(b).10	Pharmacy Prescription Update
1311.205(b).11	Pharmacy Prescription Retrieval/Report
1311.205(b).12	Prescription Data Export
1311.205(b).13	Auditable Event List and Audit Trail
1311.205(b).14	Audit Log Fields
1311.205(b).15	Internal Audit Report
1311.205(b).16	Audit Log Security
1311.205(b).17	Prescription Backup
1311.205(b).18, 1311.305(a)-(b)	Audit Log Record Retention
1306.12	Schedule II Prescriptions
1306.22(a)	Schedule III & IV Prescriptions
1306.22(b)	Refill Request Responses
1311.215(d)	Processing Integrity

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 DGI@drummondgroup.com.