



DR. OATES COMPUTER SYSTEMS D.B.A. SOAPWARE, INC. 21 CFR COMPLIANCE REPORT

SOAPware v7.0

**Report on SOAPware, Inc.'s Compliance with the Code of
Federal Regulations Title 21 Parts 1300, 1304, 1306, and
1311**

As of March 19, 2015

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Introduction

The United States Drug Enforcement Administration's ("DEA") rule, "Electronic Prescriptions for Controlled Substances" ("EPCS") provides regulations to practitioners who choose to write prescriptions for controlled substances electronically. These regulations permit pharmacies to receive, dispense, and archive these electronic prescriptions. When developing applications for EPCS use, software vendors must take into account the applicable requirements outlined in the Code of Federal Regulations Title 21 ("21 CFR") in order to meet or exceed these requirements in order to enable their application to allow providers to electronically prescribe controlled substances.

Assessment Scope

Compliance with applicable requirements of the 21 CFR Parts 1300, 1304, 1306, and 1311 have been assessed as of March 19, 2015 for Dr. Oates Computer Systems, Inc.'s d.b.a. SOAPware, Inc.'s ("SOAPware") SOAPware v7.0 application. During the course of the assessment, the design and implementation of controls to achieve compliance with applicable requirements of the 21 CFR Parts 1300, 1304, 1306, and 1311 have been reviewed.

SOAPware uses DrFirst.com, Inc. ("DrFirst") as a subservice organization that provides EPCS prescription processing services through their EPCS Gold 2 system. The DrFirst EPCS Gold 2 system is integrated into the SOAPware v7.0 application and leveraged when a prescription is issued for a controlled substance.

The procedures included examining, on a test basis, evidence about SOAPware's compliance with those requirements and performing such other procedures as was considered necessary in the circumstances. The procedures were performed against SOAPware and the SOAPware v7.0 application, along with DrFirst and the EPCS Gold 2 system.

The assessment was conducted in accordance with consulting standards established by the American Institute of Certified Public Accountants ("AICPA"). The assessment does not provide a legal determination on SOAPware's or DrFirst's compliance with the 21 CFR Parts 1300, 1304, 1306, and 1311.

Overall Results

During the course of the assessment, SOAPware has complied with applicable requirements of the 21 CFR Parts 1300, 1304, 1306, and 1311 as of March 19, 2015, in all material respects.

About the Service Auditor

BDO USA, LLP ("BDO USA") is a public accounting firm registered with the AICPA and the Public Company Accounting Oversight Board ("PCAOB"). BDO USA is qualified to conduct Service Organization Control Reports (SysTrust, WebTrust, and SAS 70 audits) and our team of Information Systems Assurance specialists includes Certified Information System Auditors who performs compliance audits as a regular ongoing business activity. Based on 21 CFR §1311.300, BDO USA meets the requirements for performing the third party audits.

