



Rite Aid Corporation

DEA's IFR on EPCS for Electronic Prescription Application Providers

Compliance Assessment

February 16, 2012

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Mr. Robert V. Lautsch
Director of IS Security
Rite Aid Corporation
30 Hunter Lane
Camp Hill, Pennsylvania 17011

Dear Mr. Lautsch:

Thank you for allowing McGladrey & Pullen, LLP to provide professional compliance assessment consulting services for Rite Aid Corporation (Rite Aid). Consistent with the approved engagement plan, McGladrey & Pullen performed an assessment of Rite Aid's compliance with the Drug Enforcement Administration's (DEA's) Interim Final Rule (IFR) on E-Prescription of Controlled Substance (EPCS) for pharmacy application providers, specifically, Section 1311.205 and 1311.215 requirements. The assessment took place during the period October 13, 2011, to February 1, 2012.

Our report is presented in the following manner:

- **Executive Summary**—an overview of the DEA's IFR EPCS for pharmacy application providers, specifically, Section 1311.205 and 1311.215 requirements considered in the compliance conclusion
- **Findings**—details related to findings of instances of noncompliance with regulations

This report is intended solely for the information and use of management and the board of directors of Rite Aid. It is not intended to be, and should not be, used by anyone other than these specified parties. The DEA may be provided with a copy of this report in connection with fulfilling their oversight responsibilities.

We would like to express our thanks to the staff of the Rite Aid, who were helpful and candid throughout the process. We hope this report provides your staff with meaningful feedback.

If you have any questions concerning this report, please contact Mr. Joe Benfatti at 619.516.1180.

Sincerely,



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I. EXECUTIVE SUMMARY**A. INTRODUCTION****DEA's IFR EPCS for Pharmacy Application Providers (Specifically, Section 1311.205 and 1311.215 Requirements)**

On March 31, 2010, the Drug Enforcement Administration's (DEA's) Interim Final Rule (IFR) with Request for Comment titled "Electronic Prescriptions for Controlled Substances" was published in the Federal Register. The rule became effective June 1, 2010.

The rule revises DEA regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions. These regulations are an addition to, not a replacement of, the existing rules. The regulations provide pharmacies, hospitals, and practitioners with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substances.

E-Prescription of Controlled Substance (EPCS), as with paper prescriptions, requires the individual practitioner be responsible for ensuring that the prescription conforms to all legal requirements and the pharmacist, acting under the authority of the DEA-registered pharmacy, has a corresponding responsibility to ensure that the prescription is valid and meets all legal requirements. The EPCS application must be reviewed in order to provide the prescriber and pharmacist the level of assurance needed in order to use the application. Further, the DEA requires that pursuant to Section 1311.300 of the IFR, independent audits be performed by CPA's under attestation rules governed by the American Institute of Certified Public Accountants or compliance audits be performed by Certified Information System Auditors (CISAs) before EPCS transactions can be processed by provider or pharmacy systems, whenever an application is altered in a way that could affect the functionalities within the electronic prescription or pharmacy application related to controlled substance prescription requirements or every two years, whichever occurs first.

Rite Aid Corporation (Rite Aid) falls subject to the requirements for DEA-registered pharmacies components of the IFR.

B. SCOPE AND COVERAGE

McGladrey & Pullen, LLP performed an assessment of Rite Aid's DEA's IFR EPCS for pharmacy application providers, specifically, Section 1311.205 and 1311.215 requirements for pharmacy EPCS applications from October 13, 2011, through February 1, 2012.

The purpose of the compliance consulting activities at Rite Aid was to independently assess compliance with the DEA's IFR EPCS for pharmacy application providers, specifically, Section 1311.205 and 1311.215 requirements.

The scope of our DEA's IFR EPCS for pharmacy application providers, specifically, Section 1311.205 and 1311.215 requirements for logical access, digital signatures, logging and audit trails, reporting, logical security, and archival storage over the following application: Rite Aid NexGen Pharmacy Application.

In order to conduct our compliance assessment against DEA's IFR EPCS for pharmacy application providers, specifically, Section 1311.205 and 1311.215 requirements, we inquired, inspected, observed and reperformed identified controls by the DEA in the Rite Aid NexGen Pharmacy Application from October 13, 2011, through February 1, 2012. Whenever

possible, we used the same sample selection to test compliance with identified controls by the DEA. When this was not possible, we expanded our judgmentally derived sample to identify specific transactions that met the coverage parameters of a particular regulation. The compliance assessment was conducted by CISAs qualified to perform compliance assessments under the rule.

C. CONCLUSION

Based upon our assessment procedures, we found that the DEA's IFR EPCS for pharmacy application providers, specifically, Section 1311.205 and 1311.215 requirements were met by the NexGen Pharmacy Application and procedures in place at Rite Aid. As with any compliance assessment, our procedures were limited to a selection of tests during a limited period of time. Because of their nature, controls over NexGen may not prevent, or detect and correct, all errors or omissions in processing or reporting transactions. Also, the projection to the future of any compliance assessment of controls to ensure compliance is subject to the risk that controls may become inadequate or fail.

II. FINDINGS

We did not identify findings or instances of noncompliance in our assessment procedures.