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Pharmacy Management Application (PMA) Willow Ambulatory EPCS Assessment Report

Application: Willow Ambulatory EPCS

Version: 2012

Assessment Dates: 10/29/2012 - 11/09/2012

Prepared For:

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Introduction

DEA's 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 should take into account the requirements outlined in the 21 C.F.R. parts 1311, subpart C in order to meet or exceed these requirements in order to enable their application to receive electronically prescribed controlled substance prescriptions.

This document provides Coalfire's opinion on the application vendor's compliance to the DEA's EPCS rule for the following application:

- Company: Epic
- Application: Willow Ambulatory EPCS
- Application Version: 2012

Scope of DEA's EPCS Rule and Epic's Application

Coalfire worked closely with Epic to complete the assessment of their EPCS application, its components, vendor personnel and relevant documentation. The first step of this process was to understand the nature and architecture of the application and determine if the DEA Rule for EPCS applies. Based upon this initial analysis, it is Coalfire's determination that Willow Ambulatory EPCS version 2012 is a *pharmacy application* subject to DEA EPCS Rule requirements as it has the capability to receive electronically prescribed controlled substance prescriptions.

Coalfire Methodology

Coalfire employs a 2 step methodology applied to all DEA EPCS projects, as follows:

1. DEA EPCS rule compliance assessment testing of the EPCS application in a lab environment including:
 - a. Lab setup and EPCS application implementation following vendor guidance.
 - b. Technical testing of the EPCS application in the lab environment.
 - c. Review of all relevant documentation.
 - d. Interview of vendor personnel.
2. Completion of the Pharmacy Management Application (PMA) Assessment Report including:
 - a. Internal QA process prior to submittal to Epic.

EPCS Application Compliance Status

Coalfire has completed the full assessment testing process as outlined above for Willow Ambulatory EPCS version 2012 according to the documented EPCS Requirements as outlined in the *Code of Federal Regulations Title 21–Food and Drugs, Part 1311 "Electronic Prescriptions for Controlled Substances; Final Rule"* defined by the Drug Enforcement Administration (DEA). This document provides the findings from the extensive assessment process for this EPCS application.

Based upon these findings, Coalfire finds Willow Ambulatory EPCS version 2012, to be fully **COMPLIANT** with all applicable requirements of *Part § 1311 "Electronic Prescriptions for Controlled Substances; Final Rule"* as of 11/09/2012.