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CASE STUDY:

Software company receives groundbreaking DEA EPCS compliance assessment

Background

RSM US LLP recently completed its first compliance assessment of a major electronic prescription for controlled substances (EPCS) software solution offered by NewCrop, LLC. NewCrop's early-to-market software solution pharmacy technology for controlled substances represents a groundbreaking application of Drug Enforcement Agency (DEA) compliance rules to a software company.

Project

RSM's assessment of the NewCrop-EPCS software module used Verizon's Universal Identify Service™ against the requirements of the Drug Enforcement Agency's (DEA) Interim Final Rule on EPCS for software solution vendors. As a result of their thorough review, RSM compliance specialists found the NewCrop-EPCS software to be in full compliance with the defined security and non-repudiation criteria set forth in the DEA rules.

The assessment findings mark the successful completion of an 18-month project that began with the release of the Drug Enforcement Agency's requirements in June 2010. The DEA's mandate for non-repudiation of electronic prescriptions for controlled substances necessitated a complex foundation of the National Institute of Standards and Technology (NIST) Level 3 requirements for registration, authentication, authorization, and legally enforceable digital signatures. RSM's assessment confirms that NewCrop-EPCS has met this strict standard.

"At RSM, we understand the importance of providing cutting-edge compliance assessment services to our clients who so often find themselves dealing with new, ever-changing and often complex regulatory requirements," said Doug Underwood, principal and practice lead, Technical Risk Advisory Services at RSM.

“By helping to establish a baseline of compliance for NewCrop’s–EPCS software solution, and its integration with electronic medical records (EMRs) and other medical software, we are proud to have helped this significant client demonstrate that they have adequate controls in place to provide their in–demand e–prescription services to their clients.”

“We were pleased to participate in this early–tomarket EPCS product release. NewCrop’s modular solution allows an important benefit for EMRs needing to demonstrate DEA compliance. Since much of the technology will have already been assessed, an expedited compliance assessment can be performed,” said Joe Benfatti, director, Technology Risk Advisory Services at RSM.

“Of equal importance, NewCrop–EPCS is designed to be easily integrated with a wide variety of EMRs and networks,” said Craig Wagener, chief information officer, NewCrop LLC. “We offer the choice of utilizing our self–installing user interface or of using our data services to seamlessly incorporate individual components into existing workflow.”

RSM offers EPCS compliance assessment services to EMRs and other medical software users selecting NewCrop’s EPCS user interface and/or those integrating the core product on their own. RSM has a team of compliance professionals dedicated to this and other regulatory areas.

Outcomes

“Our goal was to meet the complex DEA mandates, yet provide doctors with an efficient and transparent prescribing workflow,” said Lawrence Susnow, M.D., president and chief medical officer, NewCrop, LLC. “NewCrop–EPCS accomplishes this. Doctors can now bring the patient safety and efficiency of electronic prescribing to all narcotics and scheduled drugs.”

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