## INTEGRATED MODULES of Drummond Audited EPCS Product

An integrated module is built to allow a software vendor to incorporate EPCS without requiring them to develop their own user interfaces, workflows, or back end processes. The application vendor will embed or redirect the user to the software reseller's module. This module will handle all EPCS functions on behalf of the software vendor, including: access controls, prescription creation, two factor authentication, logging and reporting, and transmission of controlled substance prescriptions.

### Testing Requirement

21 CFR 1311 defines a provider of an electronic prescription application as an entity that develops or markets electronic prescription software either as a stand-alone application or as a module in an electronic health record application. This includes application vendors who have elected to integrate EPCS module(s) from a reseller.

Per 21 CFR 1311.300 the application provider of an electronic prescription application must undergo a third-party audit before the application may be used to create, sign, transmit, or process controlled substance prescriptions.

### Testing Process

The EHR vendor is expected to have a thorough understanding of the requirements presented in this documentation for this short review. We highly suggest that they review and audit themselves using these test cases to prepare for this review. The review is expected to require less than one hour.

Upon successful completion of the review, a report will be issued to the EHR vendor. If there are no discovered issues, the report will demonstrate that the application has undergone a third-party audit as required by 21 CFR 1311, and can now be used for EPCS. If the review discovers items of non-compliance, a "corrective action" report will be issued that will detail which requirements were not met. If the outcome is not successful, then retesting fees will apply and another date will be scheduled upon receipt of payment.

### Drummond Group Audit

Drummond Group will conduct the Audit against a production release version of application enabled with EPCS in a staging environment. No code changes will be permitted during testing. For applications employing loosely integrated modules one hour is allotted for the review

## Audit Procedure

The Drummond Group audit procedure for integrated modules consists of the following categories.

1. **User Creation and Access Controls**
    a. Application provider will demonstrate the process for creating a new user that does not have the EPCS permission or role.

2. **Prescription Creation**
    a. Application provider will demonstrate that any prescription created contains all information required for it to be a valid prescription.

3. **Prescription Signing**
    a. Application provider will demonstrate that the application requires controlled substance prescriptions to be reviewed and marked ready to sign before they can be signed or transmitted, and the page for reviewing prescriptions displays all of the required information. For testing purposes, only 1 prescription will be used for demonstration purposes.

4. **Reports and Audit Trail**
    a. Application provider will demonstrate that the application maintains an audit trail, prescription report, and security incident report capable of capturing the DEA required events.

## Audit Final Report

Upon successful completion of the Audit of your product (with version) Drummond Group will issue your company an Audit Final Report. If no non-compliant items were discovered, at this point, you may initiate communication with your customers that your application has undergone third-party audit, and they may begin use of your EPCS application.

# Additional Important Information:

### DEA Approval of Drummond Group as a 3rd Party Auditor

- Drummond Group has been authorized by the Drug Enforcement Administration (DEA) to serve as a neutral third-party certification organization of EPCS applications.
- During the EPCS Audit, EPCS systems must undergo a rigorous process where we carefully review and test EPCS applications to provide assurance that the application fully meets all of the requirements of the Drug Enforcement Administration's (DEA) Interim Final Rule for Electronic Prescriptions for Controlled Substances.
- For general questions, please refer to our FAQs on our website.

## Audit Method:

This audit will be run remotely using conference call and a screen viewing software e.g. GoToMeeting.

## Re-Audit:

Re-audit is required by the DEA every two years. If the integrated module is modified in a manner that does not alter the integration functionality, Drummond Group will review the re-seller's changes and the integrating product can inherit those changes without attestation or re-audit. If changes to the integrated module affect the integration functionality the integrating EHR application must also undergo re-evaluation.

If the integrating EHR application changes modules or vendors the Final Audit Report does not apply to the new version. It only applies to the version that was audited.

For changes to the integrated module, the software vendor of the integrated module will be required to complete an EPCS Attestation form on the change (send email to EPCS@drummondgroup.com for attestation form) and the Drummond Review Board will rule whether your product has to be re-tested and to what degree. Pricing will also be issued at that time.
**Pricing for re-audit is generally less than your initial fees.**

**We look forward to working with you!**