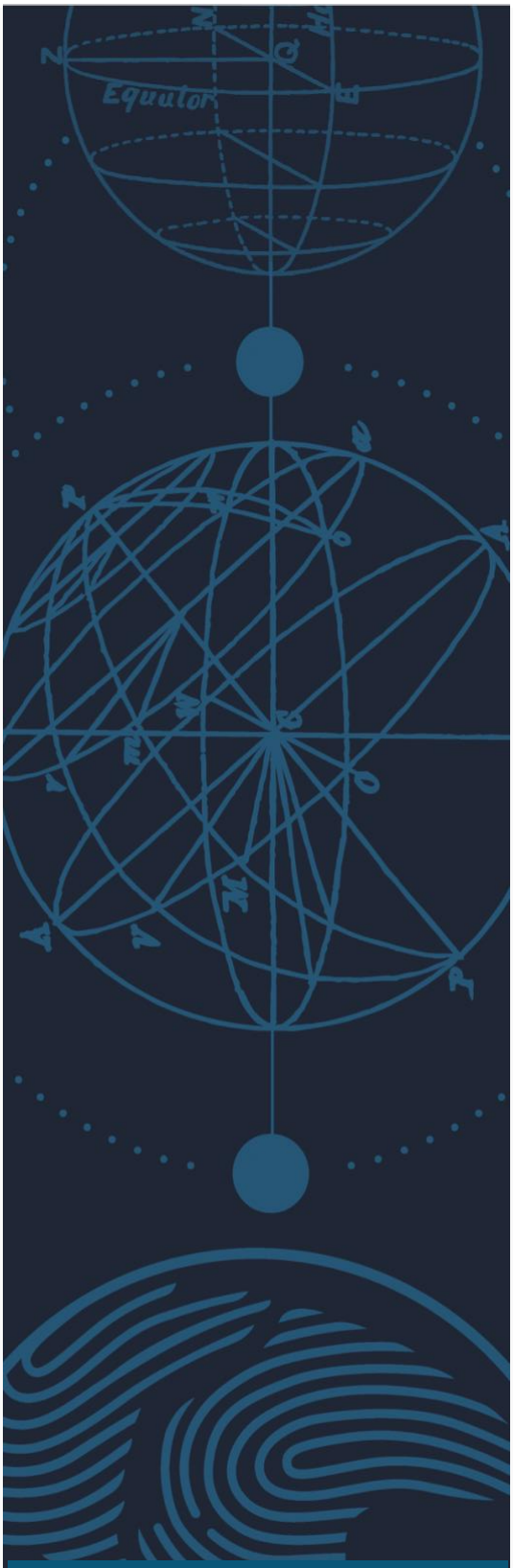

INTEGRATED MODULES of Certified EPCS Product

APRIL 2021

DRUMMOND

Your Partners In Compliance

INTEGRATED MODULES OF CERTIFIED EPCS PRODUCT

An integrated module is built to allow software vendors 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 (EHR) 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 prescriptions for controlled substances.

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 recommend vendors complete a review and self-audit using these test cases to prepare in advance. 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 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 and 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 integrated modules, one hour is standard 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.
    b. Application provider will demonstrate the user cannot mark prescriptions ready to sign, sign prescriptions or elevate their privileges to be able to do so.
    c. Application provider will detail the process for identity proofing a practitioner and providing their authentication credentials for two-factor authentication.
    d. Application provider will demonstrate the process for granting EPCS permissions to a user account. They will demonstrate the actions of two individuals are required to add permissions, one of which must be a practitioner who must provide two-factor authentication to confirm the adding of EPCS permissions.

2. **Prescription Creation**
    a. Application provider will demonstrate any prescription created contains all information required for it to be a valid prescription: full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address and registration number of the practitioner. This also includes the information required for special case drugs: GHB and detoxification drugs.

3. **Prescription Signing**
    a. Application provider will demonstrate 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 one prescription will be used.
    b. Application provider will demonstrate the application displays all required information when prompting the practitioner to provide their two-factor authentication.
    c. Application provider will demonstrate that prescriptions can only be signed with the two-factor credential of the prescriber.

4. **Reports and Audit Trail**
    a. Application provider will demonstrate the application maintains a sortable report containing all controlled substance prescriptions.
    b. Application provider will demonstrate the application maintains an audit trail and demonstrate through sample entries the audit trail captures the creation, alteration, indication of readiness for signing, signing, transmission, or deletion of a controlled substance prescription, setting or changing the logical access controls related to EPCS, or notice of a failed transmission. They also will demonstrate each audit log entry contains all of the required pieces of information.
    c. Application provider will demonstrate the application maintains a security incident report that is provided for the practitioners' review. They will demonstrate the report captures all required entries.

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, any communication with your customers may now disclose your application has undergone third-party audit and use of the audited EPCS application may begin.

ADDITIONAL IMPORTANT INFORMATION

DEA Approval of Drummond Group as a Third-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 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 reseller'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 (email EPCS@drummondgroup.com for attestation form). The Drummond Review Board will then 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!