NCPDP SCRIPT 2017071 Update Audit for Prescribing Applications

In April 2018 Centers for Medicare & Medicaid Services (CMS) issued its Final Rule that updates Medicare Advantage (MA) and the prescription drug benefit program (Part D). This rule included notice that CMS will be adopting version 2017071 of the NCPDP SCRIPT standard starting January 1, 2020. SCRIPT 2017071 will be replacing the SCRIPT 10.6 standard for e-prescribing messages.

Testing Requirement

Applications seeking to upgrade to the new NCDPD SCRIPT 2017071 standard for electronic prescribing must undergo DEA required re-audit of their e-prescribing application. Per 21 CFR 1311.300 the application provider of an electronic prescription application must undergo a third-party audit whenever a functionality related to controlled substance prescription requirements is altered or every two years, whichever occurs first.

Applications upgrading from SCRIPT 10.6 to SCRIPT 2017071 must undergo re-audit of their e-prescribing functionality by a DEA approved third-party prior to moving the changes to production. In addition to DEA re-audit, applications using Surescripts network must also re-certify with Surescripts. The DEA and Surescripts audits may be conducted in parallel.

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 upgrading SCRIPT standards two hours are allotted for the review. If the application vendor is unable to demonstrate the required functionality of the application to the auditor's satisfaction within the allotted time the application vendor must arrange for additional testing and payment. In case of failure, your company must make the appropriate corrections, and arrange for additional testing and payment.

Audit Procedure

The Drummond Group audit procedure for NCPDP 2017071 consists of the following categories.

1. **NewRx Messages**
    a. Application provider will demonstrate that any prescription message 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 must be included in every prescription message.
    b. Application provider will demonstrate that prescriptions for Schedule III-V detoxification drugs include the Narcotics Addiction DEA Number (NADEAN) in the prescription message.
    c. Application provider will demonstrate that the earliest-fill-date is included in prescription messages which require it (multiple identical schedule II medications).
    d. Application provider will demonstrate that the medical reason note is included in prescription messages for drugs which contain GHB.

e. (Optional) Application provider will demonstrate that prescription messages created by an agent contain the agent information.
f. (Optional) Application provider will demonstrate that prescription messages created by a prescriber with multiple DEA numbers include the correct DEA number.
g. (Optional) Application provider will demonstrate that prescription messages created by a mid-level practitioner include their supervisor information.

2. (Optional) RxRenewalResponse

a. Application provider will demonstrate that workflow to respond to RxRenewalRequest messages requires the prescriber to mark prescriptions ready-to-sign and sign prescriptions with two-factor authentication IF the change authorizes dispensing of additional or new controlled substances.
    i. Note: Per guidance from NCPDP and DEA, SureScripts does not allow approval of a RxRenewalRequest. RxRenewalRequest messages for controlled substances must be responded to with Replace or Deny.
b. Application provider will demonstrate that renewal responses are limited to 0 refills for Schedule II medications.
c. Application provider will demonstrate that renewal responses are limited to 5 refills for Schedule III-IV medications.

3. (Optional) NewRxRequest

a. Application provider will demonstrate that workflow to respond to NewRxRequest messages requires the prescriber to mark prescriptions ready-to-sign and sign prescriptions with two-factor authentication.

4. (Optional) RxChangeResponse

a. Application provider will demonstrate that workflow to respond to RxChangeRequest messages requires the prescriber to mark prescriptions ready-to-sign and sign prescriptions with two-factor authentication IF the change authorizes dispensing of additional or new controlled substances.

5. **Prescription Signing and Timestamp**
    a. Application provider will demonstrate that controlled substance prescriptions are digitally signed.
    b. Application provider will demonstrate that controlled substance prescriptions are archived electronically and linked to the associated digital signature.
    c. Application provider will demonstrate that all prescription messages are date and timestamped when the signing function (two-factor authentication) is used.

6. **Audit Trail**
    a. Application provider will demonstrate that the application maintains an audit trail and demonstrate though sample entries that the audit trail captures the creation, alteration, indication of readiness for signing, signing, transmission, deletion of a controlled substance prescription, and notice of a failed transmission.

Audit Final Report

Upon successful completion of the re-audit of your product (with version) Drummond Group will issue your company an updated Certification Report and your new version of your product will be listed on the Drummond Group website. At this point, you may publish the certified changes to your production application.

Audit Method

This audit will be run remotely using conference call and a screen viewing software via GoToMeeting provided by Drummond Group.

Re-Audit Requirement

A re-audit is required by the DEA every two years or when you make changes to your software in areas that affect the application EPCS criteria. For minor changes within this 2-year period, Drummond offers an EPCS attestation audit at reduced fees to maintain your Certification Report current.

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.