

Electronic Prescribing of Controlled Substances

Emdeon Town Hall

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What is NCPDP?

- An ANSI-accredited standards development organization.
- Provides a forum and marketplace for a diverse membership focused on health care and pharmacy business solutions.
- A member driven organization that has been named in various government legislation and rulings, such as HIPAA and the Medicare Prescription Drug Benefit.
- One of several Standards Development Organizations (SDOs) involved in Healthcare Information Technology and Standardization.
- Focus on pharmacy services, and has the highest member representation from the pharmacy services sector of healthcare.

NCPDP Standards Used in Electronic Prescribing

- **SCRIPT Standard**
 - Exchange between prescribers, pharmacies, intermediaries, payers
 - New prescription request
 - Change of new prescription
 - Cancel of prescription
 - Refill/renewals request/response or Resupply in long term care

NCPDP Standards Used in Electronic Prescribing

- **SCRIPT Standard**
 - Exchange between prescribers, pharmacies, intermediaries, payers
 - Fill Status notification
 - Medication history exchange
 - Drug Administration exchange in long term care
 - Prescriber-reported samples for more robust medication history

NCPDP Standards Used in Electronic Prescribing

- **Formulary and Benefit Standard**
 - Pharmacy benefit payers (including health plans and Pharmacy Benefit Managers) to communicate formulary and benefit information to prescribers via technology vendor systems. Information for the prescriber to consider for the most appropriate drug choice for the patient.
 - Which drugs are considered to be “on formulary,” and alternative medications for those drugs not on formulary
 - Limitations that may impact whether the patient’s benefit will cover a drug being considered (such as age limits, gender limits, step therapy rules, benefit-specific coverage exclusions, etc.)
 - The cost to the patient for one drug option versus another

Next Version of SCRIPT - 10.6

The regulation - 42 CFR Part 423 [CMS–0023–IFC] RIN 0938–AP49
Medicare Program; Identification of Backward Compatible Version of
Adopted Standard for E–Prescribing and the Medicare Prescription
Drug Program (NCPDP SCRIPT 10.6) -

http://www.access.gpo.gov/su_docs/fedreg/a100701c.html

- permits the voluntary use of NCPDP SCRIPT 10.6 for conducting certain e-prescribing transactions for the Medicare Part D electronic prescription drug program.
- *Effective date:* July 1, 2010.
- *At some point* retire, SCRIPT 8.1.
 - HHS is seeking industry input.
 - Comments due by August 30, 2010 5 p.m. EDT

Current Long Term Care Exemption

- From the regulation:
 - The LTC setting issues are addressed in NCPDP SCRIPT 10.2 and subsequent versions.
 - It would not be appropriate to lift the LTC exemption prior to retiring any NCPDP SCRIPT versions prior to NCPDP SCRIPT 10.2.
 - As the retirement of NCPDP SCRIPT 8.1 and the elimination of the LTC exemption will be substantive changes to the Part D eprescribing regulations, CMS will need to use notice and comment rulemaking to effectuate these changes.
 - We anticipate proposing these changes at a later date in a notice of proposed rulemaking.
- *Voluntary use at this time.*

Controlled Substance Prescriptions

- **Interim Final Rule *with comments***

- We could see a Final Rule with discussion of comments submitted
- Items may or may not be modified

- DEA guidance website

http://www.deadiversion.usdoj.gov/ecomm/e_rx/index.html

Two options for verification:

- Digitally signing the prescription with the individual practitioner's private key.
- Verify that the practitioner signed the prescription by checking the data field that indicates the prescription was signed; or Display the field for the pharmacist's verification.

Digitally signing the prescription with the individual practitioner's private key (option 1)

- An individual practitioner who has obtained a digital certificate per regulation
 - may digitally sign a controlled substance prescription using the private key associated with his digital certificate.
- The electronic prescription application **must**
 - require the individual practitioner to complete a two-factor authentication protocol to use his private key.
 - digitally sign at least all information required under regulation
 - full name and address of the patient, drug name, strength, dosage form, quantity prescribed, directions for use, and the name, address, and registration number of the practitioner
 - electronically archive the digitally signed record

Digitally signing (continued)

- A prescription that is digitally signed with a practitioner's private key may be transmitted to a pharmacy without the digital signature.
 - If without the digital signature, the electronic prescription application must check the certificate revocation list of the certification authority that issued the practitioner's digital certificate. If the digital certificate is not valid, the electronic prescription application must not transmit the prescription. The certificate revocation list may be cached until the certification authority issues a new certificate revocation list.
- When the individual practitioner digitally signs a controlled substance prescription with the private key associated with his own digital certificate, the electronic prescription application is not required to digitally sign the prescription using the application's private key.

Digitally signing (continued) - PKI

- DEA is allowing any registrant to use the public key infrastructure (PKI) option proposed for Federal healthcare systems
 - the interim final rule does not include separate requirements for these systems.
- Under the interim final rule, using a private key to sign controlled substance prescriptions will be an option provided that the associated digital certificate is obtained from a certification authority that is cross-certified with the Federal PKI Policy Authority at a basic assurance level or above.
- The electronic prescription application will have to support the use of digital signatures, applying the same criteria as proposed for Federal systems.
 - The private key associated with the digital certificate will have to be stored on a hard token (separate from the computer being accessed) that meets the requirements for FIPS 140–2 Security Level 1 or higher.
- If a practitioner digitally signs a prescription with his own private key and transmits the prescription with the digital signature attached, the pharmacy will have to validate the prescription, but no other digital signatures will need to be applied. (If the practitioner uses his own private key to sign a prescription, the electronic prescribing application will not have to apply an application digital signature.)
- If the digital signature is not transmitted, the pharmacy or last intermediary will have to digitally sign the prescription.
- Federal systems will be free to impose more stringent requirements on their users, as they have indicated that they do.

Checking the data field (option 2)

- Verify that the practitioner signed the prescription by checking the data field that indicates the prescription was signed; or
- Display the field for the pharmacist's verification.

Impact to NCPDP SCRIPT 8.1 and 10.6

- Option 1 is not supported *at this time*
 - If Option 1 is desired by the industry, the requested changes will need to be submitted, and upon approval, would be effective in a **future version** of SCRIPT
 - Could be a wrapper around the transaction?
 - How to submit a recommendation for enhancement – Data Element Request Form (DERF) - http://www.ncpdp.org/standard_changes.aspx (NCPDP DERF process)

Supporting New Business Need

- SCRIPT 8.1 currently in use. The industry is preparing for 10.6. How does the industry support transmission of prescriptions, with least impact?
 - NCPDP convened an industry task group of interested people
 - The task group reviewed the standard and considered multiple suggestions
 - The task group reached consensus to bring forward recommendations to the larger NCPDP work group body
 - NCPDP Work Group 11 ePrescribing and Related Transactions discussed, modified, and then approved recommendations during August Work Group meetings
 - Industry support on consistent use to exchange
 - Directed to publish the information in the **SCRIPT Implementation Recommendations document**

Impact to NCPDP SCRIPT 8.1

- Option 2 is supported
 - Digital Signature Indicator
 - Controlled Substance Indicator
 - Earliest Fill Date
 - Drug Abuse Treatment Indicator
 - Medication Indication for GHB (Gamma-Hydroxybutyric acid)
- **SCRIPT Implementation Recommendations document**
 - http://www.ncpdp.org/members/members_download.aspx
 - Choose “SCRIPT Standards Guidance Documents” from pull down

Digital Signature Indicator

- Use Drug Coverage Status
 - Drug Coverage Status repeats up to five times
 - Value “SI” (Signed Prescription)
 - Description: This indicates the prescription has been signed according to the DEA requirements for electronic prescribing of controlled substances.
 - In future versions of SCRIPT this will be a separate data element.

Controlled Substance Indicator

- Use Drug Coverage Status also
 - Drug Coverage Status repeats up to five times
 - Value “CS” (Controlled Substance)
 - Description: This is a controlled substance as defined by the DEA or more restrictive applicable regulation.
 - DEA Schedule has been added in SCRIPT 10.5 and will be used for this indicator in the future.

Earliest Fill Date

- Use Effective Date
 - EDI – use Date (DRU-Ø4Ø) with qualifier for Effective Date
 - Note: DRU-Ø4Ø Date occurs up to 5 times in SCRIPT 8.1 and up to 9 times in SCRIPT 10.6, so multiple occurrences are supported for NewRx requirements.
 - XML – use <EffectiveDate>
 - In the future we will add a new date for Earliest Fill Date

Drug Abuse Treatment Indicator

- Use Free Text
 - *For Schedule II usage*
 - Use text “NADEAN:xxxxxxxx” (Narcotics Addiction DEA Number)
 - The qualifier for Data 2000 Waiver ID (Used for prescriptions for opioid addiction treatment medications) was added to the External Code List (ECL) in January 2010 and that can be used when updating to a new ECL

Medication Indication

- Use Free Text
 - *For GHB (Gamma-Hydroxybutyric acid)*
 - A free text description of the medical need for GHB
 - In the future it may become a separate field or be incorporated into the Sig fields

Impact to NCPDP SCRIPT 10.6

- Option 2 is supported
 - The same ***except***
 - Controlled Substance Indicator is not placed in Drug Coverage Status. The field DEA Schedule is to be used.

NCPDP Resources

- Obtain NCPDP standards
 - If a member –
http://www.ncpdp.org/members/members_download.aspx
 - If not a member – all NCPDP standards are available free of charge with yearly membership
 - http://www.ncpdp.org/standards_purchase.aspx
- Eprescribing information
 - <http://www.ncpdp.org/eprescribing.aspx>

NCPDP Task Groups

- Task Groups are open to any interested party who are willing to participate and work...http://www.ncpdp.org/get_involved.aspx - under Task Groups
 - NCPDP Formulary and Benefit Task Group meets to provide further clarification, enhancements to the standard as needs come forward
 - NCPDP Prior Authorization Workflow to Transactions Task Group on the exchange of prior authorization information
 - NCPDP-HL7 Eprescribing Functional Profile Task Group completing criteria for standalone and pharmacy/pharmacist functional profiles
 - Clinical Health Information Exchange (CHIX) Task Group
 - Industry Sig Task Group on the exchange of structured prescription instructions

Thank You

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