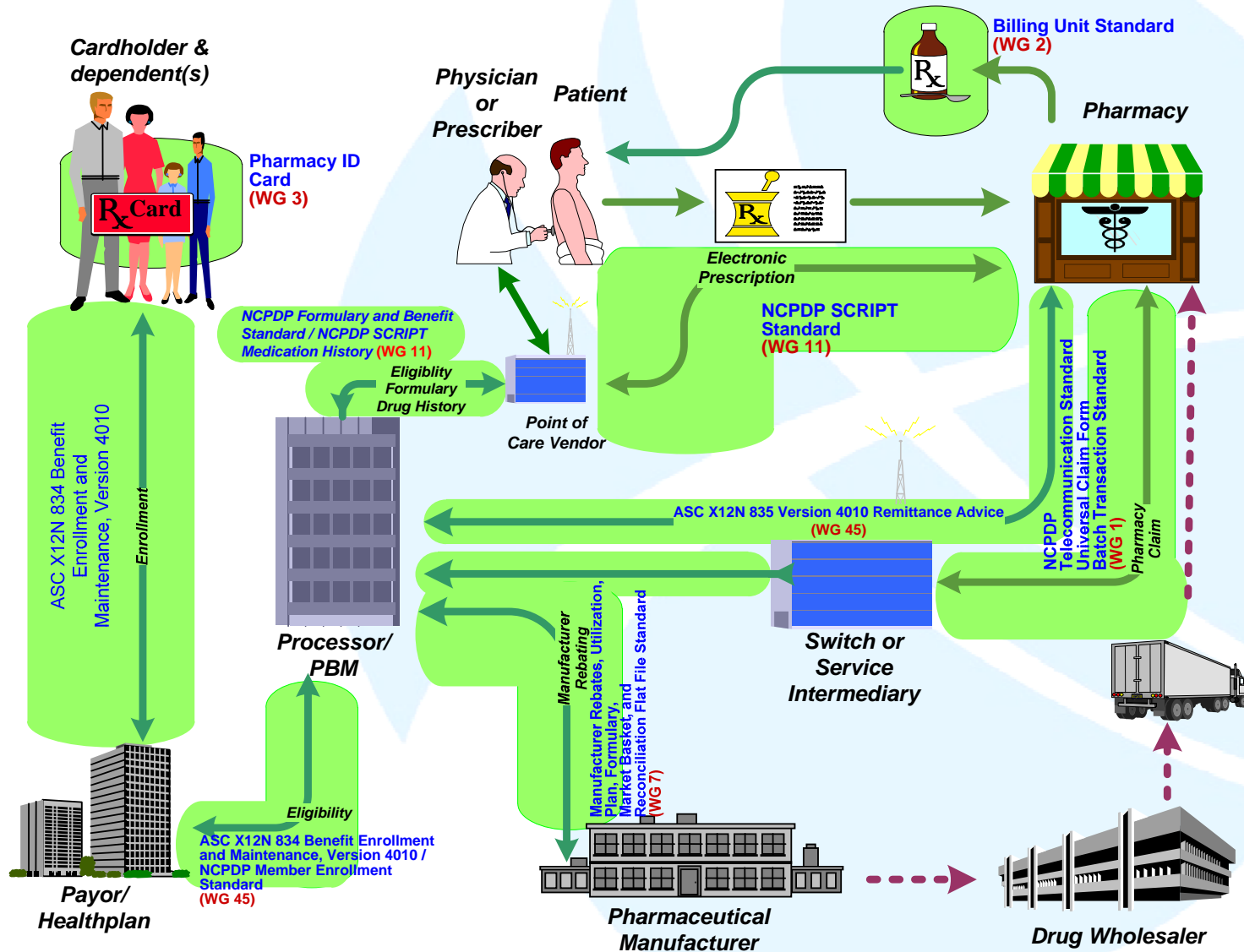


# **NCPDP Electronic Prescribing Standards**

November 2011

## *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, the Medicare Prescription Drug Benefit, and healthcare reform.
- 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 are used in pharmacy processes, payer processes, electronic prescribing, rebates, and more.
- NCPDP dataQ™ - provides healthcare stakeholders with up-to-date, comprehensive, and in-depth pharmacy information.
- NCPDP Online - enumerator of the NCPDP Provider ID number.
- HC Idea - NCPDP's relational healthcare prescriber database of over 2.1 million prescribers created for the industry, by the industry.
- RxReconn™ - NCPDP's legislative tracking product.



# 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
    - Fill Status notification
    - Medication history exchange
    - Drug Administration exchange in long term care
    - Prescriber-reported samples for more robust medication history

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## CMS Regulation 2010

- July 1, 2010 published
  - The Centers for Medicare and Medicaid Services (CMS) published to the Federal Register July 1, 2010 an Interim Final Rule (IFR) entitled, "Identification of Backward Compatible Version of Adopted Standard for E-Prescribing and the Medicare Prescription Drug Program (NCPDP SCRIPT 10.6)."
  - The regulation names NCPDP SCRIPT 10.6 effective for use July 1, 2010 and continues to support NCPDP SCRIPT 8.1.
  - See <http://www.ncpdp.org/eprescribing.aspx>
  - Long term care may use the MMA standards, but are not required at this point
- October 24, 2011
  - 42 CFR Chapter IV [CMS–9070–P] RIN 0938–AQ96 Medicare and Medicaid Program; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction.
  - Section 4. E-Prescribing which proposes to move from the ASC X12 270-271 version 4010A1 to the 5010, and from the NCPDP Telecommunication Standard version 5.1 to D.0, to be aligned with the HIPAA regulations for January 1, 2012.
  - The industry had requested this regulatory update so that the electronic prescribing and claims processing environments would be in sync for versions of standards used. [http://www.access.gpo.gov/su\\_docs/fedreg/frcont11.html](http://www.access.gpo.gov/su_docs/fedreg/frcont11.html)

## CMS Regulation 2012

- Sometime in 2012 it is expected CMS will publish a regulation that will give the sunset dates for SCRIPT version 8.1 based on industry input.
- CMS will publish an Notice of Proposed Rule Making (NPRM) that, based on industry input, will remove the long term care exemption for eprescribing and require that if electronic exchange, the named standards are to be used by long term care.

## DEA Regulation

March 31, 2010 published

- The Drug Enforcement Administration (DEA) issued an Interim Final Rule (IFR) with Request for Comment to provide practitioners with the option of writing prescriptions for controlled substances electronically and permit pharmacies to receive, dispense and archive these electronic prescriptions.
- See <http://www.ncpdp.org/eprescribing.aspx>
- The effective date is June 1, 2010.
- The DEA has published guidance at [http://www.deadiversion.usdoj.gov/ecommm/e\\_rx/index.html](http://www.deadiversion.usdoj.gov/ecommm/e_rx/index.html)
- The **SCRIPT Implementation Recommendations** Document contains guidance for the use of one of the DEA options in SCRIPT 8.1 and in SCRIPT 10.6

## DEA Regulation

September 9, 2010

- The DEA solicited public comments on how best to standardize the specific internal code number associated with each individual practitioner permitted by the hospital or other institutional practitioner to administer, dispense, or prescribe controlled substances using that institution's DEA registration.
- DEA is taking this action in response to comments it received to its Notice of Proposed Rulemaking regarding electronic prescriptions for controlled substances. 21 CFR Part 1301 [Docket no. DEA-321a] RIN 1117-AB22 Identification of Institution-based Individual Practitioners.

[http://www.access.gpo.gov/su\\_docs/fedreg/frcont10.html](http://www.access.gpo.gov/su_docs/fedreg/frcont10.html)

## DEA Regulation

October 19, 2011

- 21 CFR Parts 1300, 1304, 1306 and 1311 [Docket No. DEA–360] Electronic Prescriptions for Controlled Substances Clarification
- DEA wishes to emphasize that third-party audits of software applications for Electronic Prescriptions for Controlled Substances (EPCS) must encompass all applicable requirements in our regulations, including security, and must address “processing integrity” as set forth in our regulations.
- Likewise, where questions or gaps may arise in reviewing a particular application, DEA recommends consulting federal guidelines set forth in NIST Special Publication 800–53A.
- DEA is also announcing the first DEA approved certification process for EPCS. Certifying organizations with a certification process approved by DEA pursuant to the regulations are posted on DEA’s Web site once approved.  
[http://www.access.gpo.gov/su\\_docs/fedreg/frcont11.html](http://www.access.gpo.gov/su_docs/fedreg/frcont11.html)

## What do I need to implement SCRIPT 8.1?

Check with trading partners – you may need to move to SCRIPT 10.6!

- Implementation Guide
  - **SCRIPT Version 8.1**
    - Format choice:
      - EDI format
        - Contained in **SCRIPT Implementation Guide**
      - XML
        - Implementation rules contained in **SCRIPT Implementation Guide**
        - **Companion Guide to SCRIPT Standard v8.1** (Publication of January 2008)
  - **Data Dictionary**
    - October 2005
  - **External Code List**
    - Publications of October 2005 through most recent are applicable
  - **SCRIPT Implementation Recommendations Document**
  - *Industry is actively moving to SCRIPT 10.6*

# What do I need to implement SCRIPT 10.6?

- Implementation Guide
  - **SCRIPT Version 10.6**
    - Format choice:
      - EDI format
        - Contained in **SCRIPT Implementation Guide**
      - XML
        - Implementation rules contained in **SCRIPT Implementation Guide**
        - **XML zip file** included in download
- **Data Dictionary**
  - October 2008
- **External Code List**
  - Publications of October 2008 through most recent are applicable
  - It is recommended that ECLs through 201009 are used as reference
- **SCRIPT Implementation Recommendations Document**

# NCPDP Standard Documents

NCPDP publishes the following three types of documents:

**Standard Implementation Guide**

**Data Dictionary**

**External Code List**

The documents are used together, to provide a complete picture of the implementation of the standard.

See the “read me” document on the member CD or

[http://www.ncpdp.org/members/members\\_download.aspx](http://www.ncpdp.org/members/members_download.aspx)

Each document contains an appendix of the running list of changes

# NCPDP Standard Implementation Guide

The **Standard Implementation Guide** contains the

- business and technical definition of the transactions
  - the actual transaction layouts, the syntax and formatting rules, the transaction rules, usage,
  - further information about the implementation of the standard by the use of descriptive paragraphs, business situations, examples, and frequently asked questions.

*This one document combines what was in the Standard and in the Implementation Guide in previous versions.*

## NCPDP Data Dictionary

The **Data Dictionary** contains the actual field descriptions, sizes, formats, comments, and usage instructions

Which Data Dictionary do I use?

- See the Matrix [http://www.ncpdp.org/pdf/Standards\\_Matrix.pdf](http://www.ncpdp.org/pdf/Standards_Matrix.pdf)  
(or on the member CD)

Use of the correct publication of the data dictionary for a version of a standard is critical as each publication directs the proper use of a data element and data element values where applicable.

For SCRIPT 10.6

- **Data Dictionary**
  - October 2008

## NCPDP External Code List

The **External Code List** is a list of value codes with descriptions for data elements.

The actual data elements still appear in the main Data Dictionary.

The External Code List process allows values to be added to a data element without going through a ballot.

The timeline to incorporate a value into a business need is shortened.

Versions are upgraded quarterly if needed and are available for business use.

For SCRIPT 10.6

- **External Code List**

- Publications of October 2008 through most recent are applicable
- It is recommended that ECLs through 201009 are used as reference

# NCPDP Data Dictionary and External Code List and SCRIPT Transition

Of importance, the SCRIPT Standard version 8.1 – 10.11 contained both “EDI” and “XML” syntax. The Data Dictionary and External Code Lists published during this time reflect the “EDI” data elements.

The industry requested that the SCRIPT Standard sunset the “EDI” and only support the “XML” syntax post SCRIPT version 10.11. The Data Dictionary and External Code Lists of 201012 and forward contain only the XML data elements.

In the Data Dictionary of 201012 and future, we included Appendix B – **CROSS REFERENCE OF FIELDS USED IN NCPDP SCRIPT TO THE MODEL-DRIVEN** to assist as a cross reference between the old EDI fields and the XML fields.

# NCPDP Data Dictionary and External Code List and SCRIPT Transition

SCRIPT 10.6 can use 201012 or 201104 ECL, but if implementers are using only “EDI” syntax, it is recommended to reference the Data Dictionary and External Code List of 200810 through 201009.

If you are implementing XML only, the current Data Dictionary and ECL contain data element references. But if you are implementing SCRIPT in “EDI” syntax, you hit a transition between the Data Dictionary and the ECL.

*We didn't try to make it difficult, but we had to have a transition.*

# Guidance

## **SCRIPT Implementation Recommendations Document**

- Provides guidance, recommendations that could not be put in an “officially named version” of SCRIPT Implementation Guide but have been incorporated in a subsequent Implementation Guide version.
- Of importance to industry for consistent use
  - Best practices for prescription data elements
  - Controlled Substance prescription data elements using one of the two options of the DEA regulation
  - RxNorm information
- Updated as needed, so check back quarterly
- Included in CD, and found under “SCRIPT Standard Guidance Documents” at [http://www.ncpdp.org/members/members\\_download.aspx](http://www.ncpdp.org/members/members_download.aspx)

# 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

# What do I need to implement Formulary and Benefit 1.0?

- Implementation Guide
  - **Formulary and Benefit Implementation Guide** Version 1.0
- **Data Dictionary**
  - October 2005
- **External Code List**
  - Publications of October 2005 through most recent are applicable

## Code Lists Used

The NCPDP **External Code List** contains

- Values to NCPDP-defined data elements and
- Qualifiers for external code lists used in the standards, such as drug databases, product identifiers, etc
- Links to other terminologies such as RxNorm, NCI (Strength, Form, etc), SNOMED, ASC X12, etc
  - *Some external code sources are publicly available, others are not.*

## Medication Identification

Electronic prescribing functions require the exchange of medication information. There are medication terminologies, databases, products and services available – which may support different perspectives.

*For example, the medication a prescriber prescribes may be less specific than the product a pharmacy dispenses. The medication information exchanged in formulary files may represent a class of medications. All are important perspectives and there is not one terminology that satisfies all.*

The industry has long used the NDC and other identifiers for the product dispensed. A gap was identified years ago for a prescribed identifier. The industry is moving toward the use of RxNorm for the prescribed product. See the **SCRIPT Implementation Recommendations** Document.

# Specialized Standard

This implementation guide supports these business functions.

- Census Functions
- Medication Therapy Management Functions
- Query Functions

PHARMACY typically will:

- Respond to a request for census events
- initiate a request for clinical information
- initiate a response for clinical information

PRESCRIBER typically will:

- notify a pharmacy or other entity of drug administration events such as suspending administration
- initiate a request for clinical information
- initiate a response for clinical information

Entities (pharmacy, prescriber, intermediary, payer/health plan) typically will:

- initiate a request by the facility in a long term care environment to notify the pharmacy about census events
- initiate a request for clinical information
- initiate a response for clinical information

## NCPDP Task Groups

- Task Groups are open to any interested party who are willing to participate and work (held via conference calls)...
  - **NCPDP Formulary and Benefit Task Group**
    - Meets to provide further clarification, enhancements to the standard as needs come forward
  - **NCPDP-HL7 Pharmacist Functional Profile Task Group**
    - Has built profiles for criteria for functions required/optional and the timeline for meeting criteria for standalone eprescribing systems and pharmacy/pharmacist interfaces for input to Certification Commission for Health Information Technology (CCHIT) criteria. Is working on “Pharmacist/Pharmacy Provider systems” by creating one updated functional profile of the HL7 EHR System-related functions release 2
  - **NCPDP Industry Sig Task Group**
    - Enhancing the structured and codified format incorporated into SCRIPT for the Sig (instructions) on electronic prescriptions. They are enhancing the structure and guidance based on pilot feedback.
    - The MC Modeling & Methodology Task Group is looking at “grammar” tools for implementers to use in deconstruction/construction of structured and codified sigs.

# NCPDP Task Groups

- **Clinical Health Information Exchange (CHIX) Task Group**
  - Patient-centric exchange (versus medication-centric) in ambulatory settings
  - Focus on Questions/queries between parties – need to know more information, follow up question
  - Exchange of conditions/allergy/medical history information in ambulatory settings
  - See SCRIPT version 201107 and the new Specialized version 201107
- **Central Fill Task Group**
  - Building transactions to exchange information between pharmacies and central fill sites for electronic prescribing.
- **REMS and ePrescribing Task Group**
  - Evaluating the activities between pharmacy and prescriber, prescriber and manufacturer for safe use programs.

## Of Interest

- NCPDP electronic prescribing web page for resources, industry information, fact sheet, etc.
  - <http://www.ncpdp.org/eprescribing.aspx>

## Of Interest

- CMS E-Prescribing resources
  - <http://www.cms.hhs.gov/EPrescribing/>
  - [http://www.cms.gov/EHRIncentivePrograms/30\\_Meaningful\\_Use.asp](http://www.cms.gov/EHRIncentivePrograms/30_Meaningful_Use.asp)
- Medicare Improvements for Patients and Providers Act of 2008 (MIPPA:)
  - <http://www.cms.gov/ERxIncentive/>
- Health Information Technology
  - Meaningful use
  - HIT Policy Committee
  - HIT Standards Committee
  - <http://healthit.hhs.gov/portal/server.pt>

# Prior Authorization

**NCPDP Prior Authorization Workflow to Transactions Task Group** is working on the exchange of prior authorization information

- When the pharmacy needs to obtain a prior authorization, they use the NCPDP Telecommunication Standard prior authorization transactions. So that piece of the exchange has been available for awhile, and was considered out of scope since it exists.
- The task group had active participation and evaluation of first AHRQ/CMS prior authorization pilots using current transaction sets named in HIPAA. But the transactions were cumbersome.
- Based on industry input, the task group created an XML-based exchange of prior authorization data between provider and plan. CMS provided dispensation for testing of this new transaction for a HIPAA-named function.
- Information on the transaction is available at [http://www.ncdp.org/industry\\_outreach.aspx](http://www.ncdp.org/industry_outreach.aspx)
- There are activities underway in ePA.
- **NCPDP held a focus group in October 2011 to bring together entities to share their information, information on pilots. The focus group agreed to participate in the re-activated NCPDP Prior Authorization Workflow to Transactions Task Group.**

## Questions?

- NCPDP task groups - <http://www.ncdp.org/resources.aspx> - Click on Task Group Listing on page left
- Electronic prescribing info - <http://www.ncdp.org/eprescribing.aspx>
- See [www.ncdp.org](http://www.ncdp.org)
- Contact [ncdp@ncdp.org](mailto:ncdp@ncdp.org)