

# Electronic Signature Guidance

*Version 1.0*

February 2014



This document provides clarification and guidance to the industry for the use of electronic signatures associated with electronic prescriptions, including validation, authentication, and meeting regulatory requirements. This document will assist prescribers, pharmacy and third party auditors to validate the available data transmitted and stored using industry approved datasets.

## Electronic Signature Guidance

Version 1.0

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**National Council for Prescription Drug Programs**  
**9240 E. Raintree Drive**  
**Scottsdale, AZ 85260**  
**(480) 477-1000**  
**ncpdp@ncpdp.org**

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The writers of this paper will review and possibly update their recommendations should any significant changes occur.

*This document is for Education and Awareness Use Only.*

## **EXECUTIVE SUMMARY**

This white paper was created to clarify and provide guidance to the industry for the use of electronic signatures associated with electronic prescriptions. There is confusion regarding validation of electronic prescriptions and how each of the different types of electronic signatures are used, including which are not used. This document will assist prescribers, pharmacy and third party auditors to validate the available data transmitted and stored using industry approved datasets.

This paper is directed to all parties involved with electronic prescribing, including state legislators, pharmacists, intermediaries, payers, boards of pharmacy, auditors, software vendors, prescribers, manufacturers, and REMS Administrators. This paper limited its focus specifically to electronic prescribing transactions and how to identify the elements defined as mandatory for the purposes of validation. This paper also assists readers with references to the complete source data.

There are many similar terms used to refer to an electronic signature. We define each type and indicate which elements are used for electronic prescribing and how these elements are used for validations, including auditing source (prescriber) and destination (pharmacy) for these electronic prescriptions.

This paper also addresses common transaction payer rejections from audits based on missing or incorrect data elements. The intent is to bring together all parties with this White Paper to reduce the occurrences of confusion and number of rejected claims.

## ***CONCLUSION***

NCPDP is recommending that all stakeholders follow common validation based on the current industry standards and the related regulations regarding the standard electronic prescribing process to ensure that all involved parties follow common standards and process based on the type of transaction, and that each touch-point within the specific transaction can be validated so that the need for additional authentication of prescribers, pharmacies or patients is minimal.

## 1. PURPOSE

The purpose of this white paper is to clarify and provide guidance to the industry for the use of electronic signatures associated with electronic prescriptions, including validation, authentication, and meeting regulatory requirements. This document will assist prescribers, pharmacies and third party auditors to validate the available data transmitted and stored using industry approved datasets. Readers will develop an understanding of how electronic prescribing transactions are validated between trading partners. The paper will also review additional authentication concepts that are reportedly confusing for stakeholders including auditors reviewing electronic prescriptions. Said concepts include electronic signatures and digital signatures.

### 1.1 AUDIENCE

The following are stakeholders that are involved with the exchange of prescription information, either directly or indirectly.

- Prescribers
- Pharmacists
- Facilities
- Payers
- Software vendors
- State legislators
- Boards of pharmacy
- Federal agencies
- Auditors
- Intermediaries
- Manufacturers
- Risk Evaluation and Mitigation Strategies (REMS) Administrators

### 1.2 REFERENCE DOCUMENTS

*CFR - Code of Federal Regulations Title 21—Food and Drugs, Chapter I—Food and Drug Administration, Department of Health and Human Services, Subchapter A—General, Part 11 Electronic Records; Electronic Signatures*

Located at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?cfrpart=11>

*DEA's Interim Final Rule with Request for Comment titled "Electronic Prescriptions for Controlled Substances" [Docket No. DEA-218, RIN 1117-AA61] published in the Federal Register.*

Located at: [http://www.deadiversion.usdoj.gov/e-comm/e\\_rx/index.html](http://www.deadiversion.usdoj.gov/e-comm/e_rx/index.html)

*Electronic Signatures in Global and National Commerce Act (eSign Act)*

Located at: <http://www.gpo.gov/fdsys/pkg/STATUTE-114/pdf/STATUTE-114-Pg464.pdf>

*Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy (Model Act)*

Located at: <http://www.nabp.net/publications/model-act/>

*NCPDP SCRIPT Implementation Recommendations Document*

Located at: <http://www.ncdp.org/ePrescribing.aspx> under "NCPDP Resources" banner

## 2. CURRENT ENVIRONMENT

Electronic prescribing networks utilize various authentication protocols to ensure all parties can exchange transactions on the network in a secure and reliable way. The following data may be validated as part of these protocols:

- 1) Sender identification and password
- 2) Recipient identification
- 3) Contractual relationships between sender and receiver
- 4) Transaction syntax, including field lengths, data types, and code values

All pharmacies on electronic prescribing networks utilize their unique NCPDP IDs so prescribers are aware of which pharmacies can receive specific transactions (e.g. NewRx, RefillRequest). All prescriber vendor installations are assigned unique IDs based on user locations because some prescribers utilize different clinical applications and need to be uniquely identified in a way that using only their DEA or NPI would not allow. All participants are assigned service levels based on the services they are certified on. These service levels ensure that participants can only send/receive transactions based on what services they are certified on and what trading partners they have agreed to work with.

There is a different level of requirements and restrictions for networks supporting non-controlled substance prescriptions versus those that transmit and accept controlled substance prescriptions. All state boards of pharmacy regulate restrictions on non-controlled substances. While the DEA regulates controlled substances in all states, many individual state boards of pharmacy impose more stringent requirements for infrastructure and prescribing.

NCPDP standards support the exchange of both controlled and non-controlled electronic prescribing transactions. It is expected that most prescribers and pharmacies will move to environments that comply with requirements for all types of electronic prescriptions. NCPDP works with both prescriber and pharmacy technology vendors to give guidance as they move to support exchange of these transactions.

### 3. SCOPE

#### 3.1 *IN SCOPE*

- Electronic prescribing functions
- Auditing functions related to prescribing
- Electronic signature
- Limited discussion of digital signature
- To clarify to entities for how to identify the person sending the electronic prescription consistently using the SCRIPT Standard data elements.
- Only when originated by the prescribing system.

#### 3.2 *OUT OF SCOPE*

The following are out of scope for this white paper:

- Digitized signature
- Digital certificate
- The implementation or legal interpretations of the regulations noted in this document.
- The mechanisms for implementation of digital signature in electronic systems.
- A request to a prescriber that requires a response from the authorizer (transactions like RefillRequest, NewRxRequest,....). See section "[Electronic Prescribing Transactions](#)".

## 4. ELECTRONIC PRESCRIBING TRANSACTIONS

The NCPDP SCRIPT Standard is a data transmission intended to facilitate the communication of prescription information between prescribers, pharmacies, facilities, intermediaries, and payers. The transactions support the following business functions that are germane to this white paper.

Transaction	Definition	In Scope/Out of Scope
<b>NewRx</b>	This transaction is a new prescription from the prescriber to the pharmacy.	In scope
<b>RefillRequest</b>	This transaction is from the pharmacy to the prescriber requesting additional refills.	This is out of scope but see RefillResponse.
<b>RefillResponse</b>	This transaction is the response to a request for additional refills (RefillRequest).	This transaction is in scope if the RefillResponse is returned with "Approved", "Approved with Changes". All other responses are out of scope.
<b>RxChangeRequest</b>	This is used when the pharmacy is asking for a change in the original prescription. An example may be to allow for generic substitution.	While this transaction is out of scope, the corresponding transaction, "RxChangeResponse" is not.
<b>RxChangeResponse</b>	This is the response from the RxChangeRequest.	This transaction is in scope if the RxChangeResponse is returned with "Approved", "Approved with Changes". All other responses are out of scope.
<b>Resupply</b>	This transaction is a request to send a refill from a facility to a pharmacy. An example use case is when a medication supply for a resident is running low (2-3 doses) and a new supply is needed from the pharmacy, the nurse needs a way to notify the pharmacy that a refill for the medication is needed.	This is in scope if the transaction is treated as an event that justifies a dispensing of a prescription.
<b>NewRxRequest</b>	This transaction is a request from a pharmacy to a prescriber for a new prescription for a patient.	This is out of scope but see NewRx.
<b>NewRxResponseDenied</b>	This transaction is a denied response to a previously sent NewRxRequest. (If approved, a NewRx would be sent.)	This is out of scope as it is a denial.
<b>PARequest</b>	This transaction is a request from the prescriber to the payer with information (answers to question set; clinical documents) for the payer to make a PA determination (approved, denied, pended, etc.).	In scope
<b>PAResponse</b>	This transaction is a response from the payer to the prescriber with the status of a PARequest.	This is out of scope but see PARequest.
<b>PAAppealRequest</b>	This transaction is a request from the prescriber to the payer to appeal a PA determination.	In scope
<b>PAAppealResponse</b>	This transaction is a response from the payer to the prescriber with the status of a PAAppealRequest.	This is out of scope but see PAAppealRequest.

## **5. DEFINITIONS**

### **5.1 ELECTRONIC PRESCRIBING**

It is the computer-to-computer transfer of prescription data between pharmacies, prescribers, and payers. It is not the use of an email or a facsimile transaction. Electronic prescribing functions include messages regarding new prescriptions, prescription changes, refill requests, prescription fill status notification, prescription cancellation, and medication history.

### **5.2 ELECTRONIC SIGNATURE**

#### **5.2.1 FROM ESIGN ACT**

(5) ELECTRONIC SIGNATURE.—The term “electronic signature” means an electronic sound, symbol, or process, attached to or logically associated with a contract or other record and executed or adopted by a person with the intent to sign the record.

#### **5.2.2 FROM NABP MODEL ACT**

“Electronic Signature” means an electronic sound, symbol, or process attached to or logically associated with a record and executed or adopted by a person with the intent to sign the record.

### **5.3 DIGITIZED SIGNATURE**

A digitized signature is the capture of an image of a wet signature, which is reproduced by electronically to create a computer-generated signature. A digitized signature resembles a wet signature, but rather than being handwritten in ink on paper, it is computer-generated.

### **5.4 WET SIGNATURE**

A “wet signature” is an original physical signature handwritten in ink on a piece of paper.

### **5.5 DIGITAL SIGNATURE**

#### **5.5.1 FROM NABP MODEL ACT**

“Digital Signature” means an electronic signature based upon cryptographic methods of originator authentication, and computed by using a set of rules and a set of parameters so that the identity of the signer and the integrity of the data can be verified.

### **5.6 DIGITAL CERTIFICATE**

“Digital Certificate” is commonly referred to as “X.509”. A Digital Certificate is an electronic document that assures the authenticity of the digital signature by binding a public key that allows others to verify the information sent belongs to the originator, in this case the prescriber. The primary task of a digital certificate is to provide access to the prescriber’s public key. The certificate also confirms that the certificate’s public key belongs to the prescriber.

### **5.7 ELECTRONIC PRESCRIPTIONS FOR CONTROLLED SUBSTANCES (EPCS)**

On March 31, 2010, the DEA’s Interim Final Rule with Request for Comment titled “Electronic Prescriptions for Controlled Substances” [Docket No. DEA-218, RIN 1117-AA61] was published in the Federal Register. The rule became effective June 1, 2010.

The rule revises DEA regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions. These regulations are an addition to, not a replacement of, existing agency rules. The regulations provide pharmacies, hospitals, and practitioners with the ability to use modern technology for controlled substance prescriptions while maintaining the closed system of controls on controlled substances. ([http://www.deadiversion.usdoj.gov/ecom/e\\_rx/index.html](http://www.deadiversion.usdoj.gov/ecom/e_rx/index.html))

## 6. DISCUSSION AND CLARIFICATION

### 6.1 *DIFFERENCES BETWEEN “DIGITAL SIGNATURES” AND “ELECTRONIC SIGNATURES”*

#### 6.1.1 WHAT IS THE DIFFERENCE BETWEEN A “DIGITAL SIGNATURE” AND AN “ELECTRONIC SIGNATURE”?

Response:

A digital signature is a type of electronic signature, but not all electronic signatures are digital signatures.

A digital signature incorporates **mathematical** authentication, which an electronic signature does not.

#### 6.1.2 WHAT IS THE DIFFERENCE BETWEEN AN “ELECTRONIC SIGNATURE” AND A “DIGITAL SIGNATURE” FOR *ELECTRONIC PRESCRIBING IMPLEMENTATION*?

Response:

For electronic prescribing of non-controlled substances, an electronic signature as defined by the E-Sign Act and/or state board of pharmacy rules is required.

For electronic prescribing of controlled substances, more specific digital signature requirements are defined by the DEA regulations.

Additional resources:

<http://dictionary.reference.com/browse/digital+signature>

<http://dictionary.reference.com/browse/electronic+signature>

<http://legal-dictionary.thefreedictionary.com/Digital+signatures>

<http://encyclopedia.thefreedictionary.com/Electronic+signatures>

<http://www.arx.com/digital-signatures-faq>

### 6.2 *DIFFERENCES BETWEEN “WET” SIGNATURES AND “ELECTRONIC SIGNATURES”*

#### 6.2.1 WHAT IS THE DIFFERENCE BETWEEN A “WET SIGNATURE” AND AN “ELECTRONIC SIGNATURE”?

Response:

A “wet signature” is an original physical signature handwritten in ink on a piece of paper. An electronic signature, as defined by the federal eSign Act is an electronic sound, symbol, or process, attached to or logically associated with a record and executed by a person with the intent to sign the record. The primary difference between wet and electronic signature is that wet signatures are written on paper, electronic signatures are created electronically on a computerized device.

#### 6.2.2 IS A “WET SIGNATURE” AN ACCEPTABLE AUTHENTICATION METHOD FOR ELECTRONIC PRESCRIBING?

Response:

No. While it is possible to associate a wet signature with an electronic transaction, it is not a secure process because such scanned images are easily produced by unauthorized individuals.

#### 6.2.3 WHAT IS THE DIFFERENCE BETWEEN A “DIGITIZED SIGNATURE” AND AN “ELECTRONIC SIGNATURE”?

Response:

A digitized signature is the capture of an image of a wet signature, which is reproduced electronically to create a computer-generated signature. A digitized signature resembles a wet signature, but rather than being handwritten in ink on paper, it is computer-generated. A digitized signature differs from an electronic signature because a digitized signature reproduces the handwritten signature and *simulates* the act of hand-signing by affixing to documents by computer. It is impossible to visually authenticate a digitized signature because it is computer-generated.

#### **6.2.4 IS A “DIGITIZED SIGNATURE” AN ACCEPTABLE AUTHENTICATION METHOD FOR ELECTRONIC PRESCRIBING?**

Response:

No. Digitized signatures may be used for printed output from EHRs and electronic prescribing systems. Digitized signatures are typically captured “one-time” and pre-programmed to appear on every printed document where signature is required, in a methodology analogous to a “rubber signature stamp”.

Many state boards of pharmacy specifically exclude “rubber stamp” signatures on prescriptions. For example, ND North Dakota Administrative Code (NDAC) Chapter 61-04-06 – Prescription Requirements, subsections 02 and 03 states “Rubber stamps, signature by a nurse or any other office personnel, for the prescriber and computer-generated signatures are all examples of illegal signatures, when affixed to a hard copy prescription given to the patient.”

Because the use of computer-generated signatures is widely prohibited, digitized signatures are not considered to be valid signatures for the purposes of this white paper.

## 7. BEST PRACTICES FOR PRESCRIPTION SIGNATURE DATA ELEMENTS FOR AUDITING

It is recommended that a trusted network that follows appropriate industry and government regulations be used for transmission of electronic prescriptions. This provides the electronic prescription with an end-to-end linkage.

### ***7.1 WHAT DATA ELEMENTS ARE RECOMMENDED FOR PRESCRIPTION AUDITS FOR VALIDATION OF THE SIGNATURE OF THE ELECTRONIC PRESCRIPTION?***

Response:

The following data elements are standardized business components of the “electronic signature” of a prescription that are transmitted via the electronic standard transactions. It is suggested that because these elements are included in all electronic prescriptions, they can serve as the foundation for in authentication of electronic signatures for auditing purposes. It is recommended that these elements should be available for standardization of audit reporting (whether available via screen print, hard copy, or other means). These data elements when considered in the aggregate can be used to effectively determine that the prescription was transmitted by the authorized prescriber using a prescribing system employing industry standards and meets all regulatory requirements.

From the SCRIPT Standard Version 1.0.6, the references are to the EDI field name and segment, or the XML tag (<xx>).

- Transaction identifier (aka document number or transaction number)
  - EDI: Transaction control reference (UIB 030-S303-01-0306)
  - XML: <MessageID>
- Prescriber
  - EDI: PVD Segment (fields of IDs (there may be multiple identifiers), name, demographic information)
  - XML: <Prescriber>
- Date and Time of the transmission (only required to be available for electronic prescription controlled substance prescriptions)
  - EDI: Date of Initiation (UIB 080-S300-01-0017)
  - XML: <SentTime>
  - EDI: Event time (UIB 080-S300-02-0114)
  - XML: <SentTime>
- Written Date
  - EDI: Date (DRU 040-I006) value 85 = Date Issued (Written Date)
  - XML: <WrittenDate>

Conditional information (only when the designated agent is submitting on behalf of the authorizing prescriber):

- Designated Agent
  - EDI: PVD Segment (PVD 100-I002 Name fields)
  - XML: <PrescriberAgent>

For some states, a paper copy of the electronic prescription is required to be filed. It is recommended the data elements above be available on this paper copy.

If a prescription arrives via a computer-generated fax, a paper copy of the fax may be required to be filed.

Industry participants have noted that some auditors have included the field Prescription Origin Code among the elements above. Prescription Origin Code is a field which may be captured by the pharmacy

when the prescription is received by pharmacy and used for billing purposes. However, Prescription Origin Code is a field used in the exchange of billing transactions using the NCPDP Telecommunication Standard. It might be used for selecting prescriptions received electronically, but it is **not a prescription data element** and is not a field in the SCRIPT Standard. Specific usage of the field can be found in the NCPDP Telecommunication Version D and Above Questions, Answers and Editorial Updates (the "Version D Editorial document) found at <http://www.ncdp.org/Hipaa.aspx> under "Telecommunication D.0" banner.

## ***7.2 COMMON DATA GAPS TO AVOID PROBLEMS IN AUDITING OF ELECTRONIC SIGNATURE PRESCRIPTIONS***

Response:

- A report or screen print does not show the recommended data elements listed above; therefore the 'details' of the electronic prescription may be insufficient.
- Missing the 'document number or transaction number' associated with the electronic prescription, which provides an audit trail back to the document at the doctor's office.
- Missing prescriber's electronic signature elements when a prescription is entered and transmitted by the nurse on behalf of the doctor. In these cases, the following elements from the transmitted prescription include:
  - Optional component information (only provide if prescribing system sends to pharmacy system):
    - Designated Agent
      - EDI: PVD Segment (PVD 100-1002 Name fields)
      - XML: <PrescriberAgent>
- Lack of "Electronically signed by" with a time stamp requirement.
  - "Electronically signed by" with the date time stamp requirement is supported by the recommended data elements listed above (required only for electronic prescribing of controlled substances).

## **8. APPENDIX A. REVISIONS**

**National Council for Prescription Drug Programs**

9240 East Raintree Drive, Scottsdale, AZ 85260

phone: 480.477.1000

fax: 480.767.1042

e-mail: [ncdp@ncdp.org](mailto:ncdp@ncdp.org)

[http: www.ncdp.org](http://www.ncdp.org)

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