

# Operating Rules Recommendations

NCVHS Subcommittee on Standards

July 20, 2010

Session: B1: Presentations from authors of operating rules and standards

## *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 Part D Regulation.
- 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.

# *Pharmacy Standards Adopted under HIPAA*

- Version upgrade:
  - Telecommunication Standard Implementation Guide Version D.Ø
  - Batch Standard Implementation Guide Version 1.2
- New standard:
  - Medicaid Subrogation Standard Implementation Guide Version 3.Ø
- Note: pharmacy industry utilizes the ASC X12 835 (remittance advice), 834 (enrollment) and the 270/271 (eligibility) is used in electronic prescribing
  - ASC X12N 005010 Technical Report Type 3

# ***Operating Rules Definition***

***(1) DEFINITION OF OPERATING RULES.—Section 1171 of the Social Security Act (42 U.S.C. 1320d) is amended by adding at the end the following:***

***“(9) OPERATING RULES.—The term ‘operating rules’ means the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part.”***

Points from the regulation:

- Recognized that business rules and guidelines may already be present in the implementation specifications.
- Operating rules may cover exchange not already defined in the implementation specifications.
- SDOs govern the data content of the transmissions and the business rules and reference documents required to support the data content.
- Operating Rules cannot add, modify or remove requirements defined in the implementation specifications.

# *Operating Rules Recommendations*

- Must conform to ANSI essentials
  - Open, balanced, consensus, public review, appeals, etc
  - *It is the right thing to do*
- If there are multiple operating rules entities named
  - Collaboration of artifacts and processes
  - Collaboration of actions when bringing requests to the DSMO
- Collaboration with SDOs – a two-way street of impact on implementation specifications and on operating rules
  - Operating rules should be brought forward and developed during early phases of the standards development process to ensure compatibility with the implementation specifications and provide timeliness of industry participation and business requirement inputs.
  - Effects of new versions of existing documents
  - Effects of new transactions/new business
  - Effects of new methods of exchanges
- NCPDP supports the DSMO recommendations to NCVHS

# *Operating Rules Recommendations*

- Publication of documents
  - Operating rules are impacted by implementation specifications
  - Operating rules may also be updated between implementation specifications to satisfy appropriate business requirements that would not have an impact on the implementation specifications
  
- Operating Rules entities must use the existing process to bring regulatory requests forward – *the industry understands this process*
  - Submission of new versions of operating rules to DSMO
  - DSMO recommends new versions of operating rules to NCVHS
  - NCVHS recommends new versions of operating rules to the Secretary of HHS

## *NCPDP and Operating Rules*

- HITSP discussion of Committee on Operating Rules for Information for Information Exchange (CORE) Phase I Operating Rules
  - Certification and Exemption
  - Operating rules sections for batch, real-time, connectivity, availability
  - Operating rules section for X12 270/271 eligibility transactions
  
- Pharmacy industry not involved, so outreach began
- NCPDP formed a task group and CORE representatives joined
  - Phase II Operating Rules were reviewed instead of Phase I

## ***NCPDP and Operating Rules***

- NCPDP task group created the NCPDP **Connectivity Standard *Implementation Guide for the CAQH CORE Connectivity Rule Version 1.0***
  - Addressed connectivity only
    - International Standards Organization (ISO) "Open Systems Interface" standard - level 1 Application Layer - level that interfaces with the users' application
    - NCPDP implementation guides support other layers
    - NCPDP defined Payload data elements for use
    - Only supports real-time transactions due to Phase II scope
    - *Limited interest from pharmacy industry due to established connectivity*
  - NCPDP task group submitted recommendations for Phase III enhancements to CORE
    - CORE has recently identified NCPDP recommendations as "high priority"



## *Eligibility Impact and Timing*

**“(i) ELIGIBILITY FOR A HEALTH PLAN AND HEALTH CLAIM STATUS.—The set of operating rules for eligibility for a health plan and health claim status transactions shall be adopted not later than July 1, 2011, in a manner ensuring that such operating rules are effective not later than January 1, 2013, and may allow for the use of a machine readable identification card.”**

Eligibility impact – claims processing environment

- Prior to Medicare Part D, Telecom Eligibility Verification transactions – negligible volume (pharmacy submits the claim real-time, there is less need for eligibility checking only)
- Medicare Part D Telecom Eligibility Verification to TrOOP Facilitator for - 2009 total: 47,539,971\* (specific standardized use of eligibility for coordination of benefit information)
- Recommendation that operating rules for Telecom Eligibility Verification transactions are not needed due to industry standard use already
- Serious concern if any impact affects development and testing of Telecom D.0 transactions already underway.

\*Source: RelayHealth (TrOOP Facilitator)

## *Eligibility Impact and Timing*

### Eligibility impact – electronic prescribing environment

- ASC X12 270/271 are used to obtain patient Formulary and Benefit information for a given patient
- Recommendation that operating rules created for the X12 270/271 do not hinder the use of this specific exchange
- NCPDP has mapped the pharmacy-industry routing identifiers (BIN/PCN/Group) to the 4010A1 270/271 and the 5010 270/271 for use in eligibility verification. This provides vendors the information to support a prescriber office using the standard pharmacy ID card to perform an eligibility check on a patient's pharmacy benefits using the 270/271 (of which they are familiar).

## ***Situational Requirements of HR 3590***

**“SEC. 1104. ADMINISTRATIVE SIMPLIFICATION.**

**(4) REQUIREMENTS FOR FINANCIAL AND ADMINISTRATIVE TRANSACTIONS.—**

**(A) IN GENERAL.—***The standards and associated operating rules adopted by the Secretary shall—*

- (i) to the extent feasible and appropriate, enable determination of an individual’s eligibility and financial responsibility for specific services prior to or at the point of care;*
- (ii) be comprehensive, requiring minimal augmentation by paper or other communications;*
- (iii) provide for timely acknowledgment, response, and status reporting that supports a transparent claims and denial management process (including adjudication and appeals); and*
- (iv) describe all data elements (including reason and remark codes) in unambiguous terms, require that such data elements be required or conditioned upon set values in other fields, and prohibit additional conditions (except where necessary to implement State or Federal law, or to protect against fraud and abuse).”***

## ***Situational Requirements of HR 3590***

- We believe NCPDP has met the criteria in (iv) and recommend it be recognized as such.
- If NCPDP has not met these criteria, we seek clarification of what problem(s) this statement was trying to solve related to NCPDP standards named in HIPAA.
- Impact to the minimum data set requirements of previous regulation would need to be assessed.
- See details in letter attached “201006 NCPDP Response Elements Situational”.

## ***Section (iv)***

### ***(iv) describe all data elements (including reason and remark codes) in unambiguous terms***

- NCPDP has met this criterion.
- The NCPDP ***Data Dictionary*** contains the data elements and associated attributes (field ID, name, size, format, definition, comments, etc.)
- The NCPDP ***External Code List*** contains the value set of each data element (value, definition, description) or the external reference if this isn't a code set NCPDP maintains (SNOMED, ICD-10, etc). Values brought forward by the industry must contain descriptions before publishing.
- NCPDP does not have reason and remark codes, but our Work Group 45 External Standards Assessment, Harmonization, and Implementation Guidance works closely with ASC X12 on areas where standards and external codes used in X12 standards are also used by the pharmacy industry (e.g. X12 835).

## Section (iv)

***require that such data elements be required or conditioned upon set values in other fields, and prohibit additional conditions (except where necessary to implement State or Federal law, or to protect against fraud and abuse).***

- NCPDP has met this criterion.
- NCPDP ***Telecommunication Standard Implementation Guide version D.0*** represents the culmination of six years of industry working to gain consensus, provide clarification of transactions, data elements, data values, and situations of usage.
- Guide contains rules, guidance, and examples. Each transaction is explained in detail. Each segment within each transaction is stipulated. Data elements within each transaction have situations.
- Freely available ***Version D Editorial*** document, which is updated quarterly, and contains frequently asked questions, examples, and further clarifications, as well as Medicare Part D needs, that the industry brings forward



## *Section (iv)*

***require that such data elements be required or conditioned upon set values in other fields, and prohibit additional conditions (except where necessary to implement State or Federal law, or to protect against fraud and abuse).***

- NCPDP publishes a ***Payer Template Implementation Guide***
  - Provides rules on the creation of the payer-specific information they need to share with their customers, within the bonds of the Telecom guide.
  - Plans and payers use this template and guide to create their “payer sheets”.
  - Payer sheets are an important part of the pharmacy industry and relay specific information needed for processing of transactions.
  - The pharmacy industry has used payer sheets for many years, and has had the NCPDP payer template guide available since version 5.1.

## *Section (iv)*

### ***data elements be required or conditioned upon set values in other fields***

- NCPDP has met this criterion.
- We believe that while this statement could be taken literally, that was not the intent.
- The industry has worked long and hard at coming to consensus on situational rules that reflect industry usage, but do not allow non-standard use of data elements.
- **It is not possible to make every conditional data element dependent upon set values in other fields. Data elements exist that are *constrained by business situations* but do not always have a dependency on another field.**



## Section (iv)

### **Examples:**

- A pharmacy cannot send Medicare Part D information if the pharmacy does not have knowledge the patient has Part D coverage. The situation is stated in the guide, but is not dependent on “another field”.
- A pharmacy cannot send Workers’ Compensation Segment if they are not filing a Workers’ Compensation claim. The situation is stated in the guide, but is not dependent on “another field”.
- A processor will return preferred product information that may assist the patient with choices when this information is based on the patient’s benefit structure. It is based on a business case; not on dependencies of fields.
- Situations defined for sending or responding with contract/pricing fields could violate contracts, if required to be shared by this regulation because they are not dependent on other fields. The industry worked long and hard to establish the payment and balancing rules of the claim.
- Coordination of Benefits (COB) – A pharmacy cannot send other payer information if another payer doesn’t exist. The guide has clear instructions on usage of the segment, fields and situations.

## ***Section (iv)***

***and prohibit additional conditions (except where necessary to implement State or Federal law, or to protect against fraud and abuse).***

- The Telecom guide clearly states the situations must be followed. Additional conditions are not supported.
- The Telecom guide has situations that state the usage of the field for regulatory requirements.

## *Finally*

- NCPDP believes the requirements have been met.
- It is very important to recognize that the publications of the Standards Development Organizations (SDOs) represent the work of volunteers of the industry. Before we undertake any additional work it is important for the volunteers to understand what the problem(s) are and what is trying to be solved that is not already being met.

***Thank You***

Lynne Gilbertson  
VP, Standards Development  
NCPDP  
[lgilbertson@ncpdp.org](mailto:lgilbertson@ncpdp.org)