

January 21, 2020

William Stead, MD
Chair, National Committee on Vital and Health Statistics
c/o Rebecca Hines
CDC/National Center for Health Statistics
Office of Planning, Budget and Legislation
3311 Toledo Road
Hyattsville, MD 20782

Dear Dr. Stead,

On August 17, 2000, the Secretary of Health and Human Services (HHS) named six entities as the Designated Standards Maintenance Organizations (DSMO) under the Health Insurance Portability and Accountability Act (HIPAA) in § 162.910(a). The DSMO organizations work together on the maintenance and development of HIPAA adopted administrative simplification transaction standards.

The six organizations include three standard setting organizations (SSO):

- X12
- Health Level Seven (HL7)
- National Council for Prescription Drug Programs (NCPDP)

And three data content committees:

- Dental Content Committee of the American Dental Association (DeCC)
- National Uniform Billing Committee (NUBC)
- National Uniform Claim Committee (NUCC)

The DSMO Steering Committee is comprised of one voting member from each of the six organizations and a non-voting liaison from HHS, specifically the Centers for Medicare and Medicaid Services' Division of National Standards. The Steering Committee convenes as necessary and is charged with establishing consensus on all requested changes to HIPAA transactions and code sets. Changes are submitted through the DSMO Change Request System, either directly or through the moving forward of a transaction or code set from the applicable maintenance body.

The DSMO is requesting the following Change Request proceed through the regulatory process for industry adoption under HIPAA expeditiously.

CRS 1208

Retail Pharmacy Claim

“On August 17, 2017, NCPDP entered DSMO Change Request 1201 which requested Version F2 of the Telecommunication Standard Implementation Guide be named in HIPAA. NCVHS held a hearing in March of 2018 and sent a letter to the Secretary of HHS on May 17, 2018 recommending the Secretary adopt the new versions of the standards.

Since that time, the pharmacy industry has experienced several new drugs coming into the market with prices over \$1 million dollars. Researchers expect three dozen new drugs with the potential price over \$1 million dollars will come on the market over the next few years with hundreds more therapies under development. These new treatments include gene therapies, which target certain cancers and rare diseases.

The Telecommunication Standard Implementation Guide Version F2 does not support dollar fields greater than \$999,999.99. NCPDP has modified the Telecommunication Standard to support dollar fields up to \$999,999,999.99. Other enhancements have been made to the standard which are provided under separate cover.

The NCPDP membership is requesting Version F6 of the Telecommunication Standard Implementation Guide be named in HIPAA.

The Telecommunication Standard Implementation Guide supports the following processes:

1. Eligibility Verification
2. Claim
3. Service
4. Information Reporting
5. Prior Authorization
6. Predetermination of Benefits

Note: There is no change to the Batch Standard Implementation Guide Version 15 requested in Change Request 1201 as it supports the Telecommunication Standard Version F6 in a batch mode. There is no change to Change Request 1202 - requests the Subrogation Implementation Guide for Batch Standard Version 10 be named in HIPAA to replace the Medicaid Subrogation Standard Implementation Guide, Version 3.0 for Medicaid use only.”

DSMO Recommendation:

“Approve. The DSMO is supportive of the work done by NCPDP to update this adopted standard and begin the process for a new version to be named in HIPAA.”

The DSMO recommends NCVHS expeditiously begin the process of recommending adoption to the Department of Health and Human Services. Should you have any questions, please do not hesitate to contact me at laurie.burckhardt@wpsic.com.

Sincerely,

Laurie Burckhardt

Laurie Burckhardt, DSMO Chair

Cc: DSMO Steering Committee

Lorraine Doo, Senior Policy Advisor, Center for Medicare & Medicaid Services

Richard W. Landen, NCVHS Standards Subcommittee Co-Chair

Alexandra Goss, NCVHS Standards Subcommittee Co-Chair

1.1. VERSION F3 JULY 2018

Section 28.3.1 Other Coverage Code (308-C8) – Descriptions for codes 2, 3 and 4 were modified.

Section 28.6.3 Split Billing In Long Term Care – The term “expires” was replaced with “no longer applies”.

1.2 VERSION F4 JANUARY 2019

Increased all dollar fields by 3 digits except the Other Payer Patient Responsibility Amount (352-NQ) which was increased by 1 digit.

The Request Patient Segment and the Response Patient Segment were updated to include the Patient ID Count (618-RR) and the Patient ID Qualifier (331-CX) and Patient ID (332-CY) were changed to repeating data elements to support the communication and sharing of multiple universal patient identifiers from different enumerating entities on a single transaction.

Request Patient Segment

- Add Patient ID Count (618-RR) to and update Patient ID Qualifier (331-CX) and Patient ID (332-CY) from “not used” to Situational repeating fields in the Patient Segment of Eligibility Transaction; add situation of “Required when agreed upon between trading partners in order to enhance the accuracy of patient data exchange and/or to improve care or benefit coordination “ to Patient ID.
- Add new situation (“Required when agreed upon between trading partners in order to enhance the accuracy of patient data exchange and/or to improve care or benefit coordination “) to Patient ID (332-CY) in Patient Segment to transactions listed below.
- Remove existing situation of use “Required if necessary for state/federal/regulatory agency programs to validate dual eligibility” from Patient ID (332-CY) in Patient Segment in transactions listed below.
- Update Patient ID Qualifier (331-CX) and Patient ID (332-CY) to be repeating fields for the transactions listed below.
- Add Patient ID Count (618-RR) with a maximum count of 9 to transactions listed below

Claim Billing or Encounter; Service Billing; Claim Rebill; Service Rebill; Prior Authorization Request and Billing;

Prior Authorization Request Only; Information Reporting; Information Reporting Rebill

- Add Patient Segment to Prior Authorization Inquiry (including new data elements)

Response Patient Segment

- Add Patient ID Count (618-RR), Patient ID Qualifier (331-CX), Patient ID (332-CY) as situational fields to Response Patient Segment of transactions listed below. Indicate Patient ID Qualifier and Patient ID as repeating fields.

- Add situation to Patient ID (332-CY) in Response Patient Segment of transactions listed below. . “Required when agreed upon between trading partners in order to enhance the accuracy of patient data exchange and/or to improve care or benefit coordination“

Eligibility; Claim Billing or Encounter; Service Billing; Claim Rebill; Service Rebill; Prior Authorization Request and

Billing; Prior Authorization Inquiry; Information Reporting; Information Reporting Rebill

- For Prior Authorization Request Only transaction, add Response Patient Segment (including new data elements).
- For Prior Authorization Inquiry transaction, add Response Patient Segment (including new data elements) to those transaction types (captured, approved, deferred) that currently do not use it.

All examples which contained the Patient Pay Component Qualifier (C95-KQ) values of 1 – 5 or 7 – 9 were modified by adding a preceding zero to the value.

The Prescriber DEA Number (D01-KV) situation was modified.

A new field, Species(E06-S8), was added to the Request Patient Segment to support billing for non-human species.

Patient Middle Name (E09-0C), Patient Name Suffix (E11-0E) and Patient Name Prefix (E10-0D) were added to the Request Patient Segment to keep the segment in-sync with the Prescription Drug Monitoring Programs (PDMP) Reporting Standard. These fields are not used for any transaction codes contained in this guide.

Prescriber Middle Name (E12-0F) was added to the Request PrescriberSegment to keep the segment in-sync with the Prescription

Drug Monitoring Programs (PDMP) Reporting Standard. This field is not used for any transaction codes contained in this guide.

1.3 VERSION F5 JULY 2019

Section 5.3 – removed purchaser and service provider segment references.

Section 24.2.1, 24.2.2, 24.2.3, 24.4.1, 24.4.2, 24.4.3 – removed purchaser and service provider segments.

Section 25.1.2 - removed the purchaser and service provider segments.

The Scheduled Prescription ID Number (454-EK) was increased from 12 bytes to 30 bytes.

1.4 VERSION F6 JANUARY 2020

CMS Part D Defined Qualified Facility (997-G2) was removed.

Field Name Change: From Formulary Alternative Cost Share Incentive (555-AT) to Formulary Alternative Estimated Patient Cost Share (555-AT).

Section 28.3.3 Other Payer Amount Paid (431-DV) was modified: Updated examples to include additional fields and removed some fields to improve readability and replaced Other Payer Amount Paid (431-DV) Reporting Order Chart with two new charts.

Added new field - Formulary Alternative Effective Date (E89-ZO) to the Response Claim Segment. The purpose of this new field is to aid in the proactive communication of upcoming formulary change information with both patients and prescribers, mitigating access to care and adherence risks.

Added a new segment – Response Provider Segment with two new fields: Data Source of Invalid Provider Determination (E87-ZV) and State Code for Data Source of Invalid Provider Determination (E88-ZZ). The purpose of this new segment is to expedite the resolution and provide appropriate access to care, by providing the specific federal/state file source and the associated state code (if applicable) used to determine the point of service reject. The name of the specific data source will allow the pharmacy provider to clearly communicate to the prescriber or provider business units the conflict details and determine next steps. This may include operational and workflow actions to service the patient and/or corrective action plans.

Increased the field length from 15 characters to 35 characters for the following fields: Prescriber ID (411-DB), Primary Care Provider ID (421-DL), Associated Prescription/Service Provider ID (580-XY), Prescriber Alternate ID (A26-ZP) and Provider ID (444-E9).

Added the following new fields to the DUR/PPS RESPONSE Segment:

- DUR/DUE Co-Agent Description (E93-ZC)
- Unit of Measure for Previous Dispensed Quantity (E94-ZA)
- Other Pharmacy ID Qualifier (E95-Z9)
- Other Pharmacy ID (E96-Z8)
- Other Pharmacy Name (E97-Z7)
- Other Pharmacy Telephone (E98-Z6)
- Other Prescriber Last Name (E99-Z5)
- Other Prescriber ID Qualifier (F01-Z4)
- Other Prescriber ID (F02-Z3)
- Other Prescriber Telephone (F03-Z2)
- DUR/DUE Compound Product ID (F04-Z1)
- DUR/DUE Compound Product ID Qualifier (F05-Z0)
- DUR/DUE Maximum Daily Dose Quantity (F06-YO)

- DUR/DUE Maximum Daily Dose Unit of Measure (F07-YL)
- DUR/DUE Minimum Daily Dose Quantity (F08-YJ)
- DUR/DUE Minimum Daily Dose Unit of Measure (F09-YI)

Modified the field name of DUR Co-Agent ID (476-H6) to DUR/DUE Co-Agent ID and DUR Co-Agent ID Qualifier (475-J9) to DUR/DUE Co-Agent ID Qualifier and added the fields to the DUR/PPS RESPONSE segment.

Modified the field name of DUR Free Text Message (544-FY) to DUR/DUE Free Text Message and increased the length from 30 characters to 360 characters.

DUR Additional Text (570-NS) was removed.

Section 27.1.11.7 Multi-Ingredient Compounds and DUR Rejects and Section 27.2.8.1 DUR/PPS and Multi-Ingredient Compounds were deleted. Guidance will be included in the Editorial Document.

Section 27.2.8 and 38.3 were updated to address the new fields.

Section 27.2.3 Response Insurance Segment was deleted. The guidance was erroneously carried over from older versions of the standard (5.1 or earlier) and beginning with Version D.0 the Response COB/Other Payers Segment should be used to report known other payer information.

Increased the field length of Original Manufacturer Product ID (C01-4N) to 40 characters to align the length with the other Product ID fields.

The Other Payer Percentage Tax Exempt Indicator (D51-P7), Other Payer Regulatory Fee Type Count (D53-P9), Other Payer Regulatory Fee Type Code (D63-RN), and Other Payer Regulatory Fee Exempt Indicator (D52-P8) grouping was incorporated into the "Coordination Of Benefits/Other Payments Segment," "In Payment Scenarios" details (Section 7.13.1.4.1.1). Language was added within the Coordination of Benefits/Other Payments Segment section, Other Payer Coverage Type (338-5C) field, "May be grouped with the Other Payer Percentage Tax Exempt Indicator (D51-P7), the Other Payer Regulatory Fee Type Count (D53-P9) and its grouping, and/or the Benefit Stage Indicator Count (C50-9W) and its grouping, when applicable for the Other Payer."

Changed the field name of D32-MS from Other Benefit Detail Information Qualifier to Other Benefit Detail Information Indicator allowing additional business cases to be added as an Indicator within the ECL.

Deleted Other Benefit Detail Information (D27-MK). The field was initially created to prepare for future business cases where other benefit information was available. The structure of this 5 character field with the associated Other Benefit Detail Information Qualifier (D32-MS) was not beneficial as it is unknown as to what information would be returned without some type of ECL reference.

The Response Other Related Benefit Detail Segment and all associated fields was added to the Claim Billing (B1, B3), Service Billing (S1, S3), Prior Authorization Request and Billing (P1), Prior Authorization Inquiry (P3) and Pre-Determination of Benefit (D1) responses.

Removed verbiage from Section 6 and referred reader to Appendix A.