November 2015 Work Group Recaps:


Work Group 1 Telecommunication

Ballot Adjudication:
• None

DERFs/ECLs Reviewed:
• DERF 001303/ECL 000184 was withdrawn by the submitter.
• DERF 001306/Emergency ECL 000187 was approved with modifications.
• DERF 001307 was approved with modifications.
• DERF 001308 was pended to WG16.
• DERF 001309 was denied.
• DERF 001310 was pended to WG16.
• DERF 001328/ECL 000191 was approved with modifications.
• DERF 001329/ECL 000192 was approved.
• DERF 001330 was approved with modifications.
• DERF 001331/Emergency ECL 000193 was approved.
• DERF 001332/Emergency ECL 000194 was approved with modifications.
• DERF 001333/Emergency ECL 000195 was approved.
• DERF 001334/Emergency ECL 000196 was approved with modifications.

Old Business:
• A HIPAA Standards, Operating Rules, and regulations (HPID/ICD/NPI/EFT/ERA) update was given.
• Use of Quantity Prescribed (460-ET) in the Telecommunication Standard claim billing - Note this field would be required for Part D Schedule II Controlled Substance claims; however the use of this field is not limited to Part D claims only.
  • Telecom D.0 and all versions from that point have been updated (November 2012).
  • 03/2014 NCPDP received a response from HHS to the 03/2013 letter. The change will go through NPRM and Final Rule process.
    ▪ We have asked the industry to have input on the implementation timeframe before the NPRM is published.
    ▪ We have asked for a timeframe of NPRM publication.
  • 06/2014 Update: OESS has responded that an NPRM including Quantity Prescribed and SCRIPT electronic prior authorization is going through the review process.
  • WG1 Telecommunication FAQ Task Group brought forward a recommendation timeframe for Quantity Prescribed regulation implementation for OESS.
  • 07/21/2015 Update from NSG: Our new target for this regulation is early 2016.

Task Groups:
• The Telecommunication FAQ Task Group finalized six questions and three questions are under discussion. Four DERFS from WG16 were reviewed and commented on by WG1 FAQ members. There were five Editorial Guide requests this quarter. Four requests were approved and one request was pended.
• The Coordination of Benefits Task Group reviewed five business cases and completed drafting a DERF for Other Payer Reconciliation ID. The draft DERFs for the COB modifications presented at the last WG meeting are available on the NCPDP Collaborative Workspace.
The Information Reporting Problems Task Group merged the TRoOP Eligible Supplemental Payers sub-task group with the OHI sub-task group. The new sub-task group was renamed “Improving OHI Reporting for Part D Sub-Task Group”. The newly formed group will work on developing a Best Practice Guide for Managing Medicare OHI for Prescription Drug Plans. The task group reviewed the CMS Memo released 8/28/15 Announcement of the November 2015 Software Release, the CMS Memo 9/23/15 Annual Establishment of Fir and Nx Report Distribution Emails for Plan Sponsors, and the SPAP ADAP Data Exchange White Paper was presented to the task group for review. They are also reviewing and updating the COB White Paper, the Transaction Facilitator Matching Logic to validate if “DOB” needs to be added and N2 scenarios for orphan N1 transactions.

The Post Adjudication Task Group did not meet this quarter.

The Definition of a Valid Prescriber Task Group reviewed five business cases, brought forward a provisional fill FAQ which was approved and four DERFs. The task group provided comments to the CMS Provider Outreach Letter template, provided examples of type 2 NPIs identified within the Individual Provider Enrollment file to CPI (CMS previously responded to this specific question indicating the NPI is validated against NPPES to confirm it is a type 1 NPI), and continues to develop Part D POS hierarchical rules for prescriber validation.

The Part D Supplemental Payment Reporting Task Group continues to work on a reject code guide applicable to Medicare Part D N transactions and will develop a FAQ Document. In addition, the task group is coordinating with the WG1 Information Reporting NX Matching sub-task group to determine which fields are critical for primary matching and secondary matching. Based on the results, the task group will identify the appropriate reject codes for those fields; all other reject codes that are not appropriate will be identified.

The Eligibility Verification Enhancements Task Group did not meet.

The Transaction ID Task Group did not meet. The task group was disbanded.

The Benefit Integration Task Group continues work on creation of XML guidance for Benefit Integration and on the Single Book of Records.

The Standardized Subrogation Task Group has been modifying the current Medicaid Subrogation Standard to create the new Standardized Subrogation Standard. The “Specific Field Discussion” section which includes both request and response data elements is being reviewed. The task group recommends naming the new standard “Universal Payer Pharmacy Subrogation”. The task group will continue to create the new standard and identify the modifications to the Telecommunication Standard.

**Work Group 2 Product Identification**

**Ballot Adjudication:**

- Ballot WG020007 for Product Identifiers Standard Implementation Guide v1.2 is considered a Valid Ballot having received the required 60%+ of Consensus Group votes and 75%+ approval rating having received no comments. Following a 30-day appeal period, notification of the ballot results and the ballot documents will be sent to the Board for approval.

**Task Groups:**

- The Structured Product Labeling Activities Task Group tracks the activities of the SPL and offers suggestions to improve access and usability of the FDA Structured Product Label and Electronic Drug Listings. The task group has sent 20 letters to the FDA. Task Group Leads reached out to Lonnie Smith of the FDA regarding the graphical versus the textual representation of data within the SPL and will schedule a call or face to face meeting with him. The Drug Compendia group, that submits the monthly NSDE file to the FDA containing the NCPDP Billing Units by NDC for inclusion in the SPL, continues to review and provide monthly validation information to the FDA. For calendar
year 2015 over 8,000 new billing unit indexing files were generated by FDA based on the files received by the compendia and the compendia group reconciled 536 NDCs.

- The **Product Review and Billing Unit Exception Task Group** is reviewing the exceptions within the Implementation Guide and issues that result from changes to existing products or release of new products. The task group reviewed four products to determine the billing unit and package size:
  - **Lumason NDC 00270-7099-16 BU=EA per vial (not kit); PS=5 per Sections 5.1.2 and 5.1.16 of the BUS.**
  - **FlexePax NDC 69597-003-31 BU=EA (not kit); PS=75 per Section 5.1.18 of the BUS since all components share the same billing unit.**
  - **Egrifta NDC 62064-011-60 BU=EA with a package size of 60 (based upon the number of vials of lyophilized powder) per Section 5.1.2 of the BUS. It is not a 1 EA kit per Section 5.1.16 of the BUS which states diluents, syringes, and needles are to be ignored for purposes of billing (the contents of Box 2).**
  - **Vizamyl Vial – 10ml NDC 17156-0067-10 and Vizamyl Vial – 30ml NDC 17156-0067-30 BU=EA vial and PS=1 per Section 5.1.17 and FAQ 7.39 of the BUS.**

The task group also reviewed the following QUIC forms and submitted them for adjudication by WG2: (see by final adjudication determination by the WG in this report).

  - **QUIC #201518 New Product by Optinose/Avanir**
  - **QUIC #201519 Oto-201- New product by Otonomy, Inc.**
  - **QUIC #201520 Defitelio® (defibrotide)**

- The **NCPDP Product Identification Standard Task Group** developed the NCPDP Product Identifiers Standard Implementation Guide and have successfully balloted version 1.2 of that standard. This version of the standard was balloted with the August 2015 ballots and received no comments. Following an appeal period and pending BOT approval, the standard will be posted to the website.

- The **SPL REMS Requirements Task Group** is to gather the data needed to develop a template for pharmaceutical manufacturers to use in electronic submission of all the components for risk evaluation and mitigation strategies (REMS) drugs to a central repository (DailyMed) via FDA’s Structured Product Labeling system. DailyMed has released two new SPL Indexing files:
  - Biologic or Drug Substance Indexing files (used for tracking of Biologic Substance versioning –1 file as of Oct. 20)
  - Product Concept Indexing Files (contains FDA Orange Book rating data and Application Product information – 1842 files as of Oct. 20)


- The **Dates Associated with Pharmaceutical Products Task Group** investigates definition inconsistencies, involves government agencies to make them aware of the issues, and provides...
education on the importance via a white paper or other means. The draft white paper is on the collaborative work space for comments to be submitted to this task group by the end of this year.

- The **Naming Standards for Drugs, Biologics and Biosimilars Task Group** reported release on August 27th of FDA’s Draft guidance for industry, titled, Nonproprietary Naming of Biological Products and also a Proposed Rule: Designation of Official Names and Proper Names for Certain Biological Products. NCPDP provided comments to both in one letter posted on October 27th. The letter restates NCPDP’s opposition to the nonproprietary naming of biological products and stresses the need to apply consistency in the naming conventions to all products, including biologicals.

- The **Application of the Billing Unit Standard Clarification Task Group** continues to make progress in identifying the rationale used to determine the billing unit from past QUIC forms/products reviews and is capturing the rationale/reasons for those decisions. Once the forms have been reviewed and the results compiled, a guidance document will be written.

- An update on the **WG9/WG2 Unbreakable Packages Task Group** was provided. See WG9 meeting minutes.

- An update on the **WG2/WG11 Harmonization of Prescribing and Dispensing Units Task Group** was provided. See WG11 meeting minutes.

**New Business:**

**QUIC Form Review:**

- QUIC #201518 **New Product by Optinose/Avanir**
  BU= EACH with a total quantity of 16 per section 5.1.3 of the BUS

- QUIC #201519 **Oto-201- New product by Otonomy, Inc.**
  BU=ml with a quantity of one per Section 5.2.2 of the BUS

- QUIC #201520 **Defitelio® (defibrotide)**
  BU=ml with a quantity of 2.5 ml per vial and 25 mL for the case of ten per Section 5.2.2 of the BUS

**Work Group 7 Manufacturer and Associated Trading Partner Transaction Standards**

**Task Groups:**

- The **Rebate Reference Guide Task Group** did not meet this quarter.

- The **Medical Rebate Standard Task Group** is reviewing the Medical Rebate Standard to determine if changes are needed.

- The **Medicaid Drug Rebate Program Task Group** revised its goals to remove the development of an encounter file standard as the new **Government Programs Encounter Reporting Standard Task Group** under WG9 will do this work.

- The **Rebate Standard Update Task Group** did not meet this quarter.
  - Specialty Pharmacy Data Exchange Sub-Task Group did not meet this quarter.

- The **Regulatory Tracking/Pedigree Task Group** did not meet this quarter.

- The **Formulary Management Survey Task Group** released the manufacturer and payer/processor surveys with the goal being to understand the current scope, process and challenges of formulary validation for commercial and Part D contracts. The surveys are open through November 20, 2015. The survey results will be reviewed at the February Work Group meeting.

- WG7 received an update from **WG9 OIG Report OEI 05-12-00540 Task Group**. See WG9 minutes.

**New Business:**

- A detailed overview of the Manufacturer Rebate Reconciliation File was presented.

- The work group reviewed DERF 001340 (assigned to WG11) requesting changes to the Formulary & Benefit Standard which will significantly reduce file size and improve the usability of the Formulary
& Benefit Standard to encourage greater utilization of its component parts. This requested change will impact the Manufacturer Rebate Standard.

Work Group 9 Government Programs

DERFs/ECLs Reviewed:

- 001327/Emergency ECL 000190 – recommendation to MC to approve the DERF/Emergency ECL.
- 001335/Emergency ECL 000197 – recommendation to MC to pend the DERF/Emergency ECL to request review by WG1 Telecommunication FAQ Task Group and remove the Medicare Part D restriction.

Task Groups:

- The **340B Task Group** reviewed the comments submitted in response to the 340B Drug Pricing Program Omnibus Guidance.
- The **Government Programs Encounter Reporting Standards Task Group** reported on the work to map the various state file formats to the standard on which they were based (e.g. Batch or Post Adjudication Standard) to determine where states are currently adding additional fields to the layout, deviating from the layout, and/or using NCPDP field numbers but modifying the name or definition.
- The **Health Insurance Exchange/Marketplace Task Group** did not meet this quarter.
- The **Hospice Task Group** continued to work on a retrospective reconciliation file for use between Hospice and the Part D Sponsor/Processor.
- The **Medicaid Subrogation FAQ Task Group** did not meet as no new questions were received.
- The **Medicare Financial Information Reporting Task Group** brought forward four questions and responses which were approved. The Financial Information Reporting FAQ document will be updated and published.
- The **Medicare Part D FAQ Task Group** brought forward four questions and responses for review/approval. One question was approved, one question was pended to the Task Group for modification and two questions will not be published. The Medicare Part D FAQ document will be updated and published.
- The **Medicare Prescription Drug Event (PDE) Task Group** reported on current questions under review, questions submitted to CMS and pending new questions.
- The **Medicare Standardized Fraud, Waste and Abuse Training Attestation Task Group** presented a revised version of the standardized FWA Training Attestation document which was approved by WG9.
- The **OIG Report OEI 05-12-00540 Task Group** is finalizing the survey being developed for distribution to the task group to assist in ranking and prioritizing the identified solutions. The task group will schedule a webinar to review solutions prior to distributing the survey. The survey will be finalized during the next quarter.
- The **Prescription Monitoring Program (PMP) Task Group** provided an update on the development of a National PDMP Administrator Requirements document. The task group also provided updated information for states that have prescription monitoring programs. The updated tracking document will be published.
- The **Supplemental Payer Part D Reconciliation Standardization Task Group** did not meet this quarter.
- The **Unbreakable Package Task Group** (WG9/WG2) submitted a letter to CMS recommending a NCPDP definition for unbreakable package. No response from CMS has been received.
- WG9 received an update from the **WG1 Standardized Subrogation Task Group**. See WG1 minutes.
New Business:
• WG9 received a Legislative update.

Work Group 10 Professional Pharmacy Services
Ballot Adjudication:
• **Ballot WG100008** for the Structured and Codified Sig Implementation Guide is considered a valid ballot having received the required 60+% of Consensus Group votes. One affirmative with comments, one negative with reason and one object with reason comments were received. WG10 reviewed and adjudicated the comments on this ballot as persuasive and editorial (causing minor changes to the implementation guide). See Letter Ballot Comment spreadsheet for the ballot results. If the submitters agree to change their vote/comment to affirm/accept or abstain as appropriate, the ballot will not be recirculated and will proceed to the Board of Trustees for approval after the required appeal period. If the submitters do not wish to change their vote/comment to affirm/accept or abstain as appropriate, the ballot will be recirculated.

Task Group Reports:
• The **MTM Communications Task Group** continues to develop new functionality using the CCDA Release 2 Clinical Notes. Currently under development are the specifications for a the Pharmacist eCare Plan.
• The **Acetaminophen Best Practices Hospital Safety Sub-Task Group** has submitted the *NCPDP Recommendations for Dose Accumulation Monitoring in the Inpatient Setting: Acetaminophen Case Model* white paper for publication.
• The **Scope and Goals Modernization Task Group** presented a draft proposal for discussion which included a possible name change for the work group. Comments will be solicited via the Collaborative Workspace and the revised draft presented at the February meeting for approval.
• WG11 **Specialty Requirements for ePrescribing Task Group** is continuing identification of other elements and messaging needed to support specialty pharmacy, including electronic prescribing of compound medications.

New Business:
• Pamela Schweitzer, RPh, PharmD and USPHS Chief Professional Officer, Pharmacy provided a brief overview of federal initiatives related to pharmacy and pharmacists as providers.
• Tricia Lee Wilkins provided a discussion on the importance of the ecare plan to the integration of pharmacy clinical services in to the National Interoperability Roadmap.

Work Group 11 ePrescribing & Related Transactions
Ballot Adjudication:
• **Ballot WG1100666** for the SCRIPT Standard is considered a valid ballot having received the required 60+% of Consensus Group votes. Four affirmative with comments and four negative with reason comments were received. WG11 reviewed and adjudicated the comments on this ballot as not persuasive, persuasive and editorial (causing a minor change to the implementation guide) and persuasive and substantive (causing removal of changes to the implementation guide requested under DERF 1292) See Letter Ballot Comment spreadsheet for the ballot results. The ballot will be recirculated.

DERFs/ECLs Reviewed:
• DERF 001336 was approved with modifications.
• DERF 001337 was approved without modifications.
• DERF 001338/ECL 000198 was recommended to be pended.
• DERF 001339 was approved with modifications.
• DERF 001340 was pended to the Task Group for additional work.

Old Business:
• Reviewed timeline for requesting the next version of the SCRIPT Standard in regulation. The version to be requested will be the one published in July 2015.
• Industry updates were provided on NCVHS Subcommittee on Standards, CMS (eprescribing), and DEA eprescribing for controlled substances and implementation activities.

Task Groups:
• The **Formulary and Benefit Task Group** brought forward DERF 001340 for the reduction of the Formulary and Benefit file sizes and to improve usability.
• **XML Task Group** reviewed submitted DERFs and brought forward recommendations.
• **NCPDP/HL7 Pharmacist Functional Profile Task Group** is developing EHR-S R2 functional profiles for the pharmacy practice specific setting.
• **WG11 Electronic Prescribing Best Practices Task Group** provided recommendations for the SCRIPT Implementation Recommendations document for updates to the Section: Use of Diagnosis Code and the Frequently Ask Question: ePrescribing Best Practices when Rejecting a NewRx when the Pharmacy Is Unable or Unwilling to Dispense.
• **WG14 LTPAC ePrescribing Task Group** is working on retrospective electronic prior authorizations for long term and post-acute care.
• The **Electronic Prior Authorization Workflow to Transactions Task Group** brought forth DERFs 001336, 001337, and 001338/ECL 000198.
• The **Meaningful Use and NIST Test Methods for ePrescribing Task** did not meet.
• **Implementation of Structured Sig Task Group** requested a new DoseUnitOfMeasure value for MilliUnits and began identifying discrepancies with XML structure. They also presented a webinar in October.
• **Specialty Requirements for ePrescribing Task Group** create a new Sub-Task Group to look at issues with ePrescribing of compounded prescriptions.

New Business:
• Discussed guidance provided by the DEA on Refill/Renewal Requests for Controlled Substances. A new task group was created (EPCS Renewal Request Task Group) to identify solutions for requests of controlled substance prescriptions for continued therapy that complies with the DEA requirements.

**WG14 Long Term and Post Acute Care (LTPAC)**

Old Business:
• Industry/Regulatory updates were provided which included HIPAA, NCVHS, and Meaningful Use.
• Received update on the Medicare & Medicaid Programs; Reform of Requirements for LTC Facilities NPRM, Management Standards for Hazardous Waste Pharmaceuticals and HIPAA Audits for Privacy and Security.

Task Group Reports:
• The **ePrescribing Task Group** are looking at the use of the ePA transactions in the long term and post-acute care industry.
• The **LTPAC Current Billing Issues Task Group** is looking at the NCPDP Telecommunication Standard to determine if the long term and post-acute care setting needs are met. They discussed ICD-10 Guidance and Backup Pharmacy issues.
• Received updates from the **WG9 Hospice Task Group** and the **Medicare Part D FAQ Task Group**.

**New Business:**
• Created a new task group for **Consultant Pharmacy Interoperability**.
• Reviewed DERF 1330 for Facility ID Qualifier and proposed modification.
• Created recommendations for Non-Long Term Care backup pharmacies.

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**Work Group 16 Property & Casualty/Workers Compensation**

**DERFs/ECLs Discussed:**
• DERF 001307 was approved by WG1 with modifications.
• DERF 001308 was pended by WG1 for additional review by WG16.
• DERF 001309 was denied by WG1.
• DERF 001310 was pended by WG1 for additional review by WG16.

**Task Group Reports:**
• The **Legislative/Regulatory Monitoring and Education Task Group** provided an update on state regulatory and legislative initiatives affecting Workers’ Compensation programs.
• The **Billing and State Reporting Task Group** provided an update regarding states moving to adopt regulations for e-billing, standard paper billing and EDI reporting.
• An update on discussion by the **MC Real Time Pharmacy Benefit Inquiry Task** regarding inclusion of a workers’ compensation use case was provided. It has been agreed that a WC use case will not be included in the initial requirements.

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**Work Group 45 External Standards Assessment, Harmonization and Implementation Guidance**

**Old Business:**
• Industry updates were provided for WEDI, ASC X12, and CAQH CORE.

**Task Groups:**
• The **Document Revision Task Group** reviewed seven new CARC for the mapping document and a revision to the NCPDP Procedure via the Collaborative Workspace. None of the CARCs will be used by pharmacy. The change to the mapping document was approved by the work group and will be go through the inter SDO process.
• The **834/835 FAQ Task Group** received no new questions.
• A **DSMO Task Group** received no DSMO requests for review.
• **CAQH CORE Task Group** did not meet.
• An update was provided on a WG9 discussion of the Louisiana Provider fee to be continued in WG1.
• An update was provided on the **MC UDI Task Group**.

**New Business:**
• WG3 has been disbanded and possible absorption of WG3 work efforts into WG45 will be discussed at the February meeting.

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**MC Maintenance and Control**

**Ballot Adjudication:**
• **Ballot WG010066** for the Telecommunication Standard is considered a valid ballot having received the required 60+% of Consensus Group votes. No comments were received. The ballot will go to the Board of Trustees for approval.
• **Ballot WG010067** for the Batch Implementation Guide is considered a valid ballot having received the required 60+% of Consensus Group votes. No comments were received. The ballot will go to the Board of Trustees for approval.

• **Ballot WG020007** for the Product Identifiers Standard Implementation Guide is considered a valid ballot having received the required 60+% of Consensus Group votes. No comments were received. The ballot will go to the Board of Trustees for approval.

• **Ballot WG100008** for the Structured and Codified Sig Implementation Guide is considered a valid ballot having received the required 60+% of Consensus Group votes. One affirmative with comments, one negative with reason and one object with reason comments were received. WG10 reviewed and adjudicated the comments on this ballot as persuasive and editorial (causing minor changes to the implementation guide). See Letter Ballot Comment spreadsheet for the ballot results. If the submitters agree to change their vote/comment to affirm/accept or abstain as appropriate, the ballot will not be recirculated and will proceed to the Board of Trustees for approval after the required appeal period. If the submitters do not wish to change their vote/comment to affirm/accept or abstain as appropriate, the ballot will be recirculated.

• **Ballot WG110066** for the SCRIPT Standard is considered a valid ballot having received the required 60+% of Consensus Group votes. Four affirmative with comments and four negative with reason comments were received. WG11 reviewed and adjudicated the comments on this ballot as not persuasive, persuasive and editorial (causing a minor changes to the implementation guide) and persuasive and substantive (causing removal of changes to the implementation guide requested under DERF 1319.) See Letter Ballot Comment spreadsheet for the ballot results. The ballot will be recirculated.

**DERFs/ECLs Reviewed:**

• 21 new and pended DERFs/ECLs were reviewed (see WG1 and WG11 above).

• **MC reviewed:**
  o DERF 001280 which was withdrawn.
  o DERF 001341 which was approved with modifications.

• The DERFs approved at this meeting will result in five ballots for the February 2016 ballot period
  o WG010068 for Telecommunication vE9 (DERFs 1307 and 1330 and the Prior Authorization portion of 1341)
  o WG110067 for the SCRIPT Standard v2016xx#
  o WG110068 for Prescription File Transfer Standard v34 (DERF 1339 and the Prior Authorization portion of 1341)
  o MC000007 for Post Adjudication v45 and Prior Authorization Transfer Standard v11 (note see Telecommunication and Prescription File Transfer ballots for changes to DERF 1341)

**Old Business:**

• Updates are available in the MC November 2015 download file:
  o Board of Trustee
  o HIPAA
  o NCPDP Legislative/Regulatory Activities

**Task Groups:**

• The **Education/Legislation and Regulations Task Group** did meet to provide comments on the Office of the National Coordinator (ONC) Interoperability 2016 Interoperability Standards Advisory.

• The **Unique Device Identifier (UDI) Task Group** continued their ongoing discussions, outreach, and research on how UDI will be implemented for devices in retail Pharmacy.
• The **Real Time Benefit Check Task Group** continues working on use cases. They presented two open questions to the Work Group for guidance. See the NCPDP Collaborative for more information.

• The **Prior Authorization Harmonization Task Group** brought forth DERF 1341 which was approved with modifications.

• The **API Task Group** has defined their scope and deliverables and will be surveying the membership on the status of API usage.

**Project Development Form:**

• New Project Development Form 00040 was reviewed and will recommend the formation of a new Task Group in Work Group 2.

**New Business:**

• The attendees received recaps of each Work Group’s activities.