NCPDP WG9 MEDICARE PART D QUESTIONS AND ANSWERS

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1. Purpose of this Document

In May 2Ø12, the Medicare Part D Frequently Asked Questions Task Group was formed in Work Group 9 Government Programs with the following scope:

> "The task group will review questions that warrant consistent application across the industry of Medicare Part D policy where claims or other applicable transactions, Prescription Drug Events (PDE) are involved. When questions involve the Telecommunication Standard, the question and response will be sent to the Telecommunication FAQ Task Group for approval. When questions involve the coordination of benefits, the question and response will be sent to the Coordination of Benefits (COB) Task Group or other task groups as appropriate. When coordinating with other task groups, timelines/prioritization will be included in the request for review. Recommendations from the task group will be submitted to CMS for review or reference and may require publication as guidance."

This document provides a consolidated reference point for questions that have been posed regarding Medicare Part D policy. These questions were addressed in Work Group 9 Government Programs meetings. This document will continue to be updated as questions and responses are formed.

2. Frequently Asked Questions

2.1 Notice of Appeal Rights

Question:

The Medicare Appeal group is looking for assistance in walking through reject codes to identify why certain reject codes are not appropriate for an appeal notice and those that might warrant an appeal.

Response:

- The Editorial Document has been revised to document the appropriate actions for compliance with the CMS requirement.
- CMS provided guidance in the HPMS memo "Revised Guidance for Distribution of Standardized Pharmacy Notice (CMS-10147) on December 27, 2012.

2.2 Addition of Benzodiazepines and Barbiturates

Question:

Barbiturates are only covered under Part D for certain diagnoses. In order to determine the member's diagnosis, we've recommended covering these drugs with a PA. However, since these are also considered anticonvulsants, the PA must apply to new starts only. Therefore, based on standard transition rules, new enrollees would be able to obtain these products during transition, and then would never be stopped for PA review to determine the diagnosis, and current enrollees on plans that covered these drugs as an Excluded benefit would also be able to continue therapy as of 1/1, and would never be stopped for PA review, as they would not be considered new starts only. Rather than "Grandfather" all members to continue coverage, without verifying diagnosis, are we permitted to stop these claims for PA review to determine if the diagnosis is covered under Part D? Do these fall into a similar scenario as Cialis, where plans are allowed to apply the PA during transition to determine if it's being used for a Part D covered diagnosis (for which a transition claim would then be required) vs. being used for a Part D excluded diagnosis (and therefore a transition fill would not be required.)

Response:

Question was clarified by CMS memo titled "Transition to Part D Coverage of Benzodiazepines and Barbiturates Beginning in 2013" October 2, 2012."

- Specifically, we expect Part D sponsors to consider all claims for drugs in these classes during the first 90 days of 2013 to be continuing therapy for the purpose of transition requirements.
- We do not believe Part D sponsors should implement point-of-sale edits on phenobarbital to confirm the Part D medically-accepted indication.

As a result of the section 1927 revision by ACA, effective 2014 there will be total coverage of barbs under Part D." This will be clarified in the Call Letter.

2.3 Invalid/Missing Prescriber ID and process for 24-hour resolution

Question:

When does the Medicare Part D plan sponsor need to provide 24 hour follow up with the pharmacy due to a prescriber validation error?

Response:

(Provided by the WG1 Definition of a Valid Prescriber Task Group)
Refer to prescriber validation reject scenario matrix in Version D Editorial.

Medicare Part D plan sponsors should have policies in place consistent with CMS guidance for all prescriber validation reject scenarios identified within the matrix.

This Question/Response will be added to the Version D Editorial Document.

2.4 Daily Cost Sharing Rates for LTC Appropriate Dispensed Claims (a.k.a. Short Cycle Dispensing)

Question:

We are contemplating moving forward with the Prorated co-pays for Short Cycle Dispensed claims on 01/01/2013. If we use CMS guidance on this we see a significant loss of Co-pay associated with using the CMS calculation. They state:

"Daily cost-sharing rate is defined as the established monthly copayment under the enrollee's Part D plan, divided by 30 or 31 and rounded to the nearest lower dollar amount, if any, or to another amount, but in no event to an amount which would require the enrollee to pay more for a month's supply of the prescription than would otherwise be the case.''

If we use the example of a Flat Co-Pay of $40.00 you would calculate that the daily prorated Co-Pay would be $1.33 per day. On a 14 day supply the Co-pay would calculate out to 14X1.33 = $18.62. If you round the daily cost sharing rate to the nearest lower dollar amount the calculation would be 14X1.00 = 14.00 and thus the plan would lose $4.62 of Co-pay on a 14 day supply as a result of the prorated rounding. On one claim this is not significant but, when multiplied by 100's of thousands of claims this quickly becomes a significant number.

Is this what CMS intended? What is the purpose of rounding down to the lower dollar amount? If no rounding is applied the end result is the same whether you charge the 30 day supply Co-pay or charge the Co-pay at $18.62 + $18.62+2.66 = 39.90 less than the $40.00 paid on a 30 day supply.
Response: Rounding to the nearest dollar amount refers to the "cents" portion of the amount.

Response:

In 2014, Plans will be required to file the following items with CMS:

1) Day Supply
2) 1-Month Copayment
3) Daily Copayment

For 2013 plans filed the Days Supply and 1-Month Copayment and may OPTIONALLY have filed a Daily Copayment if they plan to allow a daily copayment when processing claims in 2013. If they have filed a daily cost share, and they choose to implement a reduced copayment for day supply less than the monthly day supply filed, the daily cost share should be utilized. If a plan did not file a daily cost share, but wishes to apply a reduced copayment for day supply less than the monthly day supply filed, the plan may prorate based on the following calculation:

1-Month Copayment divided by Day Supply.

In some instances downward rounding may be required to ensure that the computed prorated daily cost share times the Days Supply filed does not exceed the 1-Month Copayment filed.

EGWPs that do not file their benefits with CMS should follow the same logic.

In 2014, Plans that have copayments must establish a daily cost share. HPMS will put edits in place to ensure that the Day Supply times the daily cost share does not exceed the 1-Month Copayment. Plans must use the daily cost share filed with CMS if the days supply on the claim is less than the Day Supply filed with CMS. This includes all solid oral doses of drugs, except antibiotics or drugs which are dispensed in their original containers and will apply to both brand and generic drugs.

2.5 LTC Appropriate Dispensed Claims (a.k.a. Short Cycle Dispensing) Scenarios

Question:

Under the new circumstances what happens if:

Prorated: 21 Feb and 28 Feb you've collected $6.00 in copay. If you grant LIS status on 1 Mar then you've already charged too much copay.

Pre-Fill: You have collected the entire copay and it's like the current situation.

Post-Fill: Do you treat the entire prescription as LIS (which would be done currently as the Service Date is still before the LIS status change)?

Response:

- Whether pre-consumption or post-consumption billing, LIS would not be applied as date of service is prior to the LIS effective date. In this example, if billing is based on dispensing then LIS would apply for March 7 and March 14.
- LIS should be treated as any other cost share. LIS should not be first or last but should be prorated as well.

  "Because Part D sponsors would have to address copayment methodology in connection with the LTC dispensing requirements, we proposed to supersede our quoted guidance in the April 2011 final rule (76 FR 21432), and thus proposed that the daily cost-sharing rate requirement would apply to prescriptions dispensed in LTC facilities, beginning January 1, 2013."

  "Under our requirement, LIS enrollees would not pay any more in cost-sharing for a month's supply of medication than they would otherwise. However, we are revising our proposed definition of ''daily cost-sharing rate'' to make this clearer, as indicated by the underlining later in this final rule with comment period. Thus, with respect to copayments, ''daily cost-sharing rate'' is defined as ''the established monthly copayment under the enrollee's Part D plan, divided by 30 or 31 and rounded to the nearest lower dollar amount, if any, or to another amount, but in no event to an amount which would require the enrollee to pay more for a month's supply of the prescription than would otherwise be the case.''"

  In the example provided if you are going to do the first fill method and the first fill is only for 14 days your copay is $30 but your drug is $10. The most you can charge on that first fill is $10 for copay. Do you have logic in place for subsequent fills to make up the $20 difference in the copay based on the cost of that drug which would be $10 each time?
- Roll up on PDE is not required for short cycle. PDE should be submitted as billed.

2.6 Reject Code A6

Question:

Is there a specific reject code or combination of reject codes that should be returned when the prescription drug or DME product is categorized as B versus D, to ensure the pharmacy is aware of the coverage rules and can determine the appropriate Medicare program that should be billed or contacted for further review?

Response:
Use of Reject Code (511-FB) = "A5" OR "A6"

A5	Not Covered Under Part D Law
A6	This Medication May Be Covered Under Part B

- When a drug/supply may be covered under Medicare Part B, but will never be covered under Medicare Part D (for example, CMS Medicare Part D exclusions that may be covered under B), return Reject Code "A5" (Not Covered Under Part D Law) and "A6" (This medication may be covered under Part B).

- When a drug/supply may be covered under Medicare Part B, and if not covered under Part B may be covered under Medicare Part D (B vs. D), return Reject Code "A6" (This medication may be covered under Part B). The plan must also return the applicable coverage determination type reject code (e.g. 75 Prior Authorization Required, 39 Diagnosis Required, 4X Missing Invalid Patient Residence). Free form text should not be used in lieu of a coverage determination reject code but can be used to provide further clarification.

2.7 Prescription Drug Event Reporting Changes Effective 2/2013

Question:
To prevent point of service disruptions, and the operational impact that would occur if Part D processors require the Patient Residence and Pharmacy Service Type on all non-LTC claims should the Part D processor default to the below values, when the Service Provider ID is not associated to a LTC provider and Fields 384-4X and 147-UP are not sent on the submitted transaction.

Patient Residence Default – 1: Home
Pharmacy Service Type – 1 – Community Retail Pharmacy

Background:
August 3, 2012 CMS memo sent to all Part D sponsors outlining the changes in the PDE (prescription drug event) reporting process effective 2/2013. Three new fields have been added to the PDE. One is applicable to LTC claims, while the other 2 are applicable to all claims.

- All Claims
- Patient Residence (384-4X). Full list of values copied below
- Pharmacy Service Type (147-UP) Full list of values copied below
- LTC Claims
- Submission Clarification Code (420-DK)

Response:
CMS Guidance "Revised Reporting Requirements for Prescriber Identifiers and Other Prescription Drug Event Fields" provided on 10/1 (note revised PDE layout 10/5) excerpts below:

- Effective January 1, 2013, CMS will require sponsors to submit an active and valid NPI on PDE records; however, the NPI reported may be a group identifier if the prescriber has not yet obtained an individual NPI. Beginning May 6, 2013, sponsors must report only a Type 1 (individual) NPI on the PDE record.
- We will require Patient Residence and Pharmacy Service Type fields on all PDE records for claims with dates of service (DOS) February 28, 2013 or later. For those claims where the Patient Residence code is 03- Nursing Facility, the Submission Clarification Code (SCC), if applicable,

must also be a valid value. For DOS prior to February 28, 2013, Patient Residence and Pharmacy Service Type can be spaces or any of the valid values listed in the file layout. If Patient Residence is not "03" or the DOS is before February 28, 2013, the Submission Clarification Code must be spaces.

- For 2013, a valid Patient Residence and Pharmacy Service Type will be required on PDEs with a date of service of February 28, 2013 or later for all beneficiaries in a nursing facility, assisted living facility, group home, intermediate care facility for the mentally retarded, or hospice facility when the drug is dispensed under the pharmacy's contract with the facility.
- For 2013, retail pharmacies may default to a Patient Residence of 01 (Home Community/Retail Pharmacy Services) and a Pharmacy Service Type of 01 (Community/Retail Pharmacy Services) on the claim transaction or leave these fields blank. If the retail pharmacy fails to include a Patient Residence and/or Pharmacy Service Type on the claim, the Part D sponsor may accept the transaction and report the default values (Patient Residence of 00 (Not specified) and Pharmacy Service Type of 99 (Other)) on the PDE. However, if the pharmacy reports non-default values in either field, the sponsor may report these values on the PDE in lieu of the default values.
- Beginning in 2014, we are considering requiring that sponsors report valid (i.e., non-default) Patient Residence and Pharmacy Service Type values on all PDEs. This requirement would require all pharmacies to collect and record patient residence at point-of-sale.

2.8 2007 and 2008 Part D Payment Reconciliations

Question:

For plans with ED drug PDE records in need of deletion for 2007 and 2008, does CMS expect plans to adjust TrOOP and Drug Spend balances for these PDE records as well as submit adjusted PDE records for all downstream PDEs?

Regarding memo dated June 25, 2012: Modification to the Drug Data Processing System (DDPS) in relation to the reopening of the 2007 and 2008 Part D Payment Reconciliations:

"The OIG found eighteen unique NDCs for ED drugs that are excluded from the Part D program and were associated with PDEs for 2007 and 2008 (See Attachment A). ED drugs covered under a supplemental benefit were excluded from the review. Unless covered under a supplemental benefit, plans should submit deletion PDEs for any PDEs submitted with the NDCs found in Attachment A of this memorandum."

Response:

CMS indicates the manner in which claims should be adjusted in two memos:

- The requirement to adjust claims within 45 days (Section 423.464)
- The requirement to coordinate benefits up to 36 months (Section 423.466)

There is no other guidance, so based on this, these transaction changes are outside of the 36 months window.

2.9 Reprocessing Retroactive Changes to LTC Appropriate Dispensed Claims (a.k.a Short Cycle Dispensing)

Question:

Claim originally processed as generic, but there was retroactive change to brand (either on FDA file or other reason). Concern that when re-adjudicating and resubmitting the claim as an adjusted PDE, it will reject for missing SCC.

Response:
This will not be an issue in 2013 because CMS is only editing these fields to ensure that valid values are being sent in the fields when they have values. In 2013, CMS is not looking at drug to validate whether brand or generic. Continue to do these how you do them today without the short cycle codes submitted on them.

Note: This question will be reopened for 2014 to determine how to handle.

2.10 Daily Cost Share

Question:
In the off chance that a claim is submitted for a day supply greater than a standard month's supply (30 or 31), should the copay still be prorated? The member will be charged a higher amount in this situation. My interpretation of the guidance is: prorate if the DS is for a month's supply or less. Anything greater, apply the flat copay.

Days Supply = 90
Quantity Supply = 90
Copay = $30

Response:
The requirement is to apply the daily cost share amount to any prescribed amount less than 30/31 day supply (whatever is filed for a month's day supply in HPMS). The purpose of reduced day's supply, which resulted in the copay guidance, was driven by the incentive to reduce waste.

The rule does not require proration for amounts greater than a month's supply but less than the next applicable cost share. CMS is silent on the handling of these situations other than the beneficiary liability must not exceed the cost of the drug.

Since we have no guidance on setting cost sharing for amounts greater than a month's supply but less than the next applicable cost share (other than the "lesser of" policy referred to above), using the daily cost amount for the incremental days would not be inconsistent with that (nonexistent) guidance. This would presumably be easier for a beneficiary to understand and accept than paying the higher cost share. However, we are aware that sponsors' benefit designs and bids may involve non-linear cost sharing strategies, so programmers should consult with internal experts.

2.11 Question from COB Task Group: Barbiturates

Question:
For 2013, barbiturates used for epilepsy, cancer, or a chronic mental health disorder are to be newly covered by Part D. PA and/or Diagnosis may be necessary for paying when meets Part D requirement.

- If not paid by Part D then for Medicare/Medicaid, would be payable under Medicaid – however many COB payers are likely to want to see why this was not payable under D and that the provider made proper determination.
- How can this be reported on a COB claim?

Response:

Medicaid may be billed as primary due to barbiturates previously being excluded under Medicare Part D and the patient's Medicaid plan being set as the primary payer for this prescription or drug. If Medicaid is billed as primary, per CMS guidance, the claim should be rejected as P/A required rather than code "41" (Submit to Primary) to avoid patient care disruptions.

The claim denied by Medicare Part D will be represented in the COB segment within the Other Payer Reject Code (472-6E) field. Other payer reject codes may include:

- 75 (P/A Required)
- 3Y (P/A Denied) Note: Reject Code is not commonly used today as payers P/A review process is not linked to the claims adjudication system.
- 70 (Product/Service Not Covered – Plan Benefit Exclusion)
- MR (Product Not on Formulary)
- 39 (M/I Diagnosis Code)
- 80 (Drug/Diagnosis Mismatch)

If the COB claim contains any of the above Other Payer Reject Code (472-6E) values, the Medicaid plan may choose to accept and pay the claim or deny using Reject Code (511-FB) values '75' (P/A Required) or '39' (M/I Diagnosis Code) confirming patient's disease state.

Other Payer Reject Code	Medicaid COB Claim Response Recommendation
75 (P/A Required)*	Reject as P/A required or diagnosis required to validate Medicare Part D determination of drug not covered.
39 (M/I Diagnosis Code)*	Reject as P/A required or diagnosis required to validate Medicare Part D determination of drug not covered.
70 (Product/Service Not Covered – Plan Benefit Exclusion)*	Reject as P/A required or diagnosis required to validate Medicare Part D determination of drug not covered.
MR (Product Not on Formulary)*	Reject as P/A required or diagnosis required to validate Medicare Part D determination of drug not covered.
80 (Drug/Diagnosis Mismatch)*	Reject as P/A required or diagnosis required to validate Medicare Part D determination of drug not covered.
3Y (P/A Denied)**	Options are to accept or reject the claim as P/A required or diagnosis required if additional information is needed for documentation.
Any other Reject Codes not listed above	Reject using standard processes

*Unable to determine if reject codes are from initial reject or subsequent to a P/A request being denied where processor returns the same reject code.

**Intent was to be used with the P/A Request Billing Transaction (P1) and P/A Request Only (P4) therefore not commonly used with the Billing Transaction (B1).

The business case is not limited to Medicare Part D/Medicaid claims for benzodiazepine and barbiturates. The effort to obtain a prior authorization approval cannot be effectively communicated by the pharmacy to the downstream payer unless the rejected claim response includes reject code '3Y' (P/A Denied) when the prior authorization request has been denied. Currently most processor systems do not link prior authorization denials to the claims

processing. The following short and long term Industry recommendations should address this business case.

Recommendation: Downstream payers should not automatically assume that the P/A has not been requested. (This assumes that the pharmacy software is reporting all prior payers reject code values on the claim.) Until such time as the industry links the P/A process to indicate the pending status or rejection of a P/A request within the payers adjudication system, downstream payers need to develop processes to evaluate the actual status of Other Payer Reject Code (75 P/A Required). For example, Patient is a Part D beneficiary, drug is a barbiturate and prior payer has rejected the claim for "P/A Required" and by verbal or other communication provider has determined the P/A has been denied.

For future consideration: Payers need to refine the P/A process to log the status of the request; approved, pending or denied in order to provide the information back on a claim so that downstream payers may react accordingly. This minimizes additional pharmacy provider intervention downstream.

2.12 CPP for LIS Beneficiaries in Gap

Question:

The Data Analysis findings memo dated 1/4/2013 states the following:
Covered D Plan Paid (CPP) Amount in the Coverage Gap for Low-Income Beneficiaries
The Coverage Gap phase of the Part D benefit has been closed for low-income beneficiaries since the inception of the Part D program. The Coverage Gap Discount Program and the additional cost-sharing provided by sponsors in the coverage gap for brand and generic drugs do not apply to low-income beneficiaries.

CMS evaluated PDEs for benefit years 2011 and 2012 and discovered that some sponsors are reporting CPP in the coverage gap phase on generic drugs for low-income beneficiaries. Low-income beneficiaries should not have CPP on PDEs falling in the coverage gap phase. CMS expects sponsors to correct all benefit year 2011 and 2012 PDEs in which CPP is reported in the coverage gap phase for low-income beneficiaries. CMS expects sponsors to correct all PDEs with 2012 dates of service by the reconciliation cut-off date for the 2012 Part D payment reconciliation, which is 11:59 PM on Friday, June 28, 2013.

This conflicts with the table pasted below that shows CPP is 15% of claim cost falling in Gap (Rule 4) for LIS eligible beneficiaries in enhanced alternative plans. This table is on page 10 of the Final Operational Guidance for PDE Changes Gap Disc 2011 dates 7/9/2010. Should the 1/4/2013 guidance be amended to state that CPP reported for LIS claims that fell in CPP rule 3 should be corrected?

MAPPING TO THE DEFINED STANDARD BENEFIT TO CALCULATE CPP AMOUNT 2011 LIS ELIGIBLE BENEFICIARIES

RULE #	YEAR-TO-DATE (YTD) GROSS COVERED DRUG COSTS	PERCENTAGE TO CALCULATE DEFINED STANDARD BENEFIT
1	<= $310	0%
2	>$310 and <= $2,840	75%
3	>$2,840 and <= $6,447.50	0%
4	>$6,447.50 and <= OOP threshold	15%
5	> OOP threshold	Lesser of 95% or (Gross Covered Drug Cost -$2/$5)

Response:

CMS analyzed Rule 3, not Rule 4 PDEs in the Coverage Gap phase and found that sponsors were reporting CPP for LI beneficiaries when they should not. If the PDE falls within Rule 4, there can be CPP but our analysis was limited to Rule 3 PDEs.

2.13 Benefit Stage Qualifier and Employer Group Waiver Plan Wrap

Question:

Based on some issues experienced with some SPAPs that require BSQ and BSA (benefit stage) on their claims, we think that we need additional clarification in our guidance around the following scenarios:

Scenario 1: There are three payers for a member, Part D, A supplemental payer and an SPAP. These are three distinct payers, two of whom are separate COB transactions. The SPAP requires the BSQ and BSA. Our guidance indicates that the only entity that should provide the BSQ/BSA in a response is the Part D Plan. In this instance, the second payer in line is not entitled to the BSQ/BSA. Do not send eligibility for the co-administered plan to CMS thereby preventing the pharmacy from submitting a separate transaction based on the E1 response.

Response:

The exact business case is unclear as the discussion across the 3 task groups varies between claim formatting on the pharmacy side, downstream payers who are entitled to the benefit stage information (amounts) and potentially downstream payers who are not entitled to the benefit stage amount however the benefit design is dependent upon the benefit stage or determination that the previous payer was Medicare D.

From a pharmacy, we can send what we receive and if downstream is not entitled to the fields they cannot receive. On the first COB claim, the primary payer will not contain the BSQ/BSA but on the second COB claim, the primary payer will contain the BSQ/BSA.

COB Task Group Response:

- When a co-administered benefit applies after the Part D portion of the claim has adjudicated, the Part D plan must return the Benefit Stage Qualifiers and Amounts associated to the Part D benefit.
- Supplemental payers who do not meet the criteria cannot request the benefit stage information on COB claims.
- Pharmacy software must be able to transmit or suppress the benefit stage information based on COB payer's entitlement regardless if the payer is secondary, tertiary, etc.

Scenario 1: Three Separate Claims	
Claim Billing	**Claim Response**
Part D payer billed	Part D pays with Benefit Stage 1 - 4
Supplemental payer not entitled to Benefit Stage information is billed **COB segment:** • Primary Payer info without Benefit Stage values	Supplemental payer pays – No benefit Stage info provided
SPAP payer entitled to Benefit Stage is billed **COB segment:** • Primary Payer info *includes* Benefit Stage	SPAP processes using criteria as needed. The NCPDP pricing formula and COB reported financial amounts should be used

values • Secondary payer info does not have Benefit Stage values to submit (not returned)	to determine claim reimbursement. The Benefit Stage Amounts should not be used for this purpose. See Section 9.1 Clarification of Net Amount Due in Coordination of Benefits of the vD.0 Editorial Guide.

Scenario 2: Two Separate Claims	
Claim Billing	**Claim Response**
Part D payer billed	Part D pays with Benefit Stage 1 – 4 and applies co-administered benefits
SPAP payer entitled to Benefit Stage is billed **COB segment:** • Primary Payer info *includes* Benefit Stage values	SPAP processes using criteria as needed. The NCPDP pricing formula and COB reported financial amounts should be used to determine claim reimbursement. The Benefit Stage Amounts should not be used for this purpose. See Section 9.1 Clarification of Net Amount Due in Coordination of Benefits of the vD.0 Editorial Guide.

2.14 No Gap Discount for Pharmacy Submitted Paper Claims

Question:

We would like to confirm with CMS through NCPDP WG 9, Med D FAQ Task Group, that the 2010 interpretation of no gap discount for pharmacy submitted paper claims still stands, and run the following example by them:

Paper claim (e.g. UCF) has been submitted by the pharmacy for an applicable drug and applicable beneficiary. Claim processes fully in the coverage gap, $98.00 ingredient cost, $2.00 dispensing fee; total claim cost $100.00. Defined standard cost sharing applies.
Beneficiary liability: $100.00 * 97.5% = $97.50
Plan liability: $100 - $97.50 = $2.50

Response:

CMS: "Our guidance was never intended to exclude pharmacy claims, paper or otherwise, that are payable under Part D. When we wanted to exclude a specific type of claim (e.g. MSP), we said it. Therefore, the default is that such claims are discountable if they are otherwise payable under Part D. At this point we do not believe we need to issue additional guidance on this question, as we consider it addressed by current guidance. However, we will consider adding the point to a future manual version." Updated email received 4/24.

2.15 Order for Error Processing and Messaging

Question:

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Is there a particular order for error processing and messaging that Part D transactions should follow? For example, with the new 2013 CMS requirement to implement short cycle dispensing, should NDC's submitted on a transaction be edited as a Part D excluded drug before editing for a brand/oral/solid and submission clarification codes/special package indicator associated with a LTC short cycle claim? Another example is when to edit for a valid prescriber NPI?

This question was driven by a CMS audit finding where we were instructed in the attached example, 'Prior Authorization Reqrd' was the first error message that was returned to the pharmacy, but instead, CMS auditors told us that the 'Transition Supply Exceeded' error should have been returned to the pharmacy first.

TCD Sbm Product ID	TCD Sbm Date of Serv	TCD Date Submitted	TCD Sbm Qty Dispense	TCD Sbm Days Supply	RJC Reject Cde 1	REJ Reject Code Desc	RCM Message	PRD Description Abbrev	TCD GPI Number	TCD Claim Status	TCD Plan Drug Sts	TCD Final Plan Cde	TCD Final Plan Eff D	Drug Name
310075590	20120206	20120206	30	30	1	3	5	75	Prior Authorization Reqrd	Transition Supply Exceeded-866-618-6739	569	CMS Appeal Rights Notice	Drug Requires Prior Authorization	CRESTOR TAB 5MG
310075590	20120214	20120214	30	30	1	3	5	75	Prior Authorization Reqrd	Transition Supply Exceeded-866-618-6739	569	CMS Appeal Rights Notice	Drug Requires Prior Authorization	CRESTOR TAB 5MG
310075590	20120220	20120220	30	30	1	3	5	75	Prior Authorization Reqrd	Transition Supply Exceeded-866-618-6739	569	CMS Appeal Rights Notice	Drug Requires Prior Authorization	CRESTOR TAB 5MG

Response:
CMS clarified that if there are more rejects than the allotted five occurrences, the 569 must be in one of the occurrences. CMS is not concerned with the prioritization of the reject codes.

The FAQ Task Group recommendation to CMS is that auditors not dictate the order of the reject codes or message text. CMS confirms that this should be the case and will conduct outreach to the auditing group and the specific auditor in question.

2.16 Classifying LTC Claims

We're going through an audit with CMS and they indicated to us we should ONLY be looking at Patient Residence value of '3' and '9' to classify a claim as LTC and to apply all LTC rules. We displayed Section 8 (LTC) of the Version D Editorial document to them and indicated that we are using the NCPDP combination of Patient Residence, Pharmacy Service Type, and CMS Qualified Facility. They came back that the August 3, 2012 PDE guidance only references that the patient is in a LTC facility. The area of that guidance referred to by the auditor is highlighted in yellow.

"In our final rule published April 15, 2011 (76 FR 21432), the Centers for Medicare & Medicaid Services (CMS) set forth the requirements for appropriate dispensing of prescription drugs in long-term care

(LTC) facilities under PDPs and MA-PD plans. The new regulations at 42 CFR § 423.154 require that, beginning January 1, 2013, Part D sponsors require all pharmacies servicing LTC facilities to dispense solid oral doses of brand-name drugs in no greater than 14-day increments to Part D enrollees residing in LTC facilities, subject to the exclusions and waivers specified in the regulation. The regulation also describes a requirement for the collection and reporting of information on the dispensing methodology for each dispensing event to enrollees in LTC facilities subject to the 14-day-or-less dispensing requirement."

Our thought has been that any LTC guidance 'built' upon the earlier LTC designations used so, interpreted that we need a LTC 'claim' that is identified via the combination of Patient Residence, Pharmacy Service Type, CMS Qualified Facility and Place of Service.

CMS Response: The identification of a LTC claim is more complex than just a place of service. CMS' expectation is that the identification of a resident in LTC is accurate. CMS expects sponsors to know who is in LTC and to whom LTC policies apply.

The auditors should be looking at auditing LTC claims in this way:

- Did the sponsor correctly identify claims that were LTC?
- Were the applicable policies for LTC correctly administered?

If the client points to the NCPDP Editorial document as a justification for what they are doing, that should be taken into consideration. If the auditors don't understand what is going on they should contact the appropriate staff in the central office. The issue seemed to be that the auditors were instructing people on how to process claims and that is not appropriate. The issue isn't whether NCPDP guidance is correct. The auditors shouldn't be telling people how to process claims. If there are questions or concerns as a result of an auditor or audit, please contact the CMS folks at the policy division. They welcome questions and please don't be concerned about repercussions.

2.17 Trial Fill/Resynchronization of Refills

With the CMS Guidance expectation (final 4/1), we think the current SCC codes to support the "reasons" a script may be trial filled are more varied than the current SCC codes already support and correlate to the cost share sent to pharmacy. We are also concerned that from an emergency ECL perspective, we would need to provide a recommendation/DERF on new codes to be submitted for May WG.

Background:
In the May 2012 work group meetings, two Submission Clarification Codes and one Approved Message Code were added, related to DERFs 1058 and 1059.

New Submission Clarification Codes:

47 Shortened Days Supply Fill - only used to request an override to plan limitations when a shortened days supply is being dispensed.

48 Fill Subsequent to a Shortened Days Supply Fill - only used to request an override to plan limitations when a fill subsequent to a shortened days supply is being dispensed.

New Approved Message Code

Ø23 Prorated copayment applied based on days supply. Plan has prorated the copayment based on days supply.

NCPDP WG9 Medicare Part D Questions and Answers

DERF 1058 Emergency ECL 000113 – This DERF requests "CMS has issued a Final Rule that allows for the pro-rating of copay for less than a 30-days supply on prescriptions for Medicare Part D beneficiaries effective January 1, 2014. Part D sponsors can voluntarily choose to apply a daily cost-sharing rate in the LTC setting in 2013 or not, or for that matter, in the retail setting or not. We are proposing two new Submission Clarification Codes. These Submission Clarification Code values will allow the pharmacy to notify the plan of the shortened day's supply fill and allow the pharmacy to request to bypass refill too soon edits on a subsequent shortened day's supply fill." WG9 recommended approval of the DERF/Emergency ECL with modifications.

DERF 1059 Emergency ECL 000114 - This DERF requests "CMS has issued a Final Rule that allows for the prorating of copay for less than a 30-days supply on prescriptions for Medicare Part D beneficiaries effective January 1, 2014. Part D sponsors can voluntarily choose to apply a daily cost-sharing rate in the LTC setting in 2013 or not, or for that matter, in the retail setting or not. In addition to the new Submission Clarification Code for this issue, we are proposing two new Approved Message Codes to allow the plan to communicate back to the pharmacy that a prorated copay was either given or not given." WG9 recommended approval of the DERF/Emergency ECL with modifications.

Questions:

- I'm assuming that plans are not required to use these codes but may do so based on payer agreement with providers. Is that correct?
  Response:
  Our understanding of CMS' expectation is that the beneficiary's access to drugs is not disadvantaged. Our recommendation is to utilize automation of override requests (SCC 47 & 48) where appropriate and that plans should have controls in place to identify fraud, waste and abuse issues related to these codes.

- I'm assuming SCC47 is submitted for the fill for less than a one-month supply and that SCC48 is submitted when an override was not required for the fill less than a one-month supply but is required for the fill immediately following 30 day fill. Is this correct?
  Response:
  If the shortened days supply (trial/synchronized) rejects with a plan limitation error, the SCC 47 may be utilized. If the full fill subsequent to a shortened days supply fill rejects with the plan limitation error, the SCC 48 may be utilized.

- Since the pharmacy is not required to send anything on a claim providing a reason for dispensing less than a one-month supply, we're not going to know if a shortened days supply has truly occurred. I'm assuming we could ensure that we are rejecting for RTS for a fill for the same drug that is less than a one month's supply before allowing the override with SCC48. Is that the expectation?
  Response:
  See #1 and #2 above.

- With both SCC47 and SCC48, it seems there is a possibility of misuse of the override request. I'm assuming plans can limit these overrides as they see fit. Is that correct?
  Response:
  See #1 and #2 above.

- There was also a question in the 2013 Final Rule about whether or not plans can limit the number of times that refill synchronization can occur during a year. Has that been discussed?

Response:
No specific limitations have been discussed.

- What is the expectation around dispensing fees with trial fill and synchronization?
  Response:
  This is a trading partner agreement.

- Is the pharmacy at risk for not submitting a SCC when a trial fill or synchronized fill is denied for plan limitations?
  Response:
  Our understanding of CMS' expectation is the pharmacy should help the beneficiary upon request to synchronize their medications. The pharmacist would use their professional judgment to determine if an override to the plan limitation reject is appropriate (for example, prevent availability of excessive medications in the patient's home).

2.18 Requirement to Report Valid (i.e., Non-Default) Patient Residence and Pharmacy Service Type Values on all PDEs in 2014

Question:
The verbiage below is from page #3 of the CMS memo dated 10/1/2012 (Revised Reporting Requirements for Prescriber Identifiers and Other Prescription Drug Event Fields). Do you know if it is the intent of CMS to move forward with this requirement?

> "Beginning in 2014, we are considering requiring that sponsors report valid (i.e., non-default) Patient Residence and Pharmacy Service Type values on all PDEs. This requirement would require all pharmacies to collect and record patient residence at point-of-sale. Thus, we would expect sponsors and their network pharmacies to develop and implement controls to improve the accuracy of this information during 2013, and do not consider initial failure to report Patient Residence and/or Pharmacy Service Type on the claim transaction as a reason to deny or recoup payment. Messaging to attempt to correct missing or invalid data during claim adjudication with LTC, home infusion and specialty pharmacies would be permissible. We encourage plan sponsors to provide comment on such a requirement and will work with the industry through NCPDP to evaluate the costs and benefits associated with requiring the reporting of valid data in these PDE fields."

Revised Reporting Requirements for Prescriber Identifiers and Other Prescription Drug Event Fields, dated October 1, 2012

> "For 2013, retail pharmacies may default to a Patient Residence of 01 (Home Community/Retail Pharmacy Services) and a Pharmacy Service Type of 01 (Community/Retail Pharmacy Services) on the claim transaction or leave these fields blank. If the retail pharmacy fails to include a Patient Residence and/or Pharmacy Service Type on the claim, the Part D sponsor may accept the transaction and report the default values (Patient Residence of 00 (Not specified) and Pharmacy Service Type of 99 (Other)) on the PDE. However, if the pharmacy reports non-default values in either field, the sponsor may report these values on the PDE in lieu of the default values. We expect that, if a retail pharmacy without a contractual arrangement with a facility delivers drugs to a facility on an ad hoc (i.e., non-routine) basis, PDE reporting will comply with routine retail pharmacy, not dual-purpose provider, reporting requirements."

Response:
See 2.19 below for recommendations.

2.19 PDE Layout – Pharmacy Service Type/Patient Residence

NCPDP WG9 Medicare Part D Questions and Answers

Question:
The question surrounds the attached CMS guidance on updated PDE layout. I compared both the Pharmacy Service Type and Patient Residence from the PDE layout to acceptable values by NCPDP. I have found differences with the Patient Residence. For the PDE, CMS accepts the values of 0, 1, 3, 4, 6, 9 and 11. However, NCPDP accepts the values of 0, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, & 15. Values 7, 8 10, 12, 13, & 14 are not applicable to pharmacy benefits. There are a few questions here.

1. Can we find out from CMS why there is a difference in the accepted values on the PDE from the accepted values on the claim according to the NCPDP ECL?
2. Why are these fields considered to be numeric for NCPDP but alphanumeric for CMS?
3. The thought is that these fields were added to the PDE to provide supporting evidence a claim is an LTC SCD claim. If this is truly the case, why are the fields being validated for non-LTC SCD claims? Having to blank out a valid value from an adjudication perspective for a non-LTC SCD claim, to allow for PDE acceptance, would seem counterproductive to any potential future data analysis to be done for non-LTC SCD claims.

Inconsistency with industry standards requires PDE records to be updated to null which is an unnecessary modification to the record. Wherever possible we should be striving towards minimal changes to the submitted claim.

Response:
Recommendations for Part D Claims effective 1/1/2014
Patient Residence Code:

- All Part D claims will require a valid Patient Residence Code 0,1,3,4,6,9 and 11
- For all pharmacy providers (excluding long term care) if the patient residence is not known, the claim may be submitted using patient residence code =1 (home) as a default.
- Claims may be rejected at point of sale provided plan has a process to ensure the beneficiary receives the drug.
    - If values 2, 5, 7, 8 10, 12, 13, 14 and 15 are submitted then reject with 4Y Patient Residence Not Supported
    - If the field is not submitted or if submitted with non ECL values, reject with 4X M/I Patient Residence

Pharmacy Service Type:

- All Part D claims will require a valid Pharmacy Service Type =1-8, 99.
- If the is field not submitted or if submitted with non ECL values, reject with U7 – M/I Pharmacy Service Type

Q: Is the recommendation to edit this based on claim date of fill or claim submission date?
A: When guidance is released for a plan year, it is for date of service for that plan year.

CMS Memo:
2014 Requirements for Coding Patient Residence and Pharmacy Service Type on Claims Transactions

In October 2012, CMS issued guidance requiring sponsors to report Patient Residence and Pharmacy Service values on PDE records submitted February 28, 2013 or later. The guidance permits retail pharmacies to default to a Patient Residence of 1 (Home) and a Pharmacy Service Type of 1 (Community/Retail Pharmacy Services) on the claim transaction or leave these fields blank. If the retail pharmacy fails to include a Patient Residence and/or Pharmacy Service Type on the claim, the Part D

sponsor may accept the transaction and report the default values (Patient Residence of 0 (Not specified) and Pharmacy Service Type of 99 (Other)) on the PDE.

Since issuance of the guidance, CMS has engaged in consultation with the industry through NCPDP regarding the requirements for 2014. The following requirements are based on the industry recommendations.

Beginning in 2014, CMS will require that sponsors report valid Patient Residence and Pharmacy Service Type values on all PDEs. Valid Patient Residence codes at this time include:

- 0- Not specified, other patient residence not identified below;
- 1- Home;
- 3- Nursing Facility
- 4- Assisted Living Facility
- 6- Group Home
- 9- Intermediate Care Facility/Mentally Retarded; and
- 11- Hospice

Retail pharmacies and mail order pharmacies must include a valid Patient Residence code on all Part D claims transactions; however if the patient residence is unknown, these pharmacies may default to a Patient Residence of 1 (Home). We expect that LTC pharmacies, home infusion pharmacies and specialty pharmacies, since they deliver to the patient residence, will know with precision the patient residence and, thus this information will be appropriately reported on PDEs associated with claims from these providers.

We expect all pharmacies will know the appropriate (i.e., non-default) pharmacy service code to include on all Part D claims. Valid Pharmacy Service Type codes currently include the following values:

- 1- Community/Retail Pharmacy Services;
- 2- Compounding Pharmacy Services;
- 3- Home Infusion Therapy Provider Services;
- 4- Institutional Pharmacy Services;
- 5- Long Term Care Pharmacy Services;
- 6- Mail Order Pharmacy Services;
- 7- Managed Care Organization Pharmacy Services;
- 8- Specialty Care Pharmacy Services; and
- 99- Other

Claims with a missing or invalid code may be rejected at point-of-sale, if the sponsor has implemented a process to ensure the corrected claim is resubmitted promptly.

(Refer to CMS memo of June 20, 2013: 2014 Requirements for Coding Patient Residence and Pharmacy Service Type on Claims Transactions)

2.20 NX Reject Code 84

Question:

DERF 1097 requested “To identify the situation where an N transaction was not able to be processed because a valid Part D claim could not be found.” When the new values were created was it to not allow 84 at all for Nx or just in these two scenarios?

610	Supplemental Claim Could Not Be Matched To A Claim Covered By Part D Plan	Returned if no Part D claims could be found to match
611	Supplemental Claim Was Matched To A Claim Covered By A Benefit Other Than Part D	Returned when a covered claim is found, but the N transaction was not applied because the claim is not for a Part D Covered Drug. An example of this would be claims paid with Benefit stage qualifiers that are not equal to 1-4

Response:
Reject Code 84=Claim has not been paid/captured is still applicable in certain situations for Nx processing. **(See update below where Reject Code 84 is no longer a recommendation)**.

External Code List, January 2015:
DERF 001212/Emergency ECL 000163. We have clarified existing reject codes and added new N transaction reject codes that are specific to N transactions where reject 84 no longer needs to be made a recommendation.

607	Information Reporting (N1/N3) Transaction Cannot Be Matched To A Claim (B1/B3)	**Telecom. ECL Emergency Implementation Dt. Is July 1, 2Ø15** The associated Billing Transaction (B1/B3) is not found as a match for the submitted Information Reporting Transaction (N1/N3)
610	Information Reporting Transaction (N1/N3) Matched to Reversed or Rejected Claim Submitted Under Part D BIN PCN	**Telecom. ECL Emergency Implementation Dt. Is July 1, 2Ø15** The associated Billing Transaction (B1/B3) was rejected or reversed under the Part D BIN/PCN and therefore no coordination of benefits is required at this time. (Rejected or Reversed Billing transaction found under the Part D BIN/PCN.)
611	Information Reporting Transaction (N1/N3) Was Matched To A Claim Submitted Under The Part D BIN/PCN Paid As Enhanced Or OTC Or By A Benefit Other Than Part D	**Telecom. ECL Emergency Implementation Dt. Is July 1, 2Ø15** The associated Billing Transaction (B1/B3) submitted Under Part D BIN PCN is found, but the Information Reporting Transaction (N1/N3) is not applied because the Billing Transaction is paid as Enhanced or Over the Counter (OTC) or by benefit other than Part D. An Example Of This Would Be Claims Paid With Benefit Stage Qualifier Not Equal To 1 through 4

769	Medicare Part D Paid Claim Found (B1/B3), But Information Reporting Reversal (N2) Cannot Be Matched To An Information Reporting (N1/N3) Transaction in Approved Status; Reversal Not Processed	**Telecom. ECL Emergency Implementation Dt. Is July 1, 2Ø15** The associated Billing Transaction (B1/B3) submitted under Part D BIN PCN is found, however the Information Reporting Transaction (N1/N3) associated was reversed or rejected and doesn't allow the reversed Information Reporting Transaction (N2) to be processed.
770	Medicare Part D Paid Claim (B1/B3) Not Found And Information Reporting Reversal (N2) Cannot Be Matched To An Information Reporting Transaction (N1/N3) in Approved Status; Reversal (N2) Not Processed	**Telecom. ECL Emergency Implementation Dt. Is July 1, 2Ø15** The associated Billing Transaction (B1/B3) submitted or not submitted under Part D BIN PCN, therefore the Information Reporting Transaction (N1/N3) was not associated or processed without an approved status for the following scenarios: 1. When N2 cannot be matched to a N1/N3 Or 2. When N2 is matched to: a) A paid Billing Transaction (B1/B3) not submitted under Part D BIN PCN Or b) Any reversed or rejected Billing Transaction (B1/B3) And c) Corresponding Information Reporting Transaction (N1/N3) found in reversed or rejected status or not found; Reversal Not Processed
820	Information Reporting Transaction (N1/N3) Matched To Reversed Or Rejected Claim Not Submitted Under Part D BIN PCN	**Telecom. ECL Emergency Implementation Dt. Is July 1, 2Ø15** The associated Billing Transaction (B1/B3) not submitted under Part D BIN PCN is reversed or rejected, however, the Information Reporting Transaction (N1/N3) is matched but cannot be processed.
821	Information Reporting (N1/N3) Transaction Matched To Paid Claim Not Submitted Under Part D BIN PCN	**Telecom. ECL Emergency Implementation Dt. Is July 1, 2Ø15** The associated Billing Transaction (B1/B3) not submitted under Part D BIN PCN is paid, however, the Information Reporting Transaction (N1/N3) is matched but cannot be processed.

2.21 Benefit Stage Qualifiers Returned with a Gap between Values

Question (From the WG1 Information Reporting Task Group):

What are the situations where a beneficiary's Benefit Stage Qualifiers might be returned with a gap between values (e.g. claim with non-adjacent Benefit Stage Qualifier 1 and 3, or 1 and 4, or 2 and 4)

Response:
This happens in two situations:

1. When a claim is reversed by the pharmacy that is in a prior phase. The next claim submitted will fill the hole left by the reversed claim first and continue to process under the next open phase once the prior phase is satisfied.
2. When the processor is restacking claims (reconciliation) and a claim is submitted that fills in the phase amount.

2.22 Recognition and Coverage of Medical Foods

Question:
Can medical foods be considered part of step therapy or will there be a separate category for recognition?

CMS Response:
Re: CMS letter to Plan Sponsors dated August 21, 2012:
"The memorandum makes clear CMS' view that Theraproxen-90™ is not a Part D drug. We are sharing this information with you because you inquired or we are aware that recent administrative law judge (ALJ) decisions involving enrollees in your plan(s) (or prior plans your organization has since acquired) have found Theraproxen-90™ to meet the definition of a Part D drug. While the CMS memorandum itself does not change the effect of the specific ALJ decisions, we thought that it was important for you to know that in our view Theraproxen-90™, and similar unapproved products, are not Part D drugs."

2.23 Reject Codes and Messaging Returned with Hospice/ESRD Claims

Question:
Are there standardized reject codes and messaging that should be used by the Medicare Part D processors when the claim meets the Medicare Part D versus Hospice/Medicare A and Medicare Part D versus ESRD Facility Bundled Payment situations as outlined in the 2014 Draft Call letter?

Response:
As published in the July 2013 Emergency Telecommunication External Code List Value Addendum, plans should return

- A3 This Product May Be Covered Under Hospice – Medicare A
- A4 This Product May Be Covered Under The Medicare- B Bundled Payment To An ESRD Dialysis Facility

These reject codes would be in combination with reject code 569- Provide notice Medicare Prescription Drug Coverage and Your Rights and 75 – Prior Authorization Required, when the claim meets the situations as defined in the 2014 Medicare D Draft Call Letter.

2.24 Multi-Ingredient Compounds that Contain a CII Ingredient

Question:
Do the CII incremental fill editing requirements apply to multi-ingredient compounds that contain a CII ingredient? There is not a quantity prescribed field at the ingredient level in the compound segment, so it appears the only alternative is to compare the quantity prescribed to the quantity dispensed in the clam segment. What does the pharmacy submit in the claim-level quantity dispensed vs. quantity prescribed fields for a multi-ingredient compound? Would the comparison of these two fields be valid for CII incremental fill editing of a compound?

Response:
The following language has been added to the SNIP guidance document that will be released when the regulation/rule is published: In the case of a multi-ingredient compound containing one or more CII ingredients, in which the entire dispensing is considered to be CII under federal or state law, the quantity dispensed and quantity prescribed logic at the claim level will apply for purposes of determining incremental fill.

Example: If the Quantity Prescribed (Field 460-ET) is 100 and the Quantity Dispensed (Field 442-ET) is 50, the dispensing is considered to be incremental.

2.25 Published FAQs Related to LTC Short Cycle Dispensing

Question:
I would like to have the WG9 FAQ group review the FAQ responses that have been published related to long-term care short cycle dispensing prorated cost-sharing to determine if any updates need to be made for 2014. In the 2014 Call Letter, CMS provides additional guidance on how daily cost sharing should work, and some of these responses may be dated and applicable for only CY2013.

Response:
Recommended updates for Questions 2.4 and 2.5 were reviewed and approved by WG9 during the November Work Group meeting. Question 2.9 in this document will not be updated and will be reopened for further review pending a CMS response.

2.26 DMR Claims for Patient Residence and Pharmacy Service Type

Question:
What are the defaults on the PDE for DMR claims for Patient Residence and Pharmacy Service type since they are required now on all PDE's but those fields are not in the DMR form for the member submission?

CMS Response:

- If the residence of the patient is not known through means other than the claim, default to Home.
- If the pharmacy service type is not known through means other than the claim, default to Retail (i.e. the processor/plan cannot determine through NPI alone the service type of the pharmacy).

Note: The sponsor must explore other sources of information before automatically defaulting.

2.27 Reject Code for FDA Non-Matched Drugs

Question:
When rejecting claims for NDC's not on the NSDE file, what is the appropriate reject code? The information below came from WG1's FAQ Task Group in **2009**.

Fifty – Reject Code FDA non-matched drugs – WG Reportable Only
Is there a consistent NCPDP Reject code and message that can be used by all processors to identify those Medicare D claims rejecting due to the product service ID being an FDA Non-matched NDC?

09/08/2009 Discussion: 01/01/2010 implementation for Part D. Request a different reject code and message than "not on formulary". Discussion of using existing code: "54" (Non-matched Product/Service ID Number). Text of "NDC not FDA listed". Discussion of using a new reject code in D.0 and using the A5, A6 codified message for the 5.1 environment. We would need this code in D.0

as well. Timing is a concern for the 01/01/2010 date. A new reject code can be added in the future as a DERF/ECL. There is a concern that states may follow CMS direction. (Code 70 is too general.)

Response:
Recommend that for short term "54" (Non-matched Product/Service ID Number). Text of "Product Identifier not FDA/NSDE listed" be sent in the message.

DERF 001156/Emergency ECL 000149 requesting a new Reject Code was submitted and approved at the NCPDP November 2013 Work Group meetings. The new Reject Code definition is "Product Identifier not FDA/NSDE Listed." The emergency implementation date is July 2014.

2.28 How to Populate PDE: EGWP with TrOOP Qualified N Transaction

Question:
What would the listed PDE field values be in the following scenario after a TrOOP Qualified N Transaction is received and applied to the claim? Where Value = 'x.xx', we are looking for NCPDPs opinion on what the values would be in the above scenario.

Response:

Scenario #1 – Qualified N Transaction

- Member is enrolled in an EGWP plan and is non-LICS (to keep the example more simplistic). Member is in the Initial Coverage Phase.
    - Defined Standard Patient Pay Amount (PPA) = $25.00
    - EGWP PPA = $50.00
    - Incoming TrOOP Qualified N Transaction PPA = $40.00

- PDE field values for original claim ***before*** application of TrOOP Qualified N Transaction:

PDE Fields	**Value**
Patient Pay Amount	$50.00
Other TrOOP Amount	$0.00
Patient Liability Reduction due to Other Payer (PLRO) Amount	$-25.00

- PDE field values for claim ***after*** application of TrOOP Qualified N Transaction:

PDE Fields	**Value**
Patient Pay Amount	$40.00
Other TrOOP Amount	$10.00
Patient Liability Reduction due to Other Payer (PLRO) Amount	$-25.00

Scenario #2 – Non-Qualified N Transaction

- Member is enrolled in an EGWP plan and is non-LICS (to keep the example more simplistic). Member is in the Initial Coverage Phase.
    - Defined Standard Patient Pay Amount (PPA) = $25.00
    - EGWP PPA = $50.00
    - Incoming Non-Qualified N Transaction PPA = $40.00
- PDE field values for original claim ***before*** application of Non-Qualified N Transaction:

PDE Fields	**Value**
Patient Pay Amount	$50.00
Other TrOOP Amount	$0.00

Patient Liability Reduction due to Other Payer (PLRO) Amount	$-25.00

- PDE field values for claim ***after*** application of Non-Qualified N Transaction:

PDE Fields	**Value**
Patient Pay Amount	$40.00
Other TrOOP Amount	$0.00
Patient Liability Reduction due to Other Payer (PLRO) Amount	$-15.00

2.29 PDE Reporting Coverage Year 2008 - Disenrollment

Question:

CMS issued the following memo for the 2008 PDE Reopening, see attached. I have talked to two other very large plans and there seems to be some confusion about this request from CMS. The memo says that if member is retroactively disenrolled from Medicare Part D that any accepted PDEs need to be reversed for 2008 and for all future years also. CMS then gave a list of members that needed to have their 2008 PDEs deleted and the list included members that were still Part D eligible but instead had been retroactively disenrolled from our plan, but still Part D eligible. At the time the claim was processed the member was eligible with our plan and the PDE was accepted. My specific questions are:

1. The wording of the memo makes it sound like it is just for members not Part D eligible, but CMS' 2008 list of deletes required included Part D eligible members. What was the intent of CMS?

2. If the intent is to have PDEs deleted where members are still Part D eligible, but retro disenrolled to another plan, then the plans need to discuss how to recoup the costs from the subsequent plan. Claims seem too old to ask Pharmacy to reverse so what do the plans suggest, a manual P2P?

Excerpt:
"CMS has performed analysis of accepted PDE data for beneficiaries that were retroactively disenrolled from Medicare Part D and that analysis revealed that some sponsors failed to delete PDEs associated with these beneficiaries. If a beneficiary is not enrolled in Part D, the PDEs with dates of service after the disenrollment date must be deleted because the costs associated with these PDEs are not Part D costs. CMS expects sponsors to delete these PDEs by the reopening cutoff deadline. CMS will remove any PDEs from the reconciliation file that the sponsor fails to delete by the deadline. This issue is not limited to benefit year 2008. CMS expects sponsors to evaluate their PDE data for all benefit years and delete any PDEs with dates of service after the disenrollment date. In future reconciliations and reopenings, CMS will remove these PDEs if the sponsor fails to delete them."

Response:

- Beneficiary not necessarily disenrolled from Part D. Plan was notified because the beneficiary was disenrolled from their plan. Plan did not have the beneficiary. Beneficiary was retroactively disenrolled.
- No method today to do plan to plan recoupment in this situation. If you are getting PDEs deleted or retroactive disenrollments; you potentially also received beneficiaries that were moved into your plan as a result of the disenrollments.

2.30 Medicaid Subrogation Claims/PDE

Question:

How should Medicaid Subrogation claims be handled regarding the Pharmacy Service Type and Patient Residence being required on PDE's?

CMS Response:
Sponsors that submit a PDE using data from a Medicaid Subrogation claim should populate the non-standard format code field with a 'C' to indicate that the source of the data is a coordination of benefits (COB) claim. For PDEs with dates of service on or after February 28, 2013, edits associated with Patient Residence, Pharmacy Service Type, and SCC will be bypassed if the non-standard format code field is populated with 'C.' The edit is setup such that if the non-standard format code = 'C' and there are SPACES in patient resident, pharmacy service type, and/or the SCC fields, the PDE does not issue edits 835 (pharmacy service type is missing or invalid), 836 (patient resident code is missing or invalid), and/or 837 (the SSC is invalid). (Note that SPACES is a valid value for the SCC, so the reject does not include the "missing" language.)

Also see HPMS Memo: Medicaid Subrogation Claims and Upcoming Change to the Drug Data Processing System, February 12, 2013.

2.31 PDE Rejects – Timestamp Before Fill Date

Question:
We have east coast clients and pharmacies that submit claims from 11:00 – 11:59 PM, that get a fill date on the next day, but the timestamp for submission is the current date Central Time. These reject on PDE because the timestamp is before the fill date. How are other processors handling this issue?

Response:
The timestamp should be reported in Greenwich Mean Time. GMT is CST + 6 hours always being ahead of our time zones. I think if that is the case, then the adjudication timestamp in GMT would be ahead of the east coast timestamp avoiding this issue. So, in our example where a claim is submitted from a pharmacy at 12:02 AM EST on 3/28, it would translate to be 05:02 AM GMT on 3/28 instead of 11:02 PM CST on 3/27.

Note: Subsequent to the response the task group identified that even with this logic, Guam would continue to have problems. CMS requested specific PDE examples showing PDEs that have rejected for this issue. None have been provided; therefore we will close this question. If specifics examples are received, we will create a new question for CMS review.

2.32 Vaccine Administration Fee

Question:
One item noted in the call letter is throughout the document it is stated that dispense fee is shared in the Gap, which we understand as that was implemented for 2013. However, Vaccine Admin fee is still not referenced fully in the 2014 guidance. What is the member's responsibility for this fee? Is it also 47.5% and treated in the same fashion as Dispense Fee, we are assuming so but it is not addressed? They are recognizing that Plan is 52.5% of dispense fee but again don't mention Vaccine Fee. All they state is to recognize in other phases but what if I am not a straddle claim – how do we handle?

CMS Response:
In regards to the Vaccine Administration fee, the 2013 Advance Notice and Call letter defines the policy on how beneficiary and plan cost-sharing is determined for dispensing fees and vaccine administration fees. The 2014 PDE Reporting and Calculations Guidance is not intended to provide examples on all Part D policies and the guidance does not change the policy announced in the 2013 Advance Notice and Call

Letter. The guidance provides some examples to demonstrate how to report PDEs based upon the policies that were announced in the 2014 Advance Notice and Call letter. The guidance is to be used as a tool along with other documents instructing sponsors on PDE reporting.

2.33 Out Of Network Differential And The Discount

Question:

All PDE's with a network differential since 2011 are rejecting because CMS does not know that amount to subtract prior to calculating the discount on their side. The discount should be computed discounted on contracted rates and differential should be added in later, and these PDE's are rejecting with an 870. We recommend a new field to populate the value for this so that CMS can use the information in the calculations.

CMS Response:

CMS Response: This section was included in the 11/01/2013 guidance: *November 2013 Updates to the Drug Data Processing System*

Reported Gap Discount Amount Editing for Out-of-Network PDEs:

"The Network Differential costs applied to PDEs where the beneficiary visited an out-of-network pharmacy cannot be part of the eligible costs for the gap discount. DDPS has modified the coverage gap discount calculation logic for out-of-network PDEs. This change applies to PDEs with DOS on and after January 1, 2011. CMS will identify out-of-network PDEs by the Pricing Exception Code of "O" for out-of-network pharmacy. Sponsors may resubmit any 870 rejected PDEs that meet this criteria beginning on November 10, 2013. As a result of the change in the gap discount editing logic for out-of-network PDEs, the following edit codes may apply:

- Reject edit code 871: Reported Gap Discount exceeds amount estimated by CMS +/- 0.05.
- Informational edit code 876: Reported Gap Discount (minus rounding error) is less than the discount amount estimated by CMS, provided that NPP includes supplemental benefits in the Coverage Gap. This PDE may be subject to additional scrutiny.
- Informational edit code 877: Reported Gap Discount +/- rounding error equals the discount amount estimated by CMS, provided that NPP reports supplemental benefits in other benefit phases excluding the coverage gap. This PDE may be subject to additional scrutiny."

Reject Code 871 will be updated in 2014 to remove the negative sign: Reject edit code 871: Reported Gap Discount exceeds amount estimated by CMS +/- 0.05.

This is an incorrect description and is not currently impacting the editing. With the reject being removed from 870 when the discount is less than the CMS calculated discount and the Pricing Exception Code of "O" is submitted, Network Differential claims will pass this edit. All other edits listed in the November guidance 876, 877, and 878 will be informational edits and will not cause rejects.

2.34 Cost Component Liability (2014 Call Letter)

Question:

We are looking at the cost component section on the Call Letter. We are looking to get confirmation if other PBMs are interpreting this guidance the same as we are. That claims must not be adjudicated as follows:

Currently when a member falls squarely in the initial coverage phase with the CMS standard benefit the member pays 25% of the total drug cost. See example:

Total drug cost is: 107.00

Ingredient cost: 100
Sales tax: 5
Dispense Fee: 2

Member pay: 107 x .25=26.75

In the CMS 2014 Call letter CMS States that the plan and beneficiary liability for each cost component of the negotiated price be calculated proportional to plan and beneficiary liability for the entire negotiated price in all phases of the benefit. For example, if a beneficiary has a 25% coinsurance on a claim in the initial coverage phase with a $100 negotiated price that includes a $2 dispensing fee and $5 Sales tax, the beneficiary would be responsible for 25% of the ingredient cost, 25% of the dispensing fee and 25% of the sales tax and the plan would be responsible for the remainder of each cost component.

The reasons for doing so included ensuring a level playing field, uniform treatment of beneficiary liability across all Part D plans, and consistency of benefit administration across all phases of the benefit. For example, if a claim is adjusted post point of sale to eliminate one price component, such as sales tax, there would be on consistent basis for reimbursing the beneficiary.

We were thinking that CMS expects plans to adjudicate claims as:

Ingredient cost: 100 x .25 = 25
Sales tax: 5 x .25= 1.25
Dispensing fee 2 x .25 =.50
Member pay: 25 + 1.25 + .50 =26.75

If this claim would be reversed and reprocessed post point of sale (out of cycle) and no longer contained the sales tax the member should be reimbursed what they paid for the sales tax which is 1.25. We are not sure why a plan would need to break it down to the detail listed above to do this. If you look at how the claims is processed today by using the total it would work out with the same refund happening.

Original claim:
Ingredient cost: 100
Sales tax: 5
Dispense Fee: 2
Member pay 107 x .25=26.75

New claim with no sales tax:
Ingredient cost: 100
Dispense Fee: 2
Member pay 102 x .25=25.50 Member refund would be 26.75-25.50 = 1.25

CMS allows plans to handle cost components in two ways; this particular question addresses the aggregate method only. The alternative method is to apply percentages at the cost component level. Each pricing element of the total claim cost will be calculated before any member or plan liability is calculated.

CMS Response regarding beneficiary and plan cost component liability:

1. The denominator in determining the portion of beneficiary liability is the total claim cost from all payers.
2. The beneficiary liability percentage needs to be based upon what the beneficiary actually paid, NOT all TrOOP amounts.

2.35 Charity Payments And N Transactions

Question:

We have a client whose members get part of their prescriptions paid for by a charity. This charity does not have a BIN or PCN, and there is no cardholder ID. What is the correct process to account for these payments in the N transactions, as they are TrOOP eligible? If you have a standard process that is used, could you please share that with us?

CMS Response:

If a charity chooses not to participate in eligibility data-sharing with CMS and the real-time transaction-based COB process, the sponsor is not required to coordinate benefits with the charity even if the sponsor receives notice from the beneficiary that the charity is making payments on the member's behalf. The sponsor should notify the beneficiary that claims adjustments resulting in refunds will be sent to the member and the beneficiary should work directly with the charity to refund the charity's portion.

2.36 2014 Retroactive Hospice Claims

Question:

Will CMS expect us, for 2014, on retroactive Hospice claims, to have the pharmacy reverse the claim and take the monies back from the pharmacy, as outlined in the 2014 Call Letter, or will they expect that the Pharmacy not be involved in the reversal and the Sponsor is not to take the monies back from the pharmacies, as outlined in the October 30th Clarification of Recovery of Part D Payment for Pain Medications for Beneficiaries Enrolled in Hospice guidance?

It would seem to me that if they didn't want the pharmacies impacted on the recovery of payment for 2011 and 2012 that they would carry that forward for future retro Hospice claims.

CMS Response:

Clarified guidance will be forthcoming. In the interim, plans should follow the October 30 memo guidance in handling recoveries for at least the 2011 and 2012 claims for pain medications and plan for extending the approach into 2014.

Note: The task group's interpretation is that recoupment should come from the hospice provider and continue with the prior authorization of the four drug categories until subsequent guidance is released.

This question addresses the Part D component only – an additional question will be submitted to address downstream impact to supplemental payers and pharmacies.

2.37 Subset of PDEs for EGWPs

Question:

Should payers submit PDEs if they have not coded for the new EGWP guidance or should they hold them until coding is complete?

CMS Response:
For the subset of PDEs for EGWPs, sponsors can withhold submission until the coding is completed. We expect the sponsors to continue to follow PDE submission guidelines for all other PDEs (non-EGWP PDEs). CMS will be monitoring submissions and if there is a significant delay in submitting PDEs for EGWPs, CMS will reach out to sponsors and may issue compliance actions.

2.38 Medicare/Medicaid Demonstration Plans

Question:
Can Medicare/Medicaid demonstration plans (MMP) be submitted with the Part D BIN/PCN? If so, should a Benefit Stage Qualifier (BSQ) be returned when it pays under the Medicaid portion of the MMP similar to the BSQ 50 when the claim pays under the MA portion of a MAPD plan?

Task Group Response:
In order to identify these claims that are submitted to a Part D BIN/PCN but paid under the Medicaid component, DERF 001173/Emergency ECL 000153 was approved with modification at the February Workgroup. The New Benefit stage qualifier will be available for use as of October 2014. Additionally the 4Rx Document has been updated to include the new BSQ and posted on NCPDP's website: http://www.ncpdp.org/Resources/Guidance-Documents.

1. Are these plans subject to the same Part D rules as MAPD, EGWP and PDPs, including the unique 4Rx requirement? Processors are unclear whether these should have unique BIN/PCNs etc.
   CMS Response:
   Yes.

2. Are these plans allowed to have Medicaid contributions to the copays? For example, if the Part D component has a $30 copay can the Medicaid component contribute or reduce the Part D copay?
   CMS Response:
   No, that is prohibited by statute. Nothing about the demonstration changes the statutory prohibition on using Medicaid funds to pay for Part D drugs.

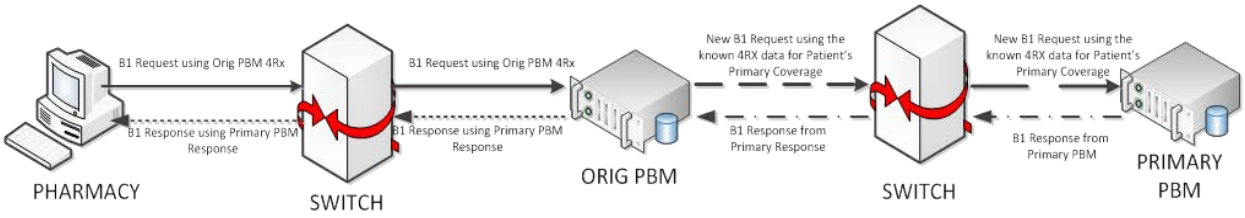
3. Are states allowed to apply specific requirements to these claims because of the Medicaid component? For example, some states mandate that a pharmacy can't turn a beneficiary away without their medication because they can't pay the Medicaid copay. The pharmacies must waive the copay. Are they allowed to require the same for these Demo plans?
   CMS Response:
   That would only be permissible for Medicaid covered drugs. Part D drugs will be subject to the same rules as under the Part D program.

2.39 4Rx Requirements on Part D Transactions

Question:
Is the following scenario compliant for 4Rx requirements on Part D transactions: There are instances where PBMs (Discount, Coupon, 340B, etc.) have knowledge on file that cardholders in a claim have other Primary coverage (Part D coverage) without performing NCPDP E1 transactions? Rather than rejecting to the pharmacy with a free text message of other coverage existing, the PBM would suspend in real-time the original claim, create a separate claim using the 4Rx data for the primary PBM and sends a request, via a switch, to be routed to the Primary PBM. As the Primary PBM responds, the original PBM uses the information in that response and completes the processing of the original submitted sent claim and responds to the pharmacy.

Process flow:

- Pharmacy submits an NCPDP B1 request to a PBM
- PBM has information on file that the cardholder has primary coverage (either commercial or Part D)
- PBM holds that original request in a real time suspended mode and creates a new NCPDP B1 request using the 4Rx data for the Primary PBM that they have on file for the member
- PBM submits the newly created claim to a switch
- Switch routes to the Primary PBM
- Primary PBM responds
- Switch returns Primary PBM response to original PBM
- Original PBM completes processing of the original B1 submitted based on the information returned from the Primary PBM and responds to the Pharmacy



Two scenarios where this is or has been coded to happen:

1. Where the plan has changed processors and the pharmacy is submitting the claim to the new processor 4Rx, but the claim is being paid under and by the old processor. This is being done to reduce rejects at POS.
2. Where the pharmacy is submitting the claim to a 340B processor, who determines that they should bill the Part D plan first and does so in a similar manner described above.

In these examples, the pharmacy is not aware that a different BIN-PCN has paid; the pharmacy transaction does not match what would be returned for the DOS on an E1. The 835 payment will contain the old processor PBM, yet the submitted transaction contains the new processor PBM.

CMS Response:
Methods that route the claim to a different payer or processor behind the scenes is not consistent with CMS policy requiring that claims be routed to the 4Rx submitted to CMS and returned in an E1 transaction for that date of service.

- In scenario #1, the claim is being submitted with 4Rx that is not active in the CMS system for the DOS.
- In scenario #2, the claim is being initially routed to a BIN/PCN that not a Part D BIN/PCN and behind the scenes is being rerouted to the Part D BIN/PCN, therefore the claim submitted by the pharmacy does not contain the Part D 4Rx and does not match the E1.

The scenarios outlined above are **inconsistent** with the CMS and NCPDP jointly developed COB process which REQUIRES consistent use of the same unique identifier by all participants in the COB process. We recommend adding language to the NCPDP 4Rx whitepaper clarifying this.

Note: The *NCPDP Recommendations for Effective 4RX Usage in Medicare Part D Processing* document was updated (including new Benefit Stage Qualifier 63) and is available on the NCPDP website: http://www.ncpdp.org/Resources.

2.40 Prescriber Date of Death Information

Question:

Is there another central source of date-of-death information that is publicly available that Plan Sponsors and their delegated entities could utilize to ensure that their records on prescriber's date-of-death are as current as the data CMS utilizes?

Task Group Response:

No, there is not a publicly available source for prescriber date of death information. The NPI active status is being used for Medicare Part D edits as opposed to the practitioner's death date. There is a one year grace period post the inactivation date of the NPI. Payers and pharmacies are not reporting this as a recent issue.

CMS Info: DDPS edit was put in place May 6, 2013 for the 1 year leeway (with retroactive of January 1, 2012). DDPS shall reject (edit 834) PDEs submitted with a DOS on or after January 1, 2012 with Prescriber ID Qualifier = '01' if the Prescriber ID is found in the NPPES NPI database and the DOS is more than one year after the NPI Deactivation Date, and the NPI Reactivation Date is not populated. As of February 9, 2014, edit 834 became an informational edit.

A copy of the Social Security Death Master File can be purchased through the National Technical Information Service (NTIS). Social Security does not sell the document directly. There are limitations; please check: Fact Sheet: Change to the Public Death Master File.

2.41 NPRM: Disaster Edits and SCC 13

Question:

The NPRM included a section on disaster recovery and the use of SCC 13 for emergencies that are not categorized as national disasters. I did not see this section addressed within the NCPDP comment letter. We may need to be prepared to develop an FAQ, based on what is released in the final rule.

Below are just some thoughts. Part D processors and LTC pharmacies may be the best source of information.

- What documentation is required to allow the use of SCC 13 (appropriate sources)
- Do we need to consider creating a new field that would categorize the disaster that warrants a RTS override, or potentially create additional SCC values which describe specific disaster situations?
- Or, does the Part D plan sponsor need to develop a PA process, when SCC 13 is submitted, and there is no known national disaster associated to the patient zip code area?
- CMS also mentioned the Part D plan sponsor(s) allowing for RTS overrides for all patients within the facility, once the facility communicates the disaster.
    - How would this work if there is not a facility file?
    - At a minimum, should the claim be submitted with SCC 13?

CODE	DESCRIPTION
13	Payer-Recognized Emergency/Disaster Assistance Request - The pharmacist is indicating that an override is needed based on an emergency/disaster situation recognized by the payer.

Task Group Response:
CMS is not finalizing this proposal. "There was simply not a consensus regarding any aspect of the proposed regulation to sufficiently inform a decision to finalize. The current guidance will remain in place (found in Prescription Drug Benefit Manual, Chapter 5, Benefits and Beneficiary Protections, Section 50.12)." There was not enough support from Task Group Participants to make a proactive recommendation for possible future guidance.

2.42 Payment Resolution Period

Regarding section 50.14.4 of Chapter 14 and this paragraph in particular:

"Therefore, sponsors should implement processes to handle payment resolution directly with other payers, beneficiaries, and others who are holding receivables on the beneficiaries' behalf. Sponsors may not restrict the payment resolution process by imposing timely filing requirements on these other parties that are more restrictive than the timeframe required in Federal regulations at 42 CFR 423.466(b). This provision requires Part D sponsors to coordinate benefits with SPAPs and other entities providing prescription drug coverage, beneficiaries and others paying on the beneficiaries' behalf for a period not to exceed 3 years from the date on which the prescription for a covered Part D drug was filled."

Does this guidance (about the 3-year period) apply to the retro-active claim adjustment - the Med D reprocessing, or only to the initial request for payment (i.e. original claim submission or change in the order of payment)? Since, in compliance with CMS, we reprocess back at least to 2008, but, if reimbursement of SPAPs (and ADAPs) from the claim adjustment should not exceed the 3 year period, I can think of a couple of complications in the process.

For example, we reprocess today using Med D claim re-adjudication, and today we are within the 3-year time frame, we determined SPAP is to be reimbursed and issue a check and reflect that difference in the PDE's Other TrOOP. Then, at some later time, we have to reprocess same member/claim again and calculate that the amount of the check should have been smaller - but now, we are beyond the 3-year period, thus would have to collect the difference from the member. Would that be appropriate? And, obviously, the results could be opposite - initially issued a collection to SPAP, then reimburse the member for the difference produced by a subsequent reprocessing.

§ 423.466 Timeframes for coordination of benefits.
(b) Coordination of benefits. Part D sponsors must coordinate benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf for a period not to exceed 3 years from the date on which the prescription for a covered Part D drug was filled.

Questions:

1. What is the expectation from CMS for Part D sponsors to coordinate outside of the 3-year period for claims in which the Part D sponsor received the claim after the 3-year period?

   Example: A Part D beneficiary's claim is processed by a payer primary to Medicare Part D and later it is determined this payer should not have paid on the claim or paid in the same way. Medicare Part D and a supplemental payer are attached to the same member. What is the Part D sponsor's obligation to the beneficiary and supplemental payer in this example?

2. What is the expectation from CMS for Part D sponsors to coordinate outside of the 3 year period for claims in which the Part D sponsor received the claim within the 3-year period but the adjustment is being made after?

   Example: A Part D sponsor receives a LICS adjustment in 2014 backwards to 2008 and a supplemental payer (SPAP/ADAP) is attached where a refund is due to the beneficiary, does the 3-year limit prohibit the Part D sponsor from reimbursing the supplemental payer, beneficiary or others?

   Example: We reprocess today using Med D claim re-adjudication, and today we are within the 3-year time frame. We determine SPAP is to be reimbursed and issue a check and reflect that difference in the PDE's Other TrOOP. Then, at some later time, we have to reprocess same member/claim again and calculate that the amount of the check should have been smaller - but now, we are beyond the 3-year period, thus would have to collect the difference from the member. Would that be appropriate? And, obviously, the results could be opposite - initially issued a collection to SPAP, then reimburse the member for the difference produced by a subsequent reprocessing.

   CMS Response for 1 & 2: The regulation, as stated below, only requires that Part D sponsors coordinate benefits for a period not to exceed 36 months.

   § 423.466 Timeframes for coordination of benefits.
   (a) Retroactive claims adjustments, underpayment refunds, and overpayment recoveries. Whenever a sponsor receives information that necessitates a retroactive claims adjustment, the sponsor must process the adjustment and issue refunds or recovery notices within 45 days of the sponsor's receipt of complete information regarding claims adjustment.
   (b) Coordination of benefits. Part D sponsors must coordinate benefits with SPAPs, other entities providing prescription drug coverage, beneficiaries, and others paying on the beneficiaries' behalf for a period not to exceed 3 years from the date on which the prescription for a covered Part D drug was filled.

3. The requirements in Chapter 14 have always indicated that Part D sponsors must coordinate benefits with supplemental payers within 36 months of the date of service. The COB contractor, however, can only hold 27 months of OHI data in certain situations. This is causing beneficiaries a financial impact. How is CMS addressing this with their COB contractor? What is the Part D sponsor's obligation in this scenario?

   CMS Response: CMS is aware of this gap. At this point in time there is no project to address this issue. This generally occurs in the situation where the supplemental payer updates their data annually as opposed to an open ended termination date. Plans need to coordinate with the information they have available from the COBC. An issue was identified with deceased beneficiaries and the fact that their OHI is falling off when the beneficiary is deceased. Is it falling off because the supplemental payer isn't sending it any longer?

4. If CMS were to modify the requirements of 36-months to coordinate benefits this would have a ripple effect to supplemental payers and beneficiaries as well as Part D sponsors. Some of this data may not be able to be sent to CMS due to PBM changes. We would need CMS to work with NCPDP on data sharing agreements and modifications to CMS guidance.

CMS Response: No change in guidance is anticipated.

2.43 Medicare Secondary Payer (MSP) Claims with PLRO Greater Than Zero

Question:

For Medicare Secondary Payer (MSP) claims that have MSP that have a PLRO greater than zero due to primary payer, should all financial fields including PLRO be submitted as a zero on the PDE?

The dispensing event happened, the event was in error (i.e., the drug should not have been dispensed), a**nd the drug is a Part D drug**. In this situation, recoup the cost for the drug and submit a $0.00 PDE. Adjust the accumulators since the event should not have occurred. For example, a drug was prescribed by an excluded provider and the drug was dispensed.	C3 - Adjust Accum Claim Zero Dollar PDE

Task Group Response:

Yes, all financial fields including the PLRO should be set to zero.

2.44 Indian Health as a Secondary Insurance

Question:

In 2015 we are going to be dealing with a Medicare plan that will have members with Indian Health insurance as a secondary insurance. I see that this is the same Insurance Type Code of "T" as other Government programs. The difference being that in 2011 the Indian Health Service is Troop eligible and the other programs are not. I have looked through the NCPDP notes and I am not seeing this topic anywhere.

Typically the insurance type code determines if the secondary payer is troop eligible or not. In this case the same type code is used for both eligible and non-eligible payers. How are other Medicare plans distinguishing between the two? Are they having to use a combination of Type code and Insurance name? If so will the name always be Indian Health Service?

I have heard that nothing comes over on the OHI file for IHS members. Also, that the pharmacy never submits a COB claim for these members so there would be no N Transaction. They are putting an indicator on the submitted claim showing that it is an IHS claim. Based on that indicator that plan is to move the Medicare D copay dollars to the Other Troop field on the PDE. Is this accurate? If so, what indicator would that be and in which field. We have reviewed payer sheets and are not finding this information.

Task Group Response:

Claims paid for by Indian Health Services are typically not considered a supplemental carrier and as far as we know today OHI is not provided to CMS. As such, the only way you know it is being covered by IHS is by pharmacy/claims identification.

2.45 Data Sharing of Records/Actions

Questions:

There isn't a file/process/standard for plans to exchange POS edits and case management for overutilization of drugs but CMS does require this in 2013. How do you transmit the information and make it available to subsequent (or prior) plans? If a member is identified as an over-utilizer what can a

plan do to manage that beneficiary? Should we put together an industry best practice/recommendation?

Task Group Response:
A sub-task group was formed to identify the critical data elements necessary to support the communication that needs to occur between Part D sponsors. This included the offer of information, the acceptance of that offer and the transfer of the relevant overutilization information. The sub-task group wrote and published a white paper "NCPDP Recommendations for a Standardized Process to Share Medicare Part D Opioid Overutilization Data Between Sponsors, Version 1.Ø" and the accompanying Standardized Overutilization Data Sharing Template.

In a CMS memo dated January 17, 2014, subsequent guidance was provided on the Medicare Part D Overutilization Monitoring System. CMS is now providing sponsors with a quarterly Overutilization Monitoring Package and expects a new sponsor to use the appropriate overutilization contact to initiate communication and request the applicable overutilization records from the former sponsor within two weeks of receiving a relevant Transaction Reply Report notice of enrollment in a new plan.

Based on these changes, the sub-task group wrote "NCPDP Recommendations for a Standardized Process to Share Medicare Part D Overutilization Data Between Sponsors, Version 2.Ø" The Standardized Overutilization Data Sharing template was also updated to ensure consistency with requests and responses for data sharing. The documents have been approved by NCPDP and will be published on the website.

2.46 PDE Calculations

Question:

1. Straddle Claim Cost Share Calculations – On a claim straddling two benefit phases where the first phase has a copayment less than the amount remaining to meet the limit of the phase, should Part D plans cap the starting phase copayment at the amount remaining to meet the limit of the phase or apply the 'lesser of' test and charge the full copayment of the starting level as long as the total patient pay for all benefit phases does not exceed the full negotiated price of the claim?
    - Does the same rule apply regardless of the cost share of the ending phase (e.g., copayment-to-copayment straddle claim vs. copayment-to-coinsurance straddle claim)?
    - Does the same rule apply regardless of levels being straddled (e.g., Initial Coverage Period to Coverage Gap vs. Gap to Catastrophic)?
    - The objective of these questions is to ensure that Part D processors are following consistent rules for computing cost share on a straddle claim. Since processors may have interpreted previous guidance differently, will the clarification guidance provided by CMS apply to dates of fill 1/1/2013 and greater, or will prior year claims need to be adjusted?

    Examples to illustrate question 1 from 12/7/2012 CMS memo titled "Prescription Drug Event (PDE) Reporting for Coverage Gap Phase Claims with Dates of Service (DOS) beginning in 2013."

    Example 11 shows a situation of a $150 claim straddling the Coverage Gap and Catastrophic phases, and both phases have a copayment. $30 of the claim cost falls in Gap; $120 of the claim cost falls in Catastrophic; the Gap phase has a $35 copayment; the Catastrophic phase has a $6.60 copayment. This example shows that the beneficiary pays only a $30 Gap copayment *(the amount remaining to meet the out-of-pocket threshold)*. Should the $35 Gap copayment apply since it is less than the full

negotiated price of the claim, or should the Gap copayment be capped at the amount remaining to meet the TrOOP limit?

Example 6 is a $202 claim processed with $1 left to meet the Initial Coverage limit. The lesser of test is applied at the claim level by first computing a $30 Initial Coverage Period copayment and a $195.47 Gap coinsurance (97.5% of ingredient cost plus tax in Gap and 47.5% of the dispensing fee in Gap). The sum of these amounts is $225.47, which exceeds the full negotiated cost of $202. Because the lesser of logic applies, the beneficiary cost share in Initial Coverage is reduced to $1.

What would the result of example 6 be if there was $29 left to meet the Initial Coverage limit? In that case, the lesser of logic would compute a $30 Initial Coverage copayment and a $168.67 Gap coinsurance (97.5% of the $173 ingredient cost that falls in Gap). The sum of these two amounts is $198.67, which is less than the full negotiated cost of $202. In this situation, would the full $30 ICP copayment apply, or would CMS expect this amount to be capped at the $29 remaining to meet the Initial Coverage limit?

Task Group Response:
Refer to CMS document "Prescription Drug Event (PDE) reporting examples for benefit year 2014," dated December 2013, page 39:

"Example #21: A beneficiary is enrolled in a Basic Alternative plan and purchases a $202.00 drug. The cost of the drug includes a $2.00 dispensing fee. The beneficiary has a $30 copay in the initial coverage phase for this drug.

Step 1: Determine costs that fall in the Coverage Gap:
In this example, the drug cost is $202.00, which includes a $2.00 dispensing fee. When the claim adjudication begins the TGCDC Accumulator is $2,821.00 and the TrOOP Accumulator is $937.75. The beginning phase is the initial coverage phase. The beneficiary copay is $30.00 but there is $29.00 in drug cost remaining in the initial coverage phase.

Because the copay exceeds the amount of drug cost remaining before the ICL is reached, the copay is capped at the remaining amount of $29."

2. For claims exempt from Gap Discount, should the beneficiary pay 97.5% coinsurance for the entire Part D brand drug in the Coverage Gap or 97.5% coinsurance for ingredient cost and tax and 47.5% coinsurance for dispensing fee and vaccine administration fee in the Coverage Gap?

   Example to illustrate question 2 from 12/7/2012 CMS memo titled "Prescription Drug Event (PDE) Reporting for Coverage Gap Phase Claims with Dates of Service (DOS) beginning in 2013"

   Example 21 is an MSP claim, which is exempt from Gap Discount. The calculation of beneficiary liability is 97.5% of ingredient cost and sales tax (because Gap Discount does not apply) and 47.5% of dispensing fee and vaccine administration fee. Processors may be applying 97.5% coinsurance for the entire Part D brand drug in Gap based on the following text found on pages 33 – 34 of the 2013 Call Letter:

   Comment: Several commenters were concerned that our clarification of non-low-income beneficiary liabilities for dispensing and vaccine administration fees for brand drugs in the coverage gap (47.5% in 2013) will lead to beneficiary confusion, as opposed to, for example, 97.5% in 2013.

Response: We disagree that this clarification will lead to beneficiary confusion. We believe it is more straightforward for a beneficiary to pay 47.5% cost sharing for the entire Part D brand drug in the coverage gap, as opposed to 47.5% of the ingredient cost and sales tax plus 97.5% of the dispensing and vaccine administration fees.

CMS Response:
In a memo dated 4/13/2013 with subject "Medicare Secondary Payer Prescription Drug Event Calculations and Reporting Standards," CMS confirmed that beneficiaries with Medicare Part D as a secondary payer will not receive the manufacturer discount on the negotiated drug price of applicable drugs. For MSP claims, the beneficiary liability is 97.5% of total claim cost and the plan liability is 2.5% of total claim cost.

2.47 Non-covered Plan Paid Amount (NPP) in PLRO

Question:
Due to the requirement to put NPP in PLRO these are currently rejecting on the PDE with error code 761. This needs to be addressed as soon as possible with clarification for 2014.

1. In looking at the PDE participant guide from 2011, Section 4.2.1.1, we assume these should be reported in NPP and not PLRO. If this is the case, the instructions for moving NPP to PLRO are too broad.

CMS Response:
Our guidance never indicated a general instruction for moving NPP to PLRO. For reporting OTC drug costs, the EGWP Part D portion is defined standard and therefore should follow the DS rules for reporting OTCs.

1. What happens if the supplemental benefit (OHI) forces a copay? This will end up in PLRO. Stated another way, because this is OTC is this appropriate to state that regardless of OHI/EGWP Copay, no PLRO should be reported for the OHI/EGWP wrap. Is this correct?

CMS Response:
EGWPs are not required to submit a PDE for an OTC drug covered under the non-Part D portion of the benefit where no portion of the total OTC drug cost is included under the plan's administrative costs of the Part D portion of the benefit.

The Medicare Part D FAQ Task Group recommendation is to not submit PDEs for OTC covered by EGWP non Part D supplemental benefit.

EGWP can have NPP when OTC is covered under the Part D benefit.

2.48 EGWP and LICS Subsidy

Question:
Please clarify the rules around LICS subsidy when EGWP copay as a result of OHI is greater than the LICS copay/cost sharing.

CMS Response:
In this example, the Defined Standard Part D benefit is applied first. Then, the EGWP benefit is applied to the PDE. If the LIS beneficiary liability under the EGWP is equal to or more than under the Defined Standard benefit for a non-LIS beneficiary, LICS is $0. In this case, the EGWP has a $5 copay, which is less

than the Defined Standard non-LIS copay and a $1.50 more than the Defined Standard LIS beneficiary copay. Therefore, the LICS amount is adjusted by adding the negative $1.50 (which is the increase in beneficiary liability under the EGWP) to get $20 is LICS.

For example:

					Final PDE
		Defined Standard non-LIS Beneficiary	Defined Standard LIS Beneficiary	EGWP	EGWP
Deductible	Beneficiary Liability	–	–	–	–
	CPP	–	–	–	–
	PLRO	–	–	–	–
Initial Coverage Period	Beneficiary Liability	$25.00	$3.50	$5.00	$5.00
	CPP	$75.00	$75.00	$75.00	$75.00
	LICS	$0.00	$21.50	$21.50	$20.00
	PLRO	$0.00	$0.00	($1.50)	$0.00

In looking at the example above, a question arose regarding the statement in the final rule "to forego LICS." We will request clarification from CMS.

> "If PLRO is negative, the negative PLRO offsets the LICS amount. In such instances, by having cost sharing in excess of the standard benefit, even though the coverage as a whole is required to be actuarially equivalent to or better than defined standard, the sponsor is electing to forego LICS because the sponsor did not subsidize the LIS beneficiary's cost sharing amount by charging the lower LIS copay amount."

CMS Response:
The negative PLRO amount will offset the LICS amount. You will not forego the entire LICS subsidy based upon having negative PLRO. If you look at pages 55-57 (A3) in the 2014 Advance Notice and Call letter, we use the word offset and we provide examples. Consult example 11 for specifics.

2.49 Inclusion of "Medicare" on Checks and Electronic Funds Transfer Payments

Question:
Refer to CMS memo dated May 9, 2014, Inclusion of "Medicare" on Checks and Electronic Funds Transfer Payments. Is the industry implementing this guidance? If so, we have a couple clarifications we would like to see how the industry is handling.

- If checks are not currently separated by line of business, can the verbiage state "May Include Medicare" or "Includes Some Medicare"?
- Where on the 835 should this be reported? Suggestion to add to the header. Is the industry implementing this guidance? If so, we have a couple clarifications we would like to see how the industry is handling.

Task Group Response:
CMS "recommended" that private insurance companies assist in preventing fraud by including the word "Medicare" on all checks, electronic funds transfers, and electronic remittance advice payments. This is not a requirement. CMS would need to engage the industry prior to implementation.

2.50 Reporting Negative PLRO – 2014 PDE Reporting Guidance, Example 16

Question:

While looking over the example that CMS gave us last year to report negative PLRO I have a question.

The cost of the drug in this example is $100 ($93 drug $2 Dispensing fee $5 tax). The OHI has a $30 copay. This example falls in the Initial Coverage Phase.

Medicare D claim –
Patient Pay: $25
Plan Pay: $75

In option 2 the member is going to still be charged their $30 copay which is $5 more than the CMS standard benefit. However, the pharmacy has $75 from the Medicare D payer and now they will have $30 from the member so the pharmacy is going to be paid $105 for a drug that is only $100.

In the rest of the CMS example they state the PDE will show:
Patient pay: $30
CPP: $75
PLRO: -$5
NPP: $0
GDCB: $100

CMS also states in OPTION 2 that the member's troop would increase by $30 and the Gross Drug Spend would increase by $100.

In theory the PDE balances but in reality the pharmacy is now overpaid by $5. How would an EGWP or other payer ever be able to make the member pay more? And if that is "ok" the member is only getting credit for $100 when really the pharmacy is now paid $105.

CMS Response:
The dollars submitted to CMS on the PDE are for PDE reporting purposes so that CMS can administer the Part D program.

Patient pay: $30
CPP: $75
PLRO: -$5 (negative $5)
NPP: $0
GDCB: $100

Task Group clarification: The actual claim reflects the amount paid by the patient and amounts paid to the pharmacy. As stated above the PDE is for reporting purposes and does not necessarily reflect the distribution of payment.

2.51 CMS Cumulative Calculations for Morphine Equivalent Dosage (MED)

Question:

For PBMs who are implementing this MED logic, are you excluding the opioid cough/cold products from accumulating at point of sale?

Reference: CMS memo dated July 11, 2014, Medicare Part D Overutilization Monitoring System – July 2014 Updates

"In accordance with recent revisions to the Center for Disease Control and Prevention (CDC) Morphine Milligram Equivalent Table, May 2014, the following changes will apply to the OMS calculations of cumulative morphine equivalent dose (MED):

All opioid cough and cold products will be excluded from the calculations of MED (morphine equivalent dose). Testing confirms that the removal of these products does not significantly impact the identification of potential opioid overutilization."

For PBMs who are implementing this MED logic, are you excluding the opioid cough/cold products from accumulating at point of sale?

Task Group Response:
Consistent with the CMS memo dated July 11, 2014 plans should not include opioid cough and cold products in the MED calculations for Part D.

2.52 PDE Guidance for Post Point-of-Sale Claim Adjustments

See Post Point-of-Sale Claim Adjustments Guidance Document.
http://www.ncpdp.org/Resources/Medicare-Part-D

2.53 ESRD vs. Medicare Part D Coverage Determination

Question:
Can CMS provide additional guidance on the following items related to ESRD versus Medicare Part D coverage determination?

1. Based on H.R. 4302, oral-only drugs will not be placed under the Part B bundled payment as of 2016, the revised date is 2024.
   Note, current CMS Part D guidance references the 2016 date. Industry stakeholders request CMS provide clarification that this has been delayed until 2024.

   Task Group Response:
   CMS memo, "Two Updates Pertaining to End-Stage Renal Disease (ESRD)-Related Drugs" dated May 12, 2015 provides the extension to 2025. CMS removed anti infectives from the categories of drugs that are always considered to be used for ESRD treatment.

2. Please clarify whether the oral only classification applies to the drug therapeutic class or the product being prescribed.

   Note: Plans are experiencing inconsistent approaches to audit review of the handling of drugs in the categories related to ESRD. The volume of handling this is too great based on the scope of drugs identified. We are concerned about the volume of rejects and prior authorizations and the situations where a drug would not be covered in the bundled payment in the majority of cases. This is creating significant delays for beneficiaries.

   While current guidance specifically lists phosphate binders and Sensipar as oral only drug exceptions to the Part B bundled payment, we are unclear how other oral only drugs should be treated. Consider both antibiotics, narcotic analgesics and diuretics as examples when addressing this question.

If the answer is that it is at therapeutic class level then plans must determine if the drug is being used for ESRD related conditions. In this case the distinguishing factor is the diagnosis associated with the use of the antibiotic. As such the plan should require diagnosis code rather than forcing all antibiotic for ESRD patient through a PA process.

If the answer is at the drug product level then products only available in oral only form would always be covered, and only those that have other forms will require diagnosis/PA. This would help limit the number of diagnosis code/PAs and improve patient access to care.

Task Group Response:
CMS memo, "Two Updates Pertaining to End-Stage Renal Disease (ESRD)-Related Drugs" dated May 12, 2015 states, "Currently, oral-only drugs used in the treatment of ESRD that are excluded from the ESRD bundled payment are limited to the oral-only drugs that fall under the bone and mineral metabolism category, which currently are only Sensipar® and the phosphate binders (such as Phoslo®, and Sevelamer). Consequently, these oral-only ESRD drugs and biologicals are currently paid under Part D and will remain so until 2025. Please note that there are other oral drugs used in the treatment of ESRD that are oral equivalents or oral substitutes for drugs that fall under the other categories of drugs used for ESRD treatment, and for which a Part B injectable form has been included in the bundle, are covered under the ESRD PPS payment and not under Part D."

2.54 Part D Coverage Determination Process for "Maybe" ESRD

Question:
The paragraph in the guidance dated November 14, 2014 needs some clarification:
"That is, sponsors should implement processes to handle payment resolution directly with ESRD facilities and beneficiaries without requiring the pharmacy reverse and rebill the original claim in the retail setting. Although, whenever the network pharmacy involved is also the ESRD facility pharmacy, as is often the case with long-term care pharmacies, reverse and rebill may be the most appropriate approach."

1. PDP plans do not have information from CMS on a member's dialysis facility that is readily available to us. Therefore can you confirm it is acceptable to handle payment resolutions directly through pharmacies that have dispensed the medications and reverse/rebill through pharmacy?

   CMS Response:
   Sponsors should not handle payment resolution directly with the dispensing pharmacy unless the beneficiary's dialysis facility also has a contract with that pharmacy. Instead, the sponsor should contact the beneficiary to identify his/her dialysis facility and seek payment resolution directly with the facility.

2. Is there a report that CMS can provide that provides a listing of Med D member's dialysis facilities?

   CMS Response:
   According to the CMS ESRD staff, no such report exists.

3. Will CMS be auditing PDE's for these "maybe" drugs?

CMS Response:
In previous ESRD PPS final rules, CMS has acknowledged that drugs in these categories may be furnished for both ESRD- and non-ESRD-related purposes. We also noted in the November 14, 2014 guidance memorandum concerning Part D payment for drugs for beneficiaries receiving renal dialysis services that our monitoring data for the first half of 2014 suggested that the majority of drugs in the "maybe" categories are used for other purposes. As a result, we stated that sponsors are not expected to place ESRD prior authorization requirements on these categories of drugs or to take special measures beyond their normal compliance and utilization review activities. At this time, we are unaware of any plans to audit Part D payment for these drugs.

4. Request dialysis facility certification number or other identifier to be included on the TRR in the same manner as hospice in order to perform payer to payer reconciliation or prior authorization. This eliminates the need to contact the beneficiary to determine the dialysis provider.

CMS Response:
Beneficiaries do not register for a dialysis facility; therefore it cannot be included on the TRR.

2.55 Reject Codes – Opioid, CPI Overutilization

Question:
CMS memo dated August 25, 2014 - Beneficiary-Level Point-of-Sale Claim Edits and Other Overutilization Issues

"Beginning in February 2014, CMS directed sponsors to submit detailed information about beneficiary-level opioid POS claim edits into the Medicare Advantage Prescription System (MARx). CMS expected sponsors to retroactively submit all beneficiary-level POS opioid claim edits into MARx by March 12, 2014. We intend to follow up with those Part D sponsors that have not yet submitted all of their beneficiary-level opioid POS claim edits into MARx and issue compliance notices as appropriate."

Can you please provide NCPDP's recommendation for the reject code to use in the following instances?

- Opioid Overutilization
- CPI Overutilization

Task Group Response:
NCPDP has approved the new reject code listed below for use for this situation. It was approved on May 2015 that has been updated in the External Code List dated July 2015 and is has an implementation date of January 1, 2016.

Reject Code	Description	Value Limitation or Explanation
828	Plan/beneficiary case management restriction in place.	Telecom. ECL Emergency Implementation Date is January 1, 2016 Patient has been identified as an overutilizer and has received notice that an edit has been put in place for overutilization and must go through an appeals process. Reject code 569 "Provide Notice: Medicare Prescription Drug Coverage and Your Rights" is required to send with the new reject code.

Until the implementation date, most processors are returning the following codes.

- Reject Code 76 – Plan Limitations Exceeded
  - Identify the quantity allowed in free form text message
- Reject Code 70- Product/Service Not Covered – Plan/Benefit Exclusion
  - Identify drug allowed in free form text message

Once the new code is available, processors should insure they are returning 828 for rejects related to overutilization as described by CMS.

2.56 Medicare Part D EOB

Question:

One of our new clients for 2015 has requested that we populate the following optional section (highlighted in yellow) on the Med D EOB (on pages 9-10 of the 2015 CMS model document, YTD totals for Chart 1). What is the industry standard for populating this section? What types of information do plans typically print here?

Year-to-date totals *[insert beginning date for the period covered by year-to-date, e.g., "1/1/15"]* **through** *[insert ending date for the month]*	**Plan paid**	**You paid**	**Other payments** (made by programs or organizations; see Section 3)
Your year-to-date amount for "out-of-pocket costs" is $*[insert year-to-date TrOOP; use "$0.00" if applicable]*. **Your year-to-date amount for "total drug costs" is $*[insert year-to-date Total Drug Costs; use "$0.00" if applicable]*.** For more about "out-of-pocket costs" and "total drug costs," see Section 3. *[If the member was enrolled in a different plan for Part D coverage earlier in the year, plans must insert the following:*	*[Insert year-to-date amount of payments made by the plan; use* $0.00 *if applicable.]* (year-to-date total)	*[Insert year-to-date amount paid by the member; use* $0.00 *if applicable.]* (year-to-date total) *[If total is not $0.00 and any of this total does not count toward out-of-pocket costs, insert: (*Of this amount, $[*insert amount paid that does count toward out-of-pocket costs]* counts toward your out-	*[Insert year-to-date total for "other payments"; use* $0.00 *if applicable]* (year-to-date total) *[If total is not $0.00 and there are any payments that do not count toward out-of-pocket costs, insert:* (Of this amount, $*[insert amount that does count toward out-of-pocket costs]* counts toward your "out-of pocket costs." See definitions in Section 3.)*]*

"NOTE: Your year-to-date totals shown here include payments of $*[insert the TrOOP balance transferred from prior plan]* in out-of–pocket costs and $*[insert amount for Total Drug Costs]* in total drug costs made for your Part D covered drugs when you were in a different plan earlier this year."*]* *[Optional: If corrections have been made that affect amounts shown in previous monthly summaries during the calendar year, plans may use this space for a explanatory note: "*NOTE: The following *[insert whichever applies: correction has OR corrections have OR adjustment has OR adjustments have]* been made to amounts that were shown in a monthly summary sent to you earlier this calendar year: *[Plans should insert a brief explanation of the correction or adjustment that identifies the change that has been made and provides relevant dates and a reason for the change, e.g., clerical error, updated information about the prescription, decision on an appeal, etc." Plans have the flexibility to report such adjustments or corrections to members using other means instead*		of-pocket costs.)*]*	

of, or in addition to, inserting this explanatory note into the EOB.]			

Task Group Response:
Plans and processors have indicated they are not populating information due to the fact there may be multiple reasons for adjustments.

2.57 Submitted Effective Date for Primary and Supplemental Records

Question:
According to PCUG 8.2 and newly released in November 2014 8.3 Appendices pages F-13 and F-17
http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Downloads/PCUG-Appendices-v82-August-28-2014.pdf
and
http://www.cms.gov/Research-Statistics-Data-and-Systems/CMS-Information-Technology/mapdhelpdesk/Downloads/PCUG-Appendices-v83-November-21-2014.pdf

F.2.3 Primary Records: Subordinate to Detail Record we are expecting "spaces" for position 1084-1100 (118 Filler 17 1084-1100 CHAR Spaces) and
F.2.4 Supplemental Records: Subordinate to DTL we are expecting "spaces" for position 516-1100 (80 Filler 585 516-1100 CHAR Spaces)

However, since October 6, 2014 we are seeing data populated in position 1084 for Primary records and in position 516 for Supplemental records.

CMS Response:
There was an update for records beginning in position 282 of primary and supplemental record related to the definition of effective date. We are unsure what is in the filler, however the information you need to load is beginning in 282 and that date may be before the Medicare effective date because it represents the date originally submitted by the supplemental payer. This change was made because the BCRC was modifying the submitted effective date to be no earlier than the Part D effective date which caused problems with retro Part D eligibility. At this point we believe you can ignore the data where spaces should be.

2.58 CMS Part D Pharmacy Notice for Part B Claims in Retail Pharmacies

Question: I'm reaching out for your assistance with a pharmacy notice issue that came up during an unrelated conversation regarding Part B drugs dispensed at retail pharmacies. In this scenario, the MA-PD plan has certain Part B drugs available through retail pharmacies, and claims are processed through the plan's Part D processor (the PBM). My understanding is that it's a variety of drug classes and that the issues relate to the location, and that a substantial number of these Part B claims reject at POS. The plan and the PBM confirmed that when Part B drugs are rejected at POS, the 569 code triggering the Part D pharmacy notice is delivered. The plan indicated that, because there is no exception outlined in NCPDP guidance (the guidance we worked on together was cited), they believed the 569 code is appropriate.

The broader discussion was about Part B benefits and the Part C EOB requirements, but we are concerned that the pharmacy notice is being delivered in a situation where the plan is rejecting claims for a Part B benefit. As you know, the notice instructs the enrollee to contact their Part D plan to request a coverage determination, but we see little value in doing so since the only conceivable response would

be a denial under Part D. When a plan is not providing coverage for a benefit under 42 CFR Part 422, we do not expect the plan to provide a description of coverage and appeal rights that apply to benefits under 42 CFR Part 423, regardless of whether the plan is using a Part D adjudication system. To clarify, I am NOT referring to drugs that hit a B v. D PA edit (which we definitely want to return the 569 code), but rather to drugs and supplies where coverage is only going to be provided under Part B.

We have instructed this plan that the pharmacy notice should not be delivered in these circumstances. However, this PBM works with many CMS plans and others may do the same, so we are concerned the practice may be happening more widely across the industry. I'm hoping you can help me better understand, (1) how MA-PDs process Part B claims in retail pharmacy settings (I assume most/many are doing it through their Part D adjudication system with Part D logic, similar to this plan/PBM, and this might be the issue), and (2) whether it's common practice to tie the 569 code to rejected Part B claims.

At this point I'm just looking for a broad, high level response.

Task Group Response (approved by WG1, August 2015):
In order to address the concerns listed above, the NCPDP Editorial Document will be updated to include the following clarification in *Section 19.4 Notice of Medicare Drug Coverage Rights – Rejected Claim Plan/Processor Action*

"Note: While it is applicable to return the 569 reject code for B vs. D determinations beginning July 1, 2013, it is not applicable to return the reject code if the drug is known to be a Part B drug."

2.59 CMS DESI File – Covered Outpatient Drug

Question:
CMS has changed their quarterly DESI files and introduced a new field called COD (Covered Outpatient Drug). After reviewing the updated data and comparing it to existing DESI information, a significant number of differences were found between these data sources (NDCs that were previously marked as DESI are no longer noted as DESI and vice versa). We have the following questions:

1. Will the data in this new field be the basis for PDE editing to generate the 206 PDE reject (DESI 5, 6)?
2. Since there are such a large number of changes from the current data, should we expect to see additional updates to this new field, or is this truly the new source of DESI status? If you would like to see examples of the differences we have identified, please let me know and I'd be happy to share.

CMS Response:
The short answer is no; the Covered Outpatient Drug (COD) field is not the only field used for DESI editing. For PDE editing we will continue to use the current data (which FDB is freezing and no longer updating) and will identify any new NDCs that appear on the new COD data.

2.60 2016 Part D EOB

Question:
Recently released 2016 EOB guidance states MMP plans that are not required by their State to use the Drug Only should report Medicaid claims on the Part EOB. There were no instructions on how the Medicaid claims should be displayed. Chart 1 of the EOB clearly states that it is for reporting Part D covered drugs and Chart 2 is to report drugs covered under a plans Supplement Coverage. Our assumption is to report the Medicaid paid claims under Chart 2 and change the title to "Your prescriptions for covered Medicaid drugs" consistent with Chart 1, but we don't want to make assumptions.

Additionally, we are not sure as a processor, what is meant by the statement below. As a processor, we are not allowed to contact CMS directly.

> Updated instructions for Medicare-Medicaid Plans (MMPs) to reflect current Medicare Marketing Guidelines (MMG), wherein they must use the Part D Model, but they can include the Medicaid-covered drugs in the Part D EOB as they appear on the ADD file that is submitted during the bid submission process.

Task Group Response:
It is the opinion of the Task Group to report the Medicaid paid claims under Chart 2 as they appear on the ADD Formulary file containing the Medicaid covered drugs.

2.61 MSP EOB

The CMS guidance below shows how to report on the PDE the scenario when the primary payer paid more than the cost of the claim.

Refer to Example 5 Primary payment > negotiated price
"In example 5, we illustrate calculating and reporting rules in an MSP situation where the primary payment exceeds the negotiated price of the drug. The plan is an alternative plan (either basic or enhanced). We also use this example to show calculations in a case where a beneficiary has no cost sharing for a particular drug under their PBP. The example is summarized in the following table and then described in detail in the text below it.

MSP: Primary Payment > Negotiated Drug Price	
	Ex #5
Primary Payer Payment	$15
Part D Plan Negotiated Price (based on NDC on COB segment)	$10
Part D Plan Liability under the PBP	$10
Beneficiary Liability under the PBP	$0
Part D Plan-Paid at POS	$0
PDE field: Patient Pay Amount	$0
PDE field: CPP Amount	$0
PDE field: NPP Amount	$0
PDE field: PLRO	$15
PDE field: GDCB	$10
PDE field: LICS Amount	$0

Example 5

A beneficiary is in the pre-catastrophic phase of his/her benefit and fills a prescription for a generic covered drug with zero beneficiary cost sharing. The primary payment was $15 which is greater than the negotiated price of the drug.

1. The plan prices the claim at its negotiated price of $10 and reports this amount in the GDCB field.
2. The plan reports the primary payment of $15 in PLRO. Note that all other payment fields will equal $0 since PLRO > gross drug cost (negotiated price).

3. It determines that there is no beneficiary liability for a generic drug under the PBP, so plan liability is $10.
4. The difference between the negotiated price and the primary payment is $10 - $15 =-$5.
5. The beneficiary is responsible for whichever is less, the cost sharing under the PBP (from Step 3, $0) or the difference between the negotiated price and the amount paid by the primary payer (from Step 4, -$5). However, the beneficiary cannot have a negative cost-share so the plan reports $0 in the Patient Pay Amount field.
6. The Part D plan is only responsible for any amount remaining after the primary payment and the beneficiary's cost sharing under the PBP have been applied, up to the Part D plan's negotiated price. The sum of the primary payment ($15) and beneficiary liability ($0) = $15, exceeding the negotiated price. Since the full negotiated price has been covered; there is no remaining amount to be paid by the plan.
7. Therefore, CPP Amount = $0.
8. The plan reports Pricing Exception field = 'M'."

Question:
Please clarify how this same scenario should be reported on the EOB.
Should the EOB include the full PLRO amount in the Other Payment column when it is greater than the negotiated price? Or should the PLRO be reported to equal the negotiated price to help reduce member confusion?

WG9 FAQ recommends that for MSP claims where the PLRO amount (claim amount paid by the primary payer) exceeds negotiated price we recommend that the Other Payment field on the EOB reflect the negotiated price as that is the amount applied to drug spend. Does CMS concur?

CMS Response:
We concur with WG9 FAQ's Task Group's recommendation that for MSP claims where the PLRO amount exceeds negotiated price the Other Payment field on the EOB reflect the negotiated price. It is clearly the only option that will make sense to the beneficiary.

NCPDP: Additionally, the task group clarifies that member pay and plan pay would equal 0 on the EOB.

2.62 Non-FDA Approved NDCs and Medicare Part D

We have two plan sponsors with different opinions on how non-FDA approved NDCs should be handled.

- One sponsor believes drugs considered to be non-FDA approved should not be covered per MED D law.
- Another sponsor feels that since a non-FDA approved NDC was accepted on the PDE it is okay to cover.

We have been told by our formulary administrator, if an NDC does not have an RxCUI and is non-FDA approved it is not covered per MED D law. If an NDC does have an RxCUI and non-FDA approved it may be covered by MED D.

Questions:

- If a NDC is listed on the NSDE file and it is categorized as unapproved, for example all phenobarbital NDCs are listed as unapproved however phenobarbital is in a protected class. Does this drug meet the definition of a Part D drug as it is listed but unapproved?

- Should drugs similar to these (not in a protected class but are listed and unapproved) meet the definition of a Part D covered drug? If a plan chooses to cover them should they be submitted on a PDE?

  51293080201 phenazopyridine
  76439030910 hyoscyamine
  00456046001 armour thyroid

CMS Response:
We want to clarify that one cannot assume that CMS' acceptance of a PDE means that the drug is a Part D drug. Part D Sponsors are expected to exercise due diligence in evaluating whether a drug is a Part D covered drug. Whether or not a drug is in a protected class does not impact this review.

2.63 Pharmaceutical Assistance Program (PAP) Coverage and Transition Supply

Question:
Does transition supply apply if the beneficiary has PAP coverage for the drug in question?

Scenario: Patient has PAP as other health insurance coverage (as defined in Medicare Prescription Drug Benefit Manual, Chapter 14) and the drug is covered by that PAP. Claim would reject as long as PAP is still covering the beneficiary (date of service is within coverage period of the PAP). If the Date of Service is outside of the PAP coverage period, and is within the Part D plan transition period, then transition rules will apply.

Task Group Response:
The claim may be rejected as long as Manufacturer PAP is still covering the beneficiary (date of service is within the coverage period of the PAP as evident in the CMS enrollment file). If the date of service is outside of the PAP coverage period, and is within the Part D plan transition period, then transition rules will apply.

Note: Minimal copay from the PAP may be submitted by the beneficiary to the Part D plan to be applied towards TrOOP and drug spend.

2.64 PA Requirements on Hospice Drugs

The 7/18/2014 CMS guidance indicates the Part D plan must apply reject code A3, only for drugs that fall within the four designated categories. If the hospice provider provides the required "unrelated to terminal illness" designation, the A3 edit must be overridden. It further indicates that drugs outside of these four categories would not be subject to the A3 reject. In the situation where a drug within these four categories is deemed by the Hospice provider to be the beneficiary's liability, the Part D plan would continue to reject these claims as A3. Since the Part D plan is not to apply the A3 reject for drugs outside the four categories, it is unclear how the Part D plan is to manage these claims where the Hospice provider may have deemed the drug to be unrelated to the terminal illness.

Question:
Can CMS clarify that as of the July 2014 guidance how the Part D plans are to manage a standardized process for the below situations in which the drug is outside the four categories:

- Prospectively, the Hospice provider optionally indicated on page 2 of the Hospice PA Plan of Care form that the drug is the beneficiary's responsibility.
- Retrospectively, the Hospice provider communicates to the Part D plan that the drug is the beneficiary's responsibility.

- The Part D plan does not have any documentation indicating that the drug is the beneficiary's responsibility.

CMS Response:

"The guidance states that Part D sponsors are not expected to place hospice PA requirements on drugs in other than the 4 categories or take special measures beyond their normal compliance and utilization review activities to retrospectively review paid claims for purposes of determining whether drugs in the other categories were unrelated to the hospice beneficiary's terminal illness and related conditions or for payment recovery. In the section on retrospective review and recovery, the guidance states that we do not expect Part D sponsors to retrospectively review paid claims for drugs outside of the four categories specifically for the purpose of determining whether the drugs were unrelated to the hospice beneficiary's terminal illness and related condition. However, the guidance also states that nothing in this guidance should be taken as a change in the definition of a Medicare Part D covered drug or Part D payment rules or drug utilization review requirements.

Thus, when a drug is determined by the hospice provider to be the beneficiary's responsibility, such as when the member has requested a non-formulary drug from the hospice and refused to try a formulary equivalent, or the drug was determined by the hospice provider to be unreasonable or unnecessary, but the beneficiary agreed to assume financial responsibility for it, Part D has no payment responsibility for the drug. If the hospice provider prospectively or retrospectively indicates on the Plan of Care form that a drug in other than the 4 categories is a beneficiary responsibility, no payment for the drug is available under Part D. In those situations involving retrospective payment recovery, the sponsor should issue a recovery notice to the beneficiary. If the sponsor has no information that a drug in other than the 4 categories is a beneficiary responsibility, the sponsor is not expected to take any action to determine whether the beneficiary has payment responsibility."

2.65 Payment Recovery (Hospice Provider/Plan Sponsors)

From the CMS Hospice FAQs dated 08/06/14 Question 27 states: If a claim is retrospectively determined to be a member liability and the sponsor collects from the beneficiary, must the sponsor request the pharmacy reverse the claim and/or delete the PDE?

A27: Beneficiaries will be responsible for drugs related to the terminal illness and/or related conditions, but waived through the beneficiary's hospice election or unavailable through the hospice due, for example, to the imposition of the hospice's formulary requirements or the hospice's determination that the drug is not medically necessary. Since the drugs are related, they are not coverable under Part D and the PDE must be deleted. However, once the Part D sponsor has recovered the erroneous payment from the beneficiary, there is no need to request the pharmacy reverse the claim.

Question:

What is the process if the Part D plan is unable to recover the erroneous payment?

CMS Response:

"In terms of payment recovery, we expect sponsors to seek recovery from the party determined to be responsible for payment; this would be the hospice provider, beneficiary, or other insurer as applicable. Sponsors should implement processes to handle payment resolution directly without requiring the pharmacy to reverse and rebill the original claim in the retail setting. This remains our expectation even when efforts to recover from the responsible party are unsuccessful."

NCPDP comment: Basically the plan is out of the money if they cannot collect from the beneficiary. Early discussion was around having a review board but that has fallen by the wayside. There is no solution.

2.66 Hospice Drugs Requirement for Beneficiary Level PA

Question:

As a Medicare Part D Plan Sponsor, all drugs in the four Hospice drug categories defined in the 2014 Call Letter will be programmed to require beneficiary level PA based on the Hospice TRC. Claims will then reject directing the pharmacy to bill the Hospice Provider. Hospice Benefit Providers often have their own formularies and only cover a limited number of products in each of the four drug categories. If a hospice member is prescribed a drug that is not on the Hospice Benefit formulary, the Hospice Provider will reject that pharmacy claim. At that point, what course of action should the pharmacy and Plan Sponsor take? Should the pharmacy resubmit the claim to the Part D Benefit, and should the Plan Sponsor then cover that claim under Part D?

Task Group Response:

The new guidance dated 7/18/2014 effective for 10/1/2014 "Part D Payment for Drugs for Beneficiaries Enrolled in Medicare Hospice" allows the Hospice provider to provide the information for drugs that are "unrelated to the terminal illness and/or related conditions, "Hospice Responsibility" and "Patient Responsibility." The form used to provide this information can be provided to the beneficiary and/or their representative to present to the pharmacy similar to BAE to help the pharmacy determine where to submit the claim and/or response to the reject.

For those Hospice entities processing claims real time, the following reject codes should be used to indicate whether the drug is being rejected because it is unrelated to the condition or because the patient is fully responsible for the drug.

If an 822 is returned, The Part D plan should override the hospice edit for those drugs because they are unrelated to the terminal illness and/or related conditions but all other edits should apply.

822	Drug Is Unrelated To The Terminal Illness And/Or Related Conditions. Not Covered Under Hospice.		**Telecom. ECL Emergency Implementation Dt. Is July 1, 2015** Response from Hospice payer that the drug is unrelated to the terminal illness and/or related conditions to allow pharmacy to submit to the Part D sponsor.

823	Drug Is Beneficiary's Liability - Not Covered By Hospice Or Part D. Hospice Non-Formulary. Check Other Coverage.		**Telecom. ECL Emergency Implementation Dt. Is October 1, 2016** Response from Hospice or Part D payer to notify pharmacy that neither Hospice nor Part D coverage applies and allows full patient responsibility. Recommend reject code MR also be returned when drug is related to the terminal illness but is non-formulary. Recommend reject code 70 also be returned when drug is unrelated to the terminal illness.

2.67 BIN/PCN for Non-Part D MMP Opt-Out Plans

Question:
My question is about the non-Part D MMP plans that "opt-out" of Part D. These claims would never pay under Part D, so should they still be submitted with the Part D BIN/PCN? If so, would the new Benefit Stage Qualifier 63 be returned for all paid claims under the opt-out MMP?

CMS Response:
There is no such thing as an MMP opt-out plan, though it is possible someone may be referring to a Medicaid-only plan which of course would not cover any Part D drugs. However, an MMP plan is required to comply with all Part D requirements. Therefore they must have a single unique BIN/PCN.

2.68 ICD-10 and Part D Claims

Question:
Does the ICD-10 Frequently Asked Questions apply to Part D claims that include diagnosis code? If so, if a code is within the ICD-10 data set but the end date is beyond the end billing date is it still considered valid?

CMS Response:
According to the group that is implementing ICD-10, CMS has not yet determined if the scope of the guidance extends beyond Part B Physician Fee Schedule claims.
(Note: no issues have been reported to the task group)

2.69 Louisiana 10 Cent Provider Fee

Louisiana requires a 10 cent Provider Fee (collected by Pharmacies from insurance plan/payers), that will be submitted in the NCPDP billing transaction standard as Flat Sales Tax:

1. Are there any issues with a state applying fees to a federal program? If the answer is yes (meaning the fee cannot be charged to Part D plan) we assume that Part D plans should not include the fee in their calculations
2. If no, does this provider fee meet the definition of a component of negotiated price?

a. If the answer is no, we assume that it may not be included in any calculations for part D coverage- please confirm.
b. If the answer is yes
    i. Is this cost only a plan paid component cost or can it be part of the calculations that include patient pay? (Including, does it count towards Total Gross Covered Drug Costs, and TrOOP if paid by patient)
    ii. Should it be combined with normal sales tax and reported in the sales tax field on the PDE? If not, where should it be reported in order for the PDE to balance?
    iii. Is it applicable for gap discount calculations? (The negotiated price for Coverage Gap Discount Program only includes Ingredient Cost and Sales Tax, and the other Fees like dispensing fee and vaccine administration fee are not eligible for the Coverage Gap Discount).
    iv. Does this apply to patient pay cost share (even situationally like during deductible)? If yes, please confirm that this would also be considered a part of the costs subsidized by LICS.

Question to CMS:
Are there any issues with a state applying fees to a federal program and if not, should they be reported in the sales tax field on the PDE?

CMS Response:

- The Louisiana provider fee is acceptable and should be reflected in the NCPDP Flat Sales Tax fields.
- The fee should be reported on the PDE as part of the calculations within the Sales Tax field.
- See NCPDP Version D Editorial Document, Section 3.6.4 Provider Fees http://www.ncpdp.org/Resources/HIPAA

2.70 Insulin Billed to Part B vs. Part D

Question:
Request CMS modify regulation for insulin to be covered under Part D regardless of route of administration. Request volume of insulin billed under D vs. B and impact to beneficiary as this approach may make things more complicated for the DME/physician provider. Is there potential to compare costs between D vs. B?

CMS Response (April 15, 2016):
Statutory change is required. Diabetic treatment is evolving so quickly that this has not been considered or discussed due to the depth of changes necessary. CMS is not the body that can make the statutory change. Task group members that are part of PCMA and AHIP should consider asking for this to be an agenda item for the next meeting with CMS.

2.71 Medicare/Medicaid Demonstration Plans (MMP)

Question:
It is our understanding that the intention of the MMPs is to provide administrative efficiency and cost savings to the Medicare and Medicaid programs. We have learned that at least one plan will require that a BIN/PCN/Group combination be used for the Medicare portion of the benefit and a separate BIN/PCN/Group combination be used for the Medicaid portion of the benefit. Does CMS support this separate adjudication? We understand that some states need to know which portion of the benefit was covered under Medicaid, but we believe that Benefit Stage Qualifier 63 was intended to be used to identify the Medicaid portion.

Response:
Based on CMS response that they may only use one BIN/PCN, the Benefit Stage Qualifier would be used to determine which portion of the benefit paid.

2.72 Postage Requirement

Question:
For a retail pharmacy mailing a prescription to a Medicare Part D member, is postage required to be submitted on the claim? Can CMS point to the definitions of remote and frontier areas, i.e. is there a geo access specific distance?

CMS Response:
The cost of postage is not an allowable component of the negotiated price unless the beneficiary location is remote. CMS hasn't defined the terms "remote" or "frontier" areas. We anticipate that in those rare instances when the costs are allowed to be included in dispensing fees, we would see higher dispensing fees but the costs would not be otherwise visible.

2.73 Non-LTC Network Back-up Pharmacy

Question:
Are non-LTC network pharmacies eligible to submit prescription drug claims for Part D members in the LTC setting?

There are circumstances where a retail pharmacy is providing services to a LTC resident such as:
When the claim is submitted:

- The patient residence value is equal to LTC.
- The pharmacy service type submitted is not equal to LTC
- The non-LTC network pharmacy does not meet the LTC performance and service criteria.
- The pharmacy is contracted with the Part D plan sponsor/PBM to perform only non-LTC network pharmacy services.

Response:
Per CMS, "nothing in CMS' policy requires that a claim from a retail pharmacy servicing a LTC beneficiary be denied." Furthermore "If denial of these pharmacy claims results in beneficiaries losing timely access to Part D drugs, Part D sponsors may be subject to compliance actions."

Per Chapter 5 of the Medicare Prescription Drug Benefit Manual, the appropriate action for the Part D sponsor to take when a pharmacy (not in the Part D sponsor's network of LTC pharmacies) dispenses into the LTC setting is to contract the pharmacy into the Part D sponsor's network of LTC pharmacies. When the Part D sponsor is unable to contract the pharmacy into its network of LTC pharmacies AND the Part D sponsor has no other pharmacy in its network of LTC pharmacies that can service the beneficiary, the Part D sponsor should contact CMS for assistance.

The provision of emergency first doses for a LTC resident, the filling of prescriptions for a LTC resident while on a leave-of-absence from the LTC facility, or the dispensing by a specialty pharmacy of a drug that is only available from a specialty pharmacy does not alone create a situation requiring participation in a Part D sponsor's network of LTC pharmacies.

2.74 Marketing Materials in HPMS

Question:

At one point CMS indicated access would be available for subcontractors to file Marketing Materials in HPMS on behalf of the plan. Could CMS provide an update on when this will be available?

CMS Response:
After careful consideration, CMS has determined that subcontractors will not be allowed to submit marketing materials in HPMS on behalf of Plans/Part D Sponsors. Plans/Part D Sponsors are still responsible for submitting their own marketing materials.

2.75 Reason for Service Code (439-E4) – Morphine Equivalent Dose (MED)

Questions:

1. Has NCPDP made any recommendations as to which Reject Code (511-FB) to use in the D.0 transaction for a soft or hard plan level reject based on MED thresholds?

   Response:
   If your plan is strictly editing based on MED quantity, for this scenario we would recommend using either Reject Code 88 or 76 in combination with the following Reason for Service Codes:
   - AT (Additive Toxicity)
   - ER (Overuse)
   - EX (Excessive Quantity)

   A cumulative edit occurs when quantities on the claim in question have caused the threshold to be exceeded. This could be due to a single claim or the current claim in combination with prior claims exceeding the threshold. For 2016, it is possible the Reason for Service code could be returned on a soft reject or a hard reject.

   If your plan is incorporating physician/pharmacy/other overutilization data elements in your edits, the following Reason for Service Code would be appropriate:
   - DM (Apparent Drug Misuse)

2. In the January 2016 version of ECL (page 249), NCPDP recommended to use Reject Code 828 for the beneficiary level opioid overutilization. Does this guidance remain true based on the most recent call letter?

   Response:
   Yes, if a beneficiary level edit has been enacted, return Reject Code 828. Additionally Reject Code 88 may be returned with the appropriate Reason for Service Codes AT (Additive Toxicity), ER (Overuse), EX (Excessive Quantity), DM (Apparent Drug Misuse).

2.76 Overutilization Related Questions

Questions:

1. Has NCPDP made any recommendations around CMS guidance for acetaminophen (APAP) overutilization? Which Reason for Service Codes (439-E4) should be used in the DUR response segment for a D.0 transaction in a scenario in which the acetaminophen (APAP) threshold has been exceeded?

Response:
Similar to opioid edit and should be treated the same.
- AT (Additive Toxicity)

- EX (Excessive Quantity)
- ER (Overuse)

2. Request discussion on this excerpt from the Final Rule page 214: "Therefore, we expect sponsors to implement a soft POS edit when an opioid prescription is presented following the initiation of buprenorphine for the treatment of opioid use disorder. CMS believes that a soft edit that only rejects the opioid prescription following the buprenorphine claim should not impede access to buprenorphine for the treatment of opioid use disorder. It is very important that a sponsor should only implement this edit if it has the technical ability to not reject buprenorphine claims."

   What type of Reason for Service code would be acceptable for this situation?

Response:

- DC - Drug-Disease (Inferred)
- DD - Drug-Drug Interaction

3. Based on the 2017 Call Letter guidance (see below) should we also include recommendations for the appropriate MED threshold for the proposed edits or would this be considered out of scope for this sub-task group or an individual plan decision?

   "Prior to implementing soft and hard cumulative formulary MED thresholds at POS, the sponsor's CY 2017 formulary submission must reflect these edits. In addition to the HPMS formulary submission, plan sponsors must submit detailed operational information by the CY 2017 formulary submission deadline. The documentation must contain at a minimum the MED level being utilized for each edit and a written description of the program's mechanics, including the mechanism by which the edits would be resolved. This information must be submitted via e-mail to partdformularies@cms.hhs.gov with a subject line of "Cumulative MED – [applicable FID number]."

Response:
Specific MED thresholds are an individual plan decision. Plans should review their own data to ensure they are not overly disruptive to member access. This is one of the items CMS expects plans to work with their P&T committees to develop and approve.

2.77 Drug Shortages and Foreign Manufactured Drugs

Question:

1. Is there a drug shortage indicator? How do you know when to turn on and turn off your formulary accruals to allow for the foreign NDC? Is there a date range associated with start date?

Response:
FDA approves a drug product for a shortage situation and indicates that the Marketing Category is "unapproved drug for use in drug shortages," as well as determining how long the drug product is approved to mitigate the shortage situation by assigning a Marketing Start Date and a Marketing End date.

Additional background- FDA's NSDE provides pertinent data fields about NDCs and HRIs (NHRIC), such as the Item Code, the NDC number, the Proprietary name, Marketing category, Marketing Start Date, Marketing End Date, etc.

The definition of three of the NSDE fields available for each NDC follows:

- Marketing Category describes the FDA regulations for marketing the product.
- Marketing Start Date is the date when the Manufacturer (etc.) started marketing the packaged product.
- Marketing End Date is the expiration date of the last lot distributed. Products that are actively being marketed will not have a marketing end date. Products that are no longer manufactured may have a future end marketing date for the expiration of the last lot distributed.

Question:

2. When we have these (ANDA, NDA, BLA) and we know the Affordable Care Act and Coverage Gap Discount Program tell us not to provide the gap discount on these claims if they are approved for a shortage, what indication is available to tell us this was only approved for shortage. Is that available to the FDA's information along with the drug application summary information?

Response:

- NSDE will have an indicator of the shortage.
- The foreign NDC would not have been submitted to FDA for NDA and BLA and this lack of NDA and BLA would indicate it is not applicable for the Coverage Gap Discount Program.
- It is possible these are defaulted to ANDA and therefore would not be applicable.

2.78 CMS Labeler List for Coverage Gap Discount

Question:

In order to minimize retroactivity, can the Labeler file be available the third week of the month?

CMS Response:

CMS has pushed back the publishing dates for monthly labeler codes based on this request. The files should be available prior to the month's end instead of after.

2.79 Medicare Part D and Hospice

Question:

Which reject code(s) should the Part D processor return when the claim is not covered or may not be covered under Part D due to the beneficiary's eligibility status with Hospice (Part A)?

Response:

NCPDP Reject Codes 822 and 823 have been published and are available for use. Please refer to the NCPDP External Code List and WG9 Hospice Scenario Grid for appropriate use.

2.80 Medicare Prescriber Enrollment Requirements and Co-administered Benefits

Question:

What rules apply in the following situations?

1. MMP
    a. If the claim is for an otherwise Part D covered drug and the prescriber fails the Medicare Enrollment validation, is the Medicaid benefit allowed to cover the claim?
    b. If the claim is for an otherwise non-Part D covered drug and the prescriber is not on the Medicare Enrollment file, is the Medicaid benefit allowed to cover the claim?
    c. Should the Medicare/Medicaid Coordination Office provide the applicable guidance to ensure all state MMPs follow the same process?
    d. If the provider is on a state sanctioned list for MMP should the claim be denied regardless of which entity is paying? (new question formed by task group)
2. Supplemental Wrap Plan

a. If the claim is for an otherwise Part D covered drug and the prescriber is not on the Medicare Enrollment file, is the supplemental benefit allowed to cover the claim?
b. If the claim is for an otherwise non-Part D covered drug and the prescriber is not on the Medicare Enrollment file, is the supplemental benefit allowed to cover the claim?
c. If the claim is covered by the supplemental benefit, what means are available to tell the patient that the claim did not apply towards their TrOOP?
    - Should Approved Message Code 18 (or a new Approved message Code) be returned, so that the pharmacy provides the Beneficiary and Your Rights Notice?
    - Approved message Code 18 = Provide Notice: Medicare Prescription Drug Coverage and Your Rights - Claim for a Part D drug submitted to the plan's Medicare D BIN/PCN is not covered by the Part D plan but is paid by the beneficiary per a plan-sponsored negotiated price. In this situation the member should be provided the notice entitled "Medicare Prescription Drug Coverage and Your Rights".

Response:
These questions and others are clarified in CMS "Technical Guidance on Implementation of the Part D Prescriber Enrollment Requirement" dated December 29, 2015. Additional information is available from the WG1 Definition of a Valid Prescriber Task Group FAQ document available on the NCPDP Collaborative Workspace.

2.81 Nx Transaction not matching to Primary Claim

Question:
We have identified a scenario where the primary claim and secondary claim are paid under the same processor for John Jones, but when the N1 is received it has the Med D Cardholder ID number for his spouse Jane Jones who is also enrolled in both the same Med D and secondary commercial plan under her own unique ID. This is causing the Nx transaction to reject since it is not matching to the primary claim.

What is the criteria used by the Transaction Facilitator in order to generate the Nx transaction and populate the Med D 4Rx information and how can it be updated to prevent receiving Nx transactions for the incorrect Med D member?

Also, the Med D Plan Sponsor's that have these examples have verified their CMS eligibility files as being correct.

All claim transaction information between the primary claim, secondary claim, and the N1 Transaction match, the only difference between the Med D primary claim and the N1 is the Med D Cardholder ID #.

The Supplemental Payer has the same ID for the primary and spouse. They are using Person Code to distinguish the difference.

Primary claim - Med D
Rx #12345
Pharmacy # 1234567890
DOF 7/5/15
Fill # 01
Med D ID # ABCD
John Jones - DOB 1/1/45
Paid Claim

Secondary claim - commercial wrap
Rx #12345
Pharmacy # 1234567890
DOF 7/5/15

Fill # 01
Secondary commercial ID # 12345
John Jones - DOB 1/1/45
Paid claim

N1 Transaction
Rx #12345
Pharmacy # 1234567890
DOF 7/5/15
Fill # 01
Med D Cardholder ID # EFGH
Jane Jones (spouse) - DOB 12/1/50

Response:
Results of Transaction Facilitator research:

1. At the time when these transactions were received, only one supplemental record was on file matching the supplemental 4Rx. That was for the spouse that the Nx was generated to.
2. In looking at these 3, we received matching supplemental 4Rx for the actual beneficiary AFTER the transactions. These transactions came during January 2015, the matching supplemental for the beneficiary was received in June - while the matching supplemental 4Rx for the spouse was already in the system when the transactions came in.
3. Since the transaction facilitator only had one matching supplemental 4Rx in the system when the transactions were received, we did not consider DOB. We only use DOB as a tie breaker when we have more than one matching supplemental 4Rx found.
4. The logic worked as expected. If this issue is identified, the plan can request the Transaction Facilitator to reverse the N and completely replay the B so that the transaction will match to the correct record based on the most current enrollment information.

2.82 Questions Regarding Chapter 6 Update - Formulary Requirements

Background: Part D Prescription Drug Benefit Manual Chapter 6:
30.3.3.1 - Policy Regarding Formulary Changes (Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)
….
CMS also considers the expiration of an approved exception to be a negative formulary change for purposes of required advance notice to the beneficiary. Sponsors should consult chapter 18, section 30.2 for further guidance on beneficiary notification requirements for approved exceptions, available at https://www.cms.gov/Medicare/Appeals-andGrievances/MedPrescriptDrugApplGriev/Downloads/Chapter18.zip.

30.4 - Transition (Rev. 18, Issued: 01-15-16, Effective: 01-15-16; Implementation: 01-15-16)
…
For the purposes of transition requirements in section 30.4, CMS defines non-formulary Part D drugs to mean: (1) Part D drugs that are not on a sponsor's formulary, (2) drugs previously approved for coverage under an exception once the exception expires, and (3) Part D drugs that are on a sponsor's formulary but require prior authorization or step therapy, or that have an approved QL lower than the beneficiary's current dose, under a plan's utilization management requirements. This is because a formulary drug whose access is restricted via UM requirements is essentially equivalent to a non-formulary Part D drug to the extent that the relevant UM requirements are not met for a particular enrollee. However, if the plan's QL is equal to an FDA maximum dose limit, plans do not have to allow doses greater than this limit as part of a transition supply.

Question:
New chapter under section 30.4 added a second paragraph (section 2). Is this telling people they need to trigger a new transition period once the coverage determination approval expires?

CMS Response:
The section is defining what would constitute a non-formulary drug for the purpose of transition. The beneficiary would also need to be eligible for a transition fill. For example, if the drug is non-formulary and remains non-formulary the beneficiary would not be eligible for a transition fill after the approval expires because no negative formulary change occurred.

2.83 Communicate Part B Claim Paid for a QMB Beneficiary

Question:
What process should Medicare Advantage processors use to communicate the identification of a Part B claim has been paid for a QMB beneficiary and that the pharmacy should NOT attempt to collect the identified copayment from the beneficiary, but instead should seek additional payment from the appropriate Medicaid coverage?

CMS Guidance exists (including an article titled **Medicare and Medicaid Reports and Other Documents, Prohibition on Balance Billing Dually Eligible Individuals Enrolled in the Qualified Medicare Beneficiary (QMB) Program, ¶65,239, Centers for Medicare and Medicaid Services, (Feb. 1, 2016)** ¶65.239. *MLN Matters*, No. SE1128, February 1, 2016) that prohibits providers from balance billing Part A or Part B copayments for beneficiaries designated as Qualified Medicare Beneficiaries (QMB).

Excerpted statements from applicable guidance –
"The QMB program is a State Medicaid benefit that covers Medicare deductibles, coinsurance, and copayments, subject to State payment limits. (States may limit their liability to providers for Medicare deductibles, coinsurance and copayments under certain circumstances.) Medicare providers may not balance bill QMB individuals for Medicare cost-sharing, regardless of whether the State reimburses providers for the full Medicare cost-sharing amounts. Further, all original Medicare and MA providers—not only those that accept Medicaid—must refrain from charging QMB individuals for Medicare cost-sharing. Providers who inappropriately balance bill QMB individuals are subject to sanctions."

Balance Billing of QMBs Is Prohibited by Federal Law
Federal law bars Medicare providers from balance billing a QMB beneficiary under any circumstances. See ***Section 1902(n)(3)(B) of the Social Security Act, as modified by Section 4714 of the Balanced Budget Act of 1997.*** *(Please note, this section of the Act is available at* ***http://www.ssa.gov/OP_Home/ssact/title19/1902.htm*** *on the Internet.)*

"Proactive steps to identify QMB individuals you serve and to communicate with State Medicaid Agencies (and Medicare Advantage plans if applicable), can promote compliance with QMB balance billing prohibitions.

1. *Determine effective means to identify QMB individuals among your patients. Find out what cards are issued to QMB individuals so you can in turn ask all your patients if they have them. Learn if you can query state systems to verify QMB enrollment among your patients. If you are a Medicare Advantage provider contact the plan to determine how to identify the plan's QMB enrollees.*
2. *Discern what billing processes apply to seek reimbursement for Medicare cost-sharing from the States in which you operate. Different processes may apply to original Medicare and MA services provided to QMB beneficiaries. For original Medicare claims, nearly all states have electronic*

crossover processes through the Medicare Benefits Coordination & Recovery Center (BCRC) to automatically receive Medicare-adjudicated claims.

- *If a claim is automatically crossed over to another payer, such as Medicaid, it is customarily noted on the Medicare Remittance Advice.*
- *Understand the processes you need to follow to request reimbursement for Medicare cost sharing amounts if they are owed by your State. You may need to complete a State Provider Registration Process and be entered into the State payment system to bill the State.*

3. *Make sure that your billing software and administrative staff exempt QMB individuals from Medicare cost-sharing billing and related collection efforts."*

Response:
This response only addresses the communication between the Medicare Advantage Plan and the pharmacy to identify a QMB beneficiary.

Value 51* was added to Benefit Stage Qualifier (393-MV) for use in Telecommunication Standard vD.0.

"Not paid under Part D, paid under Part C benefit (for MA-PD plan). Beneficiary is a Qualified Medicare Beneficiary - pharmacy should not attempt to collect cost-share, but instead should attempt to bill COB to Medicaid coverage

- This qualifier applies to MA-PD plans where the claim is submitted under the Part D BIN/PCN.
- The claim is NOT paid by the Part D plan benefit.
- The claim IS paid for by Part C benefit (MA portion of the MA-PD).
- When the qualifier value of 51 is used, the Benefit Stage Count is 1 and no other benefit stage qualifier should be used.
- The field 394-MV Benefit Stage Amount should be populated with the total amount (total of 505-F5 Patient Pay Amount, 509-F9 Total Amount Paid, and 566-J5 Other Payer Amount Recognized) of the claim."

Value 51* was also added to Benefit Stage Indicator (C51-9X) for use in Telecommunication Standard Version EB or greater but not in lower versions.

*DERF 001485, Emergency ECL 000221 was approved by WG1 and Maintenance and Control during the February 2017 Work Group meetings and published in the ECL dated April 2017. The earliest emergency implementation date is 10/15/17 however; the industry requested a 270 day implementation.

2.84 Single Claim - Multiple Adjudications

Question:
If a B1 claim was processed through both the member's EGWP and WRAP and only one B1 response was given, is there any guidance on where the amounts are accounted for in the 505-F5 calculation? Should 129-UD be used to indicate the amount picked up by the EGWP and billed under a different plan? Should COB response logic be used? We are unable to find NCPDP guidance for direction on how to reply to a single claim that is adjudicated more than once by a single processor, resulting in a single response.

Response:
This appears to be a co-administered benefit and as such is not a COB claim. Therefore, COB response pricing and other COB specific fields would not be returned. The processor should use the appropriate

Benefit Stage Qualifier to identify how the claim was processed. The Payer ID and Network Reimbursement ID returned on a co-administered claim should be based on trading partner agreement.

2.85 POS Edits for Pharmacy

Question:

How should Pharmacy Service Type be used in POS editing?

Response:

Editing outside of checking for a valid value in the field may not exist as the use of this field does not necessarily represent the network or how the pharmacy is contracted.

2.86 Partial Fills of Schedule II Controlled Substances

Issue:

- Schedule II partial fills can occur across all pharmacy types (via CARA) and are no longer limited to LTC (as in DEA regulation).
- DEA views CARA's partial fill exception to be in addition to the exceptions currently listed under 21 C.F.R. § 1306.13.
- With this expansion, it is anticipated the volume of PDEs with multiple fills will increase. NCPDP recommends CMS work with the auditors to ensure any auditing of CIIs is handled correctly and not based on the OIG finding (which has incorrect data).

The task group sent a letter to the DEA and the response below was received from the Department of Justice, Diversion Control Division:

"Title 21, United States Code, Section 829(f)(3) states that "Notwithstanding paragraph (1) or (2), in any circumstance in which, as of the day before July 22, 2016, a prescription for a controlled substance in schedule II may be lawfully partially filled, the Attorney General may allow such a prescription to be partially filled." Section 702 of CARA became effective on July 22, 2016. As such, the DEA does not have the authority to delay its implementation. Please note that the DEA is currently promulgating proposed rulemaking to address the changes to Title 21, Code of Federal Regulations, Section 1306.13 (21 C.F.R. § 1306.13) made by the passage of CARA. In the meantime, it is recommended that to ensure a complete and accurate record is maintained regarding partial fills of Schedule II controlled substances, that pharmacists use the guidance provided under 21 C.F.R. § 1306.13(b), which states the following:

> *"For each partial filling, the dispensing pharmacist shall record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of Schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed." CARA also states that "Except as provided in [emergency situations], remaining portions of a partially filled prescription for a controlled substance in schedule II ... shall be filled no later than 30 days after the date on which the prescription is written."*

Nothing in the DEA's regulations authorize or permit any person to do any act which such person is not authorized or permitted to do under other Federal laws, or under the law of the state in which he or she desires to do such act nor shall compliance with the DEA's regulations be construed as compliance with other Federal or state laws unless expressly provided in such other laws, 21 C.F.R. § 1307.02. When Federal and state law or regulation conflict, then the person involved must adhere to the stricter aspects of each."

As a result of this letter, the following additional issues were reviewed by the task group:

- The documentation requirement does not impact LTC as they currently maintain that information although it may not be on the back of the prescription.
- The Drug Enforcement Administration has confirmed in writing that the existing 60-day window for CII partial fills is not impacted by CARA.

2.87 Medicare Transition Logic

If you have a member that enrolled in Medicare Part D effective 7/1/2017 they would have 90 days of transition as a NEW member, meaning they do not need history of the drug to get a transition fill. CMS updated logic to say a minimum of a 108 day look-back is typically needed to adequately document ongoing drug therapy in Chapter 6, 30.4.3 and in 30.4.4 it says within the first 90 days of coverage under a new plan, plans must provide a transition supply.

Question:
A member tries to get a fill on 10/9/2017 that is day 100 with the 7/1/2017 start date. They are outside the 90 days they are allowed but you haven't allowed 108 day look back yet. Should a brand new member actually get 108 days of transition or only use the 108 days when determining if they are new or existing?

Response:
After 90 days, non-formulary is not covered (91 days and up is outside of the transition period). A new member would not get 108 days of transition. 108 days lookback is used to determine if the drug is new or ongoing therapy. Suggest CMS look at revising guidance or creating a FAQ as there may be confusion in the industry.

3. Appendix A. Modifications to this Document

Version 1.0
Initial Release of this document

Version 2.0
New question 2.13 – Benefit Stage Qualifier and Employer Group Waiver Plan Wrap
New question 2.14 – No Gap Discount for Pharmacy Submitted Paper Claims

Version 3.0
New question 2.15 – Order for Error Processing and Messaging
New question 2.16 – Classifying LTC Claims
New question 2.17 – Trial Fill/Resynchronization of Refills
New question 2.18 – Requirement to Report Valid (i.e., Non-Default) Patient Residence and Pharmacy Service Type Values on All PDEs in 2014
New question 2.19 – PDE Layout – Pharmacy Service Type/Patient Residence
New question 2.20 – NX Reject Code 84
New question 2.21 – Benefit Stage Qualifiers Returned with a Gap between Values
New question 2.22 – Recognition and Coverage of Medical Foods

Version 4.0
New question 2.23 – Reject Codes and Messaging Returned with Hospice/ESRD Claims
New question 2.24 – Multi-Ingredient Compounds that Contain a CII Ingredient
New question 2.25 – Published FAQs Related to LTC Short Cycle Dispensing
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