Manufacturers Webinar

June 1, 2011

Announcements

- MDBG Announcements
- Post payment confirmation procedures
- 1099 update
- 15 character manufacturer id on payments
- Payment and payment confirmation date corrections
- EFT update from 5/13
- Suggested topics for the next webinar

Webinar Schedule

• July 6th, 2011

4:00-5:00 p.m. ET

Agenda

- Low Volume Revisited
- Payment Confirmation Response Reports
- Information Flow for Dispute Process
- Dispute Edits
- Dispute File Level Edit Response File Layout
- Average Manufacturer Price Explanation

Low Volume Background Slide

- Currently no low volume invoices have been distributed.
- CMS has not decided when low volume will be invoiced.
- The definition of low volume is 10 or fewer beneficiaries with the same NDC 9 drug dispensed by the same pharmacy.

Low Volume

Information:

Quarter 2

- 10 PDEs have been identified as part of a privacy related low volume group.
 - All 10 have a gap discount amount of \$1
- These 10 PDEs will be billed in summary as a low volume summary record DETLV.

Low Volume Example Continued

Header Re	Header Record Manufacturer								
Header Record Labeler Code 54321									
Record Type	LV Ref#	Current Qtr	Prev Qtr	Labeler Code	Reported Gap Discount Previous Amount	Reported Gap Discount Current Amount	Gap Discount Amount This Period	PDE Count	
DETLV	5432102011000000 0000	201102	000000	54321	0	10	10	10	
Trailer Record Labeler Code 54321									
Trailer Red	Trailer Record Manufacturer								

Low Volume Continued

(Example 2 continued)

Information:

Quarter 3

- Enough PDEs have been submitted to satisfy the privacy related requirements of 10 beneficiaries in the low volume summary.
- A new PDE for a new beneficiary in the NDC 9/pharmacy group came in this quarter with a gap discount amount of \$1.
- 10 PDEs for 10 different beneficiaries, each with a gap discount amount of \$1, will now be billed individually. Previously these were invoiced in the low volume summary.
- An adjusted low volume summary will reflect the PDEs that have been removed. The amount of the -\$10 low volume summary and the 10 \$1 PDE's will net to zero.
- Note: The DETLV and DETCG reference numbers are different.
 PDEs that move from the DETLV record to individual DETCG records summary have a Y in Prior Low Volume Discount Flag.

Low Volume Continued

Header Record Manufacturer									
Header Record Labeler Code 54321									
Record Type	LV Ref#	Current Qtr	Prev Qtr	Labeler Code	Reported Gap Discount Previous Amount	Reported Gap Discount Current Amount	Gap Discount Amount This Period	PDE Count	
DETLV	5432102011000000 0000	201102	000000	54321	C	10	10	10	
Trailer Record Labeler Code 54321									
Trailer Record Manufacturer									

Header Record Manufacturer								
Header Record Labeler Code 54321								
Rec	LV Ref#	Current	Prev Qtr	Labeler Code	Reported	Reported	Gap	PDE
ord		Qtr			Gap	Gap	Discount	Count
Туре					Discount	Discount	Amount	
					Previous	Current	This	
					Amount	Amount	Period	
DET	54321020110000000000	201103	201102	54321	10	0	-10	0
LV								
Trailer Record Labeler Code 54321								
Trailer Record Manufacturer								

Payment Confirmation

Calendar Days vs Business Days

- Language in the Manufacturers Agreement requires payment from Manufacturers to Sponsors by the 38th CALENDAR day after the Invoice date.
- Sponsors are required to file their Payment Confirmation within 5 BUSINESS days of the payment deadline.

Payment Confirmation Response Report

Legend for hig	Legend for highlighted fields in Payment Confirmation Response Report							
RUN DATE	CCYYMMDD	The date the report was created by the TPA.						
MANUFACTURER ID	XXXXXX	The mailbox id that sent the report to the TPA for processing.						
PNUMBER	PPPPP	The p number in the header record of the returned report.						
REPORT ID	YYYYQQ	The report id of the report received by the TPA.						
FILE ID	AAAAA	The file id of the report received by the TPA.						
RECORD TYPE	TTTTT	The record type that is in error.						
TPACH SEQ NO	9999999	The last TPACH sequence number of the record in error.						
LBLR SEQ NO	8888888	The LBLR sequence number of the record in error.						
ERROR CODE(s)	EEEE	The error code issued by the TPA.						
ERROR DESCRIPTION	DDDDDD	The description of the error code issued by the TPA.						

Payment Confirmation Response Report: Status = Accepted

REPORT: TPA-RESPM THIRD PARTY ADMINISTRATOR

RUN DATE: CCYYMMDD TPA RESPONSE REPORT

MANUFACTURER ID: XXXXXX PNUMBER: PPPPP

REPORT ID: YYYYQQ FILE ID: AAAAA STATUS: ACCEPTED RECEIPT OF THE REPORT

Payment Confirmation Response Report: Status = Rejected (one reject reason)

REPORT: TPA-RESPM THIRD PARTY ADMINISTRATOR
RUN DATE: 20110526 TPA RESPONSE REPORT

MANUFACTURER ID: XP9898 PNUMBER: P9898
REPORT ID: 201101 FILE ID: 10MPC STATUS: REJECTED RECEIPT OF THE REPORT

RECORD TPACH LBLR ERROR ERROR DESCRIPTION

TYPE TPAMH SEQ NO SEQ NO

CODE E001

INVALID REPORT ID

File status: Rejected

List record type that was in error, error code and error description.

In this example, only header or trailer (TPAMH TPAMT) records are in error. No sequence number displays after the record type because header/trailer records occur only once.

Payment Confirmation Response Report: Status = Rejected (multiple reject reasons)

REPORT: TPA-RESPM THIRD PARTY ADMINISTRATOR RUN DATE: 20110526 TPA RESPONSE REPORT MANUFACTURER ID: XP9898 PNUMBER: P9898 REPORT ID: 201101 FILE ID: 10MPC STATUS: REJECTED RECEIPT OF THE REPORT ERROR DESCRIPTION RECORD TPACH LBLR ERROR SEO NO TYPE SEO NO CODE **TPAMH** E001 INVALID REPORT ID 0000001 TPACH E009 INVALID CONTRACT 0000001 0000002 E011 LBLR MISSING RECORD TYPES IN FILE PAYMENT AMOUNT NOT NUMERIC E008 TPAMT

File status: Rejected

Lists information for each error: record type, sequence number (if applicable), error code and error description.

Payment Confirmation Response Report Status: Discrepant

```
TPA-RESPM
              THIRD PARTY ADMINISTRATOR
                                TPA RESPONSE REPOR
RUNREPORT: DATE: CCYYMMDD
MANUFACTURER ID: XXXXXXX PNUMBER: PPPPP
REPORT ID: YYYYQQ FILE ID: AAAAA STATUS. DISCREPANT RECEIPT OF THE REPORT
                                         ERROR DESCRIPTION
                               ERROR
RECORD
         TPACT
 TYPE
         SEQ NO
                               CODE
TPACT
          abaaaaa
                                E012
                                         CONFIRMED PAYMENT AMT <> INVOICE PAYMENT AMT
                                          CONFIRMED PAYMENT AMT <> INVOICE PAYMENT AMT
TPAMT
                                E012
```

File status: Discrepant

Issued any time when the PAYMENT AMOUNT does not match TOTAL GAP DISCOUNT AMOUNT THIS PERIOD, either on a TPACT record or on the TPAMT record.

E012 CONFIRMED PAYMENT AMT <> INVOICE PAYMENT AMT

Lists information for each error: record type, sequence number (if applicable), error code and error description.

Files in the Dispute Process

Manufacturer Data Report

- TPA sends to Manufacturer
- Distributed on April 30, 2011

Dispute Submission File (June 17 through June 30)

- Manufacturer sends to TPA
- Dispute File Level Edit Response File (TPA sends to Manufacturer)
- Dispute Detail Level Edit Response File (TPA sends to Manufacturer)

Dispute Resolution File

- TPA sends to Manufacturer
- Scheduled distribution on (Aug 29, 2011)

Dispute Edits – File Level Rejects

DISPUTE EDIT CODES	EDIT CATEGORY	Message to be Reported	Failure Outcome (Reject)
E001	ı	Invalid Report Id	Reject
E002	M/I	Report Id in TPAMT record does not match the TPAMH	Reject
E004	M/I	Invalid File Id	Reject
E005	M/I	Invalid "P" number	Reject
E006	I	Dispute date precedes data report distribution date	Reject
E007	M/I	No date entered/invalid, or date is > current date	Reject
E010	I	Invalid record types in file.	Reject
E011	M	Missing record types in file	Reject
E014	ı	Dispute received after the 60 day deadline	Reject

Dispute File Level Edit Response File: Status = Accepted

REPORT: TPA-RESPM THIRD PARTY ADMINISTRATOR

RUN DATE: CCYYMMDD TPA RESPONSE REPORT

MANUFACTURER ID: XXXXXX PNUMBER: PPPPP

REPORT ID: YYYYQQ FILE ID: AAAAA STATUS; ACCEPTED RECEIPT OF DISPUTE

Dispute File Level Edit Response File: Status = Rejected (one reject reason)

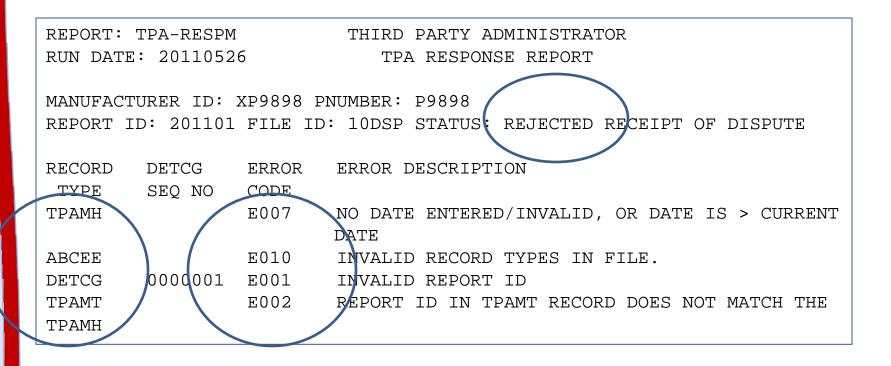
REPORT: TPA-RESPM THIRD PARTY ADMINISTRATOR RUN DATE: 20110526 TPA RESPONSE REPORT MANUFACTURER ID: XP9898 PNUMBER: P9898 REPORT ID: 201101 FILE ID: 10DSP STATUS: REJECTED RECEIPT OF DISPUTE RECORD **DETCG ERROR** ERROR DESCRIPTION CODE TYPESEQ NO E007 NO DATE ENTERED/INVALID, OR DATE IS > TPAMH CURRENT DATE

File status: Rejected

List record type that was in error, error code and error description.

In this example, only header or trailer (TPAMH TPAMT) records are in error. No sequence number displays after the record type because header/trailer records occur only once.

Dispute File Level Edit Response File: Status = Rejected (multiple reject reasons)



File status: Rejected

Lists information for each error: record type, sequence number (if applicable), error code and error description.

Dispute Resolution File-TPAMH

File Id: 10DRS - Manufacturer Dispute Resolution file Appeal notice (in field 9)

This file includes the resolution of a dispute previously filed. If the Dispute Disposition field indicates that the TPA upheld the dispute, future invoices will be credited. A manufacturer may appeal a denied dispute to the Independent Review Entity (IRE) within 30 calendar days. A link to the IRE can be found on the CMS manufacturer's page at

http://www.cms.gov/PrescriptionDrugCovGenIn/05 Pharma .asp#TopOfPage

under "Related Links Outside CMS."

Dispute Resolution File-DETDR Record

DISPUTE DISPOSITION	925 - 925	X(1)	1	The final status of the dispute 1 - Upheld 2 - Denied 3 - Denied, rejected on submission format error 4 - Denied, received after 60 days (excluding files rejected by TPA with edit code E014)
DISPUTE RESOLUTION CODE	926 - 931	X(6)	6	A unique code for the dispute resolution (Optional - codes to be developed).
DISPUTE RESOLUTION TEXT	932 - 1011	X(80)	80	Detailed explanation for why the dispute was upheld or denied (Optional).
FILLER	1012 -1024	X(13)	13	Spaces

Dispute Resolution File-TPAMT

TOTAL DETAIL RECORD COUNT		\	_	The number of disputes
UPHELD	50 - 56 9	9(7)	7	upheld.
TOTAL DETAIL RECORD COUNT DENIED	57 - 63 9	9(7)	7	The number of disputes denied.
TOTAL DETAIL RECORD COUNT DENIED, REJECTED ON ERROR	64 - 70 9	9(7)	7	The number of disputes rejected on submission format error.
TOTAL DETAIL RECORD COUNT DENIED, RECEIVED AFTER 60 DAYS	71 - 77 9	9(7)	7	The number of disputes received after 60 days (excluding files rejected by TPA with edit code E014).

Average Manufacturer Price

- <u>A M P</u> or "AMP"
 - Calculated price
 - Price paid to manufacturer for a drug in the U.S. by covered entities
 - Includes rebates, discounts, and other payment arrangements with covered entities
 - Does not include Coverage Gap Discount amounts
- SSA §1927(k)(1)
 - Defines AMP
- SSA §1927(b)(3)(D)
 - o Confidentiality of Information
- Patient Protection and Affordable Care Act §2503(a)(2)
 - Amended the definition of AMP
 - e.g., narrowed the covered entities used in AMP calculation

Average Manufacturer Price

- Medicare Part D sponsors negotiate prices with network pharmacies
 - Negotiated price is the same throughout each Part D benefit phase
 - Negotiated price may change on fluctuations in AWP

A W P

- Average Wholesale Price
- Price index published in commercial drug databases
- Set by commercial vendors
 - Based on information submitted by manufacturers
 - Mark-up factors applied by commercial vendors
 - May not include rebates, discounts, other financial arrangements between manufacturers and covered entities

Average Manufacturer Price

- AMP
 - Confidential price
 - Not published in commercial drug databases
 - Average price paid by covered entities
 - Not price paid by Medicare Part D sponsors and beneficiaries
 - Includes rebates, discounts that may not be included in AWP
- Dispute Code D06 High Price of the Drug
 - Cannot be based on AMP
 - Disputes based on AMP will be denied