

Manufacturers Webinar

July 6, 2011

Agenda

- Upcoming dates
- Low Volume Memo
- Low Volume Summary Report
- Payment Confirmation and Response
- 1099
- 340B
- Appeals and the Independent Review Entity (IRE)

Upcoming Dates

- Low Volume Summary report will be distributed in the end of July.
- Dispute Resolution File by August 28, 2011.
- Second Quarter Invoice will be released August 31, 2011.

Low Volume Memo

Discussion

Low Volume Summary Report

FIELD NO	FIELD NAME	POSITION	PICTURE	LENGTH	DEFINITION / VALUES
1	RECORD TYPE CODE	1 - 5	X(5)	5	"SUMLV"
2	REPORT ID	6 - 11	9(6)	6	Year/Quarter item was placed on the invoice. Format is: "YYYYQQ". QQ represented as "01"-"17".
3	LABELER CODE	12 - 16	x(5)	5	Labeler Code is the first 5 positions of the NDC. The format is MMMMM.
4	LOW VOLUME GAP DISCOUNT CURRENT AMOUNT	17 - 27	S9(9)V99	11	Total of LV Gap Discount amounts identified for a specific Manufacturer Labeler.
5	FILLER	27 - 512	X(485)	485	Spaces

Payment Confirmation

- Payment Confirmation Report is built using information found on the Manufacturer Invoice Report
- Manufacturer creates the report and sends to the TPA
- Confirmations are made at the contract level

Payment Confirmation Process

- Detailed instructions are found at www.cssoperations.com
- Manufacturer Confirmation of Payment Report Overview
 - How to format the file
 - Based on Invoice Report
- Payment Confirmation Procedures
 - Timing
 - How the process works
 - Null file
 - Confirmation response
 - Error codes
 - Report layouts

Payment Confirmation Response File Types

- Accepted
 - Payments match invoiced amounts
- Rejected
 - File or data errors
- Discrepant
 - Amount confirmed does not match amount invoiced

Confirmation Response - Accepted

Accepted Payment Confirmation Response Report

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

Confirmation Response - Rejected

Simple Rejected Payment Confirmation Response Report

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

MANUFACTURER ID: XXXXXX PNUMBER: PPPPP

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

RECORD	TPACH	LBLR	ERROR	ERROR DESCRIPTION
TYPE	SEQ NO	SEQ NO	CODE	
TTTT			EEEE	DDDDDD

Confirmation Response – Rejected (cont.)

Complex Rejected Payment Confirmation Response Report

REPORT: TPA-RESPM

THIRD PARTY ADMINISTRATOR

RUN DATE: CCYYMMDD

TPA RESPONSE REPORT

MANUFACTURER ID: XXXXXX PNUMBER: PPPPP

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

RECORD	TPACH	LBLR	ERROR	ERROR DESCRIPTION
TYPE	SEQ NO	SEQ NO	CODE	
TTTTT	9999999	8888888	RRRR	DDDDDD
TTTT			EEEE	DDDDDD

Confirmation Response – Discrepant

Discrepant Payment Confirmation Response Report

REPORT: TPA-RESPM THIRD PARTY ADMINISTRATOR
RUN DATE: 20110531 TPA RESPONSE REPORT

MANUFACTURER ID: XP9898 PNUMBER: P9898

REPORT ID: 201101 FILE ID: 10MPC STATUS: DISCREPANT RECEIPT OF THE REPORT

RECORD TYPE	TPACT SEQ N	ERROR CODE	DESCRIPTION
TPACT AMT	0000001	E012	CONFIRMED PAYMENT AMT <> INVOICE PAYMENT
TPAMT AMT		E012	CONFIRMED PAYMENT AMT <> INVOICE PAYMENT

1099s

- At manufacturers' request, CMS consulted with the IRS to determine if manufacturers must send 1099s to Part D sponsors for CGDP discounts the manufacturer pays to Part D sponsors.
- The IRS may provide guidance on this issue in a “private letter ruling” issued to an individual taxpayer in response to a written request. Manufacturers may consider requesting a private letter ruling.

1099s (cont.)

- The process for requesting a private letter ruling and the required user fee are described in Revenue Procedure 2011-1. Tax professionals are familiar with this procedure.
- <http://www.irs.gov/pub/irs-irbs/irb11-01.pdf>
- The IRS releases "private letter rulings" to the public in redacted form after deleting private information .
- CMS advises manufacturers to consult their tax professional to assist in submitting their questions in writing to the IRS.

340(b)

- Implemented by the Veterans Health Care Act of 1992
- Amended the Public Health Service Act - added § 340B
- Limits costs of outpatient prescription drugs
- Limited to certain health care organizations (340b entities) - statutorily defined
- Prescription drug claims from 340b entities:
 - NOT eligible for manufacturer MEDICAID rebates
 - ELIGIBLE for the MEDICARE Coverage Gap Discount

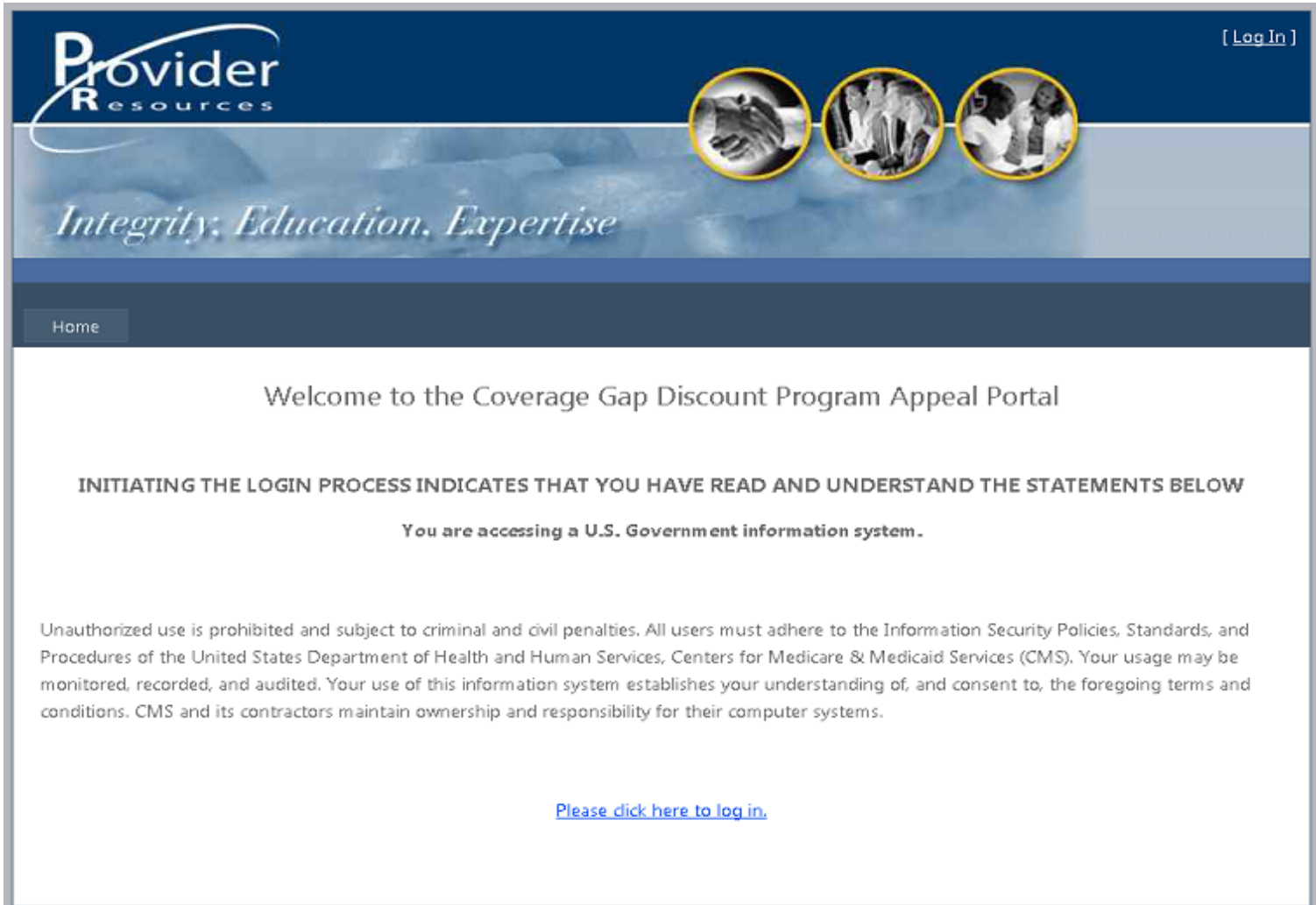
Disputes and Appeals

- Manufacturer must first submit disputes to the TPA.
- Manufacturers may appeal TPA decision
 - Within 30 days of receiving the TPA decision or
 - 60 days after filing the dispute with the TPA, if no decision has been reached. Whichever date is EARLIER.
- Provider Resources, Inc. (IRE) must provide a decision within 90 days of receiving an appeal.
- Manufacturers may appeal IRE decision to the CMS Administrator.

IRE Operations

- IRE operates independently with CMS general oversight.
- Appeals must be submitted via the IRE's portal.
- A link to the portal will be posted on the CMS Manufacturer's web page beginning July 18th at the following address:
http://www.cms.gov/PrescriptionDrugCovGenIn/05_Pharma.asp .
- Only information submitted with dispute, or in response to a specific request from the IRE will be considered.
- Manufacturers should review May 31, 2011, Discount Program Guidance prior to submitting an appeal.

IRE Operations



The screenshot shows the top of a web page with a dark blue header. On the left is the "Provider Resources" logo. On the right is a "[Log In]" link. Below the logo are three circular images: a hand holding a pen, a group of people in a meeting, and two people talking. The tagline "Integrity, Education, Expertise" is written in a cursive font. A "Home" button is visible in a dark blue bar. The main content area is white and contains the following text:

Welcome to the Coverage Gap Discount Program Appeal Portal

INITIATING THE LOGIN PROCESS INDICATES THAT YOU HAVE READ AND UNDERSTAND THE STATEMENTS BELOW

You are accessing a U.S. Government information system.

Unauthorized use is prohibited and subject to criminal and civil penalties. All users must adhere to the Information Security Policies, Standards, and Procedures of the United States Department of Health and Human Services, Centers for Medicare & Medicaid Services (CMS). Your usage may be monitored, recorded, and audited. Your use of this information system establishes your understanding of, and consent to, the foregoing terms and conditions. CMS and its contractors maintain ownership and responsibility for their computer systems.

[Please click here to log in.](#)

IRE Operations

Provider
Resources

[Log In]



Integrity. Education. Expertise

Home

CREATE A NEW ACCOUNT

Use the form below to create a new account.

Passwords are required to be a minimum of 13 characters in length. Passwords must also include at least 1 numeric character and 1 non-alphanumeric character.

Account Information

Username:

E-mail:

Password:

Confirm Password:

Coverage Gap Discount Program Appeals Submission Form - Step 1 of 2

Questions regarding the completion of this form or the website may be submitted to cgdappeals@provider-resources.com.

Instructions:

- 1) Complete the information below and click the "Save Appeal Detail" button to save your appeal.
- 2) To submit additional appeals, please fill out the Appeal Details section of the form and click "Save Appeal Detail".
- 3) Click "Review Appeal" to move to the next step.

All fields are required.

Contact Information

Manufacturer Name:

P Number (P####):

Name of Individual Submitting Appeal:

Email Address:

Telephone Number (###-###-####):

Alternate Contact Name:

Alternate Email Address:

Alternate Telephone Number (###-###-####):

Appeal Detail

Invoice Report ID (e.g., 201101):

Was the TPA Decision issued within the 60 day window?:

Detail Reference Number

Date Dispute Submitted to TPA

TPA Decision Date:

Dispute Resolution Code (if applicable)

Reason Code for IRE Appeal

Explanation for IRE Review Request

Amount Invoiced

Amount Appealed

Detail Reference Number	Date Dispute Submitted to TPA	Date of TPA Decision	Dispute Resolution Code	Reason Code for IRE Appeal	Explanation for IRE Review Request	Amount Invoiced	Amount Appealed
No records to display.							

Remove Appeal Detail

Save Appeal Detail

Please note that saving the appeal does NOT submit the appeal. Please continue by clicking the "Review Appeal" button.

Review Appeal