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Manufacturer CGDP Onboarding Training

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CGDP Onboarding Training

Onboarding is the training process that describes requirements all Drug Manufacturers are encouraged to complete to participate and fulfill program requirements of the Coverage Gap Discount Program (CGDP).

In this training you will learn about:

- CGDP (Program) Overview
- Welcome Letter and Forms to be Completed
- Manufacturer Forms
- Health Plan Management System (HPMS) Access
- CGDP Portal Access
- Accessing the CGDP Portal
- Initiating Payments
- Reports
- Disputes
- Getting Help

As of January 1, 2011, the Affordable Care Act became effective and in accordance with this legislation, the Medicare Coverage Gap Discount Program (the Program) was established.

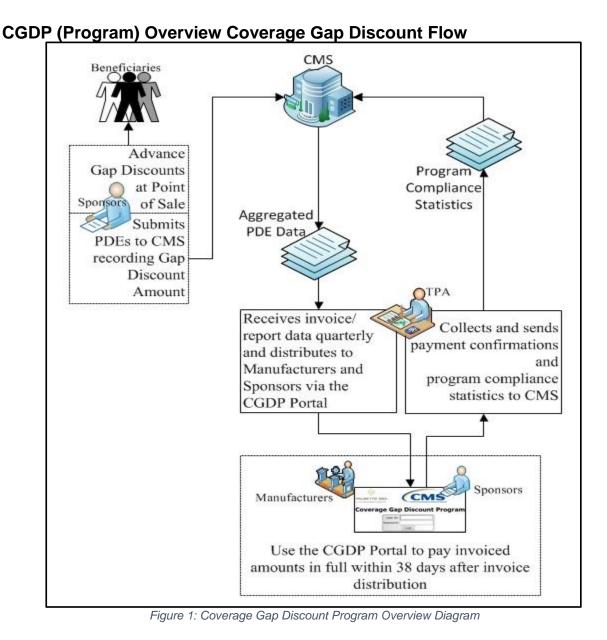
The Program requires that Sponsors provide Part D beneficiaries with a discount for applicable Program drugs at the point of sale. Drug Manufacturers are required to reimburse the Sponsor for this discount.

Section 1860D-14(A) (d) requires that the Centers for Medicare and Medicaid Services (CMS) contract with a Third Party Administrator (TPA) to:

- Receive and transmit information between CMS, pharmaceutical Manufacturers, and other entities as appropriate
- Receive, distribute, or facilitate the distribution of funds of pharmaceutical Manufacturers and Part D Sponsors to appropriate entities
- Provide adequate and timely information to pharmaceutical Manufacturers and Part D Sponsors

The TPA is the single point of contact between the pharmaceutical Manufacturers (including their third party vendors) participating in the Program.

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- Part D Sponsors (Sponsors) advance Gap Discounts to beneficiaries at point of sale
- Sponsors submit Program-qualified prescription drug event (PDE) records to CMS recording the Gap Discount amount
- · CMS aggregates qualifying PDE data and sends the resulting invoices to the TPA
- TPA sends quarterly invoice and reports data to pharmaceutical Manufacturers (Manufacturers) and Sponsors simultaneously via the CGDP Portal
- Manufacturers and Sponsors use the CGDP Portal to pay the invoice and invoice adjustment amounts in full within 38 days after invoice distribution
- TPA collects payment statuses and program compliance data from the CGDP Portal and submits statistics to CMS

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CGDP (Program) Overview Invoice Distribution Schedule

On a quarterly basis, the TPA distributes invoice and data files to Manufacturers based on qualifying PDE data submitted to CMS.

The table displayed here provides the reporting period quarter end and report distribution dates.

Quarter End Date	Report Distribution Date
March 31	April 30
June 30	August 31
September 30	October 31
December 31	January 31

Figure 2: Reporting Period Quarter End and Distribution Dates

A full program calendar can be found at the TPA website https://www.tpadministrator.com.

The <u>CGDP Calendar</u> link appears under the Topics menu. Users can select the <u>Medicare Part</u> <u>D Coverage Gap Discount Program Calendar</u> link to view the full calendar.

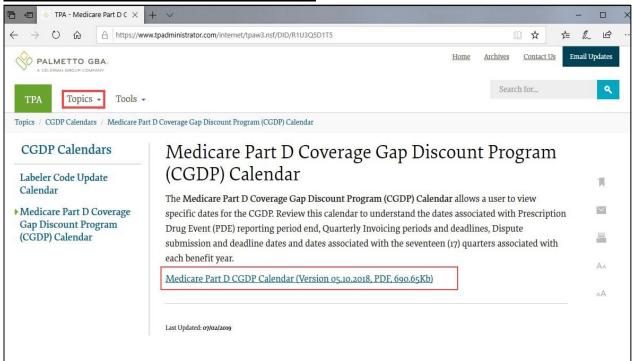


Figure 3: CGDP Calendar on TPAdministrator.com Website

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Onboarding Forms

Manufacturer Onboarding Form Requirements

Drug Manufacturers (and their third party vendors) that participate in the Program supply onboarding information to allow the TPA to act as the single point of contact to facilitate the distribution and receipt of funds between the participating entities.

Manufacturers will receive a four page Welcome Letter from the TPA Support Center with instructions for completing and submitting these forms:

- CMS HPMS Access via Enterprise User Authentication (EUA) Instruction
- Electronic Funds Transfer (EFT) Online Form (Automated Clearinghouse (ACH) Deposit and ACH Payment)
- Third Party Registration Form (if applicable)
- ListServ registration

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Manufacturer Welcome Letter

The Welcome Letter provides new Manufacturers with instructions for obtaining access to the CGDP Portal and a listing of online and paper forms requiring completion.



Figure 4: Manufacturer Welcome Letter – Excerpt of Page One (1)

Page three of the Welcome Letter requires the completion of Table 1 if the Manufacturer has opted to use a third party vendor. This table is completed if a third party vendor is authorized to receive Invoice, Data, and Tracking reports for the Manufacturer.

Table 1: Th	ird Party Vendor Reports
Distribute all report(s) to Third Party Vendor?	Yes No (If no specify which reports they should receive.) Invoice Data Tracking Reports
Third Party Vendor Name:	
Email Address:	
Phone Number:	

Figure 5: Manufacturer Welcome Letter – Table 1 Page Three (3) Third Party Vendor Reports

Once completed, the Manufacturer will scan the page(s) containing the tables and send them to the TPA Operations via email from <u>tpaoperations@tpadministrator.com</u>.

The last page of the Welcome Letter provides Manufacturers with a checklist of documents and links referenced in the Welcome Letter. This checklist is provided for Manufacturers to track the documents needed in the onboard process and provides a description of each one.

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Table 2: Documents Checklist

Checklist of Documents/Links referenced in the Welcome Letter

DOCUMENT	FORM DESCRIPTION
HPMS Point of Contact Information	Website
<u>HPMS</u>	(Ensure this is the most current information)
Electronic Funds Transfer (EFT) Online	Receive deposits from entities
Form	(Form submitted electronically)
Deposit Information Form	
EFT Online Form	Make payments to entities
Payment Information Form	(Form submitted electronically)
Listserv Registration	Ability to receive email announcements from TPA Operations
Email Updates	
Third Party Registration Form	Complete if Third Party is managing payments or retrieving reports
(If applicable)	(Form to be emailed to TPA Operations)

Figure 6: Manufacturer Welcome Letter – Table 2: Documents Checklist on Page Four (4)

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Manufacturer HMPS Access

Manufacturer CMS HPMS Access

HPMS is the system of record for all Manufacturer Agreements, Manufacturer contacts, and Labeler Codes. Manufacturers are responsible for keeping their information updated, always.

In addition, CMS uses the Manufacturer contacts within HPMS to communicate key matters of policy and compliance. Therefore, Manufacturers should ensure that individuals within their organizations have ongoing access to HPMS.

To obtain HPMS access, the requestor, and the Drug Manufacturer (company) must have a physical location within the United States. Foreign-based corporations may participate in the Program but must use their US location for managing the Program within HPMS.

Note: Individuals must have a valid Social Security Number to gain access to HPMS.

By statute, Drug Manufacturers must contract for the Program by January 30 of the year prior to the contract's effective date. The signatory must log into HPMS and sign the agreement by that time. It is strongly recommended that the signatory sign the agreement well in advance of the January 30 deadline to prevent missing the deadline due to technical or access related issues.

During the contracting process, each Drug Manufacturer participating in the Program is required to sign a Manufacturer Agreement (between CMS and the Manufacturer) and a TPA Agreement (between the Manufacturer and TPA). They are also required to provide CMS with a primary contact, a signatory contact, and a third-party submitter contact (if applicable). The Drug Manufacturer in HPMS submits this information. CMS uses this information during the process of securing Manufacturer Agreements and continues to communicate Program information to contracted Drug Manufacturers' designated points of contacts.

To obtain access to the CGDP Portal, the Drug Manufacturer must enter contact information in HPMS for the TPA Liaison and the Coverage Gap Discount Program (CGDP) Payment Contact, which allows an authorized user to review and process quarterly invoices for the CGDP.

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CMS HPMS Access - EUA Form

Manufacturer associates listed in the Welcome Letter as the TPA Liaison or Coverage Gap Discount Program (CGDP) Payment Contact must have access to HPMS to be granted access to the CGDP Portal.

To obtain HPMS access, the EUA Workflow Request online form must be completed.

Instructions for Requesting a New CMS User ID: HPMS Drug Manufacturer Users

Prior to starting this process, please add the following email addresses to your email address book and/or "safe senders list" to ensure delivery: EUA@cms.hhs.gov and ESS@cms.hhs.gov

 Open your web browser and enter the EUA Front-End Interface (EFI) URL: https://eua.cms.gov/efi

Note: At this time, you must use either IE 9+ or Firefox 35+ with compatibility mode disabled. Google Chrome is not currently supported.

- 2. Click the "Register" button.
- 3. Enter your personal details in the respective boxes. Create your own "username" and "password".

Figure 7: Example of Instructions for Requesting New CMS User ID for HPMS

To access the online form, go to the <u>CMS.gov User ID Process</u> page and select the "<u>Instructions for Requesting Plan Access via EFI (PDF)</u>" link to review the instructions for requesting a New User ID.

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Manufacturer CGDP Portal Login Credentials

To set up connectivity, CMS requires that there be a TPA Liaison Contact listed in HPMS. A Coverage Gap Discount Program (CGDP) Payment Contact can also be listed in HPMS.

Once this contact information appears in HPMS, login credentials will be provided to the Manufacturer TPA Liaison and/or Coverage Gap Discount Program (CGDP) Payment Contact, if applicable to access the CGDP Portal, which is used to facilitate the CGDP quarterly invoicing and direct payment processing.

Note: Login credentials will *only* be provided to the TPA Liaison or Coverage Gap Discount Program (CGDP) Payment contact. The TPA Liaison Contact will be assigned view and payment privileges in the CGDP Portal, unless there is a Coverage Gap Discount Program (CGDP) Payment Contact listed in HPMS.

If a Coverage Gap Discount Program (CGDP) Payment Contact is listed, they will be assigned view and payment capabilities in the CGDP Portal whereas the TPA Liaison will now be granted view-only capabilities.

In addition, CMS will not excuse or extend deadlines for failure to have the correct TPA Liaison or Coverage Gap Discount Program (CGDP) Payment contact information listed on the HPMS website.

Manufacturer CGDP Portal User ID and Initial Password

Once the TPA Liaison or Coverage Gap Discount Program (CGDP) Payment Contact is listed in HPMS, the authorized Manufacturer associate will be required to contact TPA Support Center to receive an initial temporary password. The User ID is included in the Welcome Letter and can be communicated to the applicable user via email during the initial onboarding logon process.

For information on accessing the CGDP Portal, refer to <u>The CGDP Portal</u> section of this document.

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Banking Information

ACH Deposit Form

Manufacturers are required to complete an ACH Deposit Form to provide a depository account to receive Sponsor CGDP adjustment funds initiated via the CGDP Portal.

Note: Only the TPA Liaison or Coverage Gap Discount Program (CGDP) Payment Contact is authorized to complete bank account updates for your company.



Figure 8: Request Payee Account Modification link in the CGDP Portal

The form is in the CGDP Portal and can be accessed after successful login to the portal:

- Click on "My Profile" in the upper right hand corner of the CGDP Portal.
- Under the Account Maintenance section, select "Request Payee Account Modification" to provide information for the bank account to receive CGDP payments.

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ACH Payment Form

Manufacturers are required to complete an ACH Payment Form to provide a debit account to remit Sponsor CGDP payments initiated via the CGDP Portal.

Note: Only the TPA Liaison or Coverage Gap Discount Program (CGDP) Payment Contact is authorized to complete bank account updates for your company.

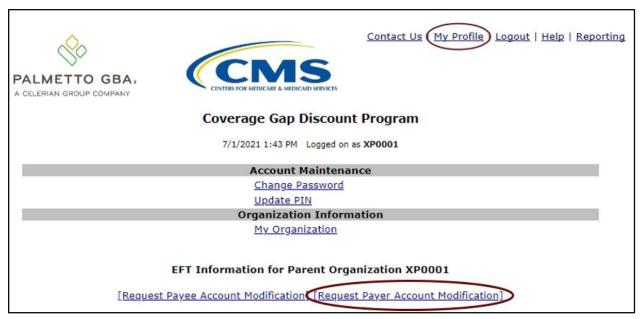


Figure 9: Request Payer Account Modification line in the CGDP Portal

The form is in the CGDP Portal and can be accessed after successful login to the portal:

- Click on "My Profile" in the upper right hand corner of the CGDP Portal.
- Under the Account Maintenance section, select "Request Payer Account Modification" to provide information for the bank account to receive CGDP payments.

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Manufacturer Third Party

Third Party Vendor Onboarding Form Requirements

If a Third Party vendor is designated by a Manufacturer in the Manufacturer Welcome Letter, the TPA Support Center will send a two page Welcome Letter to the Third Party vendor using the email supplied in the Manufacturer Welcome Letter Table 1: Third Party Vendor Reports.

Third Party Vendors: Drug Manufacturers may elect a third party vendor to receive a copy of the Invoice, Data, and Tracking reports. To designate a third party vendor, please complete the information in Table 1: Third Party Vendor Reports below and submit to tpaoperations@tpadministrator.com. We will immediately initiate procedures to establish connectivity with the third party vendor. We will also provide additional information to third party vendors to authorize report disclosures in a separate correspondence.

Table 1: Third Party Vendor Reports

Distribute all report(s) to Third Party Vendor?	 Yes No (If no specify which reports they should receive.) Invoice
Third Party Vendor Name:	Third Party Vendor Systems, LLC
Email Address:	Joe.Smith@TPVSystemsLLC.com
Phone Number:	123-555-1234

Figure 10: Example of Completed Third Party Vendor Reports Table

The Third Party Vendor Welcome Letter contains instructions for completing and returning CGDP information to the TPA Support Center via email.

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Manufacturer Third Party Vendor Welcome Letter

The first page of the Third Party Vendor Welcome Letter provides a brief introduction to the Program for Third Party Vendors, how to return the completed form back to TPA Operations, and instructions for completing the second page of the Welcome Letter.

Third Party Vendor Welcome Letter

The Third Party Administrator (TPA) Support Center for the Coverage Gap Discount Program (CGDP) welcomes you to the program. We provide online access to retrieve Invoice, Data and Tracking reports, as well as process invoice payments and dispute invoice amounts. In order for you to retrieve your Manufacturer or Sponsor reports, we must establish connectivity between the TPA and your Submitter ID. To set up connectivity, please complete Tables 1 or 2, as applicable, in this document and submit to TPA Operations via email at <u>tpaoperations@tpadministrator.com</u>.

The Third Party Vendor document is due by January 31, 20YY, 11:59 pm ET

Once we receive this information, two separate emails from the TPA Operations containing a User ID and password for the DPP System will be provided to the Primary Contact Person listed in Table 1 or Table 2.

Listserv Registration: Third Party Vendors can complete a Listserv registration via the TPA Administrator website. This provides the ability to receive pertinent information related to the CGDP via email. Select the hyperlink to complete the <u>Email Updates</u> or go to <u>www.tpadministrator.com</u> and select the *Email Updates* icon in the center of the website page to register for email updates.

Figure 11: Example of Third Party Vendor Welcome Letter – Page One (1)

The second page of the Third Party Vendor Welcome Letter provides information about the Manufacturer authorizing the third party vendor organization access to Program information.

Third Party Administrator (TPA) received information from CGDP TPA, Inc. authorizing your organization Third Party Vendor Systems, LLC to assist them in the administration of invoice-related functions for the Medicare Part D Coverage Gap Discount Program. Please validate your company and the company you are representing below:

Third Party Vendor Name	Submitter ID	
Third Party Vendor Systems, LLC	XTP099	
Drug Manufacturer /Sponsor Name	Agree	Disagree
CGDP TPA, Inc.		
Third Party Vendor Status	New:	Established:

Figure 12: Example of Third Party Vendor Welcome Letter – Page Two (2)

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The check box populated in the Third Party Vendor Status field designates information the vendor receiving the Third Party Vendor Welcome Letter will complete. The two additional tables are:

- Table 1: New Third Party Vendors
- Table 2: Established Third Party Vendors

Two additional tables are located on the second page. One of these two tables should be completed by the third party vendor with the applicable information, based on the Third Party Vendor Status check box prefilled by the TPA Support Center (as seen *Figure 12*Figure 12: Example of Third Party Vendor Welcome Letter – Page Two (2)).

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The CGDP Portal

CGDP Portal Access

The CGDP Portal is designed to assist Manufacturers with processing Coverage Gap Discount Program invoice payments. This system allows Manufacturers to review invoice line items and initiate bank-to-bank ACH transfers for invoice line item payments, like the way an online banking customer pays a monthly bill.

The CGDP Portal will provide functionality for the following:

- Invoice review
- Invoice payment selection
- Invoice payment deferment *
- · Batch Invoice payment selection
- Automatic payment confirmation
- Payment receipt review
- Reports retrieval
- Invoice dispute submission and resolution

Manufacturer Portal Payments Users Guide.

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^{*} Invoice payment deferment occurs under limited circumstances and is detailed in the CGDP

CGDP Portal Roles

The CGDP Portal contains two access roles for Manufacturers:

- Payment Initiator role
- Administrator role

The HPMS TPA Liaison contact is automatically assigned these two roles, listed above, for Manufacturers; however, the Payment Initiator role can be assigned to a separate associate, listed in HPMS as the Coverage Gap Discount Program (CGDP) Payment Contact. The Payment Initiator role will have the responsibility of processing invoice line item payments submitted each quarter.

- Users assigned the Payment Initiator role will have access to all functionality in the CGDP Portal and be required to provide a four-digit numeric PIN pass code for processing payment initiation authorization. The four-digit PIN is created during initial security setup.
- Users assigned the Administrator role will have access to all functionality, except payment initiation authorization.

If these roles require separate associates to perform these functions, the Payment Initiator should be listed as the Coverage Gap Discount Program (CGDP) Payment Contact in HPMS.

Detailed instructions for initial security setup and an introduction to the CGDP Portal functionality reside in the *CGDP Manufacturer Portal Introduction and Login Users Guide*.

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CGDP Portal via TPAdministrator.com

CGDP program participants can access the *CGDP* Portal via the TPA website: https://www.tpadministrator.com.

Once at the website, select the **CGDP Portal** graphic link on the Home Page (outlined in red).

Users can also access the *CGDP Portal* by selecting either the Topics menu or the Tools menus (both outlined in red).

In addition, the Archives page link in the upper right hand corner (underlined in red) has a **CGDP Portal** graphic link for access.

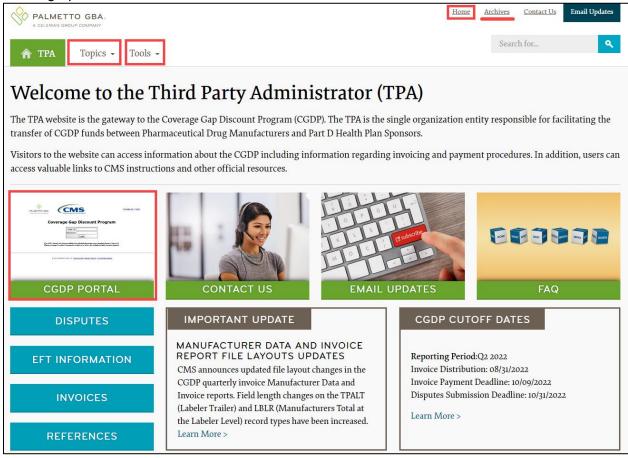


Figure 13: CGDP Portal Link

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CGDP Manufacturer Portal Users Guides via TPAdministrator.com

CGDP program participants can access the CGDP Manufacturer Portal Users Guides via the TPA website https://www.tpadministrator.com.

Once on the site, there are two (2) ways to access the *References* link. One is a box text link located on the lower left side of the page under the graphic picture links (outlined in red). The second is located under the Topics menu (outlined in red).

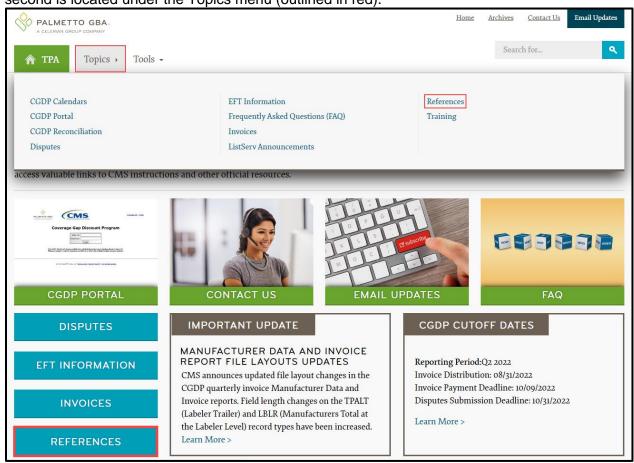


Figure 14: References Link on the TPAdministrator.com Website

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Once the *References* topic displays, select *CGDP Manufacturer Portal Users Guides* and review the four (4) topic specific manuals available.

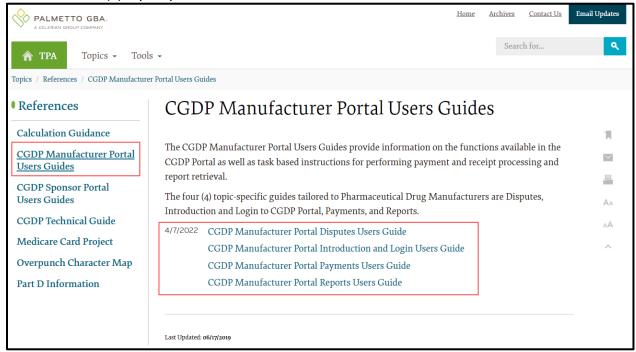


Figure 15: CGDP Manufacturer Portal Users Guides location

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Accessing the CGDP Portal

For daily access, authorized users will access the CGDP Portal via the Login form.

- The User ID is the Corporation ID for Manufacturers
- HPMS-assigned Manufacturer TPA Liaison or Coverage Gap Discount Program (CGDP)
 Payment Initiator personnel are sent a temporary password for initial access and are responsible for changing and maintaining their permanent password every 30 days
- Manufacturer associates are assigned one of two roles for access to the CGDP Portal: Payment Initiator or Administrator
- All Quarterly and Benefit Year (BY) Closeout invoice and report data for Manufacturers is loaded to the CGPD Portal for access and review by Payment Initiator and Administrator role associates
- Only associates assigned the Coverage Gap Discount Program (CGDP) Payment Initiator will be allowed to process Program invoice payments in the CGDP Portal.

Detailed instructions for accessing the CGDP Portal reside in the **CGDP Manufacturer Portal Introduction and Login Users Guide**.

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Email Verification

First time users will be required to verify their email address to allow receipt of User Validation authentication tokens required to access and use the CGDP Portal.

Once a user is authorized to access the CGDP Portal, they will receive an email from tpa.no.reply@palmettogba.com titled "TPA CGDP Portal – Email Verification".

The authorized user is required to select the link, provided in the email, to verify their email address prior to logging into the CGDP Portal.

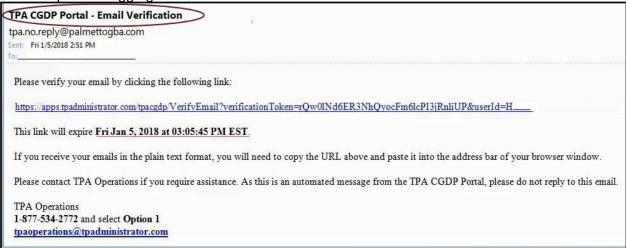


Figure 16: Example of a TPA CGDP Portal – Email Verification

Multifactor Authentication

Once the **Multifactor Authentication – Email Verification Success** screen displays, the user will select the "<u>Please click here to log into the Portal"</u> link provided on the page.



Figure 17: Multifactor Authentication – Email Verification Success Message

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After selecting the "<u>Please click here to log into the Portal</u>" the CGDP Portal Login page will appear, and authorized users will enter their assigned user ID in the <u>User ID</u> field and the corresponding temporary password into the <u>Password</u> field on the **Login form** and select the *Login* button.

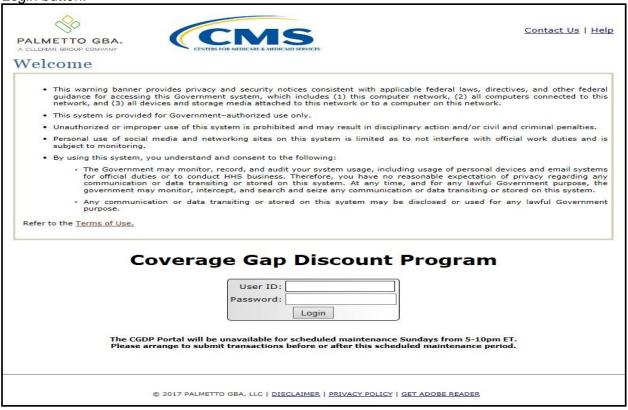


Figure 18: CGDP Portal Login Page

User Validation Form

After entering the <u>User ID</u> and <u>Password</u> successfully, the User Validation form will display and require the entry of a Multifactor Authentication (MFA) token.

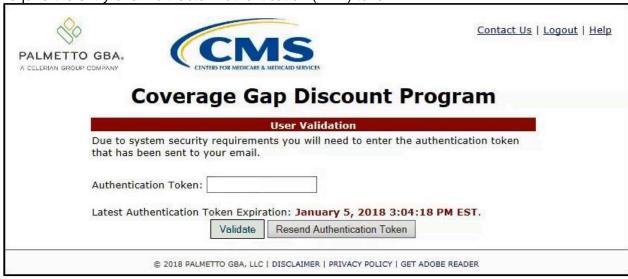


Figure 19: User Validation Form

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The authorized user will receive an email from <u>tpa.no.reply@palmettogba.com</u> titled "TPA CGDP Portal – Portal Authentication". The authorized user will be required to enter the verification code, provided in the email, into the **Authentication Token** field in the CGDP Portal.



Figure 20: CGDP Portal Authorization MFA Token Email

After entering the MFA token sent to the user's verified email, the user will select the <u>Validate</u> button.

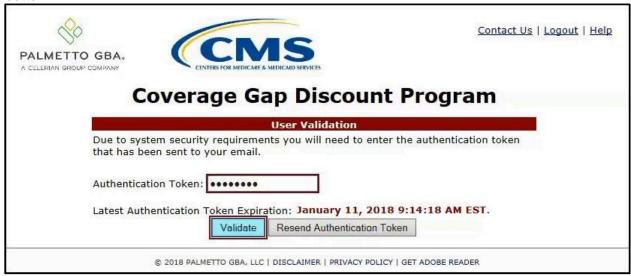
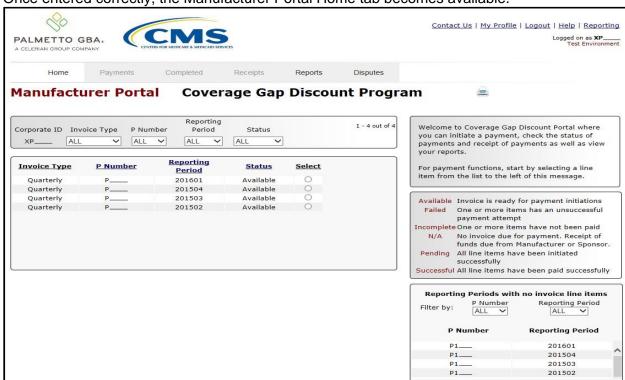


Figure 21: Completed User Validation Form with Validate Button Highlighted

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Once entered correctly, the Manufacturer Portal Home tab becomes available.

Figure 22: CGDP Manufacturer Portal Home Tab

Detailed instructions for accessing the CGDP Portal reside in the **CGDP Manufacturer Portal Introduction and Login Users Guide**.

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Initiating Payments Quarterly Invoice Payments

The CGDP Portal Payments tab allows a user to review and process payment information for quarterly invoice line items by Sponsor Contract Number for Manufacturers.

- · Payments can only be made via the CGDP Portal
- Payment amounts automatically populate from the quarterly invoice and are not subject to modification
- Payments must be paid no later than 38 days after the distribution of the invoice
- Payments must be made even if the Manufacturer is disputing the invoice

Manufacturers can perform these payment functions in the CGDP Portal

- Individual invoice payment functionality
- Future Date invoice payment functionality
- Initiate All invoice payments functionality
- Payment Initiation Upload Batch functionality
- Stop Payment functionality
- Defer Payment functionality *

Portal Payments Users Guide.

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^{*} Invoice payment deferment occurs under limited circumstances and is detailed in the *Manufacturer*

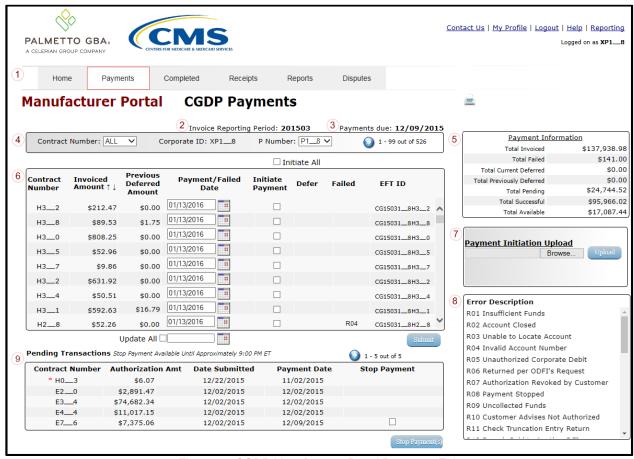


Figure 23: CGDP Manufacturer Portal Payments Tab

The **Payments** tab contains eight regions:

- (1) The Tabbed region displays the active tab
- (2) The Invoice Reporting region displays the current reporting period
- (3) The Payments Due region displays the date payments are due
- (4) The Filter region Payments allows filtering of invoices by selected criteria
- (5) The <u>Payment Information region</u> provides numerical totals of all invoice line items and their qualifying status
- (6) The <u>Payment Initiation region</u> displays payment eligible invoices by Contract Number and Invoiced Amount and/or Previous Deferred Amount
- (7) The Payment Initiation Upload region provides a location to upload payment batch files
- (8) The <u>Error Description region</u> provides a listing of error codes that will appear in the Failed column in the <u>Invoice Reporting region</u>.
- (9) The <u>Pending Transactions region</u> displays invoice line items that are pending payment processing

Detailed instructions for processing Payments reside in the *CGDP Manufacturer Portal Payments Users Guide*.

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Reporting

Invoice Reports

Are:

- Distributed quarterly to Manufacturers via the CGDP Portal
- Provides gap discount amounts summarized into invoices based on P Number
- Quarterly and Benefit Year (BY) Closeout invoice reports are available

Detailed instructions for downloading Invoice reports in the CGDP Portal reside in the **CGDP Manufacturer Portal Reports Users Guide**.

Quarterly Invoice Reports:

Manufacturers can utilize the CGDP Portal to view reports of distributed invoice line items available for processing.

The population of the <u>Invoice</u> radio button allows a user to select and view distributed invoice line item reports. The report provides abbreviated information of distributed quarterly invoices and provides the ability to download the information for review.

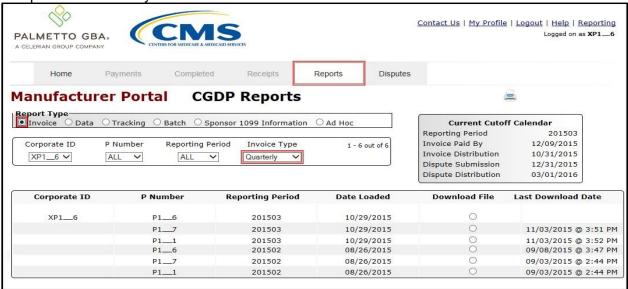


Figure 24: Quarterly Invoice Reports

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Benefit Year (BY) Closeout Invoice Report

Manufacturers can utilize the CGDP Portal to view reports of upheld dispute invoices due from Sponsors. The Manufacturer Reimbursement Summary Report allows Manufacturers to identify any amounts owed from the Sponsor for upheld disputes by specific contracts and by benefit year.

The population of the <u>Invoice</u> radio button allows a user to select and view distributed invoice line item reports. The report provides abbreviated information of distributed BY Closeout invoices and provides the ability to download the information for review.

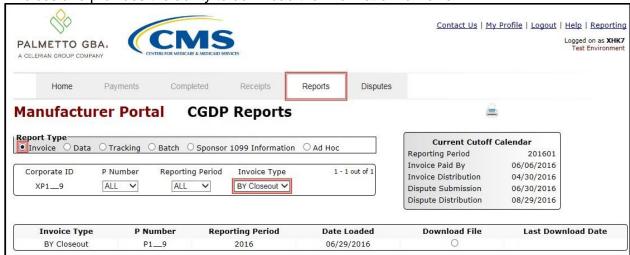


Figure 25: Benefit Year (BY) Closeout Invoice Reports

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Data Reports

Are:

- Distributed quarterly to Manufacturers via the CGDP Portal
- Provides Manufacturers the opportunity to review inputs to the invoice
- Incorporates changes in subsequent quarters due to adjustments or deletions of PDEs
- Utilized by Manufacturers for creating dispute files submitted via the CGDP Portal
- Quarterly and BY Closeout invoice reports are available

Detailed instructions for downloading Data reports in the CGDP Portal reside in the **CGDP Manufacturer Portal Reports Users Guide**.

Quarterly Data Report

Manufacturers can utilize the CGDP Portal to view detailed data reports for distributed invoice line items that provides a user with reports containing detail information of the PDE's combined to create the total invoice line item amount distributed to the Manufacturer.



Figure 26: Quarterly Invoice Reports

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BY Closeout Data Report

Manufacturers can utilize the CGDP Portal to view detail data reports for BY Closeout invoice line items.

The Manufacturer Reimbursement Detail Report only reports on upheld disputes in which the action taken by the Sponsor to resolve the dispute resulted in a partial or full repayment of the disputed gap discount amount and the respective gap discount amount has not been previously invoiced for Sponsor payment to the Manufacturer.



Figure 27: BY Closeout Data Reports

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Tracking Report

Are:

- Distributed annually to Manufacturers via the CGDP Portal
- Cumulative reports that provide the status of adjustments performed on all upheld disputes for the closed benefit year
- Tracking reports will include multiple benefit years

Detailed instructions for downloading Tracking reports in the CGDP Portal reside in the **CGDP Manufacturer Portal Reports Users Guide**.

Upheld Dispute Tracking Report

Manufacturers can utilize the CGDP Portal to view reports of all upheld disputes.

The Upheld Dispute Tracking Report for Manufacturers provides the status of invoiced PDEs that were disputed and subsequently upheld. The purpose of the report is to inform Manufacturers of any adjustment or deletion activity undertaken by the Sponsor in response to the upheld dispute.

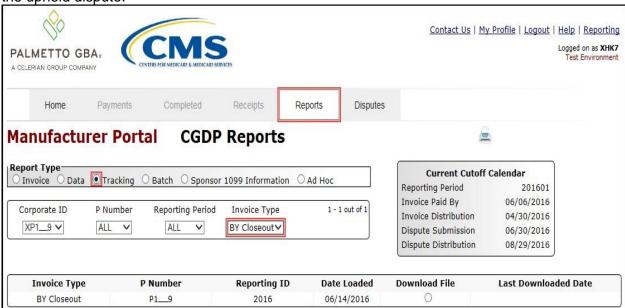


Figure 28: Upheld Dispute Tracking Report

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Batch Reports

Are:

- Generated when the Batch Upload Payment Process is utilized to process payment initiations
- Detailed instructions for utilizing the Batch Upload Payment Process functionality can be found in the *CGDP Manufacturer Portal Payments Users Guide*.

Downloading Batch reports in the CGDP Portal can be found in the **CGDP Manufacturer Portal Reports Users Guide**.

Manufacturers can utilize batch reports to review the outcome of the Payment Initiation Upload batch processing of multiple invoice line items and provide uploaded batch file results for quarterly invoice processing.

A user can view batch file status for successful processing, partially or totally rejected batch file

uploads, and review errors associated with rejected records.



Figure 29: Batch Reports

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1099 Information Reports

Are:

 Loaded to the CGDP Portal for access to 1099 non-bank account information, such as Sponsor Contract Number; Company Name; EIN/TIN; IRS Street Address, City, and State.

Detailed instructions for downloading 1099 reports reside in the CGDP Portal in the **CGDP Manufacturer Portal Reports Users Guide**.

Manufacturers can utilize the CGDP Portal to review the Sponsor 1099 Information report, which provides non-bank account information for Manufacturers to utilize for tax reporting purposes.



Figure 30: Sponsor 1099 Information Reports

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Ad Hoc Reports

Manufacturers can utilize the CGDP Portal to review Ad Hoc report requests, which provide limited access to reports that are no longer available on the CGDP Portal.

Detailed instructions for requesting and viewing Ad Hoc reports reside in the CGDP Portal in the *CGDP Manufacturer Portal Reports Users*.



Figure 31: Ad Hoc Reports

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Disputes Process

The CGDP Portal allows Manufacturers to submit disputes for invoiced PDE records included in quarterly invoices.

Manufacturers have 60 calendar days from the date of invoice receipt, known as the *Quarterly Invoice Receipt* date on the CGDP Calendar, to submit a dispute file

- Receipt of the invoice is considered to be one calendar day after the TPA loads the invoice and data reports to the CGDP Portal, known as the *Quarterly Invoice Distribution* date on the CGDP Calendar
 - Even though a Manufacturer may choose to dispute an invoiced PDE, the invoice *must be paid in full* within 38 days after invoice distribution
- The CGDP Portal provides functionality to assist Manufacturers with creating dispute files utilizing the Dispute Builder process
- The Dispute Builder process assists Manufacturers with creating dispute files from PDE line item data files received for the current quarter with required information needed to support dispute line items
- Dispute files may only contain data for a single P Number
- Files containing multiple P Numbers for a Corporate ID will error out during the CGDP Portal edit processing

Dispute files submitted by Manufacturers are subjected to multiple edit processes.

TPA performs initial edits on dispute files that are created or loaded in the CGDP Portal.

- Uploaded or Dispute Builder files that have obtained a "Passed" status are then forwarded to the Drug Data Processing System (DDPS) contract for additional edits
- Uploaded or Dispute Builder files may receive a "Delayed" status if they are duplicate dispute files submitted in the same 24-hour processing period (4:00pm 4:00 pm ET).
 - Dispute files with "Delayed" status will process in the following 24-hour processing cycle

(See the CGDP Manufacturer Portal Disputes Users Guide for full details)

Note: Manually uploaded dispute text files that receive a "Failed" status require review and correction of failed line items, resubmission of the entire file, and assignment of a "Passed" status before they are to be forwarded to DDPS for additional edits before the submission deadline

DDPS edits dispute files line-by-line, not by a submitted file in its entirety

- If a dispute record is Accepted by DDPS, it will be reviewed by CMS
- If a dispute record is Rejected by DDPS, a Manufacturer may re-file any rejected line records by correcting and resubmitting the updated PDE line items via the CGDP Portal before the submission deadline

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Manufacturers should allow enough time for dispute files to complete edit processing and error correction, which may take more than one day

- Waiting until the last day of the submission deadline is not recommended; Just because you started your dispute process before the submission deadline does not count toward meeting the deadline
- Dispute line items only count as eligible to be submitted if each line item obtains a
 Passed status from TPA and an Accepted status from DDPS prior to the submission
 deadline

After the dispute line item has been *Accepted* by DDPS, Manufacturers can send supporting documentation and attachments to <u>disputes@tpadministrator.com</u>

Dispute Resolutions are available for review in the CGDP Portal 60 days following the dispute file submission deadline

Dispute determinations can be either Upheld or Denied

Sponsors are obligated to fix the incorrect data that caused the upheld dispute within 90 days of discovery. Sponsors can adjust financial and/or non-financial fields to correct the upheld disputes

The Reported Gap Discount amount may or may not change due to an upheld dispute

The CGDP Portal provides Manufacturers with the ability to review dispute filings and their subsequent decisions rendered by CMS.

In the CGDP Portal, there are three tabs that assist Manufacturers with the dispute process. In order, they are:

- The Disputes tab:
 - Allows Manufacturers the ability to review accepted or rejected return files and upheld or denied resolution files
- The Dispute Builder tab:
 - Provides functionality for Manufacturers to create dispute files from data files received for the current quarter
- The Dispute Submission tab:
 - Provides Manufacturers the ability to submit dispute files, either created in the CGDP Portal by the Dispute Builder functionality or uploaded dispute text files created manually from data files received, for the current quarter and review the dispute file submission statuses of *Passed*, *Delayed*, or *Failed*

Note: The status of Failed only applies to manually uploaded dispute text files

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Disputes Tab

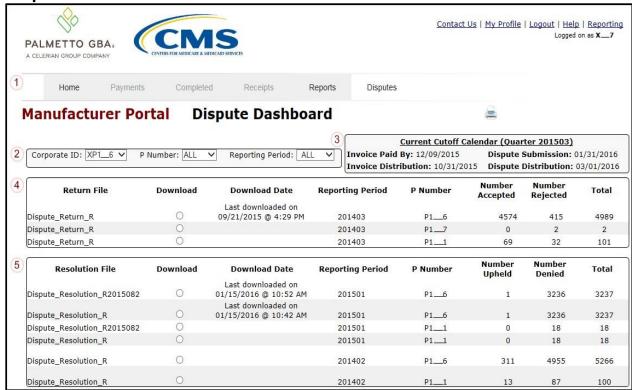


Figure 32: Disputes Tab

The Manufacturer Disputes tab contains five regions:

- (1) The <u>Tabbed region</u> displays the active tab
- (2) The Filter region Disputes allows filtering of disputes by selected criteria
- (3) The <u>Current Cutoff Calendar region</u> provides pertinent reporting period dates
- (4) The Return File region displays Accepted and Returned dispute return files
- (5) The Resolution File region displays Upheld and Denied dispute resolution files

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Dispute File Format

Documentation to assist with dispute file report formats can be located on the https://www.tpadministrator.com website under the following links:

- HPMS Memo: Updates to the Medicare Coverage Gap Discount Program Manufacturer Dispute and Appeals Submission Process
- Dispute Edits (Effective February 8, 2015)
- Dispute Reasons (Effective February 8, 2015)
- Dispute Resolution Report File Layout (Effective February 8, 2015)
- Dispute Return File (Effective February 8, 2015)
- Dispute Submission File (Effective February 8, 2015)
- Dispute Layout Side by Side Comparison

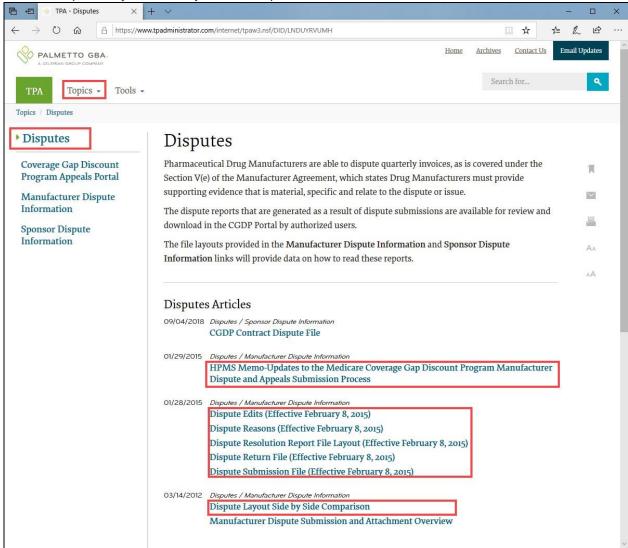


Figure 33: Dispute File Formats

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Dispute Builder Tab



Figure 34: Dispute Builder Tab

The Manufacturer Dispute Builder tab contains seven regions:

- (1) The <u>Tabbed region</u> displays the active tab
- (2) The <u>Selection Criteria Form button</u> (displaying as the "<u>Click here to add data line items</u>" button) opens the Selection Criteria form to add PDE line items to dispute files
- (3) The <u>Current Cutoff Calendar region</u> provides pertinent reporting period dates
- (4) The <u>PDE Line Item region</u> displays PDE line items selected via the Selection Criteria Search form
- (5) The Save button saves files that have been loaded to the PDE Line Item region
- (6) The <u>Delete All</u> button will delete all PDE line item files that have been loaded to the PDE Line Item region
- (7) The <u>Complete Dispute File</u> button will complete the dispute file for a specific P Number and send it to the Dispute Submission page in the CGDP Portal

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Dispute Submission Tab



Figure 35: Dispute Submission Tab

The Manufacturer Dispute Submission tab contains four regions:

- (1) The <u>Tabbed region</u> displays the active tab
- (2) The <u>Upload Disputes Files region</u> allows searching for manually created dispute files for loading to the CGDP Portal for submission
- (3) The <u>Current Cutoff Calendar region</u> provides pertinent reporting period dates
- (4) The <u>Submitted Disputes region</u> displays dispute files loaded to the CGDP Portal and provides statuses of each file as they progress through TPA edit processing

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Disputes Appeals

For denied disputes, Manufacturers can submit appeal requests to the Independent Review Entity (IRE).

- Manufacturers can appeal within 30 days of receiving the decision reported with the dispute resolution file or 60 days after filing the dispute, if no decision has been reached, whichever date is earlier
- The IRE must provide a decision within 90 days of receiving the appeal
- Manufacturers can appeal the IRE decision to the CMS Administrator

Documentation to assist with dispute appeals can be located on the https://www.tpadministrator.com website under the following links:

- Coverage Gap Discount Program Appeals Portal
- Manufacturer Dispute Submission and Attachment Overview

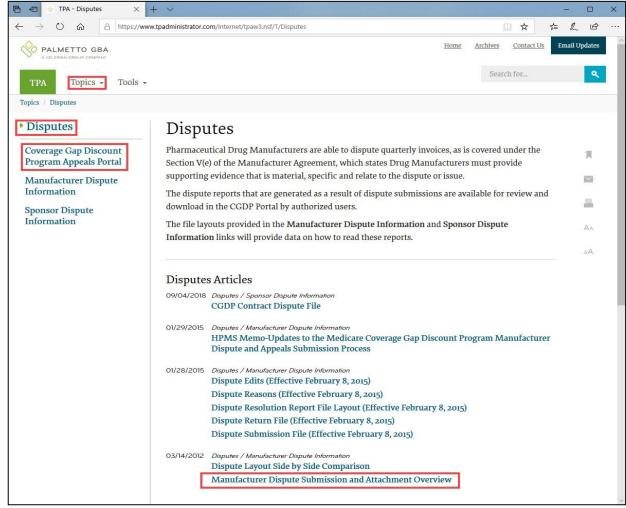


Figure 36: Dispute Appeal Link on TPAdministrator.com

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Contacting the TPA

The following provides information on how to contact the TPA Operations for questions with the Coverage Gap Discount Program (CGDP).

TPA website – https://www.tpadministrator.com
Phone

• Help Line: 1 (877) 534-2772 Option 1 • Help Line Hours: Monday through Friday 8:00 am until 7:00 pm EST

General email inquiries regarding the invoicing and payment process should be sent to

• tpaoperations@tpadministrator.com

Webinar Training

Suggestions for webinar topics should be sent to <u>webinar@tpadministrator.com</u>
 Previous webinar slides are posted to the TPA website

Questions regarding Disputes, EFT information and invoice corrections can be located on the TPA website

https://www.tpadministrator.com

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Resources

Medicare Drug Benefit and C & D Data Group

- Manufacturers Agreement, Changes of Ownership (CHOW), Terminations,
 Compliance/Administrative-related Issues, and Policy related questions
- Email: <u>CGDPandManufacturers@cms.hhs.gov</u>

Discount Program Manufacturer's Page

website: Part D Information for Pharmaceutical Manufacturers | CMS

Independent Review Entity (IRE) for Discount Program appeals

website: https://cqdp.pri-federal.com/

HPMS website for updating CMS contact and labeler code changes

website: https://hpms.cms.gov

CMS HPMS Password Resets (CMS Passwords must be reset every 60 days via CMS EUA system)

- CMS EUA Password Reset: https://eua.cms.gov
- CMS IT Service Desk phone: 1 (800) 562-1963 or 1 (410) 786-2580
- CMS IT Service Desk email: CMS IT service desk@cms.hhs.gov

CMS HPMS Non-Password access assistance

Email: CMSHPMS_access@cms.hhs.gov

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Acronyms

Acronym	Definition
ACH	Automated Clearinghouse
BY	Benefit Year
CMS	Centers for Medicare and Medicaid Services
CGDP	Coverage Gap Discount Program
DDPS	Drug Data Processing System
EFT	Electronic Funds Transfer
EUA	Enterprise User Administration
HPMS	Health Plan Management System
IRE	Independent Review Entity
Manufacturer	Pharmaceutical Drug Manufacturer
MFA	Multifactor Authentication
PDE	Prescription Drug Event
Sponsor	Part D Health Plan Sponsor
TPA	Third Party Administrator

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