Centers for Medicare & Medicaid Services

Coverage Gap Discount Program

Technical Guide

Version 1.0

August 2021

Table of Contents

List of Figures

List of Tables

1. Introduction

The Centers for Medicare & Medicaid Services (CMS) Coverage Gap Discount Program (CGDP) is committed to providing quality outreach and educational materials for participating Drug Manufacturers and Part D Sponsors in order to better understand the program.

The purpose of this guide is to educate participants about the CGDP as it pertains to Process, Reports, Payments, Disputes, and Appeals.

1.1 Accessibility

CMS is dedicated to making this technical guide accessible to the widest possible audience. In keeping with that mission, this guide complies with the regulations of Section 508 of the Rehabilitation Act and the Department of Health & Human Services (HHS) Section 508 Implementation Policy. The information contained in this guide is intended to be accessible through screen readers and other accessibility resources.

Section 508 requires that individuals with disabilities seeking information or services from this guide have access to and the ability to use information and data that is comparable to that provided to the public who are not disabled. Section 508 also requires that Federal employees with disabilities have access to and the ability to use information and data that is comparable to Federal employees who are not disabled.

To learn more about regulations governing the accessibility of Federal electronic information, review the IT Accessibility Laws and Policies page on the Section508.gov website.

1.2 Screen Examples and Links

The CGDP Technical Guide contains examples of screen shots from CMS' Health Plan Management System (HPMS), the CGDP's Third Party Administrator (TPA), the Customer Service and Support Center (CSSC) Operations, and the Independent Review Entity (IRE) websites. These examples are current as of the date on this technical guide's title page. Since changes and updates to websites may occur frequently, it is recommended that users access the sites to ensure they are viewing the most current information, training materials, file layouts, reports and program-specific information.

This guide also contains links that navigate to more information, both within the guide and to other web locations. All links appear in underlined blue font. Click the link or use the Tab key to move to the link, then press "Enter" to access the link.

2. Overview

2.1 Coverage Gap Discount Program (CGDP)

The CGDP makes Drug Manufacturer discounts available to eligible Medicare beneficiaries at the point of sale (POS) when receiving applicable covered Part D drugs while in the coverage gap phase.

The CGDP was created by the Patient Protection and Affordable Care Act, commonly referred to as the Affordable Care Act (ACA), in 2010. The program was enacted to "fill in the gap" by providing additional coverage for Medicare Part D beneficiaries eligible for the CGDP.

Prior to the passage of the ACA in 2010, non-low income beneficiaries were required to pay 100 percent of the cost of all drugs purchased within the coverage gap phase, for drug expenditures above the initial coverage limit and below the annual out-of-pocket threshold, which varies slightly based on a particular benefit year.

Beginning on January 1, 2011, eligible beneficiaries in the coverage gap began receiving manufacturer discounts for applicable drugs at the POS. Only those applicable drugs that are covered under a signed Manufacturer Agreement with CMS can be covered under Part D. In order to participate in the CGDP, Drug Manufacturers must sign an agreement with CMS to provide a discount on all of its applicable drugs.

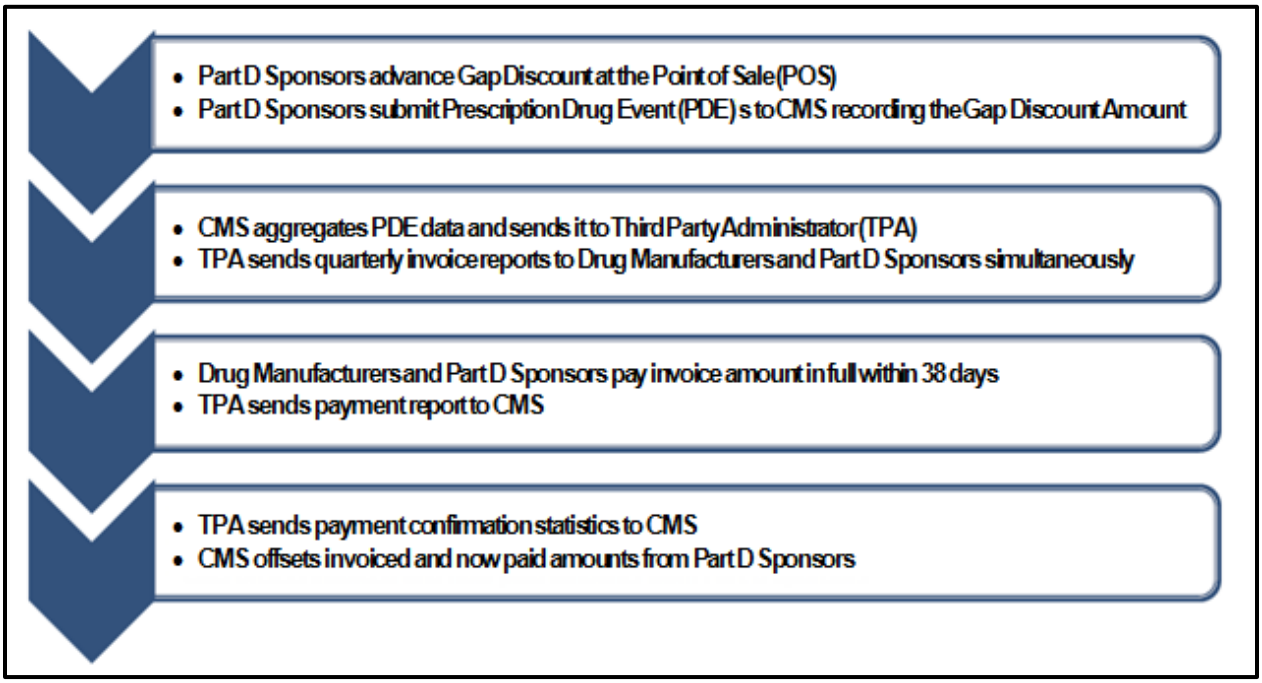
After a drug is dispensed to a beneficiary, the pharmacy submits the claim information including any gap discount advanced at the POS to the Part D Sponsor. Then, the Part D Sponsor submits a Prescription Drug Event (PDE) to CMS. The discounts are then aggregated and invoiced to the contracted drug manufacturer on a quarterly basis.

To manage these POS discounts:

- CMS makes prospective payments to Part D Sponsors, enabling them to extend the coverage gap discounts to their beneficiaries at the POS.
- On a quarterly basis, Invoice Reports containing coverage gap PDE data are generated and distributed to Drug Manufacturers and Part D Sponsors via the CGDP Direct Payment Process (DPP) Portal.
- Drug Manufacturers then make payments to Part D Sponsors for the invoiced coverage gap PDE amounts. If applicable, Part D Sponsors also reimburse Drug Manufacturers for any negative amounts invoiced as a result of adjusted or deleted PDEs that were previously invoiced to a Drug Manufacturer.
- On a quarterly basis, CMS offsets subsequent prospective payments to Part D Sponsors by the amount invoiced to Drug Manufacturers.

See **Figure 1** for a high level overview of the CGDP process flow.

Figure 1: Coverage Gap Discount Program Process Flow



2.2 Drug Manufacturers

A pharmaceutical Drug Manufacturer is any entity engaged in the production, preparation, propagation, compounding, and conversion or processing of prescription drug products, either directly or indirectly.

In order to participate in the CGDP, Drug Manufacturers must sign an agreement with CMS to provide the discount on all of their applicable drugs. For example, prescription drugs approved or licensed under New Drug Applications (NDA) or Biologic License Applications (BLA). As of 2011, only those applicable drugs that are covered under a signed manufacturer's agreement with CMS are covered under Part D.

Drug Manufacturers reimburse Part D Sponsors for the reported coverage gap discount amounts provided at the POS based on data submitted on accepted PDEs. The TPA notifies Drug Manufacturers of their liabilities to Part D Sponsors by issuing Quarterly Invoice Reports.

Drug Manufacturers must pay the entire invoiced amount to Part D Sponsors within 38 calendar days following invoice distribution.

2.3 Part D Sponsors

Part D Sponsors are non-governmental, private entities, under contract with CMS to offer prescription drug benefits through Prescription Drug Plans (PDPs), Medicare Advantage Prescription Drug Plans (MA-PDs), Program for All Inclusive Care for the Elderly (PACE) plans, or cost plans offering qualified prescription drug coverage.

The costs associated with Medicare Part D prescription coverage include a monthly premium, an annual deductible, co-payments and co-insurance for specific drugs, a gap in coverage referred to as the “coverage gap” or "Donut Hole," and catastrophic coverage once a threshold amount has been met.

Part D Sponsors participating in the CGDP calculate the discount amount at the time of the initial claim adjudication (point-of-sale), provide the discount amount in the adjudicated response, make payment to the pharmacy, and include accurate and timely information on PDEs submitted to the Drug Data Processing System (DDPS).

2.4 Health Plan Management System (HPMS)

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

In order 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 CGDP but must use their United States (US) location for managing the CGDP within HPMS. Individuals must have a valid Social Security Number to gain access to HPMS.

By statute, Drug Manufacturers must contract for the CGDP by January 30th 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 30th deadline to prevent missing the deadline due to technical or access related issues.

During the contracting process, each Drug Manufacturer participating in the CGDP 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). This information is submitted by the Drug Manufacturer in HPMS. CMS uses this information during the process of securing Manufacturer Agreements and continues to communicate CGDP information to contracted Drug Manufacturers’ designated points of contacts. To obtain access to the CGDP Portal, the Drug Manufacturer must also enter contact information in HPMS for the TPA Liaison and the CGDP Payment Contact, which allows an authorized user to review and process quarterly invoices for the CGDP.

Each Drug Manufacturer is responsible on an ongoing basis for communicating any changes in contact information to CMS. To communicate these changes, the Drug Manufacturer updates contact information in HPMS. Failure to do so will jeopardize the Drug Manufacturer's knowledge of, and thus compliance with, key program requirements and deadlines. CMS will not waive any CGDP requirements to accommodate missed communication due to outdated contact information.

Note: Refer to Appendix C – HPMS Model & Enterprise Users Administration (EUA) Access for instructions on accessing the HPMS login page and for instructions for submitting EUA forms for new and existing users.

2.4.1 Prescription Drug Event (PDE)

A prescription drug claim is used to generate a PDE that is reported to CMS. This PDE data is aggregated by DDPS for use in invoice reporting, payments, disputes, appeals and reconciliation activities.

The PDE reports a unique prescription transaction that has taken place between a beneficiary, pharmacy, and Part D Sponsor. As a result of the ACA, eleven fields specific to the coverage gap discount process were added to the PDE file layout. There are 57 data elements on every PDE record (excluding "filler" fields).

Note: Access the CSSC Operations website to view the complete PDE Inbound File Layout.

DDPS receives the PDE submitted by Part D Sponsors and runs the PDE through an extensive set of edits. Access the CSSC Operations website to view the Prescription Drug Event Edit Code Listing. The edits include a cross-check of the PDE data for a match to determine if it is an adjustment or deletion to an already existing PDE or if it is a new PDE.

Note: The Prescription Drug Program (Part D) Training tab located on the CSSC Operations website contains Part D program PDE training materials, PDE reporting rules and calculations, and other important program information as shown in Error! Reference source not found.. The Instructional Videos Training, located on the CSSC Operations website, contains PDE training materials as shown in **Figure 3**.

Figure 2: CSSC Operations website – Training emphasis

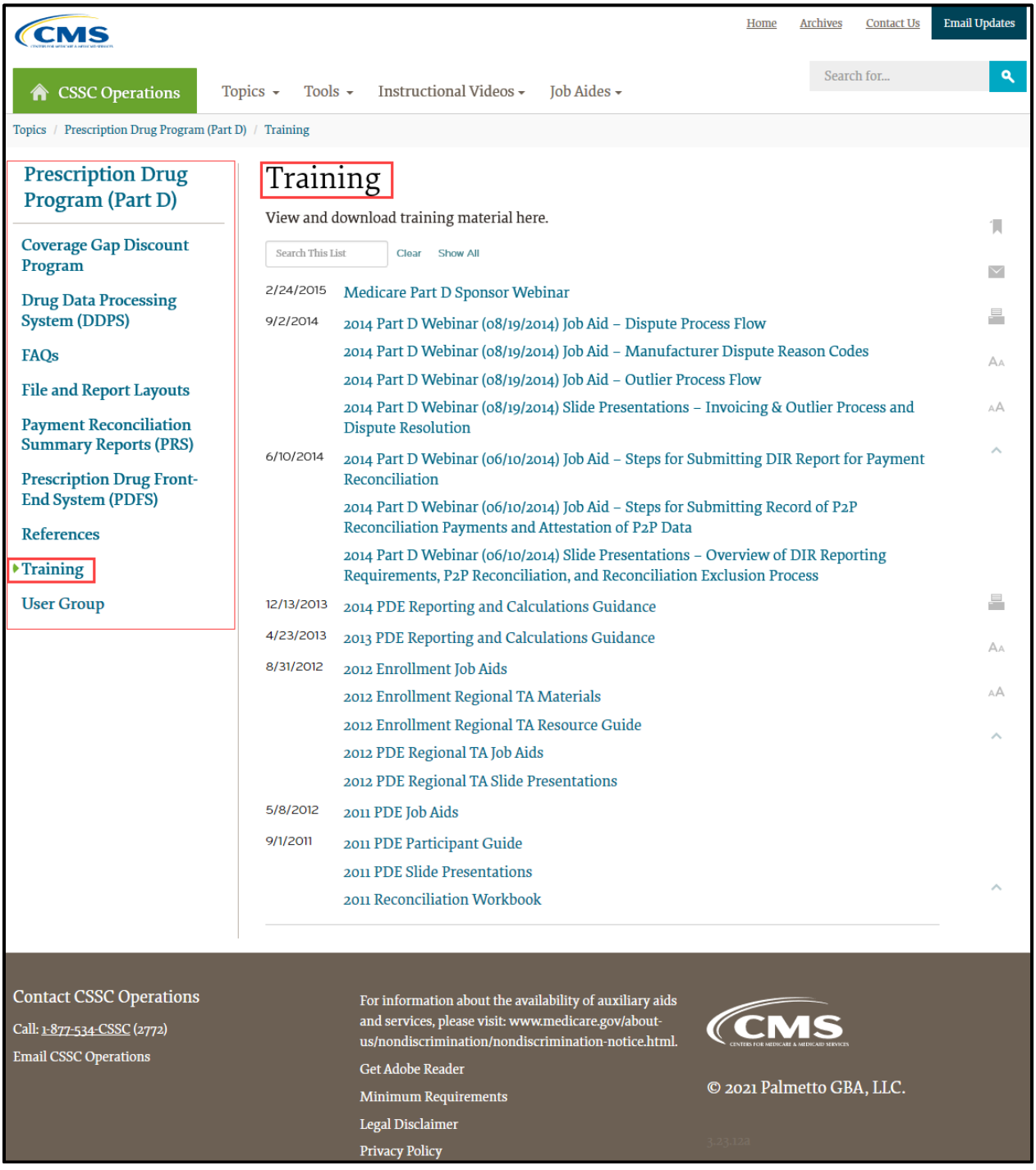
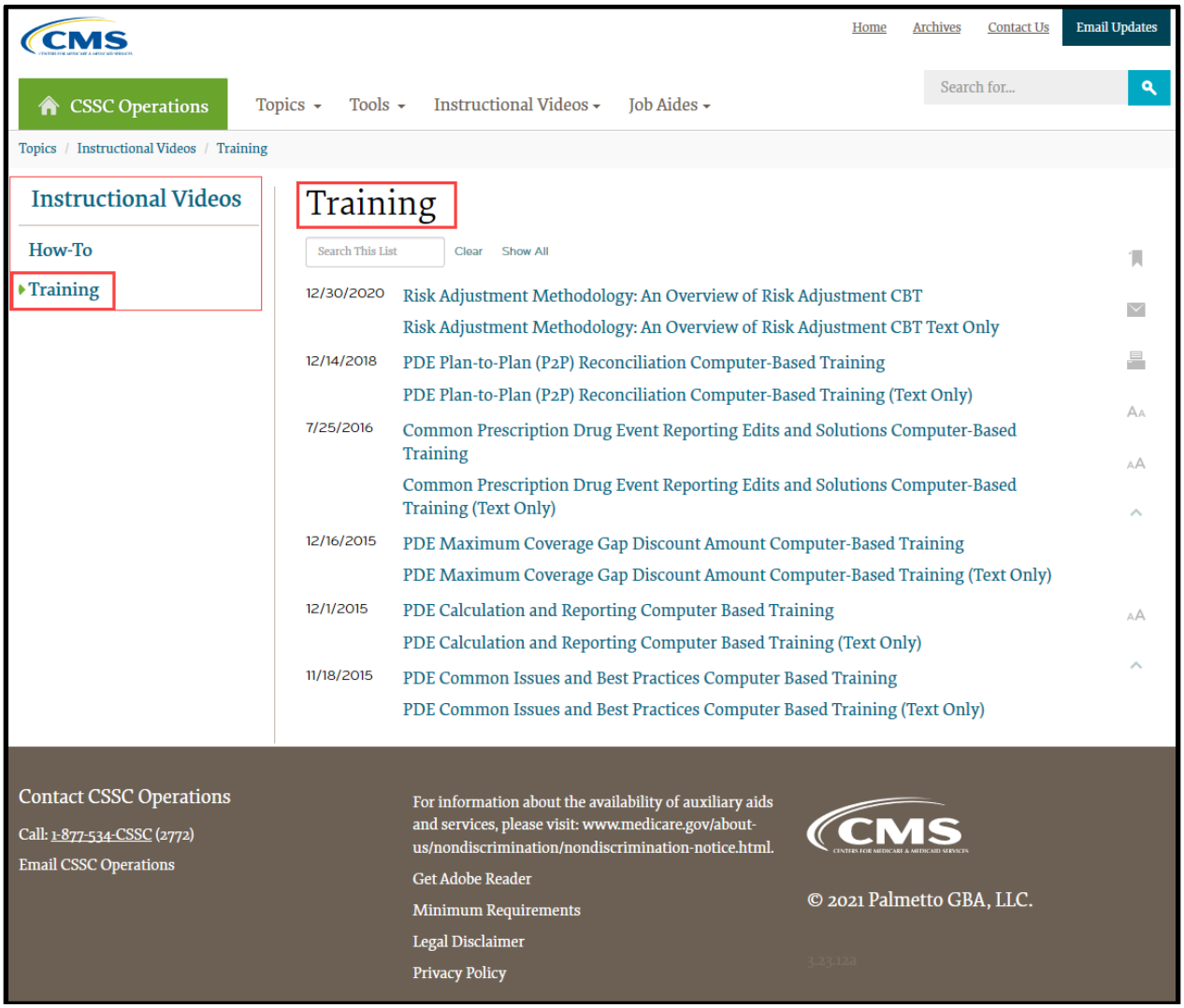


Figure 3: CSSC Operations website – PDE Instructional Videos Training emphasis



2.5 Third Party Administrator (TPA)

The TPA acts as a liaison between Drug Manufacturers and Part D Sponsors in all matters related to the CGDP. The TPA has multiple functions, including to:

- Provide customer support to both Drug Manufacturers and Part D Sponsors;
- Help establish connectivity to the CGDP portal;
- Distribute quarterly invoices and reports to Drug Manufacturers and Part D Sponsors;
- Facilitate payments related to the CGDP between Drug Manufacturers and Part D Sponsors;
- Provide reports to CMS regarding the timeliness and completeness of quarterly invoice payments.

Note: Refer to 9. Troubleshooting and Support for a list of TPA and CSSC Operations contact information, email addresses and hours of support.

2.6 Drug Data Processing System (DDPS)

In order to capture and maintain actual cost and utilization data related to Part D PDEs, CMS uses the DDPS. This system, along with the Payment Reconciliation System (PRS), utilizes PDE data to create reports to monitor, administer, and reconcile the Prescription Drug Benefit program for Medicare mandated by the Medicare Modernization Act (MMA) legislation.

The key CGDP related functions within DDPS include:

- Receiving PDE data;
- Applying edits to submitted PDEs;
- Storing PDE details and reported coverage gap discount amounts that are used to generate CGDP invoices and other reports.

2.6.1 Data Analysis Contractor

The PDE Data Analysis Contractor performs some invoice dispute analysis (based on the Dispute Reason Code) and performs outreach to Part D Sponsors in order to resolve disputes filed by the Manufacturers. More information on the dispute process is described in 6. Disputes and Appeals in this manual.

PDEs on this site are posted under one of the following five categories:

- General CGDP Data Quality Review
- PDEs Withheld from the CGDP Invoice and Invoiced Outlier PDEs
- Manufacturer Disputes
- Part D Payment Reconciliation Data Quality Review
- Upheld Dispute Tracking Reports

For more information about the PDE Analysis portal, refer to the guidance released through HPMS on April 4, 2018 titled “Updates to the Prescription Drug Event (PDE) Analysis Website and Data Quality Review Process for the Coverage Gap Discount Program, Manufacturer Disputes, and Part D Payment Reconciliation.”

3. Quarterly Reporting Process

DDPS receives and edits Part D PDE files, some of which contain coverage gap discount amounts on individual PDE records. On a quarterly basis, CMS identifies the PDEs with coverage gap discount amounts and further analyzes them against a particular set of criteria to determine if they are to be included on the Quarterly Invoice Report sent to Drug Manufacturers and Part D Sponsors for payment.

3.1 PDE Analysis

3.1.1 Outliers Defined[1]

In addition to the editing process conducted by DDPS prior to acceptance, all accepted PDEs with coverage gap discount amounts are subject to further data analysis before they are included in invoices for the CGDP. These PDEs are analyzed using a set of business rules, and those that are flagged as outlier PDEs are withheld from the invoice until they are reviewed by CMS and the Part D Sponsor. Furthermore, starting with the Quarter 1 2018 invoice cycle, PDEs which have previously been invoiced to manufacturers may be subject to further analysis and validation if the supporting data has changed or a PDE was adjusted or resubmitted after being invoiced. Invoiced PDEs that are flagged for data quality issues (i.e., Invoiced Outlier PDEs) will also be posted on the PDE Analysis website for sponsor review and correction.

Different analyses are applied to PDEs with coverage gap discount amounts to identify outliers.

A PDE is withheld from the Quarterly Invoice Report if it meets any one or more of the outlier type criteria. When PDEs are flagged as outliers, they are posted to the PDE Analysis website for Part D Sponsor review. (Note: The PDE Analysis portal is not maintained by the TPA.) Part D Sponsors are expected to review the PDE and take action by explaining why the PDE is valid or by correcting the PDE in question. Responses are reviewed by CMS before a decision is made to release the PDE to be invoiced.

Note: Outlier PDEs are posted on the PDE Data Analysis contractor's PDE Analysis portal each quarter for Part D Sponsors to review and correct as necessary. Manufacturers do not have to access this portal.

1. **<u>Retroactive Disenrollment of the Beneficiary:</u>**

   DDPS confirms the Part D enrollment of the beneficiary during online processing and issues edit 705, "The Beneficiary must be enrolled in Part D on the date of service (DOS)", if the beneficiary is not enrolled in Part D on the DOS reported on the PDE. Because there can be a lag between when the PDE is processed and edited and when the invoices are created, CMS also validates the beneficiary's Part D enrollment prior to placing the PDE on the invoice and after the PDE has been invoiced if the supporting data has changed or a PDE

[1] See the April 4, 2018 HPMS memo, *"Updates to the Prescription Drug Event (PDE) Analysis Website and Data Quality Review Process for the Coverage Gap Discount Program, Manufacturer Disputes, and Part D Payment Reconciliation."*

adjustment was submitted after being invoiced to check for retroactive losses of enrollment. If the analysis uncovers that the beneficiary is no longer enrolled on the date(s) of service due to a retroactive loss of enrollment, then the affected gap discount PDEs are flagged as withheld or previously invoiced outliers and posted to the PDE Analysis website for sponsor review.

DDPS compares the DOS to the date of death (DOD) and issues edits when the DOS is greater than 14 days after the DOD of a beneficiary using a retail pharmacy and living at home (edit code 753), or 32 days after the DOD of the beneficiary (edit code 704). Similar to the checks for enrollment described above, CMS evaluates the DOS compared to the DOD to account for changes in DOD that may have occurred after the PDE processed but prior to creating the invoice. Effective July 2017, if the analysis uncovers that the DOS on the PDE is greater than 14 days after the DOD of a beneficiary using a retail pharmacy and living at home, or 32 days after the DOD of the beneficiary otherwise, then the affected PDEs with Reported Gap Discount amounts are identified as outliers (withheld or invoiced) and posted to the PDE Analysis website. In both situations, the sponsor is required to briefly explain why the PDE is valid on the Response Form or correct the PDEs and/or enrollment information in question.

2. Retroactive Low-Income Status of the Beneficiary:

DDPS also validates the low-income (LI) status of the beneficiary during editing. If a PDE reports a gap discount amount for a beneficiary who is low-income eligible, DDPS issues edit 874, “Reported Gap Discount is > zero. The sponsor provided Low Income Cost Sharing (LICS) based on Best Available Evidence. Low income beneficiaries are not eligible to receive a Coverage Gap Discount”. However, due to lags between PDE submission and invoice generation, CMS validates the low-income status of beneficiaries with reported gap discount amounts prior to placing the PDE on the invoice and after the PDE has been invoiced if the supporting data has changed or a PDE adjustment was submitted after being invoiced to verify that the beneficiary has not received retroactive LI status during the quarter. If a beneficiary has retroactively become LI eligible, then the affected gap discount PDEs are flagged as withheld or previously invoiced outliers and posted to the PDE Analysis website. In instances of retroactive LI eligibility, the sponsor is required to briefly explain why the PDE is valid using the Response Form or correct the PDEs and/or eligibility information in question.

3. The PDE Reports a Closed Pharmacy or Inactive Service Provider ID:

In this analysis, we identify gap discount PDEs in which the DOS is after the closing date of the pharmacy. Gap discount PDEs in which the DOS of the PDE is after the closing date of the pharmacy’s Service Provider ID may occur when a pharmacy has closed or changed ownership. When the change in ownership has been reported to the National Council for Prescription Drug Programs (NCPDP), a 60-day grace period applies before PDEs are flagged as a withheld or invoiced outlier, in order to assure the most up-to-date information about the pharmacy is obtained. Affected gap discount PDEs flagged as outliers (withheld or invoiced) are posted to the PDE Analysis website for Part D sponsor review. In these instances, the sponsor is required to explain why the PDE is valid or correct the PDEs in question. The PDE must be deleted if the pharmacy is closed or resubmitted with the new Service Provider ID if there was a change in ownership.

4. Total Reported Gap Discount (RGD) is Greater than the Maximum Allowed Reported Gap Discount (Total RGD > Maximum Allowed RGD):

For beneficiaries where the Patient Liability Reduction Due to Other Payer (PLRO) for all PDEs is zero, the total gap discount amounts are reviewed. CMS identifies beneficiaries whose total Reported Gap Discount (RGD) for the benefit year exceeds the Maximum Allowed RGD amount. The Maximum Allowed RGD is calculated as 50% of the remaining coverage gap before the beneficiary reaches TrOOP after the beneficiary has paid the deductible and co-insurance in the initial coverage period.

For example, the TrOOP for 2018 is $5000 and the cost sharing percentage for the beneficiary is 35% and the manufacturer is 50%. For Defined Standard Benefit (DSB) plans, the beneficiary deductible is $405 and the beneficiary portion of the Initial Coverage Limit (ICL) is $836.25 (($3,750 - $405) x 0.25).

The Maximum Allowed RGD for DSB plans is calculated as:

($5000 – $405 - $836.25) / (0.35 + 0.5)) * 0.5 or **$2,211.03**.

The Maximum Allowed RGD for non-DSB plans is calculated as:

($5000 / (0.35 + 0.5)) * 0.5 or **$2,941.18**.

PDEs with gap discount amounts that cause the beneficiary's total RGD to exceed the Maximum Allowed RGD are flagged as outliers (withheld or invoiced) and posted to the PDE Analysis website. For PDEs flagged for this reason, sponsors are required to either briefly explain why the PDE(s) are valid or correct the gap discount PDE(s) that caused the discrepancy even if the PDEs that need correction have not been individually flagged and withheld from invoice. For these outliers, plans must carefully review all of the beneficiary's gap discount PDEs to determine the cause of the issue prior to taking action to respond to the analysis.

5. The Reported Gap Discount is greater than the Maximum Allowed Reported Gap Discount (RGD>Maximum Allowed RGD):

For this outlier analysis, we look at each PDE individually and flag as outliers any PDEs whose gap discount amounts exceed the maximum allowed RGD for a given year (see the section on *Total Reported Gap Discount (RGD) is Greater than the Maximum Allowed Reported Gap Discount* for more information regarding the Maximum Allowed Reported Gap Discount.). This analysis was conducted at the PDE level. PDEs that met this outlier criteria were withheld from invoicing and posted to the PDE Analysis website for Part D sponsor review. This outlier analysis applied to PDEs submitted prior to February 2015. Beginning in February 2015, an edit was implemented to reject PDEs meeting this criteria.

6. The Total Reported Gap Discount is Greater than the TrOOP Maximum (Total RGD > TrOOP Maximum):

In this outlier analysis, CMS reviews all PDEs submitted for a beneficiary with Reported Gap Discount amounts. If the sum of the reported gap discounts exceeds the Out-Of-Pocket

(OOP) maximum for the benefit year, this analysis flags the beneficiary as an outlier. To determine which PDEs to withhold from invoice, or flag after invoicing for resubmitted gap discount PDEs, CMS uses the Maximum Allowed Reported Gap Discount as a threshold (see the *Total Reported Gap Discount (RGD) is Greater than the Maximum Allowed Reported Gap Discount* for more information regarding the Maximum Allowed Reported Gap Discount). In this analysis, the PDEs with gap discounts which caused the beneficiary's total RGD to exceed the Maximum Allowed RGD are flagged as withheld or previously invoiced outliers, and posted to the PDE Analysis website.

Sponsors are required to either briefly explain why the PDE(s) are valid or correct the gap discount PDE(s) that caused the discrepancy even if the PDEs that need correction have not been individually flagged and withheld from invoice. For these outliers, plans must carefully review all of the beneficiary's gap discount PDEs to determine the cause of the issue prior to taking action to respond to the analysis.

7. The Calculated TrOOP exceeds the True Out-of-Pocket Threshold (Calculated TrOOP > TrOOP Threshold):

For beneficiaries with gap discount amounts, calculated TrOOP amounts are evaluated and compared to the TrOOP threshold. In this outlier analysis, CMS reviews all PDEs for a beneficiary with Reported Gap Discount amounts and flags any PDEs with a Reported Gap Discount amount after the beneficiary has already reached the maximum TrOOP Threshold for the benefit year. Gap discount PDEs where the beneficiary's calculated TrOOP amount exceeds the TrOOP Threshold for the benefit year are flagged as withheld or previously invoiced outliers, and posted to the PDE Analysis website.

This analysis flags the beneficiary as an outlier. Sponsors are required to either briefly explain why the PDE(s) are valid or correct the gap discount PDE(s) that caused the discrepancy even if the PDEs that need correction have not been individually flagged and withheld from invoice. For these outliers, plans must carefully review all of the beneficiary's PDEs to determine whether the accumulated TrOOP is being calculated correctly. Plans must also review all of the beneficiary's gap discount PDEs to determine the cause of the issue prior to taking action to respond to the analysis.

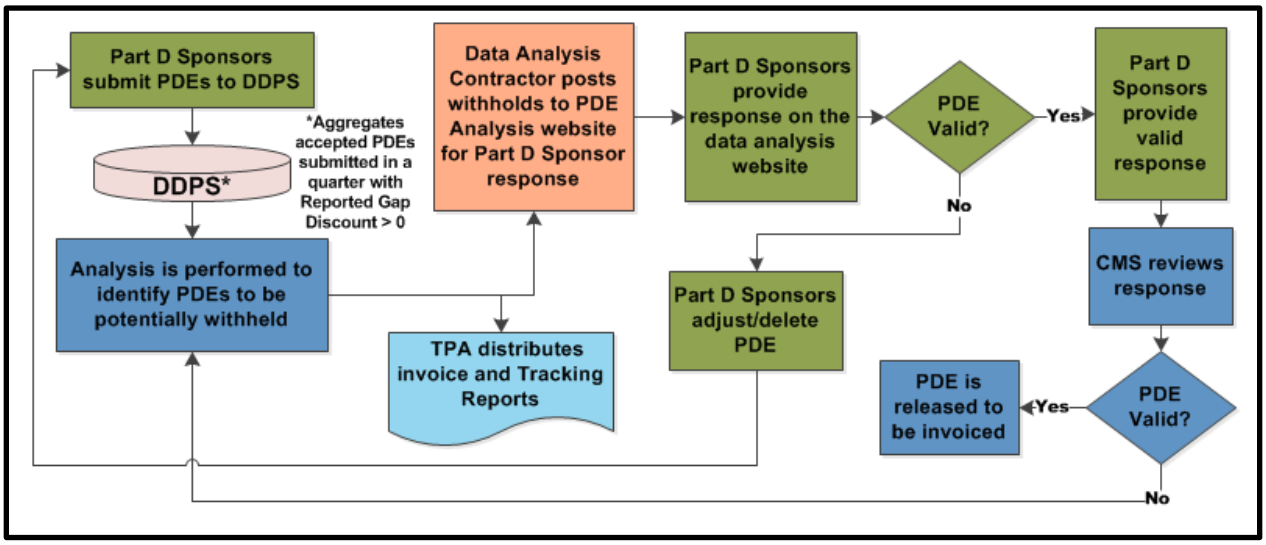
Outlier coverage gap PDEs are identified and withheld from the quarterly Manufacturer Invoice Report until resolved. These outlier PDEs are posted on the PDE Analysis website each quarter for Part D Sponsors to review and correct as necessary.

Part D Sponsors review the PDEs and provide feedback within 14 calendar days. The PDE Data Analysis Contractor sends the Part D Sponsor responses and any planned PDE actions back to DDPS.

Note: If a subsequent Deletion/Adjustment resolves the outlier PDE, and the adjustment contains a coverage gap discount amount, the PDE is included on the next Quarterly Manufacturer Invoice. If a Part D Sponsor provides an explanation of why a Gap Discount PDE that was withheld is actually valid and the response is accepted by CMS, the PDE is released to be included on the next Quarterly Manufacturer Invoice.

See **Figure 4** for a high level overview of an Outlier Process Flow.

Figure 4: Outlier Process Flow



3.1.2 Outlier Impact to Manufacturers

PDEs identified as outliers, under the conditions described in 3.1.1 Outliers Defined, are excluded from quarterly manufacturer invoicing and payment until the issue causing the PDE to be flagged as an outlier is resolved by the Part D Sponsor.

3.1.3 Outlier Impact to Part D Sponsors

The PDE analysis and outlier process has a direct effect on Part D Sponsors as withheld PDEs are not included on invoices to the Drug Manufacturer, and therefore, are excluded from reimbursement of the gap discount amount until the PDE outlier issue is resolved.

Part D Sponsors can respond to withheld PDEs in one of two ways:

1. Adjust or delete PDEs that require correction through DDPS:
    - Part D Sponsors must adjust or delete PDEs within 90 days from the date that the withheld PDEs are posted to the PDE Analysis website. This date is the same as the release date for the Quarterly Invoice Reports.
2. If the Part D Sponsor believes that the PDE is valid, they complete and submit a Response Form within 14 calendar days of the PDE's posting on the PDE Analysis website. This is mandatory if the Part D Sponsor believes that the PDE is valid as previously submitted and they will not be adjusting or deleting the PDE in question to DDPS.

3.2 Quarterly Invoice Reports

3.2.1 TPA Role in Quarterly Invoice Reports

The TPA is responsible for distributing quarterly invoice reports to Drug Manufacturers and Part D Sponsors.

Table 1 provides the Quarter End Dates and their respective targeted Report Distribution Dates for a given Plan Year.

Note: These dates may be subject to changes or delays. It is recommended that Drug Manufacturers and Part D Sponsors access the Medicare Part D CGDP Calendar on the TPA website (www.TPAdministrator.com) to verify all dates.

Table 1: Quarterly Invoice Report Distribution Schedule

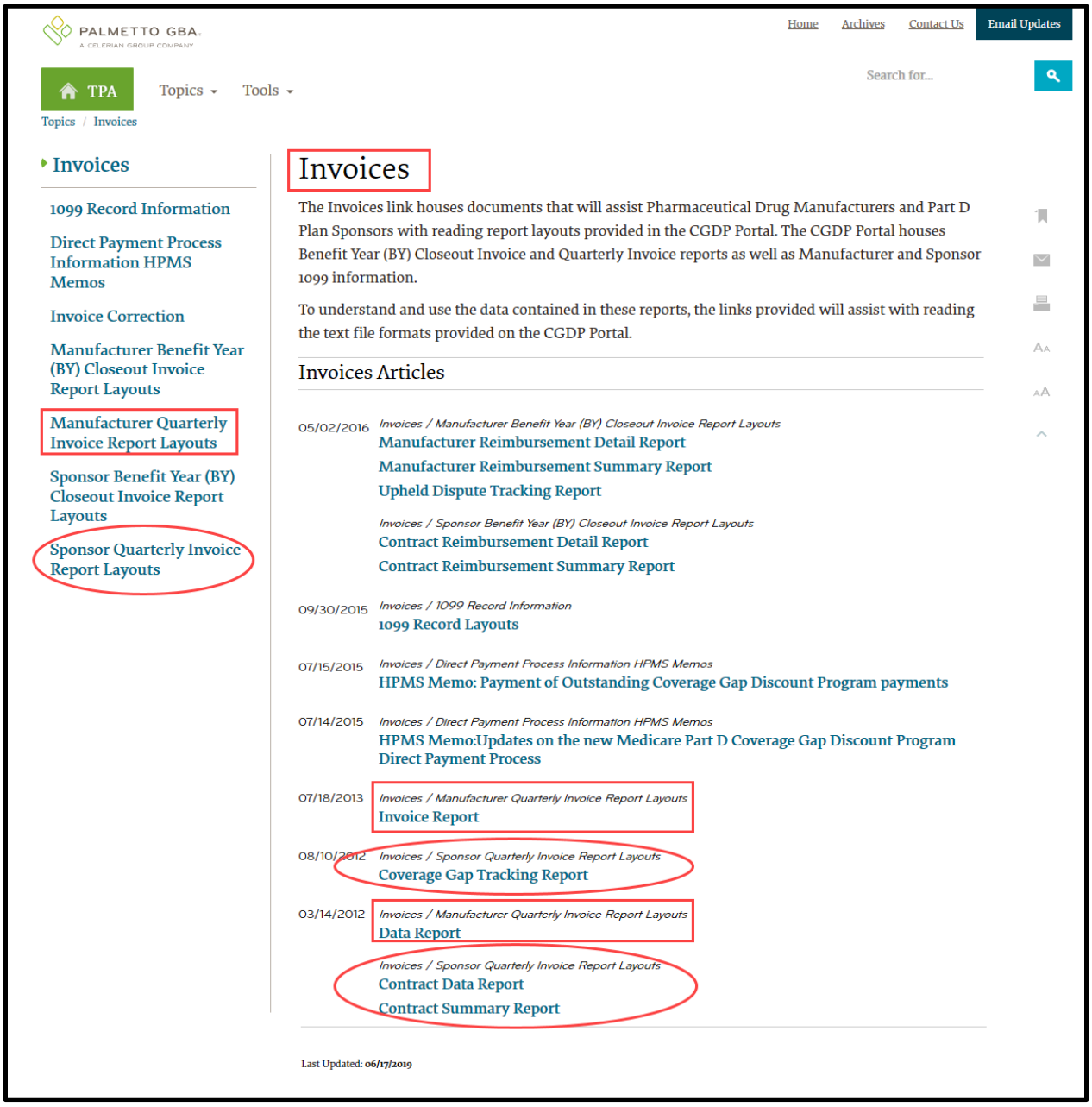
Quarter End Date	Report Distribution Date
March 31	April 30
June 30	August 31
September 30	October 31
December 31	January 31

Note: Report distribution for the quarter ending June 30th is delayed one month due to processes that occur as a result of the annual Part D payment reconciliation.

Quarterly Invoice reports consist of five reports. The TPA sends three of these reports to Part D Sponsors and two reports to Drug Manufacturers. All five reports are received in a flat file format and the file layouts are available on the TPA website. These files are then distributed through the CGDP Portal to CGDP participants.

To view all Drug Manufacturer and Part D Sponsor Quarterly Invoice Report File Layouts, access the Invoices topic on the TPA website as shown in **Figure 5**.

Figure 5: TPA website – Quarterly Invoices Report Layouts



The Manufacturer Reports include:

- Invoice Report
- Data Report (also available in an Excel format)

The Part D Sponsor reports include:

- Contract Summary Report
- Contract Data Report (also available in an Excel format)
- Coverage Gap Tracking Report

Reminder: Invoice Reports are generated quarterly for each benefit year for a total of 17 quarters. (For example, benefit year 2014 will be invoiced through January 31, 2018).

3.2.2 Manufacturer Reports

Each participating Drug Manufacturer receives a Quarterly Invoice Report identifying the payments due to (or to be received from in the case of a PDE adjustment/deletion) each Part D Sponsor for coverage gap activity that occurred during the quarter. Each Drug Manufacturer receives the Manufacturer Data Report, which provides PDE level information for final action PDEs with a gap discount amount greater than zero.

Using the CGDP Portal, the TPA sends Drug Manufacturers all available reports. The Drug Manufacturers are notified by subscription-based email distribution listings and a News Update ported to the TPAdministrator.com website regarding the availability of the reports. All reports are received in a flat file format from DDPS in defined layouts available on the TPAdministrator.com website. These files are then distributed through the CGDP Portal to CGDP participants. The TPA also sends an Excel based Data Report for enhanced readability. All Drug Manufacturer reports appear on the Reports tab of the CGDP Portal for review and download. Drug Manufacturers access the reports using the CGDP Portal. Drug Manufacturer User Guides for the CGDP Portal are posted on the TPA website.

For a high level overview of the CGDP Portal, refer to 5.5. Training, User Guides, Frequently Asked Questions (FAQ) and Webinar Information on the TPA website in this guide.

For more detailed information and instructions on how to use the CGDP Portal, access the CGDP Manufacturer Portal Users Guides topic and review the user guides on the TPA website.

3.2.2.1 Manufacturer Invoice Report

The Invoice Report is distributed quarterly to Drug Manufacturers. Positive amounts on the report summarize the payments each Drug Manufacturer will make to the Part D Sponsors. Negative amounts on the report summarize the payments Drug Manufacturers will receive from Part D Sponsors as a result of adjusted or deleted PDEs from previous quarters.

Specifically, within this file layout, the header and trailer records identify the:

- Calendar Quarter of the report (CURRENT REPORTING PERIOD),
- Drug Manufacturer (MANUFACTURER P-NUMBER),
- Part D Sponsor (SUBMITTING CONTRACT NUMBER), as well as,
- Benefit Year/Quarter (REPORT ID).

The Labeler (LBLR) record reflects the:

- TOTAL GAP DISCOUNT AMOUNT THIS PERIOD field, which is the net of the TOTAL REPORTED GAP DISCOUNT PREVIOUS AMOUNT (reported on the last quarter's Invoice) and;

- TOTAL REPORTED GAP DISCOUNT CURRENT AMOUNT (the amount as of the current quarter's cut-off date, including adjustments or deletions) for each Labeler which has coverage gap discount amounts for the Manufacturer this quarter.

Drug Manufacturers utilize the Contract trailer (TPACT) record for quarterly payment reference.

This record displays the:

- Summarized TOTAL GAP DISCOUNT AMOUNT THIS PERIOD,
- TOTAL REPORTED GAP DISCOUNT PREVIOUS AMOUNT, and
- TOTAL REPORTED GAP DISCOUNT CURRENT AMOUNT.

If the summarized net amount (TOTAL GAP DISCOUNT AMOUNT THIS PERIOD) is a positive number, this amount is paid by the Manufacturer P-Number and identified by the EFT INDIVIDUAL IDENTIFICATION NUMBER.

If this amount is a negative number, this amount is received from the Part D Sponsor to the Manufacturer P-Number.

To view all Drug Manufacturer Reports and File Layouts, access the Manufacturer Quarterly Invoice Report Layouts topic on the TPA website.

3.2.2.2 Manufacturer Data Report

The Data Report is an itemized list of each final action gap discount PDE for which the Drug Manufacturer is responsible in the quarter. This report is similar to the one provided to Part D Sponsors however, it does not contain any contract or Plan Benefit Package (PBP) identifiers. This report provides the Drug Manufacturers the opportunity to review the detail inputs to the summary invoice (DETCG record). These details reflect changes from subsequent quarters due to adjustments or deletions of PDEs made by Part D Sponsors.

The header and trailer records identify the:

- Calendar Quarter of the report (CURRENT REPORTING PERIOD);
- Drug Manufacturer (MANUFACTURER P-NUMBER),
- Labeler (LABELER CODE), as well as,
- Benefit Year/Quarter (REPORT ID).

The detail record (DETCG) includes detailed PDE data which is aggregated into the summary level invoice.

The TOTAL GAP DISCOUNT AMOUNT THIS PERIOD on the Manufacturer trailer (TPAMT) record corresponds to the same field on the Manufacturer Invoice Report Manufacturer trailer (TPAMT) record.

The detail records (DETCG) from this report are used by the Drug Manufacturer as the base records for the Manufacturer Dispute Submission File. If the Drug Manufacturer needs to dispute an invoiced PDE, as they disagree with the information included on the PDE, this file is sent back to the TPA.

See **Table 2** for a sample list of fields included on the DETCG record of the Manufacturer Data Report.

Table 2: Manufacturer Data Report Fields Sample List

Field	Description
SERVICE PROVIDER IS	The identifier for the Service Provider
PRESCRIPTION SERVICE REFERENCE NUMBER	A unique reference umber for a prescription assigned by a plan. It must be unique for any DOS and Service Provider ID combination.
DATE OF SERVICE (DOS)	CCYYMMDD (Calendar YY Month Date)
QUANTITY DISPENSED	Number of Units, Grams, Milliliters, other. If compounded item, total of all ingredients should be supplied as Quantity Dispensed.
DAYS SUPPLY	Number of days' supply provided. Number entered is from 0-999.

To view all Drug Manufacturer Reports and File Layouts, access the Manufacturer Quarterly Invoice Report Layouts topic on the TPA website.

3.2.2.3 Manufacturer Data Spreadsheet

This spreadsheet contains the same information as the Manufacturer Data Report but is in a readable format that can be viewed in Excel and is downloadable from the CGDP Portal.

3.2.3 Labeler Codes in the Manufacturer Invoice Process

Labeler Codes, as defined and assigned by the Food and Drug Administration (FDA), consist of the first five digits in an 11 digit National Drug Code (NDC). CMS relies on correct and timely Drug Manufacturer information to produce accurate CGDP invoices each quarter.

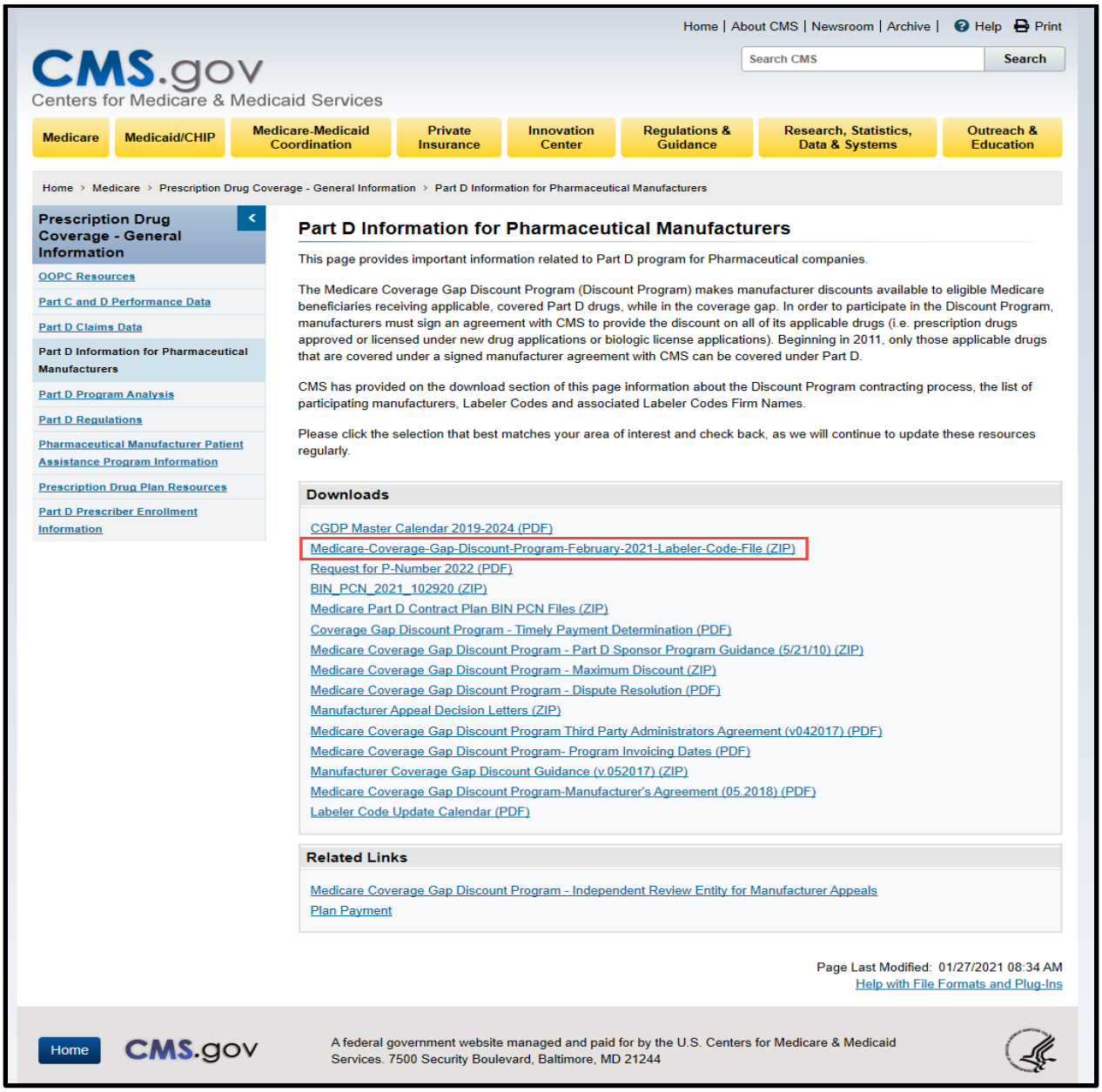
As part of a signed Manufacturer's agreement with CMS to participate in the CGDP, Manufacturers must provide CMS with all FDA-assigned Labeler Codes for the manufacturer's Applicable drugs. Manufacturers are responsible for keeping their Labeler Codes current in HPMS.

Drug Manufacturers that fail to update their Labeler Codes are then billed and are responsible for paying the amounts invoiced and cannot successfully appeal the amounts invoiced on the grounds that the Labeler Code data is incorrect. CMS does not consider such failure to be grounds for successful dispute of invoiced amounts.

Refer to Appendix C – HPMS Model & Enterprise Users Administration (EUA) Access for instructions and sample screens on obtaining access to CMS' HPMS for Labeler Code input.

Listings of current Labeler Codes by Manufacturers can be found on CMS' website Part D Information for Pharmaceutical Manufacturers as shown in **Figure 6**Figure 6.

Figure 6: CMS Part D Information – Emphasis on 2021 Labeler Codes



3.2.3.1 Adding Labeler Codes

New Labeler Codes are those that are either newly FDA-assigned or have not been previously specified by the Drug Manufacturer. A Manufacturer must add any new Labeler Codes through

HPMS as soon as the codes are assigned by the FDA, in advance of FDA drug approval. A new Applicable drug product, even if FDA approved for sale, is not eligible for coverage under the Medicare Part D program unless the Labeler Code is covered under a Manufacturer Agreement.[2]

Requests to add Labeler Codes must be received at least five business days prior to the month's end in order to become effective the following month. CMS will add newly approved Labeler Codes to the Coverage Gap Participating Labeler Code File for web posting by the first business day of the following month.

In the event that a Manufacturer has drugs associated with a new Labeler Code, the Manufacturer should do the following to make sure that their drugs are eligible for coverage under Part D as soon as possible:

- List NDCs with the FDA in advance of commercial distribution of the product so that CMS and Part D Sponsors can accurately identify Applicable drugs once they are provided to pharmacies for distribution to patients.
- Add the Labeler Code into HPMS before database vendors, such as First DataBank and Medi-Span, receive NDCs associated with the new codes.

3.2.3.2 Transferring Labeler Codes

Drug Manufacturers' business needs may call for the transfer of existing Labeler Code(s) from one Manufacturer to another. The Labeler Code owner of record remains liable for payment of all discounts until the transfer is complete. CMS requires that both Manufacturers participate in the transfer process through HPMS. One Manufacturer must request that the code be deleted from its P Number and the other Manufacturer must request an addition to its P Number.

Here is an example of a typical process to transfer a Labeler Code:

- The Labeler Code owner of record must submit a request to delete the Labeler Code within HPMS.
- The Drug Manufacturer that wishes to assume ownership of the Labeler Code must submit a request within HPMS to add the Labeler Code.
- CMS must approve both requests. Transfers are not considered complete until both Manufacturer requests have been approved. Each Drug Manufacturer's Primary Contact is notified by HPMS email when its request has been approved.
- Timely transfer requests become effective on the first day of the following month. The existing Labeler Code owner of record is responsible for payment of all discounts based upon invoice production and processing (See 3.2.4.3 Invoice Impact of Transferred Labeler Codes).
- Refer to the Labeler Code Update Calendar for key dates in the transfer process on the TPA's Labeler Code Update Calendar or CMS' Part D Information for Pharmaceutical Manufacturers websites.
- The transfer of Labeler Codes includes all NDCs associated with that Labeler Code. CMS does not transfer individual NDCs.

[2] See March 30, 2017 HPMS memo, "*Medicare Coverage Gap Discount Program Guidance",* for an explanation of invoice policies and the transfer of Labeler Codes.

3.2.3.3 Invoice Impact of Transferred Labeler Codes

Drug Manufacturers should take note of the following regarding invoice production and processing of Labeler Code transfers:

- Manufacturers' quarterly invoices are billed and distributed according to the CGDP Calendar. To view the most current version of the calendar, access the Medicare Part D CGDP Calendar subtopic on the TPA website.
- Drug Manufacturer invoices include coverage gap discount amounts by Labeler Code for an entire quarter. Labeler Code activity is not billed in time increments smaller than a quarter. This means that the manufacturer that assumes liability for a Labeler Code effective the second or third month within a quarter will be billed for all PDE activities for all three months (first, second, and third).
- The new Labeler Code owner receives the quarterly invoice if a transfer becomes effective by the third month of the quarter. See Labeler Code Update Calendar referenced above. For example,
    - If a Labeler Code transfer request is approved in February and becomes effective on March 1st, the Q1 invoice will be delivered to the new Labeler Code owner.
    - If a Labeler Code transfer request is approved in March and becomes effective on April 1st, the Q1 invoice will be delivered to the prior Labeler Code owner.
- Invoices are based upon all CGDP PDE activity received by CMS during the quarter. As the year progresses, invoices may include PDEs from prior quarters' dates of service. This means that once a Manufacturer assumes liability for discounts associated with a Labeler Code, that company is billed for any residual discounts from dates of service that occurred prior to the transfer of the Labeler Code but were received by CMS after the transfer of the Labeler Code.
- The Invoice Reporting Period for Quarter 17 (Q17) of the impacted benefit year ends on January 31[3]. For example, Q17 for benefit year 2014 ends on January 31, 2018. Although the invoice for this quarter is delivered on April 30, it only includes PDEs reporting gap discount amounts for that benefit year's Q17 submitted by January 31.
- In the event that business needs do not coincide with the timing of the transfers, Drug Manufacturers are expected to reconcile any CGDP payments amongst themselves without CMS involvement. CMS holds the HPMS owner of record responsible for making discount payments until both manufacturers submit Labeler Code change requests through HPMS and until the quarter in which the transfer takes effect.

3.2.3.4 Invoice Report Impact When a Labeler Code Transfer Occurs

When a PDE is invoiced in one quarter with one Labeler Code, and the coverage gap discount amount is adjusted or deleted in a subsequent quarter, in which the Labeler Code has changed ownership to another Drug Manufacturer, Invoice Reports are impacted as follows:

[3] See the December 28, 2016 HPMS memo, "*Annual Benefit Year Closeout for the Coverage Gap Discount Program Invoicing Cycle*".

- **Effect on Part D Sponsor Invoice Report**
  - The Part D Sponsor does not receive information regarding Labeler Code changes. Their reports are summarized at the Manufacturer P Number (PNUM) level, which reflects the coverage gap discount amounts associated with the Labeler Code within the summary of the current Manufacturer (PNUM) owner at the time of the invoice.
- **Effect on Manufacturer Invoice Report**
  - The Manufacturer (PNUM) that owned the Labeler Code on the prior invoice is no longer responsible for the gap discount amounts on any future invoice changes.
  - The Manufacturer (PNUM) that currently owns the Labeler Code is now responsible for any gap discounts per the invoice's current gap discount amount.
- **Effect when a PDE is deleted in a subsequent quarter**
  - The Manufacturer (PNUM) that owned the Labeler Code on the prior invoice is no longer responsible for the gap discount amounts on any future invoice changes (gap discount amount in the prior gap amount and zero in the current gap amount). The new owner of the Labeler Code will see any changes that impacted the previous Manufacturer (PNUM) as they now have liability for the labeler code.

3.2.3.5 Removing Labeler Codes

Drug Manufacturers may request to delete a Labeler Code from their contract through HPMS. The Manufacturer must attest that there is no intention to use or add products under that Labeler Code by clicking the Attestation check box.

CMS will approve the request only if the FDA Comprehensive National Drug Code (NDC) Structured Product Labeling (SPL) Data Elements (NSDE) file reflects retrospective last lot expiration dates for all Applicable Drugs (as defined in 42 CFR § 423.100) associated with the code.

Deletion requests must be received at least five business days prior to the month's end in order to become effective the following month. Consistent with the Manufacturer Agreement, Drug Manufacturers will be invoiced for gap discounts after a Labeler Code is deleted as long the date of service is on or before the Labeler Code End Date. PDEs for benefit year can be invoiced for 37 months following the end of the benefit year. Refer to the Labeler Code Update Calendar for key dates in the deletion process on the TPA's Labeler Code Update Calendar or CMS' Part D Information for Pharmaceutical Manufacturers websites.

For more information and instructions on making Labeler Code additions, transfers, or deletions, refer to the Drug Manufacturer User Manual available on the HPMS portal.

Note: Refer to Appendix E: Maintenance of FDA Records for information and requirements on maintaining up-to-date electronic FDA registrations and listings of all NCDs.

3.2.4 Part D Sponsor Reports

Part D Sponsors receive both a Contract Summary Report and Contract Data Report, also known as a Detail Report, communicating what they are owed from each Drug Manufacturer for the quarter as well as what is owed to the Drug Manufacturers due to PDE deletions and adjustments. In addition to these two reports, Part D Sponsors also receive a Coverage Gap Tracking Report.

Using the CGDP Portal, the TPA sends Part D Sponsors all available reports. Part D Sponsors are notified by subscription-based email distribution listings and a News Update posted to the TPA website regarding the availability of the reports. All reports are received in a flat file format and the file layouts are available on the TPA website. These files are then distributed through the CGDP Portal to CGDP participants. The TPA also sends an Excel based Data Report for enhanced readability. All Part D Sponsor reports appear on the Reports tab of the CGDP Portal for review and download. The TPA distributes an email via a subscription-based distribution list to notify Part D Sponsors that reports are available. Part D Sponsor User Guides for the CGDP Portal are posted on the TPA website.

3.2.4.1 Part D Sponsor Contract Summary Report

The **Contract Summary Report** identifies the payments Part D Sponsors will receive from each Drug Manufacturer as well as other information the Part D Sponsor can optionally use to identify Drug Manufacturer payments. In addition, negative amounts on the report summarize the payments Part D Sponsors are expected to refund back to each Drug Manufacturer as a result of adjusted or deleted PDEs from previous quarters. The information in this report is the same information that appears on the Payments and Receipts tab of the CGDP Portal.

The header and trailer records identify the:

- Calendar Quarter of the report (CURRENT REPORTING PERIOD),
- Part D Sponsor (SUBMITTING CONTRACT NUMBER),
- Drug Manufacturer (MANUFACTURER P-NUMBER).

Part D Sponsors utilize the Manufacturer trailer (TPAMT) record for quarterly payment reference. This record displays the:

- TOTAL GAP DISCOUNT AMOUNT THIS PERIOD field, which is the net of the TOTAL REPORTED GAP DISCOUNT PREVIOUS AMOUNT (reported on the last quarter's Invoice) and,
- TOTAL REPORTED GAP DISCOUNT CURRENT AMOUNT (the amount as of the current quarter's cut-off date, including adjustments or deletions).

If the net amount (TOTAL GAP DISCOUNT AMOUNT THIS PERIOD) is a positive number, this amount is received from the Manufacturer P-Number and identified by the Electronic Funds Transfer (EFT) INDIVIDUAL IDENTIFICATION NUMBER.

Note: This TOTAL GAP DISCOUNT AMOUNT THIS PERIOD also appears as a line item on the Receipts tab of the CGDP Portal.

If this amount is a negative number, this amount is paid by the Part D Sponsor to the Manufacturer P-Number.

Note: This TOTAL GAP DISCOUNT AMOUNT THIS PERIOD also appears as a line item on the Payments tab of the CGDP Portal.

Refer to **Table 1**Error! Reference source not found. for a sample list of fields included on the Contract Summary Report that are relevant to the payment process.

To view all Part D Sponsor Report File Layouts, access the Sponsor Quarterly Invoice Report Layouts subtopic on the TPA website.

Table 3: Contract Summary Report Fields Relevant to Payment Process

Field	Description
Manufacturer P NUMBER	Internal CMS number that uniquely identifies the Manufacturer.
EFT INDIVIDUAL IDENTIFICATION NUMBER	External identifier for CGDP payment, quarter, and Manufacturer.
Total Gap Discount AMOUNT THIS PERIOD	Amount Manufacturer owes Sponsor, if positive. Amount Sponsor owes Manufacturer, if negative.

For a high level overview of the CGDP Portal, refer to 5.5. Training, User Guides, Frequently Asked Questions (FAQ) and Webinar Information on the TPA website in this guide.

For more detailed information and instructions on how to use the CGDP Portal, access the TPA website and review the CGDP Sponsor Portal Users Guides subtopic.

3.2.4.2 Part D Sponsor Contract Data Report

The Part D Sponsor Contract Data Report documents each of the contract's final action gap discount PDEs invoiced in the quarter, which may include originals, adjustments, or deletions. This report is sometimes referred to as the Detail Report. It provides Part D Sponsors an opportunity to review inputs to the summary level invoice. It also incorporates changes from subsequent quarters due to adjustments or deletions of PDEs.

The header and trailer records identify the:

- Calendar Quarter of the report (CURRENT REPORTING PERIOD),
- Part D Sponsor (SUBMITTING CONTRACT NUMBER),
- Drug Manufacturer (MANUFACTURER P-NUMBER), as well as,
- Benefit Year/Quarter (REPORT ID).

The detail record (DETCD) includes detailed PDE data which is aggregated into the summary level invoice.

The TOTAL GAP DISCOUNT AMOUNT THIS PERIOD on the Manufacturer trailer (TPAMT) record corresponds to the same field on the Contract Summary Report Manufacturer trailer (TPAMT) record.

See **4**Error! Reference source not found. for a sample list of fields included on the DETCD record of the Contract Data Report.

To view all Part D Sponsor Reports and File Layouts, access the Sponsor Quarterly Invoice Report Layouts topic on the TPA website.

Table 4: Contract Data Report Fields Sample List

Field	Description
DETAIL REFERENCE (REF) NUMBER	A unique coverage gap reference number for this coverage gap detail. This number can be used between coverage gap discount reports to track adjustments that occur on this coverage gap detail.
PERVIOUS REPORT ID and **REPORTED Gap Discount PREVIOUS AMOUNT**	Indicates adjusted or deleted records that were previously invoices.
SUBMITTING CONTRACT NUMBER and **SUBMITTING CONTRACT PBP NUMBER**	Identifies the contract/PBP that advanced the CGDP discount at POS.

3.2.4.3 Part D Sponsor Contract Data Spreadsheet

This spreadsheet contains the same information as the Part D Sponsor Contract Data Report but is in a readable format that can be viewed in Excel.

3.2.4.4 Coverage Gap Tracking Report

This report is a cumulative report showing the status of each gap discount PDE saved in the DDPS database. There is one Tracking Report for each benefit year. Status codes on the report indicate if a PDE was invoiced or pended (meaning it was withheld from the invoice). These codes can be found on the DETCD record of the report.

Withheld (or pended) PDE Reason Codes typically found on this report include:

- Blank - Not Pended
- 01 - Retro Disenrollment
- 02 - Retro LI
- 04 - Other Data Quality Review
    - Total Reported Gap Discount Amount greater than the Maximum Allowed Gap Discount Amount
    - Total RGD is greater than TrOOP
    - PDE Reports a Closed Pharmacy or Inactive Provider ID

  - RGD Amount exceeds Maximum Allowed Gap Discount Amount
  - Calculated TrOOP exceeds True Out-of-Pocket Threshold
- 99 - Other – Outlier Type 99999

To view all Part D Sponsor Reports and File Layouts, access the Sponsor Quarterly Invoice Report Layouts topic on the TPA website.

4. Benefit Year (BY) Closeout Invoice Reporting Process

4.1 Benefit Year (BY) Closeout Invoice Reports

Benefit Year (BY) Closeout Invoice Reports for Drug Manufacturers and Part D Sponsors will be released annually through the TPA.

The BY Closeout Invoice Reports will communicate to Drug Manufacturers the status of all upheld disputes for the closed benefit year, i.e. whether or not the disputed PDE record has been corrected in a manner that resolved the issue that led to the dispute and whether the correction resulted in a financial or non-financial change to the invoice data.

This reporting process also allows the Part D Sponsor to remit payment for any gap discounts invoiced in Q17 that were successfully disputed and for any successful disputes from previous quarters of the benefit year in which the Part D Sponsor has only recently corrected.

Manufacturers should note that successful disputes can result in a full adjustment, partial adjustment, or no adjustment to the gap discount amount.[4]

4.1.1 TPA Role in BY Closeout Invoice Reporting Process

The TPA is responsible for distributing the BY Closeout Invoice Reports to Drug Manufacturers and Part D Sponsors. These invoice reports will be released annually approximately fifteen months after a benefit year's Q17 invoice receipt date. Drug Manufacturers and Part D Sponsors receiving these reports are notified via targeted email distribution listing, using data pulled from HPMS TPA Liaison or CGDP Payment Contact fields, regarding the availability of these reports.

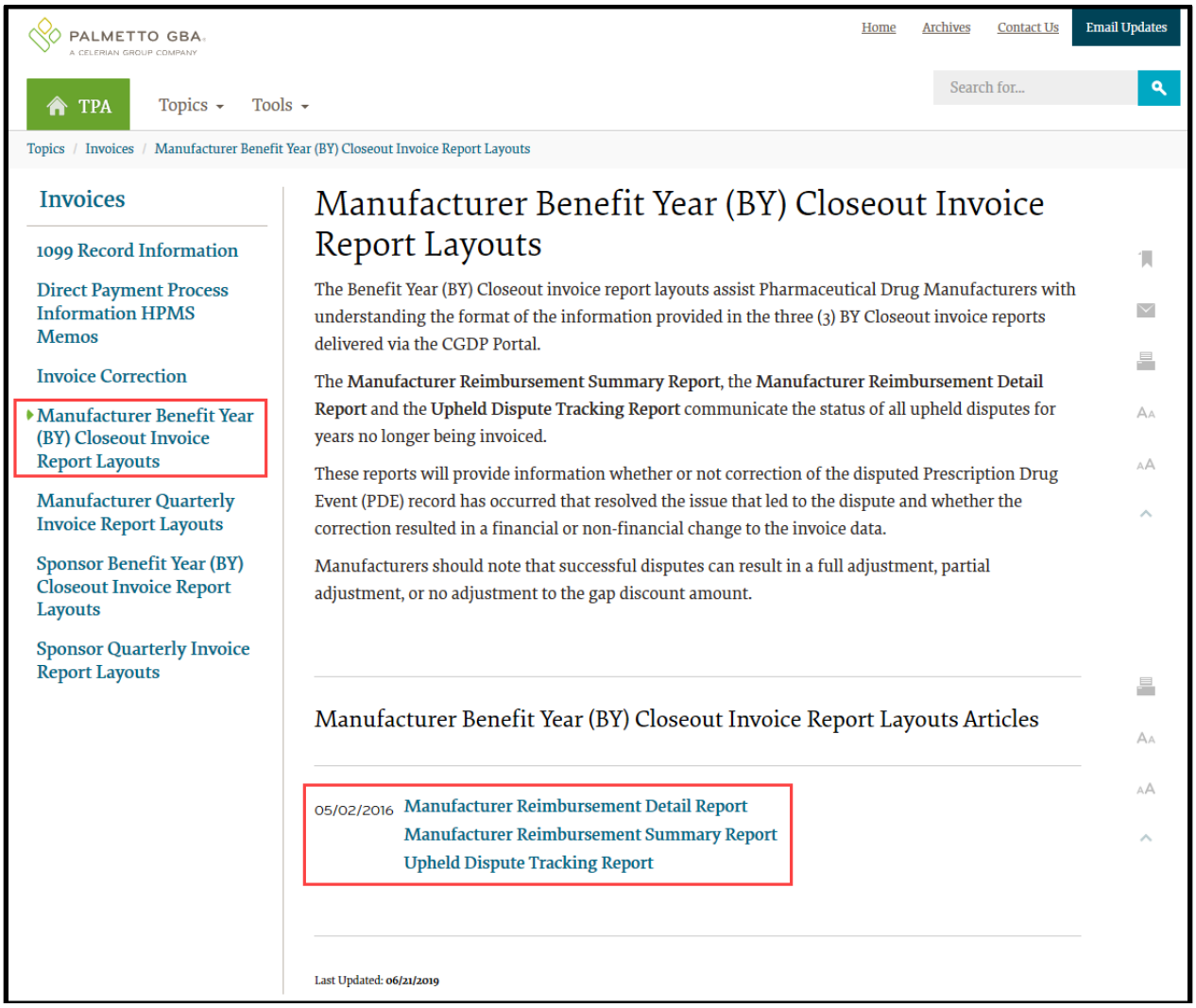
Note: The release date may be subject to change.

BY Closeout Invoice Reports consist of five reports. The TPA sends three of these reports to Drug Manufacturers and two reports to the Part D Sponsors. All five reports are received in a flat file format from DDPS in defined layouts available on the TPAdministrator.com website. These files are then distributed through the CGDP Portal to CGDP participants. **Figure 7** displays the location of the Manufacturer Benefit Year (BY) Closeout Report Layouts on the

[4] Health Plan Management System (HPMS) Memo dated May 2, 2016, *Coverage Gap Discount Program Benefit Year Closeout Invoice Reports*.

TPA website. **Figure 8** displays the location of the Sponsor Benefit Year (BY) Closeout Report Layouts on the TPA website.

Figure 7: TPA website – Manufacturer BY Closeout Report Layouts



The Manufacturer BY Closeout Invoice Reports include:

- Manufacturer Reimbursement Summary Report
- Manufacturer Reimbursement Detail Report (also available in an Excel format)
- Upheld Dispute Tracking Report

4.1.2 Manufacturer BY Closeout Invoice Reports

Manufacturers receive a Manufacturer Reimbursement Summary Report, a Manufacturer Reimbursement Detail Report and an Upheld Dispute Tracking Report which communicates to Manufacturers the status of all upheld disputes for years no longer being invoiced. These reports will provide information whether or not correction of the disputed PDE record has occurred that resolved the issue that led to the dispute and whether the correction resulted in a financial or non-financial change to the invoice data.

Using the CGDP Portal, the TPA sends Manufacturers all available reports. The TPA also distributes an Excel based Reimbursement Detail Report for enhanced readability. All Manufacturer reports appear on the Reports tab of the CGDP Portal for review and download.

Drug Manufacturers access all reports using the CGDP Portal. Drug Manufacturer User Guides for the CGDP Portal are posted under the CGDP Manufacturer Portal Users Guides subtopic on the TPA website.

For a high level overview of the CGDP Portal, refer to 5.5. Training, User Guides, Frequently Asked Questions (FAQ) and Webinar Information on the TPA website in this guide.

4.1.2.1 Manufacturer Reimbursement Summary Report

The Manufacturer Reimbursement Summary Report allows Drug Manufacturers to identify any amounts owed to them for upheld disputes by specific contracts and by benefit year.

If closed benefit years' upheld disputes are updated by Part D Sponsors after the release of the BY Closeout Invoice report, those updates will be reflected in the next BY Closeout Invoice Report, which now would include multiple benefit years' data. The amount that is owed is found on the TPACT record along with the EFT ID to be used for reference.

The Manufacturer Reimbursement Summary Report consists of seven record types. There are three header records, three trailer records, and one detail record:

- Manufacturer P Number Header (TPAMH)
- Contract Header (TPACH)
- Benefit Year Specific Header (BYRH)
- Benefit Year Specific Trailer (BYRT)
- Contract Trailer (TPACT)
- Manufacturer P Number Trailer (TPAMT)
- Manufacturer Reimbursement Total at the Labeler Level (LBLR)

The LBLR record will report the Total Upheld Dispute Reimbursement Amount, summarized by labeler, and contains the aggregated amount that the Part D Sponsor owes the Drug Manufacturer for all upheld disputes being reimbursed through the benefit year closeout invoice cycle by contract.

The Total Upheld Dispute Reimbursement Amount is the total amount owed for any upheld disputes that were resolved with financial impact, related to the labeler specified on the record. The LBLR record also reports the Total Reported Gap Discount Current Amount which is the total gap discount amounts reported on the most recent versions of the disputed PDEs for the

contract and the Total Reported Gap Discount Previous Amounts, the total gap discounts reported on the invoice when the PDEs were originally disputed. The net payment reported in the Total Upheld Dispute Reimbursement Amount is calculated as the Total Reported Gap Discount Current Amount minus the Total Reported Gap Discount Previous Amount.[5]

To view all Drug Manufacturer BY Closeout Invoice Reports and File Layouts, access the Manufacturer BY Closeout Invoice Report Layouts topic on the TPA website as shown in **Figure 7**.

4.1.2.2 Manufacturer Reimbursement Detail Report

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

The Manufacturer Reimbursement Detail Report consists of five record types. There are two header records, two trailer records, and one detail record:

- Manufacturer P Number Header (TPAMH)
- Labeler Header (TPALH)
- Labeler Trailer (TPALT)
- Manufacturer P Number Trailer (TPAMT)
- Manufacturer Reimbursement Detail Record at PDE Level (DETMD).

Any disputed PDE that meets the criteria stated above and is included in the report will have a DETMD record.

The purpose of the DETMD record is to report the Upheld Dispute Reimbursement Amount, the amount that the Part D Sponsor owes the manufacturer for the upheld dispute. This is the amount that the Part D Sponsor is being invoiced for during the benefit year closeout invoicing cycle at the detail PDE level. The manufacturer should review the Manufacturer Reimbursement Summary Report for the total amount due from the Part D Sponsor. The DETMD also reports the Reported Gap Discount Current Amount which is the gap discount amount reported on the most recent version of the disputed PDE and the Reported Gap Discount Previous Amount, the gap discount reported on the invoice when the PDE was originally disputed. The net payment reported in the Upheld Dispute Reimbursement Amount is calculated as the Reported Gap Discount Current Amount minus the Reported Gap Discount Previous Amount.[6]

Since the BY Closeout Invoice Reports are to ensure Part D Sponsor repayment for upheld disputes that remain outstanding after 17 quarters and resulted in financial changes, the Manufacturer will not be responsible for any gap discount payment during the closeout report invoicing cycle.

[5] Health Plan Management System (HPMS) Memo dated May 2, 2016, "*Coverage Gap Discount Program Benefit Year Closeout Invoice Reports*".

[6] Health Plan Management System (HPMS) Memo dated May 2, 2016, "*Coverage Gap Discount Program Benefit Year Closeout Invoice Reports*".

To view all Drug Manufacturer BY Closeout Invoice Reports and File Layouts, access the Manufacturer BY Closeout Invoice Report Layouts topic on the TPA website as shown in **Figure 7**.

4.1.2.3 Manufacturer Reimbursement Detail Spreadsheet

This spreadsheet contains the same information as the Manufacturer Reimbursement Detail Report but is in a readable format that can be viewed in Excel. This report is distributed to Drug manufacturers using the CGDP Portal.

4.1.2.4 Upheld Disputes Tracking Report

The Upheld Dispute Tracking Report for Manufacturers is a report that will provide the manufacturer with the status of invoiced PDEs that were disputed and subsequently upheld by the TPA. The purpose of the report is to inform manufacturers of any adjustment or deletion activity undertaken by the Part D Sponsor in response to the upheld dispute.
As a reminder, manufacturers should consider that not all adjustments to the PDE record in response to an upheld dispute will result in a full or even partial reimbursement of the gap discount to the manufacturer. Part D Sponsors can make changes to both financial and/or non-financial elements on the PDE record to resolve the issue that led to the successfully disputed PDE, for example through an adjustment to a field such as Fill Number, Days' Supply or Quantity Dispensed on the PDE record. This type of resolution may or may not result in the manufacturer receiving the gap discount amount back, in full or in part, from the Part D Sponsor.

The Upheld Dispute Tracking Report for Manufacturers consists of five record types.
There are two header records, two trailer records and one detail record:

- Upheld Dispute Manufacturer Header (UDTMH)
- Upheld Dispute Benefit Year Header (UDTBH)
- Upheld Dispute Benefit Year Trailer (UDTBT)
- Upheld Dispute Manufacturer Trailer (UDTMT)
- Upheld Dispute Tracking Data Record (DETUD)

Each disputed PDE that was subsequently upheld for the benefit year will have a DETUD record. The upheld dispute will be identified on the DETUD using the Detail Reference Number. The Detail Reference Number is the same number that appears on the Invoice Data Report and the Dispute Resolution Reports received each quarter. It is a unique coverage gap reference number, and it is used to track changes in the PDE record from quarter to quarter.

The DETUD record shows the original PDE data elements reported on the invoice when the PDE was disputed. The original PDE data elements are described by the term "disputed" in the field name on the detail record. The DETUD also shows the current PDE data elements as of the reimbursement report cut-off date to show any changes that have been made to the PDE since the dispute was upheld. This allows manufacturers to compare the data element at the time of dispute and the current data element to highlight how the PDE was resolved in response to the dispute. For example, if a PDE was submitted as a D04 on the basis of Aberrant Quantity and the Part D Sponsor resubmitted the disputed PDE with an adjustment to Quantity Dispensed to resolve the issue, the Drug Manufacturer would be able to use the data on the DETUD to compare the Disputed Quantity Dispensed field, which provides the amount on the original PDE, to the Current Quantity Dispensed field to identify the change to the PDE that resulted in the resolution of the issue that led to the Aberrant Quantity dispute. For more

information on Disputes and Dispute Codes, refer to **Figure 47**: TPA website – Disputes HPMS Memo

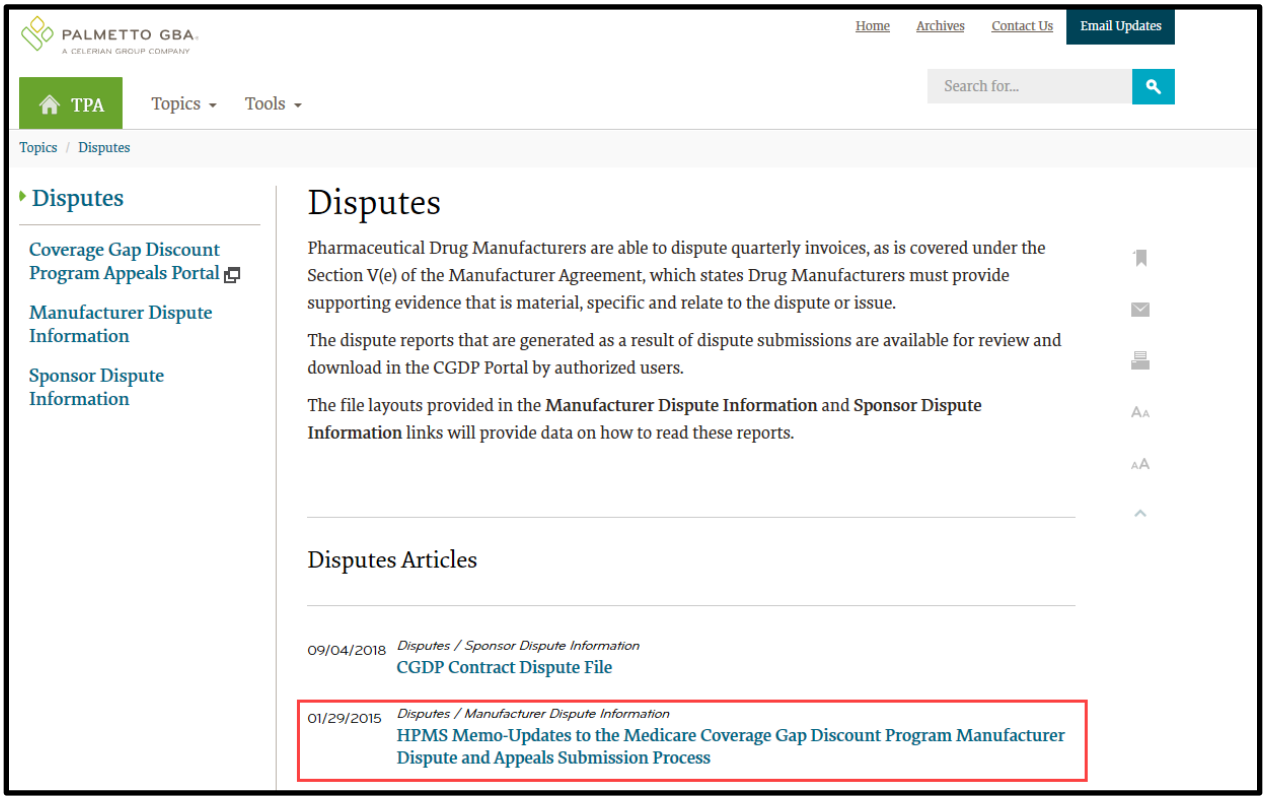


Table 5, Cross Reference of Dispute to Appeal Codes.

The DETUD also contains a field called Upheld Dispute Status. This field indicates whether it has been determined that the disputed PDE has been resolved without a financial adjustment, indicating that the PDE was updated and no other action needs to be taken by the Part D Sponsor; resolved with a financial adjustment, indicating the resolution resulted in a partial or full repayment of the gap discount amount to the manufacturer; or remains unresolved.

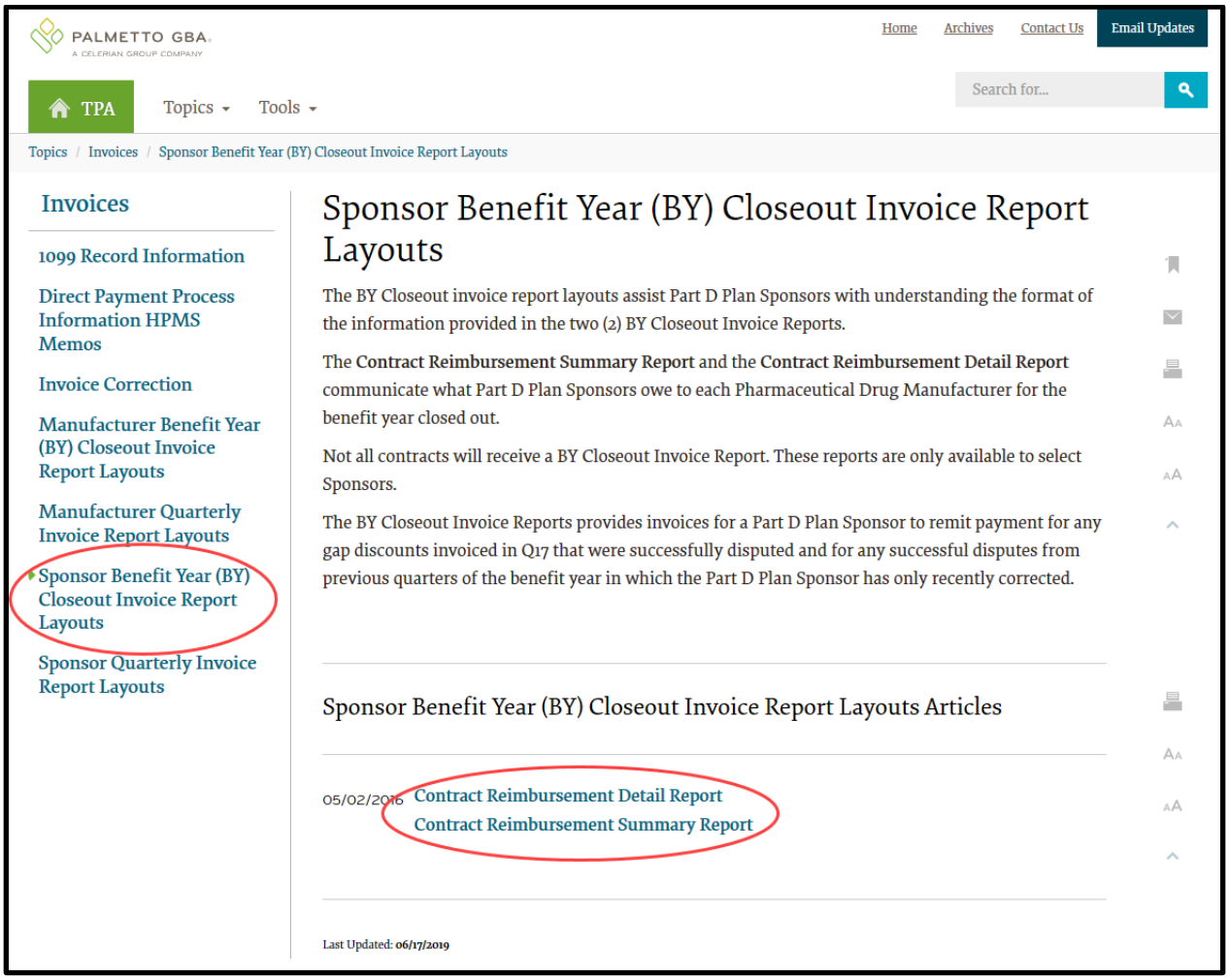
To view all Drug Manufacturer BY Closeout Invoice Reports and File Layouts, access the Manufacturer BY Closeout Invoice Report Layouts topic on the TPA website as shown in **Figure 7**.

4.1.3 Part D Sponsor BY Closeout Invoice Reports

Part D Sponsors receive both a Contract Reimbursement Summary Report and Contract Reimbursement Detail Report communicating what they owe to each Drug Manufacturer for the benefit year closed out. Each participating contract receives a BY Closeout Invoice Report identifying any gap discounts invoiced in Q17 that were successfully disputed, and for any successful disputes from previous quarters of the benefit year in which the Part D Sponsor has only recently corrected.

Using the CGDP Portal, the TPA sends Part D Sponsors all available reports. The formats of the reports remains unchanged. The TPA also sends an Excel based Reimbursement Detail Report for enhanced readability via the Portal. All Part D Sponsor reports appear on the Reports tab of the CGDP Portal for review and download. Part D User Guides for the CGDP Portal are posted on the TPA website.

Figure 8: TPA website – Sponsor BY Closeout Report Layouts



The Part D Sponsor BY Closeout Invoice Reports include:

- Contract Reimbursement Summary Report
- Contract Reimbursement Detail Report (also available in an Excel format)

4.1.3.1 Part D Sponsor Contract Reimbursement Summary Report

The Contract Reimbursement Summary Report consists of five record types. There are two header records, two trailer records, and one detail record:

- Contract Header (TPACH)
- Manufacturer Header (TPAMH)
- Contract Trailer (TPACT)
- Manufacturer Trailer (TPAMT)
- Contract Reimbursement Summary Record for the P-Number Total (PTOT)

The Contract Reimbursement Summary Report allows contracts to identify any amounts owed to the Manufacturer for upheld disputes by Manufacturer P-Number. For the first report, released in July 2016, the report only includes benefit year 2011 invoiced data. If Part D Sponsors make further updates to a closed benefit year's upheld disputes after the release of

the BY Closeout Invoice Report, those updates will be reflected in the following BY Closeout Invoice Report which would then include multiple benefit years' data.

The PTOT record reports the Total Upheld Dispute Reimbursement Amount, the aggregated amount that the Part D Sponsor owes the Manufacturer for all upheld disputes that are being reimbursed through the benefit year closeout invoice cycle. The Total Upheld Dispute Reimbursement Amount is the total amount that the Part D Sponsor is being invoiced for the specified P-Number. The amount that should be paid for a particular Drug Manufacturer is found on the TPAMT record along with the EFT ID to be used for reference. The PTOT also reports the Total Reported Gap Discount Current Amount which is the total gap discount amounts reported on the most recent versions of the disputed PDEs for the contract and the Total Reported Gap Discount Previous Amounts, the total gap discounts reported on the invoice when the PDEs were originally disputed. The net payment reported in the Total Upheld Dispute Reimbursement Amount is calculated as the Total Reported Gap Discount Current Amount minus the Total Reported Gap Discount Previous Amount.

To view all Part D Sponsor BY Closeout Invoice Reports and File Layouts, access the Sponsor BY Closeout Invoice Report Layouts topic on the TPA website as shown in **Figure 8**.

For a high level overview of the CGDP Portal, refer to 5.5. Training, User Guides, Frequently Asked Questions (FAQ) and Webinar Information on the TPA website in this guide.

4.1.3.2 Part D Sponsor Contract Reimbursement Detail Report

The Contract Reimbursement Detail Report will inform the contract of any gap discount payments to be paid to the manufacturer due to upheld disputes from Q17 or previous quarters. The Contract Reimbursement Detail Report only reports on upheld disputes in which the action taken by the Part D Sponsor to resolve the dispute resulted in a partial or full repayment of the disputed gap discount amount and that gap discount amount has not been previously invoiced for Part D Sponsor payment to the manufacturer.

The Contract Reimbursement Detail Report consists of seven record types.

There are three header records, three trailer records, and one detail record:

- Contract Header (TPACH)
- Manufacturer P Number Header (TPAMH)
- Benefit Year Specific Header (BYRH)
- Benefit Year Specific Trailer (BYRT)
- Manufacturer P Number (TPAMT)
- Contract Trailer (TPACT)
- Contract Reimbursement Detail Record at the PDE Level (DETCD).

Any disputed PDE that meets the criteria stated above to be included in the report will have its own DETCD record.

The purpose of the DETCD record is to report the Upheld Dispute Reimbursement Amount, the amount that the Part D Sponsor owes the manufacturer for the upheld dispute. This is the amount that the Part D Sponsor is being invoiced for and is required to pay the manufacturer during the benefit year closeout invoicing cycle at the detail PDE level. The Part D Sponsor should review the Contract Reimbursement Summary Report for the total amount due to the

manufacturer. The DETCD also reports the Reported Gap Discount Current Amount which is the gap discount amount reported on the most recent version of the disputed PDE and the Reported Gap Discount Previous Amount, the gap discount reported on the invoice when the PDE was originally disputed. The net payment reported in the Upheld Dispute Reimbursement Amount is calculated as the Reported Gap Discount Current Amount minus the Reported Gap Discount Previous Amount.

To view all Part D Sponsor BY Closeout Invoice Reports and File Layouts, access the Sponsor BY Closeout Invoice Report Layouts topic on the TPA website as shown in **Figure 8**.

4.1.3.3 Part D Sponsor Contract Reimbursement Detail Spreadsheet

This spreadsheet contains the same information as the Part D Sponsor Contract Reimbursement Detail Report but is in a readable format that can be viewed in Excel.

To view all Part D Sponsor BY Closeout Reports and File Layouts, access the Sponsor BY Closeout Invoice Report Layouts topic on the TPA website as shown in **Figure 8**.

5. Payments

5.1 Coverage Gap Discount Program (CGDP) Portal

Effective with the 2015 Q2 invoice, the CGDP Portal is available to Drug Manufacturers and Part D Sponsors participating in the CGDP and helps to streamline operations of all parties involved in the CGDP. The primary function of the CGDP Portal is to provide a central repository for CGDP invoices distributed by the TPA and paid by CGDP participants. All CGDP invoice payments must be initiated in the CGDP Portal.

5.2 Features of the CGDP Portal

The CGDP Portal provides Drug Manufacturers and Part D Sponsors the ability to perform the following functions:

- Invoice review
- Invoice selection for payment initiation
- Invoice payment deferment
- Batch Invoice payment selection
- Automatic payment verification
- Payment receipt review
- Invoice dispute filing (Drug Manufacturers only)
- Reports retrieval
- Review submitted dispute files (Drug Manufacturers only)
- Review resolved dispute files

The CGDP Portal allows both Drug Manufacturers and Part D Sponsors the ability to review and initiate payments for invoice line items, as well as review the payments due. It provides the ability to initiate bank-to-bank Automated Clearing House (ACH) transfers for invoice line item payments, similar to the way online banking customers pay monthly bills.

5.3 Drug Manufacturer Overview of the CGDP Portal

The CGDP Portal is designed to assist Drug Manufacturers with processing CGDP payments to Part D Sponsors as well as perform a variety of other tasks. The Drug Manufacturers Overview section of this guide provides a high level summary of the portal from a Drug Manufacturers perspective but is not intended to provide the details necessary to perform day to day operations.

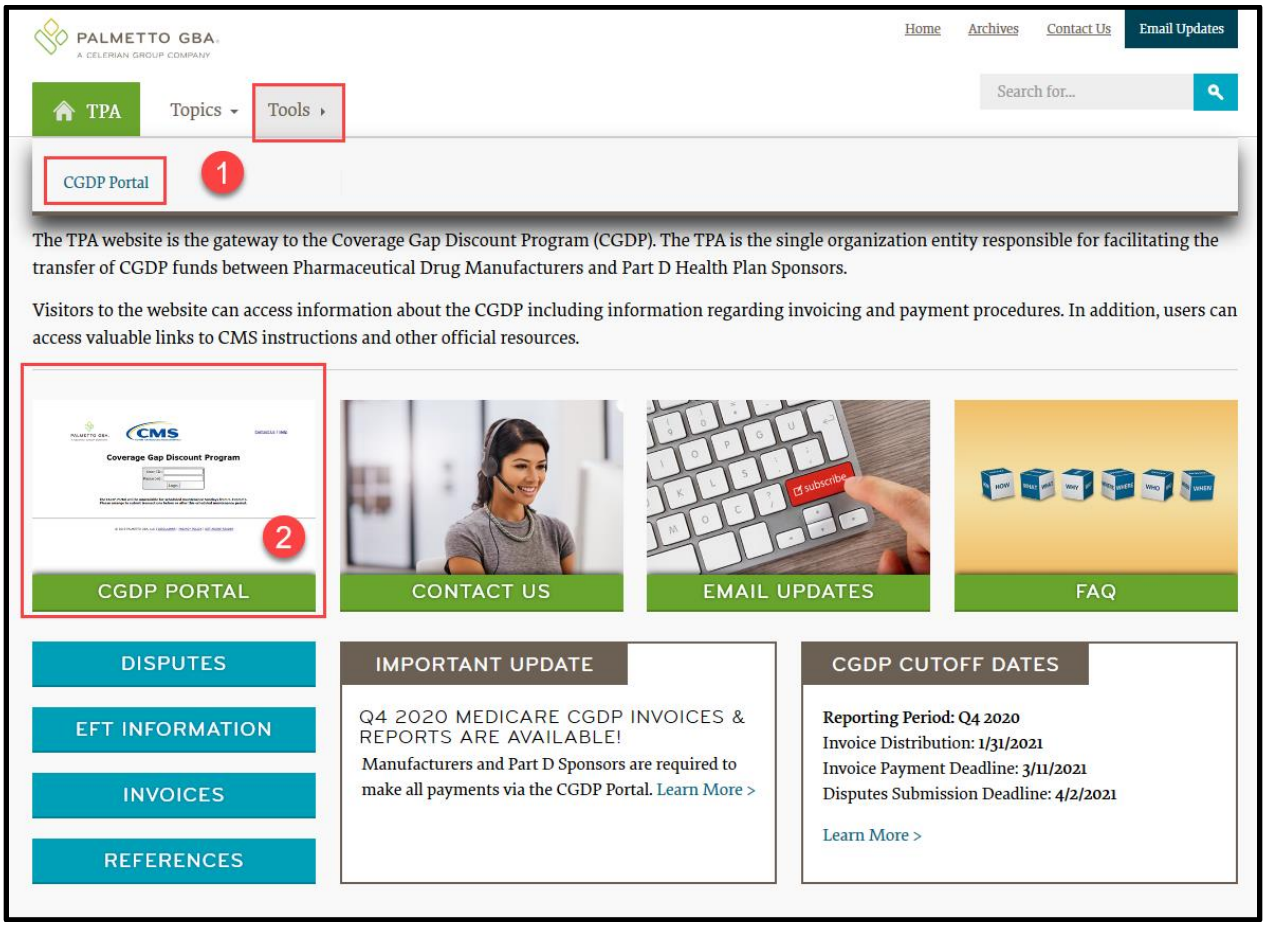
For information on how to access the TPA website and find detailed materials on how to use each tab within the CGDP Portal, refer to 5.5. Training, User Guides, Frequently Asked Questions (FAQ) and Webinar Information on the TPA website.

The CGDP Portal for Drug Manufacturers is comprised of tabs including the Home tab, Payments tab, Completed tab, Receipts tab, Reports tab, Disputes tab, Dispute Builder tab, and Dispute Submission tab.

Note: Refer to 6.1.2 Overview of the Manufacturers CGDP Portal Disputes Tab for detailed information on how to use the Disputes tabs.

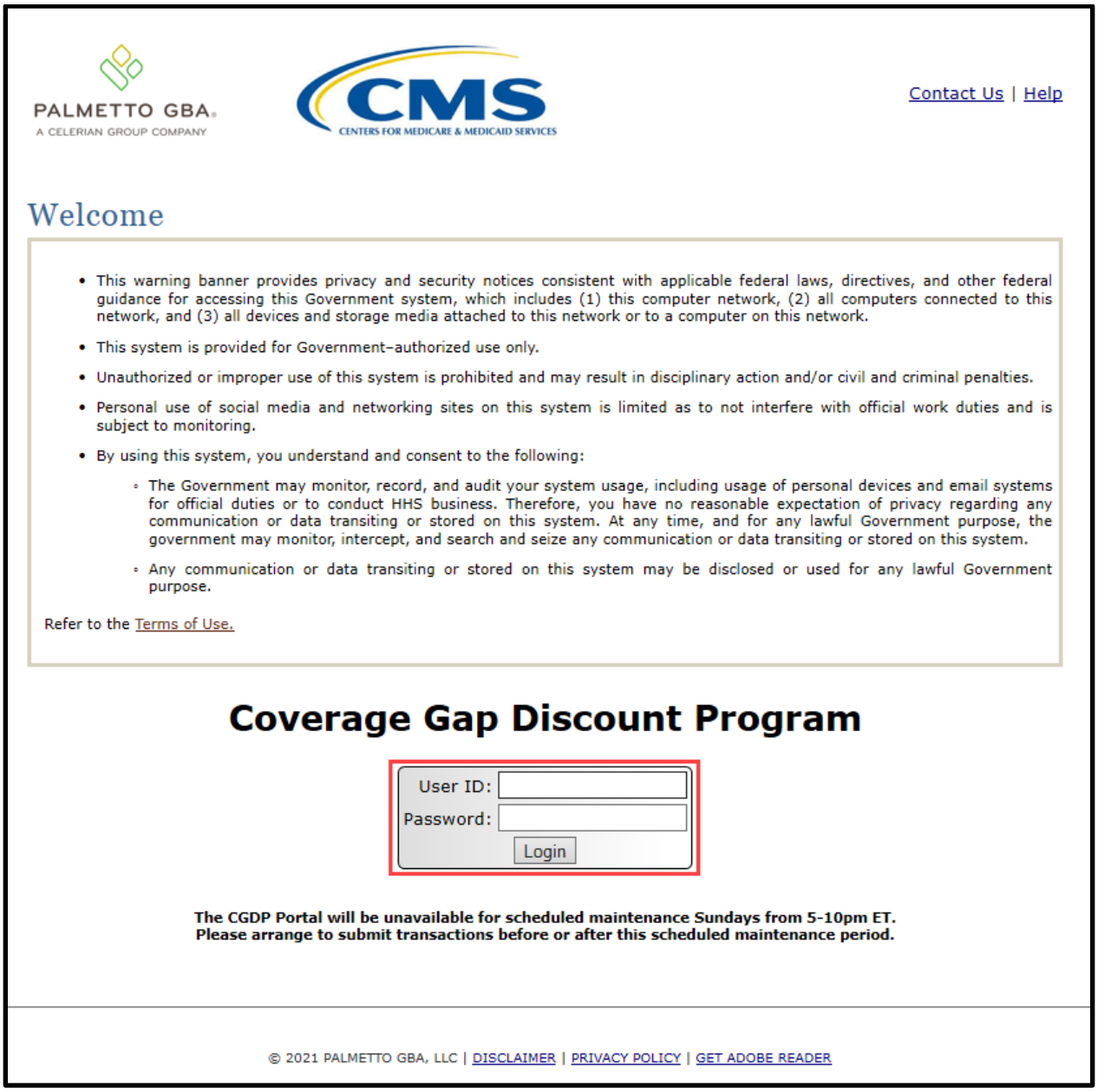
To log into the CGDP Portal, there are multiple ways to access the web-based application. From the TPA website, visitors can select the *Tools* drop down menu and click on the CGDP Portal link [Item 1] or select the *CGDP Portal graphic block* [Item 2] as shown in **Figure 9**.

Figure 9: CGDP Portal Access via the TPA website



The link to access the CGDP Portal without accessing the TPA website is (https://apps.tpadministrator.com/tpacgdp/LoginPage). The Login screen displays as shown in **Figure 10**.

Figure 10: CGDP Login Screen



Enter a valid User ID and Password then select Login.

You will then receive, via user-designated email, as shown in **Figure 11**, a multifactor authentication (MFA) validation token required to gain access to the Portal, which is entered in the User Validation screen as shown in **Figure 12**.

Figure 11: TPA CGDP Portal – Portal Authentication Email Example

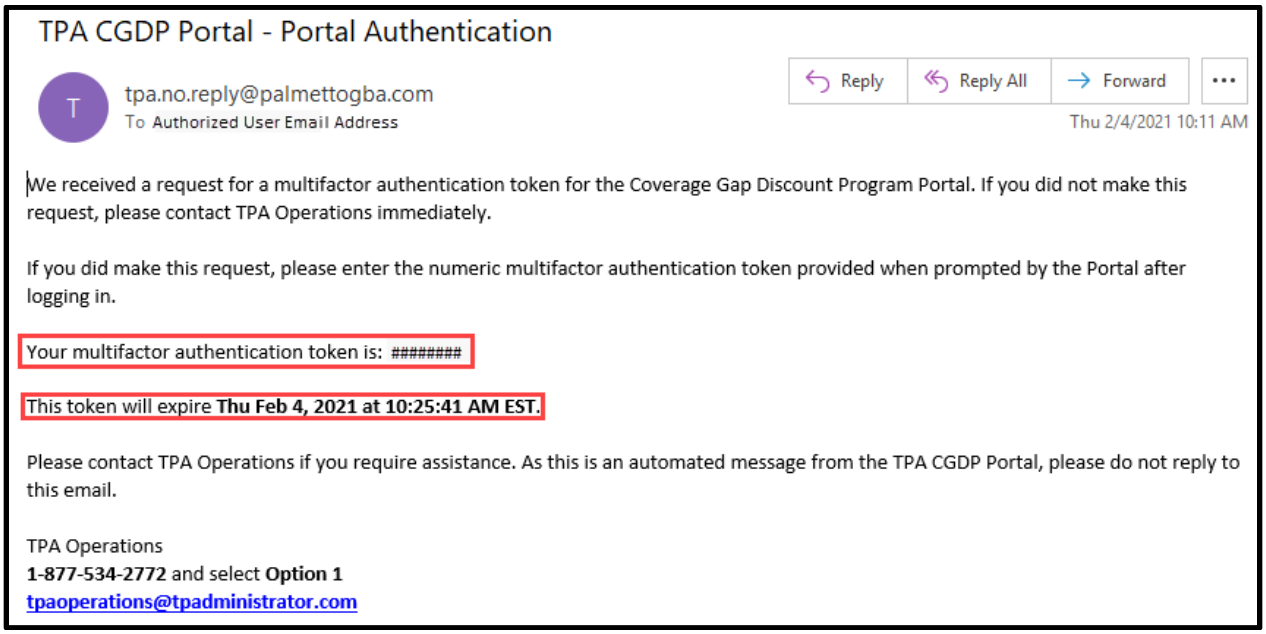
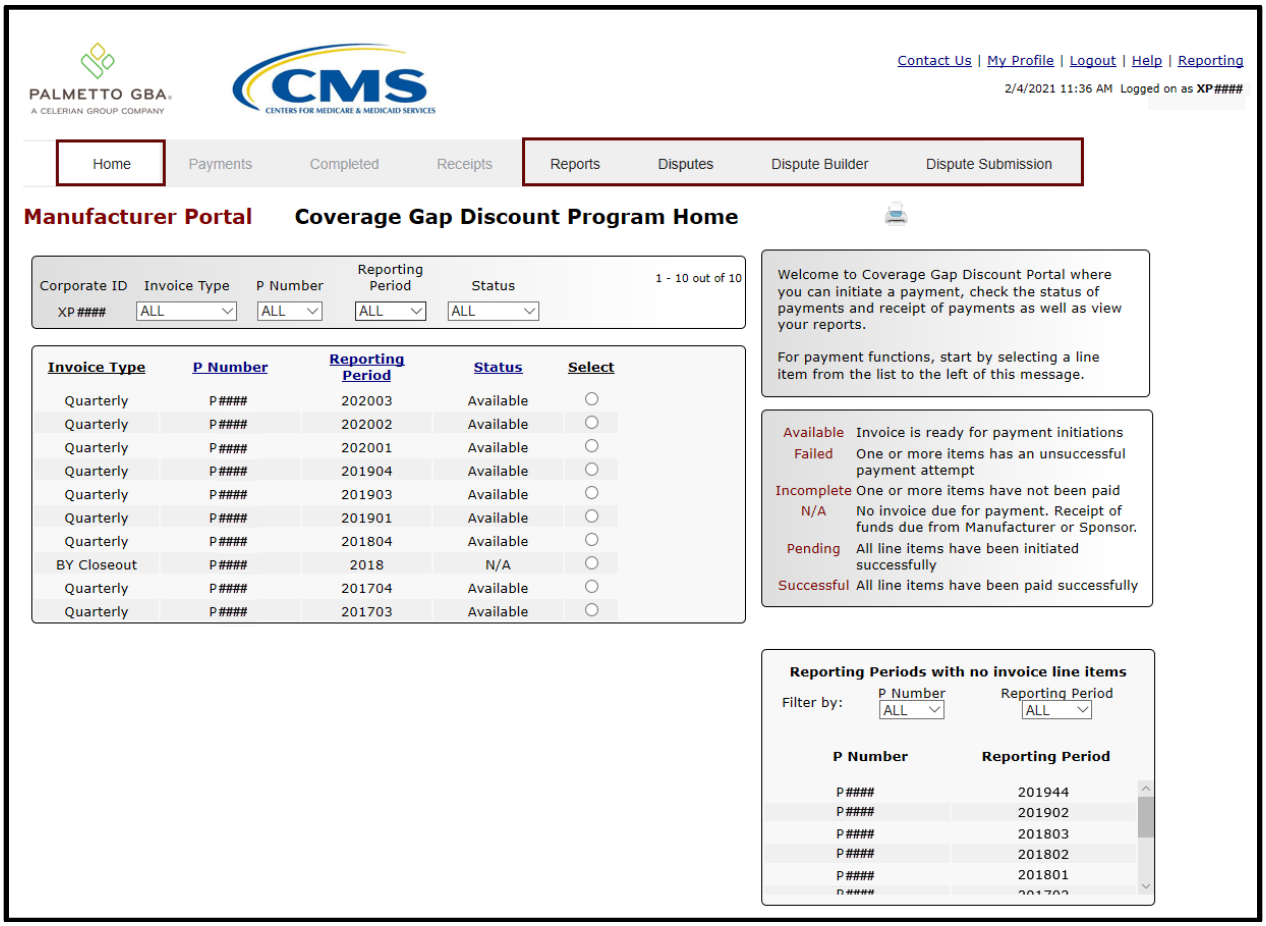


Figure 12: CGDP User Validation Screen

Once login access is verified and granted, the Home screen displays as shown in **Figure 13**.

Figure 13: CGDP Manufacturer Portal Home tab



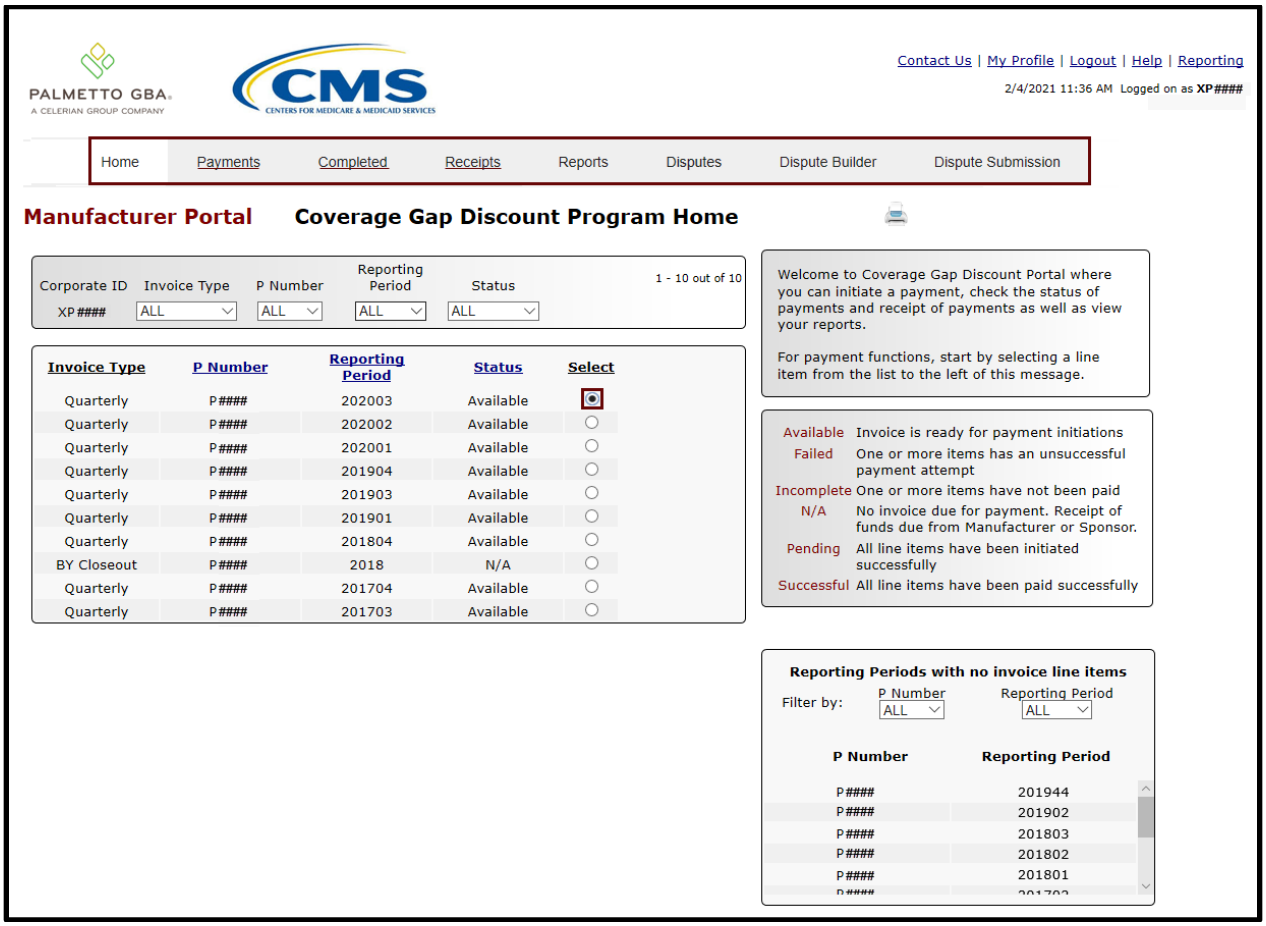
Upon entry, Drug Manufacturers have access to the Home tab, Reports tab, and Disputes tabs (Disputes, Dispute Builder and Dispute Submission).

From the Home tab, Drug Manufacturers can:

- Filter data by Invoice Type, P Number, or Reporting Period to display relevant report periods and P-Numbers available for selection;
- Quickly review distributed invoices payment status for each P-Number.

To access all available tabs or functions within the portal, a user must select a distributed invoice by activating a radio button in the Select column as shown in **Figure 14**. Once an invoice is selected, the Payments, Completed and Receipts tabs are available for use.

Figure 14: CGDP Manufactuter Portal Home tab with All Tabs Activated



From the Payments tab, Drug Manufacturers can review and process payment information for invoice line items by Part D Sponsor Contract Number.

Drug Manufacturers can also:

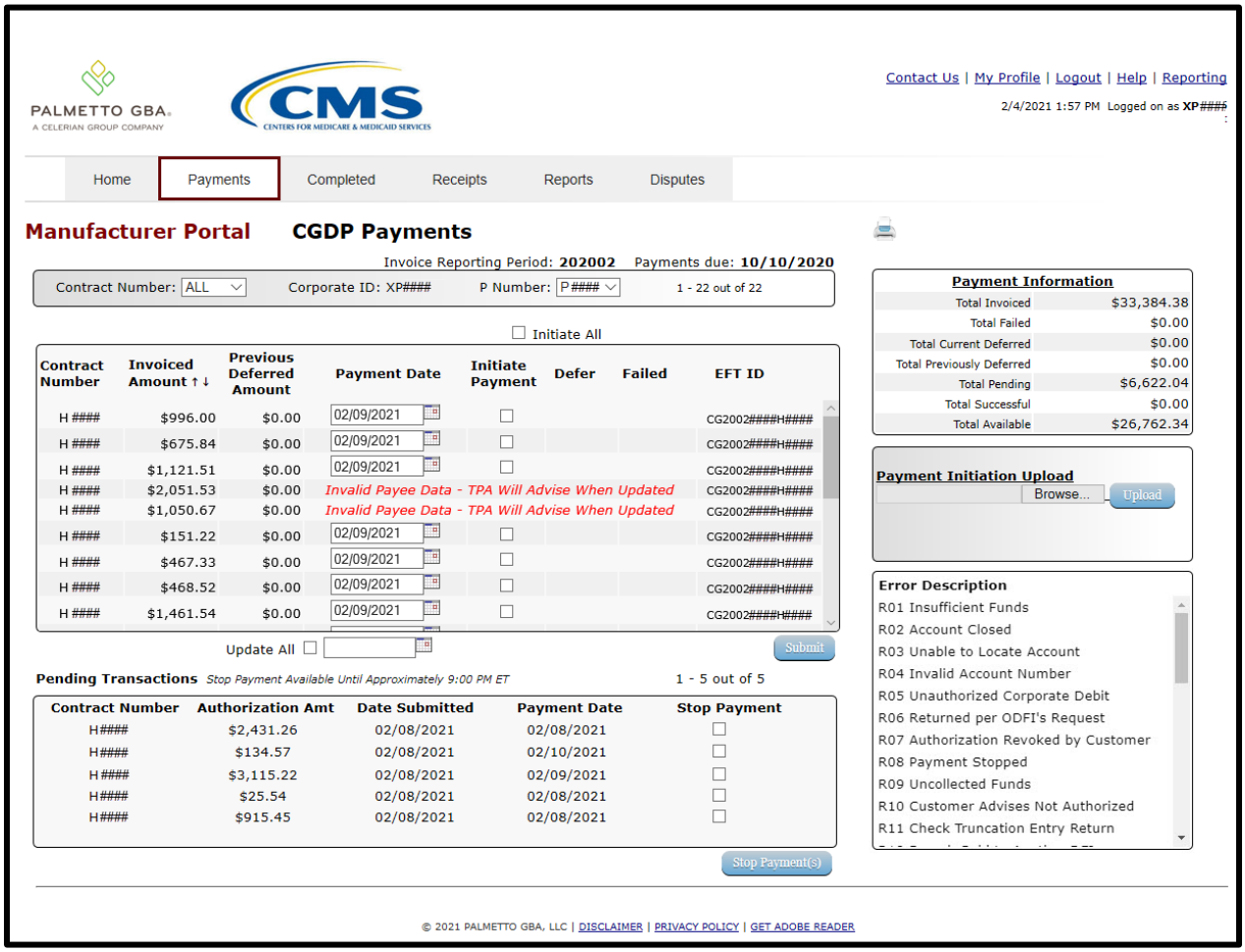
- Process invoice line item payment initiations;
- Defer invoice line item payments (when permitted – see **Note 1** below);
- Submit batch payment initiation text files created with a text editor and;
- Process stop payments.

Note 1: Selecting "Defer" is applicable only if the Drug Manufacturer's bank ACH process prevents payment of invoices that fall below the bank's minimum ACH processing amount. The Defer functionality becomes available in the CGDP Portal if the amount listed in the Total Available field on the Payments tab is less than the Portal's system-default allowable amount, currently designated as $20.00 United States Dollar (USD).

Detailed information and instructions on the defer payment process is available in the CGDP Manufacturer Portal Payments Users Guide.

An example of the Payments tab is shown in **Figure 15**.

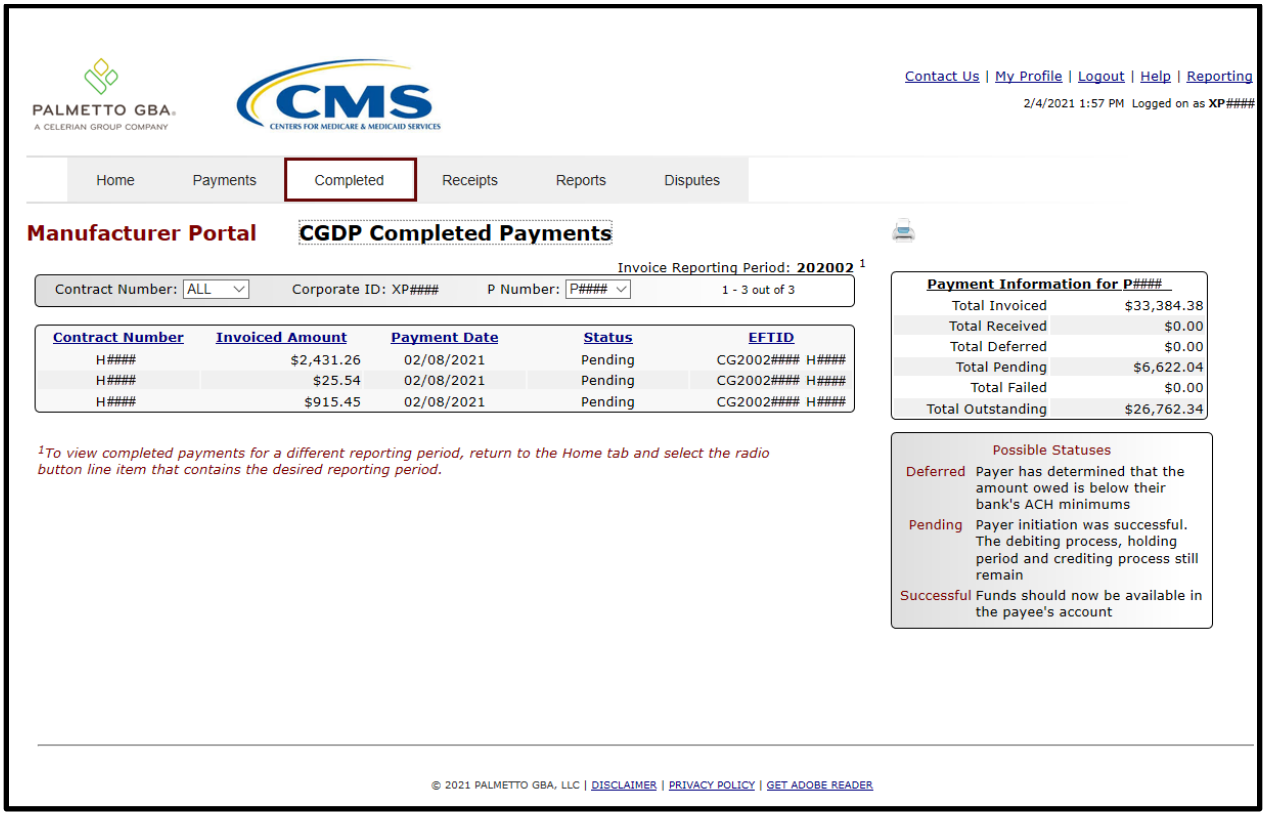
Figure 15: CGDP Manufacturer Portal Payments tab



From the Completed tab, Drug Manufacturers can review completed payment information for invoice line items by Part D Sponsor Contract Number. They can also review the status of completed payment processing for initiated or deferred payments.

An example of the Completed tab is shown in **Figure 16**.

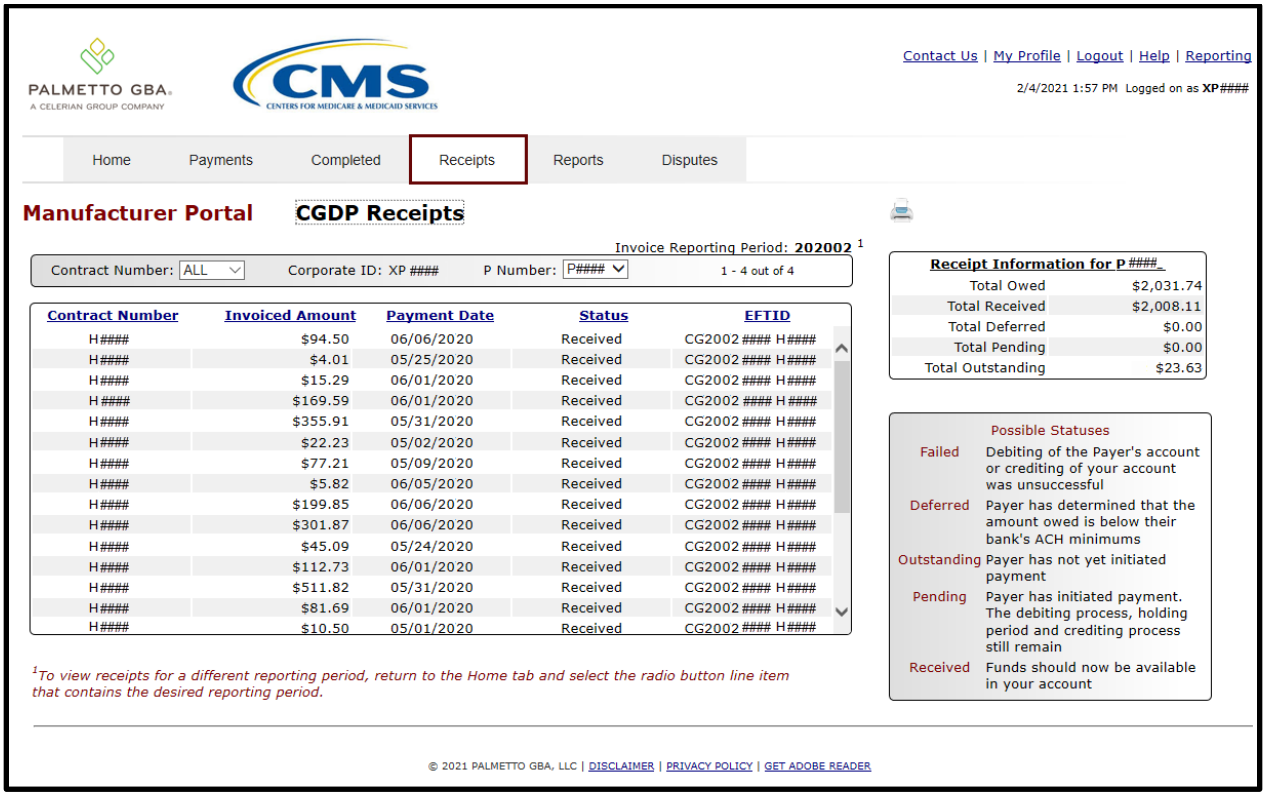
Figure 16: CGDP Manufacturer Portal Completed tab



From the Receipts tab, Drug Manufacturers can review negative invoice line item information for updated invoiced line items by Part D Sponsor Contract Number. They can also review the status of payments due from Part D Sponsors.

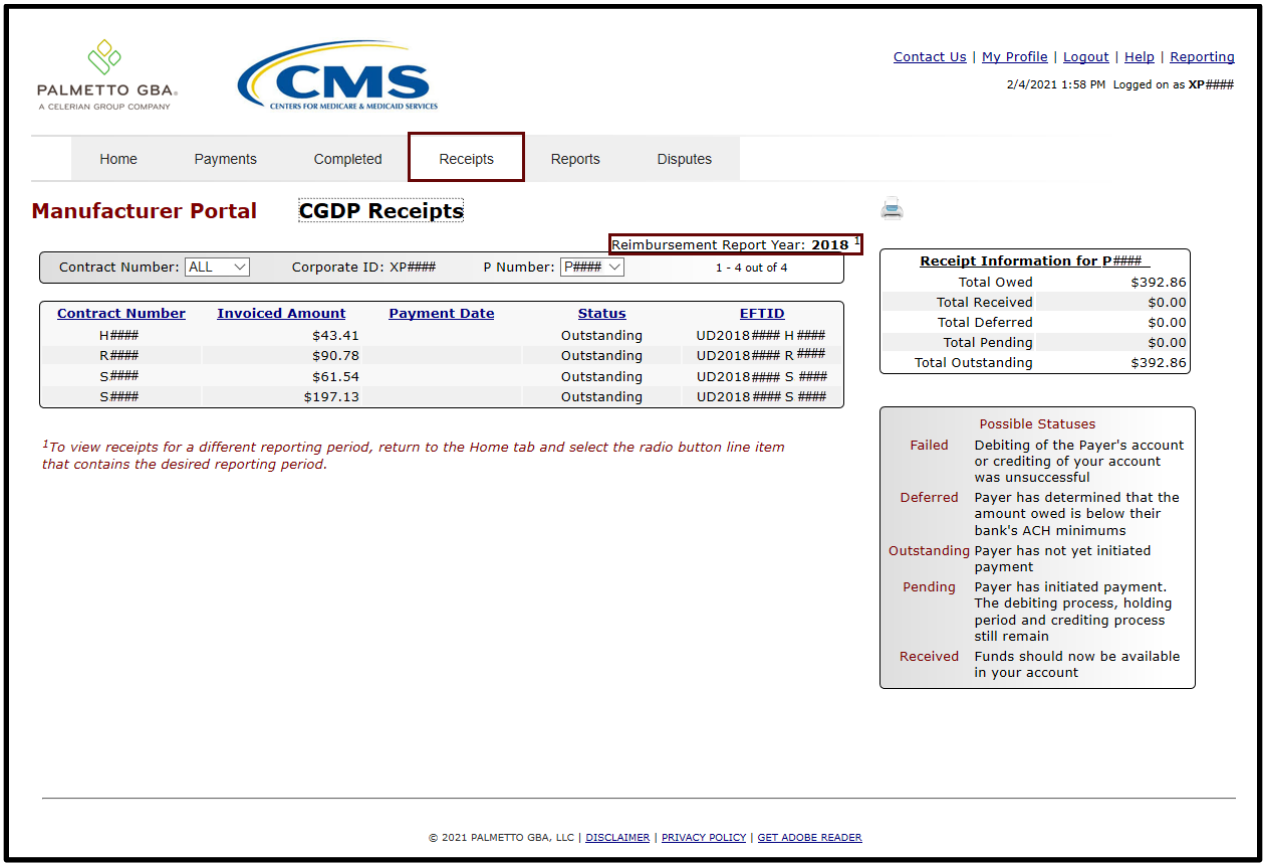
An example of the Receipts tab for quarterly invoices is shown in **Figure 17**.

Figure 17: CGDP Manufacturer Portal Receipts tab – Quarterly Reporting Period



An example of the Receipts tab for BY Closeout invoice is shown in **Figure 18**.

Figure 18: CGDP Manufacturer Portal Receipts tab – BY Closeout Reporting Period



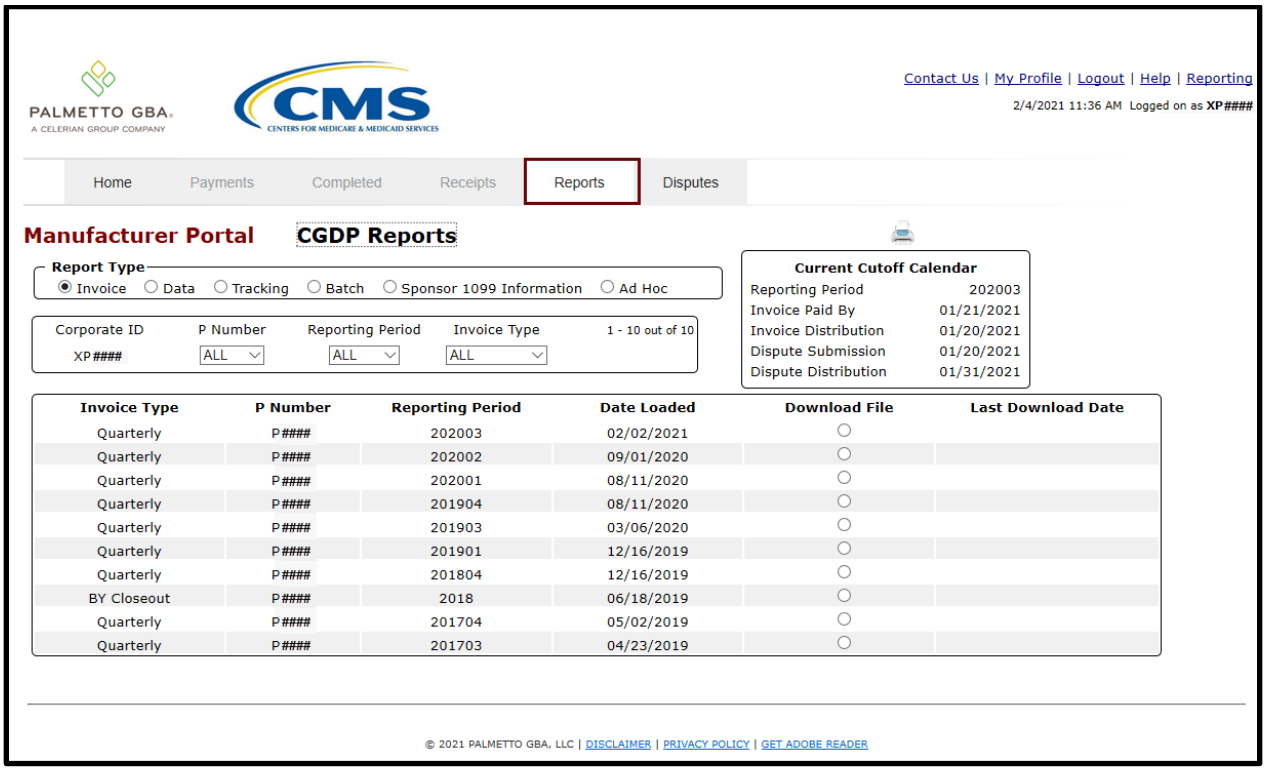
From the Reports tab, Drug Manufacturers can access six types of reports for distributed invoices. The six report views available include: Invoice, Data, Tracking, Batch, Sponsor 1099 Information, and Ad Hoc.

Selecting one of these views allows a user to:

- Review or download summary Invoice reports;
- Review or download invoice detail information of PDE Data combined to create total invoice line item amounts;
- Review or download BY Closeout tracking information regarding the status of all upheld dispute for closed benefit years;
- Review successful, partial or failed Batch upload files and errors associated with failed records and;
- Review or download, by text or spreadsheet, Sponsor 1099 Information as the TPA will no longer distribute EFT files;
- Review requested Invoice or Data reports, via the Ad Hoc functionality, that has been archived off the CGDP Portal.

An example of the Reports tab is shown in **Figure 19**.

Figure 19: CGDP Manufacturer Portal Reports tab



5.4 Part D Sponsor Overview of the CGDP Portal

The CGDP Portal is designed to assist Part D Sponsors with processing CGDP payments to Drug Manufacturers as well as perform a variety of other tasks. The Part D Sponsor Overview section in this guide provides a high level summary of the portal from a Sponsor's perspective but is not intended to provide the detail necessary to perform day to day operations.

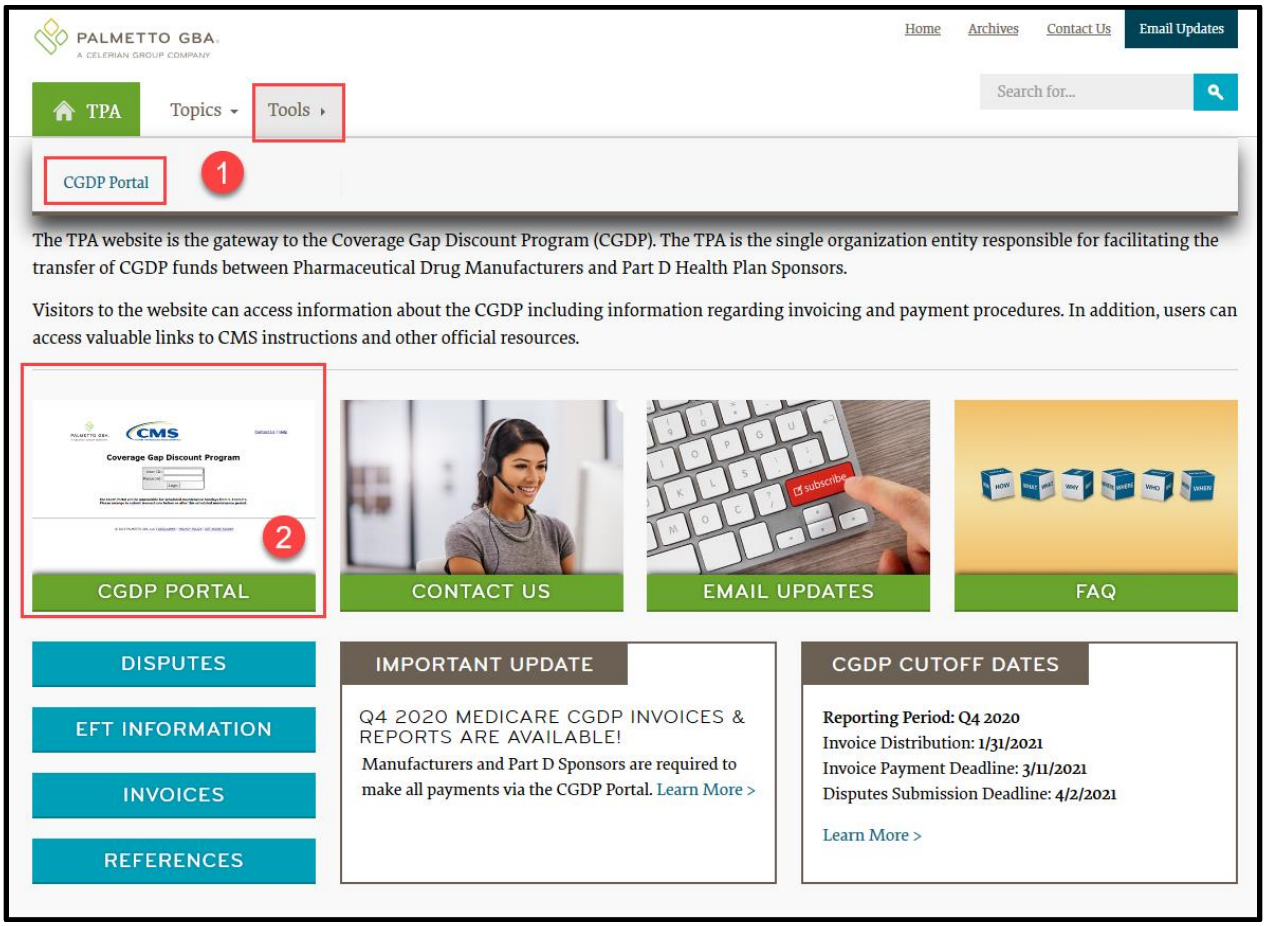
While it is most typical for Manufacturers to remit invoice amounts to Part D Sponsors, there are situations that require Part D Sponsors to refund previously paid invoiced amounts back to Manufacturers. This can occur when a PDE with an invoiced Coverage Gap Discount Amount from a prior quarter is adjusted or deleted in a future quarterly invoice period.

For information on how to access the TPA website to find detailed materials on how to use each tab within the CGDP Portal, access 5.5. Training, User Guides, Frequently Asked Questions (FAQ) and Webinar Information on the TPA website.

The CGDP Portal for Part D Sponsors is comprised of Tabs including the Home tab, Payments tab, Completed tab, Receipts tab, Reports tab and Disputes tab.

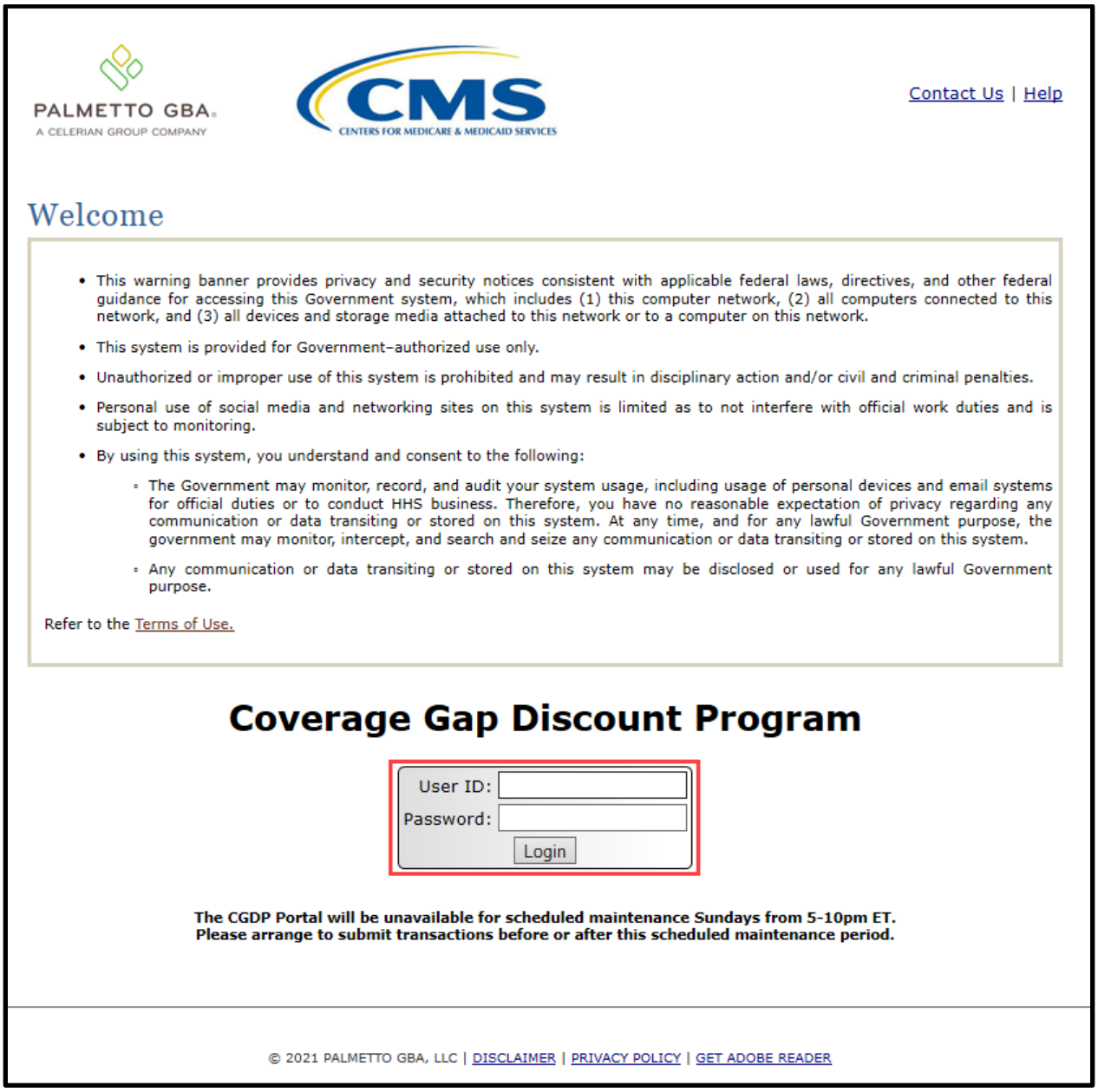
To log into the CGDP Portal, there are multiple ways to access the web-based application. From the TPA website, visitors can select the *Tools* drop down menu and click on the CGDP Portal link [Item 1] or select the *CGDP Portal graphic block* [Item 2] as shown in **Figure 20**.

Figure 20: CGDP Portal Access via the TPA website



The link to access the CGDP Portal without accessing the TPA website is (https://apps.tpadministrator.com/tpacgdp/LoginPage). The Login screen displays as shown in **Figure 21**.

Figure 21: CGDP Portal Login screen



Enter a valid User ID and Password then select Login.

You will then receive, via user-designated email, as shown in **Figure 22**, a MFA validation token required to gain access to the Portal, which is entered in the User Validation screen as shown in **Figure 23**.

Figure 22: TPA CGDP Portal – Portal Authentication Email Example

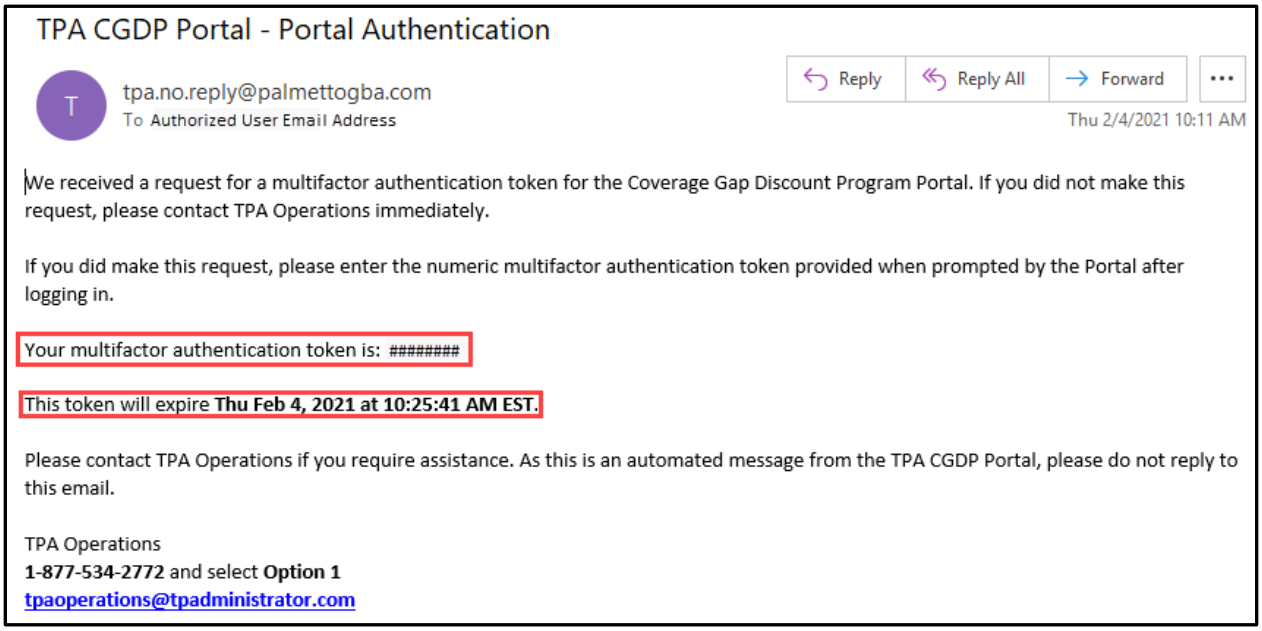
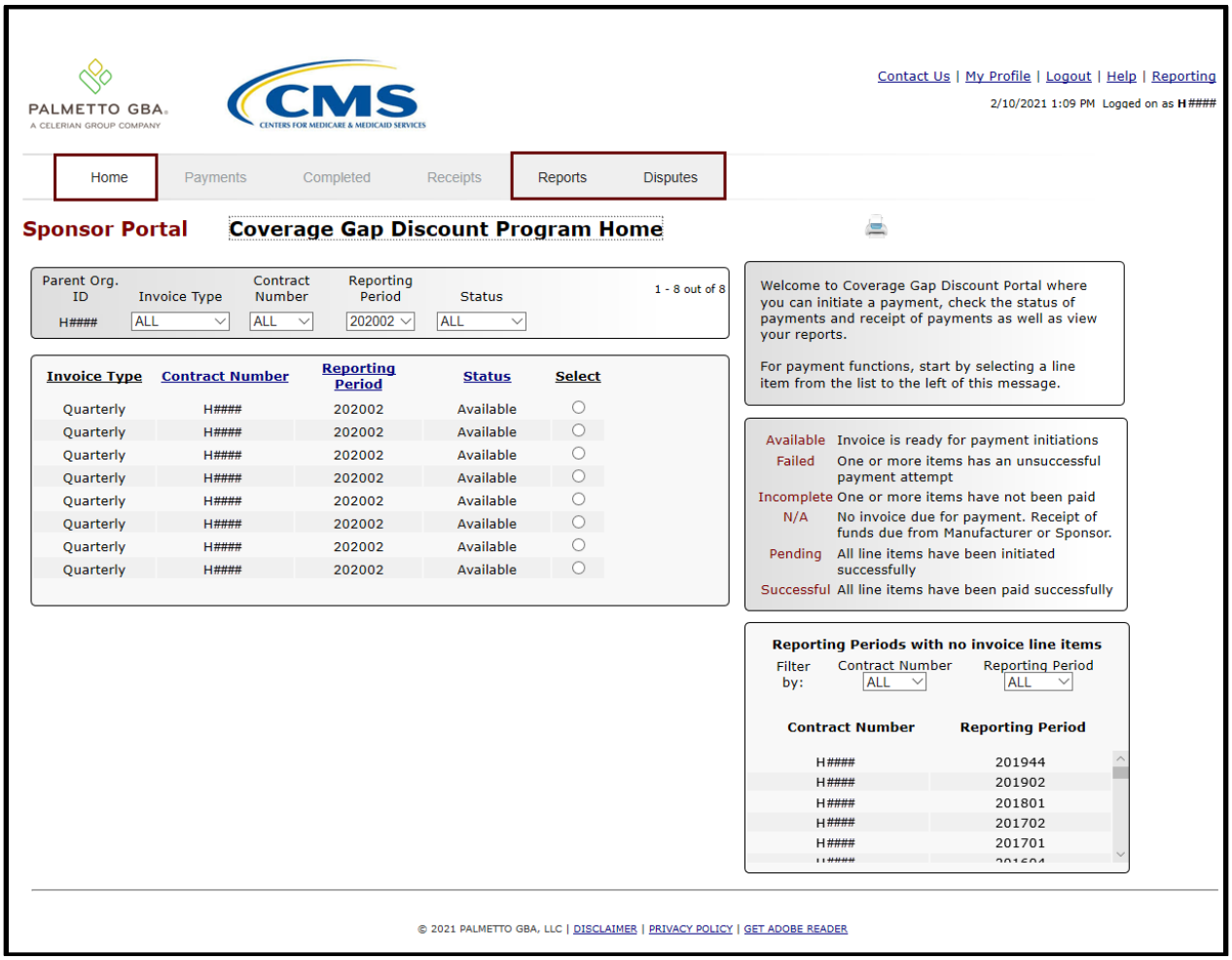


Figure 23: CGDP User Validation screen

Once login access is verified and granted, the Home screen displays as shown in **Figure 24**.

Figure 24: CGDP Sponsor Portal Home tab

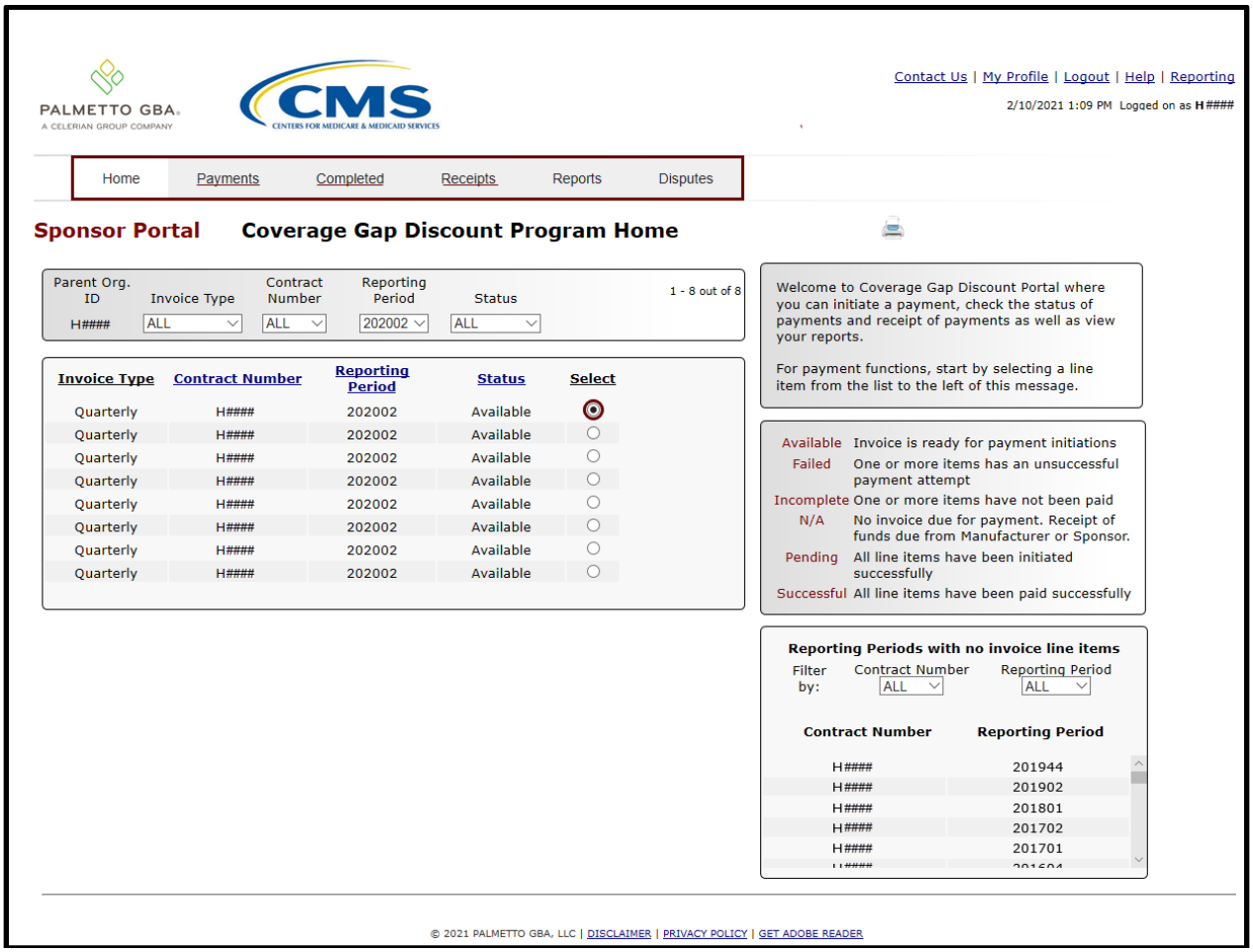


Upon entry, Part D Sponsors have access to the Home tab, Reports tab, and Disputes Tab. From the Home tab, Sponsors can:

- Filter data by Invoice Type, P Number, or Reporting Period to display relevant BY Closeout or quarterly report periods and Contract Numbers available for selection;
- Quickly review distributed invoice payment status for each Contract Number.

To access all available tabs or functions within the portal, a user must select a distributed invoice by activating the radio button in the Select column as shown in **Figure 25**. Once an invoice is selected, the Payments, Completed and Receipts tabs are available for viewing.

Figure 25: CGDP Sponsor Portal Home tab – All Tabs Activated



From the Payments tab, Part D Sponsors can review and process payment information for invoice line items by Manufacturer P-Number.

Part D Sponsors can also:

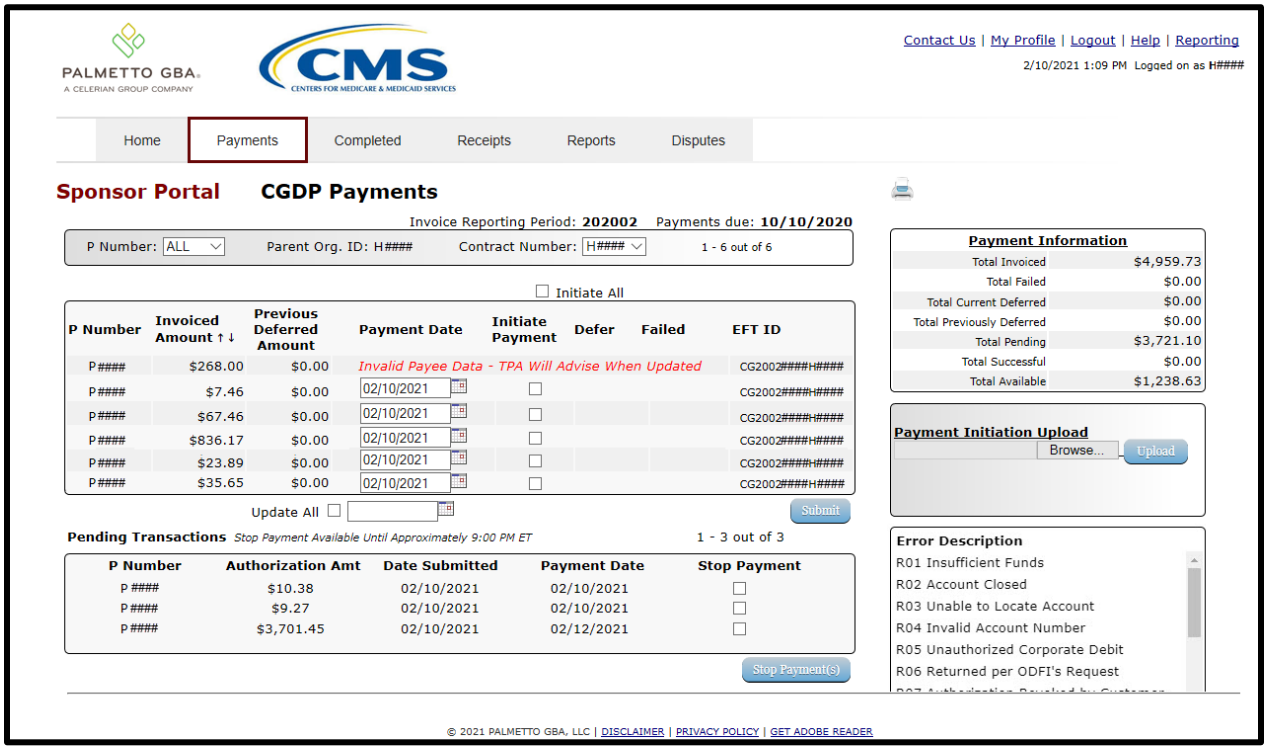
- Process invoice line item payment initiations;
- Defer invoice line item payments (when permitted – see **Note 1** below);
- Submit batch payment initiation text files created with a text editor and;
- Process stop payments.

Note 1: Selecting "Defer" is applicable only if the Part D Sponsor's bank ACH process prevents payment of invoices that fall below the bank's minimum ACH processing amount. The Defer functionality becomes available in the CGDP Portal if the amount listed in the Total Available field on the Payments tab is less than the Portal's system-default allowable amount, currently designated as $20.00 USD.

Detailed information and instructions on the defer payment process is available in the CGDP Sponsor Portal Payments Users Guide.

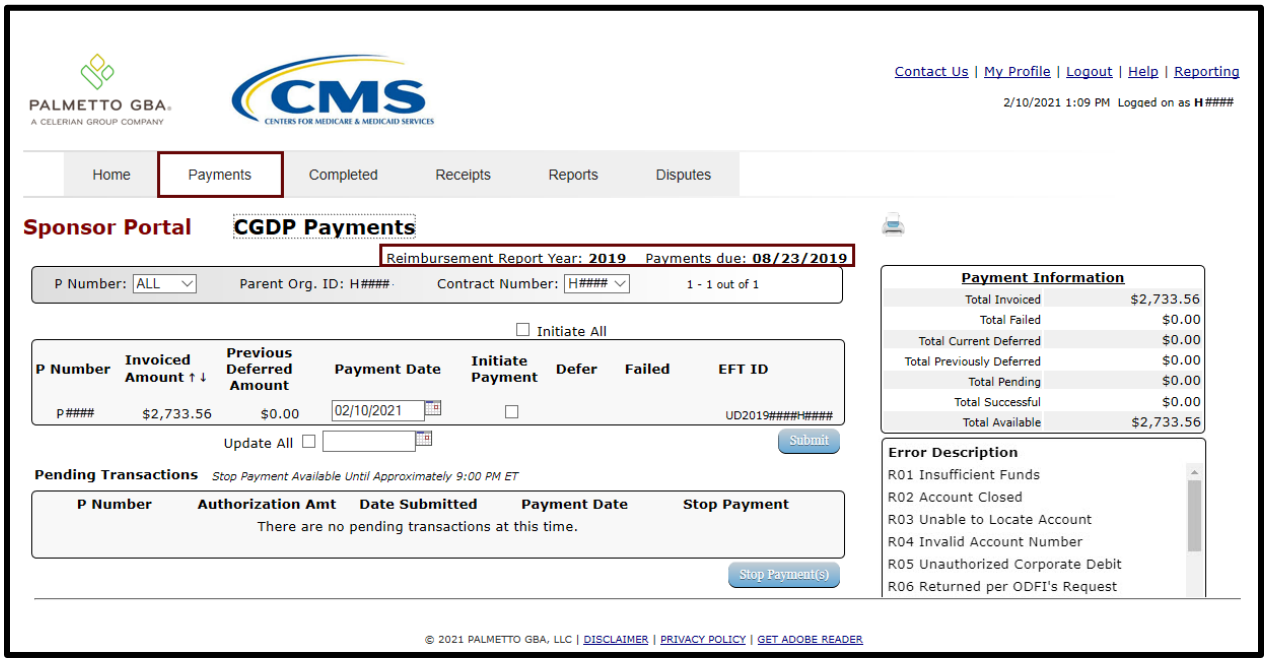
An example of the Payments tab is shown in **Figure 26**.

Figure 26: CGDP Sponsor Portal Payments tab – Quarterly Reporting Period



An example of the Payments tab for the BY Closeout reporting period is shown in **Figure 27**.

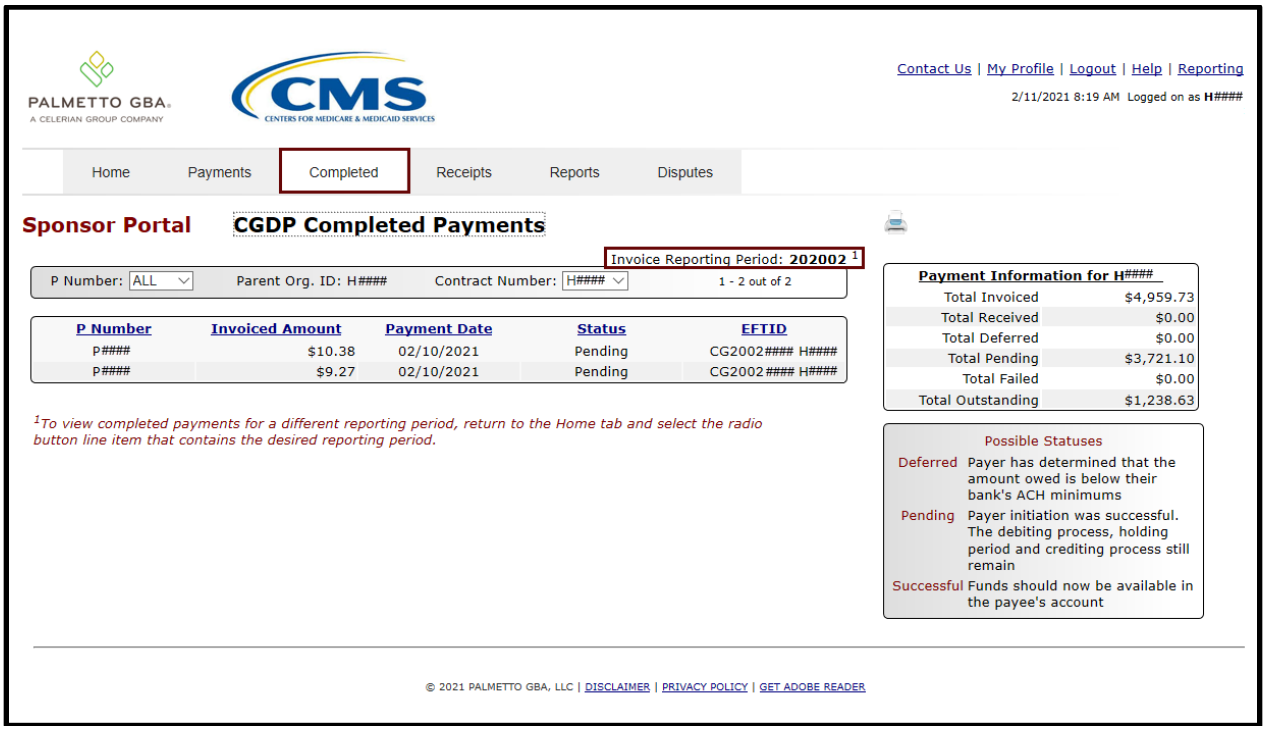
Figure 27: CGDP Sponsor Portal Payment tab – BY Closeout Reporting Period



From the Completed tab, Part D Sponsors can review completed payment information for invoice line items by Manufacturer P-Number. They can also review the status of completed payment processing for initiated or deferred payments.

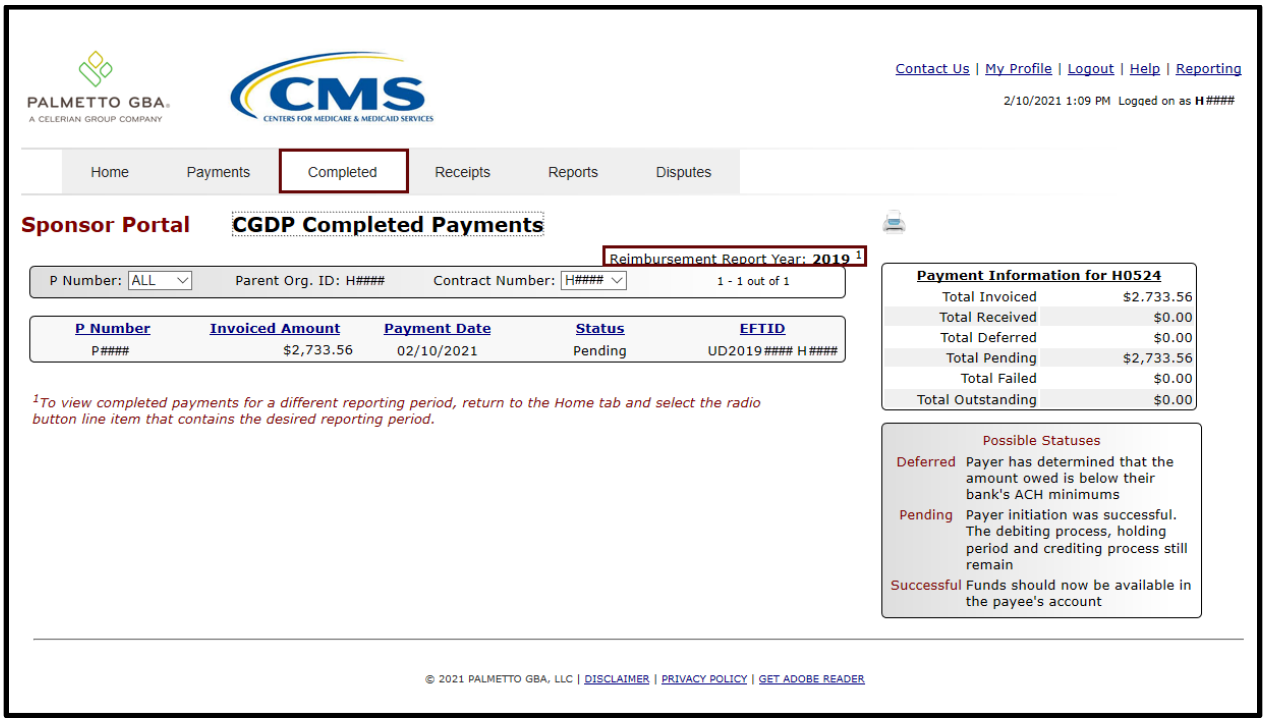
An example of the Completed tab for quarterly invoices is shown in **Figure 28**.

Figure 28: CGDP Sponsor Portal Completed tab – Quarterly Reporting Period



An example of the Completed tab for BY Closeout invoices is shown in **Figure 29**.

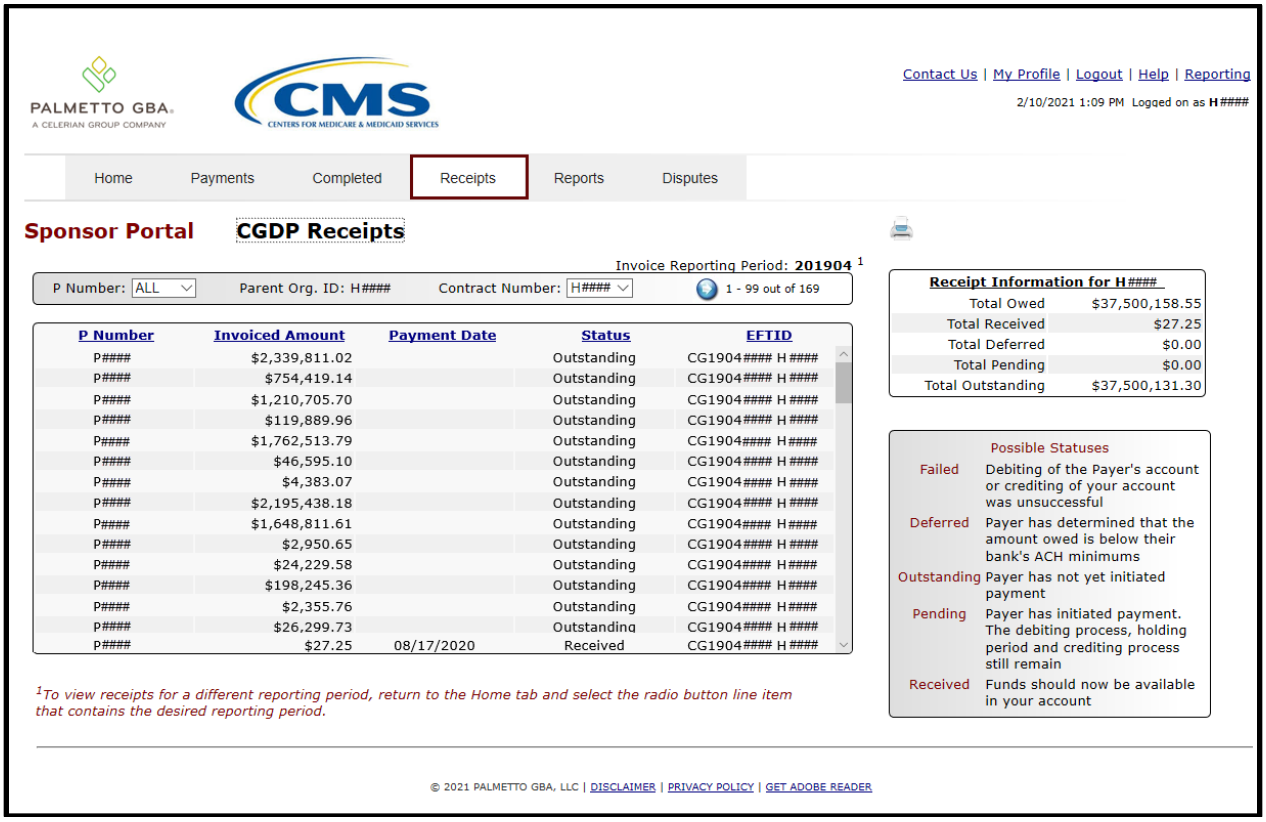
Figure 29: CGDP Sponsor Portal Completed tab – BY Closeout Reporting Period



From the Receipts tab, Part D Sponsors have the ability to view the status of invoice line item information for updated invoiced line items by Manufacturer P-Number. They can also review the status of payments due from Drug Manufacturers.

An example of the Receipts tab is shown in **Figure 30**.

Figure 30: CGDP Sponsor Portal Receipts tab



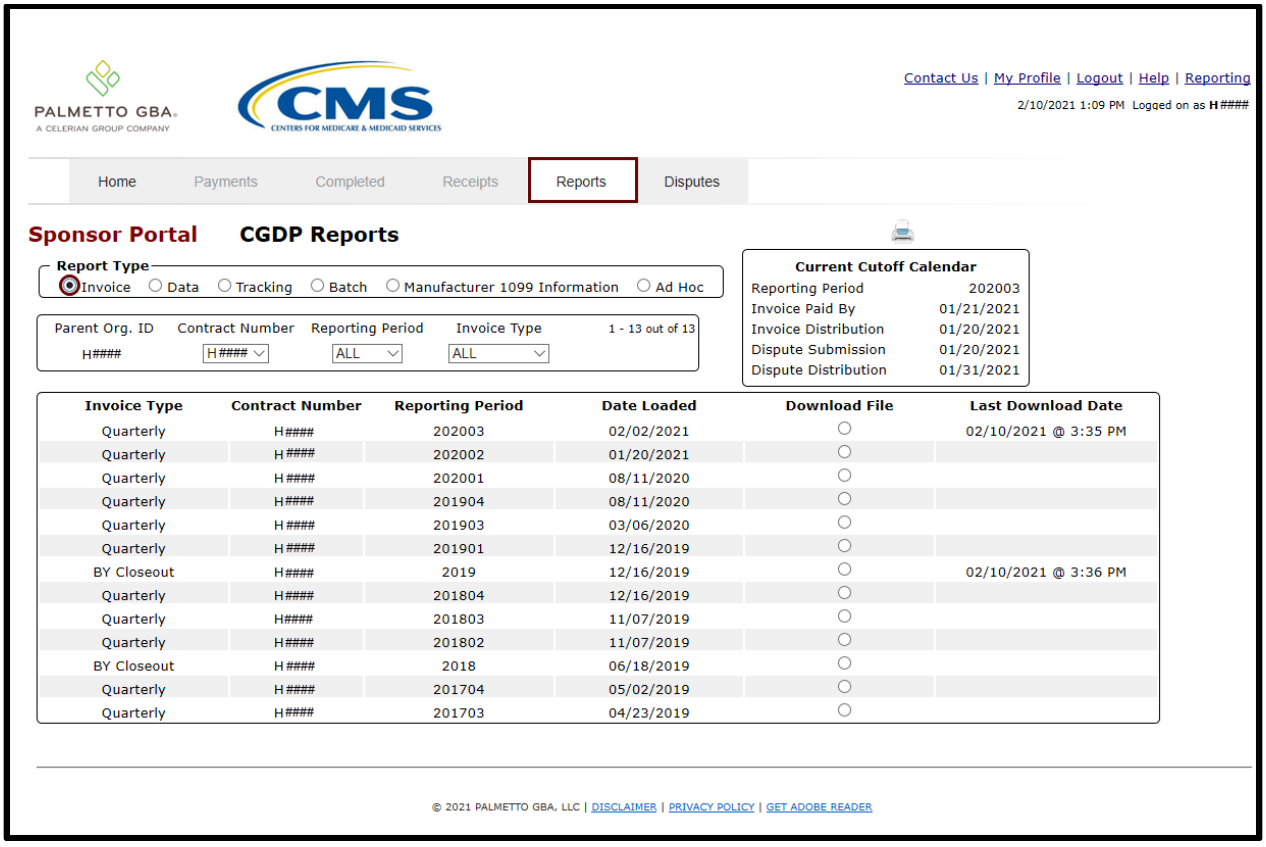
Finally, from the Reports tab, Part D Sponsors can access six types of reports. The six report views available for display or download include: Invoice, Data, Tracking, Batch, Manufacturer 1099 Information, and Ad Hoc.

Selecting one of these views allows a user to:

- Review or download summary Invoice reports;
- Review or download invoice detail Data reports of PDE Data combined to create total invoice line item amounts
- Review historical benefit year Tracking detail reports by contract;
- Review successful, partial or failed Batch file uploads and errors associated with failed records and;
- Review, by text or spreadsheet, Manufacturer 1099 Information;
- Review requested Invoice, Data, or Tracking reports, via the Ad Hoc functionality, that has been archived off the CGDP Portal.

An example of the Reports tab is shown in **Figure 31**.

Figure 31: CGDP Sponsor Portal Reports tab



5.5 Training, User Guides, Frequently Asked Questions (FAQ) and Webinar Information on the TPA website

User guides for both the Drug Manufacturers and Part D Sponsors CGDP Portal are available on the TPA website under the References topic as shown in **Figure 32** and **Figure 33**.

These user guides provide information on the functions available in the CGDP Portal as well as task based instructions for performing payment and receipt processing and report retrieval.

Figure 32: TPA website – CGDP Manufacturer Portal Users Guides

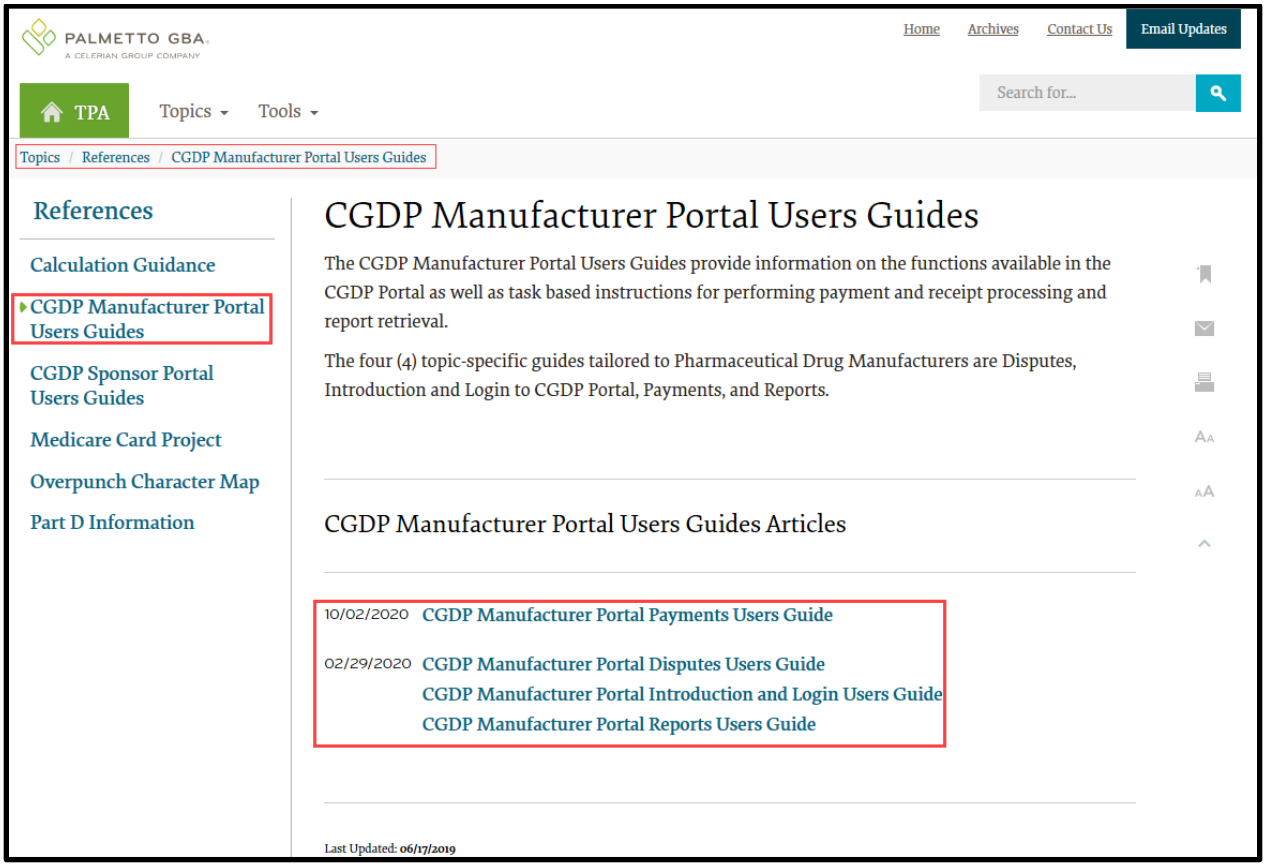
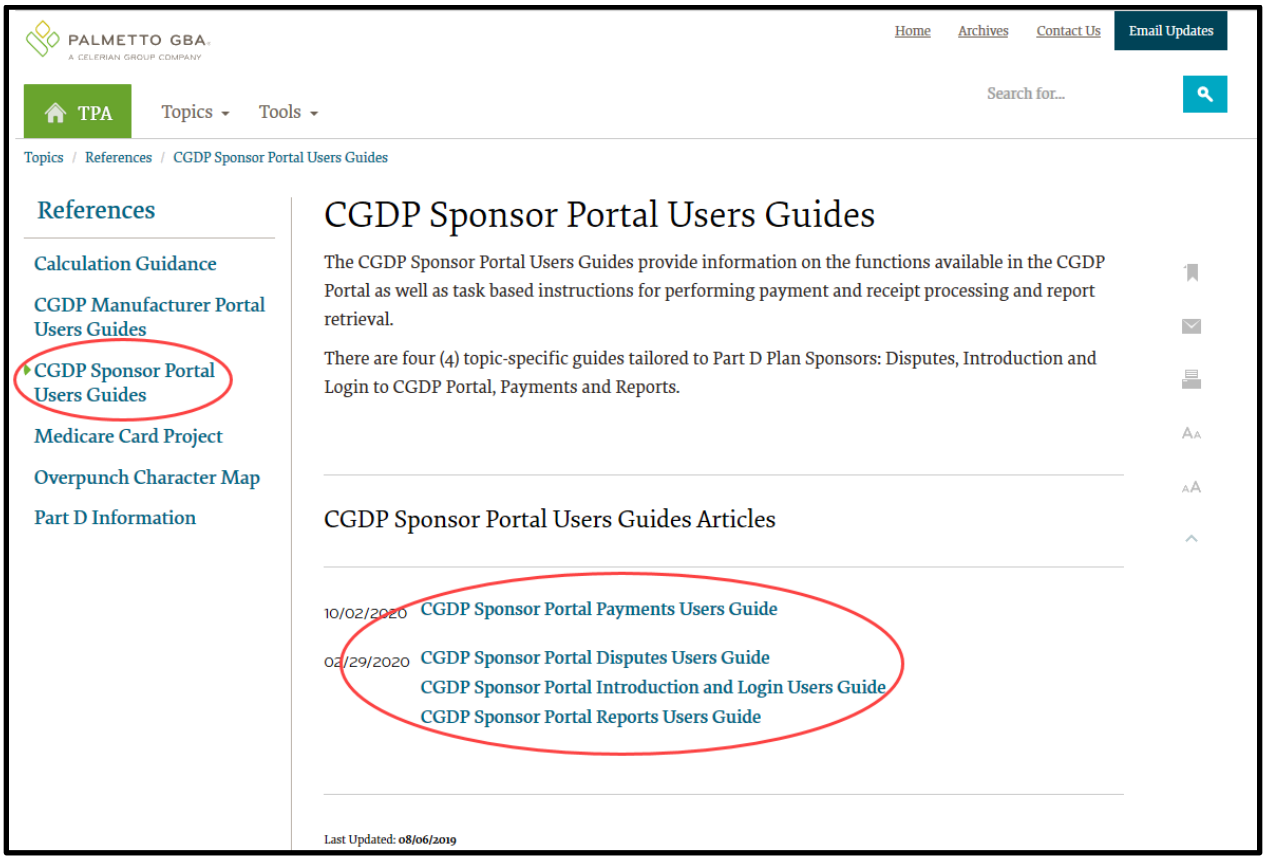


Figure 33: TPA website – CGDP Sponsor Portal Users Guides



CMS encourages CGDP participants to review the Frequently Asked Questions (FAQ) Error! Reference source not found.located on the TPA website as shown in **Figure 35**. **Figure 34** shows the two links available to access the Frequently Asked Questions (FAQ); the FAQ graphic block (Item 1) and the Frequently Asked Questions (FAQ) topic (Item 2)**.**

Figure 34: TPA website – Frequently Asked Questions (FAQ) links

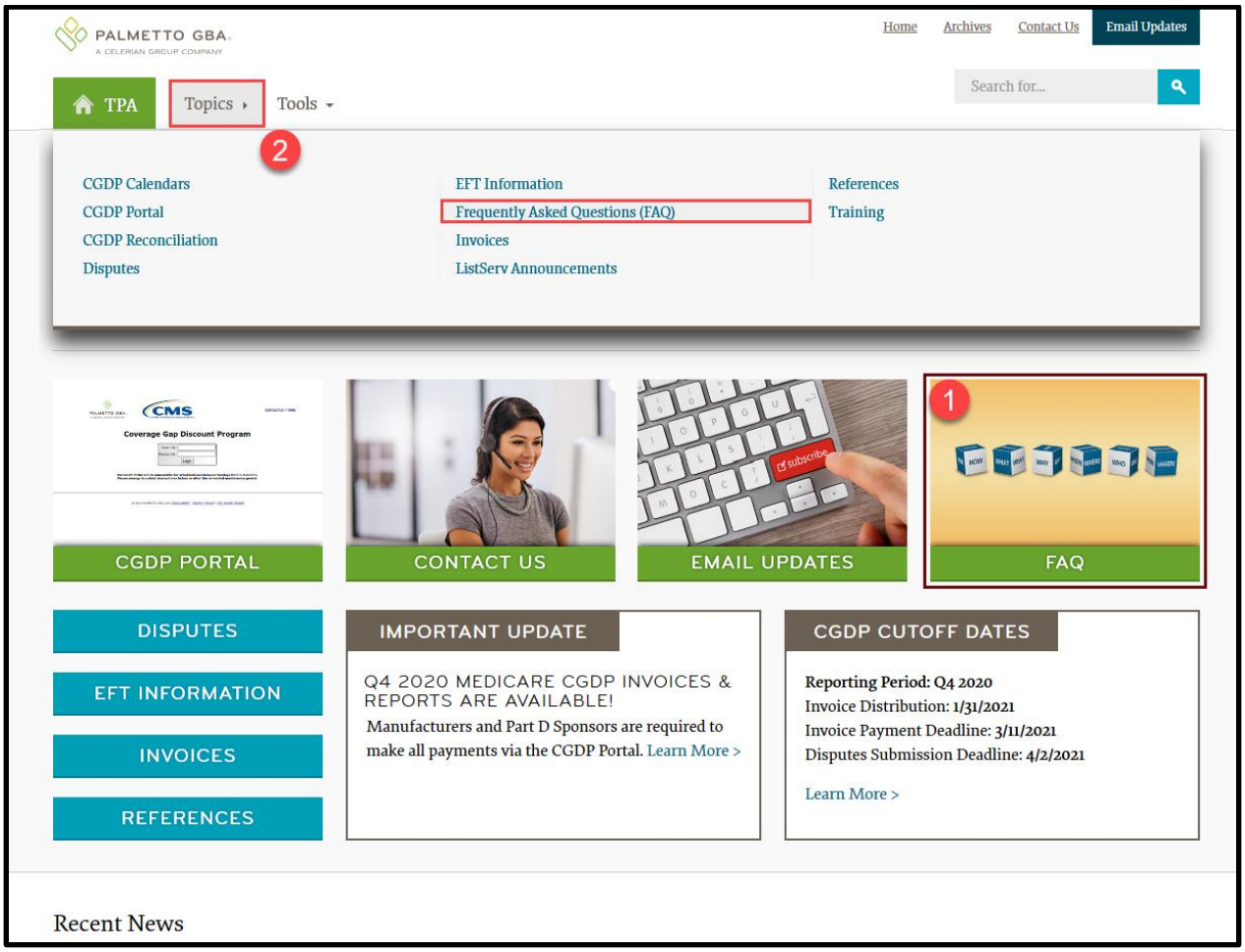
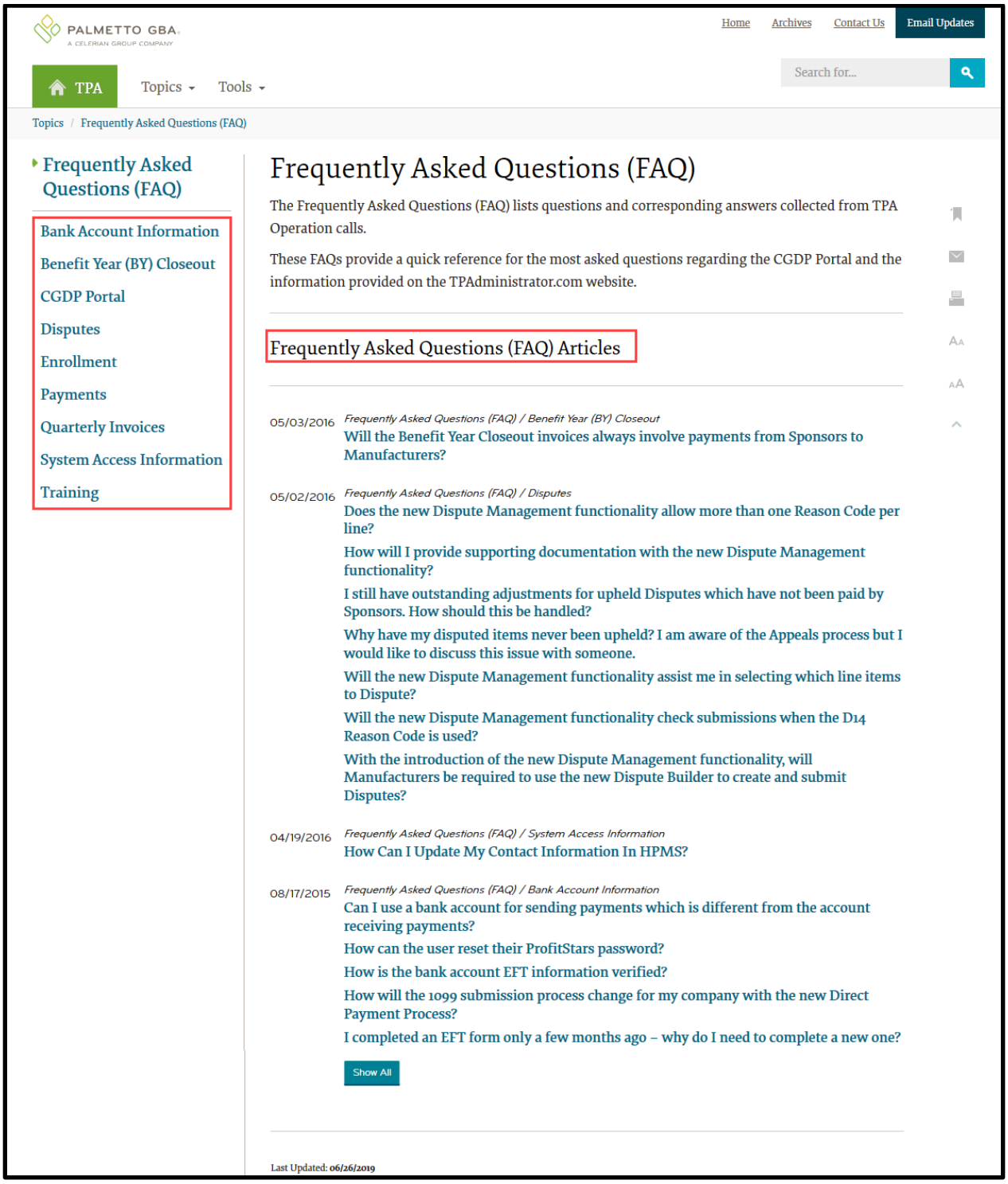


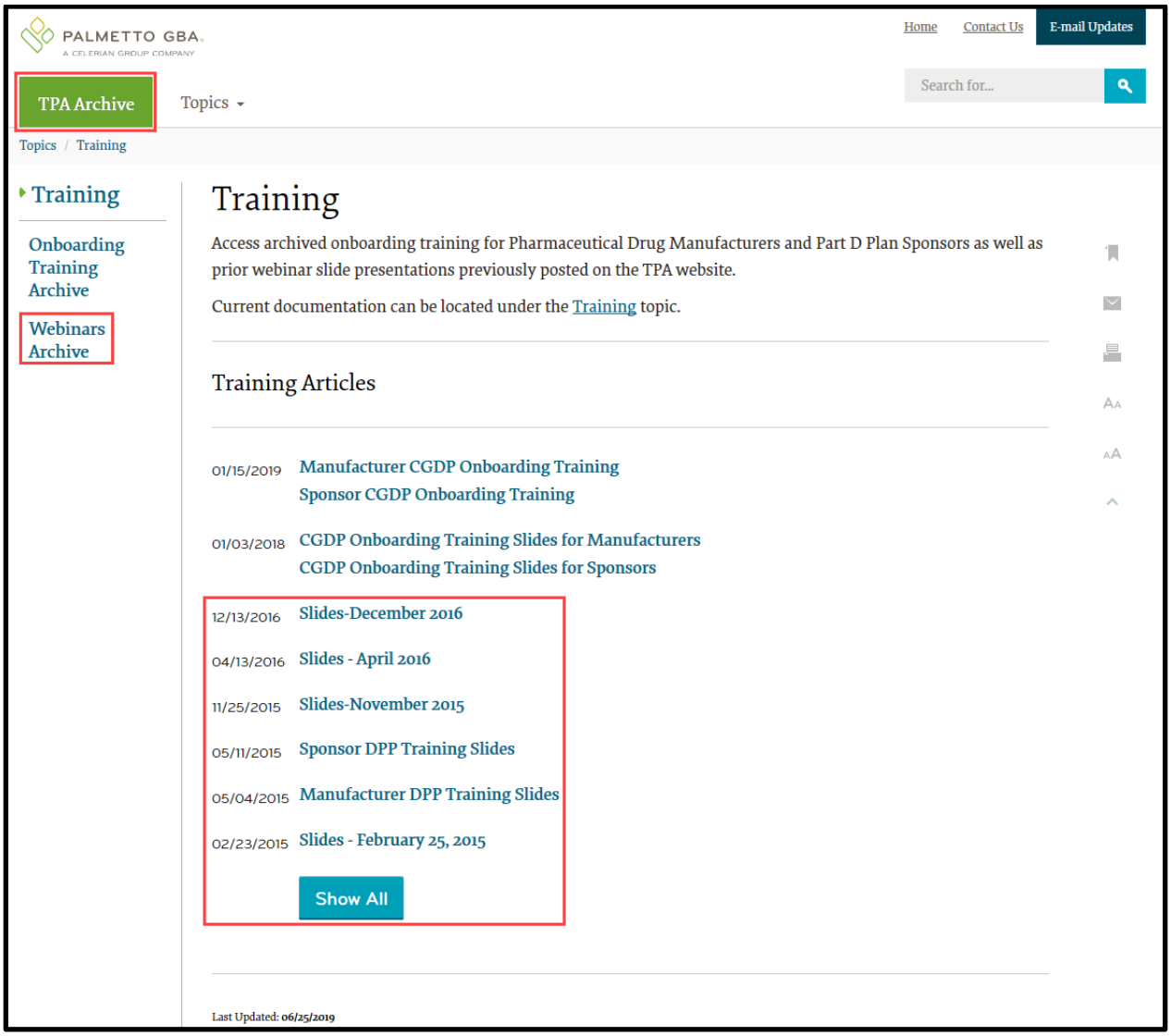
Figure 35: TPA website – Frequently Asked Questions (FAQ)



Note: The FAQ document is updated as additional questions are addressed.

In addition to user guides and FAQs, archived webinar training slides are available to both Drug Manufacturers and Part D Sponsors highlighting important activities available within the DPP. These slides are available on the TPA website under the Archives Training topic as shown in **Figure 36**.

Figure 36: TPA website – Webinar Information



6. Disputes and Appeals

6.1 Dispute Process Defined

In accordance with section 1860D-14A(c)(1)(A)(vii) of the Act and section V of the Medicare CGDP Agreement (the Agreement), CMS is required to provide a reasonable mechanism for Drug Manufacturers to resolve disputes involving the discounts provided under the CGDP.

PDEs accepted from Part D Sponsors are saved after data edits are applied upon initial PDE processing. There are over 200 PDE edits in place. These include many different edits focused exclusively on the CGDP. In addition to the substantive editing process, PDEs with coverage gap amounts are subject to further data analysis by CMS before they are used to generate invoices to Drug Manufacturers for the CGDP.

Receipt of the invoice is considered the date that the Data Invoice Report is available to the Manufacturer on the CGDP Portal and notification is sent to all manufacturers and Part D Sponsors via subscription-based email distribution lists. This is typically the date published on the CGDP Calendar. Drug Manufacturers must explain why they believe the invoiced coverage gap discount amount is in error.

Dispute Submission files are processed in the CGDP Portal during the allowed submission timeframe by the TPA and validated in two phases. Manufacturers are able to utilize the Dispute Builder functionality to assist in creation of dispute files from data files received for the current invoicing period. Disputes are submitted in the CGDP Portal utilizing the Dispute Submission tab. The Dispute Submission tab allows manufacturers to submit dispute files created using the Dispute Builder tab functionality or to create and upload manual dispute files from data files received for the current invoicing period.

Dispute files undergo system verification via the TPA edit programs to provide CMS with “Passed” system file edit disputes. Initial validation edits of disputes occur in the Dispute Builder during dispute file creation to validate that correct data elements have been included in the files. This validation also occurs during the upload process when manual disputes are loaded to the Dispute Submission page. Disputes receive a “Passed” or “Failed” status. Disputes that receive a status of “Passed” are forwarded to DDPS for additional edits. “Failed” disputes require Manufacturer review and re-submission. Dispute files can only be submitted during the dispute submission period, as noted by the Medicare Part D Coverage Gap Discount Program (CGDP) Calendar, and will undergo validation prior to the daily cutoff window of 4:00 pm ET. Submissions are required to contain data for one P Number only. Dispute files with multiple P Number data will be rejected. Only one dispute file, per P Number, can receive a “Passed” status within a specific daily cutoff window. Additional submissions of the dispute files within the daily cutoff window for the same P Number will result in a “Failed” status.

The second validation involves checking the content of the dispute(s) by DDPS. This validation is run once each evening.

A Dispute Return File is sent back to the Drug Manufacturer with an indication of the records that were “Accepted” (for example: those records that passed the second dispute editing and are being considered), and the records that were “Rejected” as they failed second dispute editing. Manufacturers utilize the Disputes tab in the CGDP Portal to review Dispute Return

reports, located in the Return File region, after submitting them for review. Dispute Return reports are available by 9:30 a.m. ET the following business day.

Manufacturers are also able to review Dispute Resolution reports on a quarterly basis, located in the Resolution File region of the Disputes tab, after disputes have been reviewed and determinations processed on the available data provided. Statuses for resolution reports can be "Upheld" or "Denied".

Note: All distributed invoices must be paid to the Part D Sponsor by the payment due date, as noted by the Medicare Part D Coverage Gap Discount Program (CGDP) Calendar, even if the invoice is going to be disputed by the Drug Manufacturer. Disputes can then be processed to review the invoice for why the manufacturer believes the invoiced coverage gap discount amount is in error.

Detailed information and instructions on how to view, build, and upload dispute files and reports is available in the CGDP Manufacturer Portal Disputes Users Guide. **Note**: A dispute that has been "Rejected" may be corrected and re-submitted. A dispute that has been "Accepted" should not be resubmitted. If it is, the second submission will be rejected.

To view the most recent list of dispute reason codes, access Dispute Reasons for a full list of approved codes and recent updates in the CGDP Manufacturer Portal Disputes Users Guide on the TPA website .

Refer to 8. Sample Reports and Disputes for links to file layouts on the TPA website.

6.1.1 Manufacturer Dispute Process

The right for Drug Manufacturers to dispute Quarterly Invoice Reports is covered under the CGDP Agreement. Section V(e) of the Manufacturer Agreement states Drug Manufacturers must provide supporting evidence that is material, specific, and related to the dispute or issue.

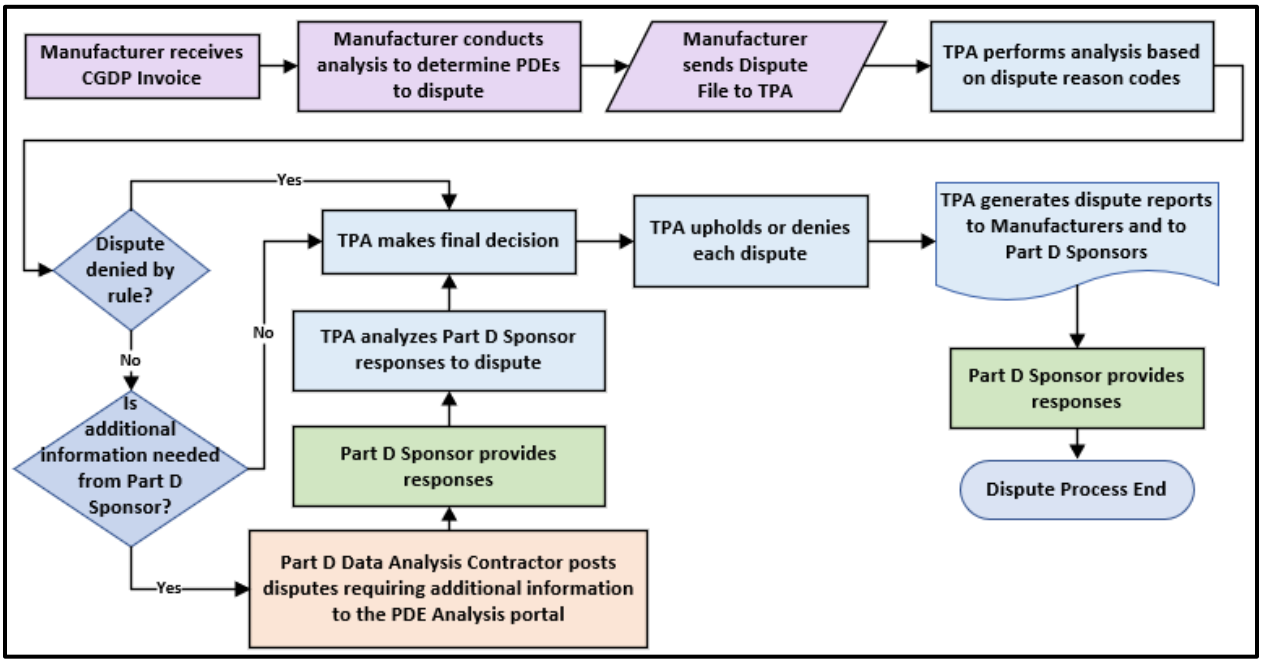
Drug Manufacturers can create disputes within 60 days of receipt of the Quarterly Invoice Report using the CGDP Portal Dispute Builder or they can electronically submit any disputes created manually using the Manufacturer Dispute Submission File format provided by the TPA. Drug Manufacturers must provide an explanation as to why they believe that the invoiced coverage gap discount amount is in error.

Prior to filing a dispute, Drug Manufacturers should consider that CMS has already performed extensive editing on PDE records and conducted outlier analysis to check for duplicates, applicable NDCs and incorrect coverage gap discount calculations, prior to invoicing.

Note: Drug Manufacturers may only choose one dispute reason per invoiced PDE.

See **Figure 37** for a high level overview of the Dispute Process Flow.

Figure 37: Dispute Process Flow



6.1.2 Overview of the Manufacturer CGDP Portal Disputes Tab

As previously noted in 5.3. Drug Manufacturer Overview of the CGDP Portal, Drug Manufacturers can use the portal to review reports of submitted invoice line item disputes.

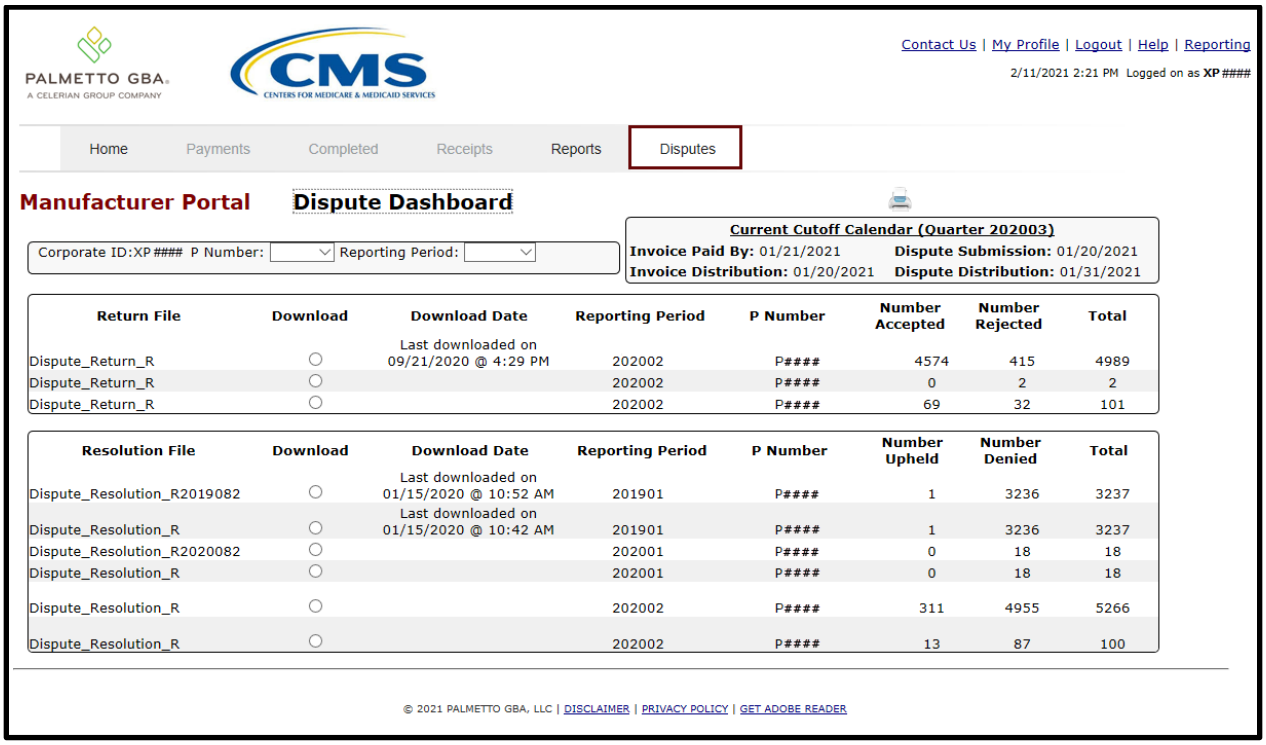
The **Disputes** tab allows manufacturers to view Return and Resolution dispute reports. Manufacturers submit disputes for PDE files included in quarterly invoices that may be incorrect and require review by CMS. TPA receives dispute files and performs multiple validations prior to final submission to CMS.

From the Disputes tab, Drug Manufacturers can also:

- Search data listed by the defaulted Drug Manufacturer Corporate ID;
- View specific quarter cutoff dates, in a MM/DD/YYYY format, for the most recent quarter. The current quarter date displays in the title bar of the region, in parentheses, displayed in YYYYMM format;
- View Accepted (validated) and Rejected (invalidated) dispute return files for specific reporting periods, and;
- View Upheld (approved) and Denied dispute return files for specific reporting periods.

An example of the CGDP Manufacturer Portal Disputes tab is shown in **Figure 38**.

Figure 38: CGDP Manufacturer Portal Disputes tab



Detailed information and instructions on how to view, build, and upload dispute files and reports is available in the CGDP Manufacturer Portal Disputes Users Guide.

For more information on how to access the TPA website and for detailed training and slides on how to use each tab within the CGDP Portal including the Disputes tab, access 5.5. Training, User Guides, Frequently Asked Questions (FAQ) and Webinar Information on the TPA website.

6.1.3 Part D Sponsor Role in the Dispute Process

Once the Dispute Submission deadline has passed, all disputes go through an initial analysis. Disputes that are not denied by rule are reviewed for potential posting on the PDE Analysis website to acquire additional information from the Part D Sponsors as described in 6.1.4 Dispute Resolution Process. Part D Sponsors must respond to the disputed PDEs within ten calendar days of being posted. The Part D Sponsor must provide the status of the PDE for each invoice number and an explanation of the selected status using the Dispute Response Form. If the PDE requires an adjustment or deletion, the Part D Sponsor reports the date of action by which the PDE will be adjusted or deleted through a submission to DDPS.

6.1.4 Dispute Resolution Process

The TPA has 60 days to make a determination of any accepted disputes. They can either uphold the dispute in favor of the Drug Manufacturer or deny the dispute.

Drug Manufacturers are able to review the Dispute Resolution Report, in the CGDP Portal Disputes tab in the Resolution File region, containing a list of all “Accepted” disputes (those that passed dispute edits) for the most recently completed Quarterly Invoice Reporting period. This report also includes the TPA decisions: “Upheld” or “Denied”.

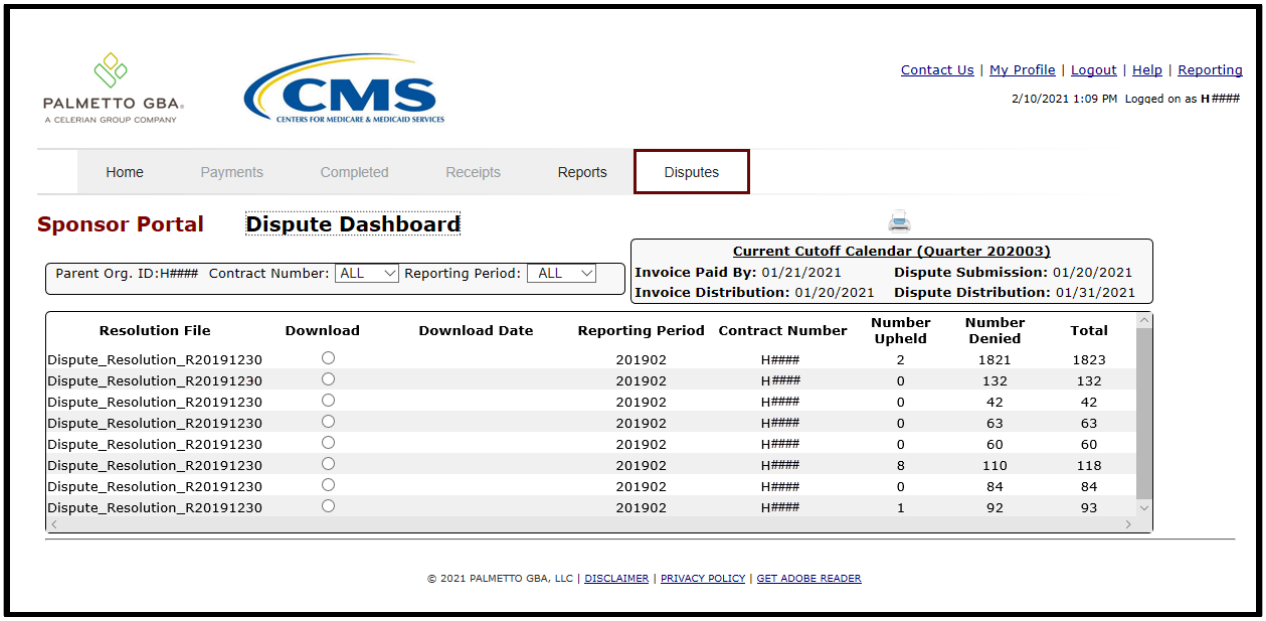
Note: The Dispute Resolution Report TPAMH record “FILLER” field definition contains the following ***text***, notifying Drug Manufacturers on how to proceed with the Appeals process should they disagree with a Dispute decision (specifically a dispute that was “Denied”).

> *“This file includes the resolution of a dispute previously filed. If the Dispute Disposition field indicates that the TPA upheld the dispute, there will be an adjustment on a future invoice; if the required action taken by the sponsor results in an adjustment to the reported gap discount field.*
>
> *A manufacturer may appeal a denied dispute to the Independent Review Entity (IRE) within 30 calendar days of distribution of the dispute resolution file. A link to the IRE can be found on the CMS Manufacturer’s page at* http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/Pharma.html *under “Related Links”.*

When a dispute has been upheld, the Part D Sponsor that submitted the successfully disputed PDE has 90 days upon discovery (the date the Dispute Disposition Report is received) to submit a corrected PDE to CMS. The Dispute Disposition Report contains a listing of all “Accepted” Manufacturer Disputes (those that passed Dispute Edits) for the most recently completed Quarterly Invoice Report period, along with the TPA decisions: “Upheld” or “Denied”.

An example of the CGDP Sponsor Portal Disputes tab is shown in **Figure 39**.

Figure 39: CGDP Sponsor Portal Disputes tab



Note: Part D Sponsors are obligated to fix the invalid data that caused the dispute. They can adjust financial or non-financial fields to correct the disputed data. The Reported Coverage Gap Discount amount may or may not change due to an "Upheld" dispute status.

For a list of File Layouts, access the Disputes topic on the TPA website.

6.2 Appeals

Drug Manufacturers may appeal disputes to the IRE that were:

- Initially submitted but received a timely unfavorable determination or,
- Not resolved within 60 days of submission.

CMS oversees the IRE to ensure it makes determinations in accordance with statutory, regulatory, and CMS requirements but otherwise, CMS does not intervene in specific IRE determinations. If a Drug Manufacturer receives an unfavorable determination by the IRE, the Drug Manufacturer may request review of the IRE determination by the CMS Administrator.

The Dispute / Appeal process consists of three steps to address invoice charges where the Drug Manufacturer disagrees with information contained on a PDE.

- **Step 1** – Drug Manufacturer files dispute(s) to invoiced PDEs. The dispute(s) for specific invoiced item(s) are submitted to the TPA within 60 days as previously described in 6.1.1 Manufacturer Dispute Process.
- **Step 2** – If any of the invoice disputes are denied or a response is not received within 60 days, the Drug Manufacturer may request an appeal to the IRE within the earlier of 30 calendar days of an unfavorable determination or 60 calendar days after the submission of the initial request for dispute, if the Drug Manufacturer does not receive a timely determination by the TPA[7].
- **Step 3** – Should the IRE deny the appeal, the final step for a Drug Manufacturer to request that a disputed invoice item be reversed is to appeal to the CMS Administrator.

6.2.1 Manufacturer Appeal Process

Drug Manufacturers may appeal an unfavorable dispute determination to the IRE if they, in good faith, continue to believe that disputed coverage gap discount payments are in error.

Therefore:

- Drug Manufacturer appeals must demonstrate why they believe the disputed coverage gap discount payment is in error in order for the IRE to further review and validate a disputed coverage gap discount payment.

[7] Medicare Coverage Gap Discount Program, 42 CFR 423.2330 (2012).

- A coverage gap discount payment is in error only if it is not accurately calculated or if it is not calculated based upon accurate data that represents the dispensing event that occurred.
- It is not an error if the coverage gap discount payment is accurately calculated based upon accurate data for dispensing events that actually occurred, even if the amount calculated appears to indicate that the dispensing event may not have been clinically appropriate.
- Drug Manufacturers need to explain why the unfavorable dispute determination was wrong and why the information provided with the original dispute demonstrates that a coverage gap discount payment is likely in error.
- Supporting evidence on appeal is limited to information submitted with the original dispute, unless additional information is requested by the IRE.
- In making the decision to appeal, Drug Manufacturers should remember and consider that CMS already performed extensive editing on PDE records, and conducts outlier analysis that checks for duplicates, applicable NDCs, and incorrect coverage gap discount calculations, prior to invoicing.
- The IRE may take into consideration previous CMS analysis and reviews performed before or during the resolution of the initial dispute when making an appeal determination.

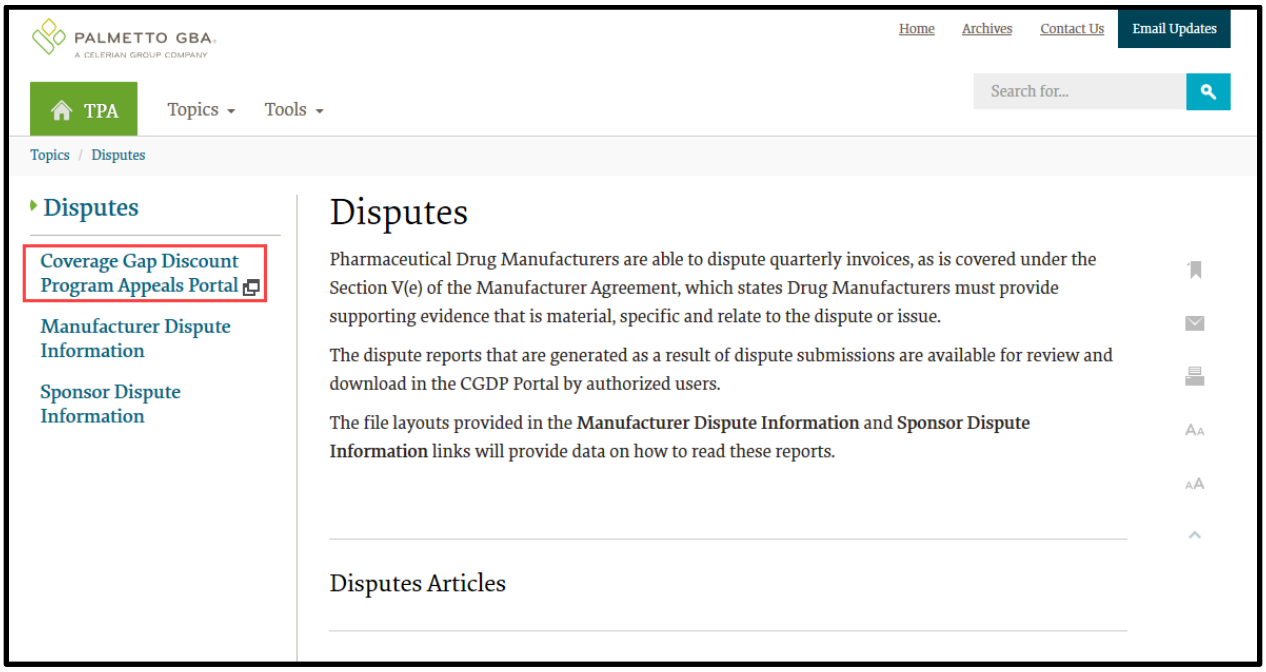
For key dates and deadlines related to Dispute and Appeals by Drug Manufacturers for the current calendar year, refer to the Medicare Part D Coverage Gap Discount Program (CGDP) Calendar on the TPA website.

Note: These dates may be subject to change or delays. It is recommended that Drug Manufacturers and Part D Sponsors access the Medicare Part D Coverage Gap Discount Program (CGDP) Calendar on the TPA website to verify dates.

6.2.1.1 Appeals Processing

To initiate an appeal to the IRE, access the Coverage Gap Discount Program Appeals Portal. The Appeals portal is located under the Disputes topic on the TPA website as shown in **Figure 40** or by accessing the IRE website as shown in **Figure 41**. Both links will direct you to the same location.

Figure 40: TPA website – CGDP Appeals Portal Link



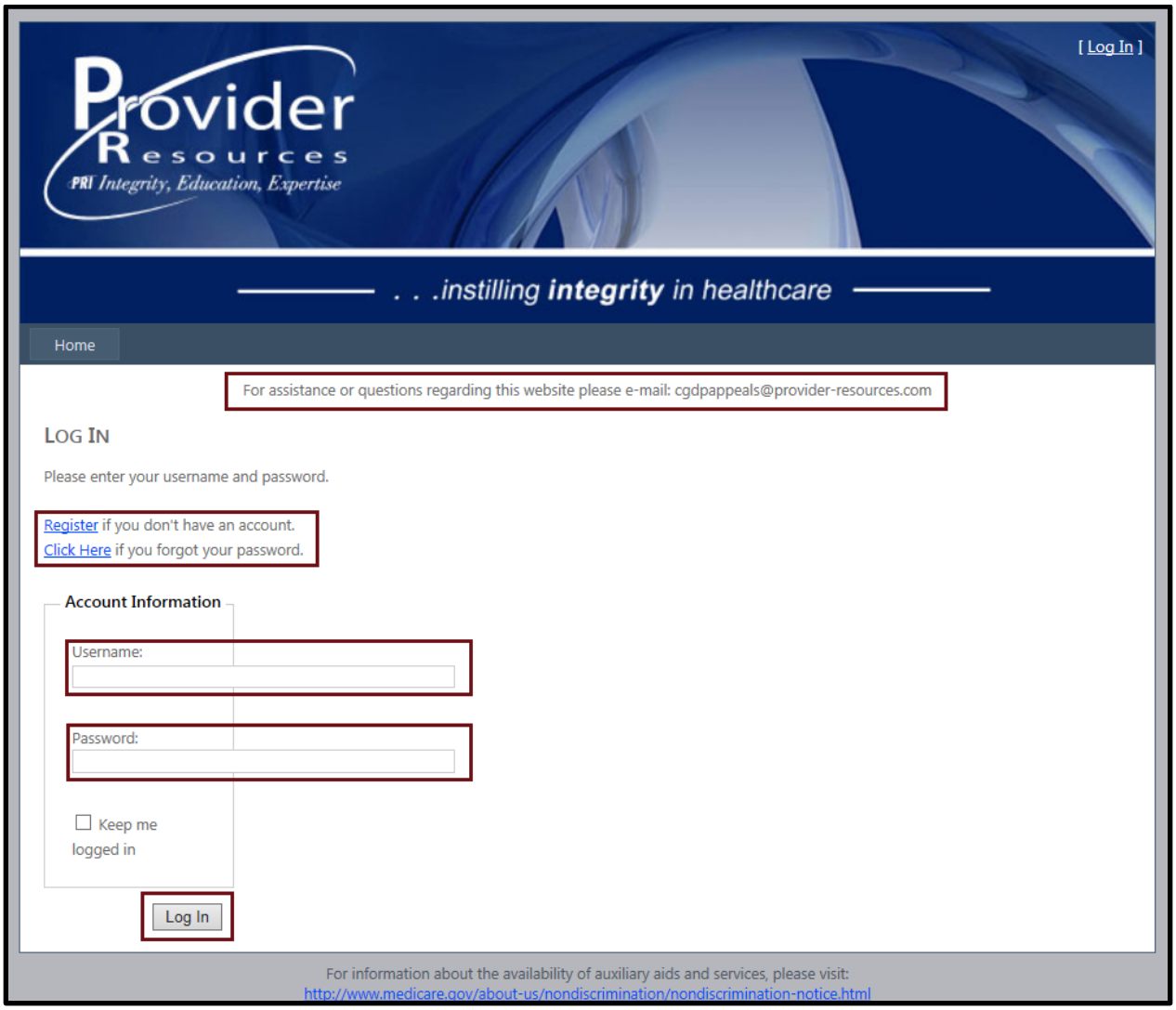
Clicking on the Appeals Portal on the TPA website directs you to the CGDP Appeals link (https://cgdpappeals.provider-resources.com/) as shown in **Figure 41**.

Figure 41: CGDP Appeals Portal – Landing Page

From this screen, select the “Please click here to log in” link. A warning screen prompts about accessing a U.S. Government information system. Read the text then select “I Accept and Agree”.

The Log In screen displays as shown in **Figure 42**.

Figure 42: CGDP Appeals Portal – Log In screen

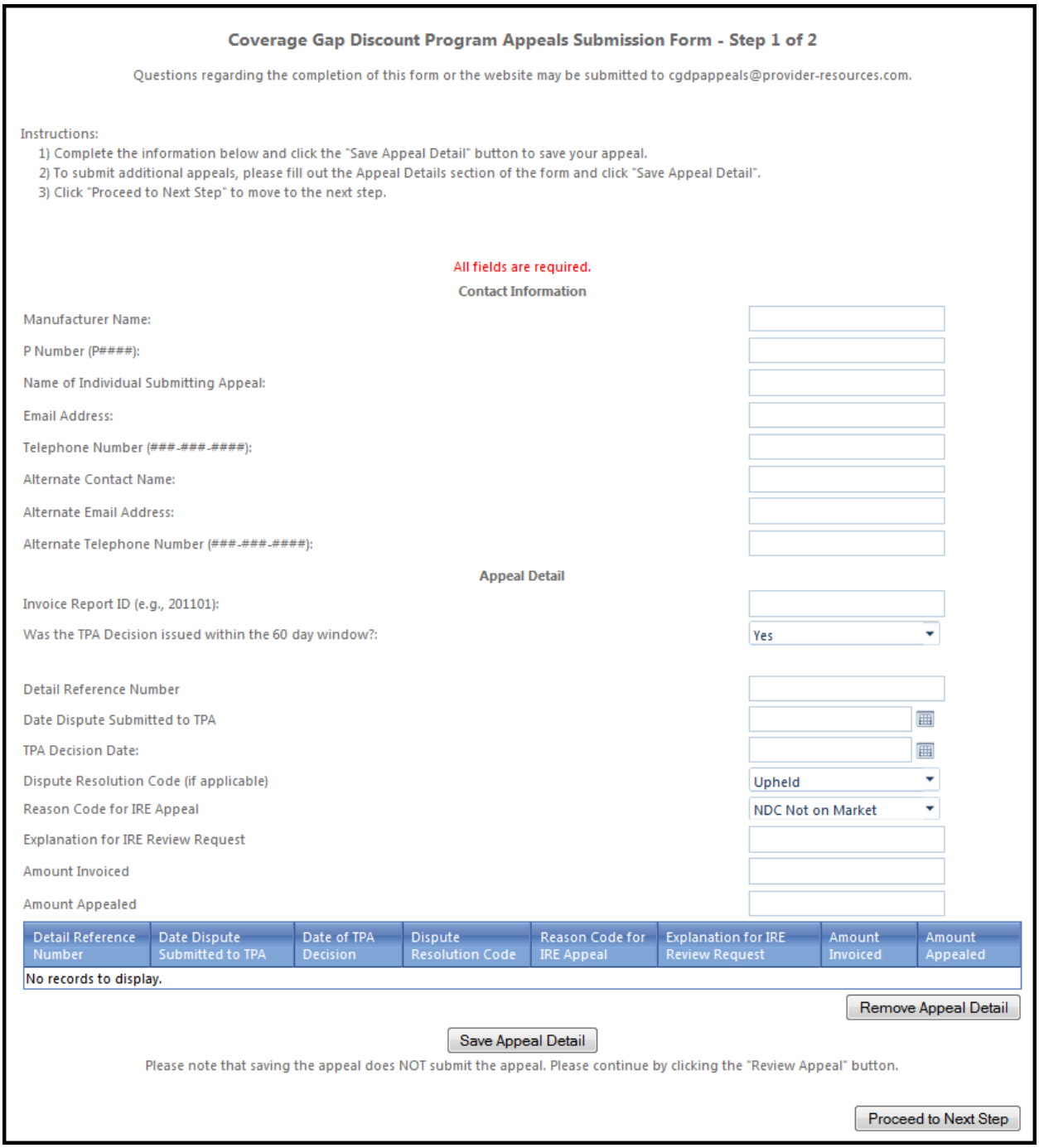


A Drug Manufacturer account must be created to proceed. If an account was previously setup, enter the Username and Password from the main screen. To set up a new account, click Register and enter the Drug Manufacturer name, a contact email address and a password.

Reminder: A Drug Manufacturer can submit new appeals and track existing appeals in the future once an account has been established.

To submit a new appeal, fill out the online Appeal Request Form as shown in **Figure 43** by clicking on the link **Submit a New Appeal**. Once the appeal submission is completed, an automated email response is sent to the Drug Manufacturer to confirm receipt of the submitted appeal.

Figure 43: Sample of CGDP Appeal Request Form



Note: For further assistance or questions regarding the Appeals Portal website, send an email to cgdpappeals@provider-resources.com.

As the IRE reviews the appeal, a Drug Manufacturer may receive a request for additional information. In addition to the information provided by the Drug Manufacturer, the IRE bases its decision on information received by CMS, the TPA, the Part D Sponsor, and other databases compiled by CMS or other sources.

The IRE then issues a determination electronically to the Drug Manufacturer's contact person of record and appropriate CMS staff within 90 days of the appeals submission deadline. The IRE includes a reason and explanation for each of its determinations on the appeal reply document.

6.2.1.2 CMS Administrator's Review

A Drug Manufacturer that has received an unfavorable determination of its appeal may request a final review by the CMS Administrator within 30 calendar days of that determination. Instructions on how to submit an appeal to the Administrator are included with the IRE determination.

The Administrator notifies the Drug Manufacturer's contact of record and CMS staff of his or her determination. All determinations by the Administrator are final and binding.

6.2.2 Part D Sponsor's Role in the Appeals Process

Part D Sponsors may play a role in the Appeals process. They may need to provide additional information to the IRE if and when requested. Part D Sponsors are sent notification of all affirmed Detail Reference Numbers (DRNs) by the IRE once the appeal determination is issued.

7. Calendar, Listings and Codes

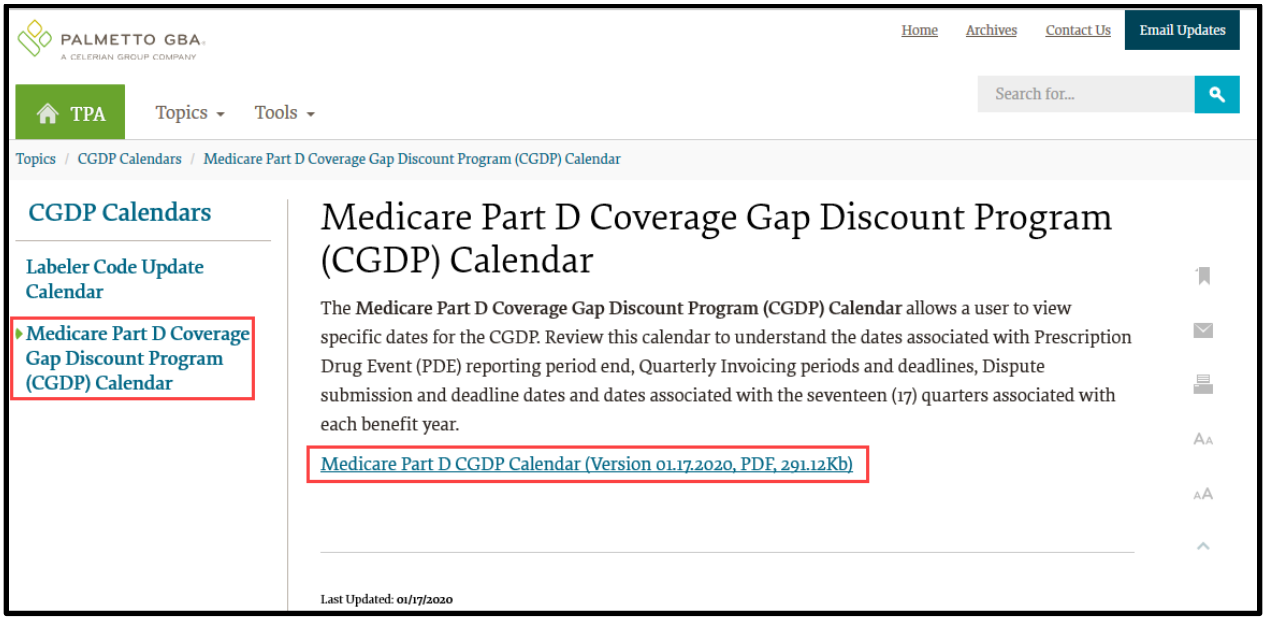
In order to ensure that CGDP participants are accessing the most current versions of program information, samples of information have been provided for example purposes only, along with links to the most current information on the TPA website.

Note: Participants should always access the TPA website for the most current information.

7.1 Program Calendar

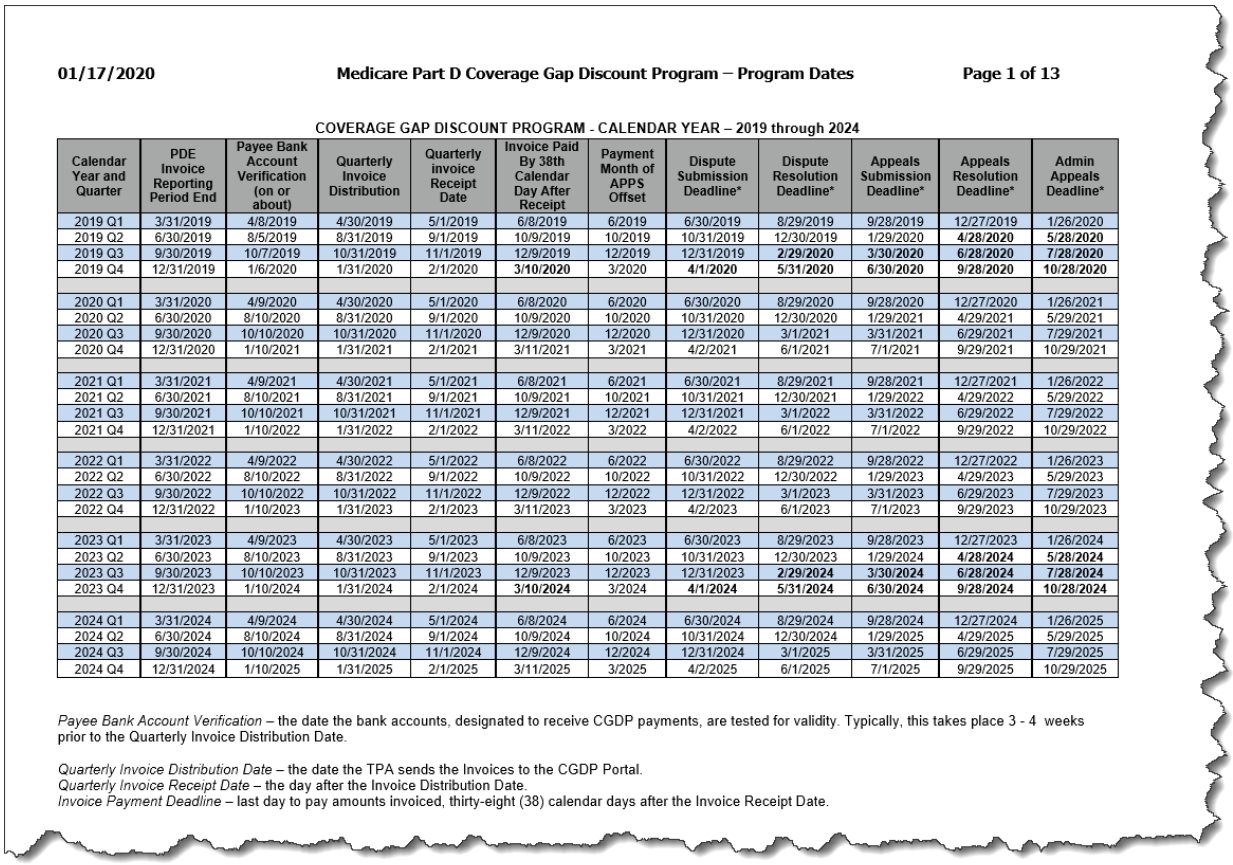
To view the most current version of the program calendar, access the Medicare Part D Coverage Gap Discount Program (CGDP) Calendar on the TPA website as shown in **Figure 44**.

Figure 44: TPA website – Part D CGDP Calendar



See **Figure 45** for a sample of the information included in the Medicare Part D CGDP Calendar.

Figure 45: Example of Page One of the CGDP Calendar



01/17/2020 Medicare Part D Coverage Gap Discount Program – Program Dates Page 1 of 13

COVERAGE GAP DISCOUNT PROGRAM - CALENDAR YEAR – 2019 through 2024

Calendar Year and Quarter	PDE Invoice Reporting Period End	Payee Bank Account Verification (on or about)	Quarterly Invoice Distribution	Quarterly invoice Receipt Date	Invoice Paid By 38th Calendar Day After Receipt	Payment Month of APPS Offset	Dispute Submission Deadline*	Dispute Resolution Deadline*	Appeals Submission Deadline*	Appeals Resolution Deadline*	Admin Appeals Deadline*
2019 Q1	3/31/2019	4/8/2019	4/30/2019	5/1/2019	6/8/2019	6/2019	6/30/2019	8/29/2019	9/28/2019	12/27/2019	1/26/2020
2019 Q2	6/30/2019	8/5/2019	8/31/2019	9/1/2019	10/9/2019	10/2019	10/31/2019	12/30/2019	1/29/2020	**4/28/2020**	**5/28/2020**
2019 Q3	9/30/2019	10/7/2019	10/31/2019	11/1/2019	12/9/2019	12/2019	12/31/2019	**2/29/2020**	**3/30/2020**	**6/28/2020**	**7/28/2020**
2019 Q4	12/31/2019	1/6/2020	1/31/2020	2/1/2020	**3/10/2020**	3/2020	**4/1/2020**	**5/31/2020**	**6/30/2020**	**9/28/2020**	**10/28/2020**
2020 Q1	3/31/2020	4/9/2020	4/30/2020	5/1/2020	6/8/2020	6/2020	6/30/2020	8/29/2020	9/28/2020	12/27/2020	1/26/2021
2020 Q2	6/30/2020	8/10/2020	8/31/2020	9/1/2020	10/9/2020	10/2020	10/31/2020	12/30/2020	1/29/2021	4/29/2021	5/29/2021
2020 Q3	9/30/2020	10/10/2020	10/31/2020	11/1/2020	12/9/2020	12/2020	12/31/2020	3/1/2021	3/31/2021	6/29/2021	7/29/2021
2020 Q4	12/31/2020	1/10/2021	1/31/2021	2/1/2021	3/11/2021	3/2021	4/2/2021	6/1/2021	7/1/2021	9/29/2021	10/29/2021
2021 Q1	3/31/2021	4/9/2021	4/30/2021	5/1/2021	6/8/2021	6/2021	6/30/2021	8/29/2021	9/28/2021	12/27/2021	1/26/2022
2021 Q2	6/30/2021	8/10/2021	8/31/2021	9/1/2021	10/9/2021	10/2021	10/31/2021	12/30/2021	1/29/2022	4/29/2022	5/29/2022
2021 Q3	9/30/2021	10/10/2021	10/31/2021	11/1/2021	12/9/2021	12/2021	12/31/2021	3/1/2022	3/31/2022	6/29/2022	7/29/2022
2021 Q4	12/31/2021	1/10/2022	1/31/2022	2/1/2022	3/11/2022	3/2022	4/2/2022	6/1/2022	7/1/2022	9/29/2022	10/29/2022
2022 Q1	3/31/2022	4/9/2022	4/30/2022	5/1/2022	6/8/2022	6/2022	6/30/2022	8/29/2022	9/28/2022	12/27/2022	1/26/2023
2022 Q2	6/30/2022	8/10/2022	8/31/2022	9/1/2022	10/9/2022	10/2022	10/31/2022	12/30/2022	1/29/2023	4/29/2023	5/29/2023
2022 Q3	9/30/2022	10/10/2022	10/31/2022	11/1/2022	12/9/2022	12/2022	12/31/2022	3/1/2023	3/31/2023	6/29/2023	7/29/2023
2022 Q4	12/31/2022	1/10/2023	1/31/2023	2/1/2023	3/11/2023	3/2023	4/2/2023	6/1/2023	7/1/2023	9/29/2023	10/29/2023
2023 Q1	3/31/2023	4/9/2023	4/30/2023	5/1/2023	6/8/2023	6/2023	6/30/2023	8/29/2023	9/28/2023	12/27/2023	1/26/2024
2023 Q2	6/30/2023	8/10/2023	8/31/2023	9/1/2023	10/9/2023	10/2023	10/31/2023	12/30/2023	1/29/2024	**4/28/2024**	**5/28/2024**
2023 Q3	9/30/2023	10/10/2023	10/31/2023	11/1/2023	12/9/2023	12/2023	12/31/2023	**2/29/2024**	**3/30/2024**	**6/28/2024**	**7/28/2024**
2023 Q4	12/31/2023	1/10/2024	1/31/2024	2/1/2024	**3/10/2024**	3/2024	**4/1/2024**	**5/31/2024**	**6/30/2024**	**9/28/2024**	**10/28/2024**
2024 Q1	3/31/2024	4/9/2024	4/30/2024	5/1/2024	6/8/2024	6/2024	6/30/2024	8/29/2024	9/28/2024	12/27/2024	1/26/2025
2024 Q2	6/30/2024	8/10/2024	8/31/2024	9/1/2024	10/9/2024	10/2024	10/31/2024	12/30/2024	1/29/2025	4/29/2025	5/29/2025
2024 Q3	9/30/2024	10/10/2024	10/31/2024	11/1/2024	12/9/2024	12/2024	12/31/2024	3/1/2025	3/31/2025	6/29/2025	7/29/2025
2024 Q4	12/31/2024	1/10/2025	1/31/2025	2/1/2025	3/11/2025	3/2025	4/2/2025	6/1/2025	7/1/2025	9/29/2025	10/29/2025

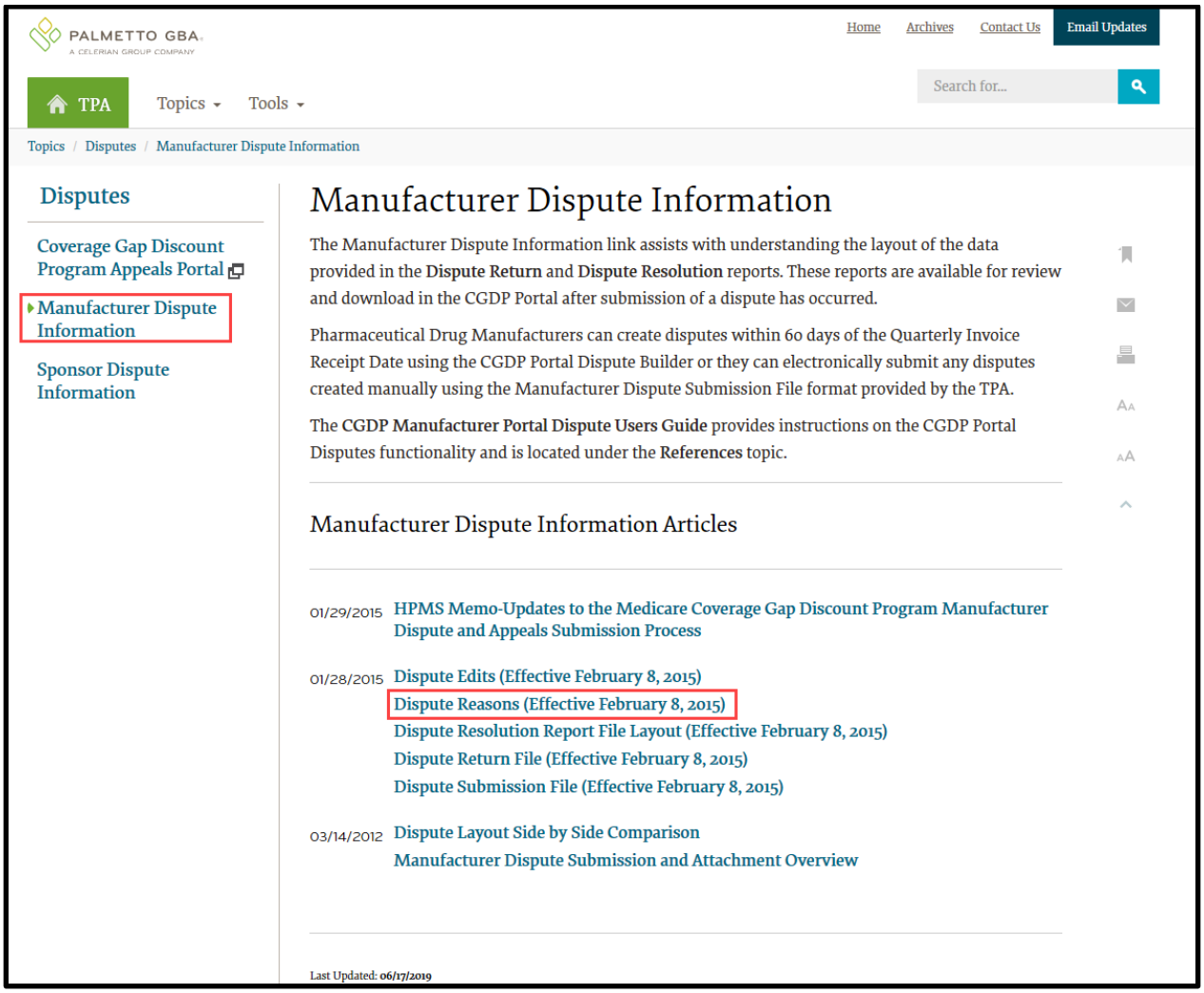
Payee Bank Account Verification – the date the bank accounts, designated to receive CGDP payments, are tested for validity. Typically, this takes place 3 - 4 weeks prior to the Quarterly Invoice Distribution Date.

Quarterly Invoice Distribution Date – the date the TPA sends the Invoices to the CGDP Portal.
Quarterly Invoice Receipt Date – the day after the Invoice Distribution Date.
Invoice Payment Deadline – last day to pay amounts invoiced, thirty-eight (38) calendar days after the Invoice Receipt Date.

7.2 Dispute Reason Codes

Dispute Reason Codes are updated periodically by CMS. To view the most recent list of dispute reason codes, access Dispute Reasons for a full list of approved codes as shown in **Figure 46** on the TPA websiteFigure 46.

Figure 46: TPA website – Dispute Reason Codes Link



7.3 Appeal Codes Cross Reference

On January 27, 2015, CMS announced updates to the codes in the Drug Manufacturer dispute and appeal process for Drug Manufacturer disputes associated with the CGDP.

The updates streamline the Manufacturer dispute process, align dispute and appeal codes, and provide Drug Manufacturers with reason codes that, if upheld, are more likely to provide meaningful invoicing updates.

Drug Manufacturers began using the codes shown in **Figure 47**: TPA website – Disputes HPMS Memo

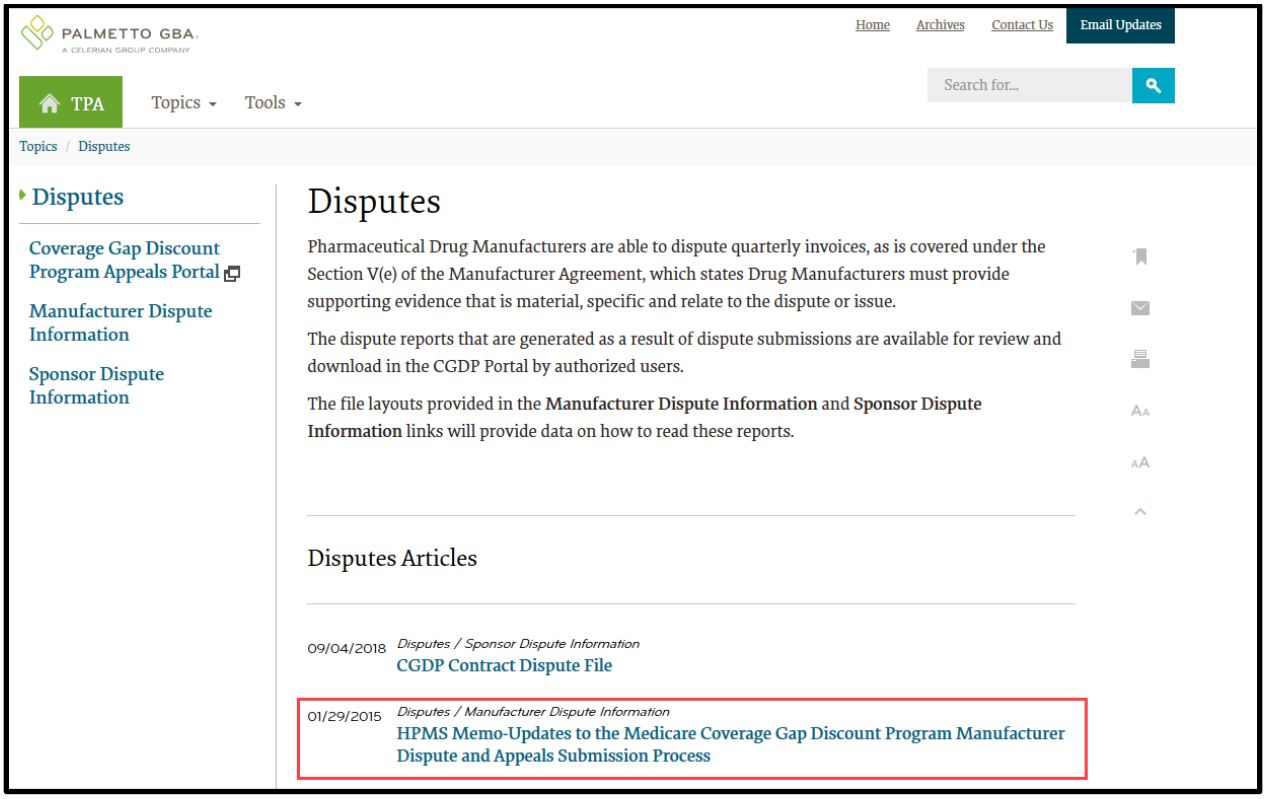


Table 5 for disputes and appeals on Q4 2014 invoiced amounts.

For more details, access the Disputes topic on the TPA website as shown in **Figure 47** to view a copy of the HPMS memo dated January 27, 2015 entitled "Updates to the Medicare Coverage Gap Discount Program Manufacturer Dispute and Appeals Submission Process."

Figure 47: TPA website – Disputes HPMS Memo

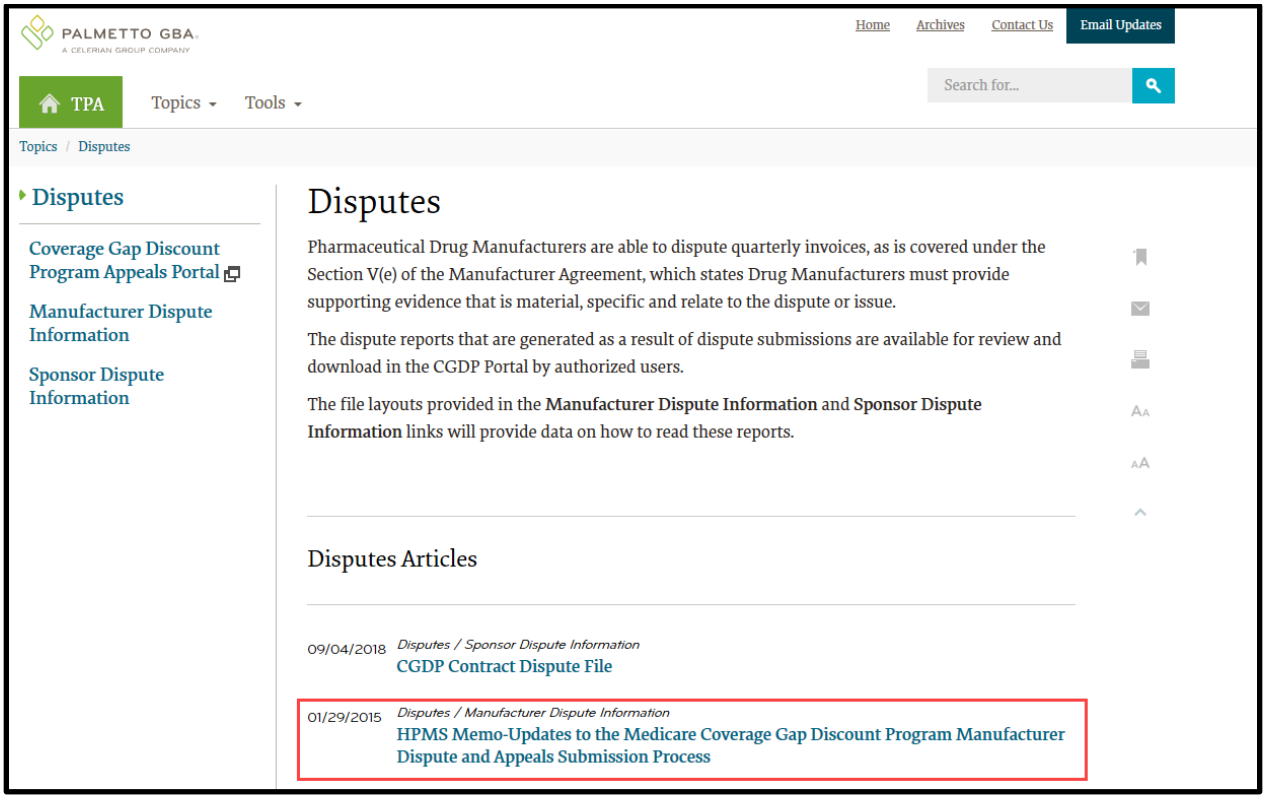


Table 5: Cross Reference of Dispute to Appeal Codes

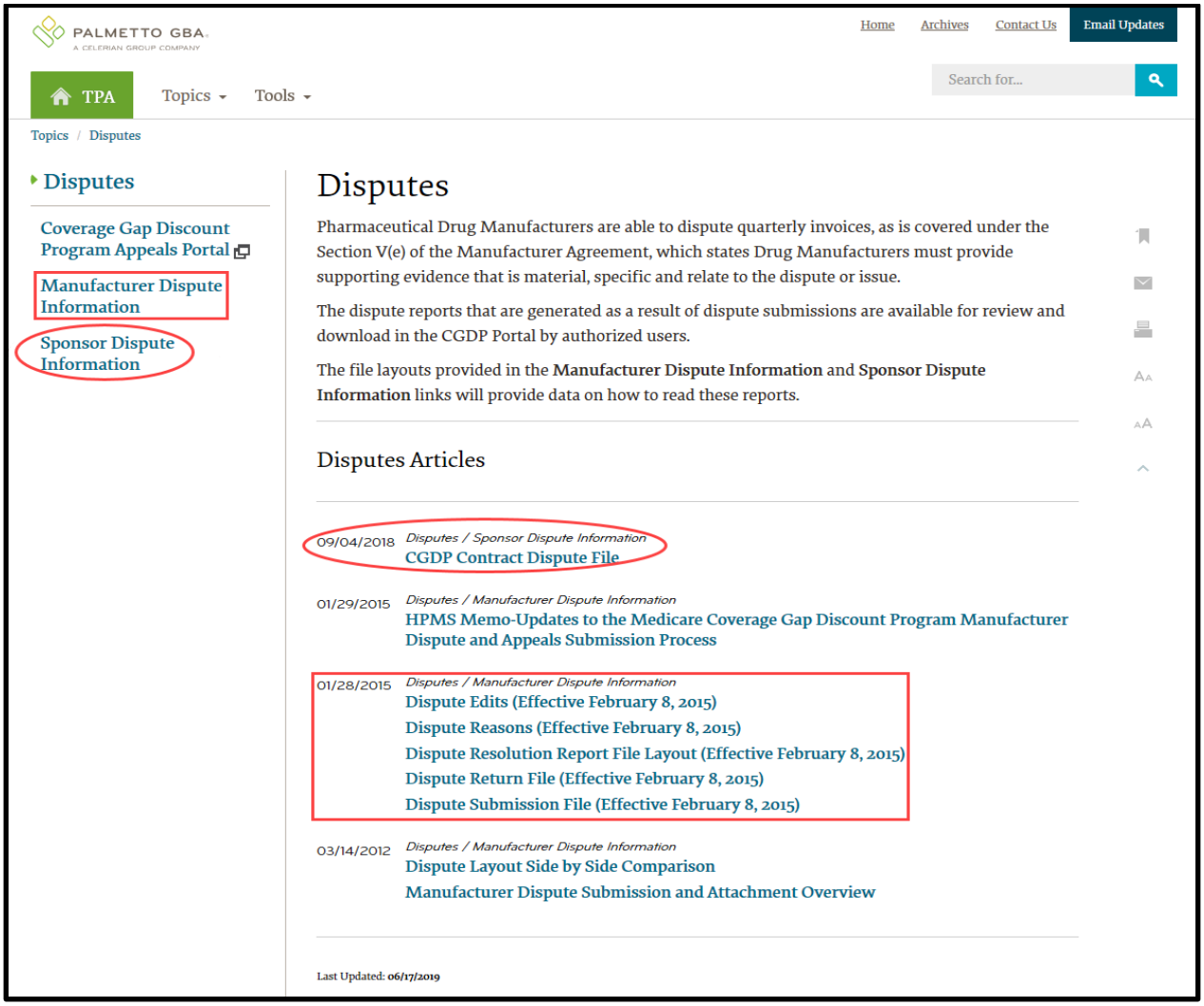
Reason for Manufacturer Dispute	Dispute Code	Appeal Code
Duplicate Invoice Item	D01	A01
Closed Pharmacy	D02	A02
Not Part D Covered Drug	D03	A03
Aberrant Quantity/Invalid Days' Supply	D04	A04
High Price of Drug	D06	A06
Last Lot Expiration Date-NDC not on the market	D07	A07
Marketing category is not NDA or BLA	D09	A09
PDE improperly invoiced beyond Manufacturer Agreement Invoice period	D11	A11
Excessive Gap Discount Gap Discount for Single PDE-disputed PDE exceeds maximum discount amount for a PDE	D13	A13
Other	D99	A99

8. Sample Reports and Disputes

To ensure CGDP participants access the most current versions of reports, file layouts, and dispute reason codes, these documents, delivered through the CGDP Portal, ***will not*** be included in this technical guide.

To view the most current Drug Manufacturer and Part D Sponsor Dispute File Layouts and Samples, access Disputes on the TPA website as shown in **Figure 48**.

Figure 48: TPA website – Dispute Report Layouts



9. Troubleshooting and Support

9.1 Third Party Administrator (TPA)

The TPA and its website are the gateway to the CGDP. From this site, Drug Manufacturers and Part D Sponsors access information about the CGDP, including information regarding the CGDP Portal, invoicing, and payment procedures. In addition, the site provides valuable links to CMS instructions and other official resources. The information provided below is available on the Contact Us page on the TPA website, as seen in **Figure 49**.

The TPA is available by Website, Help Line or Email at:

Website: http://www.tpadministrator.com

TPA Help Line: 1-877-534-2772, Option 1

Fax: 1-803-763-2010

Hours of Operation: Monday through Friday, 8:00 a.m. to 7:00 p.m., ET,

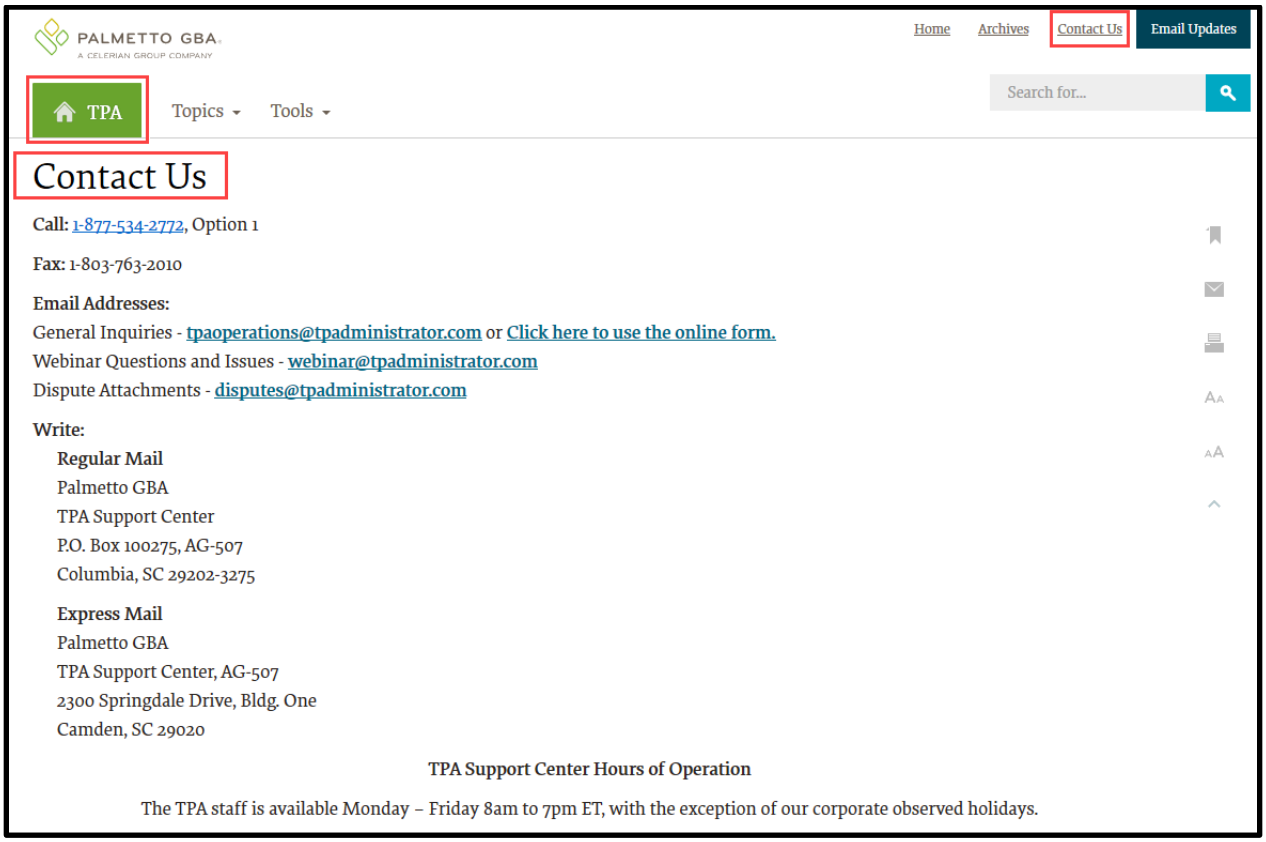
Email:

- General Inquiries - **tpaoperations@tpadministrator.com**
- Webinar Questions and Issues - **webinar@tpadministrator.com**
- Dispute Attachments - **disputes@tpadministrator.com**

Standard Mail
Palmetto GBA
TPA Support Center
P.O. Box 100275, AG-507
Columbia, SC 29202-3275

Express Mail
Palmetto GBA
TPA Support Center, AG-507
2300 Springdale Drive, Bldg. One
Camden, SC 29020

Figure 49: TPA website – Contact Us Link



9.2 Customer Service and Support Center (CSSC) Operations

The CSSC and its website are the gateway to Medicare Advantage, Medicare Medicaid Data and Prescription Drug Programs. From this site, Drug Manufacturers and Part D Sponsors can access information about Risk Adjustment, Medicare Encounter Data, Medicare Medicaid Data and Prescription Drug Programs; including opportunities to enroll to submit data and obtain comprehensive information about data submission and reporting. In addition, the site provides valuable links to CMS instructions and other official resources. The information provided below is available on the Contact Us page on the CSSC Operations website, as seen in **Figure 50**.

The CSSC is available by Website, Help Line or Email at:

Website: http://www.csscoperations.com

CSSC Help Line: 1-877-534-CSSC (2772) Option 2

Fax: 1-803-935-0171

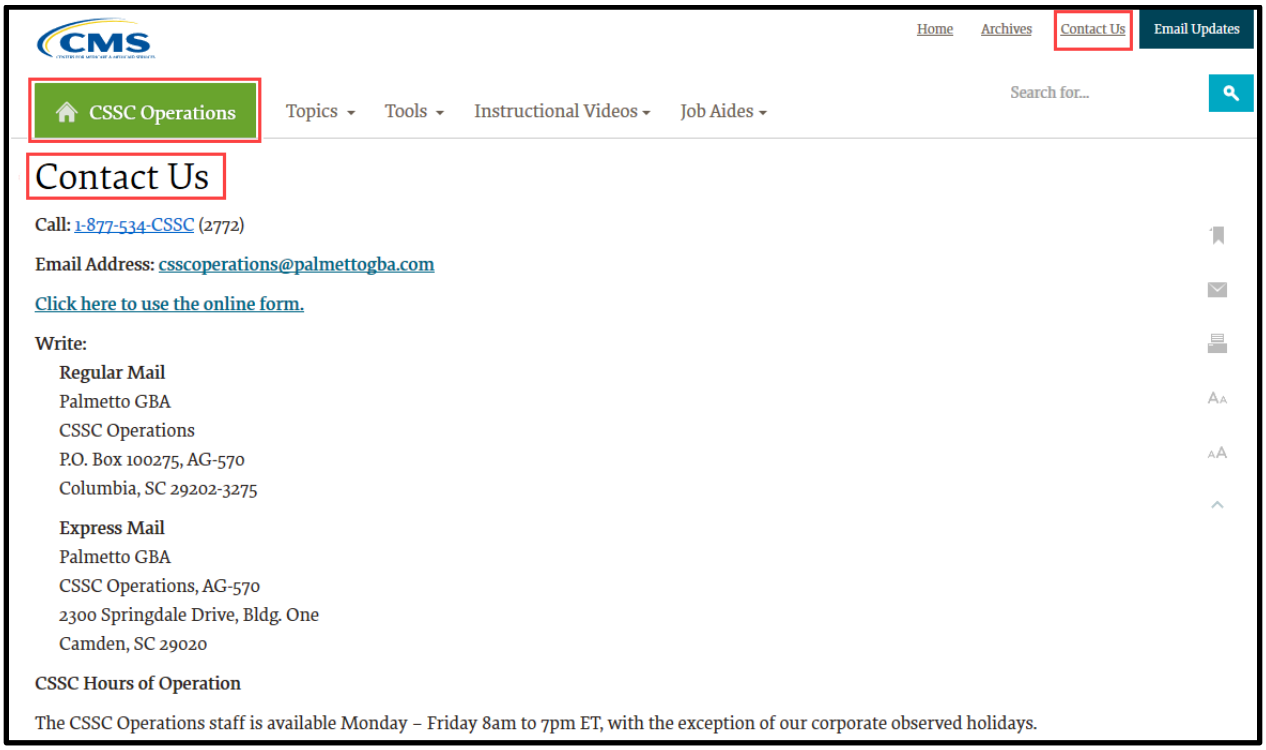
Hours of Operation: Monday through Friday, 8:00 a.m. to 7:00 p.m., ET,

Email: csscoperations@palmettogba.com

Standard Mail
Palmetto GBA
CSSC Operations
P.O. Box 100275, AG-570
Columbia, SC 29202-3275

Express Mail
Palmetto GBA
CSSC Operations, AG-570
2300 Springdale Drive, Bldg. One
Camden, SC 29020

Figure 50: CSSC Operations website – Contact Us Link



Appendix A: Record of Changes

Table 6: Record of Changes

Version Number	Date	Author/Owner	Description of Change
1.0	August 2021	CMS	Baseline Version

Appendix B: Acronyms

Table 7: Acronyms

Acronym	Definition / Translation
ACA	Affordable Care Act
ACH	Automated Clearing House
BLA	Biologic License Application
BY	Benefit Year
BYRH	Benefit Year Specific Header File Record
BYRT	Benefit Year Specific Trailer File Record
CGDP	Coverage Gap Discount Program
CMS	Centers for Medicare & Medicaid Services
CSSC	Customer Service Support Center
DETCD	Contract Reimbursement Detail Record at the PDE Level File Record
DETMD	Manufacturer Reimbursement Total at the Labeler Level File Record
DETUD	Upheld Dispute Tracking Data File Record
DOD	Date of Death
DOS	Date of Service
DDPS	Drug Data Processing System
DPP	Direct Payment Process
DRN	Detail Reference Number
DSB	Defined Standard Benefit
EFT	Electronic Funds Transfer
EUA	Enterprise User Administration
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
HHS	Health and Human Services

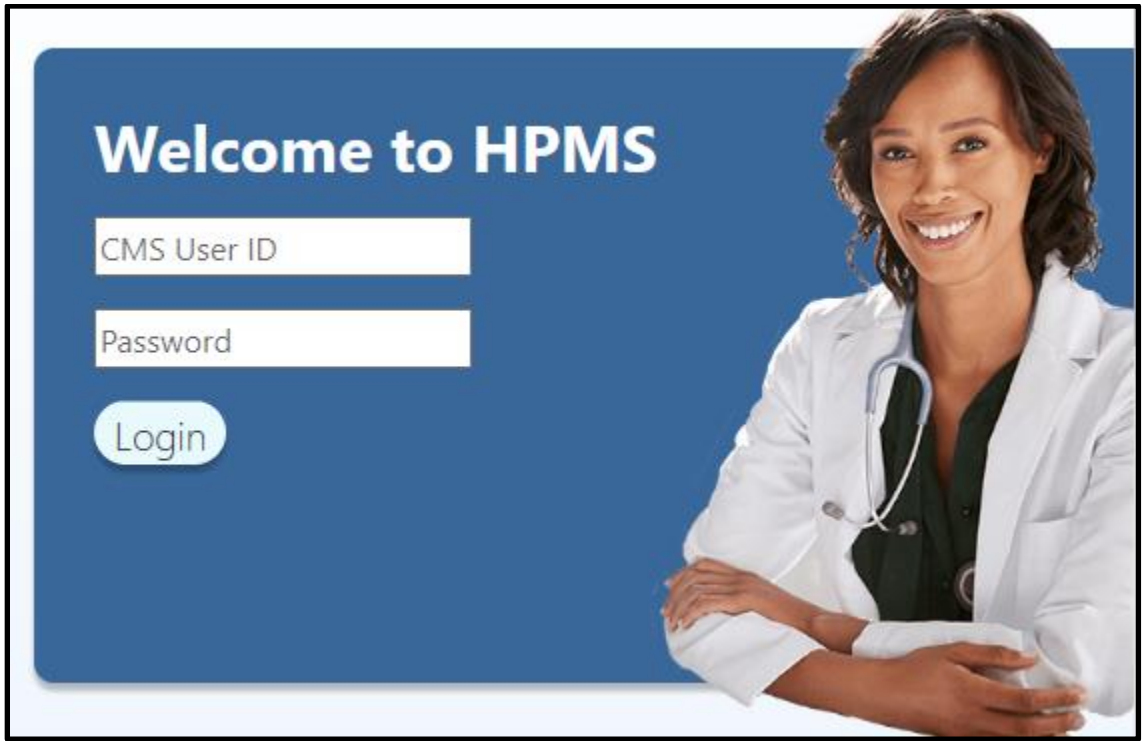
HPMS	Health Plan Management System
ICL	Initial Coverage Limit
IRE	Independent Review Entity
LBLR	Manufacturer Reimbursement Total at the Labeler Level File Record
LI	Low Income
LICS	Low Income Cost Sharing
MFA	Multifactor Authentication
MA-PD	Medicare Advantage – Prescription Drug
MMA	Medicare Modernization Act
NCPDP	National Council for Prescription Drug Program
NDA	National Drug Applications
NDC	National Drug Code
NSDE	NDC SPL Data Elements
OOP	Out of Pocket
PACE	Program for the All Inclusive Care for the Elderly
PBP	Plan Benefit Package
PDE	Prescription Drug Event
PDP	Prescription Drug Plan
PLRO	Patient Liability Reduction Due to Other Payer
PNUM	P Number
POS	Point of Sale
PRS	Payment Reconciliation System
PTOT	Contract Reimbursement Summary Record for the P-Number Total File Record
RGD	Reported Gap Discount
SPL	Structured Product Labeling
TPA	Third Party Administrator

TPACH	Contract Header File Record
TPACT	Contract Trailer File Record
TPALH	Labeler Header File Record
TPALT	Labeler Trailer File Record
TPAMH	Manufacturer P Number Header File Record
TPAMT	Manufacturer P Number Trailer File Record
TrOOP	True Out-of-Pocket
UDTBH	Upheld Dispute Benefit Year Header File Record
UDTBT	Upheld Dispute Benefit Year Trailer File Record
UDTMH	Upheld Dispute Manufacturer Header File Record
UDTMT	Upheld Dispute Manufacturer Trailer File Record
US	United States
USD	United States Dollar

Appendix C: HPMS Module & Enterprise User Administration (EUA) Access

Communications between CMS, Drug Manufacturers, Part D Sponsors, and the Third Party Administrator (TPA) is provided through the HPMS Manufacturer Module.

Figure 51: HPMS Login Region



Manufacturer HPMS New User Access

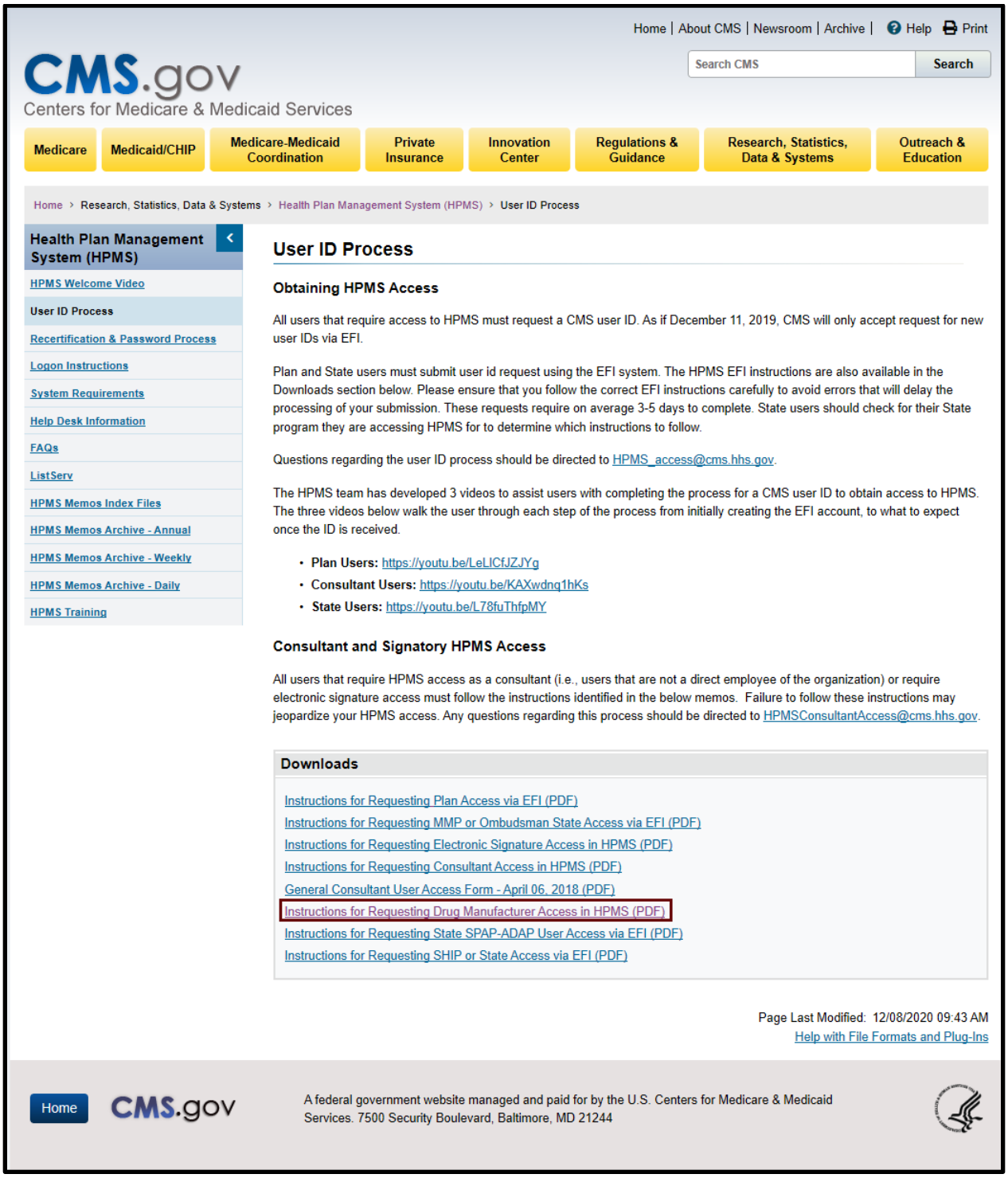
Manufacturers are responsible for maintaining their points of contact and updating and verifying Labeler Code information using the HPMS module at the HPMS Login Region as shown in **Figure 51**Error! Reference source not found..

Each Manufacturer designates an individual(s) to maintain HPMS content for their organization. Manufacturers that signed CGDP agreements after 2011 can also view and download their signed agreements through HPMS.

Completing Forms for HPMS New Manufacturer User Access

In order to gain access to HPMS, each individual must complete an electronic CMS User ID Access form. The link, HPMS User ID Process, includes a summary of the User ID Process and a link to the electronic CMS User ID EUA Access Form application as shown in **Figure 52**.

Figure 52: CMS.gov website – Drug Manufacturer HPMS Access Form Link



CMS has updated the process for all manufacturers to request a User ID for access to HPMS. They should no longer mail-in a hard copy application.

Manufacturers should review the following instructions and electronically submit a request for a CMS HPMS User ID.

- Select “Instructions for Requesting Drug Manufacturer Access in HPMS” from the CMS.gov User ID Process link as shown in **Figure 52**.

Review instructions to request Signatory access.

Add the pending P Number to an existing CMS HPMS User ID

Contact hpms@cms.hhs.gov with any HPMS technical questions.

Send an email to hpms_access@cms.hhs.gov for questions related to HPMS user access.

CMS will provide additional technical instructions on accessing HPMS, via email notification, once your User ID has been processed.

Once received and checked for completeness, it will take approximately two (2) weeks for CMS to grant access to HPMS. The individual will receive an email from eua@cms.hhs.gov containing the user ID, temporary password and the website to change the password.

Once the Drug Manufacturer’s signatory primary contact receives their user ID, they must send a letter (on company letterhead) to a designated address identifying themselves as the signatory, their role, their user ID and their pending P-Number. The letter may be converted to and sent as a pdf document and emailed electronically or it may be sent by a traceable carrier. If you have questions regarding this process, send an email to hpms_access@cms.hhs.gov.

Manufacturer Contact Information

All manufacturers participating in the CGDP are required to provide CMS with Primary, Signatory TPA Liaison, and CGDP Payment contact types, and are encouraged to use the optional Secondary Contact and Secondary Signatory Contact fields as well. Small or start-up manufacturers may have a single individual serve as several contact types. Descriptions of all manufacturer contact roles are provided within the HPMS Manufacturer Management Module.

Note: TPA Liaison and CGDP Payment contacts listed within the CGDP Portal must match CMS’ TPA Liaison and CGDP Payment contacts listed within HPMS in order for that individual to have access to invoicing information.

Each manufacturer is responsible for proactively updating HPMS with any changes to its contacts. Instructions to complete updates to contact information are included in the Drug Manufacturer Module User Guide within the HPMS’ Drug Manufacturer Management module, under ***Documentation***. Failure to provide up-to-date contacts will jeopardize the manufacturer’s knowledge of, and compliance with, key program requirements and deadlines. CMS will not waive any CGDP requirements to accommodate missed communications due to outdated contact information.

Note: Refer to Appendix D: Reporting Corporate Ownership or Company Name Changes for steps on reporting these types of changes to CMS.

HPMS contact information can be changed at any time. Send an email to HPMSConsultantAccess@cms.hhs.gov if you have any questions regarding this process as outlined in this section, newly assigned points of contact must electronically complete and submit a CMS User ID Access form in order to be able to access data in HPMS.

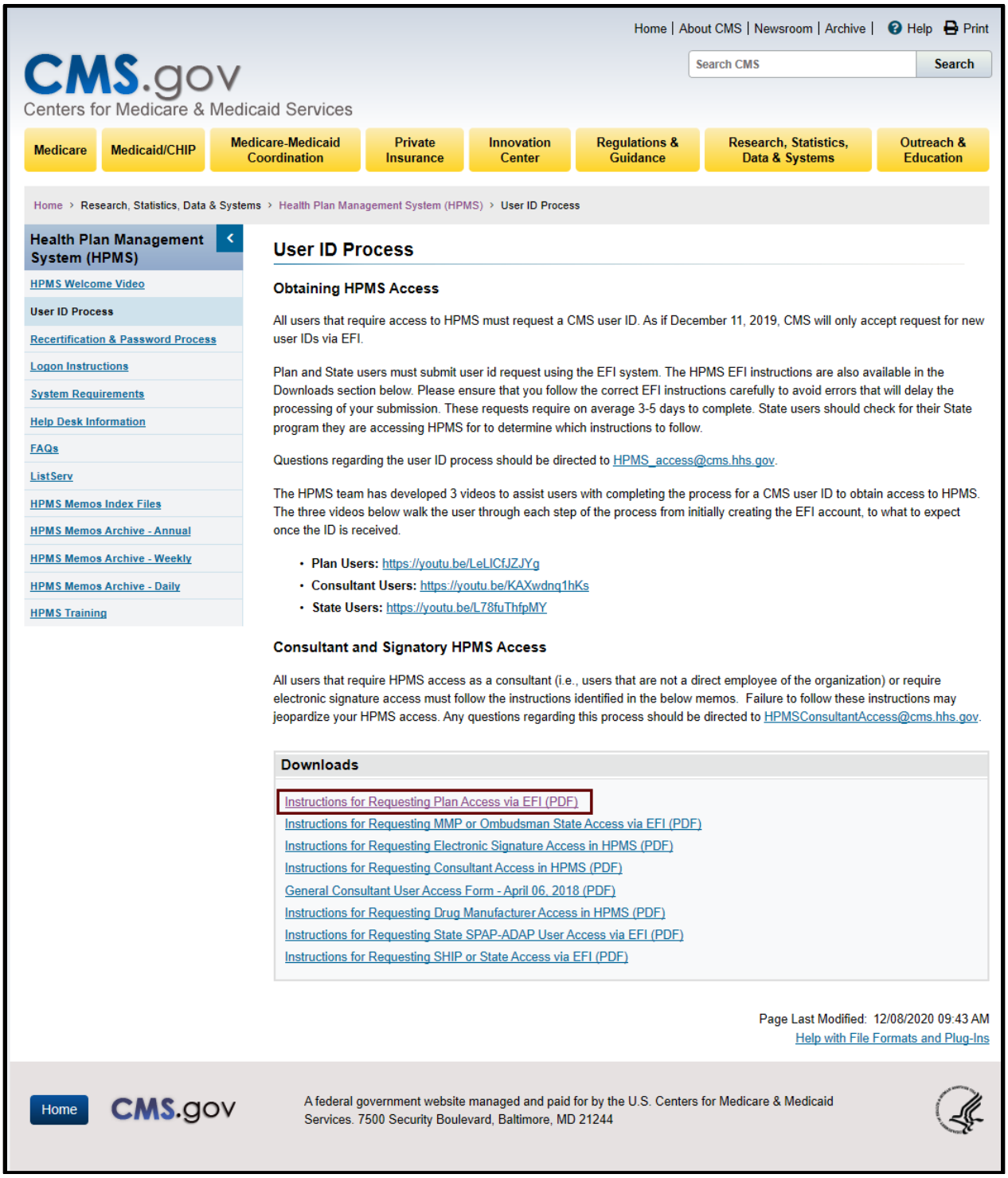
Sponsor HPMS New User Access

Sponsors are responsible for maintaining their points of contact using the HPMS module (https://hpms.cms.gov/app/login.aspx) as shown in **Figure 51**. Each Sponsor designates an individual(s) to maintain HPMS content for their organization.

Completing Forms for HPMS New Sponsor User Access

In order to gain access to HPMS, each individual must complete an electronic CMS User ID Access form. The following link includes a summary of the User ID Process and a link to the electronic CMS User ID EUA Access Form application: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/UserIDProcess.html as shown in **Figure 52.**

Figure 53: CMS.gov website – Part D Sponsor HPMS Access Form Link



CMS has updated the process for all sponsors to request a User ID for access to HPMS. They should no longer mail-in a hard copy application.

Sponsors should review instructions and electronically submit a request for a CMS HPMS User ID.

- Select the "Instructions for Requesting EUA User Access via EFI" located on the CMS.gov User ID Process link.

Contact hpms@cms.hhs.gov with any HPMS technical questions.

Send an email to hpms_access@cms.hhs.gov for questions related to HPMS user access.

CMS will provide additional technical instructions on accessing HPMS, via email notification, once your User ID has been processed.

Sponsor Contact Information

All Sponsors participating in the CGDP are required to provide CMS with Primary, Signatory TPA Liaison, and CGDP Payment contact types, and are encouraged to use the optional Secondary Contact and Secondary Signatory Contact fields as well.

Note: TPA Liaison and CGDP Payment contacts listed within the CGDP Portal must match CMS' TPA Liaison and CGDP Payment contacts listed within HPMS in order for that individual to have access to invoicing information.

Each Sponsor is responsible for proactively updating HPMS with any changes to its contacts. Failure to provide up-to-date contacts will jeopardize the Sponsor's knowledge of, and compliance with, key program requirements and deadlines. CMS will not waive any CGDP requirements to accommodate missed communications due to outdated contact information.

HPMS contact information can be changed at any time. Send an email to HPMSConsultantAccess@cms.hhs.gov if you have any questions regarding this process as outlined in this section, newly assigned points of contact must electronically complete and submit a CMS User ID Access form in order to be able to access data in HPMS.

Appendix D: Reporting Corporate Ownership or Company Name Changes

In this appendix, CMS outlines the process for reporting changes in Manufacturer's corporate ownership or asset ownership and company names. The purpose of this guidance is to help Manufacturers ensure products remain covered under a Manufacturer Agreement, without interruption, to promote the timely processing and payment of CGDP invoices.

Process Steps for Ownership Changes

The following situations describe typical types of ownership changes and the process to be followed:

A. Sale or Transfer of a Product(s) Only

CMS does not normally need to be notified of asset sales. However, manufacturers should keep in mind that CMS administers the CGDP based on Labeler Codes. As a result:

- CMS invoices manufacturers for all Applicable Drugs within a Labeler Code. If individual drug products within a Labeler Code are sold, the manufacturer that owns the code is invoiced for all products within the code.
- If an Applicable Drug is covered under an agreement and is then sold to a non-contracted manufacturer that re-labels the drug, such that it no longer is covered under a Discount Agreement, the drug can no longer be covered under Part D.

B. Corporate Sales or Mergers

- **Contracted Manufacturer to Contracted Manufacturer Purchases:** This includes the merger or acquisition of a corporate entity that holds a CGDP Agreement into another corporate entity that also holds a CGDP Agreement. The parent organization involved in these transactions must comply with the Notification Requirements listed in the section entitled "Notification Requirements for Changes in Ownership and Company Name Changes".
- **Contracted Manufacturer to Non-contracted Manufacturer Purchases:** This type of transaction involves the acquisition of a contracted manufacturer by a non- contracted manufacturer. The CGDP Manufacturer's Agreement states that the Agreement is automatically assigned to the new owner, and all terms and conditions of this Agreement remain in effect.

Notification Requirements for Changes in Ownership and Company Name Changes

All organizations considering a change of corporate ownership must notify CMS at least 60 days prior to the anticipated effective date of change. If a manufacturer fails to notify CMS of a change in ownership, the entity risks delayed notification of invoices due, and will be liable for any resulting civil monetary penalties. The notice to CMS regarding a change of ownership, as outlined above, must contain the following information:

- Name and P number(s) of the manufacturers involved in the ownership change, and the anticipated role of each party;
- The anticipated date of the change;
- A statement of which corporate entity will be responsible for processing and paying the invoices after the corporate change; and
- A statement indicating all changes in contacts and when these changes will be requested within HPMS and through the TPA.

All organizations that make a corporate name change must notify CMS immediately and submit a Certificate of Amendment within 30 days of the effective date of change. All required notifications as described above should be sent to CMS by email to: CGDPandmanufacturers@cms.hhs.gov.

Appendix E: Maintenance of FDA Records

CMS relies on FDA listings to identify applicable drugs in the CGDP. Manufacturers must electronically list and maintain up-to-date electronic FDA registrations and listings of all NDCs, including the timely removal of discontinued NDCs from the FDA NDC Directory.

Accurate NDC listings enable CMS and Part D sponsors to accurately identify applicable drugs and, accordingly, updates to the FDA NDC Directory must precede NDC additions made to commercial electronic databases used for pharmacy claims processing.

Manufacturers will not be able to successfully appeal invoiced amounts based on inaccurate or out-of-date FDA NDC Directory listings without documentation that the manufacturer notified the FDA of an error, or requested that an outdated NDC be removed from the Directory, in order to show that it was not a result of manufacturer non- compliance with the CGDP requirement.

In addition, CMS expects manufacturers to maintain up-to-date listings with the electronic database vendors for which they provide their NDCs for pharmacy claims processing. Only the manufacturers know the last-lot expiration dates for their NDCs and therefore, the manufacturers are responsible for ensuring that these electronic database vendors are prospectively notified when NDCs no longer represent products that are still available on the market.

A manufacturer’s failure to document and provide appropriate advance notice to electronic database vendors may result in the manufacturer being responsible for discounts for drugs dispensed after the last-lot expiration date.