



2012 Regional Technical Assistance Presentation Slides



Thursday, August 9, 2012

Prescription Drug Event

Prescription Drug Event



2012 Regional Technical Assistance



Baltimore, MD
August 9, 2012

2012 Regional Technical Assistance



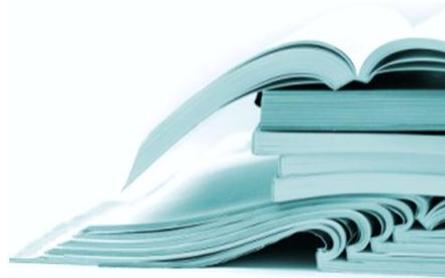
Prescription Drug Event Introduction



Housekeeping



- Materials
- Cell Phones
- Restrooms
- Question & Answer



Introduction
2012 Regional Technical Assistance

Agenda



Welcome
Introduction
Strategic Directions in Part D Payment Policy and Operations
National Drug Code (NDC) Updates & Editing
Break
Medicare Coverage Gap Discount Program
Acumen Website and Invoice/Dispute Process
Question & Answer Session
Adjourn

Introduction
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Purpose



- To provide Prescription Drug Event (PDE) operational and policy updates for Medicare Part D including National Drug Codes (NDCs), Coverage Gap Discount Program (CGDP), and PDE Analysis and Dispute process.

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Audience



- Medicare Advantage–Prescription Drug (MA-PD) Plans
- Stand-alone Prescription Drug Plans (PDPs)
- Third Party Submitters submitting on behalf of a plan
- Industry Association Representatives

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Learning Objectives



- Review strategies for implementing Part D policies and requirements.
- Describe edits associated with NDCs.
- Identify CGDP dispute disposition report and invoicing.
- Explain the invoice and dispute resolution processes.

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Technical Assistance Resources



Resources	
Part D Payment and Policy Questions	pdejan2011@cms.hhs.gov
2011 PDE Participant Guide (2012 version COMING SOON!)	http://www.csscooperations.com/internet/cssc3.nsf/docsCat/CSSC~CSSC%20Operations~Prescription%20Drug%20Event~Training?open&expand=1&navmenu=Prescription^Drug^Event
Customer Service & Support Center (CSSC)	www.csscooperations.com 1-877-534-2772 (CSSC)
Acumen	https://PartD.ProgramInfo.us/PDE PDE@AcumenLLC.com

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Prescription Drug Event

Strategic Directions in Part D Payment Policy and Operations



Purpose

- To inform Prescription Drug Event (PDE) stakeholders of recent policy and operational updates to Medicare Part D.

Learning Objectives



- Describe the strategy for reducing the coverage gap for Medicare beneficiaries.
- List the reasons for and requirements of reporting DIR.
- Identify the responsibilities and activities for the Division of Payment Reconciliation (DPR).

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Overview



- 2013 Advance Notice & Final Announcement
- 2013 Part D Regulation
- Part D DIR Reporting Requirements
- Policy Resources
- Part D Payment Operations

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2013 Advance Notice & Final Announcement

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Background

- Advance Notice informs MAOs, PDPs, and other interested parties about planned changes in the MA capitation rates, Part C payment policies, and Part D payment policies.
- CMS accepts comments and questions on the Advance Notice and considers them as the policies are finalized in the Announcement, which is released by the first Monday of each April.

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- Part D
 - Changes in Part D payment methodology
 - Updates in the Part D Benefit Parameters for the defined standard benefit, low-income subsidy, and retiree drug subsidy

- Continuing to fill in coverage gap for applicable (non-low income) beneficiaries:
 - Affordable Care Act phases in a reduction in beneficiary cost sharing for drugs in the coverage gap phase of the Part D benefit by reducing beneficiary coinsurance for drugs in the gap for non-low-income beneficiaries

Proposed & Finalized Part D Payment Policies for CY 2013 (continued)



- For generic drugs, beneficiaries will be charged 79% coinsurance of the drug's negotiated price
- For brand drugs, beneficiaries will be charged 47.5% of the drug's negotiated price
- By CY 2020, the coverage gap will be closed for non-low-income beneficiaries (after the deductible, they will have 25% cost sharing until catastrophic coverage)

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Proposed & Finalized Part D Payment Policies for CY 2013 (continued)



- **Dispensing and Vaccine Administration Fee**
 - By statute, the definition of “negotiated price” differs in the coverage gap and out of the gap. When in the gap, the term negotiated price does not include dispensing or vaccine administration fees.
 - Four step approach for coverage gap claims to address question of how dispensing and vaccine administration fees for brand drugs are handled in the gap.

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Proposed & Finalized Part D Payment Policies for CY 2013 (continued)



Four Step Approach:

- 1) Manufacturer liability** is calculated by multiplying the 50% discount percentage and the negotiated price (as defined in §1860D-14A(g)(6));
- 2) Beneficiary coinsurance** is calculated by subtracting the 50% discount defined in 42 CFR 423.104(d)(4)(iv) from the applicable gap percentage and multiplying the difference by the negotiated price (as defined in section 1860D-14A(g)(6));

Proposed & Finalized Part D Payment Policies for CY 2013 (continued)



Four Step Approach (continued):

- 3) Beneficiary liability** is calculated by adding the beneficiary coinsurance in Step 2 to a portion of the dispensing fee (and vaccine administration fee, if any) that is commensurate with their coinsurance; and
- 4) Sponsor liability** is calculated as the balance, by subtracting the beneficiary liability and the manufacturer discount amount from the total cost of the applicable drug claim. Part D sponsors must account for their liability for the dispensing fees (and vaccine administration fees, if any) in their Part D bids.

Proposed & Finalized Part D Payment Policies for CY 2013 (continued)



- Cost components of negotiated price – similar approach to determine ingredient cost, sales tax, dispensing fee, vaccine administration fee, and any other cost component
- Updates to all Part D benefit parameters for the defined standard benefit
 - Includes deductible, initial coverage limit, annual out-of-pocket (OOP) threshold, and minimum copayments for costs above the annual out-of-pocket threshold
 - Parameters for the defined standard benefit are indexed to the percentage increase in average per capita total Part D drug expenses for Medicare beneficiaries

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Proposed & Finalized Part D Payment Policies for CY 2013 (continued)

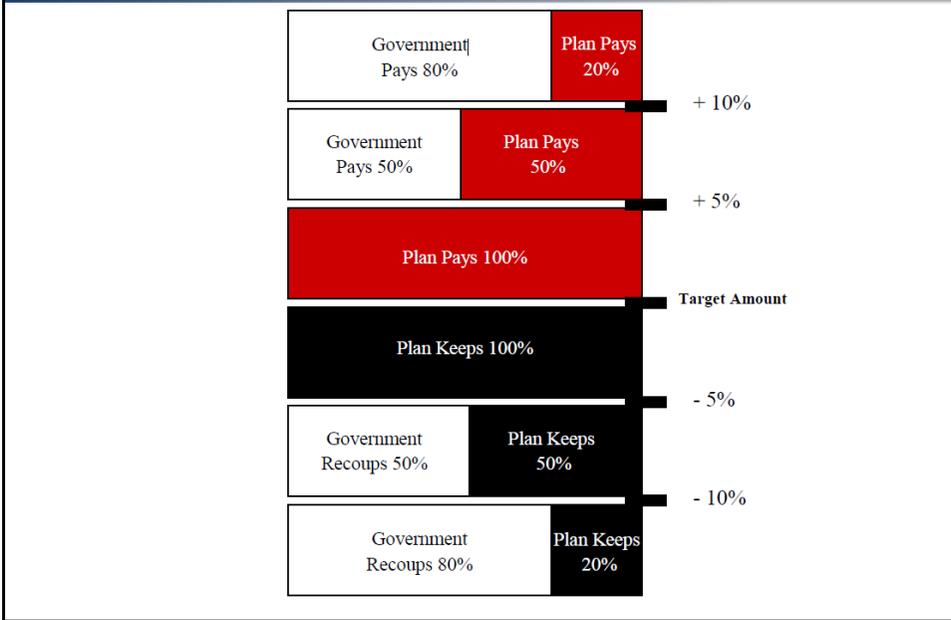


- Maintain risk corridors
 - Federal government and Part D sponsors share unexpected profits or losses
 - No changes to the risk corridors from last year

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Part D Risk Corridors for 2013



2013 Part D Regulation

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CGDP Payment Process



- CMS codified the Coverage Gap Discount Program (CGDP), including the payment processes for Part D sponsors
 - Provide monthly interim coverage gap payments to Part D sponsors (§423.2320(a))
 - CGDP Reconciliation – a process to reconcile the estimated interim coverage gap discount payments with actual Discount Program costs (§423.2320(b))

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“Other Health or Prescription Drug Coverage” and the CGDP



- Manufacturer discount applied before any “other health or prescription drug coverage” such as state pharmaceutical assistance programs (SPAPs), AIDS Drug Assistance Programs (ADAPs), Indian Health Service (IHS), or supplemental coverage required by the Commonwealth of Puerto Rico

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“Other Health or Prescription Drug Coverage” and the CGDP (continued)



- Manufacturer discount also applied before any additional coverage beyond basic Part D coverage, whether offered by an employer group waiver plan (EGWP) or by another party

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Pharmacy Benefits Manager (PBM) Transparency: Section 6005 of the ACA



- Requires PBMs, or any entity that provides PBM services on behalf of a plan, that contracts with a PDP or MAPD to report certain data elements. It also establishes confidentiality protections for reported data and penalties for failure to provide PBM data.

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PBM Transparency: Section 6005 of the ACA (continued)



- The information to be provided includes:
 - Total number of prescriptions that were dispensed;
 - Percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies;
 - Generic dispensing rate by pharmacy type that is paid by the Part D sponsor or PBM under the contract;

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PBM Transparency: Section 6005 of the ACA (continued)



- Aggregate amount and the type of direct and indirect remuneration (DIR) that the PBM negotiates that are attributable to patient utilization under the plan;
- Aggregate amount of DIR passed through to the plan sponsor;
and
- PBM spread (as in, the aggregate amount of the difference between the amount the Part D sponsor pays the PBM and the amount that the PBM pays retail pharmacies and mail order pharmacies).

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DIR Reporting Requirements for 2011

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DIR Implications

- Payment
- Adherence with Section 9008 of the ACA
- DIR Reasonableness Reviews
- OFM Financial Audits
- Division of Payment Validation monitors and evaluates program payment, including DIR

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DIR Reporting Requirements



- CMS is required by statute to calculate two types of payments to insurers (reinsurance and risk sharing) using “allowable reinsurance costs” and “allowable risk corridor costs,” both of which must be actually incurred by the Part D sponsor and net of any applicable direct or indirect remuneration (DIR). For this reason, sponsors must report Summary DIR data each year.

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DIR Reporting Requirements

(continued)



- Section 9008 of the ACA imposes an aggregate annual fee on certain manufacturers of branded prescription drugs. The aggregate annual fee in 2013 will be \$2.8 billion and will be paid by manufacturers or importers with aggregate gross receipts from branded prescription drug sales over \$5 million to specified government programs, including Medicare Part D. CMS must provide Treasury Part D drug sales dollar amounts at the 11-digit NDC level reduced by rebates and other price concessions. For this reason, starting with CY 2010, sponsors must report Detailed DIR data each year.

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DIR Reporting Requirements (continued)



- PBMs often report and retain DIR information for Part D sponsors
- Important to ensure that the Part D sponsor is reviewing the data prior to submission and is reporting 100% of the applicable DIR
- Must ensure that DIR not included on the PDE records is reported in DIR submissions

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New DIR Reporting Requirements for 2011



- Summary and Detailed DIR collected during one reporting window
- Clarification on DIR associated with rejected PDE records
- Approach for bona fide service fees
- New non-DIR field: PBM Incentive Payments
- PBM spread for retail and mail order pharmacy

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Resources

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Resources

- 2013 Advance Notice and Final Announcement at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents.html>

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Resources (continued)



- 2013 Part D Regulation

- Proposed rule: www.gpo.gov/fdsys/pkg/FR-2011-10-11/pdf/2011-25844.pdf
- Final rule with comment period: www.gpo.gov/fdsys/pkg/FR-2012-04-12/pdf/2012-8071.pdf
- Correction to final rule with comment period: www.gpo.gov/fdsys/pkg/FR-2012-06-01/pdf/2012-13362.pdf

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Resources (continued)



- Part D DIR Reporting Requirements for 2011

- Draft guidance: Published on HPMS April 5, 2012
- Final guidance: Published on HPMS May 18, 2012

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Part D Payment Operations

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Division of Payment Reconciliation (DPR)

- Processes 1.6 billion PDEs, per annum
- Collects summary and detailed DIR reports
- Conducts the annual Part D payment reconciliation and re-openings
- Approximately 250 million coverage gap discount program (CGDP) invoices, per annum
- 150-300k manufacturer disputes, per quarter

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Strategic Goals for Reopening Prior Part D Payment Reconciliations



- Account for lags in PDE submissions. For example, CMS has accepted approximately 50 million PDEs with 2010 dates of service (DOS) since the cut-off period for the 2010 reconciliation
- Account for changes in DIR
- Account for audit findings that require adjustment or deletion PDEs and/or adjustments to DIR
- Account for movement, when meaningful, on the prospective payment side

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Cleanup Strategy for Rejected PDEs Impacting the 2011 Reconciliation



- Comprehensive review of edits 671, 738, 834, 867, 870, 871, and 879
- Examine issues with straddle claims and claims from out-of-network pharmacies
- Possible edit code updates for 1st Quarter 2013 and operational/policy guidance

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Lessons Learned From CMS Review of Plan Issues



- PDE rejection issues generally fall into one of the three following categories:
 - Compliance violations by the sponsor with respect to benefits administration or PDE submission;
 - Issues that require more policy and/or PDE submission guidance by CMS; or
 - Coding errors in the Drug Data Processing System (DDPS) or code that does not adequately address special plan types (e.g., EGWPs) or circumstances (e.g., out-of-network claims).

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Lessons Learned From CMS Review Of Plan Issues *(continued)*



- Issues are best identified and brought to CMS via industry associations and workgroups. This helps to define scope, determines if an issue is program-wide, and improves efficiency.
- When possible, specific examples should be provided when an issue is brought to CMS.
- CMS cannot have individual conference calls with each plan, its subcontractors, consultants, and law firms.

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Oversight



- DPRs analytic oversight (Acumen and outlier edit outreach) activities are not intended to produce compliance actions. By contrast, these efforts exist to help fix issues before they become a compliance matter.

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Oversight (continued)



- However, DPR is required to implement changes (e.g., new edits or taking back payment) based on traditional audit oversight activities, such as the OFM 1/3 audits, the Part D Recovery Audit Contractor (RAC), and audits from the HHS Office of Inspector General (OIG).

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CGDP Challenges



- Manufacturer disputes and appeals
- Development of systems and processes to credit manufacturers for retroactive adjustments to invoices and upheld disputes or appeals
- Instability in NDC data
- Gap discount edits and guidance

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Probable Changes to the Drug Data Processing System (DDPS)



- Adding Patient Residence (NCPDP 384-4X), Pharmacy Service Type (NCPDP 147-U7), and Submission Clarification Code (NCPDP 42Ø-DK) to the PDE record by 1st or 2nd Quarter 2013
- Edit modifications for barbiturates, coverable in 2013 for certain indications

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Probable Changes to the Drug Data Processing System (DDPS) (continued)



- Edit modifications for Supplementary Patient Liability Reduction due to Other Payer Amount (PLRO) for EGWPs in 2013
- Edit modifications for 2013 dispensing fees policy

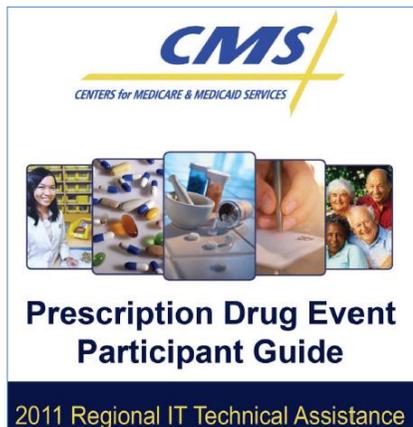
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PDE Training Guide vs Manual



- Will release updated version after the conference
- In the future, this guide will be the foundation for a Part D Payment Operations Manual Chapter



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Encounter Data

Prescription Drug Event

Risk Adjustment Processing System

TPA / Drug Manufacturer

Welcome to CSSC Operations

The CSSC website is the gateway to Medicare Advantage, TPA, Prescription Drug and Coverage Gap Discount Programs. Visitors to the site can access information about Risk Adjustment, Encounter Data, Prescription Drug and Coverage Gap Discount Program; 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.

NEWS

Encounter Data

Encounter Data End-to-End Testing - Certification

SYSTEM STATUS

All Systems

All Systems and Report Distributions are Current



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Acronyms



ACA	Affordable Care Act
ADAP	AIDS Drug Assistance Program
CGDP	Coverage Gap Discount Program
CMS	Centers for Medicare & Medicaid Services
CY	Calendar Year
DDPS	Drug Data Processing System
DIR	Direct and Indirect Remuneration
DOS	Dates of Service
DPR	Division of Payment Reconciliation
EGWP	Employer Group Waiver Plan
MA	Medicare Advantage
MAO	Medicare Advantage Organization

Acronyms (continued)



MAPD	Medicare Advantage Prescription Drug
NDC	National Drug Code
OFM	Office of Financial Management
OIG	Office of Inspector General
OOP	Out-of-Pocket
PBM	Pharmacy Benefits Manager
PDE	Prescription Drug Event
PDP	Prescription Drug Plan
PLRO	Patient Liability Reduction Due to Other Payer Amount
RAC	Recovery Audit Contractor
SPAP	State Pharmaceutical Assistance Programs

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Evaluation

Please take a moment to complete the evaluation form for the following module:

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Your Feedback is Important!

Thank you!



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Prescription Drug Event National Drug Code (NDC) Updates & Editing



Purpose

- To address updates related to National Drug Code (NDC) usage and edits including the use of the FDA's Comprehensive NDC Structured Product Labeling Data Elements File (NSDE).

Learning Objectives



- Describe PDE editing using the FDA's Comprehensive NDC Structured Product Labeling Data Elements File (NSDE).
- Review edits 738 and 867.
- Define coverage of Cialis and upcoming coverage for benzodiazepines and barbiturates.

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NSDE



- Memo, May 14, 2012: Implementation starting September 1, 2012 of PDE Editing using the FDA Online Label Repository
 - NDC Structured Product Labeling Data Elements file (NSDE)
 - NSDE file can be located on the FDA site at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm240580.htm>

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- Effective on September 1, 2012 for PDEs with DOS on or after September 1, 2012
 - PDEs with DOS prior to September 1, 2012 will continue to be edited under the current process

- Implications
 - PDEs with DOS on or after September 1, 2012 for NDCs that are not electronically listed by the manufacturer with the FDA will be rejected
 - Electronic listing requirement is NOT limited to brand name drugs nor to the Coverage Gap Discount Program
 - It applies to all package sizes, including inner package sizes
 - Rejection of PDEs when submitted to CMS
 - Possible rejection of PDEs at point-of-sale

- The implementation of the use of the NSDE file is an addition to the current PDE editing process
 - Current editing will still be completed on PDEs
 - CMS uses First Databank and MediSpan to edit NDCs on PDEs before the PDE continues through the PDE editing process
 - CMS will use the NSDE file posted on the 15th of each month to update our editing files on the 1st of each following month

- Coverage Gap Discount Program
 - For PDEs with DOS on or after September 1, 2012, CMS will use the NSDE to make marketing category determinations
 - For PDEs with DOS prior to September 1, 2012, CMS will continue to use data from both the new FDA NDC Directory and the old FDA NDC Directory

Edit 738



- CMS frequently receives emails from sponsors regarding PDEs that have received Edit 738
 - Edit 738 is “The NDC identifies a Part D Non-coverable Drug”
 - Any PDE that receives a 738 error will be returned with the subcategory to which the NDC is assigned which will clearly indicate the reason that CMS rejected the data
 - The subcategory is listed in Field 73 of the PDE Return File Layout

National Drug Code (NDC) Updates & Editing
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Edit 738 (continued)



- Beginning February 2009, CMS implemented a new “NDC Redesign” function in DDPS
 - Developed specific subcategories and reject codes that better group NDC and explain their likely non-Part D drug status
(Memo, Dec. 9, 2008: Update on National Drug Codes)
 - Since February 2009, additional subcategories have been added to provide better assistance to sponsors

National Drug Code (NDC) Updates & Editing
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Edit 738 (continued)



Subcategory	Description	Subcategory	Description
000	Default	209	FDA notice
201	Barbiturate	210	Fertility Agent
201	Benzodiazepine	211	Ingredient/Adjuvent
203	Bulk	212	Line Flush
204	Cough/Cold	213	Medical Supply
205	Cosmetic	215	OTC
206	DESI	216	Part A/Part B
207	Device	217	Vitamin/Mineral
208	Erectile Dysfnct	218	Weight Agent

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Edit 738 (continued)



Subcategory	Description	Subcategory	Description
220	NDC Not On Market	306	Fluoride Prep
221	Cialis for BPH 5mg	308	Insulin Syringe
222	Cialis for BPH 2.5 mg	310	Prenatal Vitamin
301	Alcohol Swab	311	2X2 Gauze
302	Antidote/Antitoxin	312	Miscellaneous
303	Category Exception	313	Vaccine
304	Diabetic Agent	314	HCR Exception
305	Electrolyte Fluid		

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Edit 867



- CMS frequently receives emails from sponsors regarding PDEs that have received Edit 867
 - Edit 867 is “FDA does not designate this drug as NDA or BLA; therefore it is ineligible for the coverage gap discount”
(Memo, May 4, 2012: Update on PDE 867 Edits)

Edit 867 (continued)



- CMS conducted a program-wide analysis of PDEs that triggered 867 edits
 - Minor instability in the NDC data files
 - Update of listing information with FDA corrected some of these fluctuations
 - Slightly over 20% of PDEs who received edit 867 were able to successfully resubmit after a listing correction

- Fluctuation in NDC data
 - Changing of Marketing Category Start and End Dates upon electronic listing with FDA
 - Retroactivity of changes when applied to PDEs
 - Missing listing information for inner packages
 - Multiple listings of a single NDC for different marketing categories with the FDA

- On October 6, 2011, the FDA approved the use of the drug Cialis to treat Benign Prostatic Hyperplasia (BPH)
 - CMS will accept PDEs for Cialis prescribed as 1 tablet per day at the 5mg strength or 2 tablets per day at the 2.5mg strength
 - Effective May 27, 2012
 - PDEs for DOS on or after October 6, 2011
 - No other strengths or dosages will be accepted

Coverage of Cialis (continued)



- Reject edit code 745
 - “Medicare does not pay for this drug for this strength and/or daily supply”
 - Triggered when
 - The DOS is on or after October 6, 2011 AND
 - Either more than one 5mg tablet per day or two 2.5mg tablets per day are prescribed
 - Edit will also trigger if the days supply or quantity dispensed field is zero

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Coverage of Benzodiazepines & Barbiturates



- Coverage of benzodiazepines under Part D
 - Effective January 1, 2013
- Coverage of barbiturates under Part D
 - Effective January 1, 2013
 - Only for 3 specified medical indications:
 - Treatment of epilepsy
 - Treatment of cancer
 - Treatment of a chronic mental health disorder

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Coverage of Benzodiazepines & Barbiturates (continued)



- Like any other prescription drug under the Part D benefit program, barbiturates as specified and benzodiazepines must meet all other conditions for Part D drugs found in §423.100
- CMS will provide communication through HPMS as more information and/or guidance is developed prior to the January 1, 2013 implementation date

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Evaluation

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National Drug Code (NDC) Updates & Editing

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Prescription Drug Event Coverage Gap Discount Program



Purpose

- To provide a summary of the analysis of the Coverage Gap Discount Program (CGDP), milestones achieved, and future direction.

Learning Objectives



- Summarize the accomplishments of the CGDP in the past year.
- Interpret the benefit for the Contract/Sponsor Dispute Disposition Report.

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Learning Objectives (continued)



- Identify when negative invoices occur and responsibilities for resolution.
- Describe the purpose for and benefits of the Contract/Sponsor Online Payment Confirmation process.

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Overview



- Review of the past year's milestones
 - EFT
 - Multiple Benefit years
 - Elimination of the low volume pended PDEs
- Future directions
 - Sponsor Dispute Disposition Report
 - Negative Invoices
 - CGDP Recon
 - Contract/Sponsor Online Payment Confirmation

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Invoice and Discount Statistics



- Benefit Year 2011 in Calendar Year 2011
 - 270 Drug Manufacturers under contract in CGDP
 - 750+ Contracts providing discount at POS
 - Quarters 1 – 4 2011
 - 200+ Manufacturers
 - 598 Contracts
 - 103,343 Invoices
 - \$2,000,000,000+ in discounts paid to Contracts on behalf of Medicare Beneficiaries!

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Electronic Funds Transfer (EFT)



- Improved the EFT file update process
 - Allowed online update to EFT information on TPA website
 - Added updates for bank account and EFT type
 - Developed Quarterly update process
 - Published Quarterly EFT file update schedule on TPA website
 - <http://www.csscooperations.com/eftcalendar>

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Multiple Benefit Years



- Multiple Benefit Years
 - Quarterly reports and Dispute Submission – completed for Quarter 1 2012
 - Dispute Resolution – coming in August to complete changes for Quarter 1 2012
 - Multiple Benefit year amounts accumulated into one payment per invoice

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Multiple Benefit Years (continued)



- Program Calendar added to TPA website
<http://www.csscooperations.com/cgdpcalendar>

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Low Volume



- Farewell Low Volume!
 - Original intent was to protect beneficiary privacy
 - Analysis determined that it could be safely eliminated with no negative impact to privacy or confidentiality
 - Eliminated Quarter 4 2011 – removed pended status and L-V indicator
 - Released PDEs for processing
 - Reduced the number of pended PDEs by 20+ million
 - Increased invoiced \$\$\$ by \$1,000,000,000+
 - Improved timeliness of reimbursement to contracts

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Contract/Sponsor Dispute Disposition Report



- Contract/Sponsor Dispute Disposition Report
 - Implementing for Quarter 1 2012
 - Shows final disposition of disputed PDEs

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Negative Invoices/Negative Line Items



- Occur when an adjustment to a PDE results in a negative value
- Common when a PDE is invoiced in one quarter and adjusted in another
- Results in a negative line item appearing on an invoice
- Usually absorbed within the same quarter by other invoiced PDEs
- If not absorbed, then it is \$\$s owed to the manufacturer

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Negative Invoices/Negative Line Items (continued)



- Solution Development – Analysis and Requirements
 - One-off mini reconciliation to get up to date
 - Tentative Quarter 4 2012
 - Regularly scheduled once per year beginning 2013

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Negative Invoices/Negative Line Items (continued)



- Method of payment
 - Deduct from future invoice?
 - If no future invoice, refund by
 - Reverse EFT?
 - Check?
 - Other method?
- Industry input desired – focus group, system testers

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CGDP Reconciliation



- Annual cost-based reconciliation
- Based on submitting contract
- Begins after the sixth invoicing and payment processing cycle has been completed
- Amounts reconciled are from invoiced PDEs

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CGDP Reconciliation Calculation



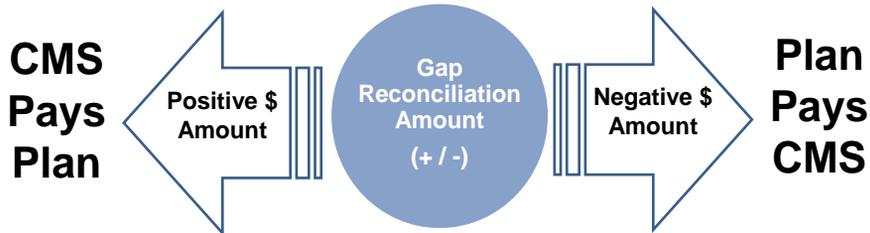
Actual Gap Discount is the amount of the discount calculated from the PDEs

Total CGD Payments are the total of all interim payments paid to the plan

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CGDP Reconciliation Calculation (continued)



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Contract/Sponsor Online Payment Confirmation



- In development now!
 - Ready for testing Quarter 3 2012 (tentative)
 - NO more ...
 - Copying the detail report
 - Creating, editing, and sending a new file to the TPA
 - Interpreting complicated file layouts
 - Overpunch!

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Contract/Sponsor Online Payment Confirmation (continued)



- Industry input needed for testing
 - Willing to parallel test for at least one quarter
 - This means preparing confirmation report manually AND through the new online system



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Contract/Sponsor Online Payment Confirmation (continued)



- How will it work?
 - Log on to TPA web site Payment Confirmation application
 - Choose from a list of your Quarterly Contract reports
 - See the amounts due to you from the manufacturers
 - Confirm payments by screen or by item
 - Receive error messages and instructions on how to fix in real time
 - Payment Confirmation file is formatted and submitted for you
 - Print or download confirmation file

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Summary



- Reviewed
 - Invoice and Discount statistics
 - EFT
 - Multiple Benefit years
 - Elimination of Low volume pended PDEs
- Future Direction
 - Contract/Sponsor Dispute Disposition Report
 - Negative Invoices
 - CGDP Recon
 - Contract/Sponsor Online Payment Confirmation

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Evaluation

Please take a moment to complete the evaluation form for the following module:

Coverage Gap Discount Program

Your Feedback is Important!
Thank you!



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Prescription Drug Event

Acumen Website and Invoice/Dispute Process



Purpose

- This module addresses the PDE Analysis Website, invoicing and the PDEs withheld from invoice analysis, the manufacturer dispute process, and the CGDP and Part D reconciliation data quality reviews.

Learning Objectives



- Identify the timeframe for submitting valid responses to PDE Analysis Website.
- Explain the invoice process flow.
- Describe reasons PDEs may be withheld from invoices.

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Learning Objectives (continued)



- List three issues resulting from CGDP quality reviews that could be subject to disputes.
- Identify two PDE data quality issues occurring in advance of Part D payment reconciliation.

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PDE Analysis Website



- Initiated in 2009, the PDE Analysis website addresses PDE data quality issues beyond the rigorous online editing process
- The PDE data quality review focuses on
 - PDE data at a beneficiary level vs. PDE level
 - NDC and pharmacy data

> PDE Analysis

Issue Tracking

On this page, Contracts can monitor the resolution status of PDEs identified with data quality issues.

For PDEs identified with a Manufacturer Dispute, submit a Dispute Response Form for each identified PDE.

For PDEs identified with all other data issues:

- For tickets that require correction: Adjust or delete the PDE through DDPS.
- For tickets found to be valid: Submit a Valid Response Form to substantiate validity.

Search

Contract: ALL

Ticket Number:

Year of Service: ALL

PDE Issue: Withheld from Manufacturer Invoice

Gap Discount: ALL

Ticket Status: ALL

Contract	Ticket Number	CCDP	Deadline	Current Status	Last Update	Discuss Ticket	Reviewed
T0001	T0001_Q12012_WMND0001	Yes	06/26/2012	Unresolved	07/10/2012	Start Discussion	
T0001	T0001_Q12012_WMND0002	Yes	06/26/2012	Unresolved	07/10/2012	Start Discussion	
T0001	T0001_Q12012_WPHM0001	Yes	06/26/2012	Unresolved	07/10/2012	Start Discussion	
T0001	T0001_Q12012_WRLD0001	Yes	06/26/2012	Unresolved	07/10/2012	Start Discussion	

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PDE Analysis Website (continued)



- Issues reports to sponsors when
 - PDEs are flagged as outliers in the data
 - Sponsor feedback is needed during the manufacturer dispute process
- Sponsors receive email notification when their PDEs are posted to the website
- Sponsors are expected to review, investigate, and act on reports:
 - If valid, briefly explain why the PDE is valid; or
 - If invalid, adjust/delete the PDE accordingly

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- Example of a sponsor response form

PDE Issue Response Form

Contract ID: [Return to Instructions](#) Form Status
Incomplete

I, certify that the following information is accurate to the best of my knowledge.

Responder Information		
Position	Email	Phone
<input type="text"/>	<input type="text"/>	<input type="text"/>

Enter the Ticket Number(s), select the Status of the ticket (Valid or Needs Correction), and enter an explanation of the selected status.

Ticket Number	Status of Ticket	Explanation	Status
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

- The PDE data quality initiative is used for
 - Part D Payment Reconciliation Data Quality Review since 2009
 - PDEs Withheld from Invoice (since 2011)
 - General CGDP Data Quality Review (since 2011)
 - Manufacturer Dispute Process in collaboration with the TPA (since 2011)



New Timeframes for Response to Website

PDE Data Quality Review	Timeframe to Provide VALID RESPONSE	Timeframe to Adjust/Delete PDE
Part D Payment Reconciliation	14 calendar days	90 calendar days
General CGDP Review	14 calendar days	
Withheld from Invoice Review	14 calendar days	
Manufacturer Disputes	10 calendar days	

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- On a quarterly basis, prior to generating an invoice:
 - CMS aggregates Gap Discount amounts reported on PDE data
 - CMS performs data quality review on gap discount PDEs
 - Flagged PDEs are withheld from invoice generation

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PDEs Withheld from Invoice (continued)

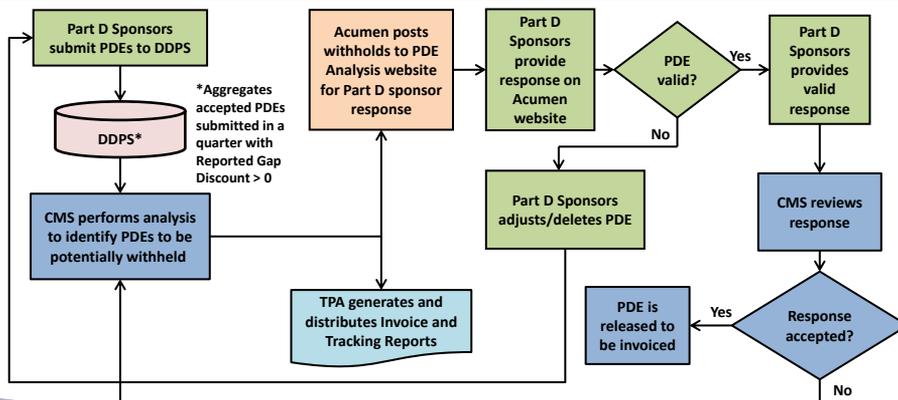


- The TPA sends quarterly invoice reports to manufacturers and Part D sponsors
- At the same time, PDEs withheld from invoice are sent to the Acumen PDE Website for sponsor review and response
- The Coverage Gap Tracking Report provides the status (withheld or invoiced) of each gap discount PDE

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Invoice Process Flow



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PDEs Withheld from Invoice

(continued)



- Retroactive disenrollment of the beneficiary
 - No Part D enrollment in any plan on the DOS
 - CMS validates beneficiary enrollment on all accepted PDEs with Reported Gap Discount (RGD) prior to generating invoices
 - CMS identifies periods of no Part D enrollment in any plan on DOS
 - If the beneficiary lost enrollment on the DOS, the affected PDEs are withheld from invoice and posted to the PDE Analysis website

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Withheld from Invoice Analysis



- Retroactive disenrollment of the beneficiary
 - Deceased beneficiaries
 - CMS also validates the DOS for deceased beneficiaries who received gap discounts during the quarter
 - For deceased beneficiaries, if DOS is greater than 32 days after DOD, the PDE is withheld from invoice and posted to the PDE Analysis website

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Withheld from Invoice Analysis

(continued)



- Retroactive low income status of the beneficiary
 - Prior to invoice generation, CMS validates the LI status of all beneficiaries with Reported Gap Discount amounts
 - If the beneficiary is retroactively made LI eligible on the DOS, the affected PDEs are withheld from invoice and posted to the PDE Analysis website

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Withheld from Invoice Analysis

(continued)



- The PDE reports a closed pharmacy
 - CMS identifies gap discount PDEs in which the DOS reported on the PDE is after the closing date of the pharmacy
 - Occurs when a pharmacy closes or changes ownership
 - Affected PDEs are withheld from invoice and posted to the PDE Analysis website

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Withheld from Invoice Analysis (continued)



- The beneficiary's total Reported Gap Discount is greater than the maximum total Reported Gap Discount (Total RGD > Max Tot RGD)
 - Beneficiary level analysis
 - Compares beneficiary's total Reported Gap Discount amount to the maximum total Reported Gap Discount amount (by benefit year)

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Withheld from Invoice Analysis (continued)



- The beneficiary's total Reported Gap Discount is greater than the maximum total Reported Gap Discount
Total RGD > Max Tot RGD
 - Maximum total Reported Gap Discount amount = 50% of the remaining coverage gap (after the deductible and coinsurance in the ICL)

Benefit Year	Maximum Total Gap Discount Amount Threshold
2011	\$1821.86 +/- \$0.05
2012	\$1,900.20 +/- \$0.05
2013	\$1,992.26 +/- \$0.05

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Withheld from Invoice Analysis (continued)



- Beneficiary's Total RGD > Max Tot RGD
 - Max Tot RGD is the threshold to withhold PDEs
 - All PDEs exceeding the threshold are withheld from invoice
 - Plans should review all PDEs with Reported Gap Discounts provided to the beneficiary during the benefit year, not just the quarter, when responding to the PDE Analysis website posting
 - Applies to defined standard plans only

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Withheld from Invoice Analysis (continued)



- The Reported Gap Discount is greater than remaining TrOOP (RGD > Remaining TrOOP)
 - Conducted at the PDE level
 - Compares Reported Gap Discount on PDE to remaining TrOOP
 - Remaining TrOOP = OOP Max – TrOOP Accumulator Amount

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Withheld from Invoice Analysis

(continued)



- Example (benefit year 2012): Reported Gap Discount is greater than remaining TrOOP

Drug Coverage Status Code	Patient Pay Amount	Reported Gap Discount	TGDC Accumulator	TrOOP Accumulator	Remaining TrOOP
C	\$75.00	\$75.00	\$6,625.00	\$4,650	+ \$50.00

- RGD is greater than remaining TrOOP
- PDE is withheld from invoice and posted to PDE Analysis website

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Withheld from Invoice Analysis

(continued)



- The beneficiary's total Reported Gap Discount is greater than the OOP Maximum (Total RGD > OOP Maximum)
 - At beneficiary level
 - TrOOP maximum used to flag the beneficiary as an outlier

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Withheld from Invoice Analysis

(continued)



- The beneficiary's total Reported Gap Discount is greater than the OOP Maximum (Total RGD > OOP Maximum)
 - Max Tot RGD is the threshold to withhold PDEs
 - All PDEs exceeding the threshold are withheld from invoice

Benefit Year	Maximum Total Gap Discount Amount Threshold
2011	\$1821.86 +/- \$0.05
2012	\$1,900.20 +/- \$0.05
2013	\$1,992.26 +/- \$0.05

Acumen Website and Invoice/Dispute Process
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Withheld from Invoice Analysis

(continued)



- The beneficiary's total Reported Gap Discount is greater than the OOP Maximum (Total RGD > OOP Maximum)
 - Plans should review all Reported Gap Discounts provided during the benefit year, not just the quarter, when responding to the PDE Analysis website posting
 - Includes all plan types

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Withheld from Invoice Analysis

(continued)



- Your PDE is withheld from invoice, now what?
 - Use the Coverage Gap Tracking Report to identify withheld PDEs
 - Download Withheld PDEs Reports from PDE Analysis website
 - Investigate PDEs to determine if the PDE is valid or needs correction or deletion

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Withheld from Invoice Analysis

(continued)



- Your PDE is withheld from invoice, now what?
 - If valid, briefly explain why on Response Form within 14 days
 - If the PDE data is invalid, make adjustments to PDE(s), enrollment data, or other relevant data as necessary

PDE Issue Response Form			
Contract ID: <input type="text"/>	Return to Instructions		Form Status Incomplete
I, <input type="text"/> , certify that the following information is accurate to the best of my knowledge.			
Responder Information			
Position	Email	Phone	
<input type="text"/>	<input type="text"/>	<input type="text"/>	
Enter the Ticket Number(s), select the Status of the ticket (<i>Valid</i> or <i>Needs Correction</i>), and enter an explanation of the selected status.			
Ticket Number	Status of Ticket	Explanation	Status
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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General CGDP Data Quality Review



- Identifies PDE data quality issues that could potentially lead to inaccurate invoicing or manufacturer disputes
 - Pricing Errors in High Cost Drugs – Per Unit Price (PUP) Outliers
 - Misreported Quantities – Quantity (QTY) Outliers
 - Potential Duplicate PDEs – Duplicate (DUP) Outliers
- Posted to the website approximately every six-eight (6-8) weeks
- Currently not withheld from invoice

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General CGDP Data Quality Review (continued)



- Pricing Errors in High Cost Drugs – Per Unit Price (PUP) Outliers
 - Identifies PDEs with potentially erroneous pricing using an algorithm based on unit cost
 - Flags PDEs in which the per-unit price of the drug is substantially higher than the program-wide median for the National Drug Code (NDC)
 - Per Unit Price = Ingredient Cost/Quantity Dispensed
 - Applies to PDEs with a positive reported gap discount amount and a Gross Drug Cost (GDC) of \$100 or higher

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General CGDP Data Quality Review (continued)



- **Misreported Quantities – Quantity (QTY) Outliers**
 - Flags PDEs with potentially misreported values in the Quantity Dispensed field
 - Identifies PDEs in which daily dosage exceeds maximum daily dosage and the program-wide median daily dosage for the NDC
 - Daily Dosage = Quantity Dispensed/Days Supply
 - Applies to PDEs with Reported Gap Discount > \$0 and with Total Gross Drug Costs > \$100

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General CGDP Data Quality Review (continued)



- **Potential Duplicate PDEs – Duplicate (DUP) Outliers**
 - In DUP Analysis, duplicates are defined as PDEs with matching information for the following:
 - Beneficiary
 - Date of Service
 - NDC

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General CGDP Data Quality Review (continued)



- **Potential Duplicate PDEs – Duplicate (DUP) Outliers**
(continued)
 - In contrast, DDPS online editing uses the following fields to identify and reject duplicates after verifying HICN:
 - Date of Service
 - Service Provider ID
 - Service Provider ID Qualifier
 - Prescription Service Reference Number
 - Fill Number

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General CGDP Data Quality Review (continued)



- **Potential Duplicate PDEs – Duplicate (DUP) Outliers**
(continued)
 - Algorithm excludes potential vacation fills & other legitimate scenarios which could potentially register as duplicate PDE submissions
 - At least one PDE in the potential duplicate set must have Reported Gap Discount > \$0
 - Applies when the sum of Total Gross Drug Costs across the potential duplicate set is at least \$100

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Manufacturer Disputes Overview



- Manufacturers have the right to dispute invoices within 60 days of receipt
- CMS has 60 days to make a dispute determination
- Such notice from the manufacturer shall be accompanied by supporting evidence that is material, specific, and related to the dispute or issue
- CMS will deny disputes if the discount payment is accurately calculated based upon accurate data for dispensing events that actually occurred

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Manufacturer Disputes Overview

(continued)

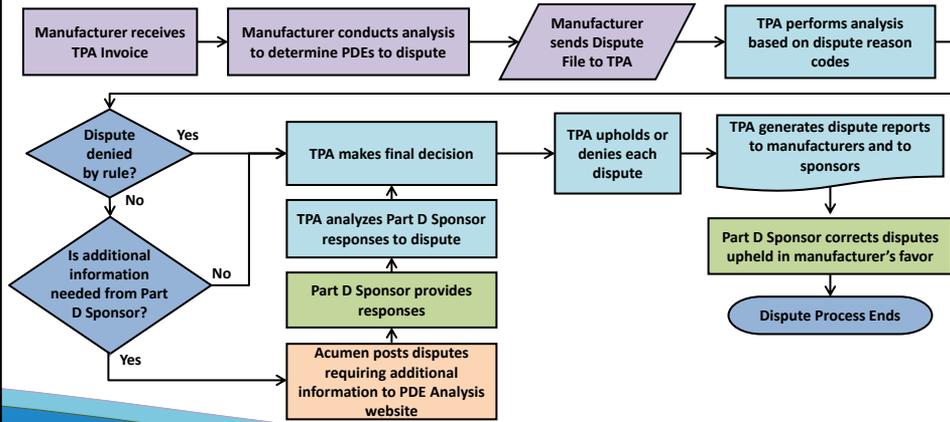


- The Manufacturer shall not withhold any invoiced discount payments pending dispute resolution
- CMS will adjust future invoices as necessary pending the outcome of any disputes
- CMS issued guidance on the dispute process for the manufacturers on March 5, 2012, titled “Medicare Coverage Gap Discount Program—Dispute Resolution”

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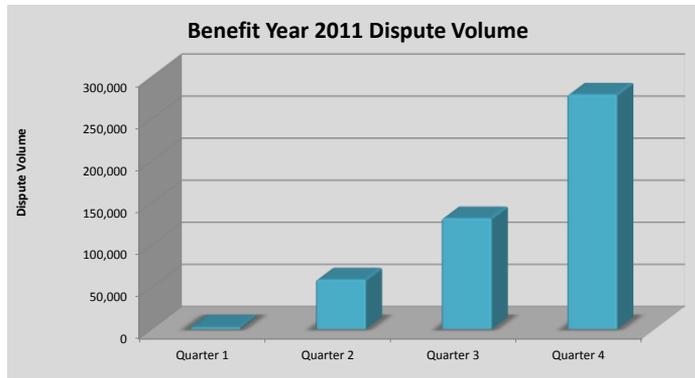
34

Dispute Process Flow



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Manufacturer Disputes



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Manufacturer Disputes (continued)



DISPUTE REASON CODE	DISPUTE REASON DESCRIPTION
D01	Duplicate Invoice Item
D02	Closed Pharmacy
D03	Not PART D Covered Drug
D04	Excessive Quantity
D05	Invalid Days Supply
D06	High Price of the Drug
D07	Last Lot Expiration Date
D08	Early Fill
D09	Marketing Category is not NDA or BLA
D10	Date of Service prior to 01/01/2011

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Manufacturer Disputes (continued)



DISPUTE REASON CODE	DISPUTE REASON DESCRIPTION
D11	PDE improperly invoiced beyond Manufacturer Agreement Invoice period
D12	Invalid Prescription Service Reference Number
D13	Gap discount for disputed PDE exceeds maximum discount amount for a single PDE
D14	Total accumulated gap discounts reported across multiple PDEs for a single beneficiary exceed cumulative maximum discount amount
D99	Other

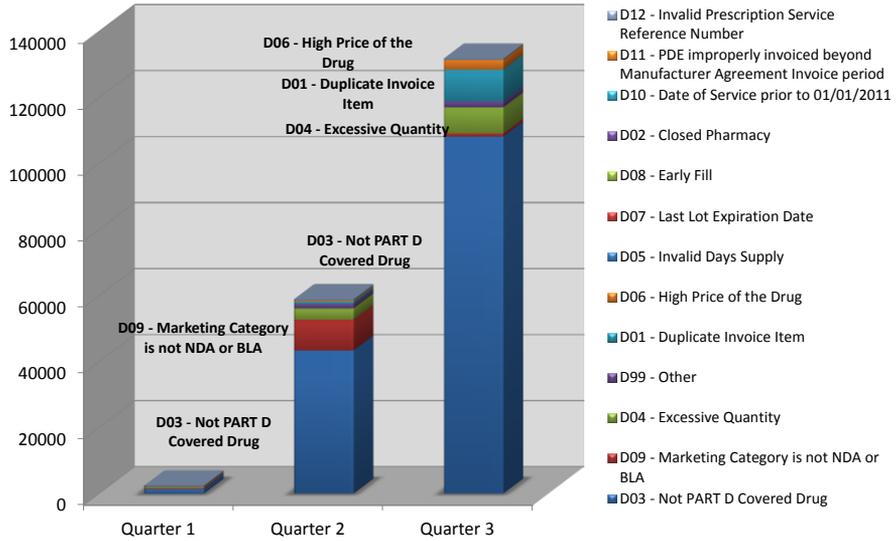
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Dispute Volume by Quarter



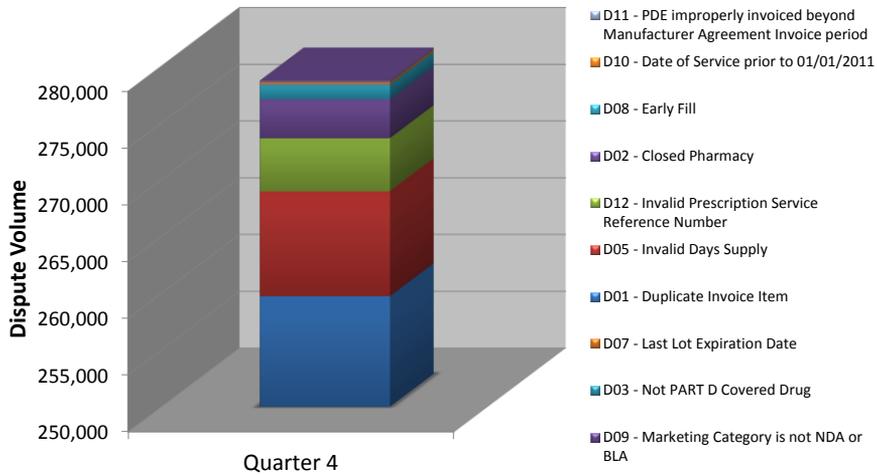
Dispute Volume by Quarter



Dispute Volume by Reason Code



Dispute Volume by Reason Code - Q4 2011



Dispute Resolution



- The TPA can either uphold the dispute in the manufacturer's favor or deny the dispute
- If the dispute is upheld, the sponsor is expected to adjust or delete the PDE accordingly
- To date, 99% of disputes have been denied

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Part D Sponsor's Role in the Dispute Determination



- Disputed PDEs may be posted to the PDE Analysis website to assist the TPA in its determination
- Disputed PDEs are posted quarterly, approximately two-three (2-3) months after the invoices are released
- Sponsors must respond within ten (10) calendar days with explanation that
 - The PDE is valid; or,
 - The PDE has been or will be adjusted or deleted

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Manufacturer Disputes



Most of the upheld disputes have been in three categories:

- Excessive Quantity,
- Invalid Days Supply, and
- High Price of the Drug

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Disputes for Excessive Quantity



- Successful disputes demonstrate that the quantity reported on the PDE is excessive, invalid, and/or unlikely in the Medicare population
- Relevant PDE fields: Product Service ID, Quantity Dispensed, Days' Supply

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Disputes for Invalid Days' Supply



- Successful disputes demonstrate that the Days' Supply reported on the PDE is inconsistent and/or unlikely in the Medicare population
- Relevant PDE fields: Product Service ID, Quantity Dispensed, Days' Supply

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Disputes for Excessive Quantity & Invalid Days' Supply



- The dispute process is not intended to be a retrospective utilization management review where the clinical decision making of the prescriber, provider, or Part D plan is called into question

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Disputes for Excessive Quantity & Invalid Days' Supply (continued)



- To prevent Quantity & Days' Supply disputes, Part D Sponsors should ensure that reported Quantity Dispensed and/or Days' Supply are consistent with the NDC reported on the PDE
- CMS utilizes the CGDP Quantity (QTY) Outliers to identify potential inconsistencies in the Days' Supply and Quantity Dispensed fields

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Disputes for High Price of the Drug



- Successful disputes demonstrate that the per unit price is excessive relative to the per unit price paid under the Part D program
- Per Unit Price = Ingredient Cost/Quantity Dispensed
- Relevant PDE fields: Ingredient Cost, Quantity Dispensed, Product Service ID

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Responding to Posted Disputes



- Do respond timely
- Do provide a concise explanation to address the disputed concern



- Do not provide a non-specific response (i.e., "The PDE is valid")

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Dispute Resolution Report



- Provides sponsors with information on which invoiced items are disputed and final dispute determination (upheld/denied)
- Report will be available for release of Q1 2012 dispute determinations

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Part D Payment Reconciliation Data Quality Review



- Identifies PDE data quality issues in advance of Part D payment reconciliation
- Posted to the website approximately every four (4) weeks
- Categories of analysis include:
 - High Cost Drugs – Total Gross Drug Cost (GDC) Outliers
 - Pricing Errors in High Cost Drugs – Per Unit Price (PUP) Outliers
 - Misreported Quantities – Quantity (QTY) Outliers
 - Potential Duplicate PDEs – Duplicate (DUP) Outliers

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Part D Payment Reconciliation Data Quality Review (continued)



- Categories of analysis include (continued):
 - Attachment and Catastrophic CPP Issues – Attachment CPP (ACP) and Catastrophic CPP (CCP) Outliers
 - Medicare as Secondary Payer Issues – Medicare as Secondary Payer (MSP) Outliers
 - Drugs Potentially Not Covered under Part D – Covered Drug (CVD) Outliers

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Part D Payment Reconciliation Data Quality Review (continued)



- High Cost Drugs – Total Gross Covered Drug Cost (TGDC) Outliers
 - Flags PDEs reporting Total Gross Covered Drug Cost greater than \$50,000 as a high cost outlier
 - For this analysis, TGDC is the sum of Ingredient Cost, Dispensing Fee, Sales Tax, and Vaccine Administration Fee
 - Flags PDEs with TGDC between \$20,000 and \$50,000 if the TGDC is substantially higher than the median for the NDC

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Part D Payment Reconciliation Data Quality Review (continued)



- Pricing Errors in High Cost Drugs – Per Unit Price (PUP) Outliers
 - Identifies PDEs with potentially erroneous pricing using an algorithm based on unit cost
 - Flags PDEs not captured in the Gross Drug Cost (GDC) outliers when per-unit price is substantially higher than the program-wide median for the NDC
 - Per Unit Price = Ingredient Cost/Quantity Dispensed
 - Applies to PDEs with GDC of \$100 or higher and no gap discount amount

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Part D Payment Reconciliation Data Quality Review (continued)



- **Misreported Quantities – Quantity (QTY) Outliers**
 - Identifies PDEs with potentially misreported values in the Quantity Dispensed field
 - Flags PDEs in which the daily dosage exceeds the maximum daily dosage and the program-wide median daily dosage for the NDC
 - Daily Dosage = Quantity Dispensed/Days Supply
 - Applies to PDEs without reported gap discount amount and a Total Gross Drug Cost (TGDC) of \$2000 or higher

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Part D Payment Reconciliation Data Quality Review (continued)



- **Potential Duplicate PDEs – Duplicate (DUP) Outliers**
 - For this analysis, duplicates are defined as PDEs with matching information for the following:
 - Beneficiary
 - Date of Service
 - NDC

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Part D Payment Reconciliation Data Quality Review (continued)



- Potential Duplicate PDEs – Duplicate (DUP) Outliers (continued)
 - In contrast, DDPS online editing uses the following fields to identify and reject duplicates after verifying HICN:
 - Date of Service
 - Service Provider ID
 - Service Provider ID Qualifier
 - Prescription Service Reference Number
 - Fill Number

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Part D Payment Reconciliation Data Quality Review (continued)



- Potential Duplicate PDEs – Duplicate (DUP) Outliers (continued)
 - Algorithm excludes potential vacation fills & other legitimate scenarios which could potentially register as duplicate PDE submissions
 - Applies when the sum of Total Gross Drug Costs across the PDEs in the duplicate set is at least \$100
 - None of the PDEs can have a positive reported gap discount amount

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Part D Payment Reconciliation Data Quality Review (continued)



- Attachment and Catastrophic CPP Issues – Attachment CPP (ACP) and Catastrophic CPP (CCP) Outliers
 - Identifies Attachment Point and Catastrophic PDEs in which CPP = 0 and LICS is positive
 - PDEs are expected to show approximately 95% of catastrophic drug cost in CPP and 5% in LICS
 - Applies to PDEs in which Gross Drug Cost Above the Out of Pocket Threshold is greater than \$100

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Part D Payment Reconciliation Data Quality Review (continued)



- Medicare as Secondary Payer Issues – Medicare as Secondary Payer (MSP) Outliers
 - Flags PDEs for the same beneficiary, NDC, and date of service and different Pricing Exception Codes as potential duplicates or having erroneous Pricing Exception Codes
 - Applies to pairs in which combined TGDC is at least \$200

PDE FIELDS	PDE #1	PDE #2
HICN	SAME	
Product Service ID	SAME	
Date of Service	SAME	
Pricing Exception Code	M	'Blank'

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Part D Payment Reconciliation Data Quality Review (continued)



- Drugs Potentially Not Covered Under Part D – Covered Drug (CVD) Outliers
 - Flags PDEs that may not be covered under Part D.
 - Checks for PDE submissions for specific drugs or labeler codes.

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Evaluation

Please take a moment to complete the evaluation form for the following module:

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Your Feedback is Important!
Thank you!



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