PRESCRIPTION DRUGS EVENTS, FORMULARY ISSUES, AND PART D COMPLIANCE

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CENTERS FOR MEDICARE & MEDICAID SERVICES

Payment Overview

- PDE submission requirements
- PDE data quality monitoring
- Part D payment reconciliation
- General timeline for Part D reconciliation activities
- PDE and reconciliation information resources

PDE Submission Requirements

- Submit original PDEs within 30 days following Date Claim Received or Date of Service (whichever is later),
- Resolve rejected records and re-submit within 90 days following receipt of rejected record status from CMS, and
- Submit adjustments and deletions within 90 days following discovery of issue requiring change.
- HPMS memo issued Oct. 6, 2011, titled “Revision to Previous Guidance Titled, *Timely Submission of Prescription Drug Event (PDE) Records and Resolution of Rejected PDEs”*

PDE Analysis and Reports

- Ensure your organization establishes access to the PDE Analysis and Reports website
- Conduct root cause analysis and develop procedures to prevent PDE data quality issues in the future
- Respond as required through the PDE analysis website
- HPMS Memo issued 4/13/17, titled “Continuation of the Prescription Drug Event (PDE) Reports and PDE Analysis Reporting Initiatives for the 2017 Benefit Year”

PDE Analysis and Reports (cont.)

- PDE Reports
  - Immediately Actionable PDE Error Report
  - Eligibility Error Reports

PDE Monthly Reports (cont.)

- Ensure procedures are in place for analysis of recurring reports to ensure that PDE data maintained by CMS and the organization's internal records correspond. Reports include:
  - PDFS Response Reports
  - DDPS Cumulative Beneficiary Summary Report (PACE) (Rept 04)
  - P2P Part D Payment Reconciliation Report (Rept 42)
  - P2P Payable Report (Rept 43)

PDFS Response Report (cont.)

- Notifies submitter if PDE file (in its entirety) passed file formatting edits and is passed to DDPS for individual PDE specific editing
- If the submission is rejected, the PDFS Response Report provides rejection reason codes

DDPS Cumulative Beneficiary Summary Report (PACE) (Rept 04)

- Provides summary of accumulated totals per beneficiary for dollar amount fields
- Totals apply to one benefit year, with each benefit year having a separate cumulative report
- Financial amounts are reported as “net”
- Report will break by contract and PBP

P2P Part D Payment Reconciliation Report (Rept 42)

- YTD cumulative report for the Contract of Record of all financial amounts reported by Submitting Contracts for use in the Contract of Record's Part D Payment Reconciliation
- Distributed monthly

P2P Payable Report (Rept 43)

- Report that serves as the “invoice” to the Contract of Record, showing how much is payable to each Submitting Contract
- Distributed monthly

Part D Payment Reconciliation

- Part D payment reconciliation relies, in part, on complete and accurate PDE data, complete and accurate Direct and Indirect Remuneration (DIR) data, and the timely completion of annual Part D attestations

DIR Submission

- There are three parts to a complete DIR submission:
  - DIR Submission Information
  - Summary DIR data
  - Detailed DIR data

DIR Rules for Certain PACE Plans

- PACE organizations reporting $0 in all Summary DIR categories in the Summary DIR Report:
  - must submit the DIR Submission Information and the Summary DIR Report showing $0 Total DIR
  - are not required to submit a Detailed DIR Report

DIR Rules for Certain PACE Plans (cont.)

- In the DIR Submission Information section, the Allocation Methodology to the PBP and NDC level questions contain an option specifically for PACE organizations ***that do not receive rebates*** from drug manufacturers that indicates that no allocation methodology is required.

DIR Helpful Hints

- Resolving DIR file upload rejection issues
  - Helpful Hints document available in the DIR module for each file that is uploaded
  - Helpful Hints details file naming conventions and all file and field format editing that occurs during upload

DIR Helpful Hints (cont.)

- Determining the most current version of DIR data accepted
  - In HPMS →DIR Reporting→Select Contract Year→DIR Reports→
    - DIR Unload Status Report (Displays whether DIR submission file was saved or rejected)
    - DIR Data Report (Displays most recent saved DIR data)

Part D Payment Reconciliation Annual Attestations

- A total of THREE attestations must be completed prior to Part D payment reconciliation reports being released to a plan:
  - Attestation of Data Relating to CMS Payment to a Medicare Part D Sponsor
  - Attestation of Data Relating to Detailed DIR Report
  - Record and Attestation of P2P Reconciliation Payments
- Part D Reconciliation settlement will NOT be made if attestations are not received

Attestation of Data Relating to Detailed DIR Report

- Certify that Detailed DIR data are accurate, complete, and truthful
- PACE organizations that report $0 in all DIR categories in the Summary DIR Report, and therefore do not submit a Detailed DIR Report, are not required to submit the Attestation of Data Relating to Detailed DIR Report.

General Timeline for Part D Payment Reconciliation

- Annual DIR Submission Guidance published in Spring
- PDE submission deadline (end of June)
- DIR submission window (month of June)
- Prior year's DIR resubmission window (month of July)
- DIR reviews (July/August)
- Attestation Memo released (August)
- Attestations for Part D Reconciliation deadline (Sept)
- Recon reports (October/November)
- Reopening reports (November/December)

Information Resources for PDE Submission and Payment Reconciliation

- HPMS
- CSSC Operations Website
- PDE Resource email address

HPMS

- Policy and operational guidance memos
- Many administrative and reporting functions
- Email distribution list
  - All official Points of Contact listed in HPMS may receive emails
  - Staff that are not official POC but wish to receive HPMS email notifications should email hpms@cms.hhs.gov and provide name, organization, contract #, and email

CSSC Operations Website

- www.csscoperations.com → select PDE from sidebar menu
- PDE file layouts, PDE edit lookup, system status updates
- Training Resources
  - PDE Participant Guide
  - Computer Based Training Modules
- Listserv – to sign up select the “Email Updates” link on www.csscoperations.com and complete the form

PDE Resource Email Address

- PDEJan2011@cms.hhs.gov
- Monitored by the staff of the Division of Payment Reconciliation

Formulary Overview

- Part D Formulary Background
- Sponsor Formulary Development
- CMS Formulary Review Process
- PACE Formulary Requirements

Part D Formulary Background

- As described in section 1860D-11(i)(2) of the Act, CMS cannot mandate a national formulary. However, CMS has exercised its antidiscrimination authority under section 1860D-11(e)(2)(D)(i) to ensure that Part D plan formularies do not substantially discourage enrollment by certain Part D eligible individuals.
- CMS' review of Part D sponsors' formularies represents a unique and unprecedented process. There was no template previously, publically available in the private sector for such a review.
- Part D formulary submissions must be reviewed and approved prior to bid approval.

Part D Formulary Background (cont.)

- CMS receives hundreds of formularies for review each year.
- Initial formularies are submitted in the summer before the beginning of the contract year.
- Due to the volume of submissions and review timeframes, a standardized submission format is essential.

CMS Formulary Review Process

- Formularies are submitted and reviewed via the Health Plan Management System (HPMS)
- Submissions are based on the Formulary Reference File (FRF)
- The drug list, associated utilization management requirements, and tiering are reviewed in 3 stages
- After each review stage, Part D sponsors can provide clinical justifications, revised submissions, or both
- The final stage of the review involves addressing any unresolved issues, formulary negotiations, and conditional approvals

CMS Formulary Reference File

- CMS Formulary Reference File (FRF)
  - The FRF includes RXCUIs, adopted from NLM's RxNorm system, to represent distinct brand names, generic names, strengths, routes of administration, and dosage forms of drugs
  - The FRF serves as a pick-list of drugs for formulary inclusion that streamlined the submission and review process, and results in improved synchronization of CMS and Medicare Plan Finder files
  - Not a "coverage" list for Part D drugs

Sponsor Formulary Development

- Part D sponsors must use a formulary that has been developed and reviewed by a pharmacy and therapeutic (P&T) committee.
- The P&T committee must also review all utilization management to be applied to drugs, including prior authorization, step therapy, and quantity limits.

PACE Formulary Requirements

- Sections 1894(b)(1) and 1934(b)(1) of the Act:
  - PACE programs must provide all Medicare and Medicaid covered services
  - State Medicaid programs may no longer cover Part D drugs on behalf of dual eligible beneficiaries

PACE Formulary Requirements (cont.)

- Generally, PACE organizations are waived from having a formulary
- PACE organizations may elect to offer a Part D plan in a similar manner as MA-PD local plans in order to account for this shift in payer source for prescription drugs
  - Subject to all the rules and regulations acted upon a Part D sponsor

PACE Formulary Requirements (cont.)

- If a PACE organization does not cover certain Part D drugs, or has limitations in place for any Part D drugs, such as prior authorization, step therapy, or quantity limits (not related to FDA-approved maximum doses), this organization is utilizing a formulary.
- All PACE organizations that utilize a formulary must submit the formulary to CMS for review and approval via the same process followed by all Part D sponsors.

POLLING QUESTION 1

- A PACE plan has rejected the coverage for a Part D drug because the patient had not tried and failed a preferred drug first. Is this PACE organization subject to the rules and regulations of a Part D formulary?

- Yes
- No

Answer

- Yes. This scenario describes a step therapy requirement and indicates that the PACE organization is utilizing a formulary. As outlined in Chapter 6 of the Medicare Prescription Drug Benefit Management, section 30.2.2.1, this type of formulary drug utilization management tool must be submitted to CMS as part of the HPMS formulary submission. This would also be true if the organization wished to apply clinical restrictions on a drug through prior authorization, or if there were quantity limit restrictions or exclusion from coverage of some Part D drugs.

Formulary Resource Email Address

- PartDformularies@cms.hhs.gov

Levels of Part D Compliance

Type of Action	
Notice of Non-Compliance (NONC)	This is the most basic compliance action. Typically, it informs a PO that it is out of compliance with Part D regulations.
Warning Letter	This notice is an escalated version of the NONC. It generally pertains to issues that have already received a NONC, and/or has greater impact on participants.
Warning Letter with a request for a business plan	This notice generally relates to issues that have already received a NONC, and/or has greater impact on participants. Additionally, CMS is requesting a thoughtful plan on how the PO plans to resolve this issue(s).
Corrective Action Plan (CAP)	This is the highest level of compliance before referral for a sanction or civil money penalty. This notice is issued for particularly egregious regulatory violations, violations for which compliance notices have already been issued, and/or has particularly high participant impact.

Compliance Actions

- As a general rule, a compliance action is not issued when there is a sanction or enforcement action for the same issue during the same time period.