

Part D Updates Formulary and Benefits Administration

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Overview

- Formulary Administration Audits
- Formulary and Transition Policy Reminders
- Formulary Administration Audit Findings
- Tips for Avoiding Beneficiary Access Issues
- Annual Performance Review
- 2012 Formulary Submission
- Training Opportunities
- Resources



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Formulary Administration Audit

- CMS will review P&T minutes and other documents to ensure compliance with P&T requirements.
- Rejected claims will be reviewed to identify where the sponsor failed to administer the approved benefit.
- PDEs will be compared to rejected claims to identify non-compliance with transition requirements.
- Sponsors will be required to run test claims so that CMS can ensure accurate formulary adjudication.



Transition Requirements

- Specifically, a sponsor must provide for an appropriate transition process with respect to:
 - The transition of new enrollees into prescription drug plans following the annual coordinated election period;
 - The transition of newly eligible Medicare beneficiaries from other coverage;
 - The transition of individuals who switch from one plan to another after the start of the contract year;
 - Enrollees residing in LTC facilities; and,
 - In some cases, current enrollees affected by formulary changes from one contract year to the next.



Transition Audit Findings

Majority of compliance actions involved current enrollees affected by changes to their plans' formularies.

- Sponsor intended to prospectively transition all members who were subject to a formulary change prior to January 1st.
- Improperly relied on Annual Notice of Change (ANOC) to effectuate the transition.
- Processed transition fills for only some drugs subject to a cross-contract year formulary change, or coding errors on processors part when implementing new formulary.



Failure to Adjudicate the CMS-Approved Formulary

- Rejection of claims for covered Part D drugs.
- Imposition of unapproved utilization management (UM) edits.
 - Age restrictions not supported by the FDA-approved label.
 - Laboratory tests and medical procedures not included in the prior authorization (PA) criteria submitted to CMS.
 - High-cost edits resulting in clinical PAs that were not submitted to CMS.



Drugs within the Protected Classes

- Anticonvulsants, antidepressants, antineoplastics, antipsychotics, antiretrovirals, and immunosuppressants for the treatment of transplant rejection.
- PA and step therapy (ST) must be limited to beneficiaries who are just starting on the drug (no PA or ST allowed on antiretrovirals).
 - If a sponsor cannot determine at point of sale whether a beneficiary is a new start or not, the sponsor must treat the beneficiary as currently taking the drug.



Failure to Display Required Materials on Formulary Websites

- Sponsors have posted only an updated search tool but not an updated comprehensive formulary.
- Others failed to post PA and ST requirements.
- Posting unapproved PA and ST requirements.
- Sponsors must ensure posted formulary information is consistent with the CMS-approved formulary.



Failure to Utilize the Required Compendia

- Some Part D sponsors failed to utilize the compendia as defined by the Act.
 - Failure to use Drugdex, AHFS.
 - Inappropriate use of other sources.
 - Failure to review the revised compendia.
- MIPPA revised the definition of medically accepted indication (MAI) for Part D drugs used in anti-cancer regimens, effective January 1, 2009.
 - In addition to the existing Part D compendia, the update included the use of the NCCN Drugs and Biologics Compendium, Clinical Pharmacology, and peer-reviewed medical literature when evaluating off-label uses.
 - HPMS memo issued on December 9, 2008

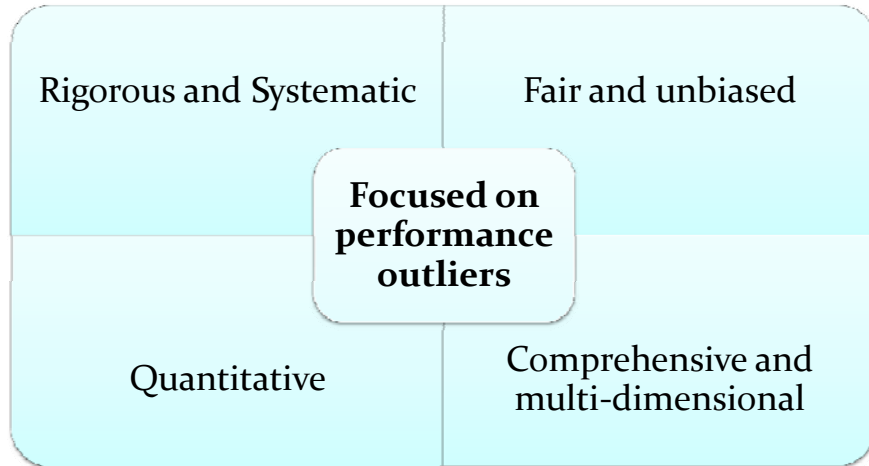


Avoiding Beneficiary Access Issues

- Review guidance and contact CMS with questions.
- Perform oversight of PBMs and other entities to ensure their processes are compliant.
 - Monitor rejected claims on a regular basis.
 - Request transition reports from PBM.
- Provide for ample testing prior to implementing approved negative formulary changes.
- Monitor CTM.



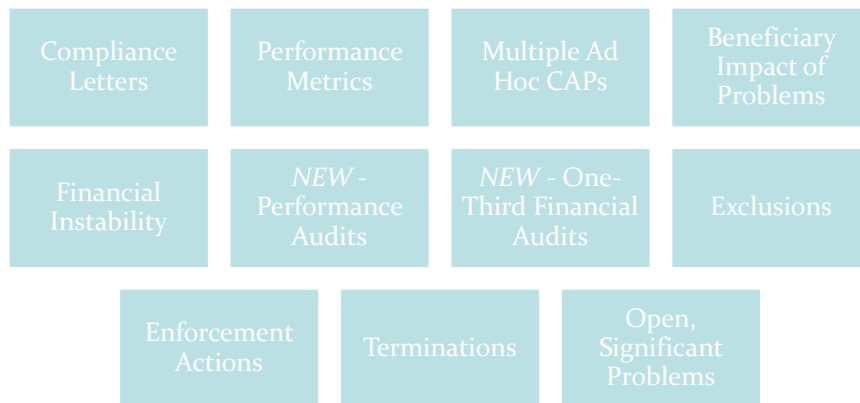
Annual Performance Review



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Eleven Performance Dimensions for 2012 Application Cycle

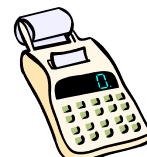
Outliers or extreme poor performers identified in each category, based on the prior 14 months experience



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Compiling Results

- Point values assigned for each dimension.
 - Point values vary depending on nature of problem and risk to program.
- Analysis identifies overall performance outliers.
 - Identifies sponsors with problems in multiple categories and/or in one or more particularly high risk area.
 - Overall negative scores calculated at the contracting entity level.



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Performance Information is Not a Secret

- Organizations have all the same information CMS has about their performance.
- Results should not be a surprise.
- 2012 Application Cycle Past Performance Methodology published in December 2010.
 - Performance outliers will not be allowed to offer new contracts or expand existing service areas.



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CY 2012 Formulary Submission Timeline

- CY 2012 formulary submission window opens on March 28, 2011.
- Formularies are due to CMS by 11:59 pm EDT, April 18, 2011.
- Transition Policy Attestations and Policy are due to CMS on April 18, 2011.
- The review of formularies will begin on April 19, 2011
- Supplemental Files are due June 13, 2011.



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Formulary Submission Files

- Plans will submit full formulary, PA, and ST files.
- Formulary upload questions are unchanged.
- **The formulary file layout has been amended to include a change type field. During the initial submission period, the value should be 'ADD' for all records.**
- All supplemental files (Partial Gap, Free First Fill, Home Infusion, Over the Counter and Excluded Drugs) will all be associated at the formulary level.



CY 2012 Formulary Review Process

- Formulary file - only changes to the formulary will be submitted.
 - Each RxCUI submitted will require a change type field value of “ADD”, “DEL”, or “UPD”.
 - Allows for a line-level review process.
- PA and ST criteria files - only changes to the files will be submitted.



CY 2012 Important Dates

- CY 2012 Plan Benefit Package/Summary of Benefits Beta Testing – Through Friday February 11, 2011.
- Release of the CY 2012 Draft Call Letter – Late February 2011.
- CY 2012 Formulary Submission Training – March 2011.
- CY 2012 Formulary Submission Training User Call Question and Answer Session – Early April.
- Release of OOPC Software – Early April 2011.
- Compliance Officer Training on Formulary and Benefit Administration – Late April/Early May 2011.



Resources

- Part D Transition Policy Reminder - HPMS 8/27/2010.
- CMS Part D Utilization Management Policies and Requirements 10/22/2010 .
- CY 2011 Formulary Updates Memo- HPMS 1/13/2011.
- Part D Prescription Drug Benefit Manual.
 - Chapter 3 (Medicare Marketing Guidelines).
 - Chapter 5 (Benefits and Beneficiary Protections).
 - Chapter 6 (Part D Drugs and Formulary Requirements).
 - Chapter 7 (Medication Therapy Management and Quality Improvement Program).

http://www.cms.hhs.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage



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Resource Mailboxes

- Part D Formulary Questions
partdformularies@cms.hhs.gov
- Part D Benefit Questions
partdbenefits@cms.hhs.gov
- Part D Transition Questions
partdtransition@cms.hhs.gov
- Part D Questions
Part D Account Managers



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Questions

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