Part D Benefits Policy and Operations

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Agenda

- Part D Policy Overview
- PBP Changes
- Supplemental File Changes
- Bid Design and Submission Requirement Reminders
- Benefit Review
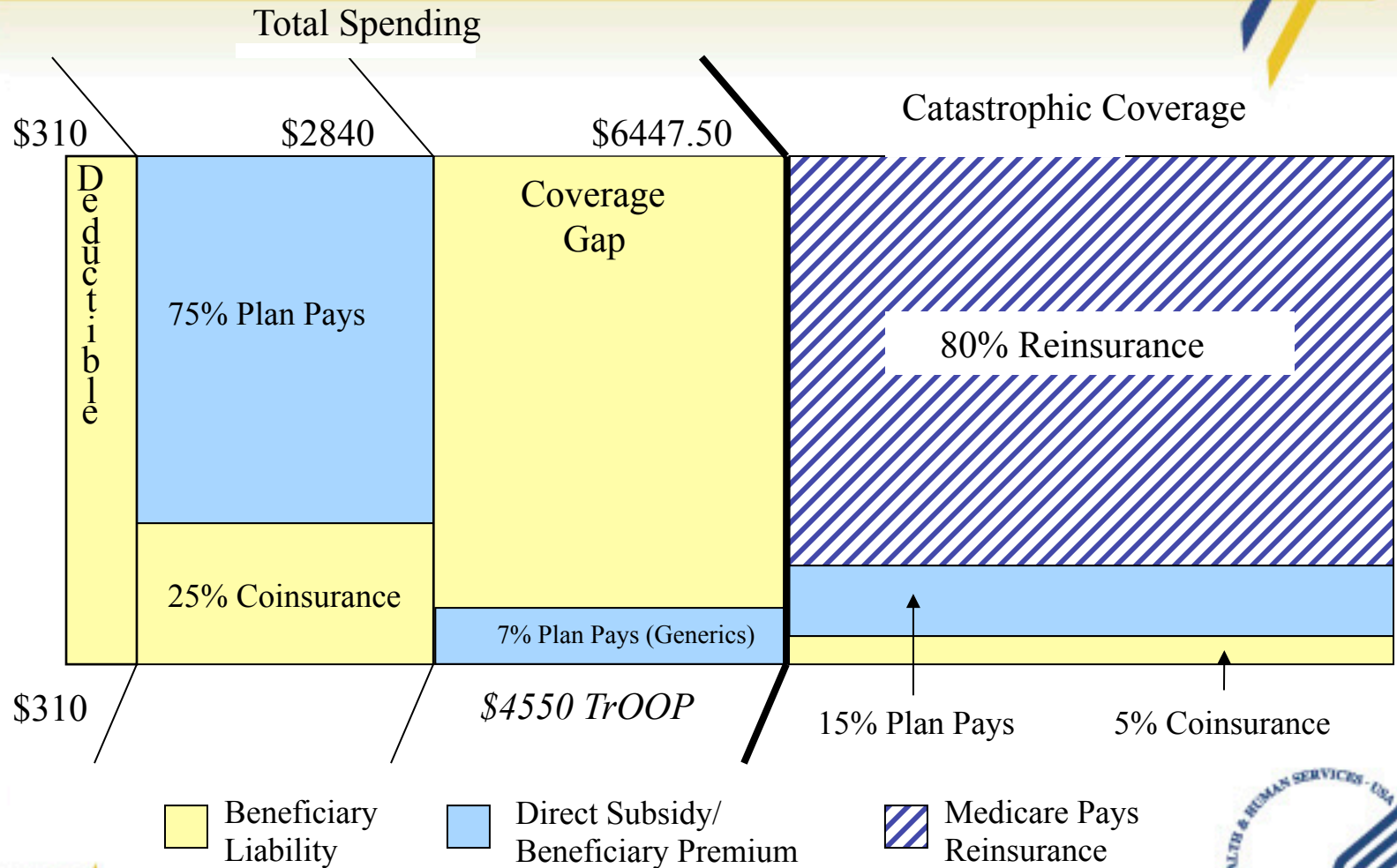- Compliance

PART D POLICY OVERVIEW

Part D Benefits Guidance

- 2011 Part D Plan Benefit Package (PBP) Submission and Review Instructions Memorandum

- Prescription Drug Benefit Manual
  (http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp #TopOfPage)

  - Chapter 5 (Benefits and Beneficiary Protections)
  - Chapter 6 (Part D Drug and Formulary Requirements)
  - Chapter 7 (Medication Therapy Management and Quality Improvement Program)

Key Components of the Benefit

- Deductible
- Initial Coverage Limit (ICL)
- Coverage Gap
- Out-of-Pocket Threshold
- Catastrophic Coverage

Standard Benefit 2011

Total Spending

$310 $2840 $6447.50

Catastrophic Coverage

Deductible

75% Plan Pays

25% Coinsurance

Coverage Gap

7% Plan Pays (Generics)

80% Reinsurance

$310 $4550 TrOOP

15% Plan Pays   5% Coinsurance

Beneficiary Liability

Direct Subsidy/ Beneficiary Premium

Medicare Pays Reinsurance

Benefit Types

- Basic Prescription Drug Coverage
  - Defined Standard (DS) Coverage
  - Actuarially Equivalent (AE) Coverage
  - Basic Alternative (BA) Coverage
- Enhanced Alternative (EA) Coverage

Important Dates

- April 19, 2010 – Deadline for submission of CY 2011 formularies in HPMS (11:59 EDT)

- May 14, 2010 – CY 2011 bid submission window opens

- June 7, 2010 – Deadline for submission of CY 2011 bid in HPMS (11:59pm PDT)

- June 7, 2010 – Deadline for crosswalking plans to a formulary submission

Important (cont.)

- June 14, 2010 – CY 2011 Supplemental File window opens

- June 16, 2010 – Deadline for submission of a CY 2011 Supplemental File

- October 1, 2010 – Deadline for submission of CY 2011 PBP Plan Correction Requests for approved contracts

PBP CHANGES

Tier Number

- Maximum of 6 tiers for 2011 PBPs
  - Includes Part D Excluded Drug only tiers
  - All benefit types except Defined Standard (DS)
- No tier designations for DS plans

Screenshot 1 of Section Rx

PBP Data Entry System - Section RX, Contract Z0001, Plan 001, Segment 000

File   Help

<<Previous   Next>>   Exit (Validate)   Exit (No Validate)   **Go To:**   Medicare Rx General 1

CLICK FOR DESCRIPTION OF BENEFIT

Does your plan offer a Medicare Prescription drug (Part D) benefit?

Select the type of drug benefit:
- Defined Standard Benefit
- Actuarially Equivalent Standard
- Basic Alternative
- Enhanced Alternative

Indicate number of Tiers in your Part D benefit:

Do you have a basic Part D plan (DS, AE, BA) that provides required prescription drug coverage to beneficiaries in the service area covered by this EA plan?
- Yes
- No

Does this EA plan have a zero dollar Part D premium that satisfies (for this service area) the regulatory requirement at 42CFR §423.104 (f)(3)(i) to provide required prescription drug coverage?
- Yes
- No

Describe the components of your network:
- In-Network Retail Pharmacy
- In-Network Preferred/Non-Preferred Retail Pharmacy
- Out-of-Network Pharmacy
- Mail Order Pharmacy
- Mail Order Preferred/Non-Preferred Pharmacy
- Long Term Care Pharmacy

A plan should specify both preferred and non-preferred mail order pharmacy locations if it will require different cost sharing amounts at different mail order locations, even if both preferred and non-preferred mail order pharmacies are not currently included in its network.

Are there quantity limits on certain prescription drugs?
- Yes
- No

Is prior authorization required for certain prescription drugs?
- Yes
- No

Do any drugs in your formulary require a step therapy plan?
- Yes
- No

Tier Labels

- New Standardized Labels
  - New drop down menu of label options
  - Based on information entered regarding the type of drugs included on the tier and designation as the specialty tier
    - Specialty tier can only be labeled as "Specialty Tier Drugs"
    - Excluded drug only tiers must include the term "Supplemental" in the tier label
  - Populated in Summary of Benefits (SB)

Screenshot 2 of Section Rx

PBP Data Entry System - Section RX, Contract Z0001, Plan 001, Segment 000

File   Help

<<Previous | Next>> | Exit (Validate) | Exit (No Validate) | **Go To:** Actuarially Equivalent - Pre-ICL Tier Type

Tier Drug type(s):
- ☐ Generic
- ☐ Preferred Generic
- ☐ Non-Preferred Generic
- ☐ Brand
- ☐ Preferred Brand
- ☐ Non-Preferred Brand

Tier Includes:
- ○ Part D Drugs Only
- ○ Excluded drugs only (e.g., benzos, barbiturates)
- ○ Both Part D and Excluded Drugs

Injectable Drugs Only Tier?
- ○ Yes
- ○ No

Specialty Tier
- ○ Yes
- ○ No

Each plan must indicate one specific cost-sharing tier from its PBP at which it will adjudicate all non-formulary drugs approved through the formulary exceptions process. Although CMS generally allows Part D sponsors to apply only one level of cost sharing from an existing formulary tier to all approved formulary exceptions, sponsors may also elect to apply a second less expensive level of cost sharing for all approved formulary exceptions for generic drugs, so long as this second level is also associated with an existing formulary tier and is uniformly applied to all approved formulary exceptions for generic drugs. When designating the exceptions tier in a PBP submission, sponsors can enter only one level of cost sharing. Thus, a sponsor that has established a second (less expensive) level of cost sharing should indicate the more expensive cost-sharing tier of the two tiers as its Exceptions Tier.

Is this Tier your Exceptions Tier?
- ○ Yes
- ○ No

When developing your plan's cost share tier structure, you should utilize standard industry practices. Tier 1 should be considered the lowest cost-sharing tier available to beneficiaries. Any and all subsequent tiers within the cost share tier structure should be higher cost-sharing tiers in ascending order. For example, drugs in Tier 3 should have a higher cost-share for beneficiaries than drugs in Tier 2.

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Screenshot 3 of Section Rx

"Additional" Gap Coverage Level Descriptions

- Standardized Gap Coverage Level Descriptions
  - Percentage of formulary drugs covered through the gap
    - Part D Excluded Drugs not used in coverage level determinations
  - Reflects coverage above the new 7% standard coverage of generic drug costs

"Additional" Gap Coverage Level Descriptions (cont.)

- Same thresholds and descriptions as 2010
  - Separate calculations and descriptions for formulary generics and brands
    - All: 100% of formulary drugs covered through the gap
    - Many: ≥65% - 100% of formulary drugs covered through the gap
    - Some: ≥10% - <65% of formulary drugs covered through the gap
    - Few: >0% - <10% of formulary drugs covered through the gap (and >15 products covered)
    - None: 0% (or ≤15 products covered)

"Additional" Gap Coverage Level Descriptions (cont.)

- No entry of coverage level description by sponsors in the 2011 PBP

- New HPMS report to review coverage level descriptions
  - Available mid-summer 2010 for plans with approved formularies

Required Prescription Drug Coverage

- New PBP questions to ensure MA-PD Part D benefits offer required prescription drug coverage throughout a service area
  - Must indicate that a basic Part D plan exists in the same service area as the EA plan

  OR

  - Must indicate that the submitted EA plan's supplemental Part D premium has been bought down to zero with MA dollars

Screenshot 4 of Section Rx

Over-the-Counter (OTC) Drugs

- Utilization Management (UM)
  - Part D sponsors may elect to offer OTCs as part of their administrative cost structure
  - New PBP question regarding the type of UM strategy applied to OTC drugs
    - Answer must agree with HPMS Formulary submission

Over-the-Counter (OTC) Drugs

- OTC Medication Attestation Statement
  - Must attest in PBP that OTC drugs covered under Part C are NOT the same as the OTC drugs covered under Part D

Screenshot of Section Rx

PBP Data Entry System - Section RX, Contract Z0001, Plan 001, Segment 000

File Help

<<Previous | Next>> | Exit (Validate) | Exit (No Validate) | **Go To:** | Medicare Rx General 2

Do you pay for Over-the-Counter medications (OTCs) under the Utilization Management Program?

○ Yes
○ No

If you select "Yes" to "Do you pay for Over-the-Counter medications (OTCs) under the Utilization Management Program?", you must indicate these specific medications in a flat file which will be uploaded through the Formulary Submission Module by June 16, 2010.

OTC Medication Attestation statement

☐ Per the CY2009 Call Letter, an MAO cannot offer the same OTC drug under both its Part C supplemental benefit and its Part D benefit. I attest any OTC drugs that are covered under Part C are separate and distinct from OTC drugs covered under Part D.

Do you offer OTCs as a part of a formal Step Therapy Protocol submitted for review and approval by CMS?

○ Yes
○ No

With respect to OTCs, a Step Therapy protocol is one that requires the use of the OTC product prior to receiving a prescription formulary drug. This is in contrast to a general utilization management strategy that offers OTCs as alternatives to prescription formulary drugs but without a requirement to try the OTC first. All OTC drugs used in either a Part D Step Therapy Protocol or a general utilization management strategy must appear in an OTC supplemental file. However, only those OTCs used in a Step Therapy Protocol must be documented in the Step Therapy Criteria text files submitted with the formulary files.

Do you offer a free first fill (i.e. $0 copayment) for any drugs?

○ Yes
○ No

Example: If your plan offers a $0 copay for the first fill of a Lipitor prescription, you should answer 'yes' to 'Do you offer a free first fill for any drugs' and indicate the RxCUI for Lipitor in the flat file which will be uploaded through the Formulary Submission Module by June 16, 2010.

Do you prorate cost sharing for partial fills of a new prescription to provide a 'trial supply' of a new medication?

○ Yes
○ No

Prorating cost sharing refers to a reduction in the cost share of a new prescription for a new medication not previously taken by the beneficiary, for which the beneficiary is only getting a partial fill for reasons such as determining tolerability to the new medication. This does not refer to scenarios where the pharmacy is out of stock of the new medication and therefore can only supply a partial fill or the beneficiary can only afford a partial fill at the time of dispensing.

Does this plan offer national prescription coverage?

○ Yes (the beneficiary can use this plan to get their prescription drugs nationally)
○ No (prescription coverage only in certain areas of the country)

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Part D Rx Notes

- New limit of 225 characters
  - Used only to clarify information that cannot otherwise be entered in PBP
  - Used infrequently, if at all
    - Must not modify, qualify or contradict information in PBP nor limit the benefit
  - No changes after bid approval

SUPPLEMENTAL FILE CHANGES

Home Infusion Supplemental File

- Plans may elect to bundle home infusion (HI) Part D drugs under Part C as a mandatory supplemental benefit
  - Bundled drugs must be submitted on both the Formulary file and the Home Infusion (HI) supplemental file
    - New HPMS validation to ensure that only drugs appropriate for home infusion are submitted on HI supplemental files

Over-the-Counter (OTC) Supplemental File

- Sponsors electing to offer OTCs must upload an OTC supplemental file
- New OTC supplemental file record layout
  - Includes Step Therapy UM type indicator
  - Includes same Step Therapy fields as Formulary Step Therapy files
    - OTC step information must be consistent with PBP and Formulary file information

BID DESIGN AND SUBMISSION REQUIREMENT REMINDERS

SNPs Targeting Zero Dollar Cost Sharing

- Dual eligible SNPs with zero dollar cost sharing must buy down the entire 25% actuarial equivalent cost sharing amount using MA rebate dollars
  - Cannot only apply rebate dollars to the statutory patient pay amounts
  - Cannot waive LIS cost sharing amounts

Administrative Costs

- Sponsors must ensure projection of sufficient administrative costs
  - Increased scrutiny of proposed funding for 2011 administrative programs and services relative to 2009 performance measures

Plan Corrections

- Plan correction requests will result in a warning letter
  - Corrective action plans issued for organizations that also had warning letters for 2010 requests
- Module available in HPMS from mid-September through October 1, 2010
  - Only for approved contracts
  - Only allow PBP changes that are supported by the BPT

BENEFIT REVIEW

Meaningful Differences

- Plan offerings within a service area must be meaningfully different with respect to benefit packages and cost structures
  - Stand-alone prescription drug plans (PDPs) must have 1 basic offering in a service area
    - If offered, the Enhanced Alternative (EA) PDP in the same service area must demonstrate greater value than the Basic plan

Meaningful Differences

- Out-of-pocket (OOPC) Cost comparisons
  - Calculated using market basket of all drugs by a nationally representative cohort from Medicare Current Beneficiary Survey (MCBS file)
    - ▶ Estimated based on each Part D sponsor's benefit design
    - ▶ 2010 values will be available in HPMS

Meaningful Differences

- OOPC (cont.)
  - Multiple PDP offerings within a service area must be meaningfully different
    - OOPC differential between an enhanced and basic plan must be at least $22 monthly ($264 annually)
      - Exclusive of premium amounts
      - Reflects $22 less in expected out-of-pocket costs for enhanced plan
    - If 2 enhanced PDPs are offered the second must have higher value than the 1st and include coverage of at least "some" brand drugs

Meaningful Differences

- Low enrollment Plans
  - CMS will scrutinize stand-alone Part D plans within the lowest quintile of enrollment in 2010
    - Applies to non-employer plans
    - May use authority to non-renew in 2011
    - Encourage withdrawal or consolidation of any plans with less than 1,000 enrollees prior to bid submission

Part D Cost Sharing

- Review cost-shares for tiered benefit designs
  - Establish nondiscriminatory cost-sharing thresholds based on 2011 benefit package data for PDPs and MA-PDs
    - 2010 thresholds: Tier 1 $10, Tier 2 $45, Tier 3 $95
  - Identify outliers based on thresholds
    - Atypical tiering structures and specialty tier placement will be considered

Part D Cost Sharing (cont.)

- New for 2011:
  - Increased scrutiny of coinsurance tiers
    - Calculation of average expected cost sharing using 2009 PDE data
    - May request sponsor documentation regarding average expected price for medications

COMPLIANCE

Formulary Administration Issues

- Failure to add protected class drugs to formulary

- Failure to adhere to CMS transition policy

- Utilization of unapproved prior authorization or step therapy edits and/or criteria

Formulary Administration Issues (cont.)

- Dissemination of marketing materials that are not consistent with approved formulary information

- Failure to process claims in accordance with the approved formulary

- Inadequate oversight of subcontractors

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