Hogan Lovells

Medicare Part D – Coverage Gap Discount Program

Melissa K. Bianchi
Partner, Hogan Lovells LLP
melissa.bianchi@hoganlovells.com

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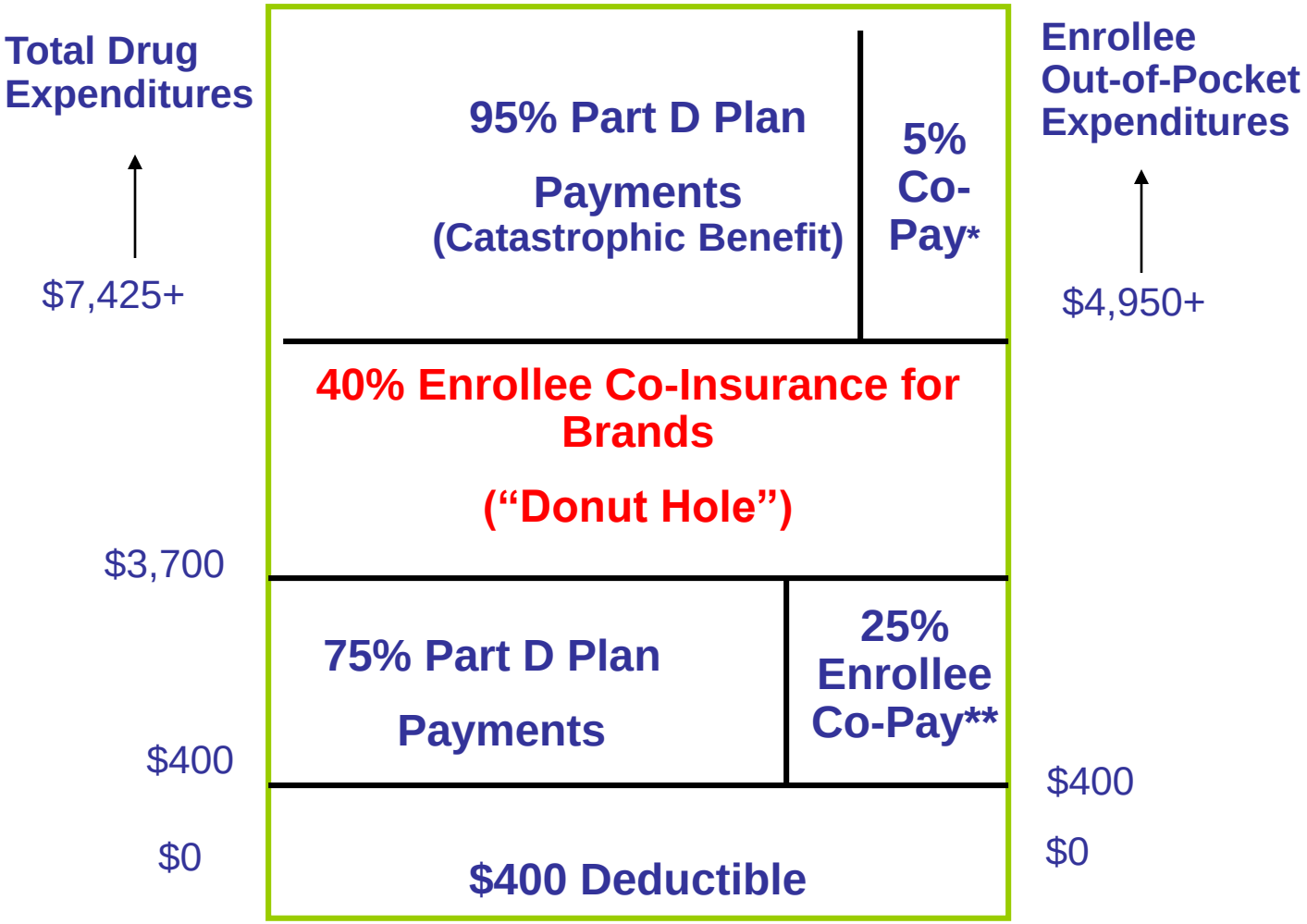
Part D "Standard" Benefit--2017



*Catastrophic benefit cost-sharing is higher of (i) 5% or (ii) $3.30 generic or preferred multi-source drug, or $8.25 for any other drug

**Generally replaced with tiered copays actuarially equivalent to 25%

Closing of Coverage Gap

- Affordable Care Act
- Two parts:
  - Generic Drugs: Gap began to close in 2011
  - Branded Drugs, Biologics and Authorized Generics: Gap began to close in 2013
- Phase-out coverage gap by reducing beneficiary coinsurance under Part D “standard” benefit
  - Manufacturers of “Applicable Drugs” pay 50% in the coverage gap
  - Manufacturers of Generics do not pay coverage gap discounts

Closing of Coverage Gap

Year	Branded, Biologic, Authorized Generic Coinsurance*	Generic Coinsurance
2010	100%	100%
2011	50%	93%
2012	50%	86%
2013	47.5%	79%
2014	47.5%	72%
2015	45%	65%
2016	45%	58%
2017	40%	51%
2018	35%	44%
2019	30%	37%
2020	25%	25%

*Represents combination of 50% Manufacturer Discount under CGDP and CMS direct subsidy contribution to reduce cost sharing to level shown

50% Discount

- CMS has authority to allow Part D coverage without CGDP participation but has declined to do so to date
- Requires 50% Discounts from Manufacturers to Part D Beneficiaries on covered Branded Drugs, Biologics and Authorized Generics Dispensed in the Coverage Gap (“Donut Hole”)
  - Available at point-of-sale
  - 50% Discounts count towards TrOOP, helps speed beneficiaries through coverage gap

Basic Conditions for Participation

- Coverage Gap Discount Program participation is required for a drug to be available under Part D
- Manufacturers must enter into two agreements:
  - CMS
  - Third Party Administrator

Manufacturer

- Any entity engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drug products, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis.
  - does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.
  - Includes entities otherwise engaged in repackaging or changing the container, wrapper, or labeling of any applicable drug product in furtherance of the distribution of the applicable drug from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer for use
  - BOTTOM LINE: by labeler code

Negotiated Price

- Discounts based on “negotiated price”
- Price negotiated between plan and pharmacy as amount pharmacy will receive in total when dispensing the drug
  - Excludes dispensing fees for CGDP purposes
  - Excludes vaccine administration fees
  - Includes sales tax
- Out-of-network pharmacies:
  - Plan allowance for OON scripts, minus dispensing/vaccine administration fees

Applicable Beneficiaries

- Does not apply to Low Income Subsidy (LIS) Beneficiary utilization
  - Individuals with incomes up to 150% FPL
  - Cost-sharing is subsidized
  - Coverage gap costs for LIS population are paid by CMS

Applicable Drugs

- Part D drug
  - Branded Drugs, Biologics and Authorized Generics
  - Part D drugs marketed under NDA or BLA
- Drugs on formulary or treated as on formulary (e.g., dispensed pursuant to formulary exception, transition fill)
- Excludes Part D compounds
  - Drugs that contain at least one Part D drug ingredient
  - Too difficult to operationalize

Supplemental Benefits

- Discount applies before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage
  - SPAPs, ADAPs
  - Any coverage paid by Employer Group Waiver Plans (EGWPs)
    - Means 50% discount is paid before any additional coverage paid by the EGWP
  - Changes nature of Part D plan design

CMS/Part D Sponsor Payment Process

- CMS provides monthly prospective (up-front), estimated payments to Part D plan sponsors
- Part D plan sponsors determine when beneficiaries are in coverage gap, what is an applicable drug, amount of discount, and pay discount amount to pharmacies through normal reimbursement mechanisms
- Pharmacies reduce price to beneficiary at point of sale
- Part D plan sponsors provide claims data (PDEs) to CMS, including data on discounts provided
- TPA bills manufacturers
- Manufacturers pay each Part D plan sponsor
- CMS annual reconciliation with Part D plan sponsors

Manufacturer Agreements

- Manufacturer agreement with CMS and with TPA
  - By labeler code; no partial participation
  - Must participate in order for drugs to be available under Part D
  - Signed agreement by January 30 of preceding year
  - Terminate by same date if choose not to participate
  - Initial term is 24 months with 1 year automatic renewals
- Process for signing an agreement starts much earlier than January
  - Request a P Code, typically in October

Third Party Administrator

- TPA
  - Manufacturers are electronically invoiced quarterly for discounts by TPA, at 11-digit NDC level
  - Manufacturer must pay each Part D plan sponsor invoiced amount, within 38 days of receipt of invoice, confirmation of payment to TPA within 5 days (by day 43)
  - Payments are by plan sponsor (sometimes smaller units)

Labeler Codes and NDCs

Manufacturer obligations

- Provide CMS with labeler codes for all applicable drug NDCs
- Promptly update any add'l labeler codes within 3 business days of written notification of code from FDA
- Electronically list and update all NDCs with FDA
- Maintain up-to-date NDC listings with the electronic database vendors for which the manufacturer provides NDCs for pharmacy claims processing
- Listing on FDA NDC listing is critical to Part D coverage (CMS relies on FDA listings)
- CMS contacts manufacturers with invalid NDCs
  - Typical problems: discontinued, awaiting FDA listing, etc.

Manufacturer must maintain data

- maintain appropriate data, including data related to:
  - manufacturer's labeler codes,
  - FDA drug approvals,
  - FDA NDC Directory listings,
  - NDC last lot expiration dates,
  - utilization and pricing information relied on by the manufacturer to dispute quarterly invoices, and any other data CMS determines are necessary to carry out the Discount Program,
- for a period of not less than 10 years from the date of payment of the invoice

Invoices and Payment

- Quarterly
- May contain data up to 3 years old
- Pay within 38 days
- Pay even disputed amounts

Direct Payment Process

- Beginning with Q2 2015 invoices, all amounts must be paid through new CGDP Portal.
- No payment confirmation reports from manufacturer
  - Instead, payment confirmation occurs when transaction is successfully processed
- Only ACH payments accepted
- Disputes also will be submitted via the Portal

Invoice Data

- Medicare Part D Discount Information
- Currently includes:
  - Claims level data derived from PDE record
  - NDC
  - Dispensing pharmacy
  - Quantity dispensed
  - Date of service
  - Days supply
  - Prescription #
  - Gap discount amount
  - CMS policy: No beneficiary identifiable data

Audit

- Manufacturers
  - May audit no more than annually
  - Must provide TPA with at least 60 days notice, reasonable basis for the audit, and the information necessary for the audit
  - Statistically significant sample available for audit
- CMS
  - May audit manufacturer no more than annually
  - At least 60 days notice, reasonable basis for the audit, and the information necessary for the audit (has right to audit information manufacturers are required to maintain and anything else deemed necessary)

Disputes

- Notice to TPA within 60 days with supporting evidence
- If received unfavorable determination or dispute is not resolved within 60 days of written notice to TPA of the dispute, may request additional review from Independent Review Entity
- Request for IRE review must be within earlier of 30 days of unfavorable determination or 90 days of written notice to TPA
  - IRE has 90 days to review
- Final review by Administrator– no further appeal

Dispute Codes for Q4 2014 and forward

Reason for Manufacturer Dispute
Duplicate Invoice Item
Closed Pharmacy
Not Part D Covered Drug
Aberrant Quantity/Invalid Days Supply
High Price of Drug
Last Lot Expiration Date – NDC not on the market
Marketing category is not NDA or BLA
PDE improperly invoiced beyond manufacturer agreement Invoice period
Excessive Gap Discount Gap Discount for Single PDE- disputed PDE exceeds maximum discount amount for a PDE
Excessive Gap Discount Gap Discount for Multiple PDEs- total accumulated gap discounts for a single beneficiary exceed cumulative maximum discount

Double-Dip

- If manufacturer is also paying Part D plan sponsor rebates on donut hole utilization, manufacturer is "double-dipped"—pays two discounts on the same script
  - CMS states in guidance that CMS "expects" that manufacturers will continue to pay rebates on Part D drugs in the coverage gap
    - Statutory Non-Interference Clause bars CMS from mandating rebates
  - Negotiating issue between manufacturers and PBMs/plan sponsors
    - Double-Dip okay?
    - Limit rebate if discount plus rebate exceeds a certain amount—e.g., 100% of WAC, or XX% of WAC?

Uses and Confidentiality of Data

- Cannot use for functions other than carrying out the agreement:
  - Rebate payments to Part D sponsors or any other federal health care programs
  - Marketing activities
  - Linking to other data
- May use aggregated summary-level data for financial forecasting and accounting purposes
- CMS owns the data
- Must retain data for 10+ years
- Report breach of identifiable data to CMS within 1 hour
- Administrative, technical, physical safeguards to protect data
- May not move data off-site

Penalties

- CMPs: amount owed plus 25%
- Owed whenever payment is late (exceptions for technical and natural disasters)
- CMS has process for terminating manufacturers