The Medicare Drug Benefit: Beyond the Basics

Third National Medicare Congress

October 15, 2006
Avalere Health LLC

Welcome

- Third National Medicare Congress
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- Medicare Drug Benefit: Beyond the Basics

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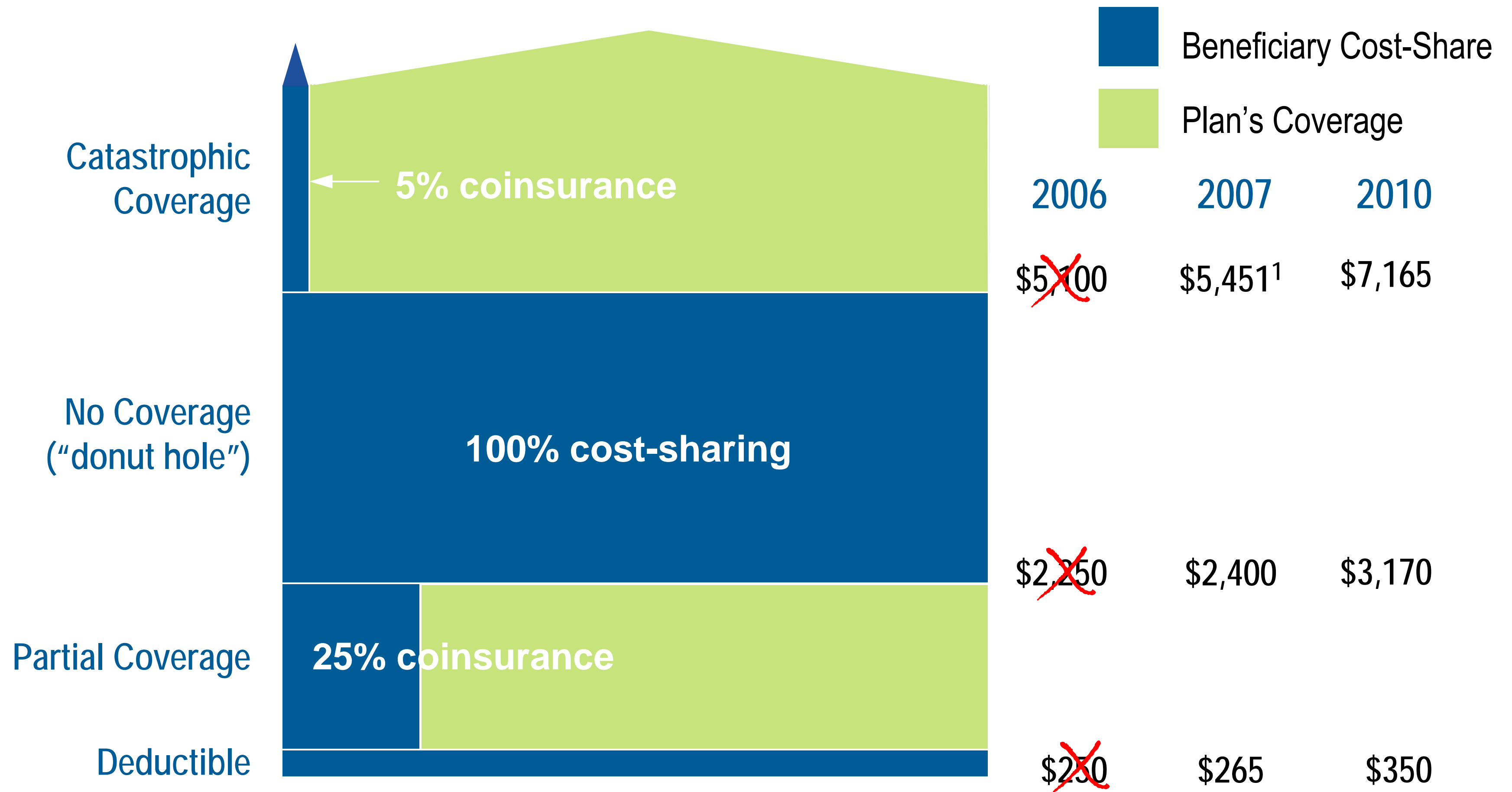
Agenda

1:00 – 1:05 PM	Welcome	Jennifer Bowman
1:05 – 1:35 PM	Part D Benefit Design	Elizabeth Hinshaw
1:35 – 2:05 PM	The Coverage Gap	Catherine Harrison
2:05 – 2:45 PM	Formularies	Lovisa Gustafsson
2:45 – 3:00 PM	Break	
3:00 – 3:30 PM	Transitions and Exceptions	Jennifer Snow
3:30 – 3:55 PM	Marketing and Enrollment	Jennifer Bowman

Beyond the Basics: Benefit Design

The intersection of business strategy and public policy

The MMA Outlined a Standard Part D Benefit Design



[1]Equivalent to $3,850 in out-of-pocket spending: $3,850 = $265 (deductible) + $534 (25% cost-sharing on $2,135) + $3,051 (100% cost-sharing in the "gap").
Source: Office of the Actuary, Centers for Medicare and Medicaid Services.

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Low-Income Assistance

Income and Assets Criterion	Premium	Deductible	Co-pays	Coverage Gap
Income up to 100% FPL *and* a dual eligible	None	None	$1 generic / $3 brand; None after $5,100	None
Income up to 135% FPL and assets <$6,000/individual or $9,000/couple; all other duals	None	None	2 generic / $5 brand; None after $5,100	None
Income from 135 - 150% FPL and assets <$10,000/individual or $20,000/couple	Sliding Scale*	$50	15% of drug cost; $2 / $5 after $5,100	None
Over 150% FPL	~$32.20*	$250	25% of drug cost; 5% after $5,100	Yes**

* Sliding scale premium defined
135% - 140% FPL, CMS will cover 75% of premium;
140% - 145% FPL, CMS will cover 50% of premium;
145% - 150% FPL, CMS will cover 25% of premium

** Between $2,250 and $5,100 of total drug spending in 2006.
* 2006 Premium
Note: 100% of FPL in 2005 is $9,570 for one-person household and $12,830 for two-person household; 135% of FPL is $12,920 and $17,321 respectively; 150% of FPL is $14,355 and $19,245 respectively

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Plans Have Flexibility to Offer Alternative Benefit Designs

OOP = Out-of-pocket
Adapted from CMS Issue Paper #31

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Most Plans Altered Benefit Design

- Very few plans used the standard benefit design (with $250 deductible and 25% coinsurance)
  - » Many offered actuarially equivalent or alternative coverage (e.g., using tiered copays or reducing the deductible)
  - » Some plans offered enhanced coverage, which may reduce the deductible or provide some coverage in the coverage gap

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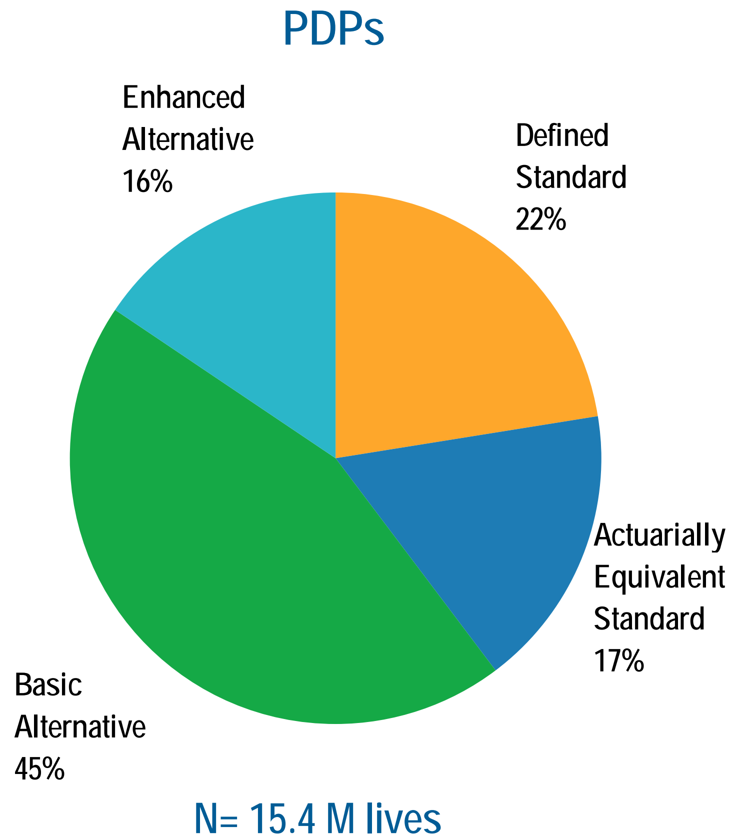
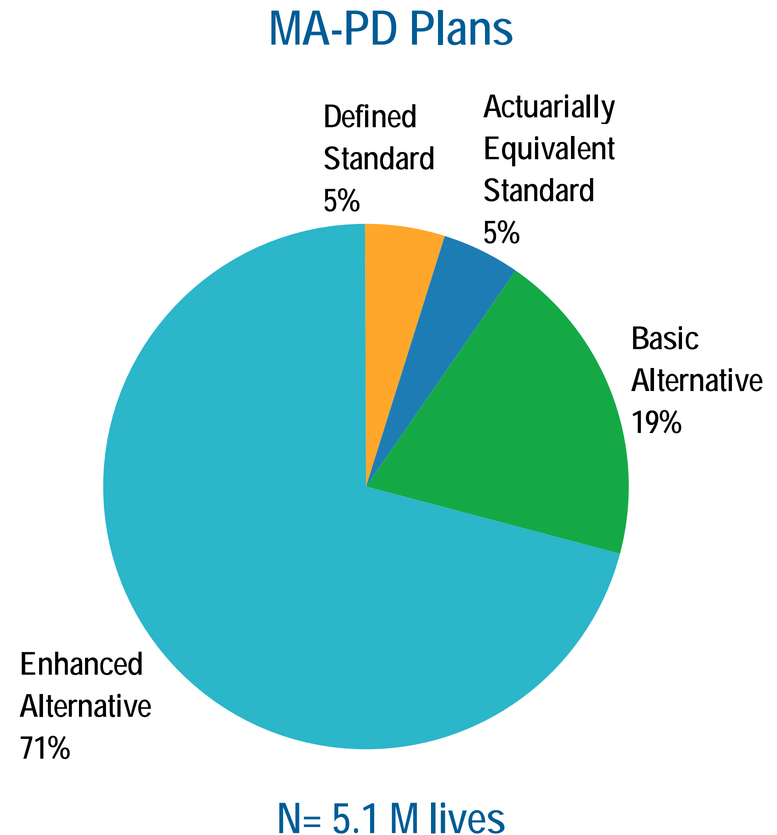
Most Beneficiaries Enrolled in PDPs Are in Basic Alternative Plans, While Most in MA-PD Plans Are in Enhanced Plans

Percent Enrollment by Benefit Type





Source: Avalere Health analysis using DataFrame™, a proprietary database of Medicare Part D plan features. Plan benefit and formulary design data from April 2006. Enrollment data from July 2006. Analysis excludes lives in MA-PD plans with fewer than 10 enrollees, lives in employer/union only Part D plans, and lives in the U.S. territories. Note: Benefit design data is unknown for two plans accounting for 106 lives.

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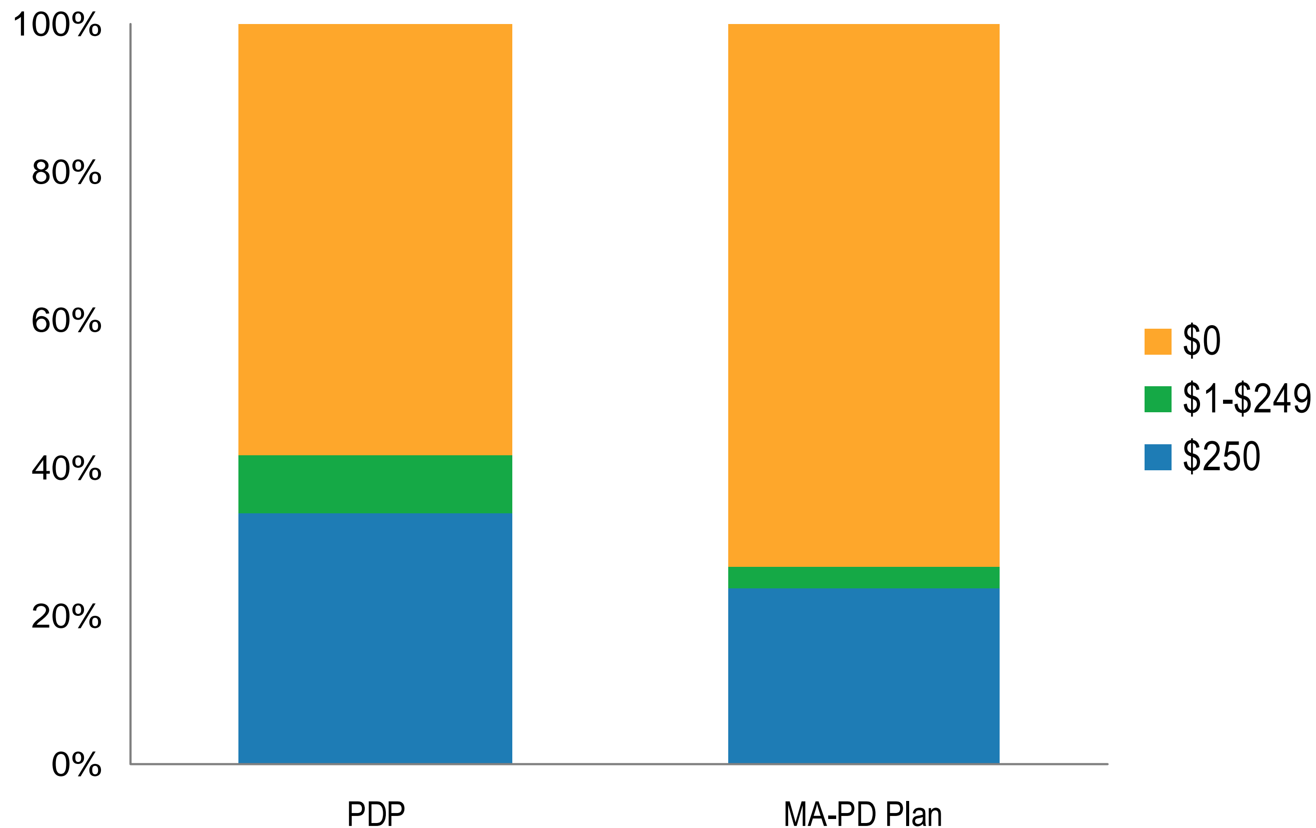
Most Part D Plans Offer Reduced Deductibles



Source: Avalere Health analysis using DataFrame™, a proprietary database of Medicare Part D plan features. Data from February 2006.

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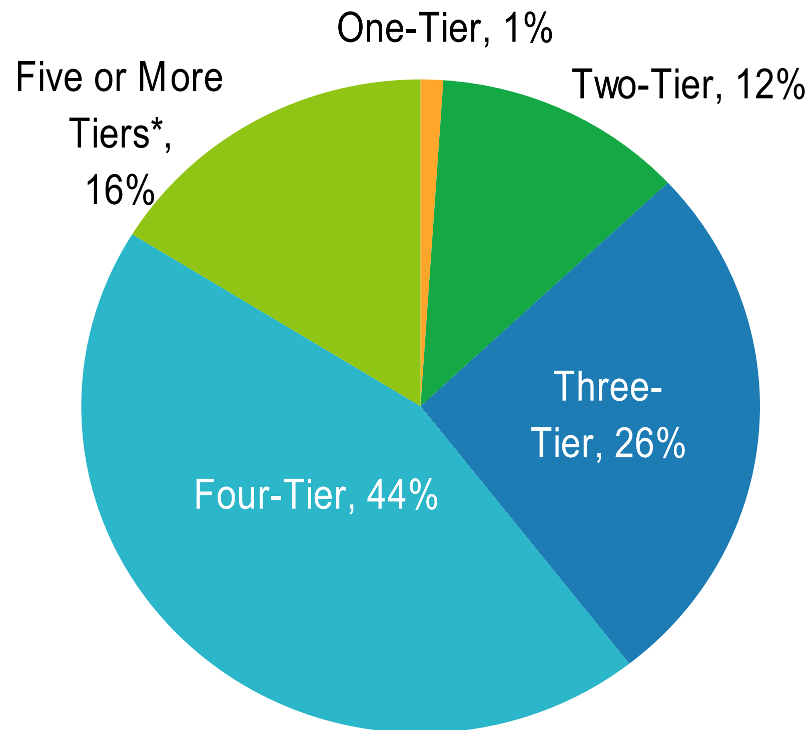
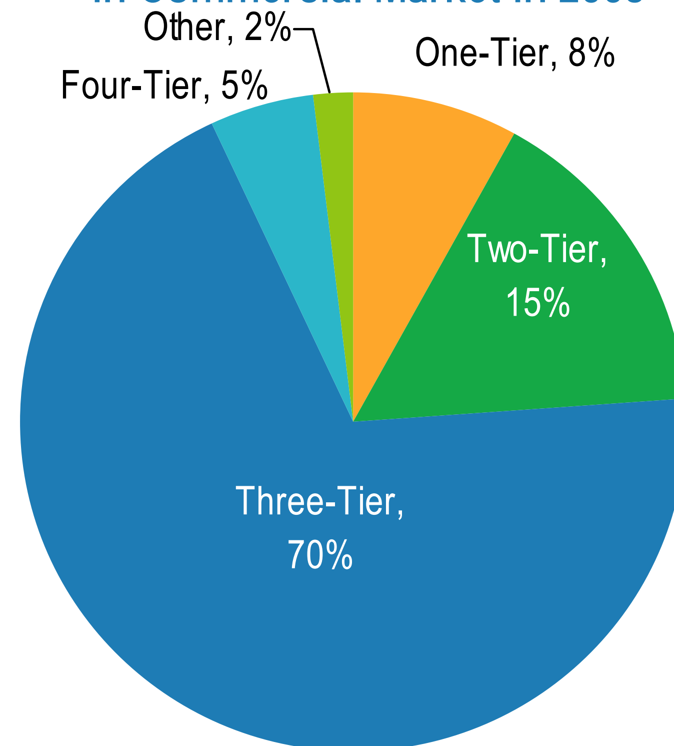
Tiered Benefit Structures Are Common in Both Part D and Commercial, But Part D Designs Tend to Have More Tiers

Prevalence of Tiering Structures in Part D in 2006



Four-tier designs are most common in Part D

Prevalence of Tiering Structures in Commercial Market in 2005



Three-tier designs are most common in commercial plans

Avalere Health analysis using DataFrame™, a proprietary database of Medicare Part D plan features.
Data from February 2006.
Kaiser Family Foundation's 2006 Survey on Employer Health Benefits.

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Typical Cost-Sharing in Part D Plans

PDPs

Tier	Cost-sharing
Tier 1	$5
Tier 2	$20
Tier 3	25%

Most common cost-sharing for 3-tier PDPs

MA-PD Plans

Tier	Cost-sharing
Tier 1	$0
Tier 2	$28
Tier 3	$58
Tier 4	25%

Most common cost-sharing for 4-tier MA-PD plans

Avalere Health analysis using DataFrame™, a proprietary database of Medicare Part D plan features.
Data from July 2006.

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Comparison of Part D, Commercial and VA Benefit Design

	2006 Part D Benefit	Commercial Plans*	Veterans
Deductible	▪ $250 standard deductible (majority offer reduced deductibles)	▪ Most plans exclude prescription drugs from deductible	▪ No deductible
Tiering	▪ Multiple tiering structures: 4-tier most prevalent	▪ Multiple tiering structures: ~75% covered workers are in plans with 3 or 4 tiers	▪ Flat copay for all brands and generics
Cost-sharing	▪ Varies plan to plan, drug to drug (0-75% coinsurance, $0-125 copay)	▪ Varies plan to plan, drug to drug Copays more common than coinsurance	▪ $8 copay for 30-day fill (or free if service related)
Coverage Gap	▪ Beneficiaries responsible for 100% of drug spending in gap (from $2,250 to $5,100 in 2006)	▪ No coverage gap	▪ No coverage gap
Catastrophic Coverage	▪ Catastrophic coverage (starts at $3,600 out-of-pocket in 2006)	▪ Typically no catastrophic coverage	▪ In 2006, annual out-of-pocket limit of $960 in 2006

* Commercial plan information based on Kaiser Family Foundation's 2006 Survey on Employer Health Benefits.

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Beyond the Basics: The Coverage Gap

Why Is There a Coverage Gap?

- Fiscal pressures to keep cost of legislation low
  - » Gap in coverage estimated to slash $200B over 10 years from total cost
- Evolution of debate guided compromise to gap in coverage
  - » Early discussions centered around providing just catastrophic coverage for beneficiaries with high annual drug costs
- Political pressures to show immediate effect of benefit
  - » Majority of beneficiaries have spending below $2,250, so impact would be felt immediately

Despite Variations in Plan Design, Some Coverage Gap Rules Apply to All

- All Part D plans must use certain spending limits for defining the coverage gap
  - » For 2006, beneficiaries enter coverage gap when total drug spending reaches $2,250
    - – Out-of-pocket spending may vary ($750 for standard benefit)
  - » For 2006, beneficiaries exit coverage gap when out-of-pocket spending reaches $3,600
    - – Total drug spending may vary ($5,100 for standard benefit)
- Beneficiary spending on off-formulary drugs does not count toward these limits, except in case of a successful appeal

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Coverage Gap Grows Dramatically Over Time:

Drug Spending ($)

9000
8000
7000
6000
5000
4000
3000
2000
1000
0

2007 2008 2009 2010 2011 2012 2013

Year

Doughnut Hole in 2006 = $2,850

Doughnut Hole in 2013 = $5,066

*Assumes that growth in drug costs significantly exceeds CPI.
Source: 2006 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, Table V.C2., p. 165.

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Only "True Out of Pocket" Costs (TrOOP) Count Toward Meeting the $3,600 Catastrophic Threshold

Payments that count toward TrOOP include:

- Deductibles and cost-sharing for formulary drugs paid by the Part D enrollee or another "person" (such as a family member) on their behalf
- Cost-sharing assistance from a qualified State Pharmaceutical Assistance Program (SPAP)
- Spending from HSAs, FSAs, and MSAs
- Copay assistance from certain charities or manufacturer patient assistance programs
- Waivers of Part D cost-sharing by pharmacies at the point of sale (must be unadvertised and non-routine)

Some Spending Does Not Count Toward the TrOOP Threshold

TrOOP does NOT include:

- Spending on non-formulary drugs
- Spending on drugs not covered by Part D at all (e.g. weight loss agents, barbiturates, benzodiazepines, etc.)
- Spending by a group health insurance plan (e.g. employer coverage, Medigap coverage)

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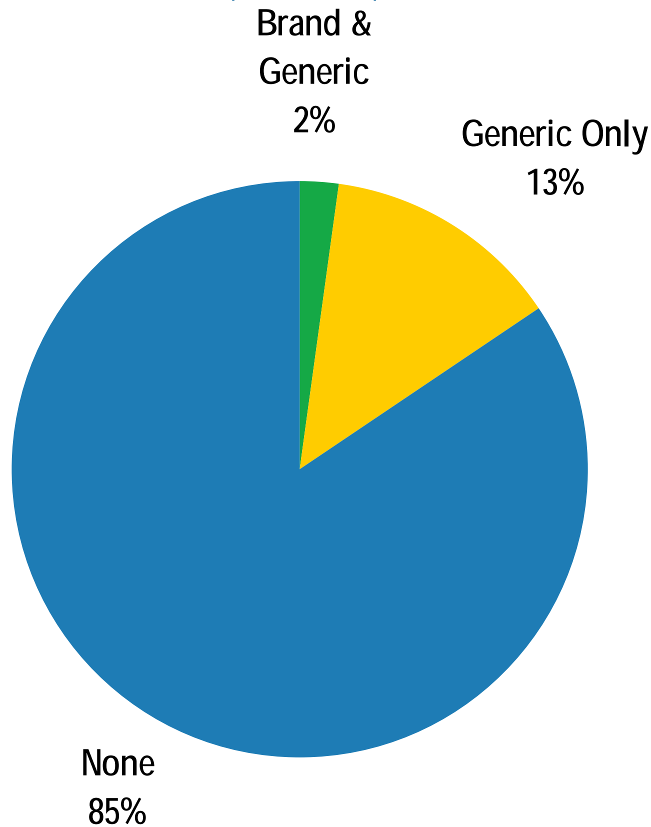
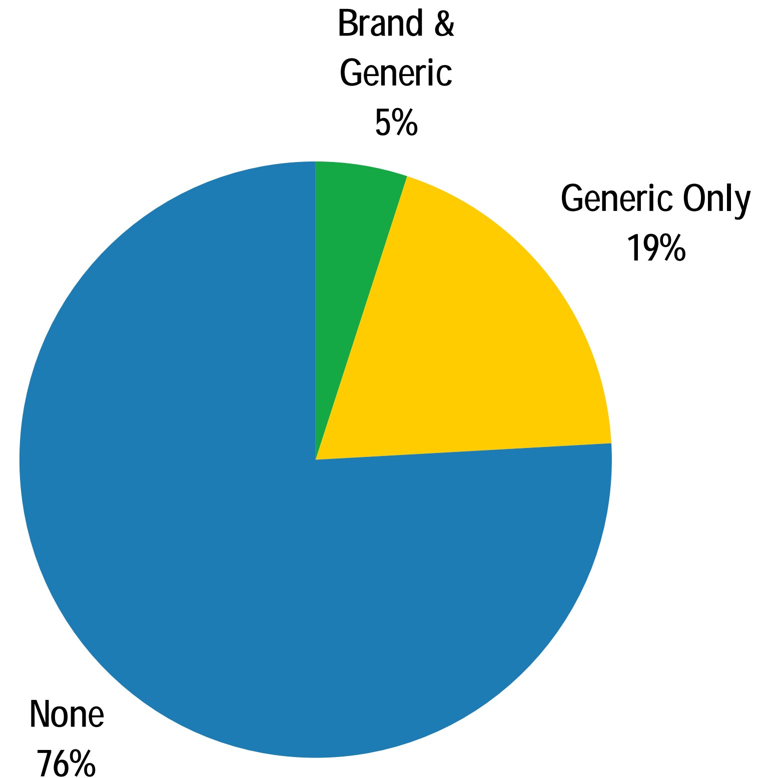
Few Part D Plans Offer Gap Coverage in 2006





Source: Avalere Health analysis using DataFrame™, a proprietary database of Medicare Part D plan features. Data from February 2006.

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Most Gap-Covering Plans Are in the Reinsurance Demonstration

Out of 590 Part D plans that offer coverage in the gap, 345 (59%) participate in the Reinsurance Payment Demonstration:

- Five-year optional demonstration program
- Plans have financial incentive to fill in the coverage gap
  - » Receive single capitated payment and forgo reinsurance payments for enrollees with out-of-pocket spending above $3,600
- 504 participating Part D plans
  - – 64% are MA-PDs, 35% PDPs, 1% Special Needs Plans

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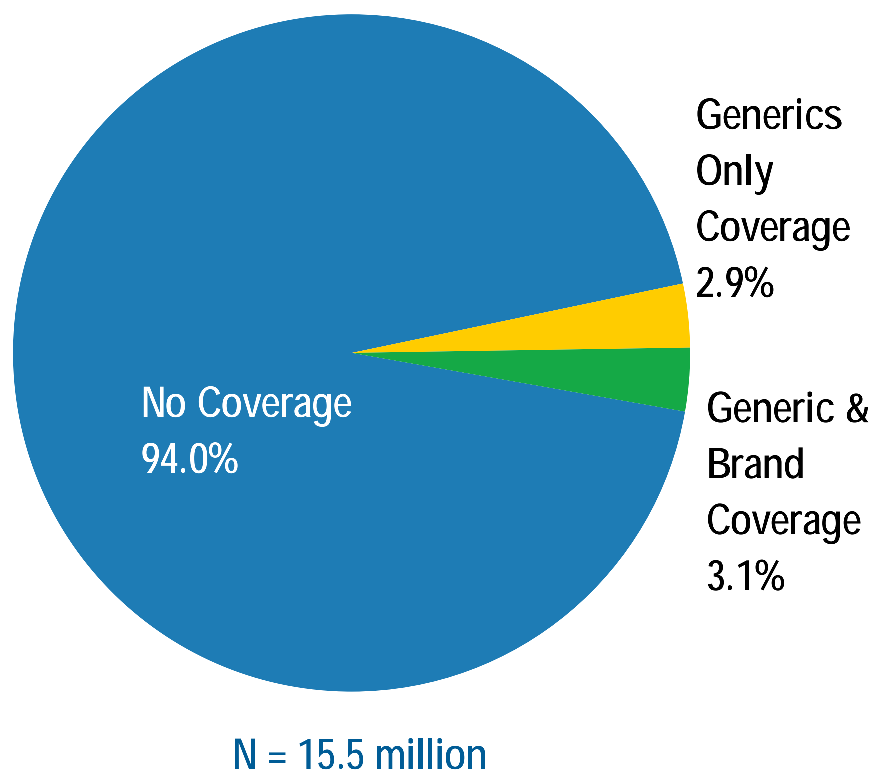
Most PDP Enrollees Have No Gap Coverage



N = 15.5 million

Most PDPs did not offer coverage in the gap; plans that did had higher premiums

- Example:

Humana Standard ($1.87 – $17.06)

Humana Complete ($38.70 - $73.17)

Source: Avalere Health analysis using DataFrame™, a proprietary database of Medicare Part D plan features. Plan benefit and formulary design data from April 2006. Enrollment data from July 2006. Analysis excludes lives in PDPs with fewer than 10 enrollees, lives in employer/union only Part D plans, and lives in the U.S. territories.

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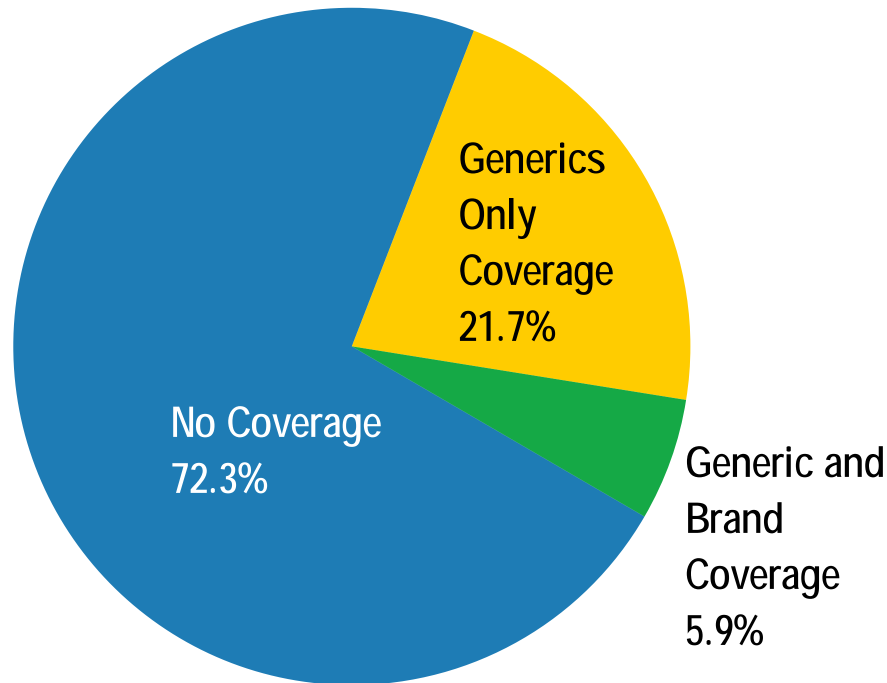
Almost a Third of MA-PD Plan Enrollees Have Coverage in the Gap



28% of MA-PD enrollees have some form of coverage in the gap

- 5% of MA-PD plans provide coverage of brands and generics
- 19% of MA-PD plans offer coverage of generics

Source: Avalere Health analysis using DataFrame™, a proprietary database of Medicare Part D plan features. Plan benefit and formulary design data from April 2006. Enrollment data from July 2006. Analysis excludes lives in MA-PD plans with fewer than 10 enrollees, lives in employer/union only Part D plans, and lives in the U.S. territories.

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Help May Be Available to Beneficiaries in the Gap

- CMS final regulations include bona fide 501(c)3 charitable organizations in the definition of a "person" whose payments may count toward the catastrophic limit
- OIG* guidance creates legal pathway for charities to assist Medicare beneficiaries without violating Federal fraud and abuse laws
- Organizations vary in coverage offered – reimbursement vs. donation
  - » Reimbursement-model charitable programs allow prescriptions to be paid for at the negotiated price at the point-of-sale; claims go to TrOOP administrator
- Currently, majority of funding for 501(c)3 organizations that provide wrap-around coverage is provided by manufacturers

*HHS Office of Inspector General

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Manufacturer PAPs' Role in Part D Will Evolve

- Currently, PAPs must operate outside of Part D (i.e., contributions don't count towards TrOOP)
- Many manufacturer PAPs have limited enrollment to only those Medicare beneficiaries not enrolled in Part D
- OIG and CMS may clarify/refine their positions further
- Congress would like to see beneficiary cost-sharing decreased
- Legislation could mitigate OIG opinion

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State PAPs Have Also Evolved Under Part D

- Existing Program Wrapping Around Part D
- Only Existing Disease-specific Program(s) Wrapping Around Part D
- Creating New Program to Wrap-around Part D
- Program Terminated
- Existing Program Not Wrapping Around Part D
- Program Wrap-around Information Unknown
- No SPAP in Operation

Source: Avalere Health Research as of May 2006
*Note: FL has active drug discount programs for which Part D wrap-around information is unknown.

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Summary of SPAP and Part D Coordination

- 7 states (FL, IA, KS, MI, MN, NC, WY) ended their pharmacy assistance programs for Medicare beneficiaries and three (OR, NM, WI) programs are not wrapping around Part D
- 24 states and the US Virgin Islands are providing Part D wrap-around coverage
  - » 9 states (HI, IL, KY, MD, MO, MT, NH, SC, VT) are creating new SPAPs to coordinate with Part D
  - » 15 states with existing programs (AK, CA, CT, DE, IN, MA, ME, NJ, NV, NY, OH, PA, RI, TX, WA) will provide Part D wrap-around coverage
- 25 states (AK, CA, CT, DE, FI, IL, IN, MA, MD, ME, MO, MT, NC, NJ, NV, NY, PA, RI, SC, TX, VT, WA, WI, WY) and the US Virgin Islands submitted qualified SPAP attestation forms for one or more programs in the state, but 3 states who submitted forms (NC, WY) have ended their SPAPs
- New CMS marketing guidelines will not hinder SPAP ability to co-brand with states

SPAP Coordination with Part D Continues to Evolve

- States will evaluate SPAP coordination with Part D over time
  - » Administrative ease of coordinating with Part D plans
  - » Total SPAP savings
  - » Sustainability of program funding
- Majority of states rely on general revenues to fund SPAPs, which compete with other state programs for funding

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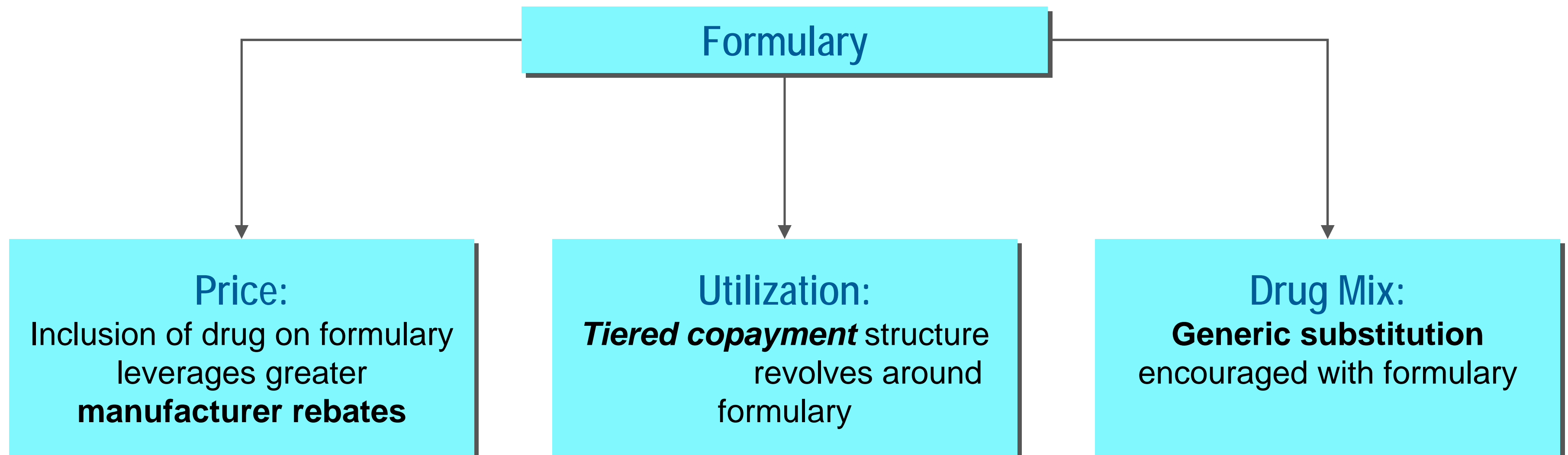
Beyond the Basics: Formularies

The intersection of business strategy and public policy

Formularies Are Central to Drug Cost Management



Part D and private sector cost containment efforts pivot around formularies, enabling plans to exert control over price, utilization, and drug mix

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Part D Plan Formularies Must Meet Basic Standards

- Plans must provide beneficiaries with choice of medications in each therapeutic class
  - » Must include at least two drugs in each category that are not therapeutically equivalent and bioequivalent
- CMS must determine that a plan's therapeutic classification system is not discriminatory against beneficiaries with certain medical conditions
- Plans will resubmit formularies and bids for approval by CMS every year

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CMS Evaluation and Review of Formulary Designs: "Balancing Access and Cost"

- CMS formulary review includes:
  - » Pharmacy and Therapeutics (P&T) committees
  - » Formulary drug lists
  - » Benefit management tools
- CMS' review is to ensure formularies remain nondiscriminatory and meet minimum standards
  - » Treatment guidelines (e.g., diabetes, gastroesophageal reflux disease)
  - » Certain classes (e.g., proton pump inhibitors)
  - » Six protected classes
  - » Commercial best practices and Medicaid existing practices

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USP Model Guidelines (MG) are "Safe Harbor" for Plans' Therapeutic Classification System

- USP sought to protect beneficiary access to drugs while supporting cost-effectiveness goal
- Plans may propose alternative therapeutic classification systems (or adapt their commercial formularies for Part D use) for CMS approval
- CMS will check a plan's proposed classification system that differs from the MGs to determine if it is similar to USP or other commonly used classification systems
  - » Example: the American Hospital Formulary Service Pharmacologic-Therapeutic Classification

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Formularies Can Be Changed During the Plan Year

- Formularies can be updated at certain times throughout the year
  - » Medicare P&T committees will meet quarterly to consider changes to the plan's drug list
  - » Therapeutic categories will be reviewed annually
  - » Formularies cannot be changed between November 15 and March 1 of each year (during open enrollment period + 60 days after)
- CMS must approve all formulary changes
  - » Plans must submit changes between the 1st and 7th days of each month
  - » CMS will review within 30 days of submission of plan's request
- Plans must review new drugs within 90 days of approval, and make a coverage decision within 180 days

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Part D Excludes More Types of Drugs Than Commercial Plans

	Statutorily Excluded from Part D	Commonly Excluded by Commercial Plans*	Excluded by National FEHB Plans				
			APWU	BCBS	GEHA	Mail Handlers	NALC
Barbiturates	✗						
Benzodiazepines	✗						
Drugs used for anorexia	✗			✗			
Weight loss drugs	✗				✗	✗	
Fertility drugs	✗				✗		
Drugs used for cosmetic purposes	✗		✗	✗	✗	✗	✗
Cough and cold medicines	✗						
Vitamins and minerals	✗		✗		✗	✗	✗
OTC drugs	✗	✗	✗		✗	✗	✗
Impotence drugs	✗	✗		✗	✗	✗	

✗ = NOT COVERED

* In 2000, 90% of covered lives were in plans that excluded these types of drugs
Academy of Managed Care Pharmacy. Common Practices in Formulary Management Systems. June 2000

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Distinction Between Part D and Part B Varies By Drug, Patient

- Part D drugs are not limited to outpatient drugs; the definition of Part D drugs includes injectables such as IM, IV, infused, and vaccines
- Part D benefit does not alter Part B coverage
- Distinction between a Part D and a Part B drug is how the drug is prescribed, dispensed, or administered to a particular individual
- Injectable drugs that Medicare considers not usually self-administered should be paid for under Part A or Part B if provided in the physician's office, and under Part D if dispensed by a network pharmacy

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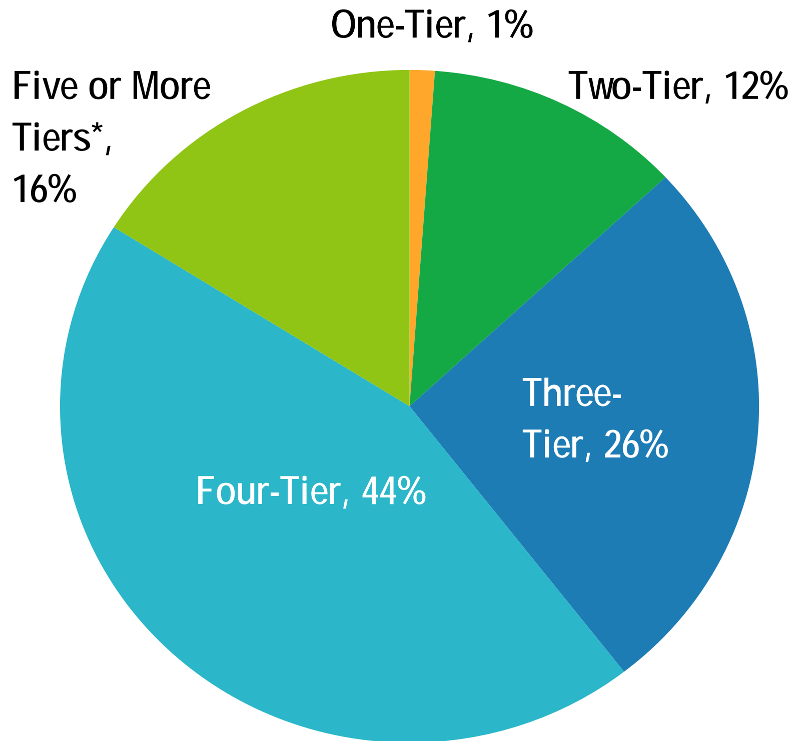
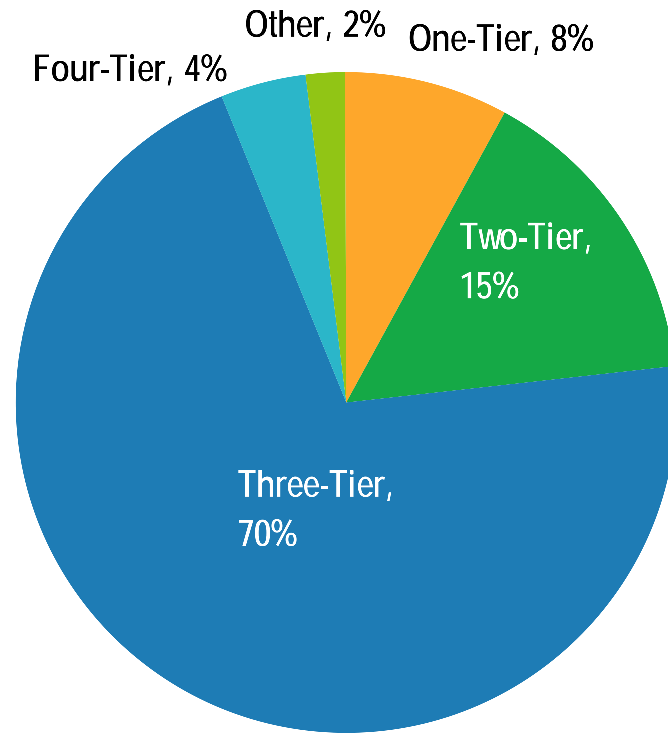
Tiered Benefit Structures Are Common in Part D and Commercial, But Part D Designs Tend to Have More Tiers

Prevalence of Tiering Structures in Part D in 2006



Four-tier designs are most common in Part D

Prevalence of Tiering Structures in Commercial Market in 2005



Three-tier designs are most common in commercial plans

Avalere Health analysis using DataFrame™, a proprietary database of Medicare Part D plan features. Data from July 27, 2006.

Kaiser Family Foundation. Employer Health Benefits. 2005 Annual Survey.

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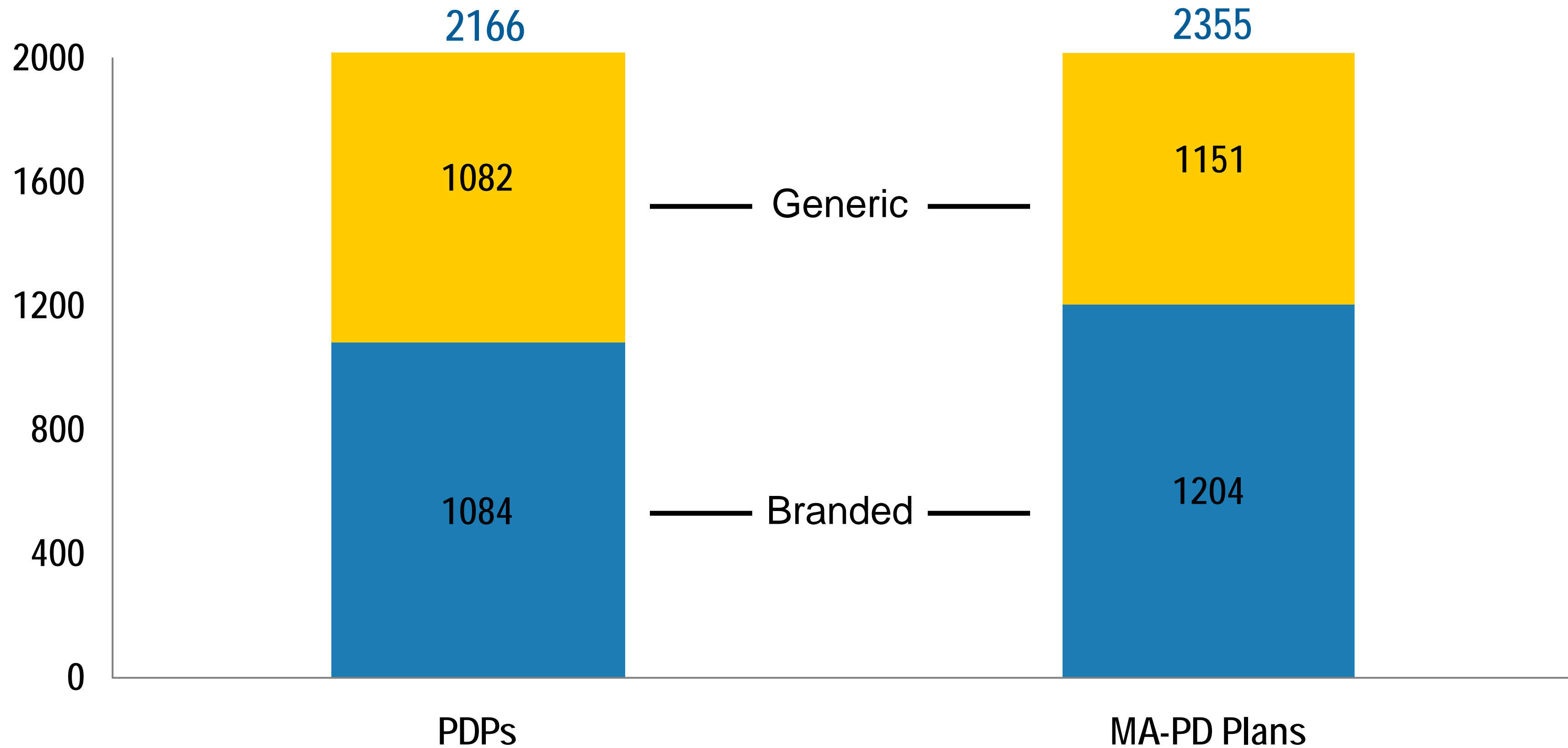
On Average, Part D Plans Cover 2263 Drugs, Over Half of Which Are Branded Drugs



On average, MA-PD plans cover slightly more drugs than PDPs. For both plan types, branded products make up over half of the formulary.

Source: Avalere Health analysis using DataFrame™, a proprietary database of Medicare Part D plan features. Data from July 27, 2006.

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Plan Formularies Vary Greatly in Size

Number of Drugs on Formulary	MA-PD Plans	PDPs
<1000	18	0
1000-1500	430	371
1501-2000	276	472
2001-2500	186	172
2501-3000	123	156
3001-3500	77	52
3501-4000	381	184
>4000	18	22

Number of Plans (y-axis: 0–500); Number of Drugs on Formulary (x-axis)

Source: Avalere Health analysis using DataFrame™, a proprietary database of Medicare Part D plan features. Data from July 27, 2006.

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Part D Plans Are Not Overly Restrictive in Their UM Tool Application

	PDPs		MA-PD Plans	
	Number of Drugs	Percentage of Drugs	Number of Drugs	Percentage of Drugs
Total Drugs Covered	2166	100%	2355	100%
Prior Authorization	211	10%	186	8%
Quantity Limits	229	11%	175	7%
Step Therapy	12	<1%	14	<1%

Source: Avalere Health analysis using DataFrame™, a proprietary database of Medicare Part D plan features. Data from July 27, 2006.

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Average Number of Drugs on Each Tier for Part D Plans with 4-Tiered Structures*

Tier	Average Number of Drugs
Tier 1	981
Tier 2	452
Tier 3	906
Tier 4	202

*Average is of 500 PDPs and 783 MA-PD plans.
Source: Avalere Health analysis using DataFrame™, a proprietary database of Medicare Part D plan features. Data from July 27, 2006.
Some drugs appear on more than one tier depending on the dosage or route of administration. For this reason, the sum of the number on each tier do not equal the total number of drugs covered.

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Part D Plans Tend to Have Larger Spreads Between Cost-Sharing Requirements on the First and Second Tiers

Avalere Health analysis using DataFrame™, a proprietary database of Medicare Part D plan features.
Data from July 27, 2006.
* Kaiser Family Foundation. Employer Health Benefits. 2005 Annual Survey.

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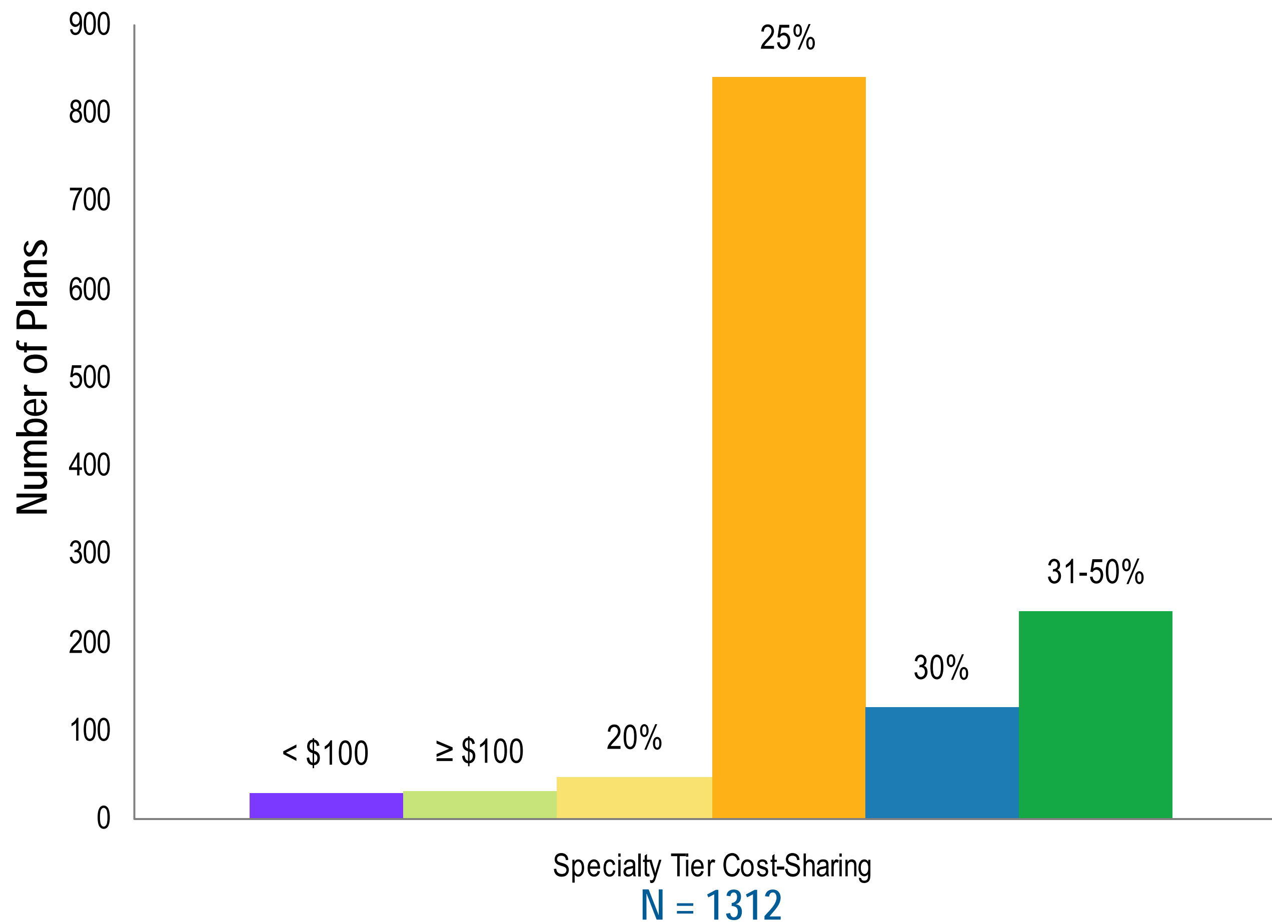
Cost-Sharing on Specialty Tiers Typically Is High



Almost all plans use percentage coinsurance on specialty tier

Fewer than 5% of plans use copays

MA-PD plans are more likely to use copays

Most plans without specialty tiers use flat copays on every tier, with highest tier at $25-60

Source: Avalere Health analysis using DataFrame™, a proprietary database of Medicare Part D plan features. Data from February 2006.

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20 Most Common Drugs Found on Specialty Tiers

Cancer
- Neupogen
- Tarceva
- Intron-A
- Gleevec
- Sandostatin

Multiple Sclerosis
- Avonex
- Copaxone
- Betaseron

Rheumatoid Arthritis
- Humira
- Remicade
- Enbrel

Anemia
- Procrit
- Aranesp

Hep C
- Peg-Intron
- Pegasys
- Intron-A

Other
- Fabrazyme
- Fuzeon
- Cerezyme
- Tracleer

These drugs are on over 70% of specialty tiers

Many drugs found on specialty tiers are eligible for Part B coverage in certain situations

Very few drugs found on specialty tiers are generics

Source: Avalere Health analysis using DataFrame[TM], a proprietary database of Medicare Part D plan features. Data from February 2006.

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Many Plans Use Specialty Tiers in Their Formulary Designs

- Specialty tiers are for very high cost and unique drugs
- CMS clarified that plans are not required to have a specialty tier
- Only one tier can be designated as a specialty tier
- Drugs must have negotiated prices >$500/month to be put on specialty tier
- Cost-sharing cannot exceed 25%
- Drugs exempt for cost-sharing exceptions

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Plan Are Mandated to Cover "All or Substantially All" Drugs in Six Protected Classes

Plan coverage for sample of protected classes:

	On Formulary	% times with PA	% times with QL	Most Common Cost-sharing
HIV/AIDS	100%	0%	4%	$20-30
Antidepressants	76%	3%	37%	$20-30
Antipsychotics	100%	15%	37%	$20-30
Antineoplastics	75%	10%	4%	$20-30

Treatment of the protected classes:

- Protected classes are covered better than most non-protected classes
- Drugs are on formulary, but UM tools applied—how does this affect access?
- Even though they're all protected, classes are treated differently

Source: Avalere Health analysis using DataFrame™, a proprietary database of Medicare Part D plan features. Data from April 2006.

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Outstanding Questions: Tiering and Cost-Sharing

- Why so much use of 4th and 5th tier? Is it necessary? Does it tend to select healthier patients into the plan?
  - » Can the same formulary control effectively be achieved with PA on 3rd tier?
- What protections are in place for patients with chronic illness?
  - » Will MTMP programs help in this regard?
  - » What will CMS likely do to shape the market?
- Part D plans provide a strong incentive to switch from tier 2 to tier 1
  - » What effect do you expect this to have on the product offerings going forward?
  - » What will utilization in Part D look like?
- Will MA-PD plans and PDPs converge or continue to differ in plan design?
  - » Do facts support idea that MA-PD plans have incentive to care for whole patient?

Beyond the Basics: Formulary Transitions, Exceptions and Appeals

Transition Guidance

Demonstrates lessons learned – CMS has strengthened expectations of plans

- For non-formulary drugs and drugs with prior authorization or step therapy
- Must allow a 30-day transition fill any time within the first 90 days of enrollment
- For LTC beneficiaries, plans must dispense 31-day transition supplies with multiple refills as necessary during 90 day transition
- Plans must notify beneficiary within 3 business days of temporary fill they must file an exception to obtain a refill
- In abridged formulary, plans required to describe transition policy

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2007 Transition Process

Enrollee Has Prescription for Drug Not on Formulary, or Drug Requires Step Therapy or Prior Auth.

Plan Must Provide 30-Day Fill Anytime in First 90 Days of Enrollment

Plan Gives Enrollee Written Notice Within 3 Business Days

Does Physician Want to Maintain Current Therapy?

Yes

No

Provider Prescribes Alternative (Covered) Therapy

Does Alternative Therapy Work?

No

Yes

End

Enrollee Can File an Exception/ Appeal

Go To Exceptions and Appeals Process

- Cost-sharing must be consistent with customary charges for non-formulary drugs approved as exception
- Step therapy or PA edits must be resolved at point of sale
- If quantity edits apply, enrollees may get refills up to a 30-day supply

Source: CMS Center for Beneficiary Choices, Transition Process Requirements for Part D Sponsors (April 2006) accessible at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/CY07TransitionGuidance.pdf

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2007 Long-Term Care Transition Process

- For LTC residents, plans must provide a minimum 31-day fill, to be refilled as necessary during 90-day transition period (i.e., beneficiary can get up to 90 days of medication)
- LTC residents outside 90-day transition period are eligible for an emergency supply while exception/appeal is being processed
- Emergency fill requirements also apply to formulary drugs that require PA or step therapy

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Plans Must Have a Process for Patients to Appeal Coverage Decisions

- Plans must have an exceptions process for hearing and resolving:
  - Grievances (e.g. customer service complaints)
  - Coverage determinations and redeterminations, including:
    - Determining whether to pay for a certain drug (e.g. not medically necessary, non on formulary, out-of-network pharmacy, or not "reasonable and necessary")
    - Plan's failure to make a coverage decision in a timely manner
    - Plan's decision on an exception to the plan's formulary
    - Decisions on the amount of cost sharing for a drug
- Plans will each determine medical necessity criteria for granting exceptions

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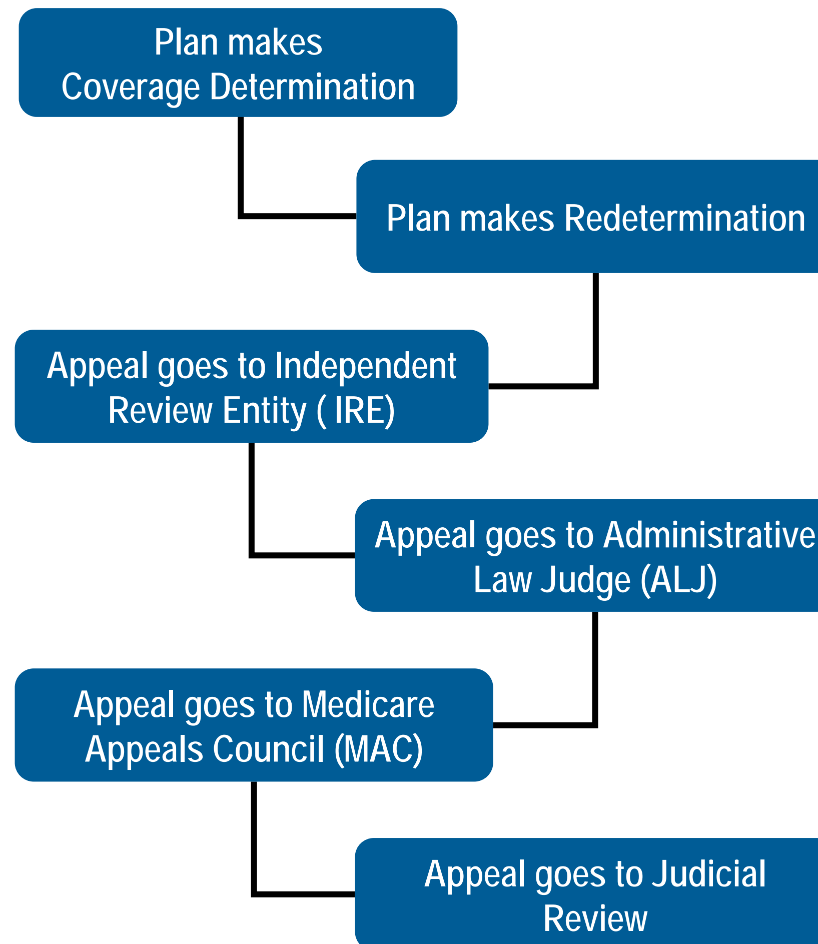
Exceptions and Appeals Process Overview



Source: CMS Prescription Drug Benefit Manual, Chapter 18, accessible at http://www.cms.hhs.gov/PrescriptionDrugCovContra/Downloads/PartDManualChapter18.pdf

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CMS Continues to Improve Process

<Plan Logo>

<Plan Mailing Address>
<Plan Phone Number>
<Plan Fax Number>

Medicare Part D Coverage Determination Request Form

This form cannot be used to request:

- Medicare non-covered drugs, including barbiturates, benzodiazepines, fertility drugs, drugs prescribed for weight loss, weight gain or hair growth, over-the-counter drugs, or prescription vitamins (except prenatal vitamins and fluoride preparations).
- **Biotech or other specialty drugs for which drug-specific forms are required. [See <Part D plan website.>] OR [See links to plan websites at http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/04_Formulary.asp]**

Patient Information		Prescriber Information		
Patient Name:		Prescriber Name:		
Member ID#:		NPI# (if available):		
Address:		Address:		
City:	State:	City:		State:
Home Phone:	Zip:	Office Phone #:	Office Fax #:	Zip:
Sex (circle): M F	DOB:	Contact Person:		

Diagnosis and Medical Information

Medication:	Strength and Route of Administration:	Frequency:
☐ New Prescription OR Date Therapy Initiated:	Expected Length of Therapy:	Qty:
Height/Weight:	Drug Allergies:	Diagnosis:
Prescriber's Signature:		Date:

Rationale for Exception Request or Prior Authorization
FORM CANNOT BE PROCESSED WITHOUT REQUIRED EXPLANATION

☐ Alternate drug(s) contraindicated or previously tried, but with adverse outcome (eg, toxicity, allergy, or therapeutic failure)
→ Specify below: (1) Drug(s) contraindicated or tried; (2) adverse outcome for each; (3) if therapeutic failure, length of therapy on each drug(s);

☐ Complex patient with one or more chronic conditions (including, for example, psychiatric condition, diabetes) is stable on current drug(s); high risk of significant adverse clinical outcome with medication change
→ Specify below: Anticipated significant adverse clinical outcome

☐ Medical need for different dosage form and/or higher dosage
→ Specify below: (1) Dosage form(s) and/or dosage(s) tried; (2) explain medical reason

☐ Request for formulary tier exception
→ Specify below: (1) Formulary or preferred drugs contraindicated or tried and failed, or tried and not as effective as requested drug; (2) if therapeutic failure, length of therapy on each drug and adverse outcome; (3) if not as effective, length of therapy on each drug and outcome

☐ Other:______________________________ → Explain below

REQUIRED EXPLANATION:______________________________

Request for Expedited Review

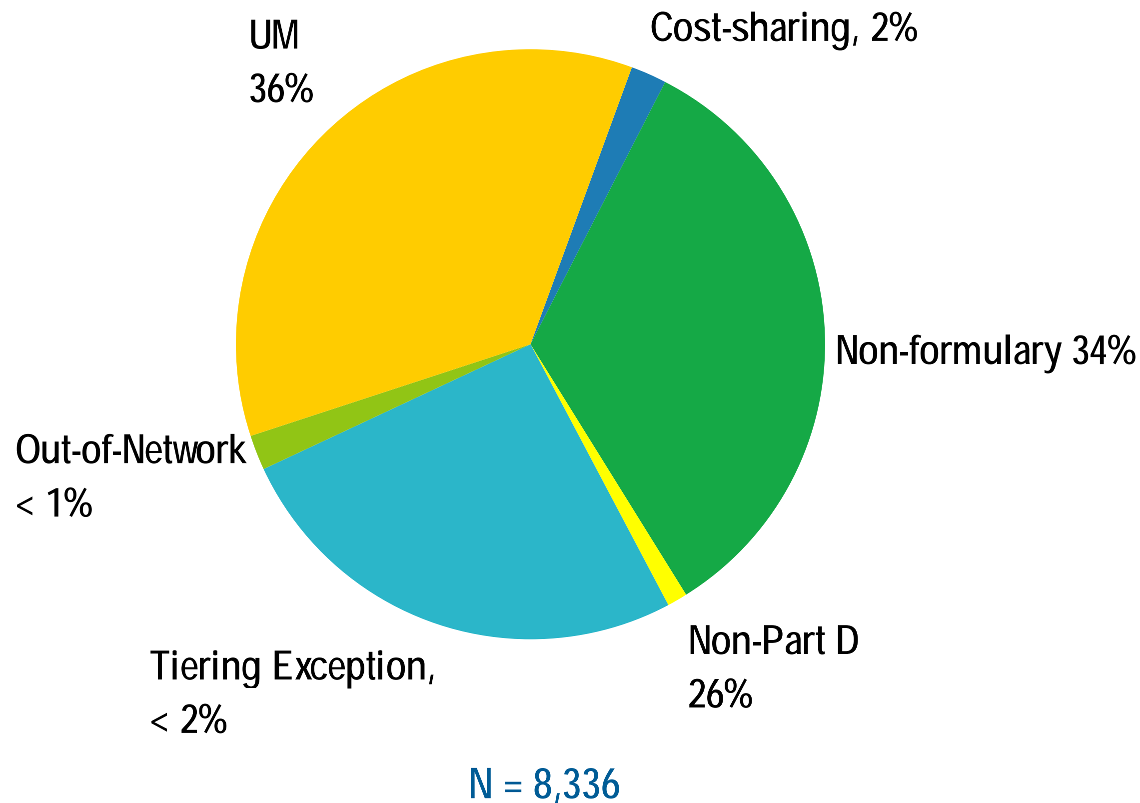
☐ REQUEST FOR EXPEDITED REVIEW [24 HOURS]
→ BY CHECKING THIS BOX AND SIGNING ABOVE, I CERTIFY THAT APPLYING THE 72 HOUR STANDARD REVIEW TIME FRAME MAY SERIOUSLY JEOPARDIZE THE LIFE OR HEALTH OF THE MEMBER OR THE MEMBER'S ABILITY TO REGAIN MAXIMUM FUNCTION

Information on this form is protected health information and subject to all privacy and security regulations under HIPAA.

- CMS said all plans must have centralized exceptions and appeals information on website
- Form developed in conjunction with American Medical Association (AMA) and America's Health Insurance Plans (AHIP)
- CMS cannot mandate that plans use the form, encouraging plans to use it as a "best practice"

Available at: http://www.cms.hhs.gov/MLNProducts/Downloads/Form_Exceptions_final.pdf

Reconsideration Requests through July 2006



Fewer appeals than expected:

- Peaked in May with 3081 appeals
- 42% of appeals were reversed by Part D IRE, including 51% of UM cases and 60% of Out-of-Network cases

Source: CMS, Part D Reconsideration Appeals Data, September 21, 2006.

Impact on Beneficiaries

- Beneficiaries may not be familiar with the appeals process or have difficulty finding and understanding plan-provided information on appeals
- Beneficiaries may not seek exceptions because of need for physician statements
- Difficult to ensure that appeal includes all necessary data elements; plans not specific on what constitutes medical necessity
- No information is provided on the outcomes of appeals – which might assist beneficiaries in picking a plan and move towards a consistent process

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Beyond the Basics: Marketing & Enrollment

Choosing to Enroll in the Medicare Drug Benefit Is a Complex Decision

- Initial open enrollment period with penalty for late enrollment
- Beneficiary decision to enroll involves assessing:
  - » Current drug coverage's formulary, premium and cost-sharing offerings
  - » Eligibility and application for low-income subsidy (LIS)
  - » Comparing plans
- Most beneficiaries had to decide whether to enroll, and pick a plan
- CMS created processes to ensure access for low-income groups
  - » Auto-enrollment for dual eligibles
  - » Facilitated enrollment for non-dual LIS enrollees who did not choose a plan voluntarily

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Partnerships Critical to Education and Outreach Effort

Physicians/Pharmacists/Seniors Organizations
- Sources of information on the benefit

CMS
- 1-800-Medicare
- Medicare.gov
- “Medicare and You” Handbook
- Local partnerships

SSA
- Determine eligibility for low-income subsidies
- Enrollment in benefit

States
- Determine eligibility for low-income subsidies
- Assist with education, outreach, and enrollment (State Health Insurance Assistance Programs)

Health Plans/ PBMs
- Education and marketing materials

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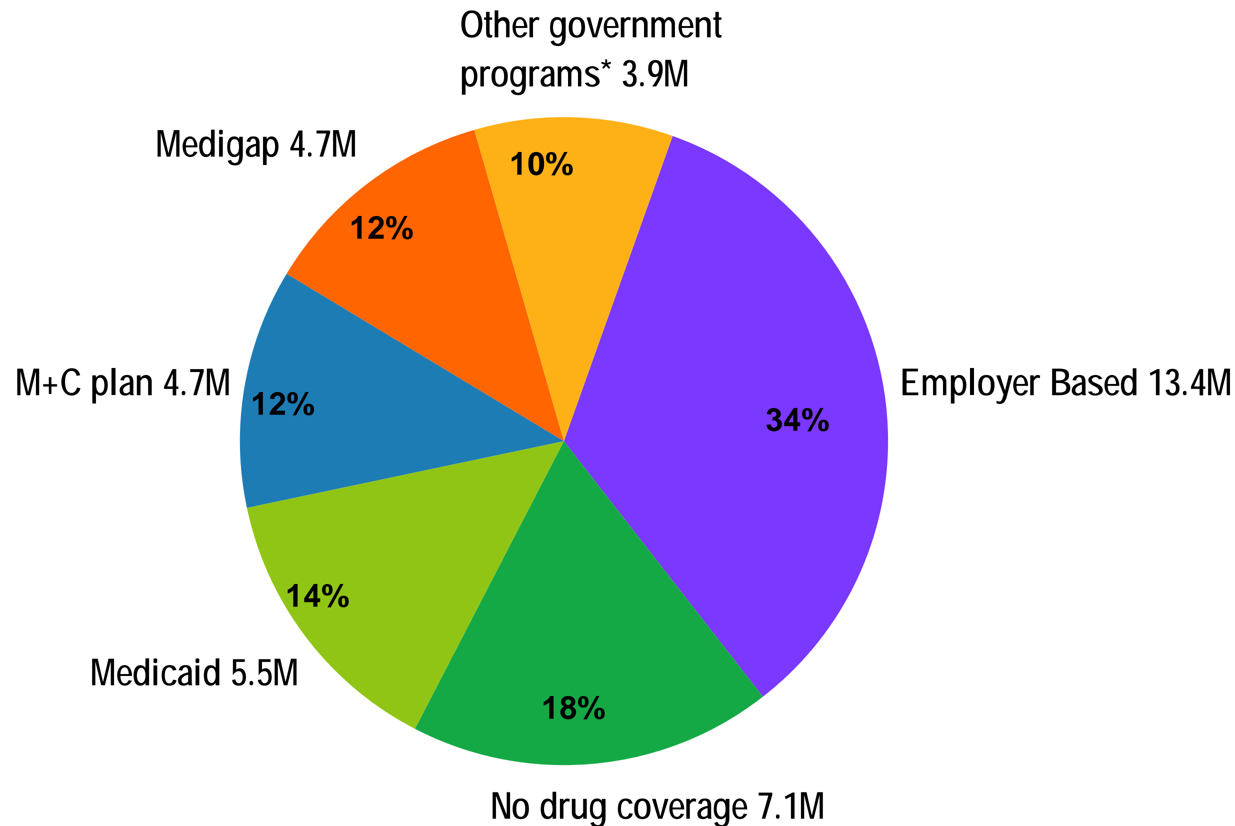
Plans Allowed to Market Directly to Beneficiaries

- Medicare plans must enroll beneficiaries one at a time (except retirees)
- Plans used a variety of strategies to attract potential enrollees in 2006
  - » Benefit design
  - » Co-branding
  - » Advertising
- For 2007, CMS modified some rules for plan marketing activities
  - » No provider co-branding on member ID cards
  - » Required information on plans' websites
  - » Additional detail in plan marketing materials
  - » Restrictions on direct-mail advertising

Medicare Beneficiaries' Prior Drug Coverage Affected Enrollment Decisions

Non-Institutionalized Medicare Beneficiaries' Prescription Drug Coverage – 2002
Total = 39.4 M



*Includes public programs such as Veterans Administration, Department of Defense, and State Pharmaceutical Assistance Programs for low-income elderly. Analysis includes community residents only.
Source: Kaiser Family Foundation analysis of the Medicare Current Beneficiary Survey 2002 Cost and Use File, in *Medicare Chartbook*, July 2005

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Nearly 23 Million Medicare Beneficiaries Enrolled During Initial Open Enrollment Period

Medicare Beneficiaries in Millions

	PDPs	MA-PDs	Unenrolled	Pre-existing coverage*
Total	16.3	6.4	4.3	
Indian Health Service				0.1
VA				2.0
SPAP Coverage				0.6
Active Workers (Medicare as Secondary Payer)				2.6
TRICARE				1.9
FEHBP				1.6
Retiree Coverage (Non-Subsidy)				0.1
Retiree Subsidy				6.9

Source: Avalere Health Analysis of Data from Department of Health and Human Services, CMS, Released August 16, 2006

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Beneficiaries Signed Up to Save Money Now & In Future

Reason for Signing Up	Percent of Respondents Who Have Signed Up for a Drug Plan
Protecting yourself in case your drug costs go up in the future	91%
Saving money on your drug costs	91%
Avoiding a penalty for enrolling later	68%
Being able to buy drugs you could not afford to buy before	66%

Source: Medicare Payment Advisory Commission, June 2006

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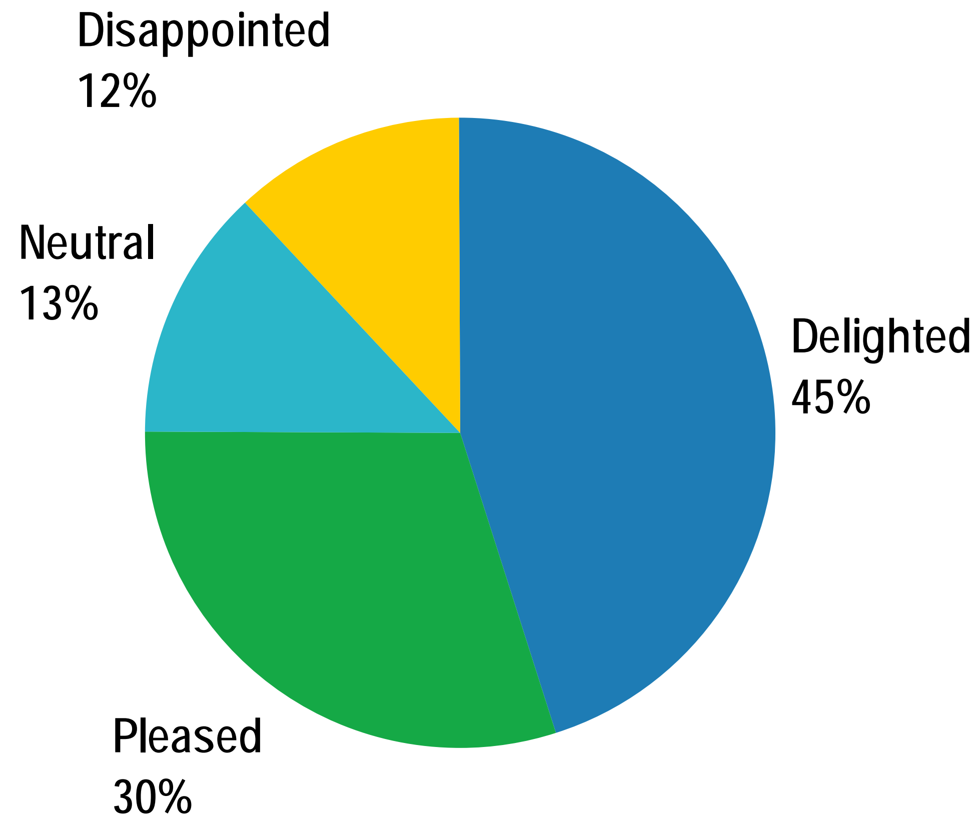
Beneficiaries Are Satisfied With the Drug Benefit, So Far



Source: JD Powers & Associates Survey, September 2006

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CMS Efforts to Correct 2006 Problems & Prevent in 2007

Category	2006 Issues	2006 Fixes	2007 Readiness Checklist
Customer Service	▪ Long waits at call centers	▪ Increased staffing, 24-7 coverage	▪ Ready for high call volume ▪ Timely resolution of complaints
Data Exchange	▪ Difficulties with timely and accurate data transmission	▪ Ongoing efforts by CMS, plans; problems have declined over time	▪ Part D plans / CMS sharing data daily; timely data to feed Plan Finder Tool
Enrollment/ Disenrollment	▪ CMS did not receive timely enrollment data from plans	▪ Clearer instructions on reporting to CMS	▪ Efficient transmission of data to CMS
Marketing	▪ Plans marketed Part D plans using unapproved materials or outside of approved timeframes	▪ CMS conducted training on marketing guidelines during conference calls with plans	▪ Marketing materials must be CMS-approved and distributed according to guidelines

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Future Direction of Medicare Part D Enrollment

- High beneficiary enrollment and satisfaction, so far
- Some low-income beneficiaries still not enrolled
- Enrollment and satisfaction are important measures of success
  - » Political support for the Part D benefit
  - » Stability of a market-based model
- If beneficiaries are unsatisfied and decide to drop out:
  - » Adverse selection
  - » Higher premiums
  - » Higher per-person spending by the Federal government
  - » Total Federal spending stays about the same

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Future Success Hinges on High Enrollment, Satisfaction

Total Enrollment (Millions)

30
25
20
15
10
5
0

100 80 60 40 20

Percent of Three Subgroups Enrolled, Ranked by Drug Spending

- Non Low-Income
- Dropped Retirees
- Low-Income Subsidy
- MA
- SPAPs
- Dual Eligibles

Source: Avalere Health LLC estimates using a model developed by the Actuarial Research Corporation for the Henry J. Kaiser Family Foundation.

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Low Enrollment Could Lead to Higher Premiums

Percent Change in Average Premium Compared to Full Enrollment

45%
40%
35%
30%
25%
20%
15%
10%
5%
0%

0% ($34.33)
11% ($38.08)
24% ($42.50)
34% ($46.17)
42% ($48.67)

100
80
60
40
20

Percent of Three Subgroups Enrolled, Ranked by Drug Spending

Source: Avalere Health LLC estimates using a model developed by the Actuarial Research Corporation for the Henry J. Kaiser Family Foundation.

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Federal Spending Similar Even If Enrollment Is Low

Enrollment (Ranked by Drug Spending)	Total Federal Costs (Billions)	Enrollment (Millions)	Average Costs per Enrolled Beneficiary
100 percent	$60.6	29.1	$2,080
80 percent	$60.8	26.3	$2,311
60 percent	$60.4	23.4	$2,587
40 percent	$58.5	20.4	$2,860
20 percent	$54.3	17.5	$3,095

Source: Avalere Health LLC estimates using a model developed by the Actuarial Research Corporation for the Henry J. Kaiser Family Foundation.

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Concluding Thoughts

- Choice and competition abound in the Medicare marketplace
- Coverage gap a potential cause for concern, especially for the chronically ill
- Plans' Medicare formularies differ from prior commercial designs in important ways
- High beneficiary satisfaction and enrollment are key measures of political and business success in the future

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