Health Industry Collaboration Effort, Inc. (ICE)
Annual Conference
December 4, 2007

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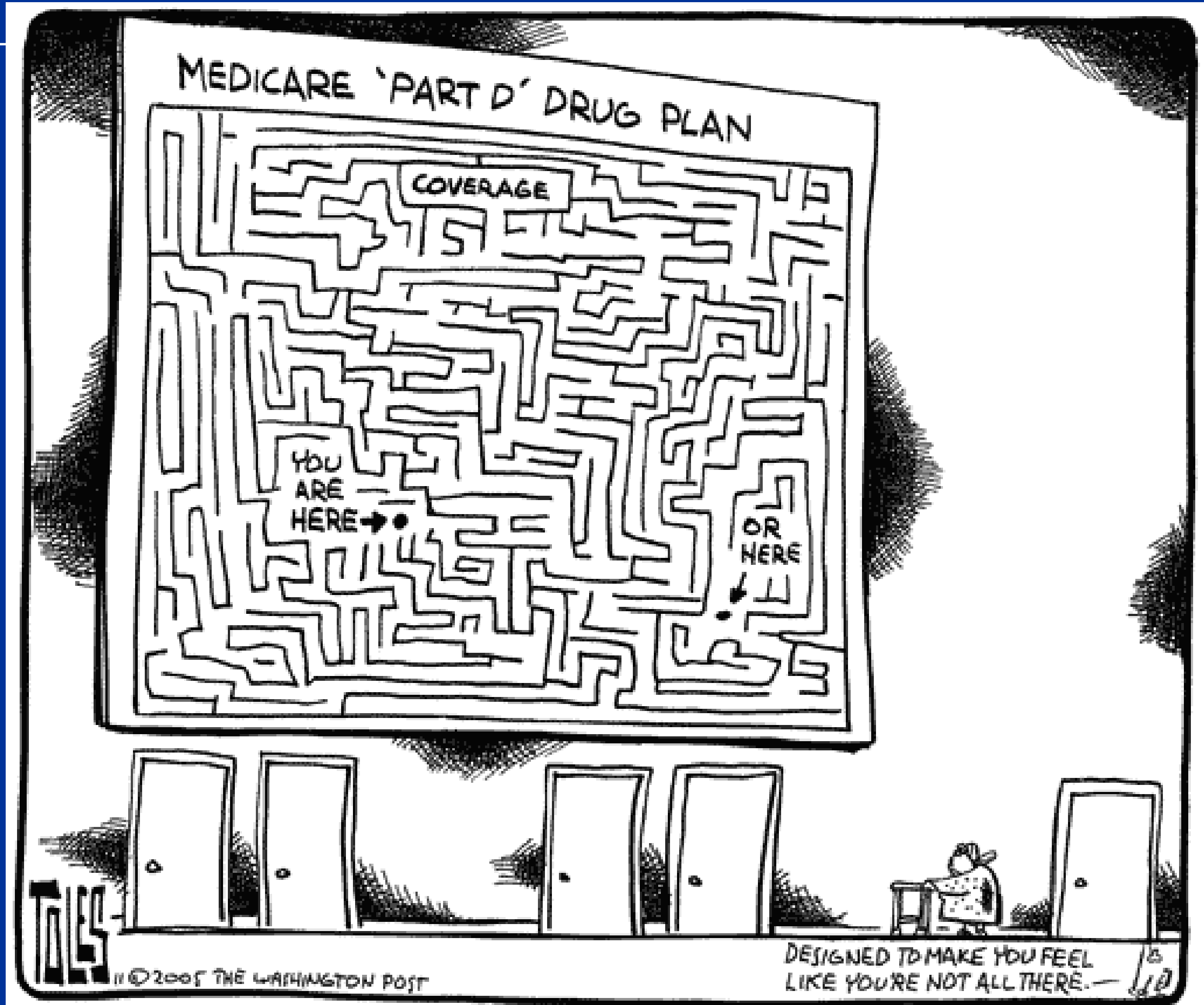
Director
Medicare Drug Benefit Group


MEDICARE 'PART D' DRUG PLAN
COVERAGE
YOU ARE HERE
OR HERE
TOLES
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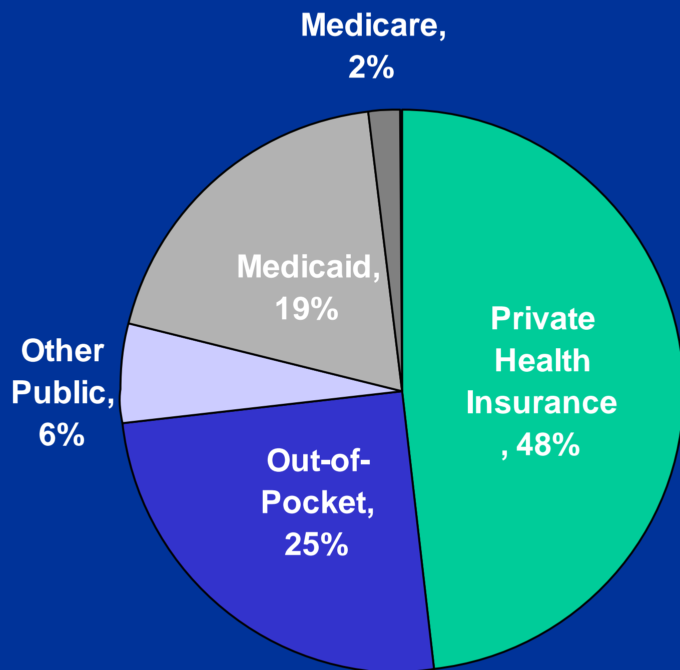
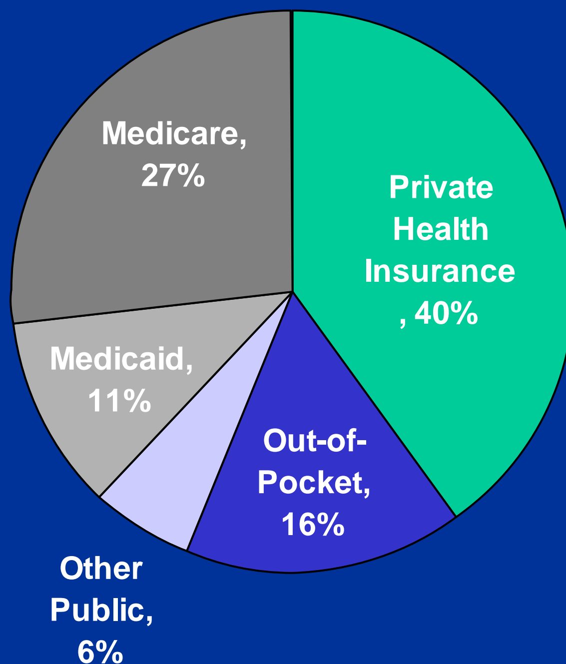
DESIGNED TO MAKE YOU FEEL LIKE YOU'RE NOT ALL THERE.

National Prescription Drug Spending, by Source of Payment, 2005 and 2006

Out-of-pocket spending as a share of all prescription drug spending decreased in the first year of the Medicare drug benefit.

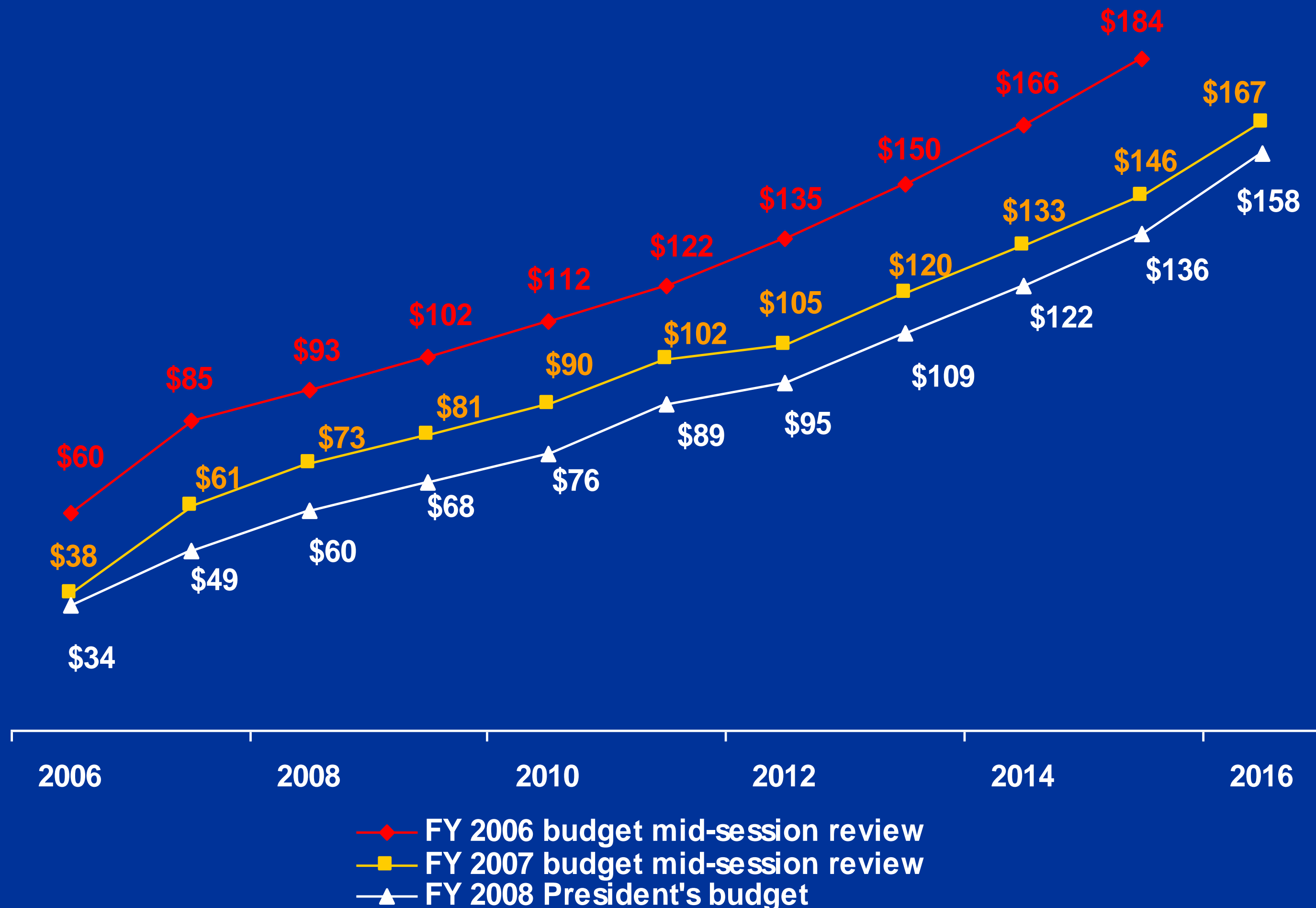




Source: Borger, et al., “Health Spending Projections Through 2015: Changes on the Horizon,” *Health Affairs* web exclusive, February 22, 2006.

Total Projected Spending Under Part D, A Comparison of 2006-2008 Estimates

Total spending under Medicare Part D is projected to be lower than previously estimated.



Note: Data are from the FY 2006 Budget Mid-Session Review, FY 2007 Budget Mid-Session Review, and FY 2008 President's Budget
Source: Office of the Actuary, CMS.

Part D Operations

- Applications & Contracts
- Formulary & Benefits Reviews
- Marketing & Policy
- Monitoring & Compliance
- Performance Measures

Plan Offerings and Analysis

CY09 Part D Contract Summary

Contract Type	2008		2007	
	Contracts	Plans	Contracts	Plans
PDP	87	1,877	90	1,909
MA-PD	493	2,041	398	1,639
Totals	580	2,918	488	3,548

Excludes Employer, PACE, SNP, and Part B only plans.

CY08 Benefit Type Analysis

Benefit Type	% of PDP Plans	Change from 2007	% of MA-PD Plans	Change from 2007
Defined Std. Benefit	11.8%	+0.3%	0.9%	-4.1%
Actuarially Equivalent Std.	12.9%	-0.4%	6.9%	+4.8%
Basic Alternative	24.7%	-2.6%	3.9%	-14.3%
Enhanced Alternative	50.6%	+3.3%	88.3%	+13.7%
Totals	100%	-	100%	-

Note: Excludes Employer, PACE, SNP, and Part B only plans.

Formulary Highlights

Formulary Review: Approach

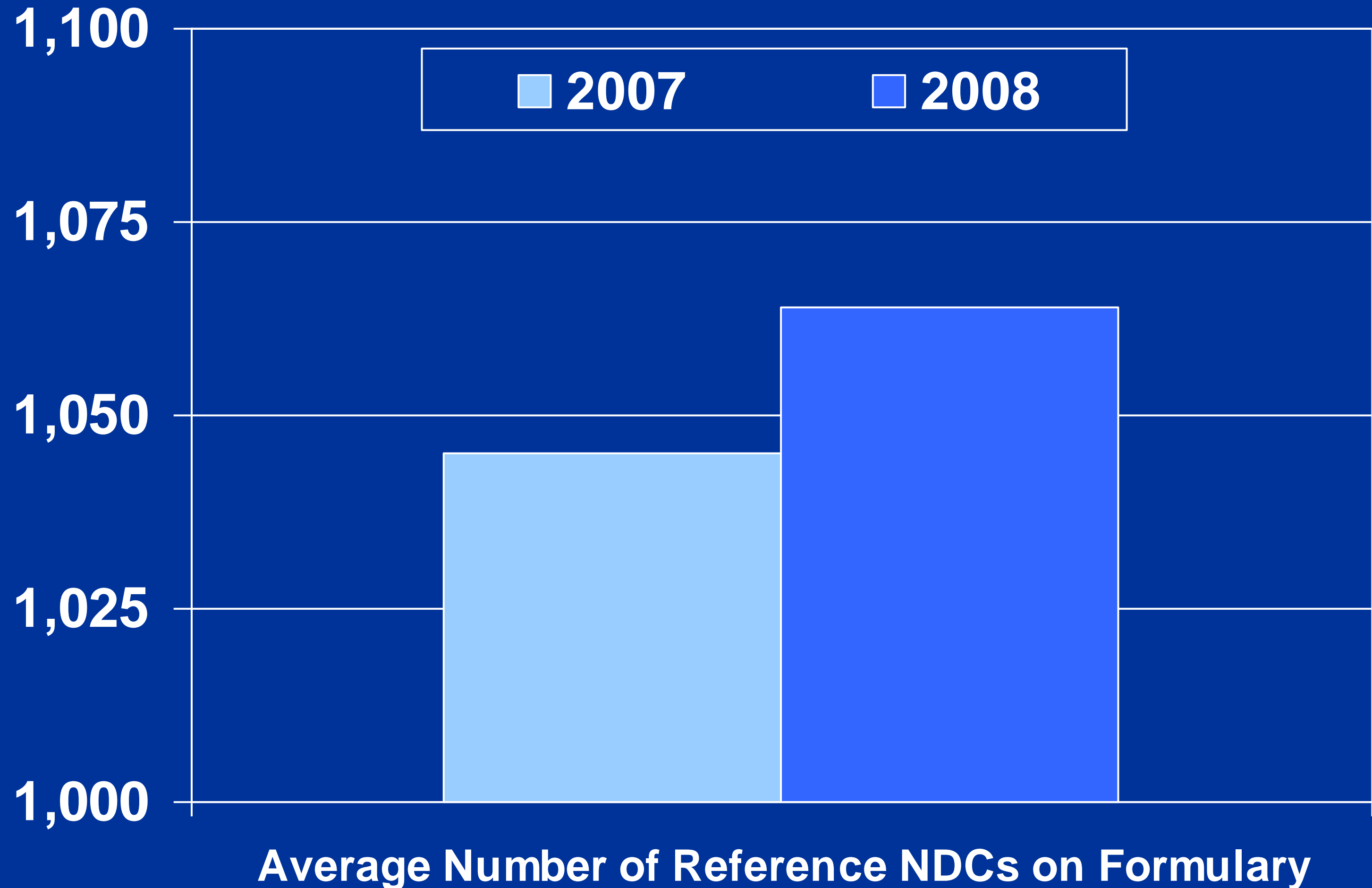
- Part D formularies are reviewed to prevent discrimination against beneficiaries by age, disease, or setting (e.g. long-term care)
- Ensure the inclusion of a broad distribution of therapeutic categories and classes
- Utilize reasonable benchmarks to check that drug lists are robust
- Review tiering and utilization management strategies
- Identify potential outliers at each review step for further CMS investigation
- Obtain reasonable clinical justification when outliers appear to create access problems

Characteristics of 2008 Formularies

USP Model Analysis		
# of Formularies	% of Formularies	% of Plans
160	43.8%	42.3%

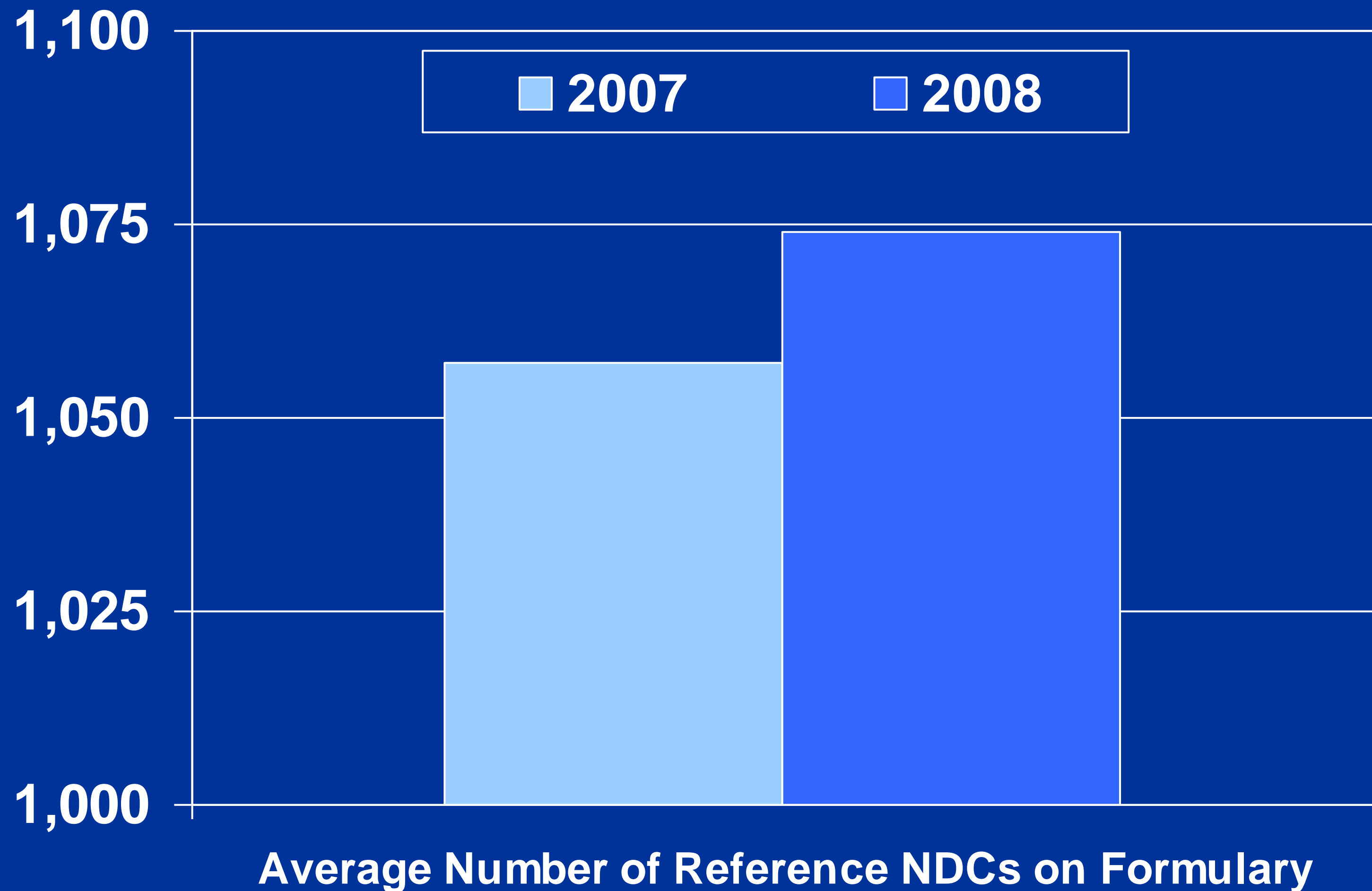
Formulary Edit Analysis		
Type	# of Formularies	% of Formularies
Specialty Tier	288	78.9%
Step Therapy	297	81.4%
Quantity Limit	357	97.8%
Prior Authorization	357	97.8%
Total Formularies	365	

2007 vs. 2008 Formularies (PDP)



Note: Adjusted for drugs comparable on both the 2007 and 2008 Medicare Formulary Reference Files. 2007 and 2008 formulary data as of 09/18/07.

2007 vs. 2008 Formularies (MA-PD)



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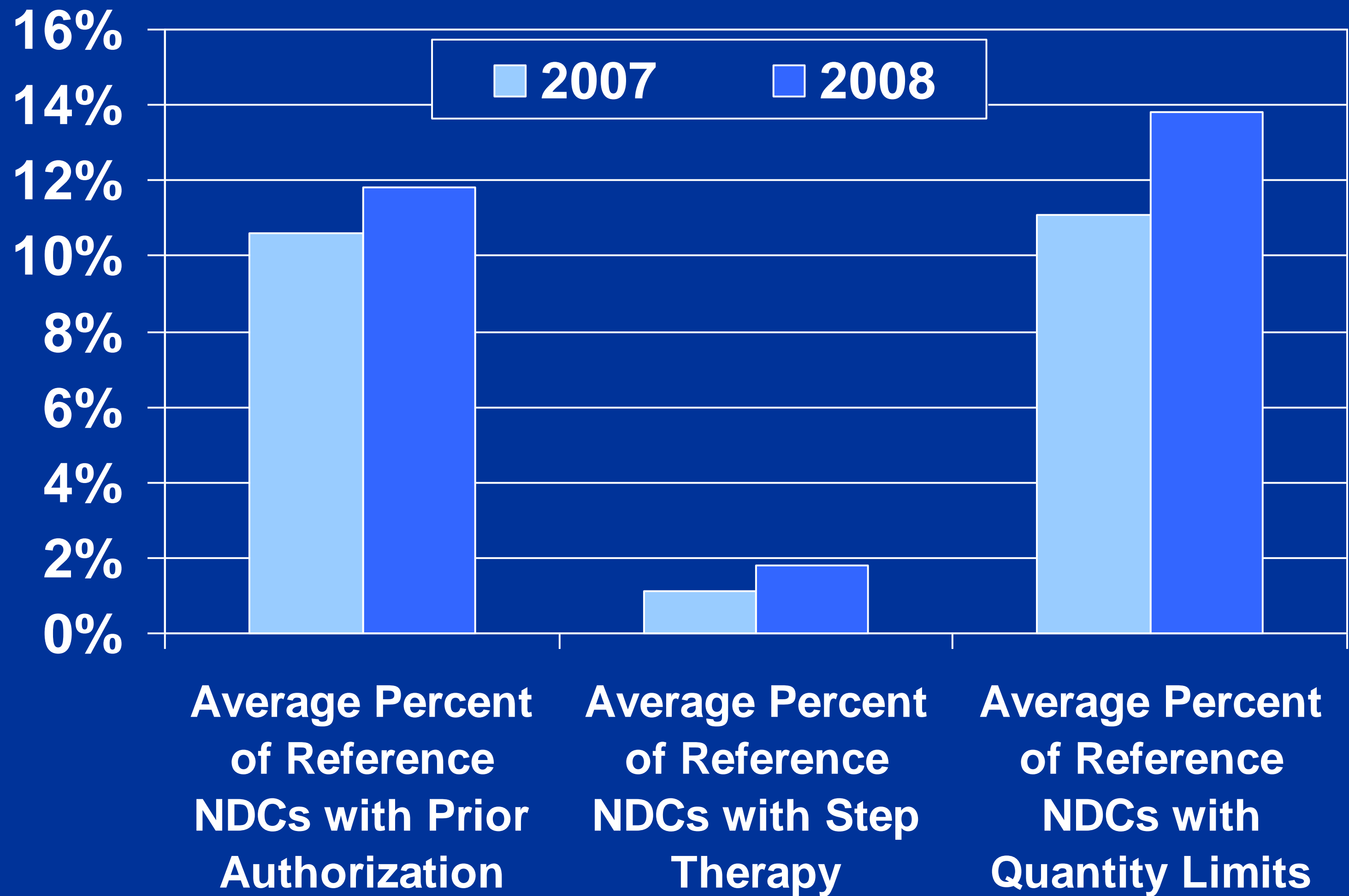
2007 vs. 2008 Formularies (PDP)



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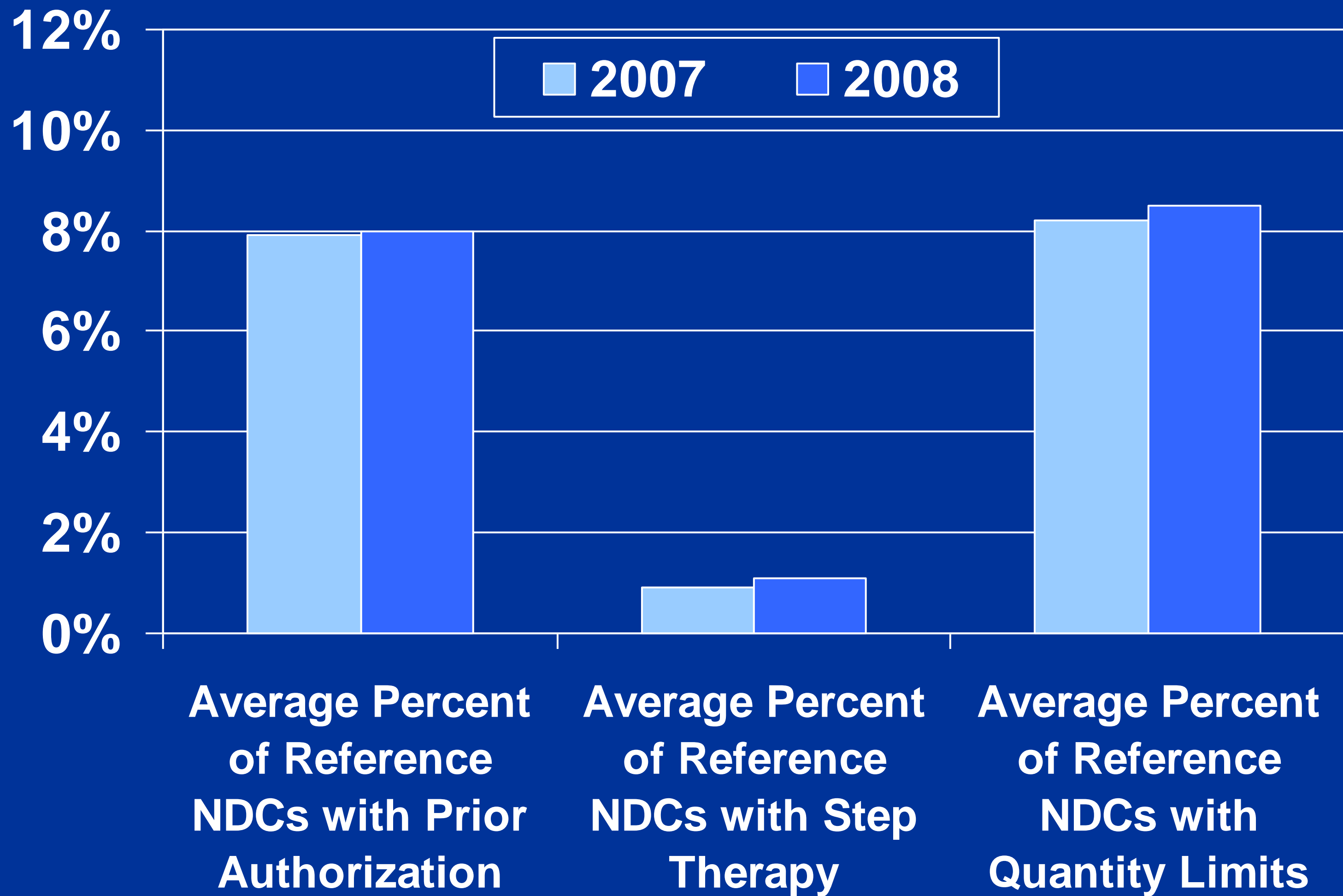
2007 vs. 2008 Formularies (MA-PD)



Note: Adjusted for drugs comparable on both the 2007 and 2008 Medicare Formulary Reference Files. 2007 and 2008 formulary data as of 09/18/07.

Key Drug Types Impact on Part D Formularies

- The number of unique FDA-approved drug entities on Part D formularies is increasing.
- The number of KDT listed in the USP Model increased significantly between 2007 (141) and 2008 (193)
- CY 2008 analyses are ongoing. Preliminary results show that for the KDTs that were consistent between 2007 and 2008, there is a negligible difference in the average percentage of KDT included on formularies (98.3% versus 98.7%)
- Based on available information, the use of KDTs as an outlier test is the appropriate method for review

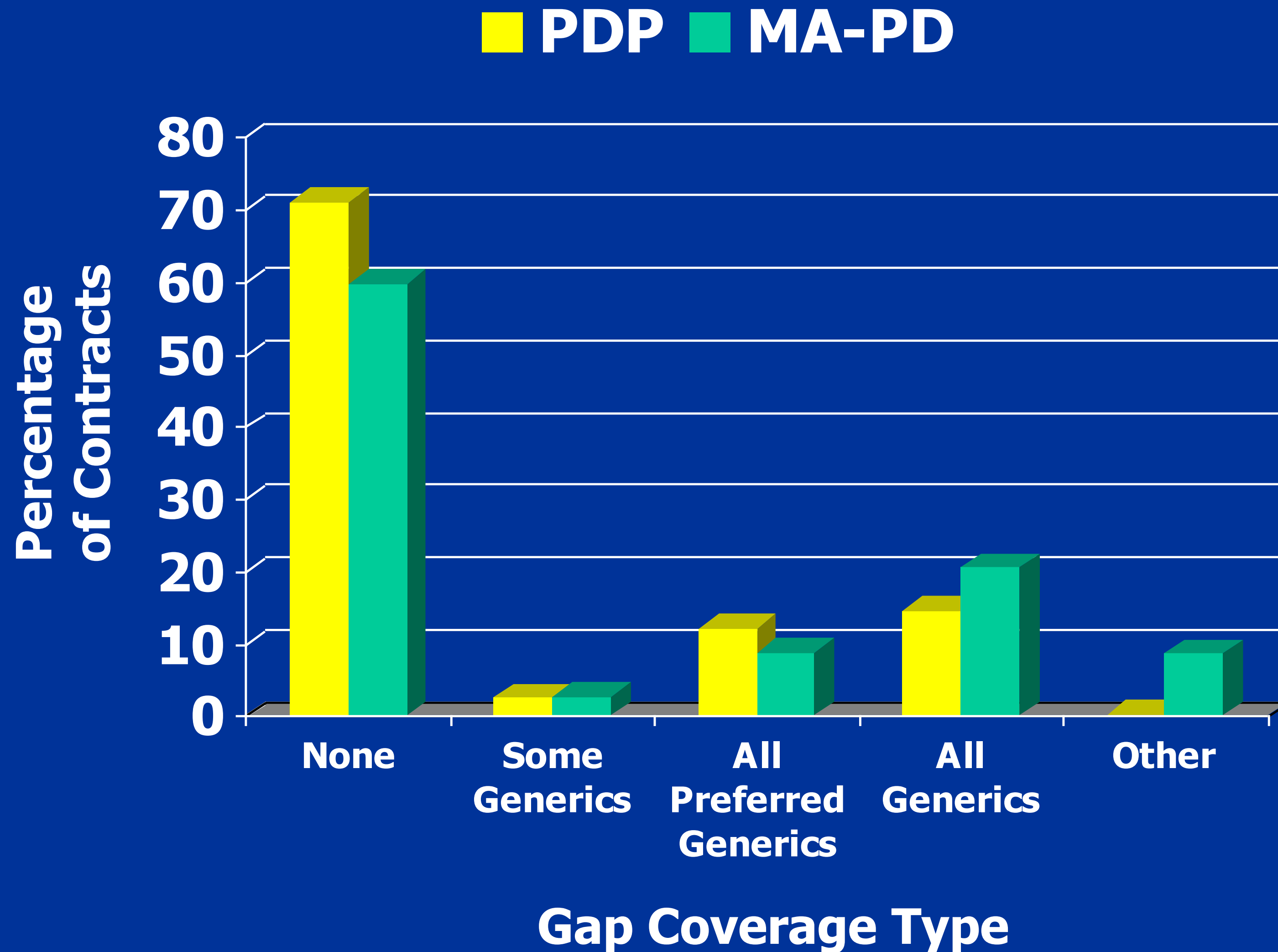
2008 Formulary Summary

- **Part D sponsors' 2008 formularies remain relatively unchanged in comparison to 2007 formularies.**
  - The comparison of formulary characteristics between benefit years must be adjusted to reflect current formulary standards. For 2008, CMS cleaned up the Formulary Reference File (FRF) to remove excluded Part D drugs that were included in 2006 & 2007 formularies. Not adjusting for this factor will lead in inaccurate coverage year comparisons.
- **On average, Part D sponsors 2008 formularies will cover approximately 2% more distinct FDA-approved drug entities in comparison to 2007 formularies.**

2008 Formulary Study Cont.

- Once again, CMS has performed an extremely rigorous formulary review to ensure appropriate access to drugs and to avoid discrimination against beneficiaries with certain conditions.
- 2008 formularies will have slightly higher rates of utilization management compared to 2007 formularies .

2008 Gap Coverage Analysis

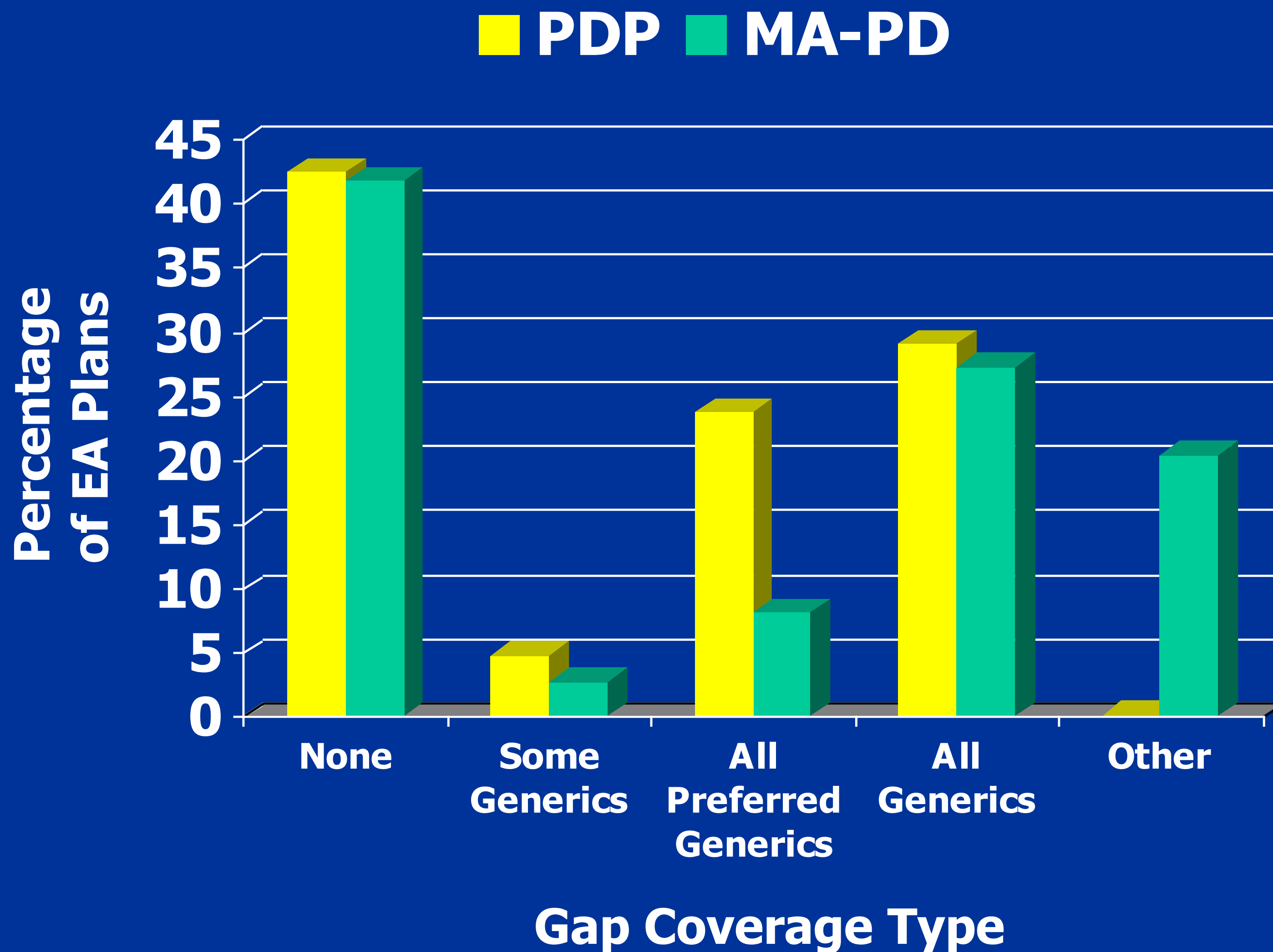


Note: Excludes Employer, PACE, SNP, and Part B only plans.

2008 Gap Coverage Summary

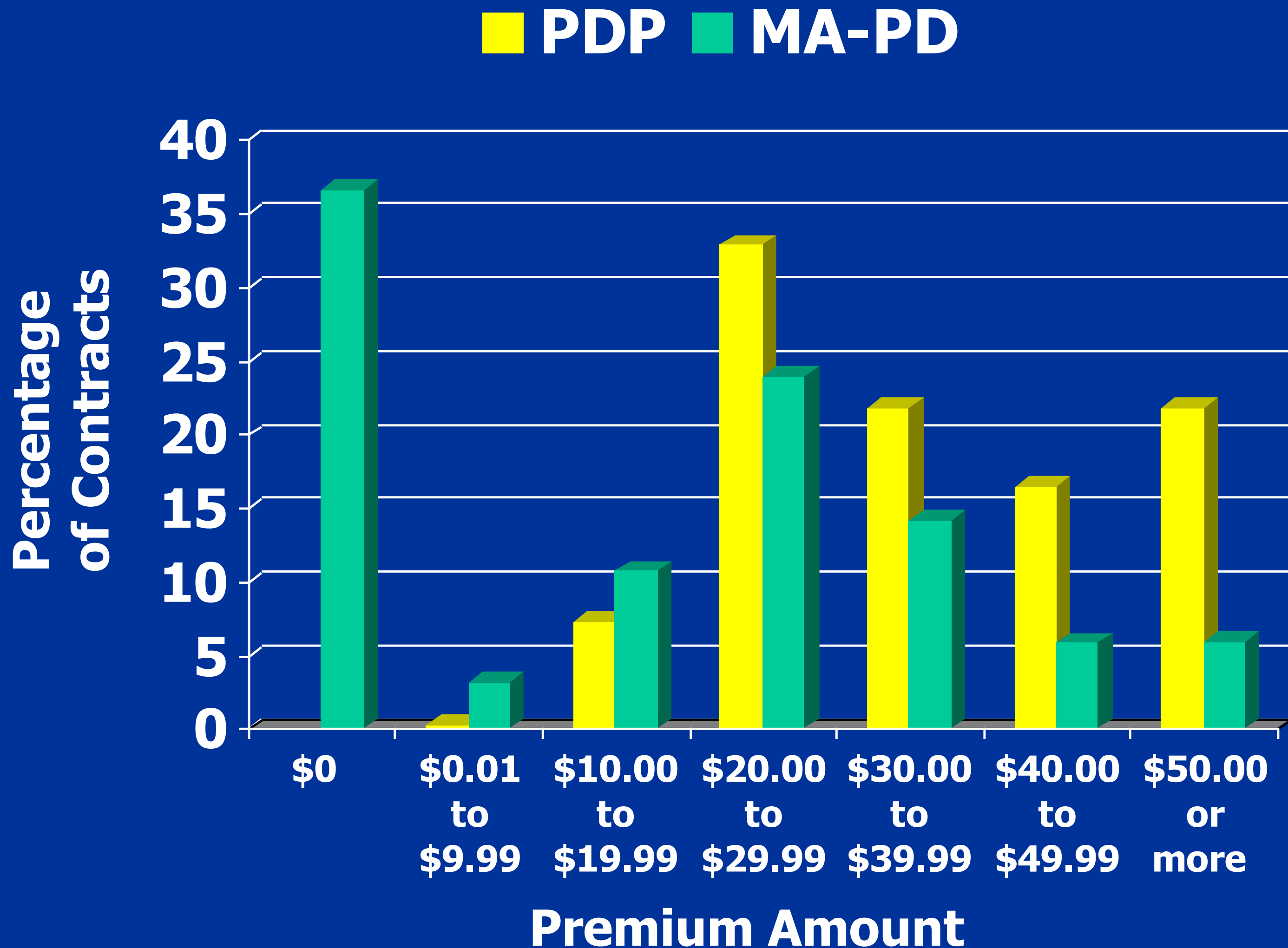
- Options are available that cover generic drugs in the coverage gap for as low as $28.70 a month and all states have PDP plans with coverage in the gap for generic drugs for under $50 a month.
- The total number of plans with any gap coverage will be decreasing in about half of the states; however there will still be many plans in each state (between 14 and 18 plans depending on the state) with coverage of generics in the gap.
- There will be no PDP plans that cover all brands or all preferred brands in the gap (note: only 1 PDP will have any brand coverage; Citrus Health Care in Florida will cover “Some Brands” in the gap)

2008 Enhance Alternative (EA) Gap Coverage Analysis



Note: Excludes Employer, PACE, SNP, and Part B only plans.

2008 Premium Analysis



Note: Excludes Employer, PACE, SNP, and Part B only plans.

2008 PDP Plan Summary

- More than 90 percent of Medicare beneficiaries in a stand-alone Part D prescription drug plan (PDP) will have access to at least one plan in 2008 with premiums lower than they are paying this year.
- In every state, beneficiaries will have access to at least one prescription drug plan with premiums of less than $20, and a choice of at least five plans with premiums of less that $25 a month.
- The lowest premiums for plans will range from under $10 ($9.80 in AZ) to just under $20 ($18.00 in AL and TN).
- In 2008, 17 organizations will offer stand-alone prescription drug plans nationwide (in all 50 dates plus Wash, D.C.)
- Beneficiaries in all states have access to a PDP with no drug deductible for a premium of less than $26 per month.
- In every state, the majority of plans offer mail-order pharmacy services.

2008 MA-PD Plan Summary

- There are more MA-PD health plan offerings in 2008 than in 2007.
- MA-PD premiums will average $11 lower than premiums for PDPs in 2008 (vs. $7 lower in 2007).
- Over 90 percent of people with Medicare will have access to a MA-PD for a $0 premium and with a $0 drug deductible.
- For Medicare Advantage, premiums will be lower in 2008 than 2007 and the vast majority of beneficiaries will have access to plans with $0 premium for Part D coverage.

Marketing

Post MMA Marketing

- **With the start of the Part D program, CMS employed not only it's usual Regional Office marketing reviewers, but also Central Office and contractors to review marketing materials for 2006 and beyond.**
- **In 2007, CMS conducted a "consistency study" to look at congruence (agreement) between the original review and a re-review of the material.**
- **CMS also conducted a File & Use retrospective study to determine whether material filed under F&U Certification met CMS requirements.**
  - Results from this study reinforced the CMS' concerns identified in the consistency study.

Consistency Study Results

- **40% congruence rate.**
- **60% of the re-reviewed materials contained errors.**
- **The EOC contained the largest number of errors.**
- **For the purpose of this study, CMS identified critical elements errors (may negatively impact understanding of the content).**
- **2/3 of all errors were non-critical.**
- **Material ID/Approval Placeholder errors account for 65% of the materials with one critical element error. Correcting for this error improved consistency to 68%.**

Marketing Recommendations

- Use Structured Checklists or Protocols for CMS review.
- Make Protocols available to plans for use in the development of marketing materials.
- Develop process within HPMS to document important communication and supporting documentation.
- Develop a system for regularly identifying, suggesting and making improvements to the review process.
- Create a system to address Global Process issues (i.e., marketing material identification numbers) quickly, eliminating a significant number of disapprovals.
- Improve training.
- Clarify marketing guidelines.

Enrollment Update

Current Part D Enrollment

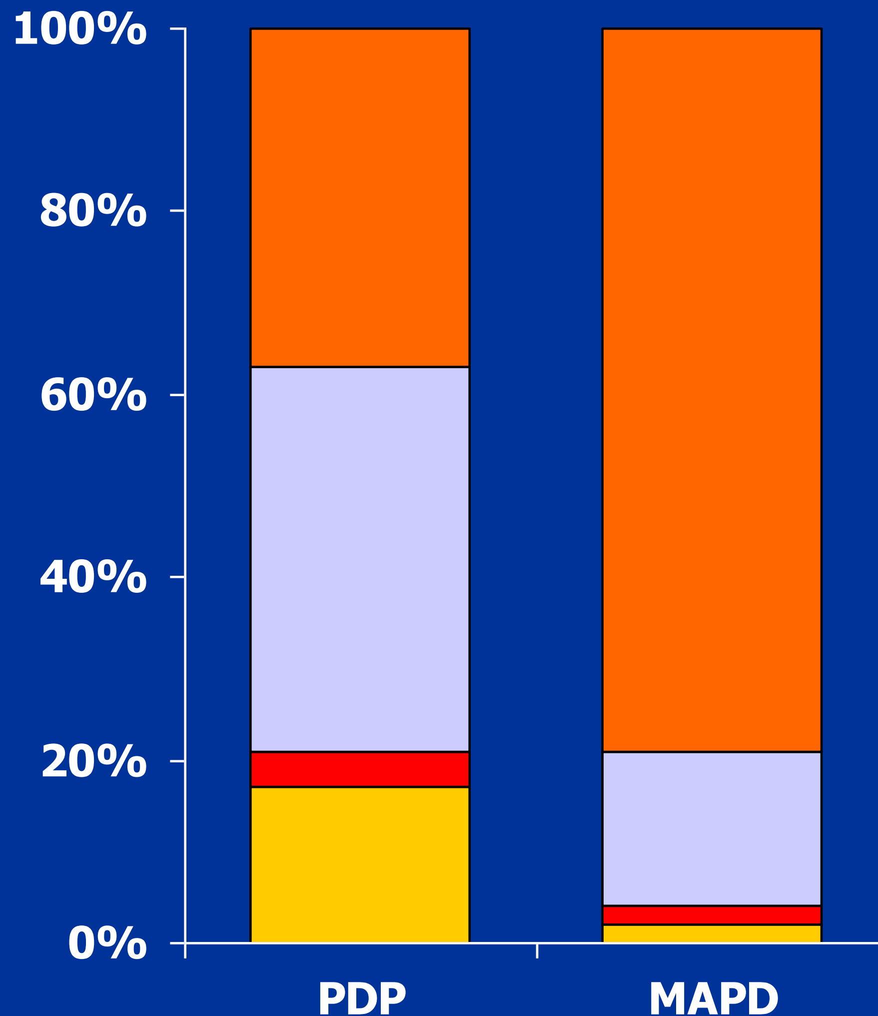
Enrollment Category	#
Stand-Alone Prescription Drug Plan	17.18M
Medicare Advantage with Prescription Drugs	7.45M
Total	24.63M

- Part C & D enrollment information is available at www.cms.hhs.gov/MCRAdvPartDEnrolData/

Data as of October 2007

Enrollment by Benefit Type

- Beneficiaries are selecting alternative design plan types.



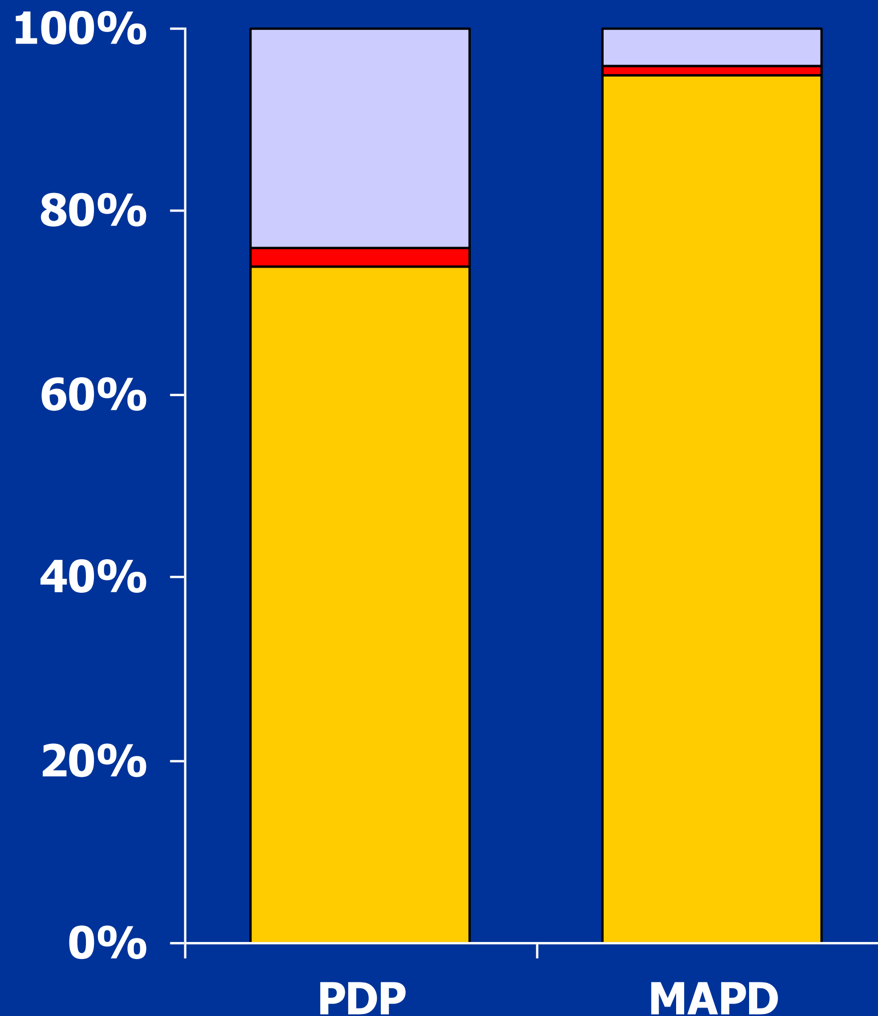
- Enhanced Alternative
- Basic Alternative
- Actuarially Equivalent Standard
- Defined Standard

Data as of Jan07

Analysis excludes FBDE & LIS

Enrollment by Deductible Category

- **Beneficiaries are selecting plans with no deductible.**

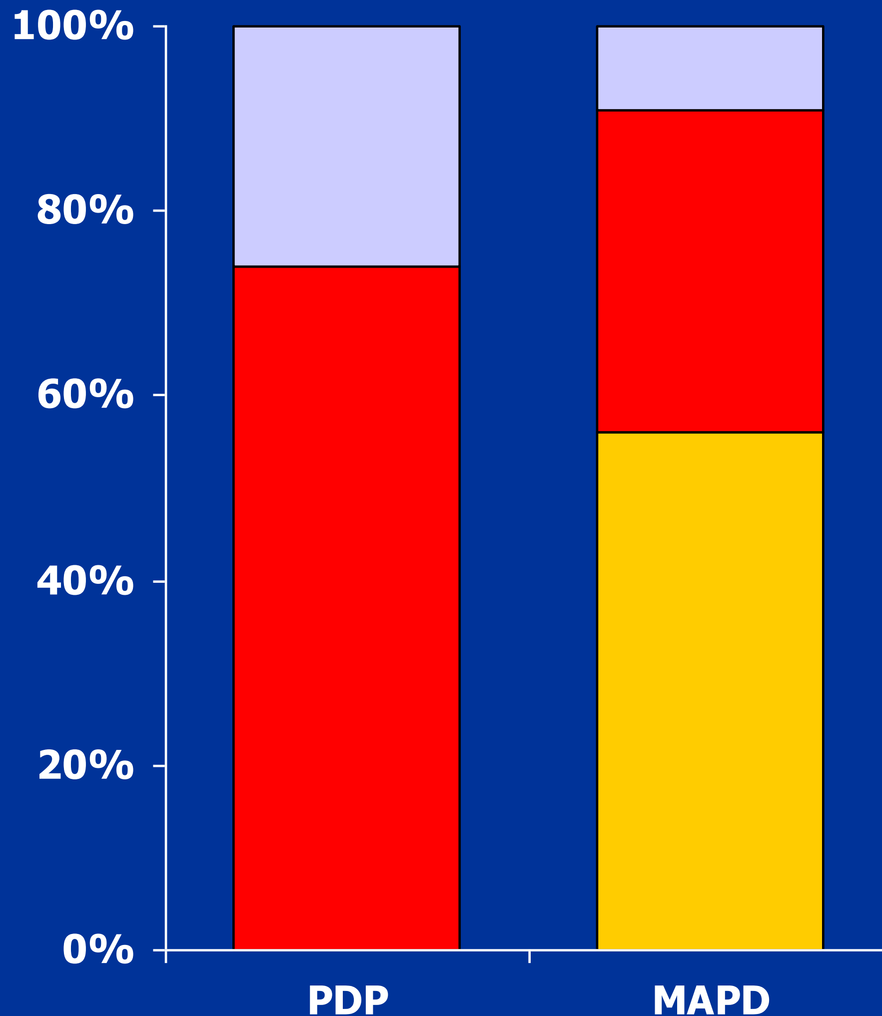


Data as of Jan07

Analysis excludes FBDE & LIS

Enrollment by Premium Category

- **Beneficiaries are selecting plans with low or no premiums**



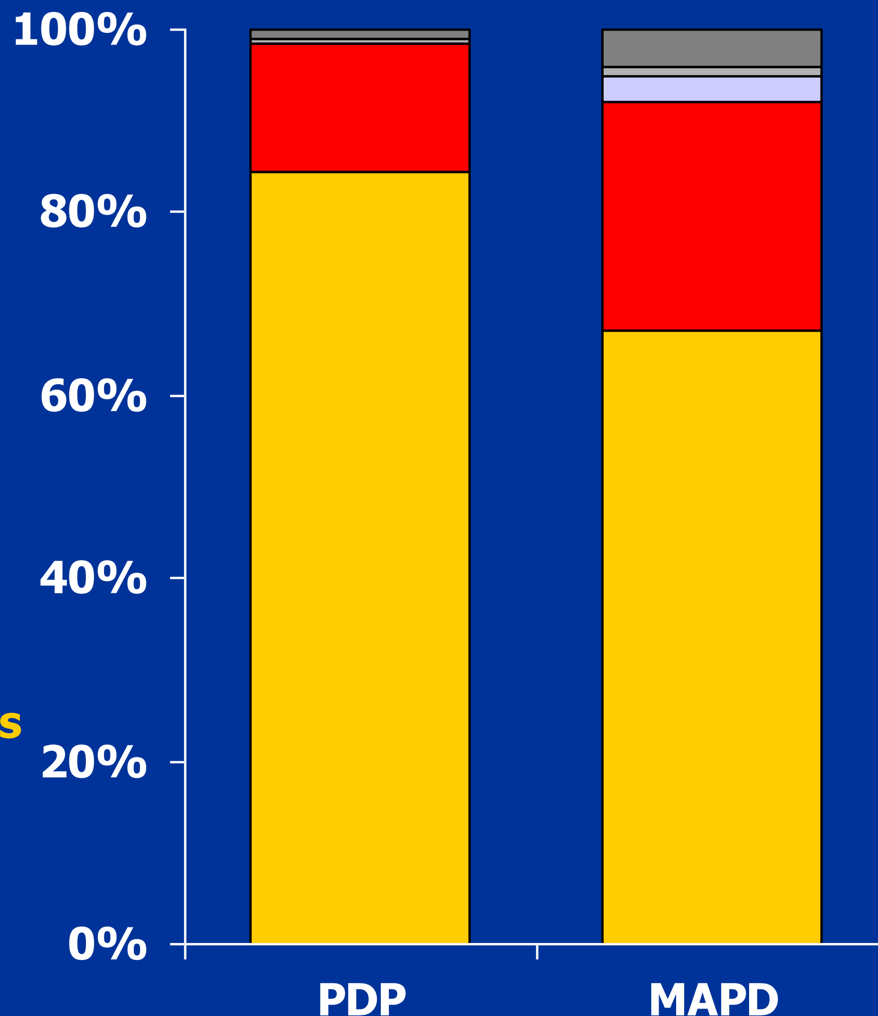
$32.20 and above
$0.01 - $32.19
$0

Data as of Jan07

Analysis excludes FBDE & LIS

Enrollment by Gap Coverage

- Coverage in the gap is not a significant factor in plan selection.

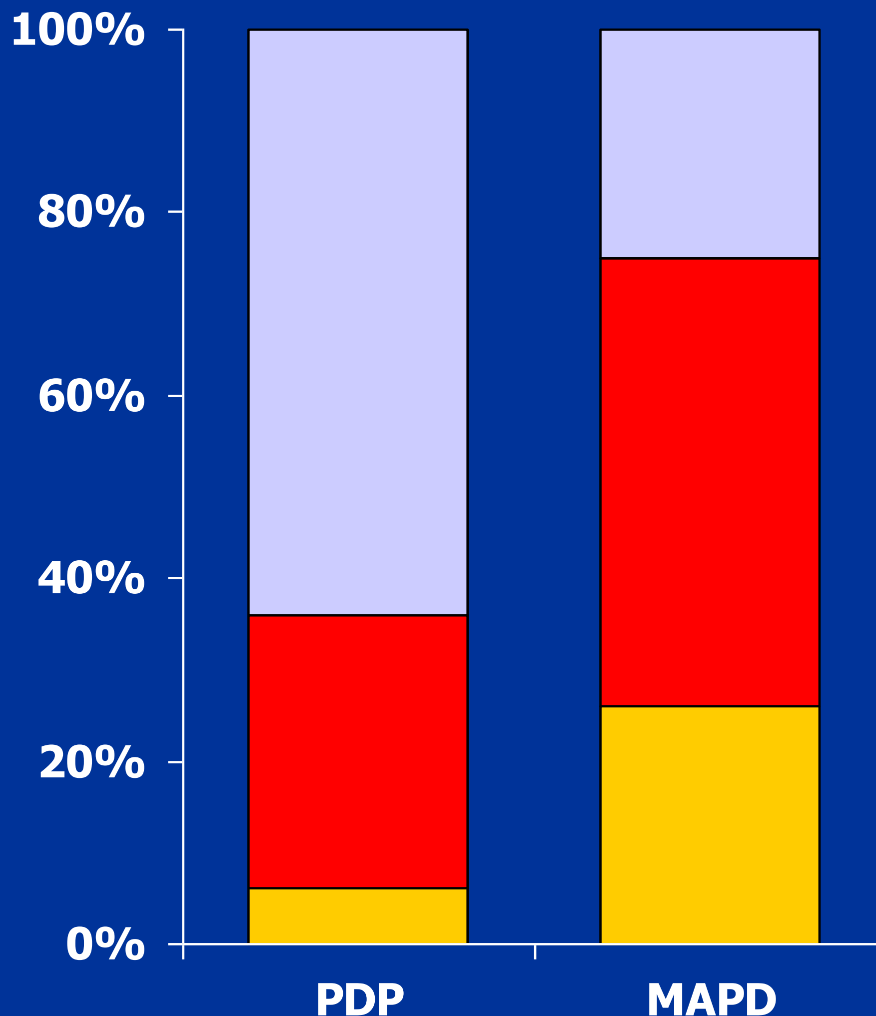


Data as of Jan07

Analysis excludes FBDE & LIS

Enrollment by Number of Generic Entities on Formulary

- **The number of generic entities on a formulary is not a significant factor in plan selection.**



1500+
1000 - 1499
<1000

Data as of Jan07

Analysis excludes FBDE & LIS

Pricing and Reimbursement

Drug Pricing and Reimbursement

- **Drug pricing data is published on Medicare.gov on the Medicare Prescription Drug Plan Finder (MPDPF) tool.**
  - The pricing data is submitted by plans and is at the pharmacy level.
  - Updated biweekly.
- **CMS monitors and reports pricing changes as a current performance measure.**
- **CMS is prohibited from negotiating prices and reimbursement with plans, pharmacy benefit managers (PBMs), distributors, and pharmacies.**

Monitoring of Drug Pricing

- CMS has a current performance metric to measure drug price changes.
- The average drug increase in the CPI (Feb. – Aug. 2006) was 5%.
- 13% of PDP drug prices exceeded the CPI increase.
- Plans were given a high rating if they had a lower percentage (<22%) exceeding the CPI.
- Plans were given a low rating if they had a higher percentage (>33%) exceeding the CPI.
  - 7 PDPs and 34 MA-PDs received low ratings (1 or 2 stars).

Part D Report Card / Plan Ratings

CMS

Goal of Performance Metrics

- Consumers need and want more useful information to get better care at a lower cost
- To ensure that Medicare beneficiaries receive the best healthcare and prescription drug coverage available and that they have the data necessary to make informed decisions.
- Support the President's Agenda on health care transparency and CMS' strategic plan goal of transparency/confident, informed consumers.

Part D Plan Ratings – New for 08

- Expansion of the number of Part D measures
- Making measures more accessible to users of the drug plan comparison websites
- Measures will be evaluated and rated at a domain and measure level

Medicare Plan Ratings Integrated with the Plan Finder

- Beneficiaries will have the opportunity to view the measures at three levels:
  - The highest level is the domain level, which summarizes all measures in that area into a single rating.
  - From each domain, beneficiaries can drill down to the summary level. This level will provide a rating for each measure.
  - Within each measure, a beneficiary can view details. This level will show a rate, time, or statistic for each measure.
- Both the domain and summary level ratings will be based on a five-star scale

Medicare Part D Plan Ratings Measure Domains

- Drug Plan Consumer Service
- Using Your Plan to get Your Prescriptions Filled
- Drug Pricing Information

Plan Ratings

Select Plans for ZIP Code 21244

Print This Page | Close Window

When you choose 3 plans to compare, quality and performance information will be available to help you make the best choice for you. Quality and Performance varies across plans. Giving good quality care means doing the right thing, at the right time and in the right way to get the best possible results.

You are comparing: ○Prescription Drug Plans ◉**Health and Prescription Drug Plans** [What is this?] View

Drug Plan Ratings | Health Plan Ratings

Choose up to 3 plans to Compare | Reset Checkboxes — Sort Table By: Plan Name | Sort

	Plans Name and ID Numbers	Drug Plan Customer Service [What is this?]	Using Your Plan To Get Your Prescriptions Filled [What is this?]	Drug Pricing Information [What is this?]
☑	Plan A (H0000-02)	★★★★★	★★★★	★★★
☐	Plan B (H0000-003)	★★★★★	★★★★	★★★★
☑	Plan C (H0000-004)	★★★★	★★★★★	★★★★
☐	Plan D (H0000-005)	★★★★★	★★★	★★★★
☑	Plan E (H0000-006)	★★★★	★★★★	★★★★★
☐	Plan F (H0000-007)	★★★★★	★★★	★★★★
☐	Plan G (H0000-008)	★★★★★	★★★	★★★★
☐		★★★★★	★★★	★★★★

Plan Ratings

The number of stars shows how well the plans perform.

Excellent	★★★★★
Very Good	★★★★
Good	★★★
Fair	★★
Poor	★

Drug Plan Customer Service Measures (Domain #1)

- Customer service wait time
- Customer service disconnect rate
- Pharmacy help desk average wait time
- Pharmacy help desk average disconnect rate
- Beneficiary ability to get help from the plan
- Beneficiary rating of plan
- Total customer service complaints

Return To Previous Page

Plan Ratings

View Plan Ratings for ZIP code 21244

Print This Page | Close Window

Review how your selected plan(s) rated on quality and performance below. Use this information to help you make the best choice for you.

Types of Plan Ratings

View: Stars Numbers | Hide All Plan Ratings

	Plan A (H0000-002)	Plan C (H0000-004)	Plan E (H0000-006)
Hide	**Drug Plan Customer Service** Click to view Data Sources		
Time on Hold When Customer Calls Drug Plan	45 secs.	7 secs.	22 secs.
Calls Disconnected When Customer Calls Drug Plan	0.5%	0.0%	0.4%
Time on Hold When Pharmacist Calls Drug Plan	14 secs.	28 secs.	16 secs.
Calls Disconnected When Pharmacist Calls Drug Plan	0.5%	3.1%	0.6%
Complaints about the Drug Plan	0.82	0.53	0.43
How Helpful Is Your Plan When You Need Information	79.8%	78.1%	82.9%
Rating of Drug Plan	68.3%	69.9%	70.9%
Show	**Using Your Plan To Get Your Prescriptions Filled** Click to view Data Sources		
Show	**Drug Pricing Information** Click to view Data Sources		
Show	**Helping You Stay Healthy**		

Learn More

Learn how Quality and Performance are measured

Plan Ratings

The number of stars shows how well the plans perform.

Excellent	★★★★★
Very Good	★★★★
Good	★★★
Fair	★★
Poor	★

★★★★★

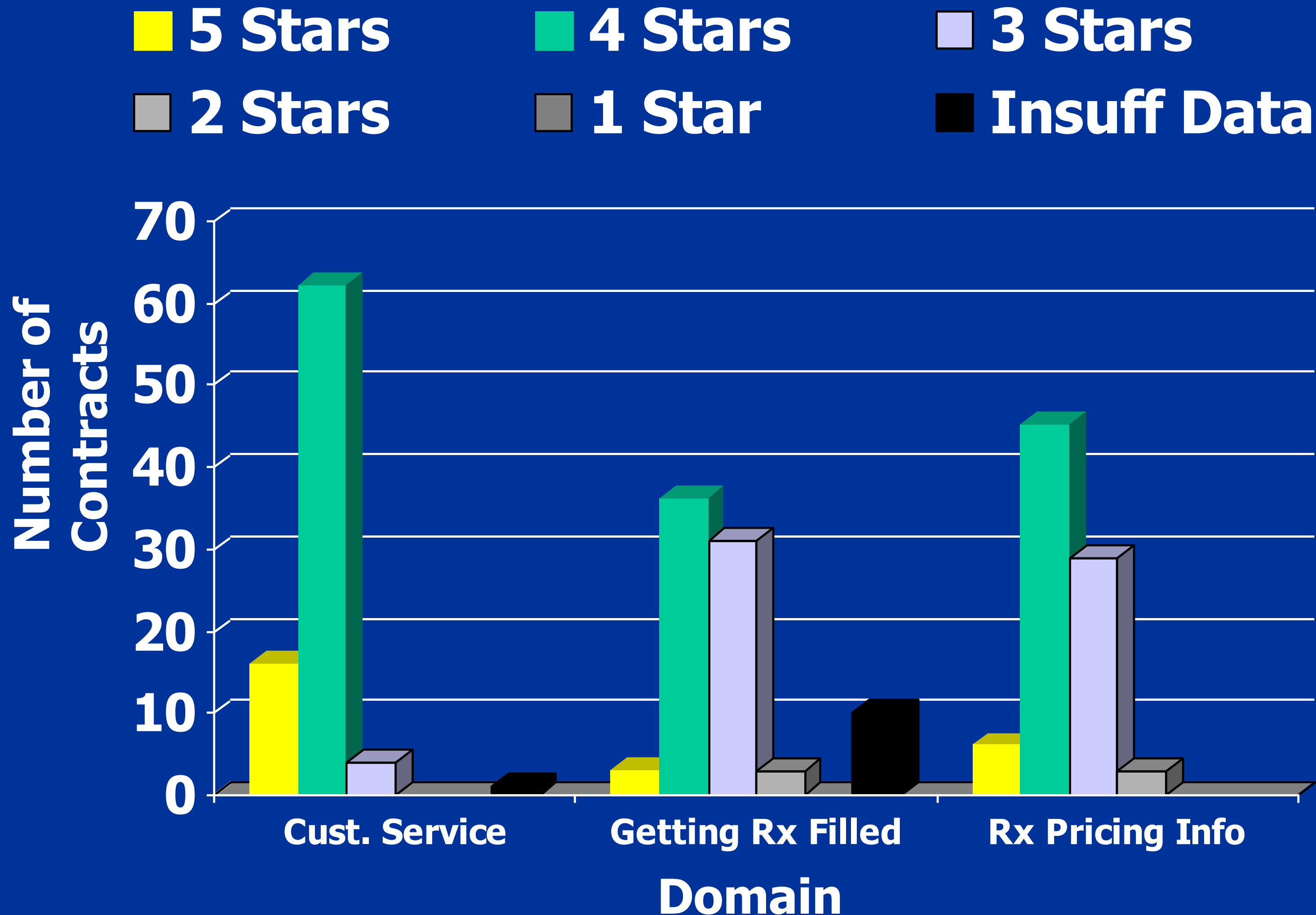
Using Your Plan to Get Your Prescriptions Filled (Domain #2)

- Getting prescriptions easily
- Pharmacists have up- to- date Plan enrollment information
- Pharmacists have up-to-date information on Plan members who need extra help
- Complaints about the Plan's benefits and access to prescription drugs
- Complaints about joining or leaving the Plan
- Delays in appeals decisions
- Reviewing appeals decisions

Drug Pricing Information (Domain #3)

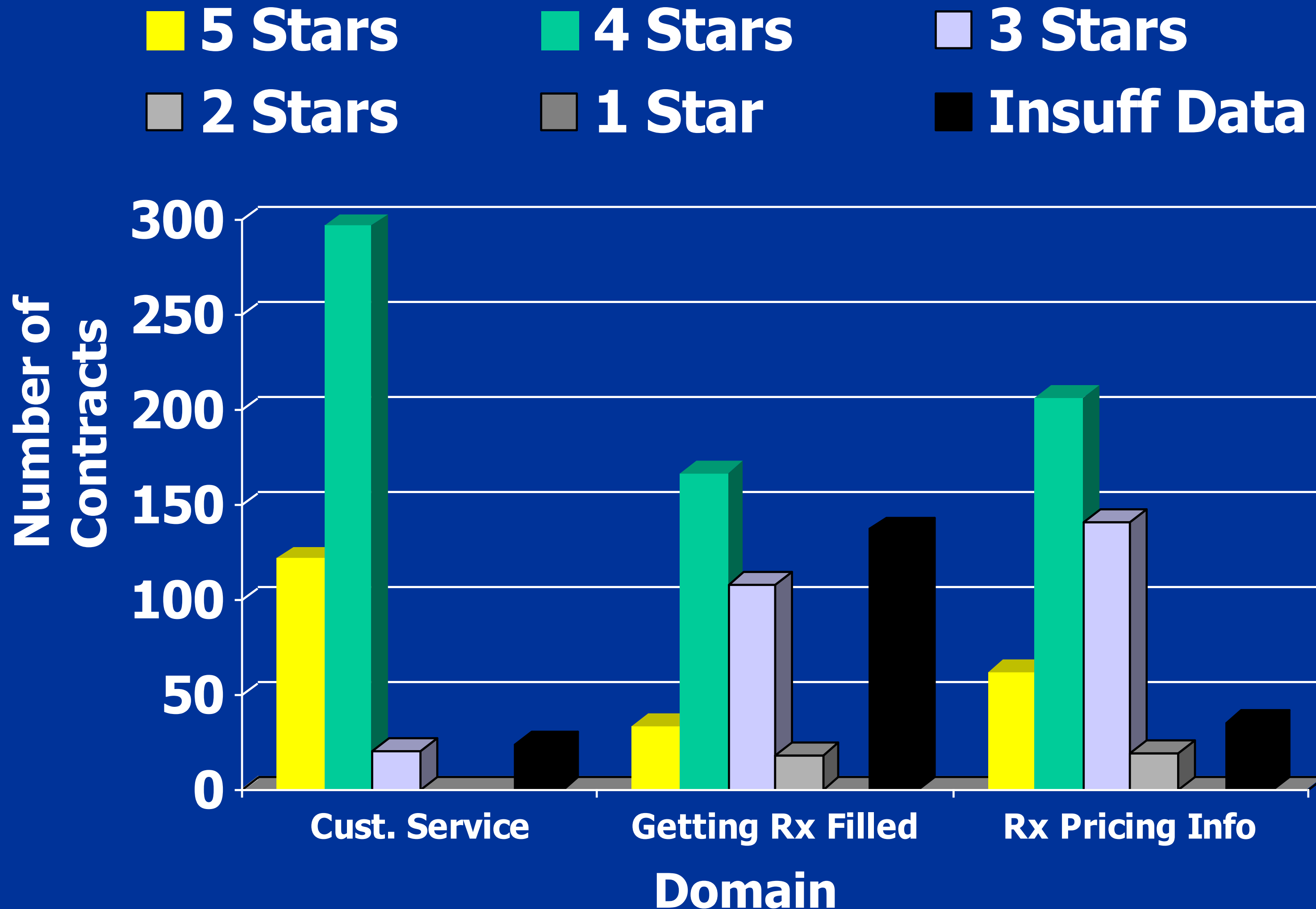
- Availability of drug coverage and cost information
- How often the Plan's drug prices change
- Complaints about the Plan's pricing and out –of-pocket costs

PDP Domain Summary



Note: Excludes new contracts. Data as of 10/25/07.

MA-PD Domain Summary



Note: Excludes new contracts. Data as of 10/25/07

Performance Measures Summary

- The expanded performance measures:
  - CMS' long-term goal is to establish performance benchmarks based on historical experience with Part D
  - Once benchmarks are established, CMS will work with plans to improve performance
  - If high performance in an area becomes standard for all plans then a measure may be retired
- The tool will substantially improve the information available to beneficiaries for selecting high-quality prescription drug plans and compare available plan options

Part D Compliance

Sources of Part D Requirements

- **Part D Statute (Medicare Modernization Act**
- **Part D Regulations – 42 CFR Part 423**
- **Part D Sponsor Contract**
- **CMS Policy/Operational Guidance**
  - Manual Chapters
  - Marketing Guidelines
  - Enrollment Guidelines
  - HPMS Bulletins
  - Q's and A's

Sources of Evidence of Non-Compliance

- Complaints from beneficiaries, advocacy organizations, pharmacies, sponsor self-reporting, other sponsors, State agencies
- Other CMS components (OIS, other)
- CMS Surveys (call centers, LIS match rates, appeals web site information, other)
- Routine Audits

Measuring Compliance

- **CMS measures non-compliance through the application of two factors:**
  - Frequency – Sponsor exhibits a pattern of poor performance of a routine function (enrollment processing, LIS match rates, other)
  - Severity – Non-compliance may have occurred only once, but has significant impact on beneficiary (for instance, use of unapproved marketing materials)

CMS' Administrative Options

- Issue Warning Letter / Corrective Action Plan
- Depending on significance of non-compliance, or if non-compliance persists, CMS may recommend the imposition of intermediate sanctions (suspending marketing/enrollment activities), civil monetary penalties (CMPs), or contract termination

Part D Policy

Part D Policy Developments

- May 2007 Policy and Technical Rule
  - Definition of Negotiated Price
  - Adequate Access to Home Infusion Pharmacies
  - Part D Vaccine Administration
  - Coordination of Benefits
- Best Available Evidence
- LTE DESI and Unapproved Drugs
- TrOOP Balance Transfer

Final Thoughts

What's New in 2008

- Continued stabilization and maturation of CMS policy.
- Shift of Part D vaccine administration reimbursement from Part B to Part D.
- Part C and D "report card" on plan quality and performance.
- Increased compliance focus on certain behaviors (e.g. brokers and agents).
- Other potential congressional actions.

For More Part D Information

www.cms.hhs.gov/PrescriptionDrugCovGenIn/01_Overview.asp

- Enrollment Data
- Performance Data
- Information for Pharmaceutical Manufacturers and Physicians
- Part D Regulations

www.cms.hhs.gov/PrescriptionDrugCovContra/01_Overview.asp

- Formulary Guidance
- Marketing Guidance
- Reporting Requirements
- Enrollment Guidance
- Coordination of Benefits Guidance
- Other Part D Related Guidance

www.cms.hhs.gov/DrugCoverageClaimsData/01_Overview.asp

- Prescription Drug Event (PDE) Information
- Risk Adjustment Information