Medicare Prescription Drug Benefit Symposium

What are Plans Doing and What is CMS Doing?

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

DEPARTMENT OF HEALTH & HUMAN SERVICES · USA

Introduction

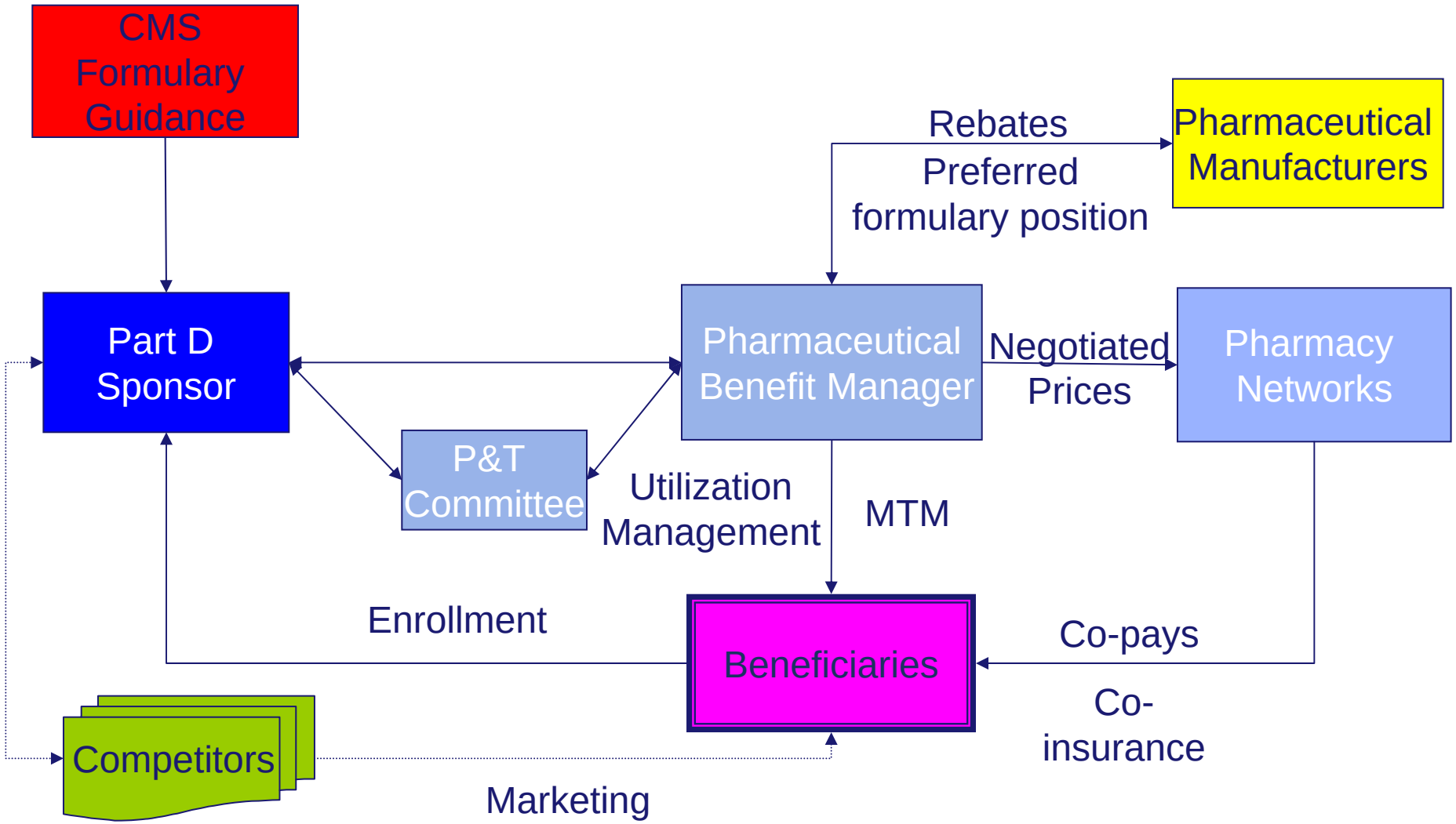
- Market negotiations result in high quality, low cost drug coverage.
- CMS policies provide stability, access and robust formularies.
- CMS is increasing transparency in Part D.

Overview

- Formulary Creation
- Drug Utilization Management
- Medication Therapy Management
- Incentives for Utilizing Lower Cost Alternatives
- Q&A Panel

Formulary Creation

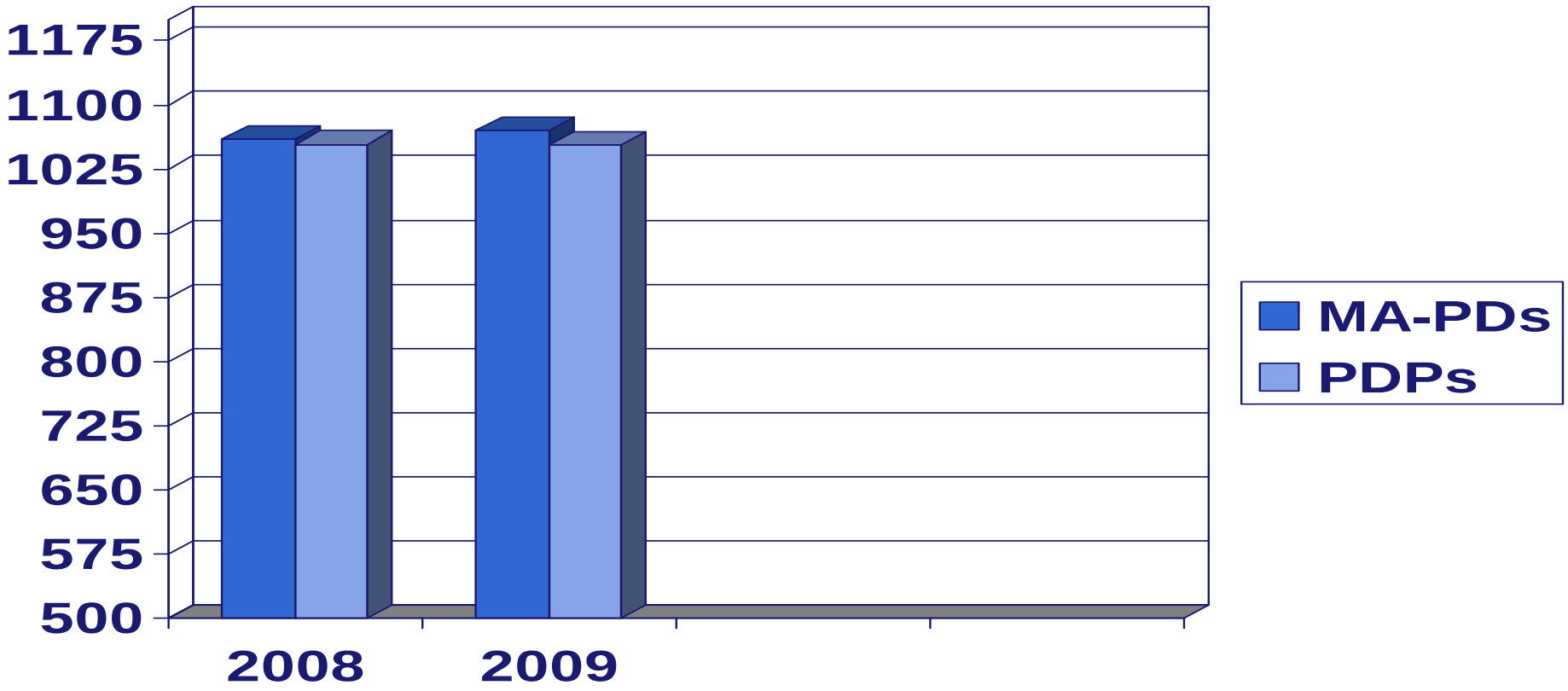
What are plans doing?



Formulary Comparisons Between Years

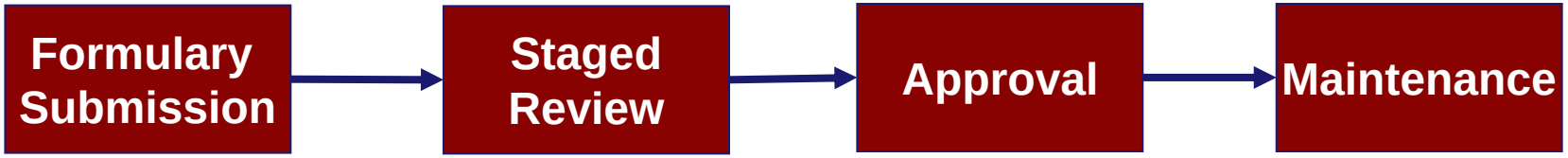
- Questions to consider if you compare aggregate formulary coverage between years?
  - At what level to do you count drugs?
  - Do you count every type of product down to the brand name, form, dosage, and strength?
  - Have you considered drugs removed by CMS from the Formulary Reference File (FRF) to ensure an appropriate comparison?
- CMS rolls up NDCs to unique chemical entities for comparison purposes.
  - Represents distinct chemical drug names regardless of brand name, strength, route, and dosage form.

Change in the Average Number of Unique Chemical Entities on Formulary (2008-2009)

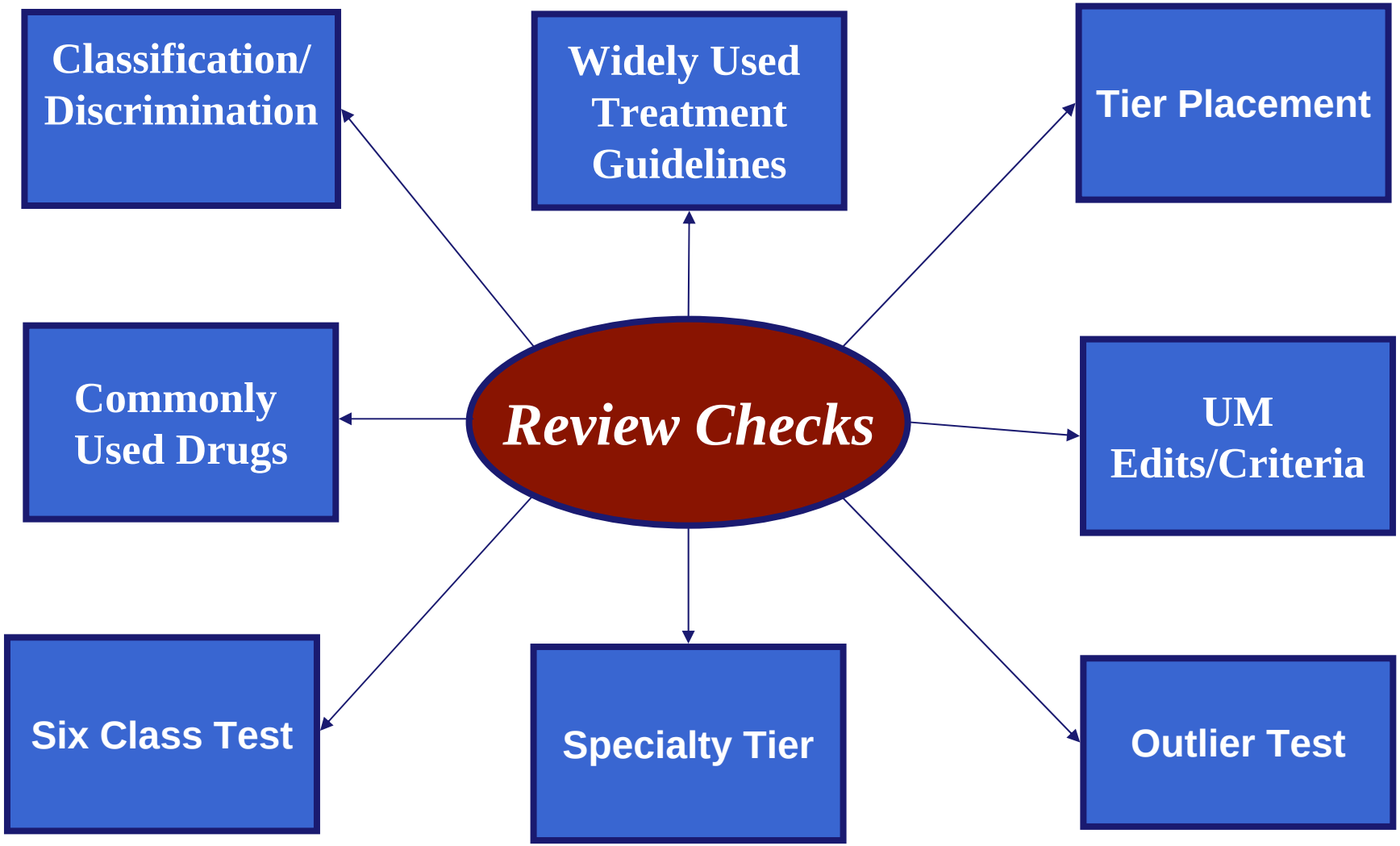


What is CMS doing?

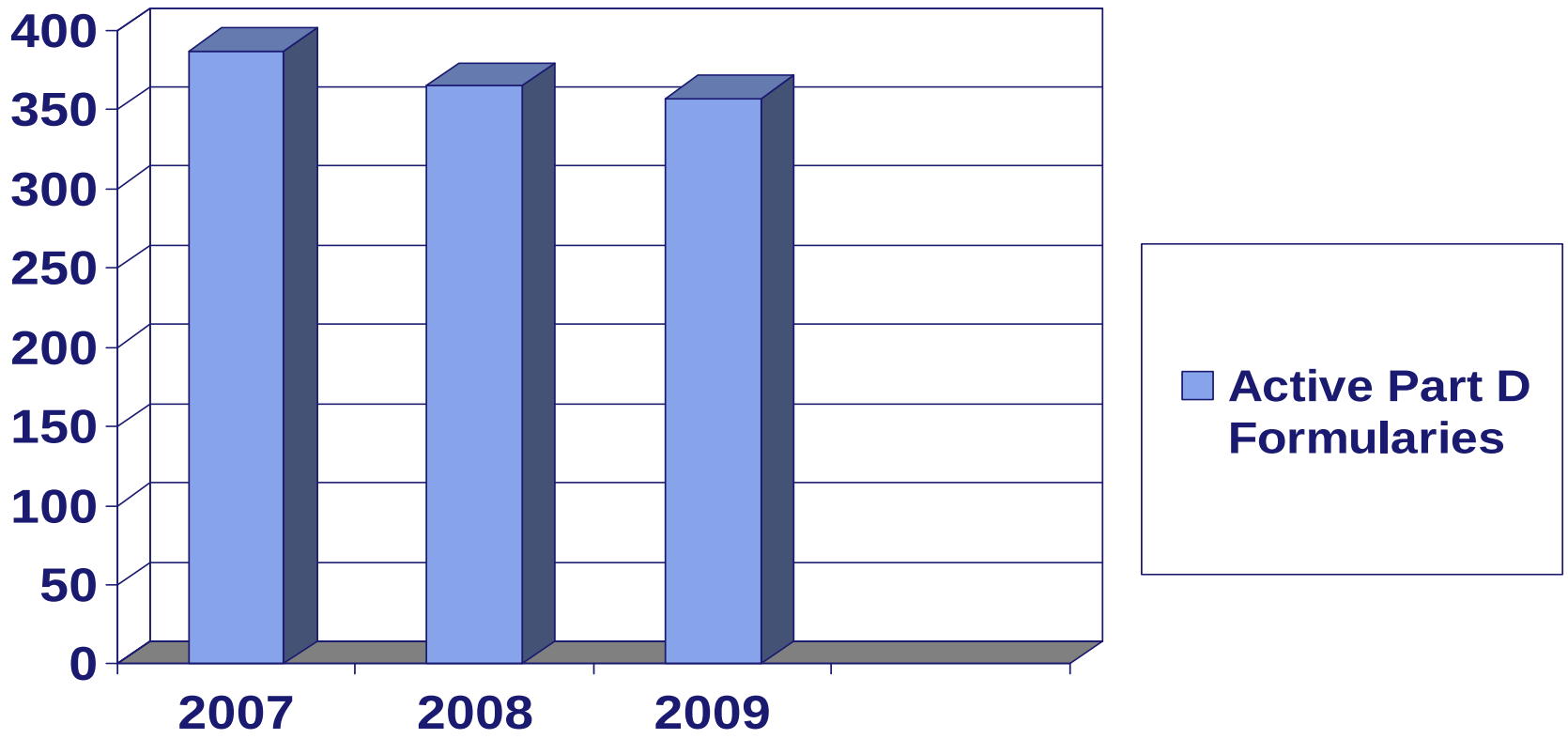
- CMS review of drug plan formularies represents a unique and unprecedented process.
- CMS performs an extremely rigorous formulary review to ensure appropriate access to drugs and to avoid discrimination against beneficiaries with certain conditions.
- “Year Long” Continuous Process



CMS Formulary Review



Approved Formularies (2007 – 2009)



Mid-year formulary changes

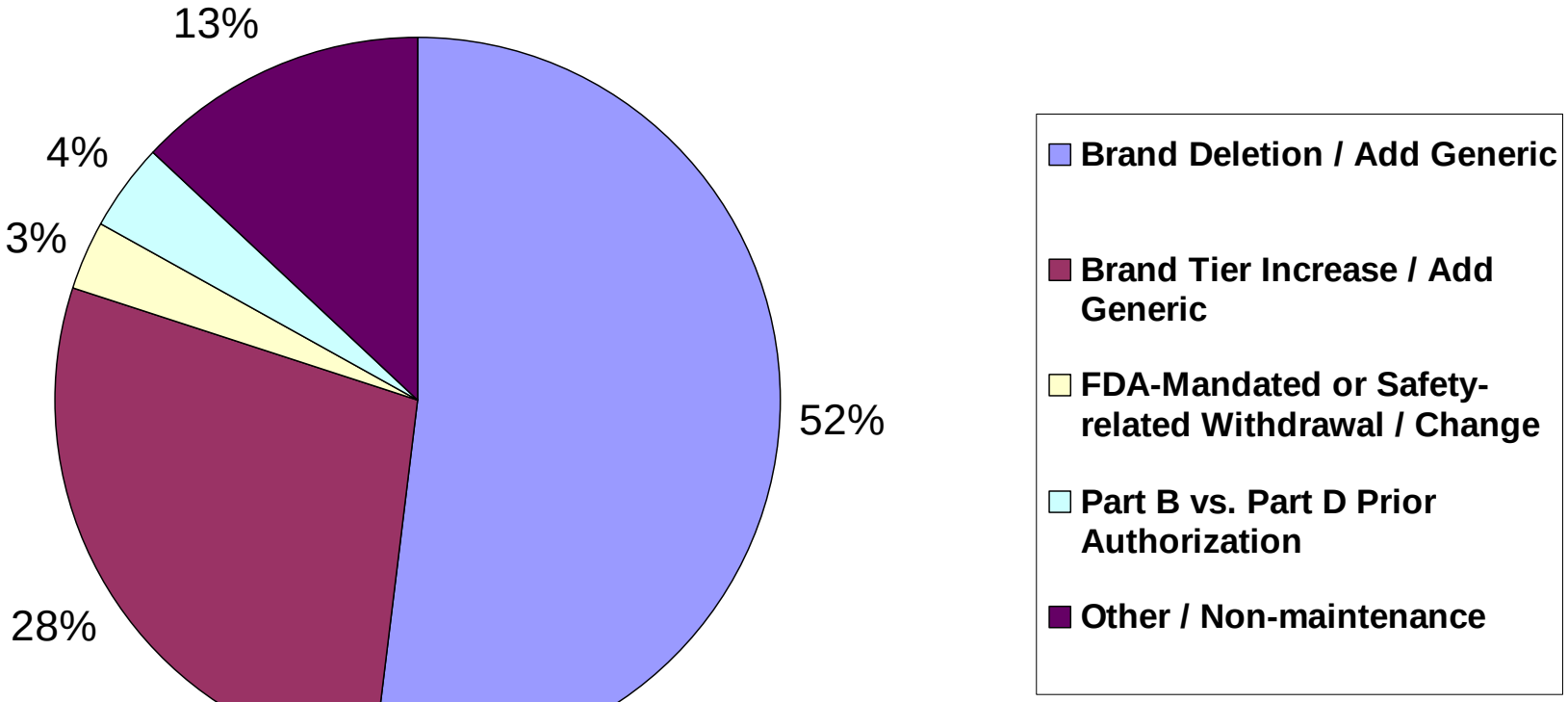
- New drug availability, advances in medical knowledge, and information on safety and quality may occur during the year necessitating formulary changes.
- Examples –
  - A new FDA “black box” warning.
  - Availability of an A-rated generic.
  - New clinical guidelines

Mid-year formulary changes

- Two Types of Negative Changes
  - Formulary Maintenance Changes
  - Non-maintenance Changes

- The number of negative change requests received for CY2008 formularies is 35% less than for the same period in CY2007.

2008 Mid-Year Formulary Changes



CMS Process Improvements:
Revision of USP Model Guidelines

Significant Stability over the years

Model Guidelines:

	Version 1.0 (2006)	Version 2.0	Version 3.0	Version 4.0 (2009)
Categories	41	49	50	50
Classes	137	117	119	119

Part D Formularies that use the USP Model Guidelines:

	(2006)	(2007)	(2008)	(2009)
# of Formularies	286	232	160	169
% of Formularies	74.0%	60.0%	43.8%	47.3%
% of all Plans	-----	78.0%	42.3%	53.2%

CMS Process Improvements: Formulary Submission Tool

- Formulary Reference File (FRF) – Proxy Codes
- CMS is moving to RxNorm as a potential alternative to FRF proxy NDCs

CY 2009 Formulary Reference File

PROXY NDC CODE	BRAND NAME	GENERIC NAME	DOSAGE FORM	ROUTE	STRENGTH	RXCUI	RX TTY	RX NORM DESCRIPTION
00173066101	ZIAGEN	ABACAVIR SULFATE	TABS	ORAL	300 MG	00213460	SBD	Abacavir 300 MG Oral Tablet [Ziagen]

CY 2010 Formulary Reference File (DRAFT)

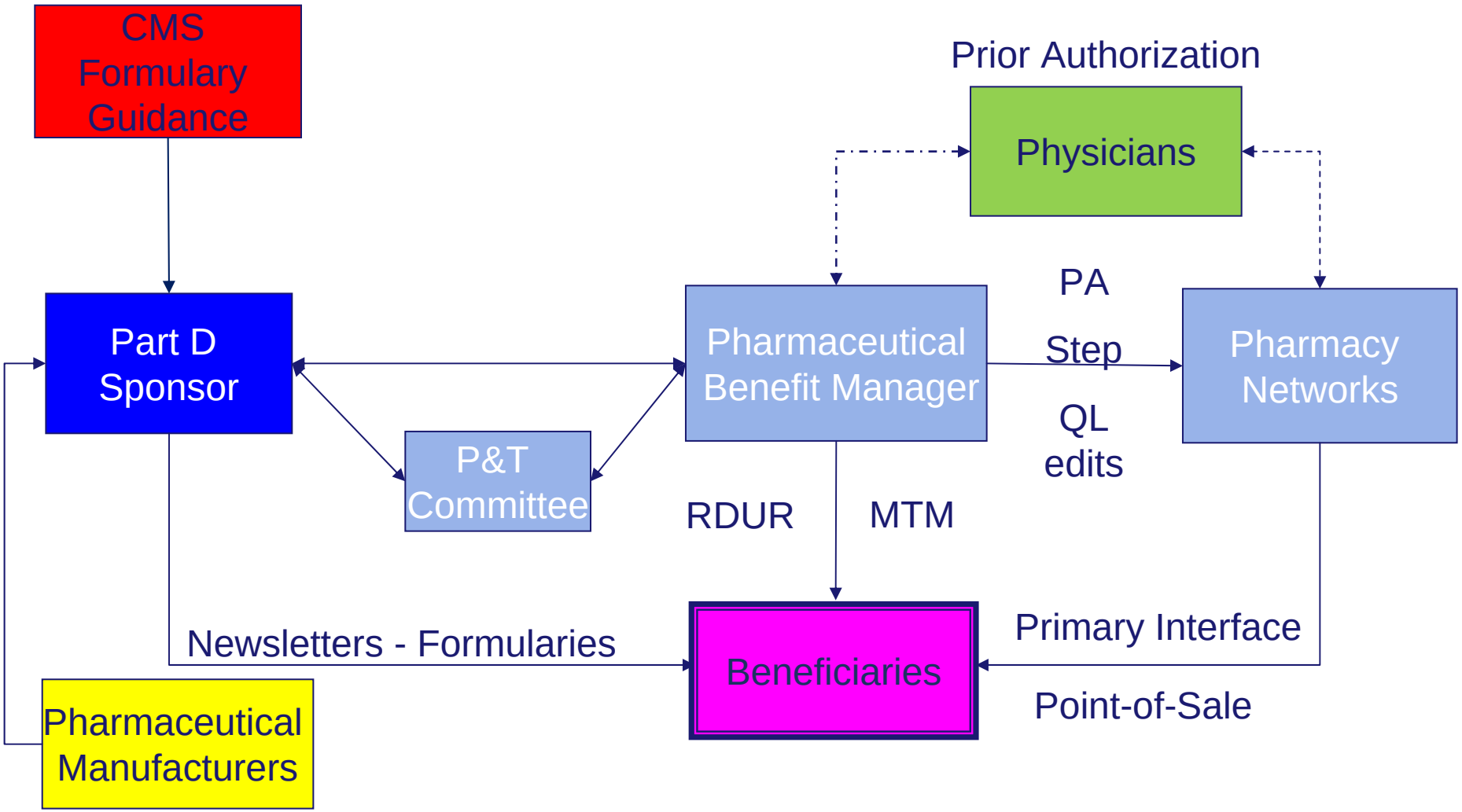
RxCUI	RxNorm BN	RxNorm SCDC	RxNorm DF	Sample Pricing NDC
213460	Ziagen	Abacavir 300 MG	Oral Tablet	'00173066101

What's Next for Part D Formularies

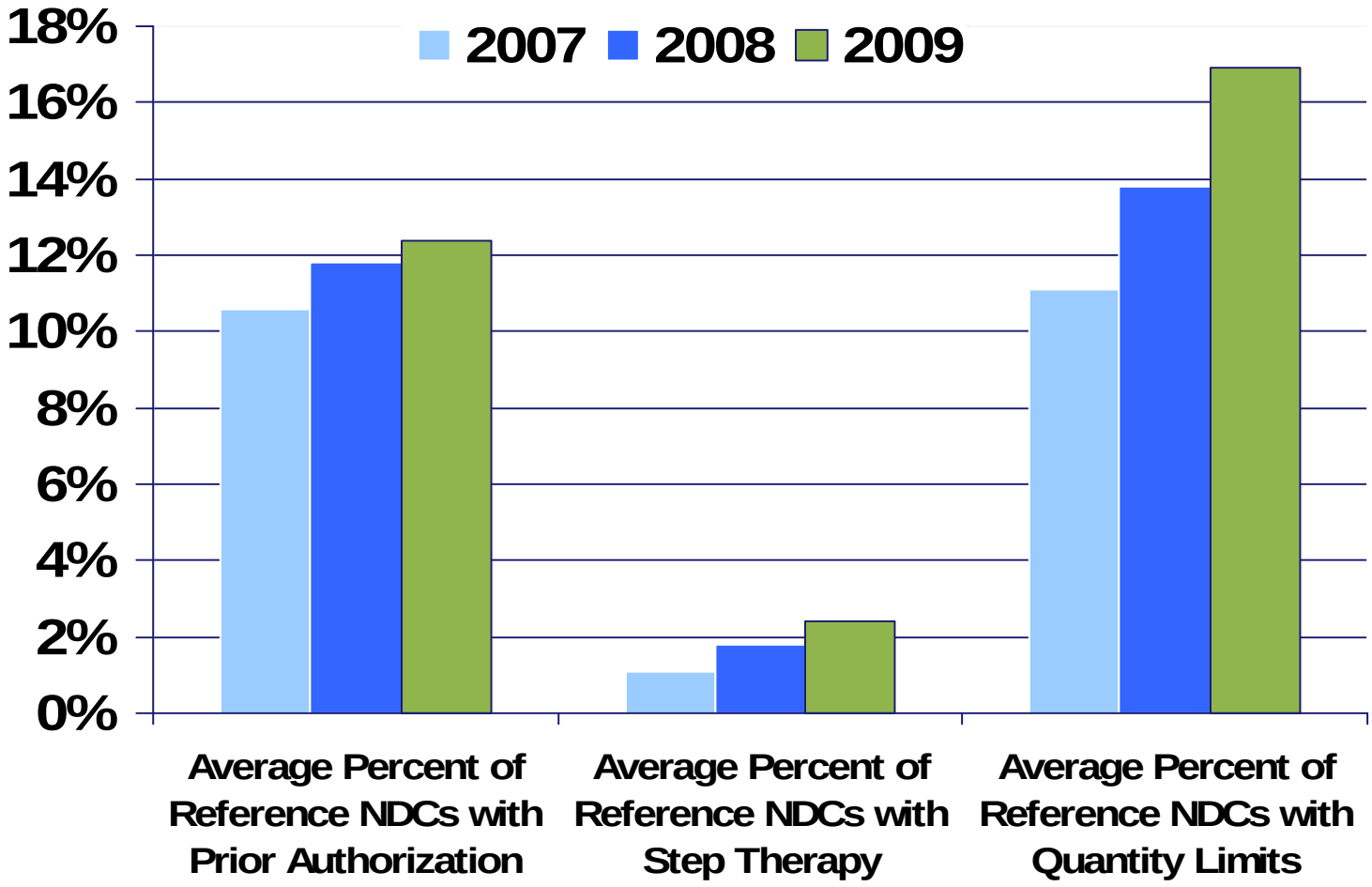
- MIPPA
  - Medically Accepted Indication (2009)
  - Protected Classes (2010)
  - Barbiturates and Benzodiazepines (2013)
- Exploring "Changes Only" Review
- Formulary Submission Automation

Drug Utilization Management

What are plans doing?



2007-2009 PDP Formularies



Note: Adjusted for drugs comparable on both the 2007 and 2008 Medicare Formulary

What is CMS doing?
Stepping Up Transparency on DUM

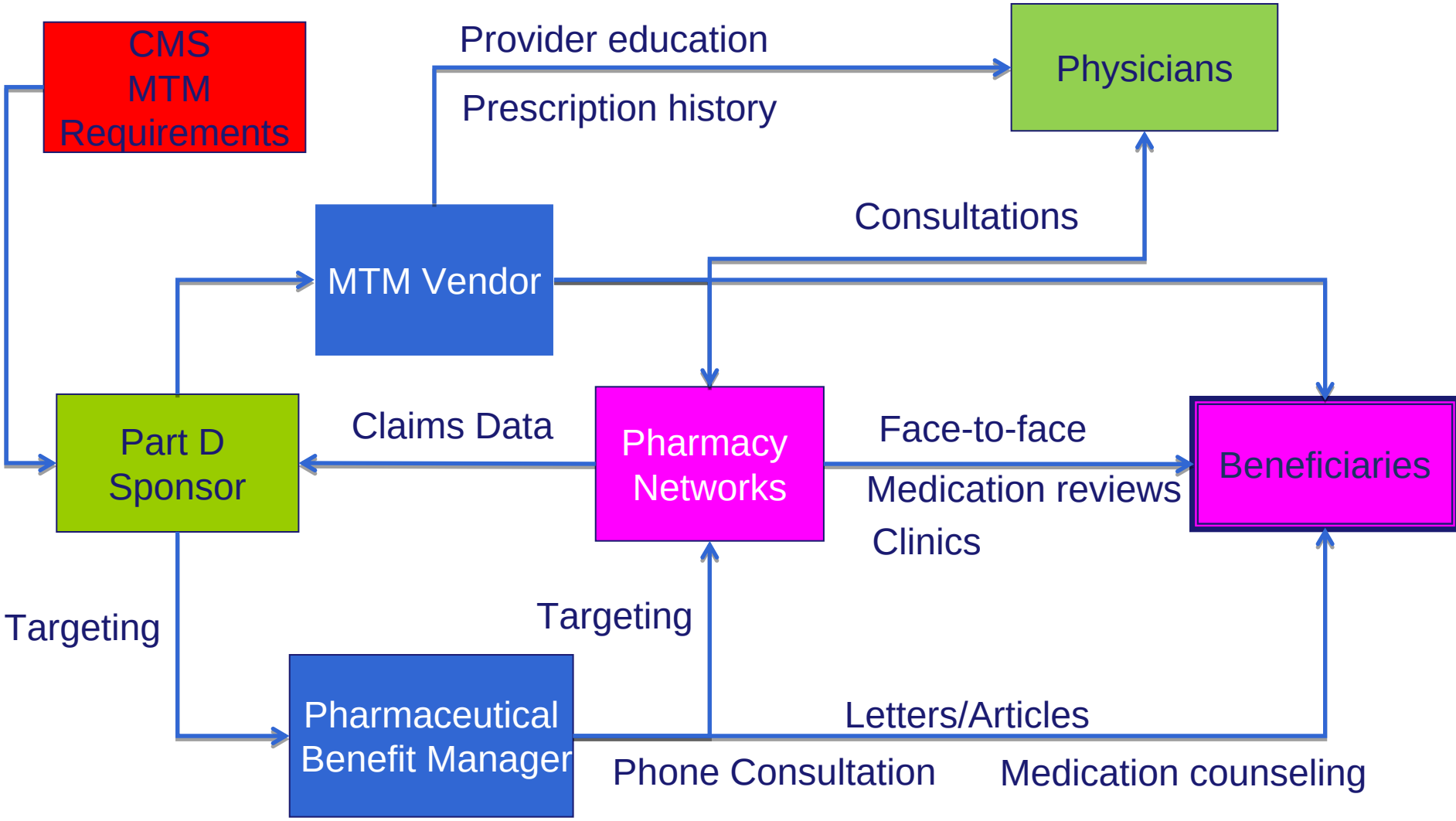
2006	**SUBMISSION/REVIEW**
2007	Submission/Review/**DISCLOSURE**
2008	Submission/Review/Disclosure/**CHANGES**
2009	Submission/Review/Disclosure/Changes/**POSTING**

Common PA Criteria Failures

- Missing FDA labeled indications/lacking default statement
- Indications listed not supported by label/compendia
- Criteria is non-specific: too vague/not defined (e.g., Evidence Based Medicine)
- Criteria too burdensome or restrictive
- Criteria listed in wrong field

Medication Therapy Management

What are Plans Doing?



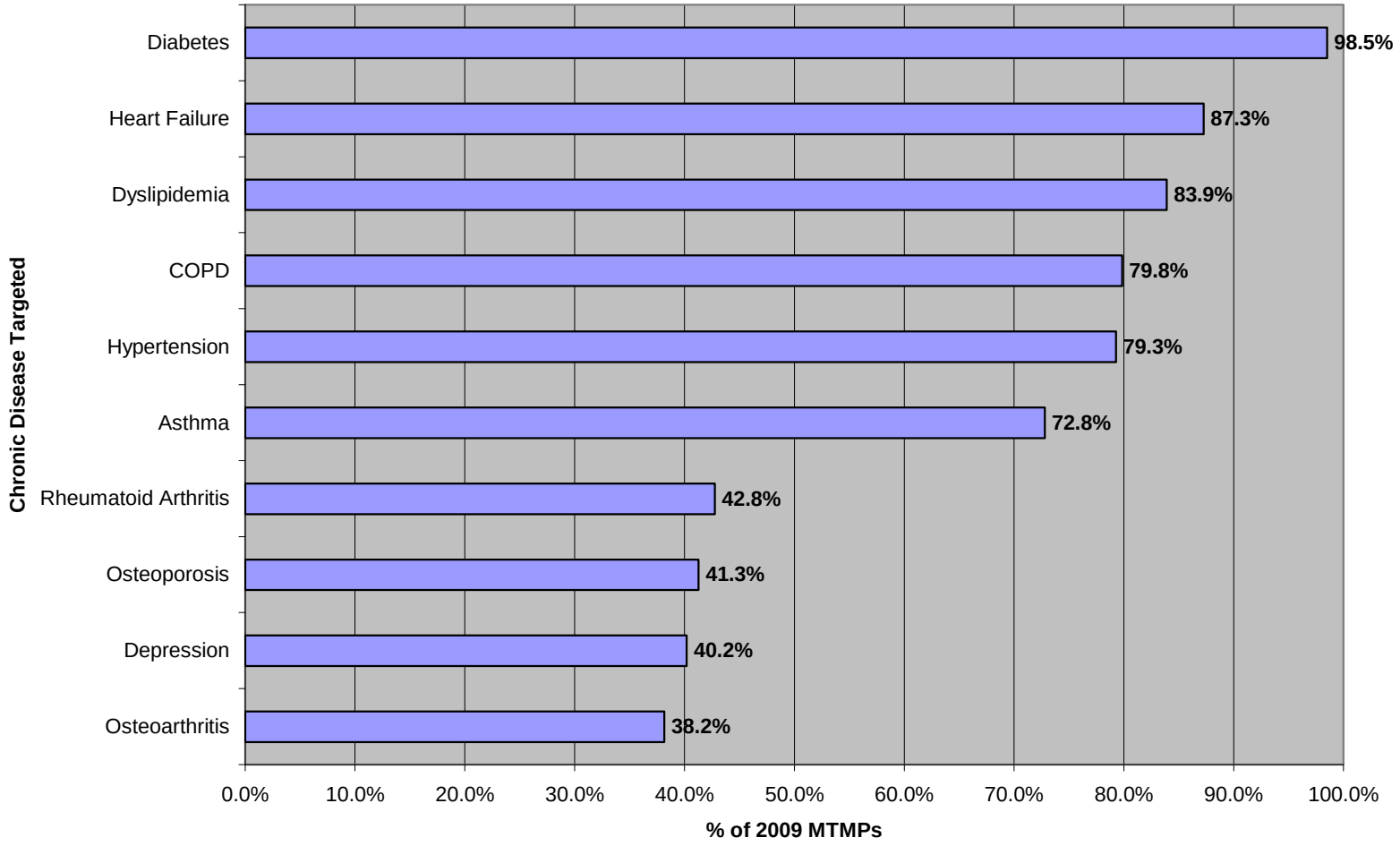
CMS MTM Requirements

Targeted beneficiaries for MTM programs are plan enrollees who:

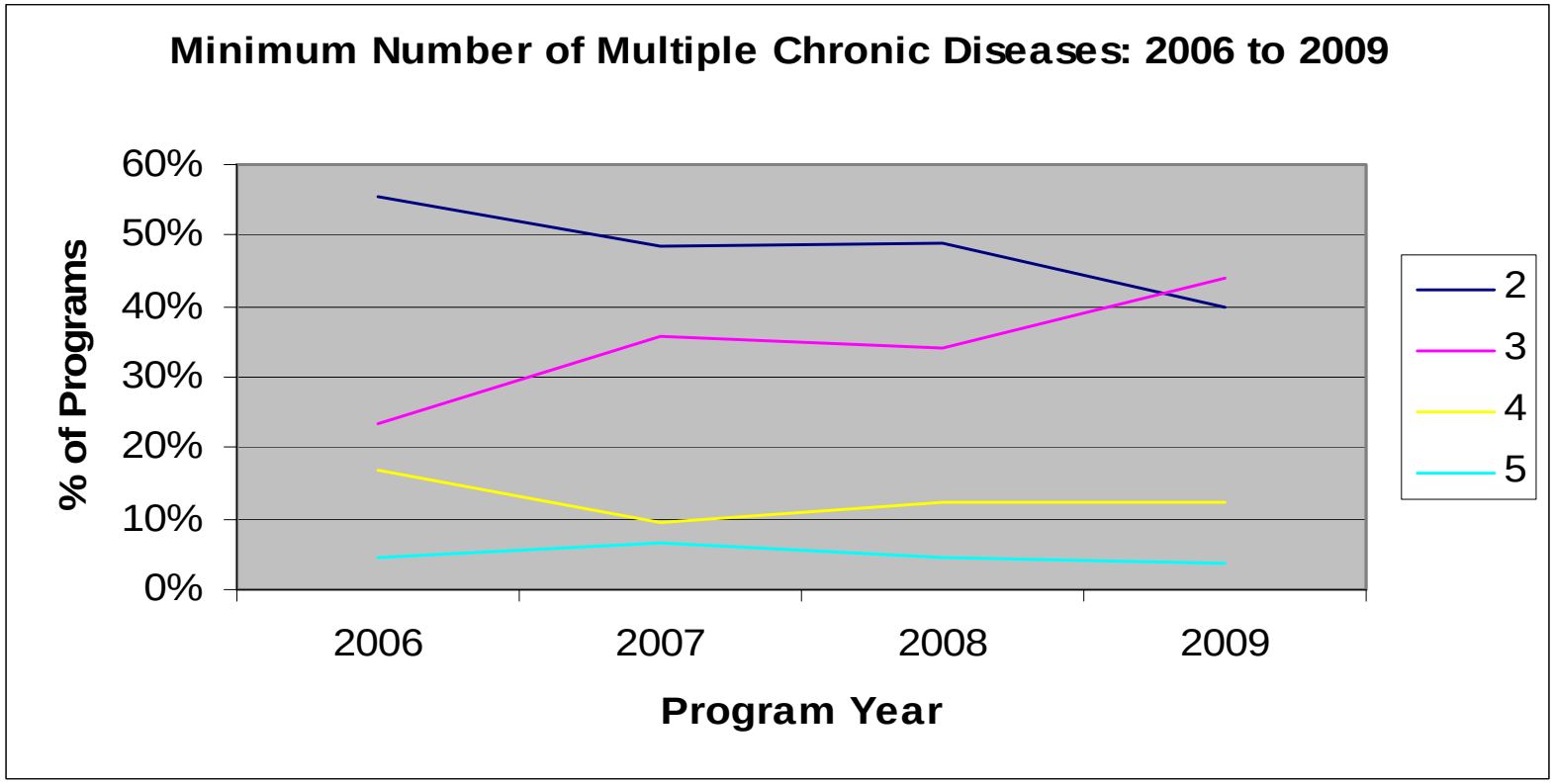
- Have multiple chronic diseases
- Are taking multiple Part D drugs
- Are likely to incur annual costs for covered Part D drugs exceeding $4,000

Top 10 Chronic Diseases Targeted: 2009

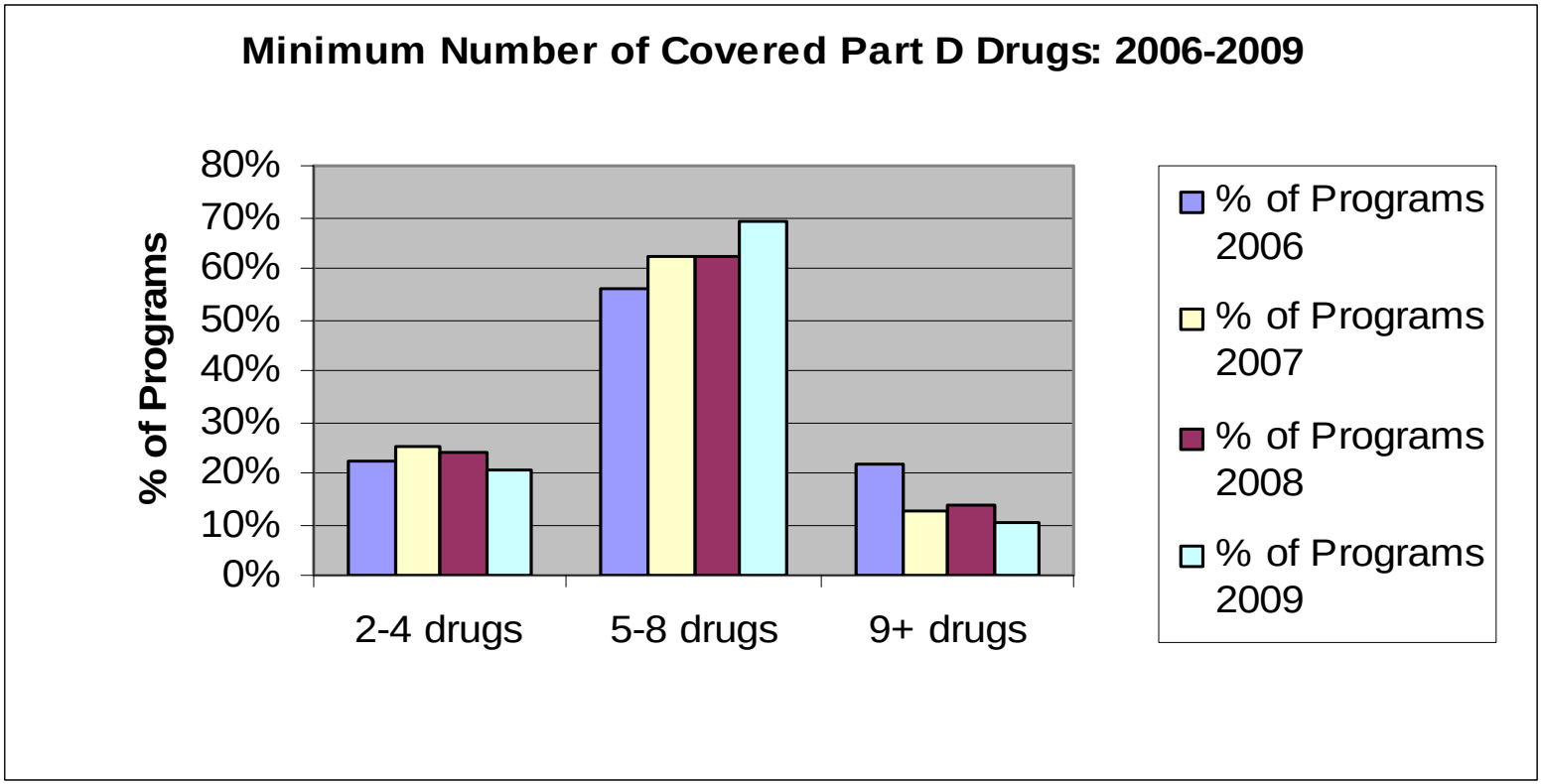
Percentage of MTM programs with Top 10 Chronic Diseases Targeted



Multiple Chronic Diseases in MTM Programs 2006 - 2009



Multiple Part D Drugs in MTM Programs 2006 - 2009



Method of Enrollment in MTM Programs 2006 - 2009

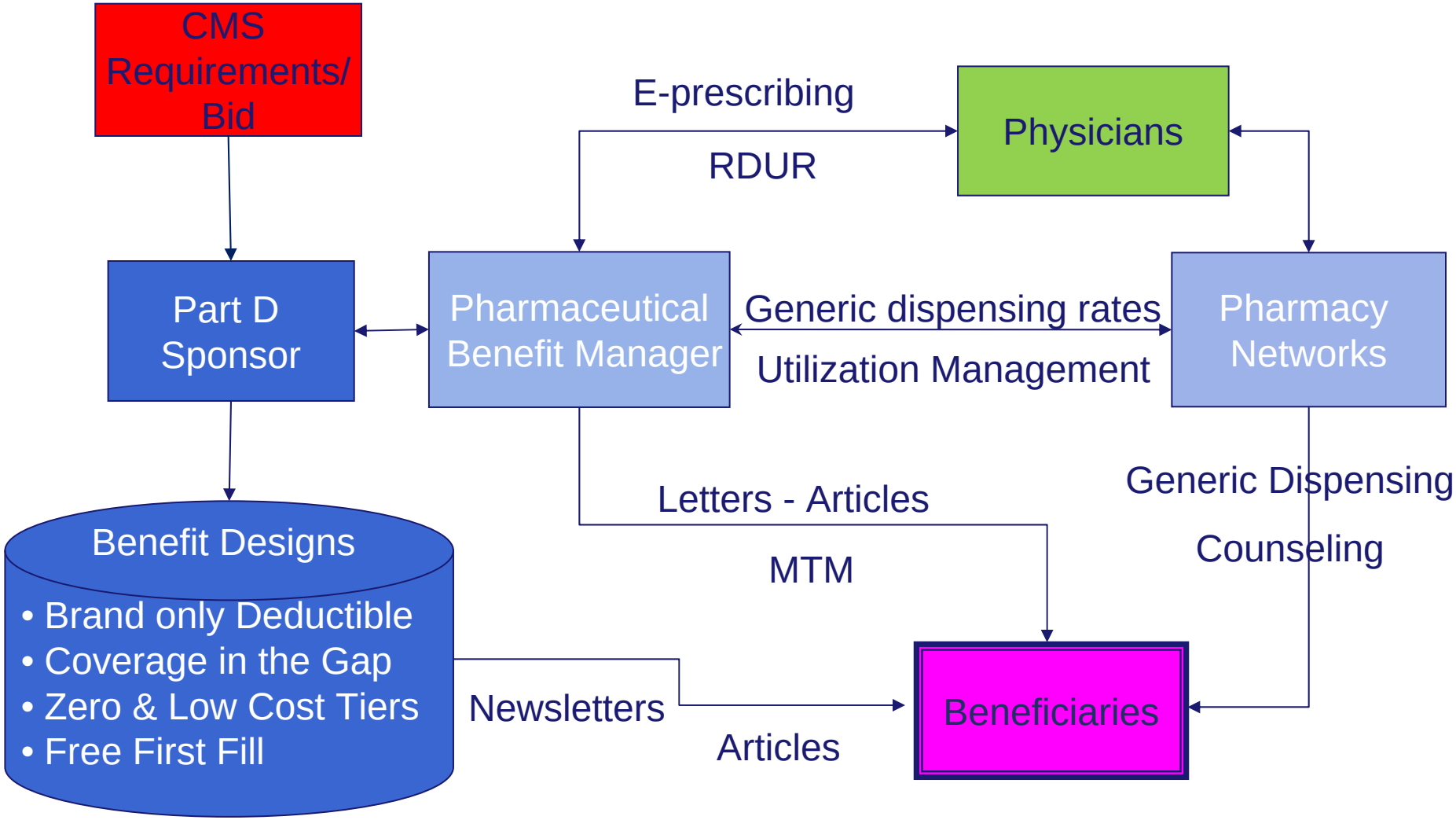
	% of Programs			
Enrollment Method	2006	2007	2008	2009
Opt-in	51.0%	19.1%	14.6%	14.7%
Opt-out	31.8%	33.6%	39.5%	51.3%
Both	N/A	47.3%	45.4%	31.3%
Other	N/A	N/A	0.6%	2.7%
Not Specified	17.2%	N/A	N/A	N/A
Totals	100.0%	100.0%	100.0%	100.0%

What is CMS doing?

- CMS Internal Workgroup to Identify Best Practices
- MTM Reporting Requirements
- MTM Monitoring Contract
- Involvement in Pharmacy Quality Alliance

Incentivizing Lower Cost Alternatives

What are Plans Doing?



What is CMS doing?
Generic Search Default in MPDPF

Medicare.gov - - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Search Favorites

Address http://plancompare.medicare.gov/drugSelect.asp?vid=597713182&drxZip=60025&useGenerics=true&alpha_search=false#drugList Go Links

Google Search Web 10 blocked AutoFill Options

Vea en Español | Use Larger Font | Print

Find and Compare Plans

Find and Enter Your Drug Information

You can search and add your drugs by entering them below and clicking the "Search for Drug" button or by searching for the drug alphabetically.

Enter Drug Name: Search for Drug

Click here to browse drugs alphabetically
Help with Common Drug Abbreviations

Why Enter My Drugs?

By entering your drugs, we can estimate what portion of your drug costs Medicare will pay.

What Drugs should I Enter?

Medicare plans cover most commonly used prescription drugs. In addition, some plans may provide additional coverage for drugs not usually covered by Medicare.

The site does not show pricing for over-the-counter drugs or diabetic supplies.

My Drug List

Drug Name	Lower Cost Generic	Remove
Ambien	ZOLPIDEM TARTRATE	Remove

☑ Use lower cost generic drugs when available. (What does this mean?)

Save My Drug List | Add More Drugs

Back | Continue

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Internet

What is CMS doing?
Therapeutic Substitution in MPDPF

Medicare.gov - Similar Lower Cost Drugs - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Address http://plancompare.medicare.gov/optimizePlanComparison_LCO.asp?dosage_id=102238&pharmacy_nabp=0202046&plan_id=7635&vid=597713182&drxZip=60025&mail_order=0&contract_yr=2009&mail_order_available=08

Some states offer assistance programs for prescription drugs. To see the details of your state's pharmaceutical assistance programs, click here.

Prescription Drug Programs:

Some Pharmaceutical Companies offer assistance programs for the drugs they manufacture. To see if any programs are available for the drugs you are taking, check the Pharmaceutical Assistance Program column in the Comparison table below. If a Pharmaceutical Assistance Program exists for your drug(s), click on the link labeled "Yes" for detailed information about the program(s).

Your Prescription			
Drug	**30-Day Quantity**	**Type**	**Cost Share**
Crestor TAB 10MG	30	TIER 2	$20.00/month

Lower Cost Option(s)				
Drug	**30-Day Quantity**	**Type**	**Cost Share**	**Pharmaceutical Assistance Program**
SIMVASTATIN TAB 80MG	30	TIER 1	$4.00/month	No

This concludes the list of less-expensive drugs that may be prescribed for people with medical conditions similar to yours.

Return to Plan Optimization **(Enrollment begins November 15, 2008.)**

This website and the information it contains are intended to assist Medicare beneficiaries in considering lower cost drug options. The information contained in the comparisons is for informational purposes only and is

Page Last Updated: 10/8/2008

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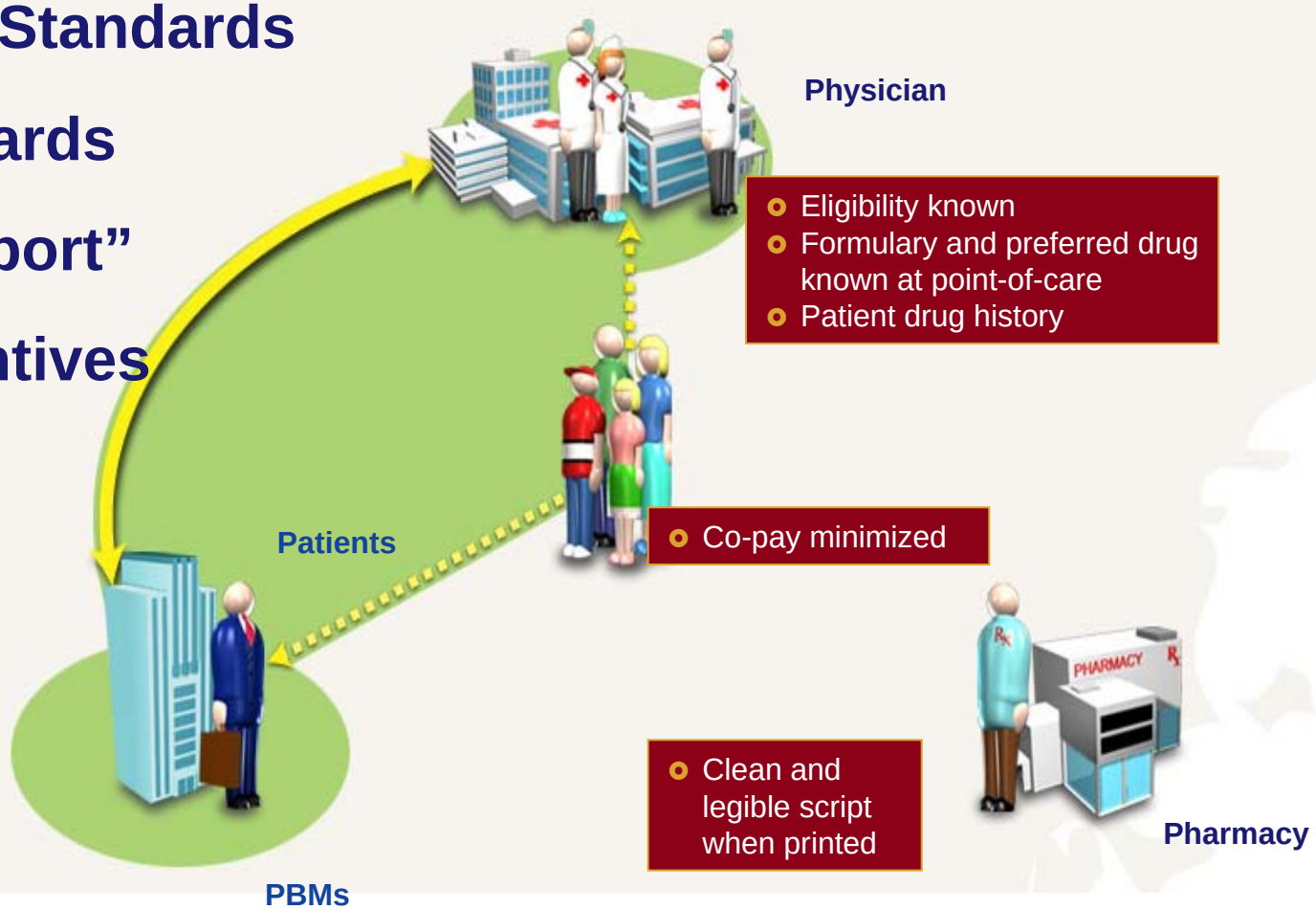
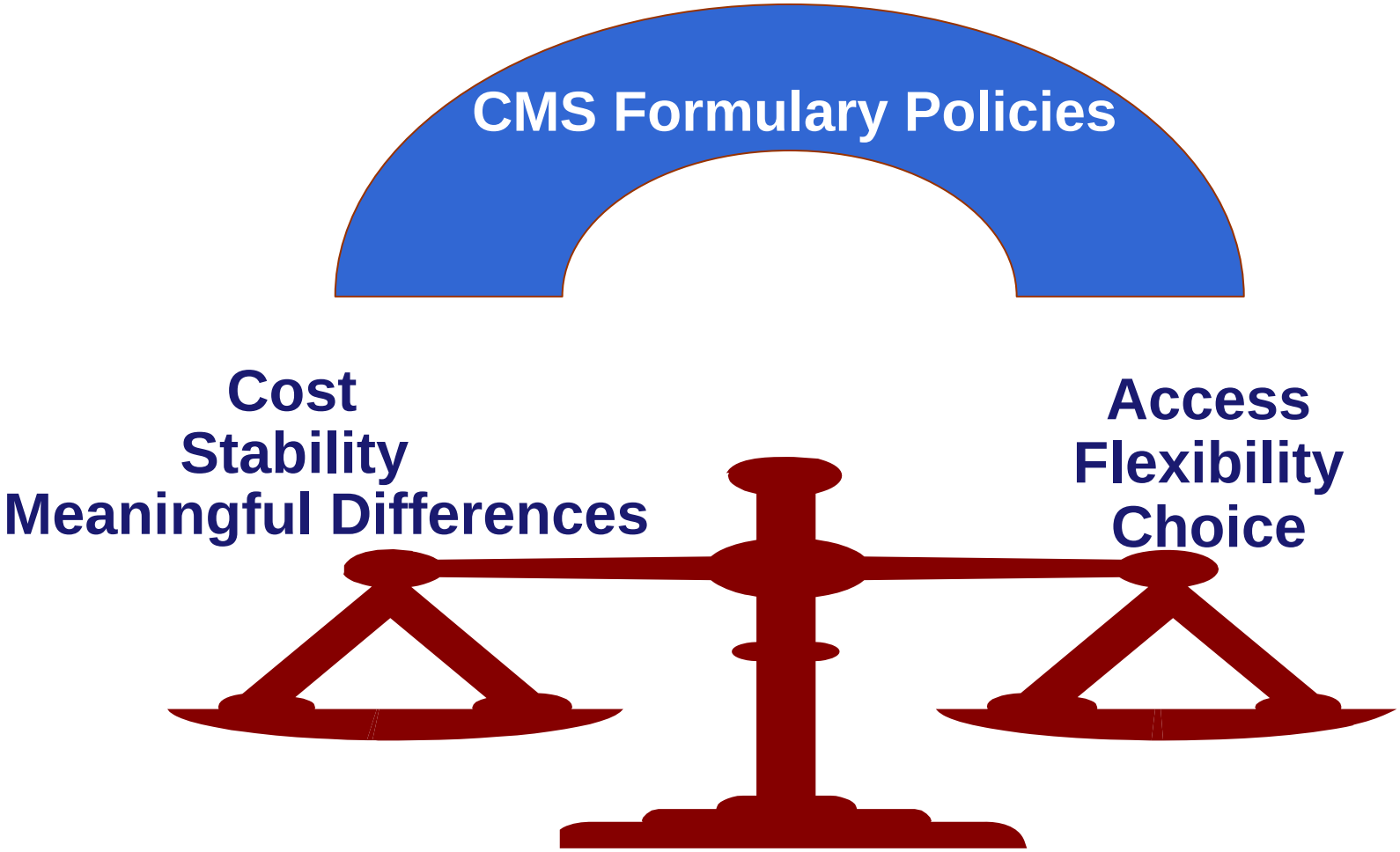
E-prescribing

- Foundation Standards
- Initial Standards
- Part D "Support"
- MIPPA Incentives



Conclusion


CMS Formulary Policies
Cost
Stability
Meaningful Differences
Access
Flexibility
Choice