

Medicare and Patient Assistance

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Medicare and Patient Assistance Summary

- AstraZeneca and other major manufacturers have a long standing commitment of improving access to medications for Medicare enrollees
- There is potential for significant legal and regulatory risk depending on the type of program and how assistance is supplied
- Guidance from CMS and OIG is needed
- We are all committed to the success of Part D

AstraZeneca Specific Assistance Efforts

- AstraZeneca Foundation Patient Assistance Program
- Caring Partner's Program
- Together Rx
- Together Rx Access

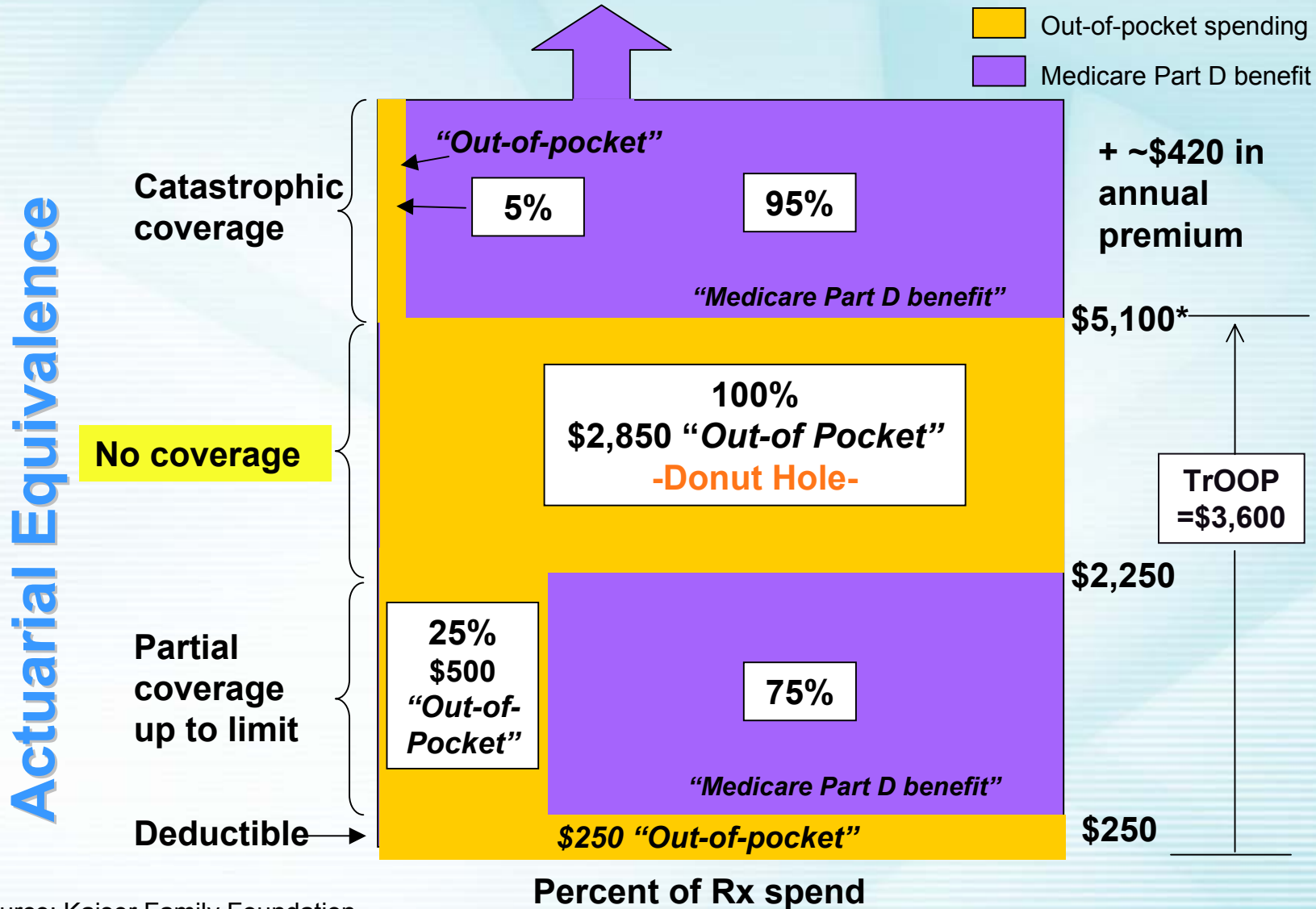
Key Questions

- Who are our patient assistance patients?
- How will the drug benefit work?
- Relevant regulatory and legal guidance?

Who are our patient assistance patients?

- Roughly 50% of AstraZeneca Foundation Patient Assistance Program patients
- More than 200,000 Together Rx enrollees who utilize the program to access AstraZeneca products

How will the drug benefit work?



How will the drug benefit work?

Income level	Premium	Deductible	Copay Gen./ Brand	Coverage Gap
Up to 100% FPL Asset \$6K & \$9K	None	None	\$1 / \$3	None
100 - 135% FPL Asset \$6K & \$9K <i>(fail the asset test move to next FPL level)</i>	None	None	\$2 / \$5	None
135 - 150% FPL Asset \$10K & \$20K <i>(fail the asset test move to standard benefit)</i>	Sliding Scale	\$50	15% of drug cost	None
150% FPL and above No Asset Criteria	~\$32/Mo	Varied by plan \$250	Varies by plan	\$2,850

Source: Medicare Program Office analysis

How will the drug benefit work?

FPL Percent	CBO-based estimate of Pt D participants	Population not subsidized	Not-subs over init'l limit	Not-subs reaching catastrophic	Estimated breakdown
0-135	12.1	4.5	1.5	0.6	Primary MMA subsidy cutoff
135-150	1.6	1.2	0.3	0.1	
150-200	4.9	4.2	1.4	0.6	Typical PAP Cutoff
200-250	3.3	3.3	1.1	0.4	
250-300	2.3	2.3	0.8	0.3	
300+	4.7	4.7	1.6	0.6	

- Low-income population (<135 FPL) failing asset test is about as large as 150-200 FPL population
- Approximately 9.9 million Part D expected enrollees below 200% FPL will not receive the low-income subsidies (does not yet exclude SPAP eligible beneficiaries)
- About 3.2 million of those will reach the Part D initial coverage limit
- About 40% of the population that reaches initial coverage limit, or 1.3 million, will reach catastrophic coverage

What Does the MMA Final Rule Say?

“Regardless of whether a manufacturer patient assistance program is a bona fide charity for the purpose of Federal fraud and abuse laws, any drug payments it makes on behalf of Part D enrollees would count toward TrOOP unless these organizations qualify as group health plans, insurance or otherwise, or similar third-party payment arrangements.

However, any arrangements pursuant to which a charitable organization pays a Medicare beneficiary’s cost-sharing obligations must comply with Federal fraud and abuse laws, where applicable, including the anti-kickback statute at section 1128(b) of the Act, as well as the civil monetary penalty provision prohibiting inducements to beneficiaries at section 1128A(a)(5) of the Act.”

Critical Questions to Answer

- Does Medicare Part D constitute credible prescription drug coverage?
- What, if anything, can be done to assist low-income patients who fall through the cracks?
- If changes are made to existing patient assistance efforts, how will it be communicated and supported?

Next Steps

- Implement and manage any potential changes needed to assistance program efforts
- Interpret and analyze any additional guidance which is received from CMS and/or OIG