



# Plan Benefit Generosity, Adherence to Statins and Hospitalizations under Medicare Part D

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(ARS Response Card: Channel 41)

# Disclosure

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“I, Tami Swenson, declare no conflicts of interest or financial interests in any product or service mentioned in this presentation, including grants, employment, gifts, stock holdings, or honoraria.”

# Learning Objectives

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- (1) Identify the data elements needed from the prescription drug event (PDE) data and plan characteristics file for purposes of creating a measure of Part D plan generosity.
- (2) Assess the impact of Part D plan benefit generosity on adherence to statin drug therapy and the likelihood of subsequent hospitalizations.

# Presentation Outline

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- Policy and Project Background
- Research Objectives
- Adherence Model
- Hospitalization Model
- ACA Policy Findings Application
- Future Research and Analysis

# Policy Background

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- Medicare Part D, outpatient prescription drug coverage, started January, 2006
- Initial enrollment was open through mid-May, 2006. Participation is optional
- Approximately 50% of the Medicare population is enrolled in the Part D program
- Beneficiaries have the option of enrolling in stand-alone prescription drug plans (PDPs) or in Medicare Advantage prescription drug plans (MA-PDs)

## Policy Background, continued

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- Phased benefit coverage
  - Deductible
  - Pre-Initial Coverage Limit (ICL)
  - ICL (also known as benefit gap or donut hole)
  - Catastrophic Coverage
- Beneficiaries' out of pocket (OOP) spending and total drug costs during the calendar year move them through the phases
- Plans have many options for structuring coverage

A choropleth map of the United States showing the number of states with a specific number of states having a certain number of states. The map is color-coded as follows:

- 1 (Yellow): Most states, including California, Texas, Florida, New York, and many others.
- 2 (Teal): States like Washington, Oregon, Nevada, Arizona, and others.
- 3+ (Dark Blue): States like Montana, Wyoming, and others.

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## Policy Background, continued

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- Low Income Subsidy (LIS) program offers different levels of premium subsidies and cost sharing amounts to beneficiaries based on income and asset level qualification
  - Medicare/Medicaid duals are a large majority of the LIS program enrollees
  - LIS beneficiaries do not encounter a coverage gap phase



## Policy Background, continued

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- Both PDPs and MA-PDs are required to submit administrative prescription drug event (PDE) data to the Centers for Medicare and Medicaid (CMS) for reconciliation purposes
- The federal legislation that allows the PDE data to be released for research purposes does not allow the release of commercially sensitive data
  - Utilization formulary only option, therefore

# Project Background

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- “Understanding Geographic Variation in Medicare Part D: Effects of Plan Design on Utilization and Expenditures”
- Pinar Karaca-Mandic, PI; Jean Abraham, Co-Investigator
- Funding from University of Minnesota Academic Health Center Faculty Development Grant

## Project Background, continued

- Purpose is to examine regional variations in benefit design and formulary characteristics and how they affect Part D drug utilization and spending
- Focus on 3 therapeutic drug classes:
  - Anti-hyperlipidemics
  - Gastrointestinal agents and proton pump inhibitors
  - Oral anti-diabetic agents
- Today's presentation is first article from project on statin adherence that is co-authored by Pinar Karaca-Mandic, Tami Swenson, Jean Abraham, and Bob Kane at the University of Minnesota

# Research Objectives

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To estimate the role of plan benefit generosity towards statins on adherence with cholesterol-lowering medications and the subsequent cardiovascular hospitalizations

- H(1): Beneficiaries with less generous benefit design will have lower statin adherence
- H(2): Beneficiaries with less generous benefit design will be more likely to have a cardiovascular hospitalization

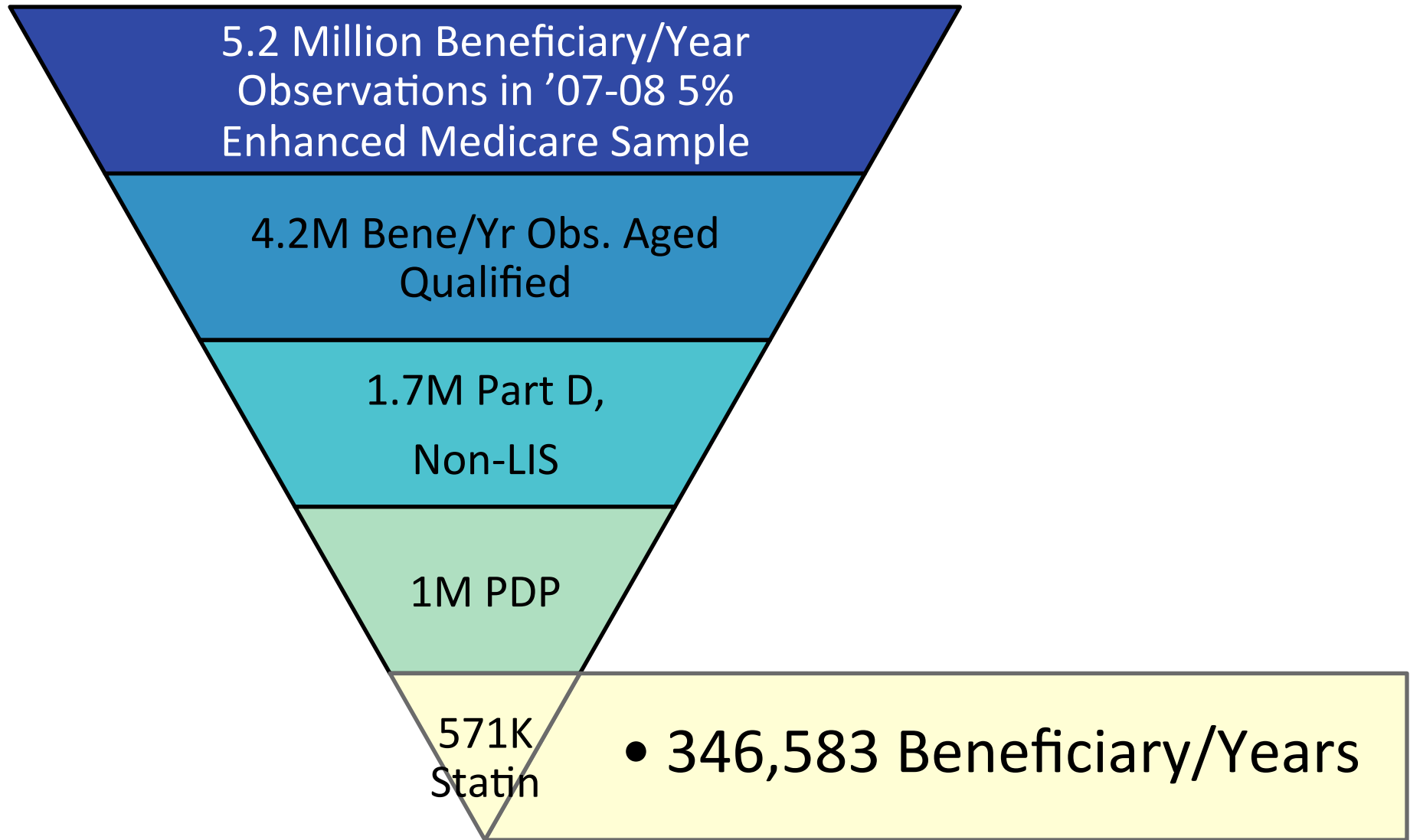
# Background Academic Literature

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- Cardiovascular disease remains the single largest cause of death in the US (Mensah & Brown 2007)
- Statin medications accounted for close to 10% of all Part D expenditures in 2007 (MedPAC 2010)
- Goldman, Joyce, and Karaca-Mandic (2006) found that full compliance with cholesterol-lowering therapy reduces the use of hospital services by 25% among high risk patients
- The relationship between plan benefit generosity and adherence within the Medicare Part D population has not been studied nor its relation with other medical service utilization

- Administrative claims for the 5% enhanced Medicare sample
  - 2006-08 prescription drug event (PDE) data
  - 2007-08 plan characteristics file
  - 2006-08 denominator file
  - 2007-2008 MedPAR
- Medispan Drug Database

# Analytical Sample



# Adherence Model

$$Adherence_{it} = f(\text{Plan design}_{it}, \text{Demographic Characteristics}_{it}, \text{Risk Adjusters}_{it}, \text{Time Fixed Effects}_t, \text{Regional Fixed Effects}_{it})$$

- Estimate model using logistic regression for adherent/non-adherent behavior
- Clustered standard errors by beneficiary



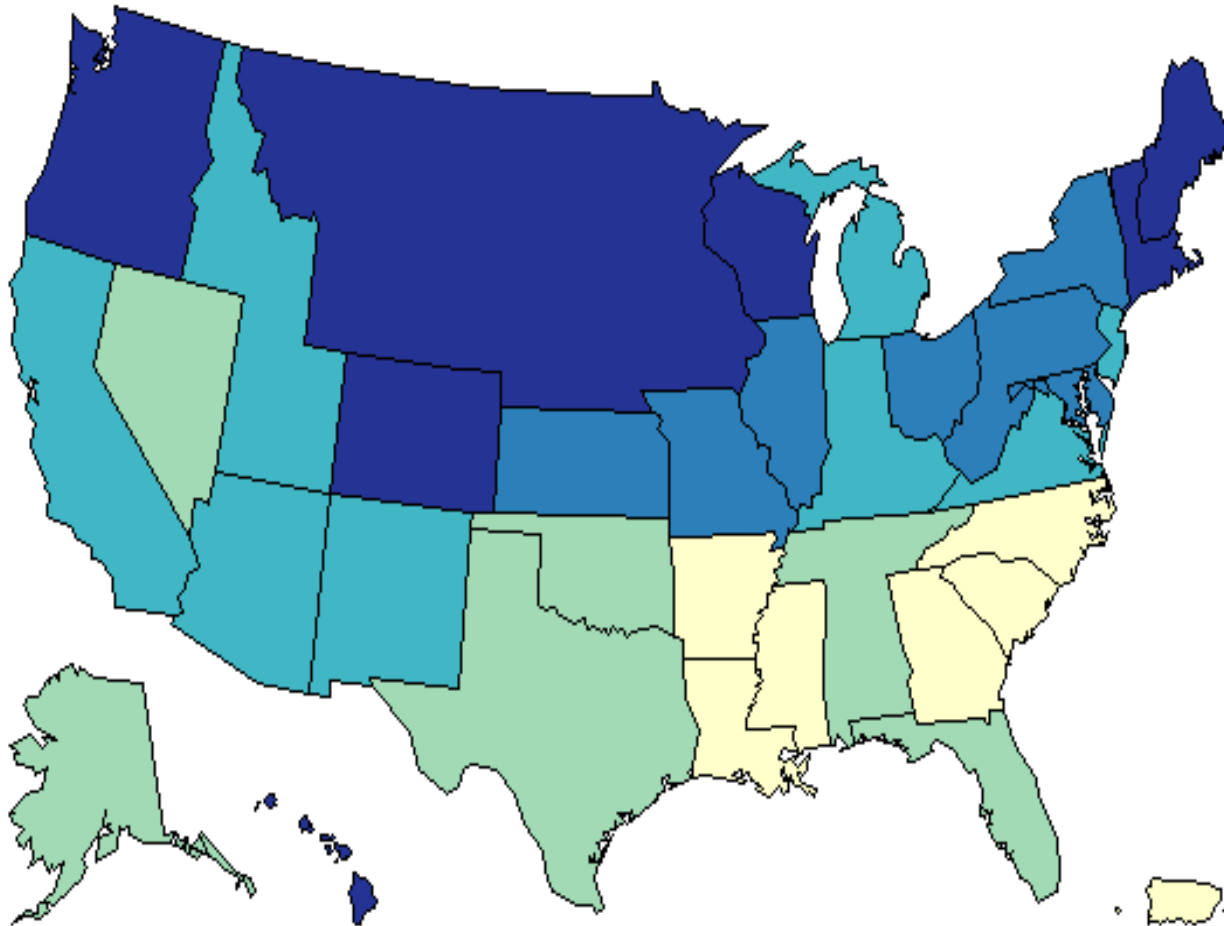
# Adherence Measure

- Proportion of days (PDC) covered during calendar year (CY)
  - January 1 index start with stock coverage from previous CY or date of first fill of CY as start index date
  - December 31 ends PDC period
  - Diary method arrays covered days during CY
  - Index adjusted for hospitalizations
  - Accumulation limited to max 30 days
- $0 < \text{PDC} \leq 1$
- $\text{PDC} \geq 0.80$  are adherent levels

## Adherence Measure, continued

- PDC Summary Statistics for '07 and '08 cohorts
  - Average 0.821
  - STD 0.224
- PDC distribution
  - 3.6% Non-compliers ( $< 0.20$  PDC)
  - 29.4% Moderate compliers ( $0.20 - 0.80$  PDC)
  - 67.0% Adherent ( $\geq 0.80$  PDC)

# Adherence by PDP Regions



PDC   0.635 - 0.796   0.799 - 0.809   0.811 - 0.822   0.823 - 0.832   0.834 - 0.858

# Plan Design Characteristics

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- Plan deductible indicator
  - 76% have zero deductible
- Plan deductible amount
  - Overall Average \$63.67 (STD 113.88)
  - Non-zero Avg. \$264.20 (STD 28.85) Min \$20 Max \$275
- Any gap coverage
  - 16% have some gap coverage
- Plan expected out-of-pocket (OOP) for a representative basket of statins (Basket OOP)

# Basket OOP

- Construct average OOP cost of a representative market basket of statins for each plan
  - OOP for each statin for each plan
  - Weighted by the overall distribution for each statin in the Part D population
- Example for two drugs
  - $\text{Basket OOP}_P = \text{OOP}_{1P} * \text{share}_1 + \text{OOP}_{2P} * \text{share}_2$
  - The major challenge is when we don't observe a fill for every drug in each plan (i.e.,  $\text{OOP}_{1P}$ ,  $\text{OOP}_{2P}$ )

## Constructing a Statin Plan Utilization Formulary

### 1. Plan Characteristics File

- Tier ID
- Pre-Initial Coverage Limit (ICL) Tier Type
  - For example in 2007: generic, preferred generic, non-preferred generic, brand, non-preferred brand, preferred brand, and any combination of these
- Pre-ICL coinsurance rate for in-network pharmacy
- Pre-ICL co-pay for in-network pharmacy

## Basket OOP, continued

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### Constructing a Statin Plan Utilization Formulary, cont.

#### 2. PDE file

- Tier ID
- Active Ingredient (merged from Medispan information)
- Days supplied
- OOP
- Using all of the PDE data for all beneficiaries, create a summary file by statin active ingredient by plan file and a statin active ingredient file
- Use the summarized PDE files and plan file to create the basket OOP measure

## Basket OOP, continued

- Step 1 - If plan has a fill for statin<sub>j</sub>, then we know the Pre-ICL co-pay/coinsurance
- Step 2 - If plan does not have a fill for statin<sub>j</sub>, then we impute OOP<sub>jP</sub> by assigning pre-ICL co-pay/coinsurance using information on:
  - Type of tier statin<sub>j</sub> is covered for all other users
    - Example: Atorvastatin Calcium (Lipitor) is covered under following tier types for all users – 87% preferred brand, 7% brand, 6% non-preferred brand
  - Universe of tiers and tier types from plan characteristics for each plan
    - Example: Plan has tier for preferred and non-preferred brand. Imputed pre-ICL copay is weighted average of pre-ICL copay of (0.94,0.06) the two tiers

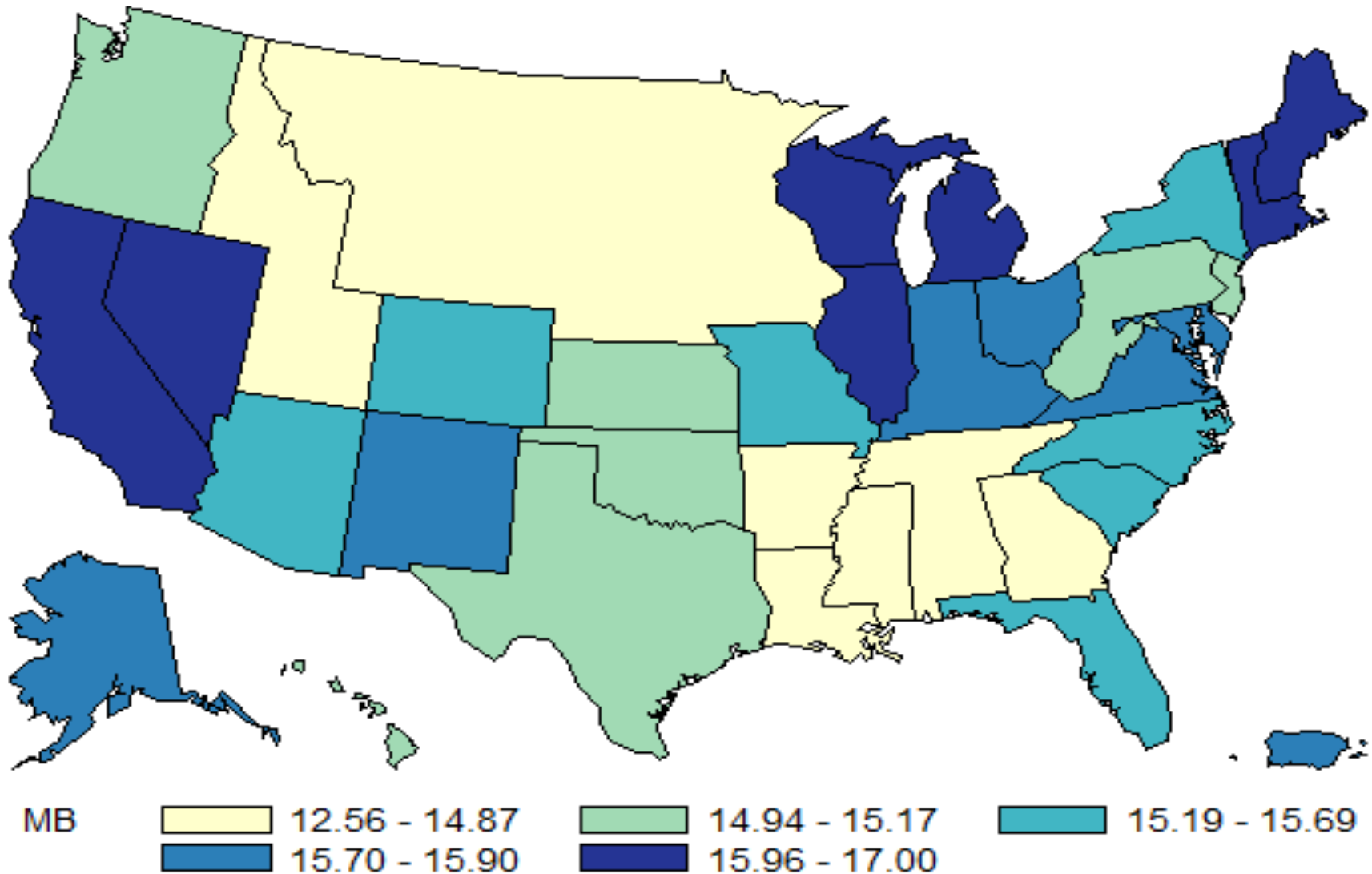


## Basket OOP, continued

- Pre-ICL Basket OOP Summary Statistics for '07 and '08 Cohorts
  - \$15.32 Average Basket OOP
  - 3.65 STD, \$6.08 Min, \$37.66 Max
- Pre-ICL Basket OOP distribution
  - 25.7% \$6.03 – \$12.35
  - 59.6% \$12.35 – \$18.67
  - 14.3% \$18.67 – \$24.99
  - 0.4% \$24.99 – \$37.66

# Basket OOP, continued

## Pre-ICL Basket OOP by PDP Region



## Basket OOP, continued

- Pre-ICL basket process was repeated to construct gap-phase OOP basket
- Plans without any gap coverage were assigned the total cost of the active ingredient as the monthly OOP gap basket

	Mean	Standard Deviation
One-month gap OOP for statin basket (\$)	\$41	\$14
For beneficiaries in a plan with gap coverage	\$9	\$4
For beneficiaries in a plan without gap coverage	\$47	\$1

## Basket OOP, continued

- The final plan generosity measure of OOP associated with a standard market basket of statin drugs was constructed using individual weights for expected time spent in each benefit phase for the pre-ICL and gap phase baskets
  - The average PDP statin user spent 9.5 months in the pre-ICL phase and 1.5 months in the gap phase (first month deductible phase)
  - Plan generosity = weighted annual OOP for the pre-ICL and gap phases combined

## Basket OOP, continued

	Mean	Standard Deviation
Annual OOP for statin basket – pre-ICL & gap combined (\$)	\$200	\$40
For beneficiaries in a plan with gap coverage	\$169	\$39
For beneficiaries in a plan w/o gap coverage	\$210	\$36
For low medication use intensity beneficiaries	\$162	\$41
In a plan with gap coverage	\$180	\$40
In a plan without gap coverage	\$159	\$41
For high medication use intensity beneficiaries	\$274	\$59
In a plan with gap coverage	\$161	\$41
In a plan without gap coverage	\$296	\$29

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# Demographic, Socioeconomic, Geographic Characteristics

- Age on January 1
  - Mean 75.2 years
  - SD 6.96
- Female Indicator
  - 63.8% Female
  - 36.2% Male
- Zip-Code Level Socioeconomic measures from Census
- Rural Indicator
- PDP region/HRR

- RTI race/ethnicity

Non-Hispanic White	92.7%
African American	3.34
Hispanic	2.23
Asian/Pacific Islander	1.03
American Indian	0.16
Other	0.43
Unknown	0.10

# Risk Adjusters

- Medispan Therapeutic Class Groups
  - Concurrent adjuster
  - 17 groups:
    - anti-infective agents
    - biologicals
    - anti-neoplastic agents
    - endocrine and metabolic drugs
    - cardiovascular agents
    - respiratory agents
    - gastrointestinal agents
    - genitourinary agents
    - central nervous system drugs
    - ADHD/Anti-narcotic/Anti-obesity/anorexic agents
    - psychotherapeutic/neurological agents
    - analgesics and anesthetics
    - neuromuscular drugs
    - nutritional products
    - hematological agents
    - topical products
    - miscellaneous products

# Adherence Model Findings

	All			High Cardiovascular Risk			Low Cardiovascular Risk		
Plan Benefit Variable	OR	(95% CI)	P> z	OR	(95% CI)	P> z	OR	(95% CI)	P> z
Annual OOP for statin basket - pre-ICL & gap combined (in \$100)	0.92	(0.91, 0.95)	< 0.001	0.93	(0.91, 0.96)	< 0.001	0.91	(0.87, 0.95)	< 0.001
Any deductible (1/0)	1.05	(0.92, 1.21)	0.46	0.98	(0.84, 1.15)	0.85	1.31	(0.99, 1.72)	0.06
Deductible amount conditional on positive deductible (in \$100)	0.99	(0.94, 1.04)	0.63	1.02	(0.96, 1.08)	0.49	0.89	(0.80, 0.99)	0.03
Number of observations	346,583			246,048			100,535		



# Adherence Model Findings, continued

	High Medication Use Intensity			Low Medication Use Intensity		
Plan Benefit Variable	OR	(95% CI)	P> z	OR	(95% CI)	P> z
Annual OOP for statin basket - pre-ICL & gap combined (in \$100)	0.88	(0.87, 0.90)	< 0.001	1.00	(0.97, 1.03)	0.80
Any deductible (1/0)	0.96	(0.79, 1.17)	0.67	1.13	(0.94, 1.37)	0.20
Deductible amount conditional on positive deductible (in \$100)	1.09	(1.02, 1.18)	0.02	0.94	(0.88, 1.01)	0.10
Number of observations	138,027			208,556		

# Cardiovascular Hospitalization models

$$\text{Cardiovascular Hospitalization}_{it} = f(\text{Plan design}_i, \text{Demographic Characteristics}_i, \text{Risk Adjusters}_i, \text{Regional Fixed Effects}_i)_{t-1}$$

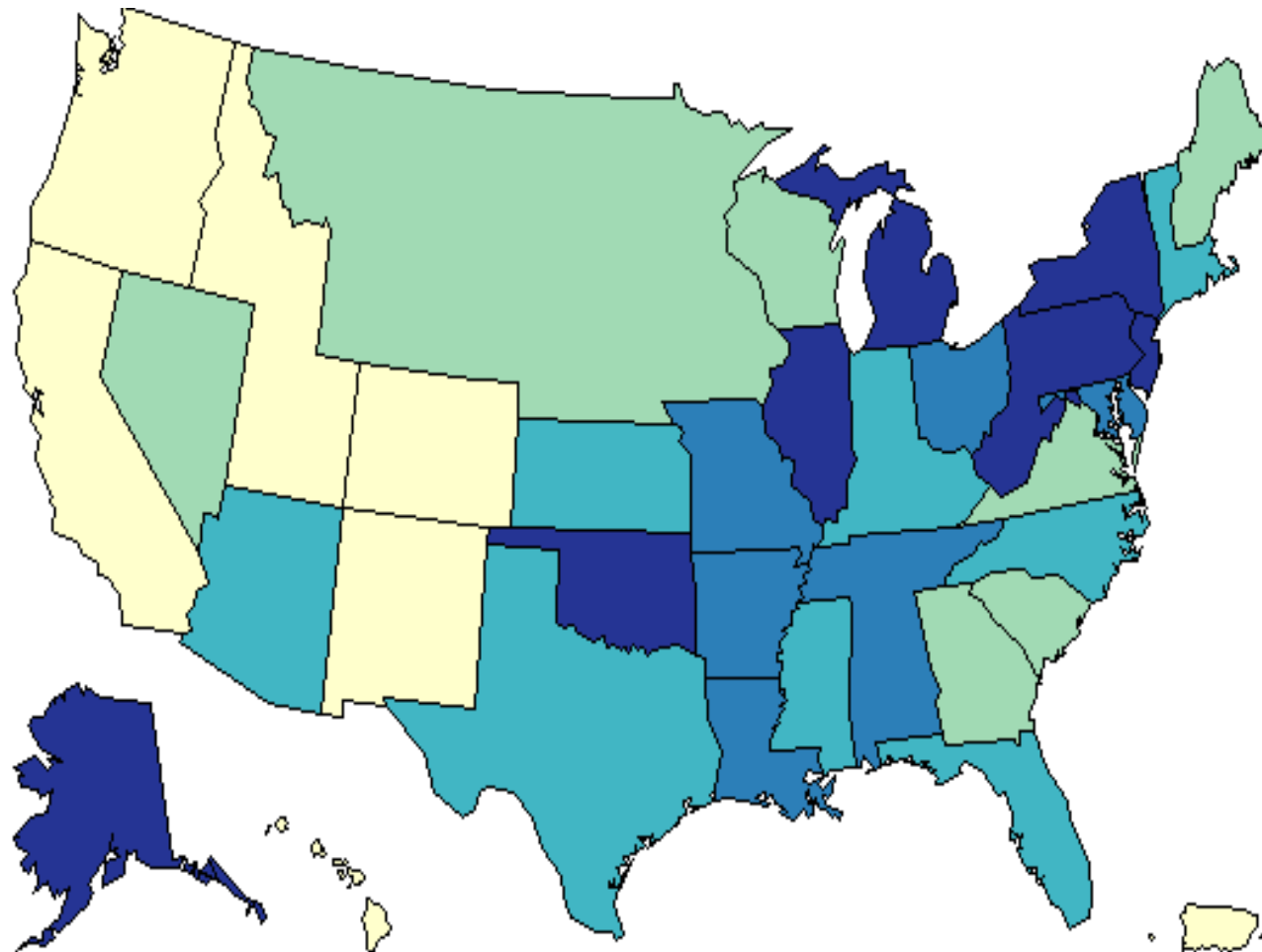
- Estimate model using logistic regression
- Examined any cardiovascular hospitalizations during calendar year as binary outcome
- Expenditures conditional on any hospitalization will be studied in future analysis

# Cardiovascular Hospitalization Definitions

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- “Any hospitalization” is an indicator for a hospital admission in the 2008 MedPAR
  - 21.5% 2007 cohort have hospitalization in 2008
- Cardiovascular hospitalizations are a subset of “any hospitalizations” and defined by the major disease classification (MDC) of the diagnostic related group (DRG) for the hospital stay
  - 7.4% have cardiovascular hospitalization

# Cardiovascular Hospitalizations by PDP Regions



CardioHsp    4.5 - 5.7    6.0 - 6.7    6.8 - 7.6    7.7 - 8.2    8.4 - 10.9

# Cardiovascular Hospitalization Model Findings

Plan Benefit Variable	All			High Cardiovascular Risk			Low Cardiovascular Risk		
	OR	(95% CI)	P> z	OR	(95% CI)	P> z	OR	(95% CI)	P> z
Annual OOP for statin basket - pre-ICL & gap combined (in \$100)	1.10	(1.06, 1.15)	< 0.001	1.09	(1.04, 1.14)	< 0.001	1.19	(1.06, 1.32)	0.002
Any deductible (1/0)	0.88	(0.66, 1.18)	0.41	0.93	(0.68, 1.27)	0.63	0.62	(0.24, 1.59)	0.32
Deductible amount conditional on positive deductible (in \$100)	1.07	(0.95, 1.19)	0.25	1.05	(0.93, 1.18)	0.41	1.20	(0.84, 1.70)	0.32
Number of observations	346,583			246,048			100,535		

# Cardiovascular Hospitalization Model Findings, continued

	High Medication Use Intensity			Low Medication Use Intensity		
Plan Benefit Variable	OR	(95% CI)	P> z	OR	(95% CI)	P> z
Annual OOP for statin basket - pre-ICL & gap combined (in \$100)	1.11	(1.08, 1.15)	< 0.001	1.04	(0.97, 1.12)	0.22
Any deductible (1/0)	0.93	(0.65, 1.33)	0.68	0.83	(0.49, 1.39)	0.48
Deductible amount conditional on positive deductible (in \$100)	1.00	(0.88, 1.15)	0.96	1.13	(0.93, 1.37)	0.22
Number of observations	138,027			208,556		

# Implications of Findings for ACA Policy Context

- The Affordable Care Act (ACA) provides beneficiaries additional OOP financial support during the coverage gap phase by discounting brand and generic drugs
  - In 2012, beneficiary OOP in coverage gap phase is:
    - 50% for brand-name drug purchases
    - 86% for generic drug purchases
- Estimation of the annual OOP cost for a representative basket of statins under the ACA discount rates for beneficiaries with high medication use intensity shows:
  - Adjusted adherence rates increase from 70.6% to 73.0%
  - Adjusted risk of cardiovascular hospitalization rates decrease from 8.9% to 8.2%

# Conclusions

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- Less generous plan benefits for coinsurance and co-payments are associated with lower statin adherence rates
  - Overall, the plan deductible does not have a statistically significant effect on statin adherence
- Less generous plan benefits are associated with increases in the likelihood of cardiovascular hospitalizations; the plan deductible does not have a statistically significant effect



## Future Research from Project

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- Apply similar framework as statin paper to diabetic analytical cohort
  - Note: This paper has been accepted for presentation at 2012 ASHE conference in June
- Followed by analysis of the final cohort of gastrointestinal agents
- Examine regional variation in adherence levels for Low Income Subsidy enrollees for three clinical cohorts, which is part of my dissertation research objectives
- Compare the regional variations in the PDP and MA-PD populations for the three clinical cohorts



# Assessments





# Assessment Question 1

Which of the following variables are NOT used in the construction of the market basket measuring Part D plan generosity:

-  1/A Drug tier identifier
-  2/B Beneficiary out-of-pocket (OOP) amount
-  3/C Beneficiary date of birth
-  4/D Drug tier type (e.g., generic, brand, preferred brand, etc...)

## Assessment Question 2

The study findings suggest that less generous Part D plan benefits (i.e., higher out-of-pocket expenses) are associated with the following effects of statin adherence levels and the risk of cardiovascular hospitalizations:

-  Lower adherence levels and increased risk of hospitalizations
-  Higher adherence levels and no statistically significant effect on hospitalizations
-  No statistically significant effect on adherence and decreased risk of hospitalization
-  No statistically significant effect on either



## Questions?

# Speaker Contact Information

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