



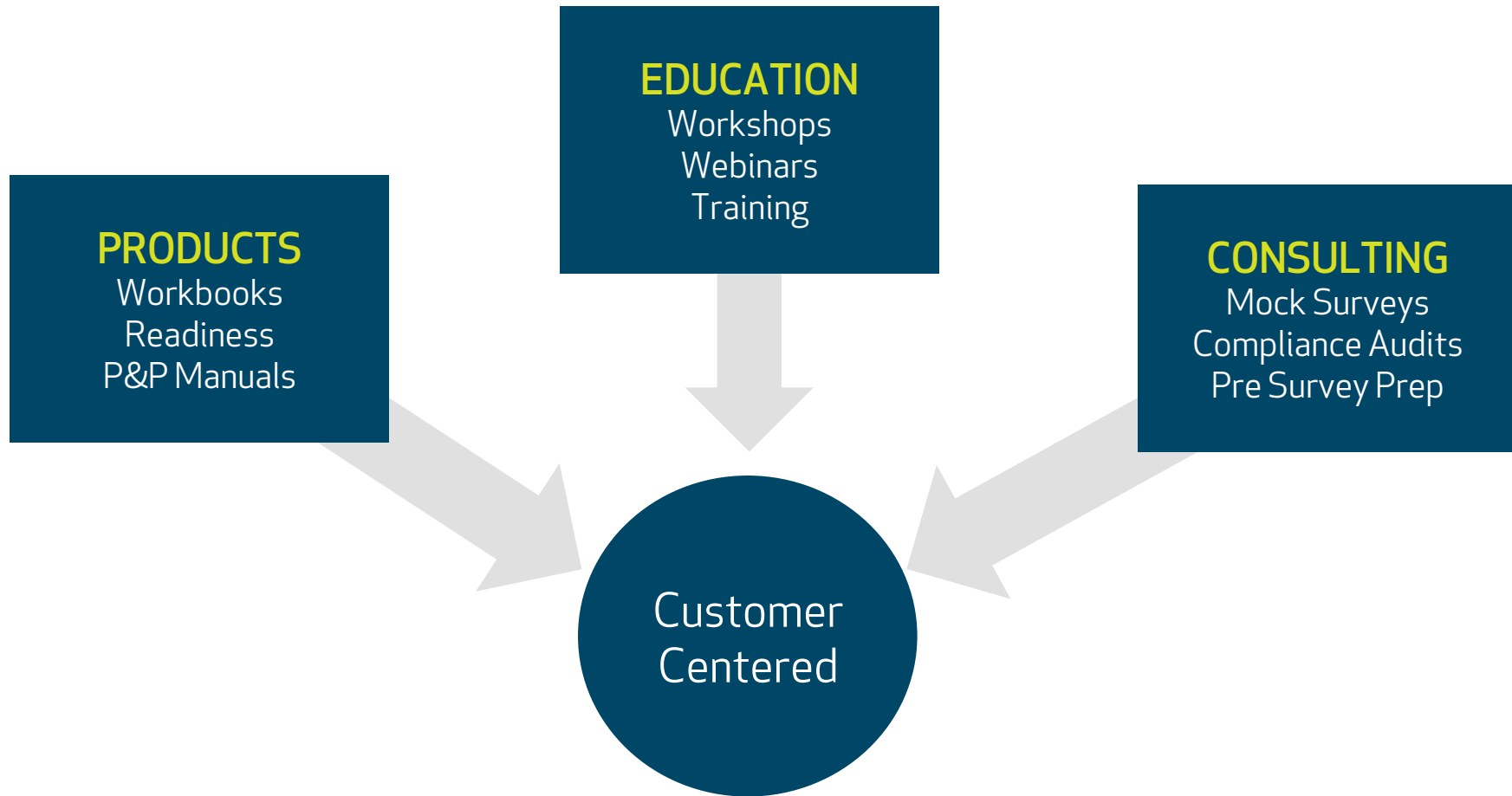
# RETAIL TO SPECIALTY: HOW LEGISLATIVE & REGULATORY ISSUES AFFECT DRUG REIMBURSEMENT

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President

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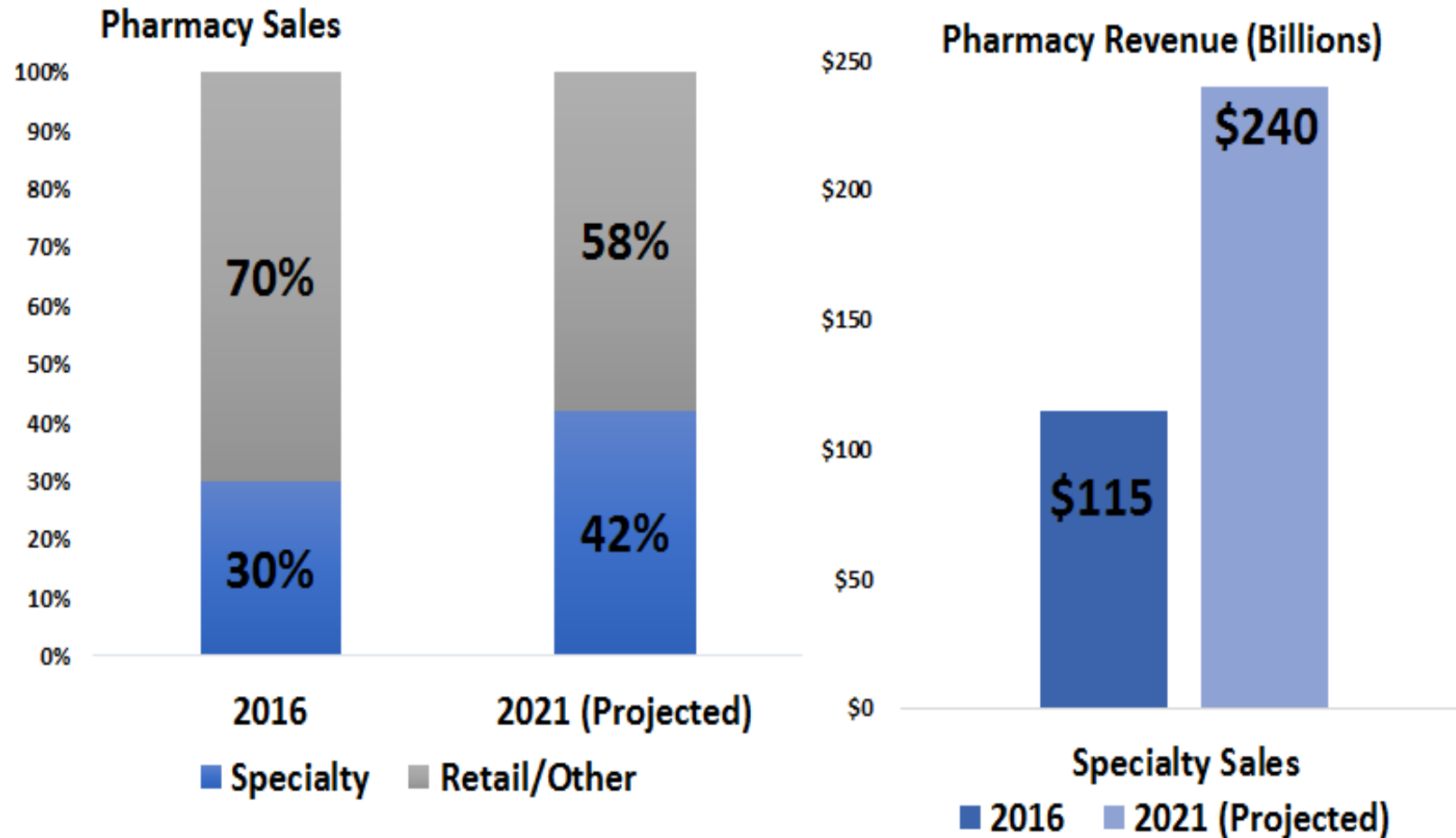
# ACCREDITATION UNIVERSITY



# INTRODUCTION

- Introduction to how this information will be presented
- Discover what is happening in the specialty drug market Learn how payers are reimbursing pharmacies that are expanding to serve specialty patients
- Become familiar with the necessary accreditation
- Learn suggestions about what disease states to start with
- Understand the current state and federal policies surrounding specialty medications
- Discussion of difference between retail and specialty

## Specialty Pharmacy is Estimated to Increase



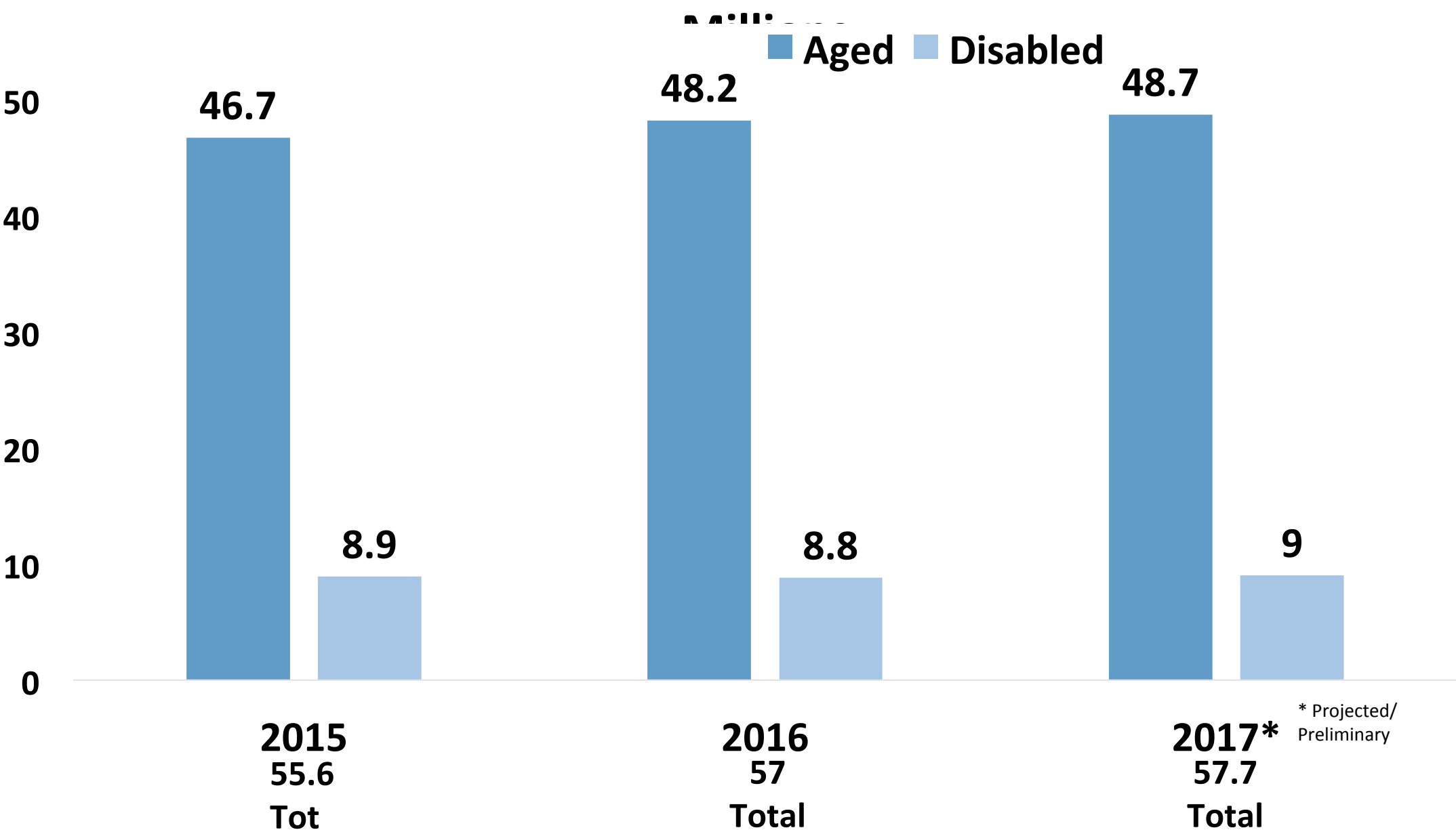
# OVERVIEW OF PART B

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## What is Part B?

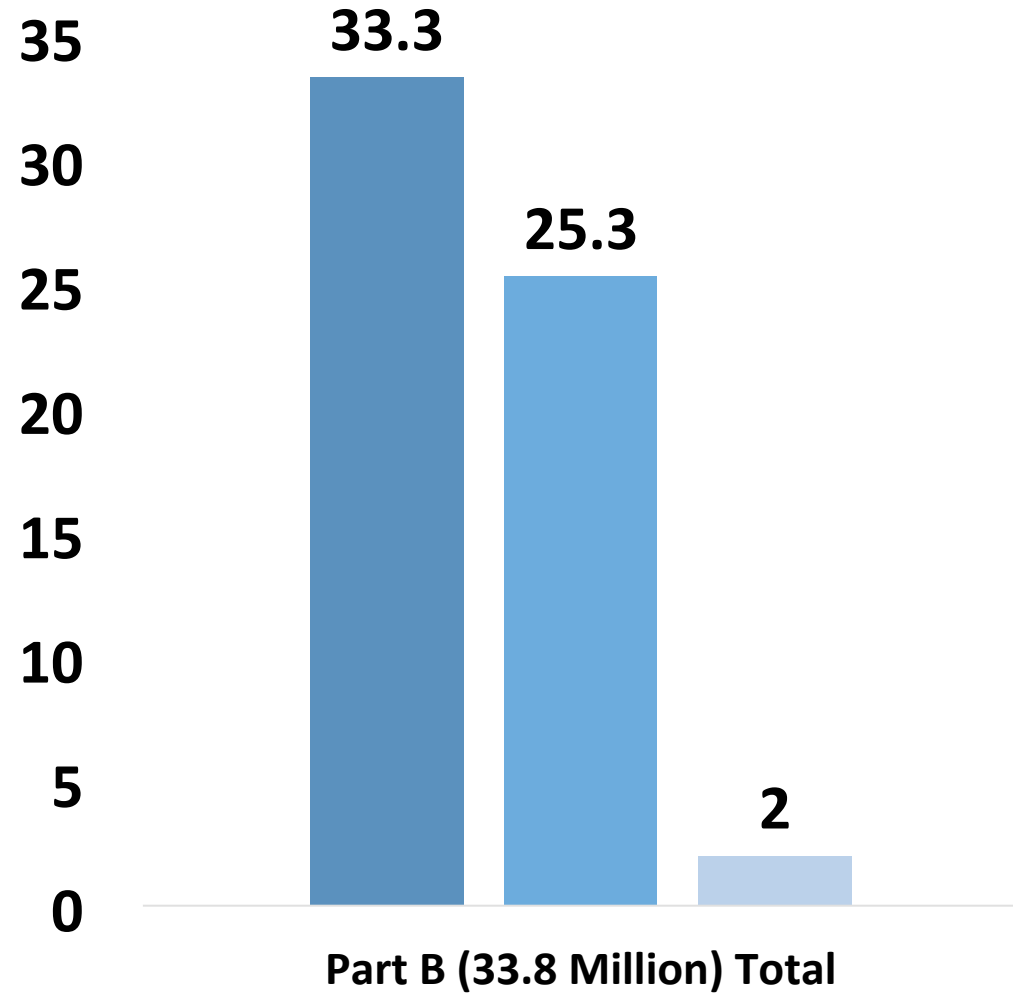
- Medicare Part B is part of the fee for service Medicare and covers outpatient services, preventative care, ambulatory services and durable medical equipment
- Patients can enroll in either Part B or Medicare Advantage Program
- Not enrolling in Part B when first eligible will incur a premium penalty
- Unlike Part A, Part B requires a premium

# Medicare Part A and/or B Enrollment (Monthly Average) in



\* Projected/  
Preliminary

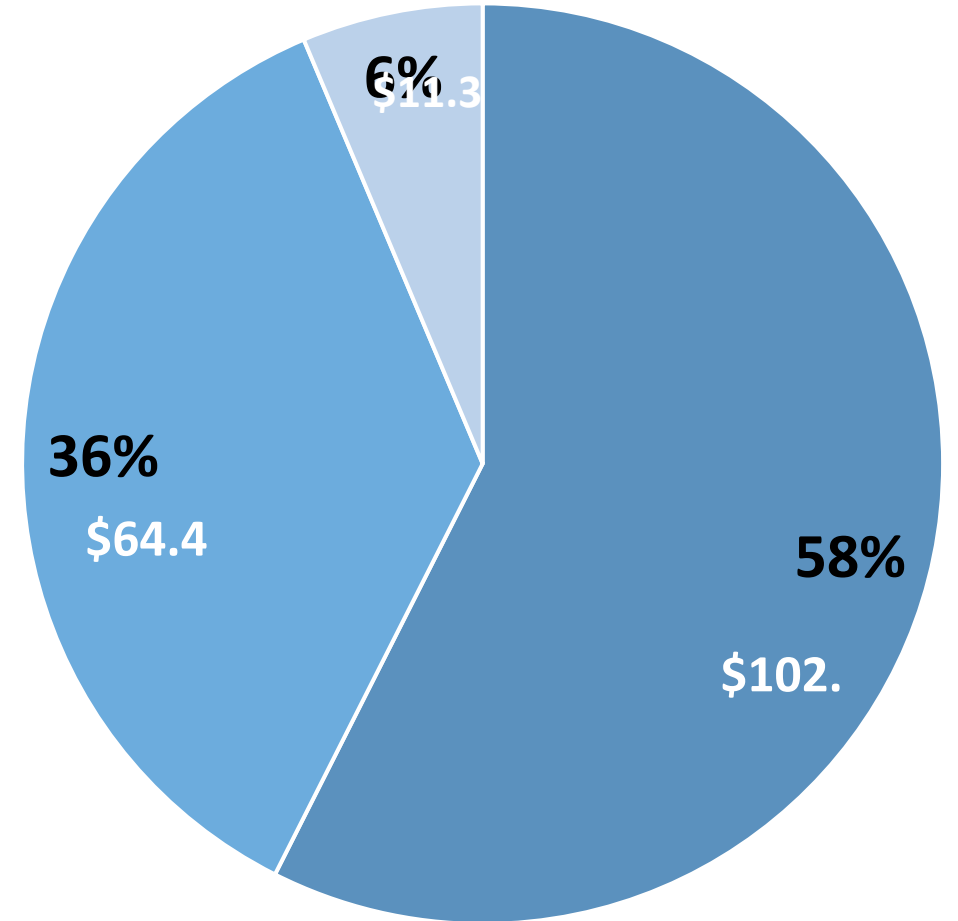
## Medicare Individuals Served by Service Type (2015) in Millions



■ Physician/DME ■ Outpatient ■ Home Health

Information obtained from: <https://www.cms.gov/fastfacts/>

## Medicare Payments by Service Type (2015) in Billions



■ Physician/DME ■ Outpatient ■ Home Health

# OVERVIEW OF PART B

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- What is covered?
- Limited prescription coverage
- Drugs that the patient would usually not give to themselves. Either they are doctor administered or through home infusion



# WHAT MEDICATION DOES MEDICARE PART B COVER?

- Drug used with an item of durable medical equipment (DME)
- Some Antigens
- Injectable Osteoporosis Drugs
- Erythropoiesis-Stimulating Agents (used from end-stage Renal Disease)
- Blood Clotting Factors
- Injectable & Infused Drugs
- Oral End-Stage Renal Disease Drugs
- Parenteral and enteral nutrition (such as feeding tube)
- Intravenous Immune Globulin provided at home
- Shot Vaccinations (such as Flu shots, Pneumococcal shots, & Hepatitis shots)
- Transplant drugs
- Oral cancer drugs
- Oral anti-nausea drugs
- Self-administered drugs in hospital outpatient settings



Information obtained from: <https://www.medicare.gov/coverage/prescription-drugs-outpatient.html>

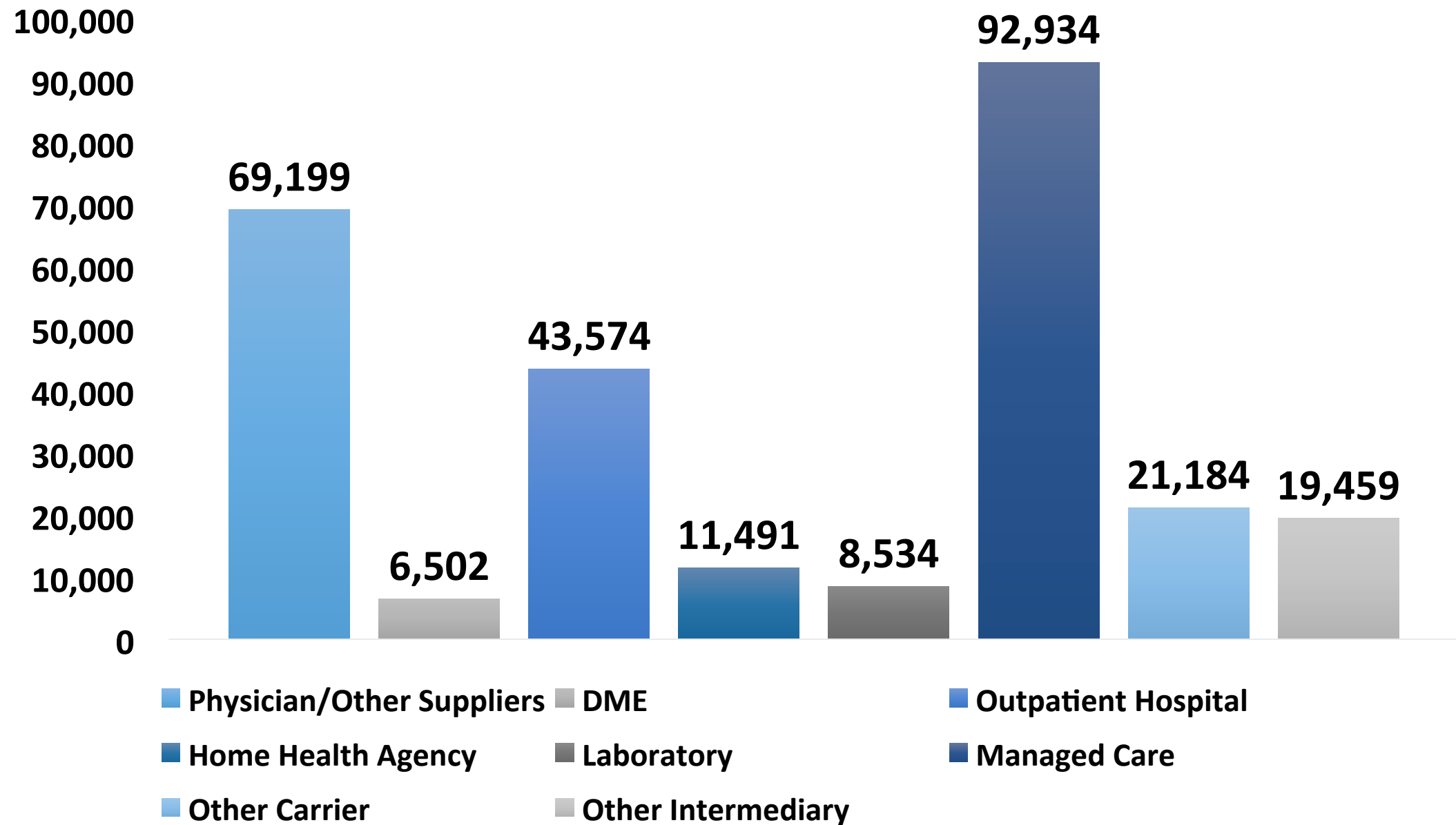
# OVERVIEW OF PART B

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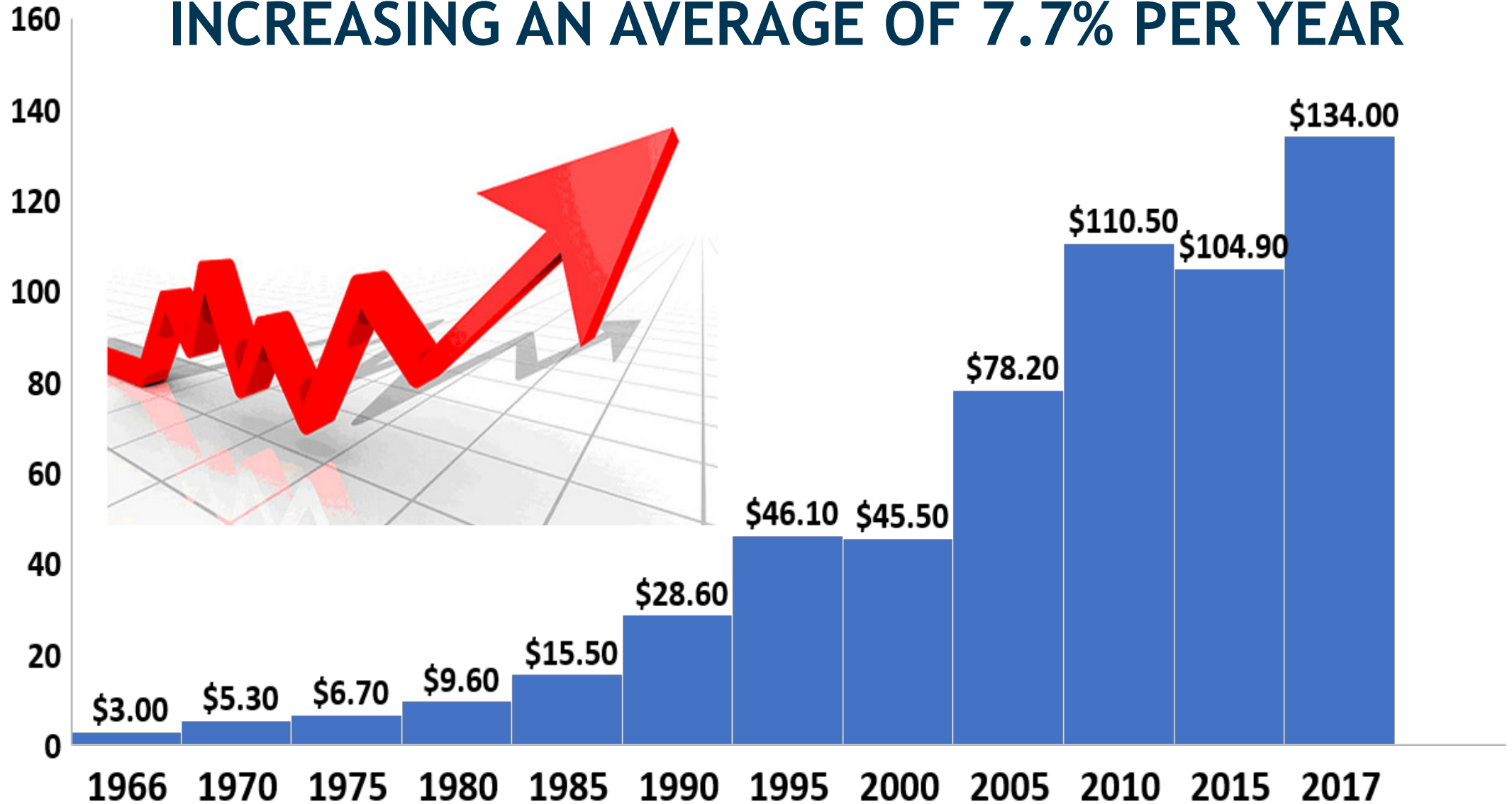
## Costs?

- The current Medicare Part B premium is \$134
- For individuals with Social Security Benefits the average premium is \$109
- The deductible is \$183 per year and the copay is 20% once the deductible is met
- Premiums have increased steadily over the years at an average rate of 8%

# Medicare Part B Payments in 2015 (Millions)



# MEDICARE PART B PREMIUMS INCREASING AN AVERAGE OF 7.7% PER YEAR



# OVERVIEW OF PART B

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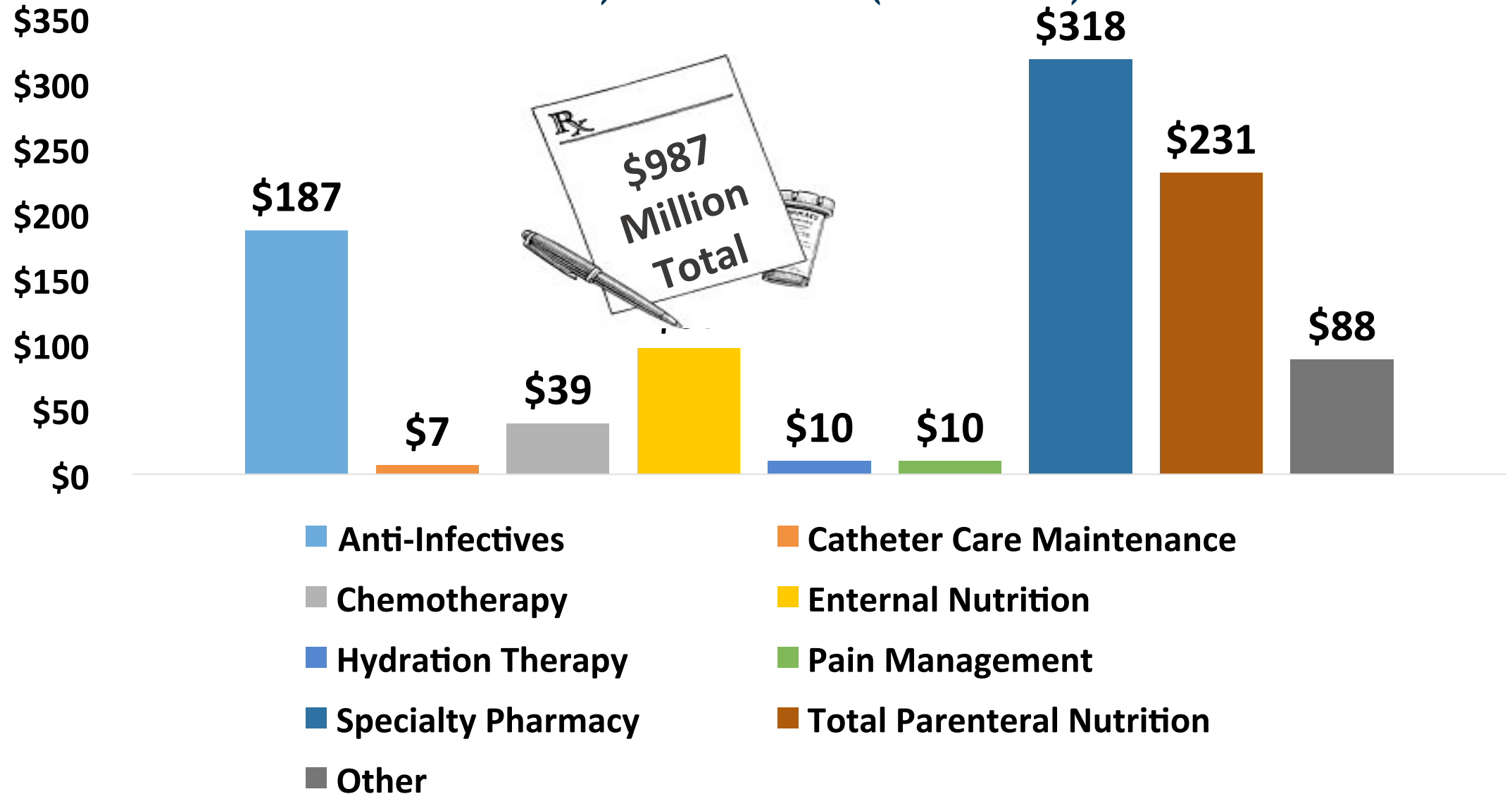
- ASP and how it works
- Medicare Prescription Drug, Improvement and Modernization Act of 2003
- ASP relies on manufacturer sales data to set pricing and the data must be reported to CMS on a quarterly basis
- Rebates and discounts are used in the ASP calculation
- Lowered reimbursement when first enacted

# OVERVIEW OF PART B

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- Home infusion changes
- Congress exempted DME drugs from the ASP calculation
- Medicare Home Infusion Site of Care Act
- Home Infusion drugs are calculated with the same ASP methodology
- The service payment will start in 2021

# MEDICARE PAYMENT AND DOLLARS SPENT BY PAYOR CATEGORY FOR EACH THERAPY CATEGORY EXTRAPOLATED TO NHIA MEMBERSHIP (730 SITES) IN MILLIONS (ROUNDED)



# POTENTIAL REIMBURSEMENT CHANGES

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## OIG recommendations

1. Least Costly Alternative
2. ASP Inflation Limit
3. Lower dispensing and supply fees



# POTENTIAL REIMBURSEMENT CHANGES

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MedPAC- Medicare Payment Advisory Committee

- WAC + 3 instead of ASP
- ASP inflation rebate
- Consolidated billing codes
- Create a Drug Value Program as an alternative to ASP payment system
- Reduce ASP add-on so that physicians will enroll in Drug Value Program

# DIR FEES

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- CMS recent report
- Higher use of DIR fees
- CMS acknowledged they lower premiums
- DIR Federal Legislation
- Sponsors
- Where is the bill now?

# MANUFACTURER POLICY

- PhRMA, increasing lobbying efforts
- PhRMA vs. ICER & PCMA
- Manufacturer Pricing Transparency
  - Allergan Pledge to keep price increases at single digits
  - Abbvie and Novo follows Allergan
  - Merck
  - JNJ

# MANUFACTURER POLICY

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- Campaign for more drug price transparency
- Investor campaign asking for price transparency
- Interfaith Center on Corporate Responsibility
- Wanted companies to show evidence as to why prices increased
- The campaign was blocked by manufacturers

# PAYOR POLICY

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- Pathways: Emerging cost-containment protocols by payers
- Pathways may incentivize doctors to prescribe a specific treatment protocol for patients with a particular diagnosis based on available evidence
- Goal is to reduce costs
- May result in different pathway protocols by each insurer

# PAYOR POLICY

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- Value Based Contracts
- These are contracts in which insurers pay for drugs based on their effectiveness
- Novartis Contract with Cigna and Aetna
- Amgen contract could be new model for Part B drugs
- Value based contracts are used to control high drug prices
- Drug Tiering

# NEW TREATMENTS TO KNOW ABOUT

- Immunotherapy and Gene Therapy
- Newest FDA approvals
- Biosimilars
- Amgen v. Sandoz
- State substitution laws
- How should retailers get involved?
- HIV, Hep. C, RA, Immunology

# ACREDITATION ORGANIZATIONS

- Accreditation Commission for Health Care (ACHC)
  - Pharmacy Compounding Accreditation Board (PCAB) - a service of ACHC
- LegitScript
- Utilization Review Accreditation Commission (URAC)



# RECOMMENDATIONS ON WHAT TO DO NEXT FROM A BUSINESS PERSPECTIVE

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- MedPAC should be monitored
- Watch the policies being implemented by HHS Secretary Tom Price; he could affect pricing with demos or direct changes via regulations
- Watch Congress and state legislatures for relevant information
- Monitor the payer and manufacturer communities for pricing policies.
- Advocate to your policymakers about your business

# CONTACT INFORMATION

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