

# Specialty Pharmacy

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# Objectives

- Obtain a general understanding of specialty pharmaceuticals
- Understand the impact and trends of specialty pharmaceuticals over the past few years
- Describe the value specialty pharmacy and products bring to the market
- Understand the challenges of specialty pharmaceuticals for managed care organizations
- Understand how specialty pharmaceuticals and their management affect patients

# What is a specialty medication?

# Definition of Specialty Pharmaceuticals

- Lack of universal definition
- Can include high cost injectable, infused product, oral agent or inhaled medication
- May require close supervision, monitoring and handling requirements
- Can be administered at home, MD office, infusion center or outpatient hospital
- Medicare's Part D definition for specialty: any drug for which the negotiated monthly price is \$600 or more

# URAC: Specialty Drug Definition

URAC: Utilization Review Accreditation Commission – a nonprofit org well known for promoting health care quality

- Product requiring special handling and administration
- Unique inventory management
- A high level of patient monitoring
- More intense support than conventional therapies

# IMS Health: Specialty Drug Definition

- Drug must have 4 or more of the following:
  - **Initiated *only* by a specialist**
    - Few prescribers/ centers
  - **High expense**
    - Low inventory important
  - **Requires reimbursement assistance**
    - Processing of pre-approval essential and competitive skill
  - **Warrants intensive patient counseling**
    - Requires patient training to administer
  - **Require special handling**
    - Support to achieve adherence needed
  - **Unique distribution**
    - Cold chain when needed
    - No need for supplying all pharmacies through all warehouses

# Commonly Targeted Disease States

- Pulmonary arterial hypertension
- Multiple sclerosis
- Hepatitis C
- Rheumatoid arthritis
- Psoriasis
- RSV
- Oncology
- Blood disorders
- Cystic fibrosis
- Crohn's disease
- Growth hormone deficiency
- Hemophilia
- HIV/AIDS wasting
- Infertility

# Question 1

- True or False: Does a specialty drug need to treat a specialty condition?



# Question 1

- True or False: Does a specialty drug need to treat a specialty condition?
  - False: There are specialty drugs on the market that do not necessarily treat a specialty condition
  - Example:
    - Medicare's Part D definition for specialty: any drug for which the negotiated monthly price is \$600 or more

What is the impact of specialty medications on the health care system?

# Impact of Specialty Products

- Specialty drugs have been the fastest growing segment of drug spend under the pharmacy benefit
- There are currently over 5,000 new medications in the biopharmaceutical pipeline

# Basic “Per Member Per Year” Equation

$$\text{\$PMPY} = \frac{(\text{Unit Cost}) (\text{Volume})}{(\text{Member-Year})}$$

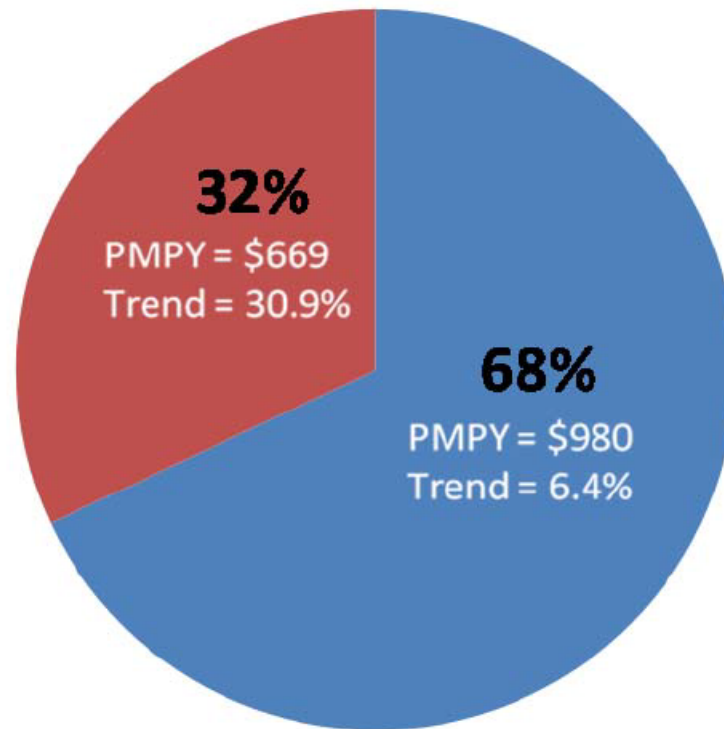
Where . . .

**Unit Cost** = Average cost per prescription

**Volume** = Total number of prescriptions during year

**Member-Year** = Number of eligible members per year

# 2014 Pharmacy Drug Spend



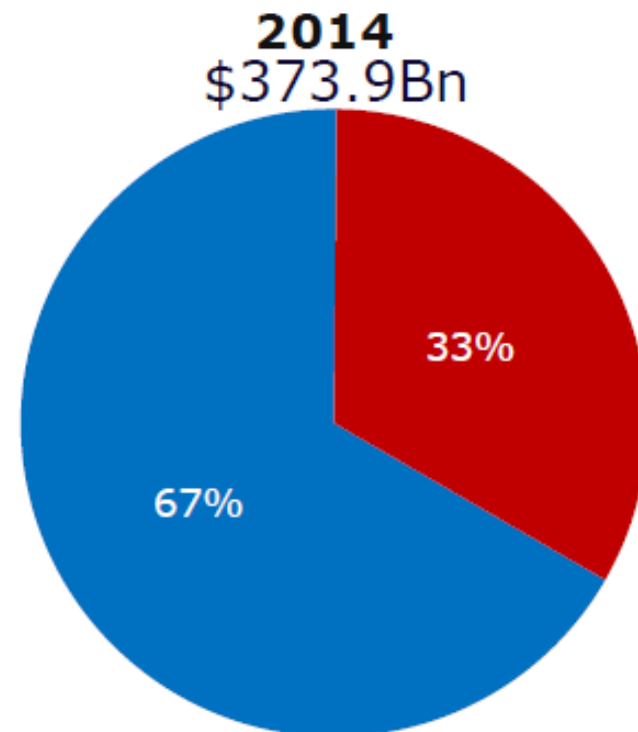
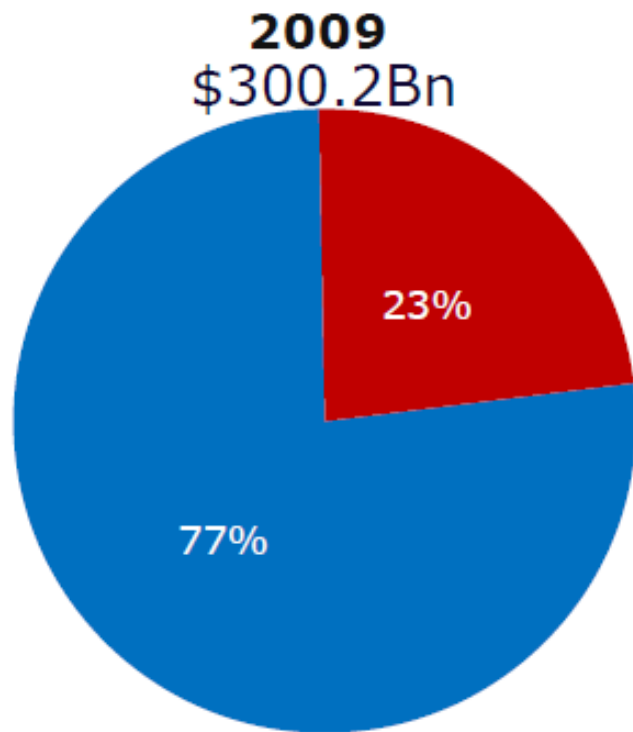
2014 Total  
Drug Spend  
=\$373.9 billion

■ Traditional  
■ Specialty

- Less than 1% of patients use specialty drugs, but they represent about 1/3 of the total drug spend
- If current trends continue, it will represent more than 50% by 2018

Source = Express Scripts' 2014 Drug Trend Report

# Change in Specialty Drug Spend

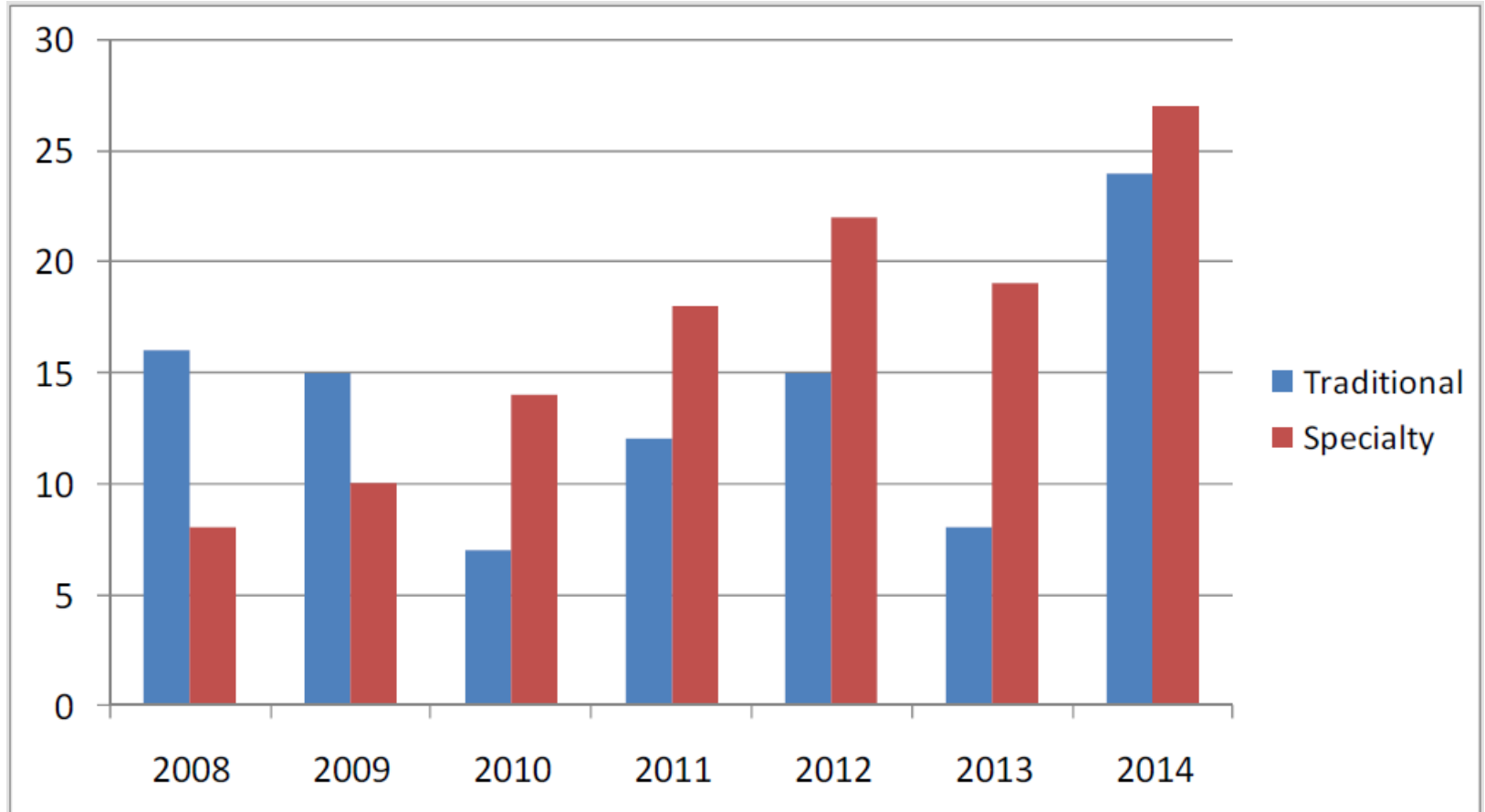


■ Traditional ■ Specialty

Specialty drugs account for 33% of spending which is up from 23% five years ago

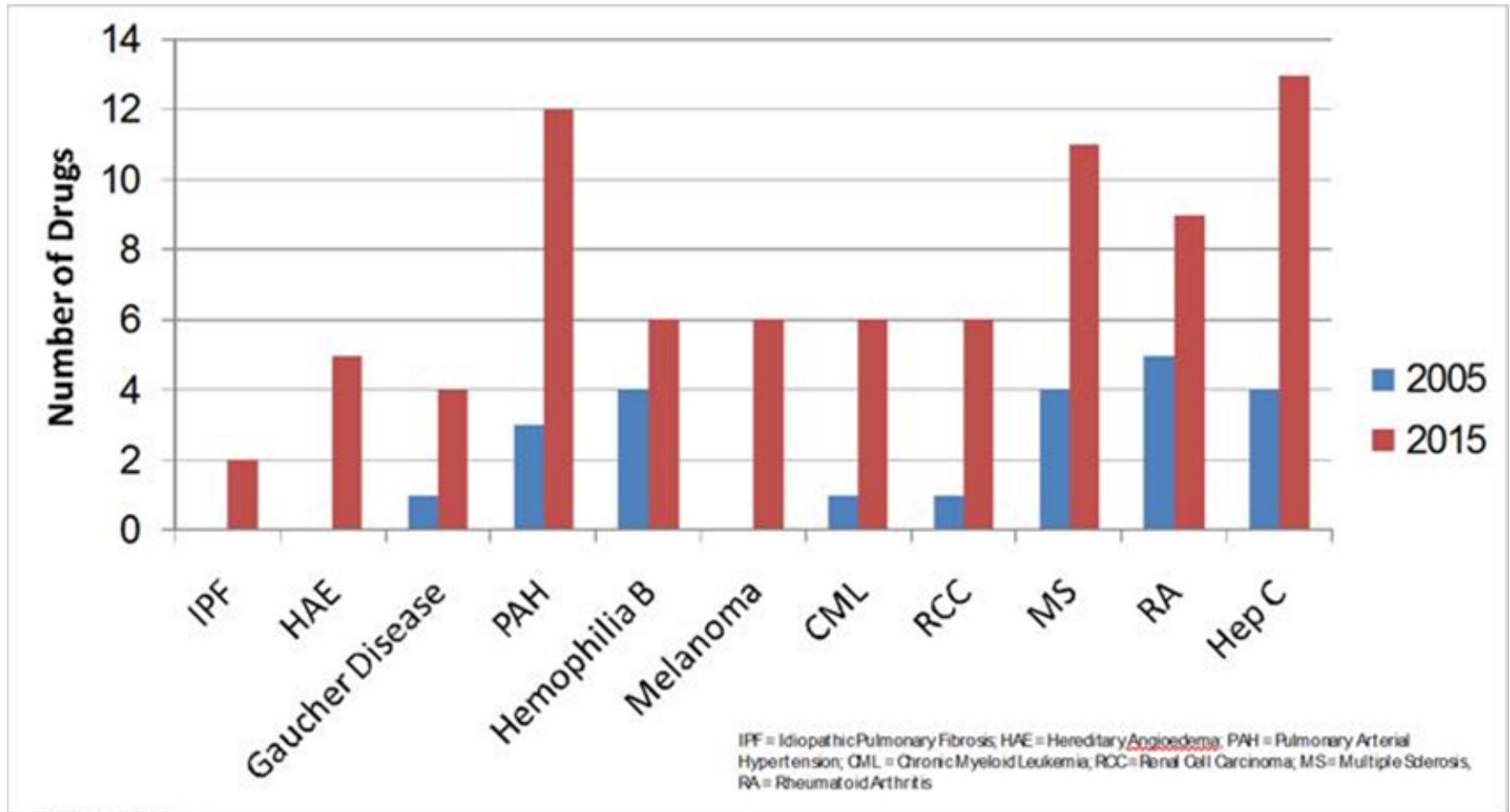
Source: IMS Health, National Sales Perspectives, Dec 2014

# FDA Drug Approvals



Source = Express Scripts' 2014 Drug Trend Report

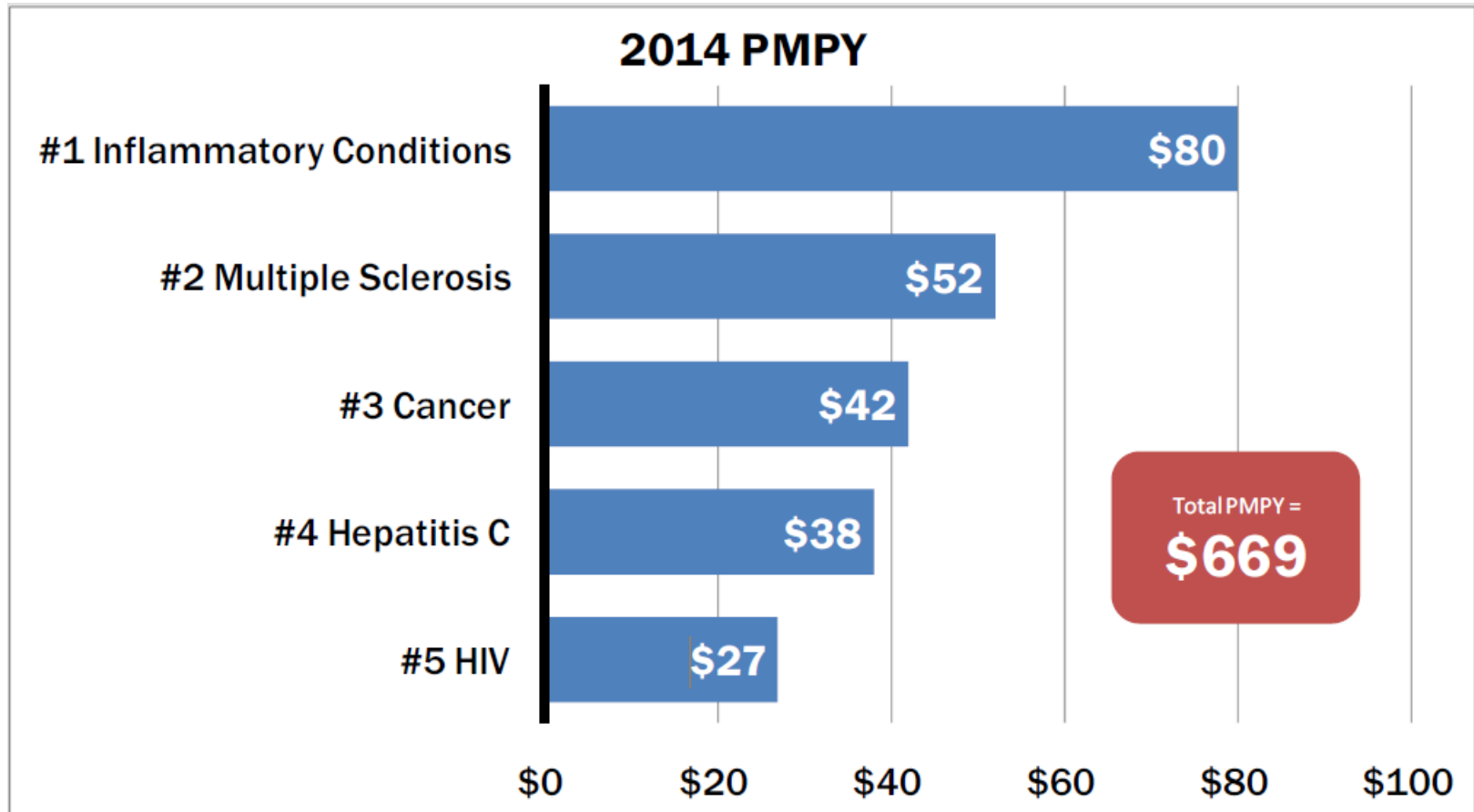
# Therapy Classes Maturing



Source = Express Scripts' 2014 Drug Trend Report



# Leading Specialty Therapy Classes



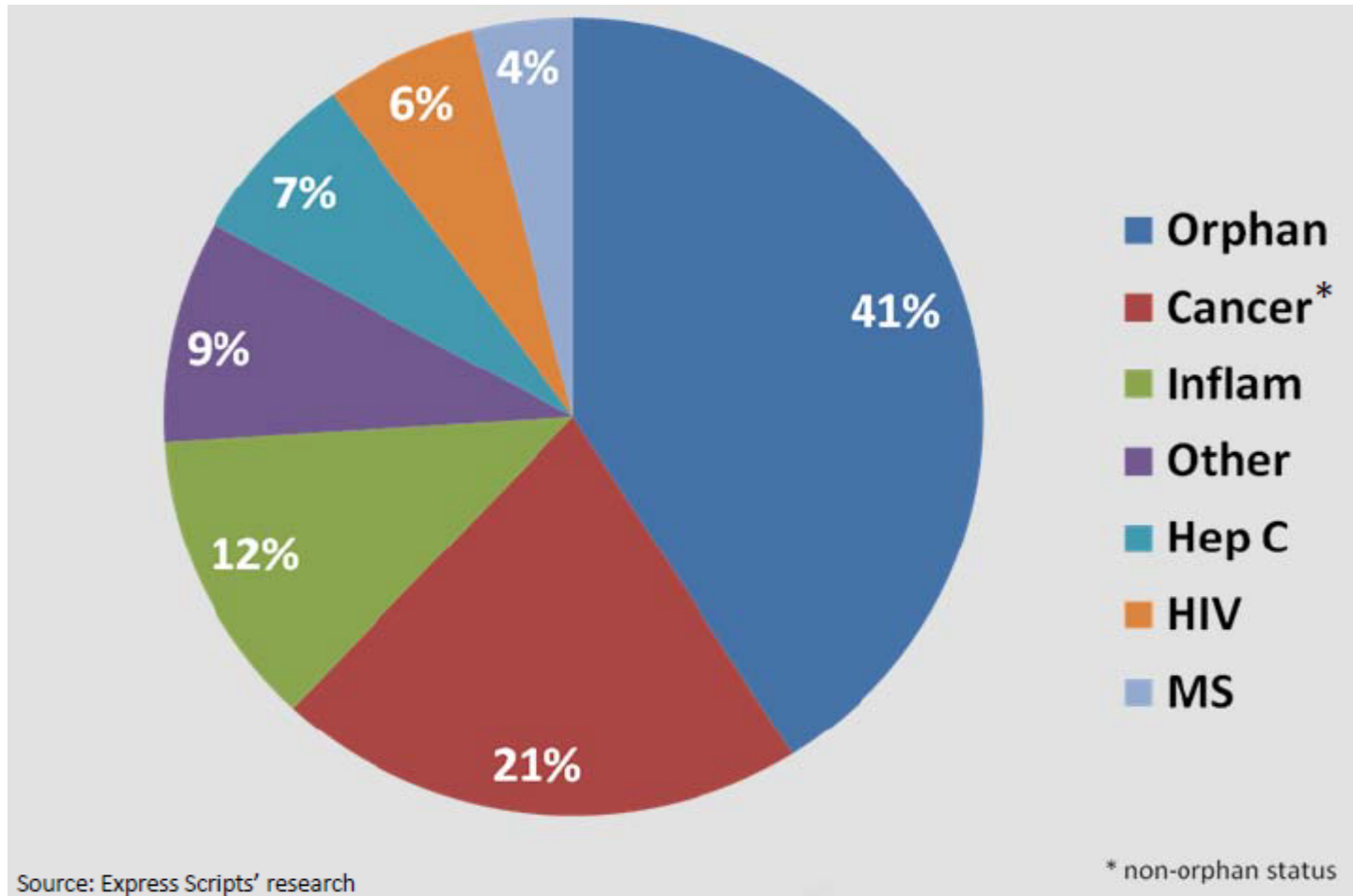
Source = Express Scripts' 2014 Drug Trend Report

# Top 10 Specialty Drugs in 2014

RANK	DRUG NAME	THERAPY CLASS	PMPY SPEND	% OF TOTAL SPECIALTY SPEND	TREND		
					UTILIZATION	UNIT COST	TOTAL
1	Humira® (adalimumab)	Inflammatory Conditions	\$37.06	11.9%	10.7%	17.1%	27.8%
2	Enbrel® (etanercept)	Inflammatory Conditions	\$25.65	8.2%	-2.2%	13.7%	11.5%
3	Sovaldi® (sofosbuvir)	Hepatitis C	\$24.38	7.8%	9,743.5%	258.4%	10,001.9%
4	Copaxone® (glatiramer)	Multiple Sclerosis	\$15.48	5.0%	-7.3%	7.2%	-0.1%
5	Tecfidera® (dimethyl fumarate)	Multiple Sclerosis	\$10.60	3.4%	130.0%	22.1%	152.1%
6	Avonex® (interferon beta-1a)	Multiple Sclerosis	\$8.18	2.6%	-17.4%	9.4%	-7.9%
7	Atripla® (efavirenz/emtricitabine/tenofovir)	HIV	\$7.42	2.4%	-4.7%	7.3%	2.6%
8	Gleevec® (imatinib)	Oncology	\$6.86	2.2%	-5.3%	17.6%	12.3%
9	Revlimid® (lenalidomide)	Oncology	\$6.85	2.2%	5.6%	6.1%	11.7%
10	Olysio® (simeprevir)	Hepatitis C	\$6.49	2.1%	14,666.0%	757.5%	15,423.6%

Source: Express Scripts Drug Trend Report: Top 10 Specialty Therapy Drugs

# Specialty Pipeline: Extensive Orphan Drug Development



There are currently over 5,000 new medications in the biopharmaceutical pipeline

# Question 2

2. Which of the following statements are TRUE regarding specialty medications?
- a) The use and cost of specialty drugs is rising
  - b) Inflammatory conditions, Hepatitis C, Multiple Sclerosis, and Oncology are the top prescribed conditions of specialty medications
  - c) The number of specialty drugs on the market is increasing
  - d) All of the above statements are true

# Question 2

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  - d) **All of the above statements are true**

# What is a specialty pharmacy and what do they do?

# Specialty Pharmacy and Programs

- Specialty pharmacy is often a subset of retail pharmacy in managed care who “specialize” in specialty pharmaceuticals
- Programs may include prior authorizations to ensure clinically appropriate and cost-effective use of treatments when certain criteria is met
- Incorporate evidence-based guidelines, dosing, discontinuation guidance, and monitoring
- Many specialty pharmacies have disease state (ex. Hep C and oncology) management programs specific for conditions that are treated with specialty medications

# Components of Specialty Programs

- Refill reminders
- Adherence counseling / monitoring
- Patient education
- Patient assistance programs
- Delivery coordination
- Insurance verification / coordination
- Clinical interventions



# Specialty Pharmacy Providers

- Payers often contract specifically with specialty pharmacies to provide specialty pharmaceutical services to their members
- Many payers own their own specialty pharmacy
  - Express Scripts – CuraScript Specialty Pharmacy and Accredo Specialty Pharmacy
  - Humana – RightSourceRx Specialty Pharmacy
  - Caremark – Caremark Specialty Pharmacy

# Question 3

3. Which of the following are TRUE regarding Specialty Pharmacies?
- a) Specialty Pharmacies help coordinate care between the member and their insurance company
  - b) Specialty Pharmacies make clinical interventions and monitor for patient adherence
  - c) Hepatitis C and Oncology agents are commonly targeted disease states by specialty pharmacies
  - d) All of the above statements are true

# Question 3

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What are some of the challenges Managed Care Organizations (MCOs) face to handle the high cost specialty medications?

# Medical vs. Pharmacy Medications

- Medical Benefit Medication: obtained by and given by a health care provider
- Pharmacy Benefit Medication: obtained by the member for self administration
- Some medications can be under the pharmacy or medical benefit. It is up to Managed Care Organizations (MCOs) to balance the two.

# Challenges in MCOs

- Billing systems - integration of medical and pharmacy claims
- Utilization management
- Drug coding- NDC vs J code

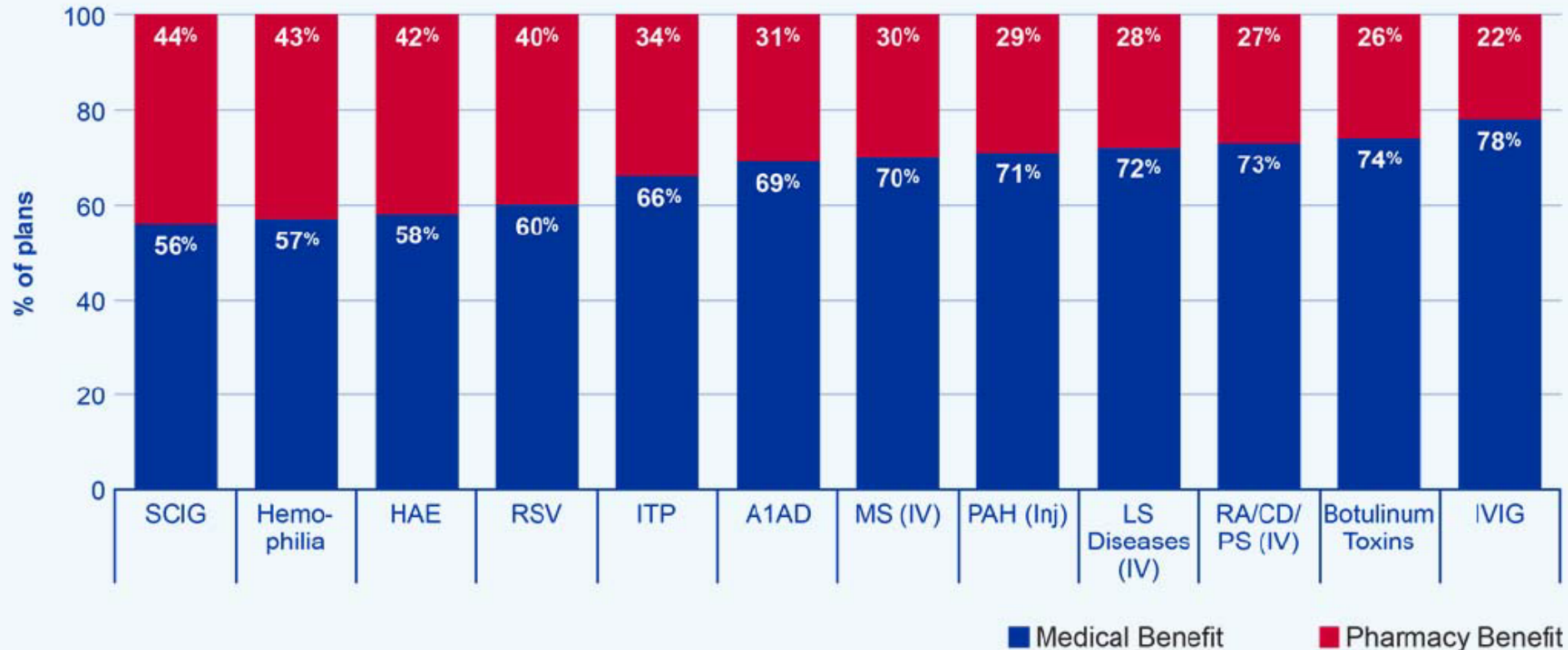
Debbie Stern and Debi Reissman, "Specialty Pharmacy Cost Management Strategies of Private Health Care Payers," *Journal of Managed Care Pharmacy*, November/December 2006. <http://www.amcp.org/data/jmcp/Nov-Dec06JMCP1.pdf>

# Benefit Designs

- Cause of much confusion
- Medical benefit vs. pharmacy benefit
  - Each MCO can design and deliver their own product and services
- Has led to additional formulary tiers
  - Tier 4, Tier 5 and Tier 6 for example
- Traditionally associated with higher co-pays or co-insurances
- Many plans are moving towards new benefit designs for specialty drugs and therapies, including a “specialty formulary”

# Benefit Coverage of Specialty Drug

Indicate the benefit under which provider-administered specialty drug categories are typically covered for your most common benefit structure



n=91

Source: EMD Serono Specialty Digest 10<sup>th</sup> edition



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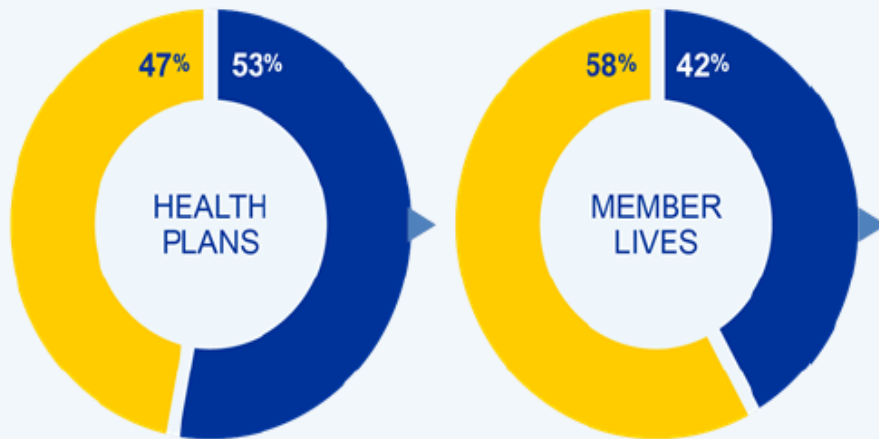
# Trends in pharmacy copays and coinsurance

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013
<b>Average Copayments</b>														
First-Tier Drugs, Often Called Generic	\$8	\$8	\$9	\$9*	\$10*	\$10	\$11*	\$11	\$10	\$10	\$11	\$10	\$10	\$10
Second-Tier Drugs, Often Called Preferred	\$15	\$16*	\$18*	\$20*	\$22*	\$23*	\$25*	\$25	\$26	\$27	\$28*	\$29	\$29	\$29
Third-Tier Drugs, Often Called Nonpreferred	\$29	\$28	\$32*	\$35*	\$38*	\$40*	\$43*	\$43	\$46*	\$46	\$49*	\$49	\$51	\$52
Fourth-Tier Drugs	^	^	^	^	\$59	\$74	\$59	\$71*	\$75	\$85	\$89	\$91	\$79	\$80
<b>Average Coinsurance</b>														
First-Tier Drugs, Often Called Generic	18%	18%	18%	18%	18%	19%	19%	21%	21%	20%	17%	18%	20%*	16%*
Second-Tier Drugs, Often Called Preferred	NSD	23%	24%	23%	25%	27%	26%	26%	25%	26%	25%	25%	26%	25%
Third-Tier Drugs, Often Called Nonpreferred	28%	33%	40%	34%*	34%	38%	38%	40%	38%	37%	38%	39%	39%	38%
Fourth-Tier Drugs	^	^	^	^	30%	43%*	42%	36%	28%	31%	36%	29%	32%	32%

Source: Kaiser/HRET Survey of Employer-Sponsored Health Benefits: 2014

# Commercial RX Benefit: Use of Specialty Drug Cost Share Tiers

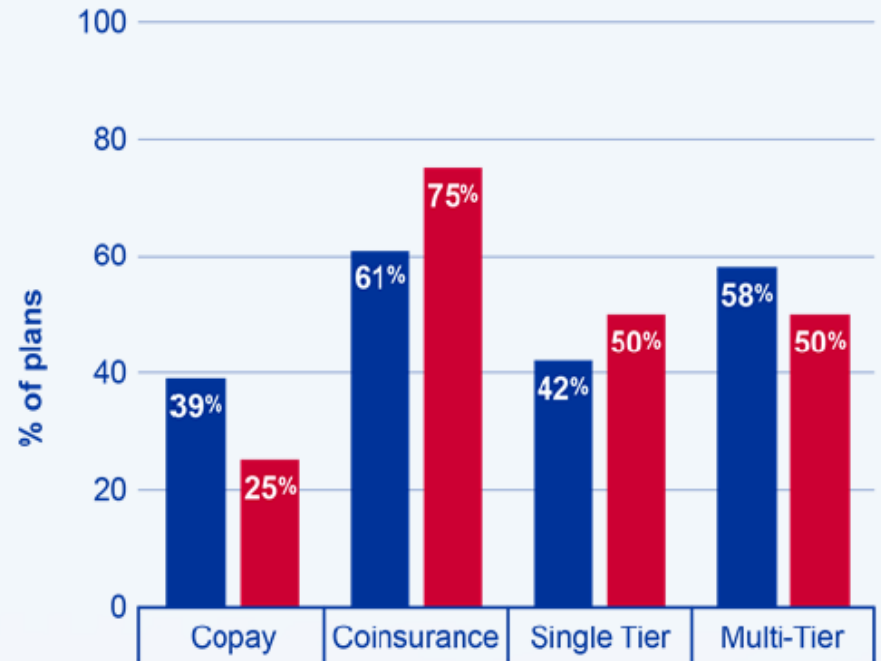
## Tier Structures



*n=62 plans (of the 72 commercial plans responding to the survey, 62 reported their cost share information for specialty drugs covered under the pharmacy benefit)*

■ Standard cost share tiers     
 ■ Specialty cost share tiers

## Dedicated Specialty Tier Structure



*n=33 (commercial plans with dedicated specialty tiers)*

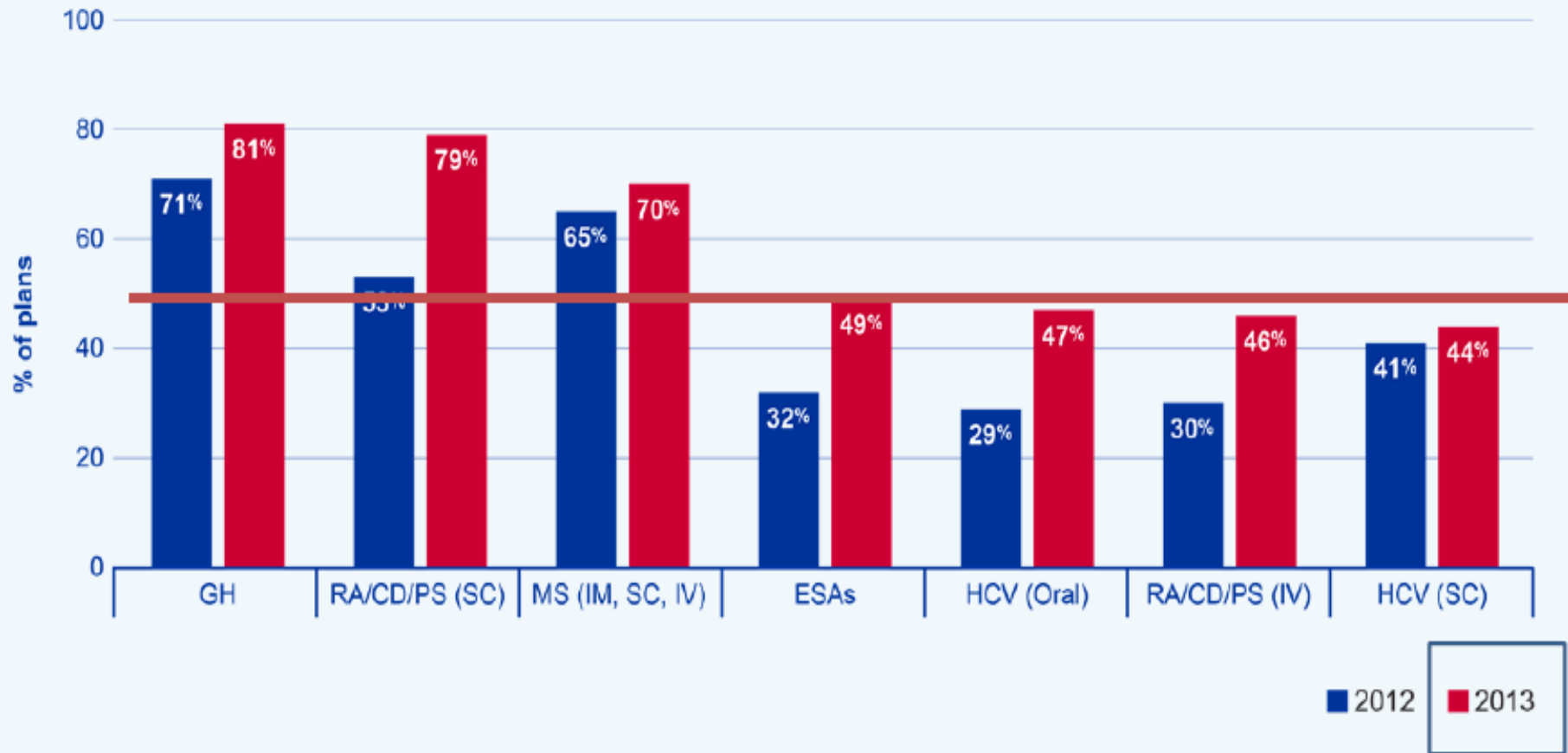
■ % of plans with dedicated specialty cost share     
 ■ % of lives with dedicated specialty cost share

Source: EMD Serono Specialty Digest 10<sup>th</sup> edition

# Benefit Designs

- Cause of much confusion
- Medical benefit vs. pharmacy benefit
  - Each MCO can design and deliver their own product and services
- Has led to additional formulary tiers
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- Traditionally associated with higher co-pays or co-insurances
- Many plans are moving towards new benefit designs for specialty drugs and therapies, including a “specialty formulary”

# Preferred Products: commercial (2012-2013)



Source: EMD Serono Specialty Digest 10<sup>th</sup> edition

# Question 4

Which of the following statements regarding benefit design are TRUE:

- a) Co-pays and co-insurances for specialty drugs are typically higher than non-specialty medications
- b) Managed Care Organizations can help contain cost through preferred specialty medications via rebates from the drug manufacturers
- c) Managed care organizations must have all their oncology agents under the pharmacy benefit
- d) A & B only

# Question 4

Which of the following statements regarding benefit design are TRUE:

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- b) Managed Care Organizations can help contain cost through preferred specialty medications via rebates from the drug manufacturers
- c) Managed care organizations must have all their oncology agents under the pharmacy benefit
- d) A & B only**

# What about the patients?



# Impact on Patients

- Federal Employees Health Benefits Program – survey of 8 million members in 2008
  - Specialty expenditures per member increased by 11.1% from 2004 to 2008
  - Median household income of \$50,233
  - An individual on 1 specialty medication had an OOP expense of up to 9% of their household's total gross income
- Potential impact of shifting costs to patients with specialty drugs:
  - Inability or refusal to pay for medications leading to decreased compliance may impact medical expenses and hospital costs

# Monitoring for Adverse Reactions

- Prescription drug safety is key with specialty pharmaceuticals
- Problems arise when a drug offers significant therapeutic benefits but also carries challenging health or safety risks
- FDA Mandated Risk Evaluation and Mitigation Strategy (REMS)
- Many biologics and new therapies are subject to REMS
  - Includes patient registries, ongoing patient monitoring, and certification for prescribers and pharmacies
  - Specialty pharmacies have a high level of patient and physician interaction and specially trained therapy teams to assist with meeting these requirements
- Short Cycle / Partial Fill Programs – initiated by MCOs

# Partial Fill Programs

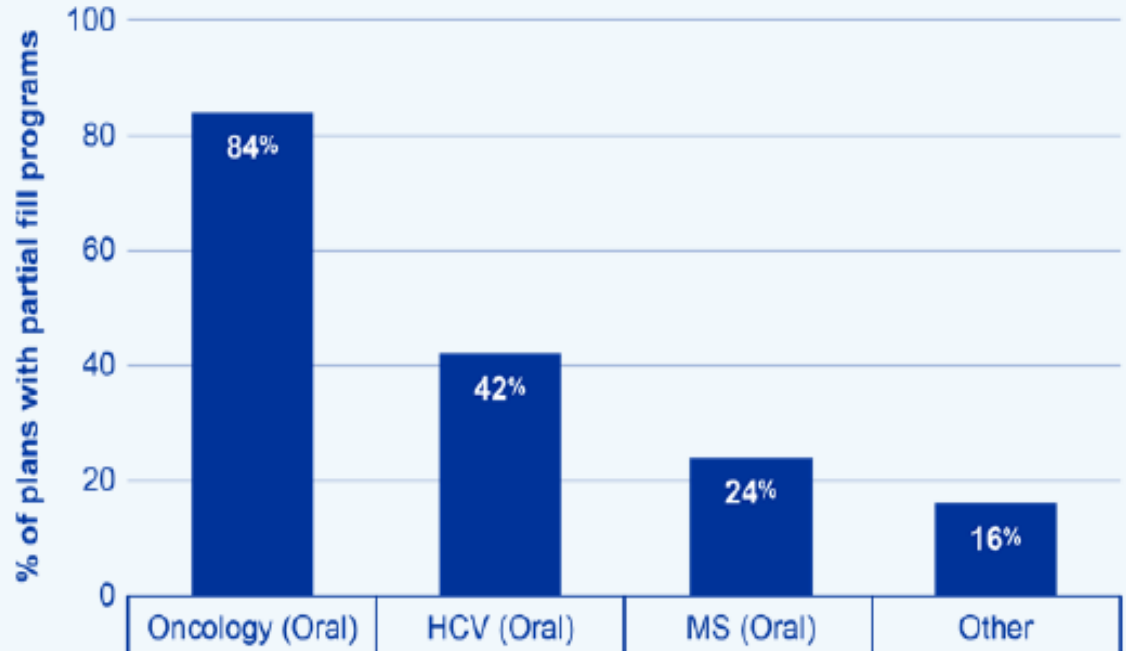
## Implement Partial Fill Program



■ No ■ Yes

n=91

## Therapy Categories Included in Partial Fill Program

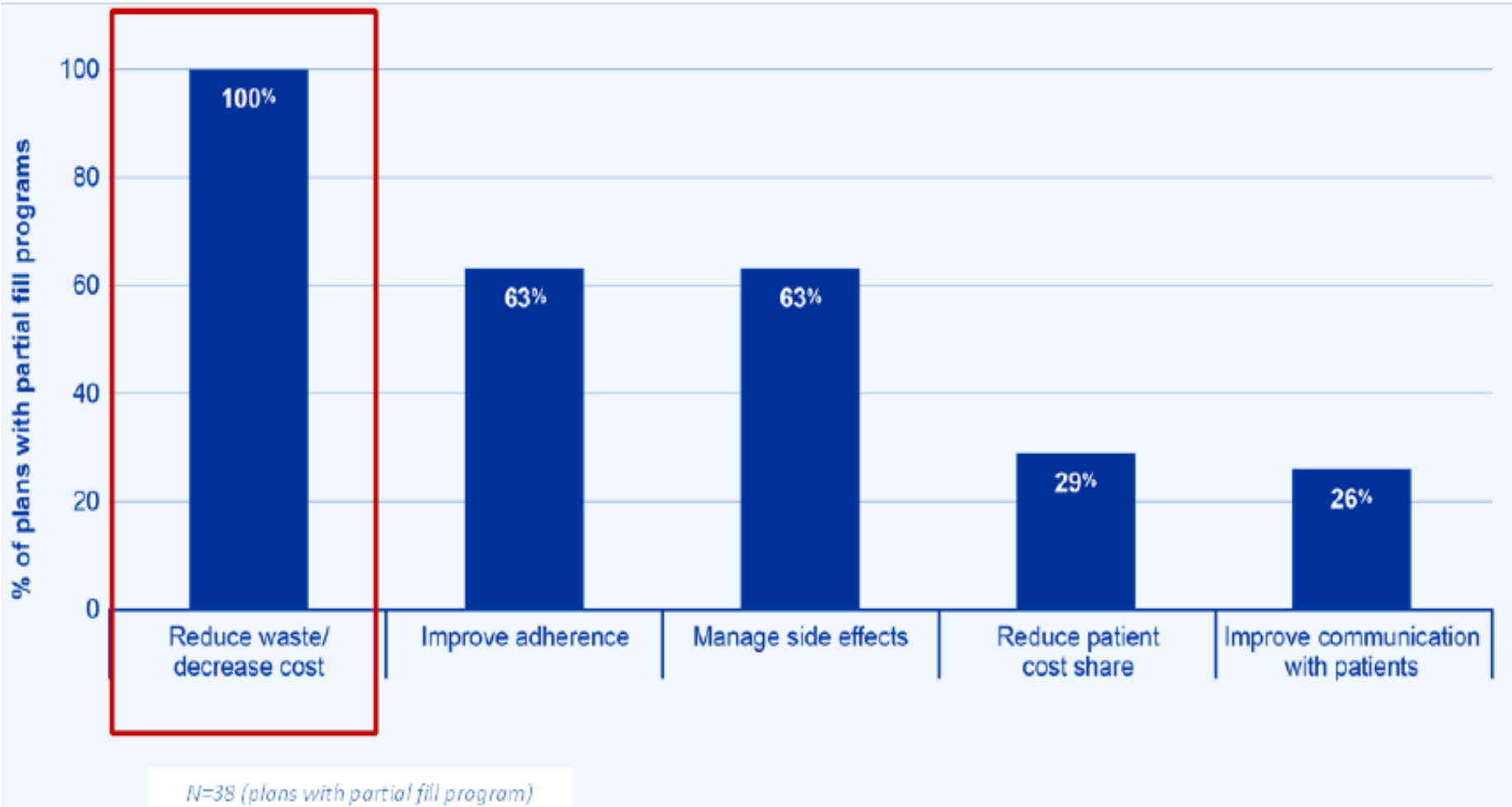


Others include: HCV (SC), MS (SC, IM) CF, LS Diseases, RA/CD/FS (SC, IM), hemophilia

n=38 (plans with partial fill program)

Source: EMD Serono Specialty Digest 10<sup>th</sup> edition

# Partial Fill Program Goals



Source: EMD Serono Specialty Digest 10<sup>th</sup> edition

# Question 5

5. Which of the following statements are TRUE?
- a) The cost of specialty medications is increasing for patients potentially leading to non-adherence
  - b) Partial Fill programs are aimed to reduce cost, improve adherence, and manage side effects
  - c) The Risk Evaluation and Mitigation Strategy (REMS) is mandated by the FDA
  - d) All of the above statements are true

# Question 5

5. Which of the following statements are TRUE?
- a) The cost of specialty medications is increasing for patients potentially leading to non-adherence
  - b) Partial Fill programs are aimed to reduce cost, improve adherence, and manage side effects
  - c) The Risk Evaluation and Mitigation Strategy (REMS) is mandated by the FDA
  - d) All of the above statements are true**

# Summary

- Specialty pharmacy is a growing part of the pharmacy industry
- Specialty pharmacy providers continue to develop programs and value-added services to better manage patients
- Payers continue to develop new strategies to manage the high costs of specialty drugs
- Patients are often affected by the variance in coverage and cost shares

# Questions?



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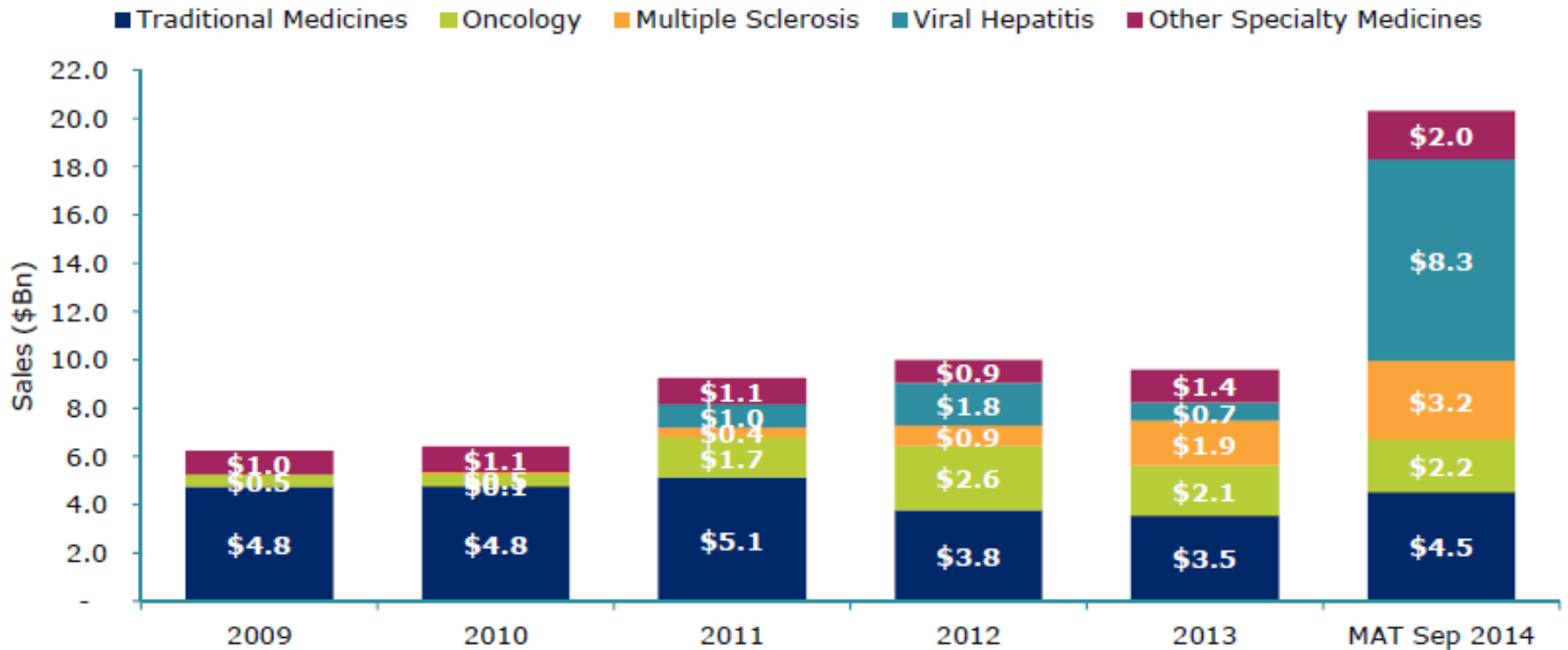


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# New brand spending shifted to specialty

New Brand Spending (\$Bn)



Source: IMS Health, National Sales Perspectives, Sept 2014