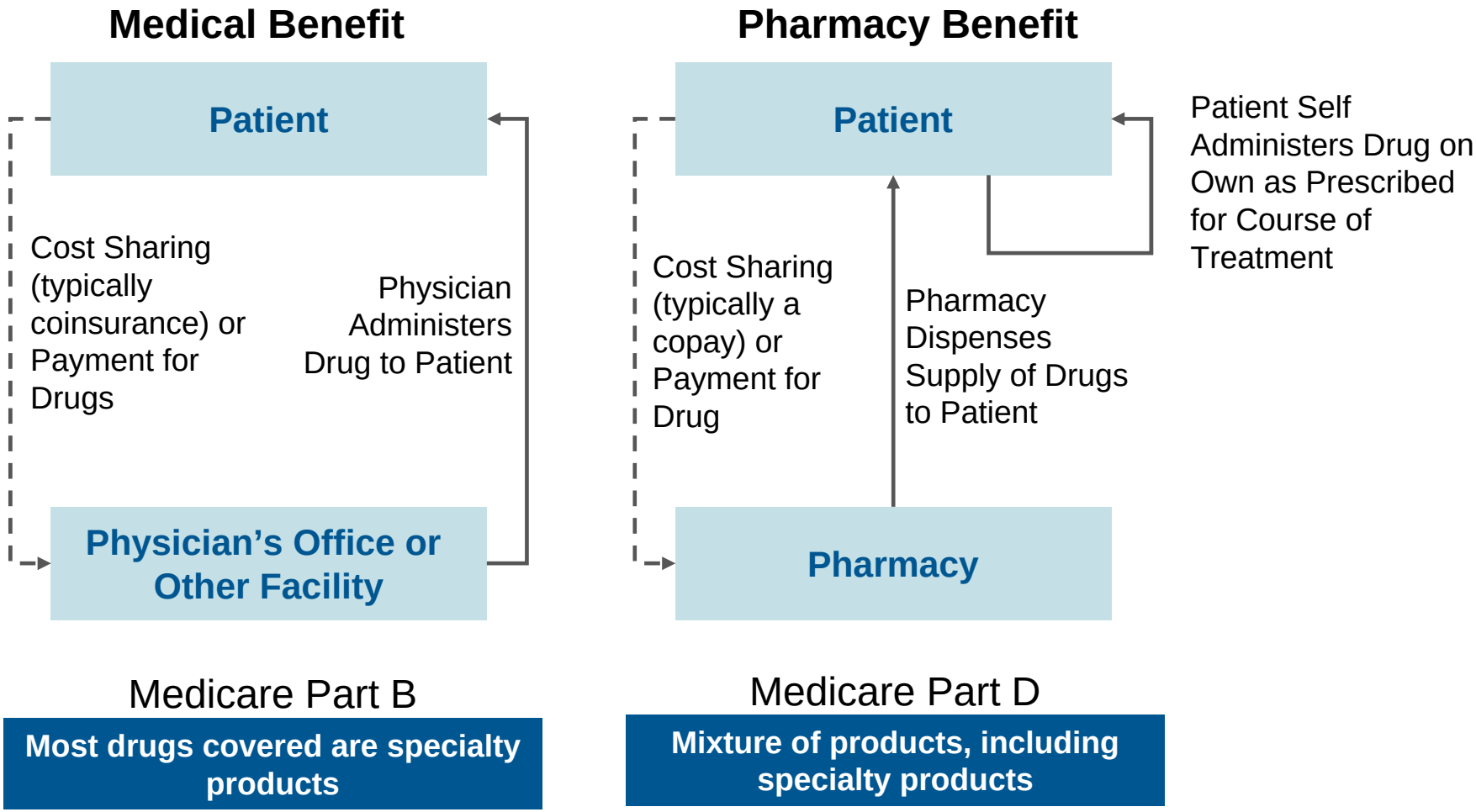
Managing Specialty Products in Medicare and Medicaid

July 16, 2008

Dan Mendelson
Avalere Health LLC

Parts B and D Mirror Typical Medical and Pharmacy Benefits



Statute Defines Part B and Part D Drugs

Part B drug*
Incident to a physician service or explicit statutory coverage

- Prescription drug or biological that is:
  - » "Reasonable and necessary"
  - » Approved by the Food and Drug Administration (FDA) and commercially marketed
  - » Furnished incident to a physician service
  - » Furnished incident to durable medical equipment (DME)
  - » Covered by statute: oral chemotherapy pro-drugs, oral anti-emetics, oral immunosuppressants, vaccines
- ESRD drugs used in dialysis also covered in Parts A and B***

Part D drug**
Outpatient prescription drug

- A prescription drug or biological that is:
  - » FDA approved
  - » Used and sold in the U.S.
  - » Used for a medically accepted indication as defined in Medicaid laws
- Over-the-counter medications are specifically excluded from coverage
- CMS has no authority to exclude coverage if products meet the statutory definition
- Vaccines that are "reasonable and necessary for the prevention of illness" if not covered under Part B
- "Medical supplies associated with the injection of insulin"

Depending on clinical circumstance or site of service, some drugs can be covered both under Parts B and D.

* Source: § 1861(s) of the Social Security Act (SSA)
** Source: § 1860D-2(e) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003
*** End-stage renal disease (ESRD) drugs are covered under separate statutory provision and are not part of the "incident to" physician services provision

Medicare Uses a Number of Tools to Control Utilization

Medicare Part B Utilization Controls

- Limited utilization controls for covered products—formularies not used
- Utilization limited by coverage and payment decisions
- Tools used to control utilization include:
  - » HCPCS* coding decisions
  - » Least Costly Alternative (LCA)
  - » Formulation coverage restrictions
- Competitive Acquisition Program (CAP)

Medicare Part D Utilization Controls

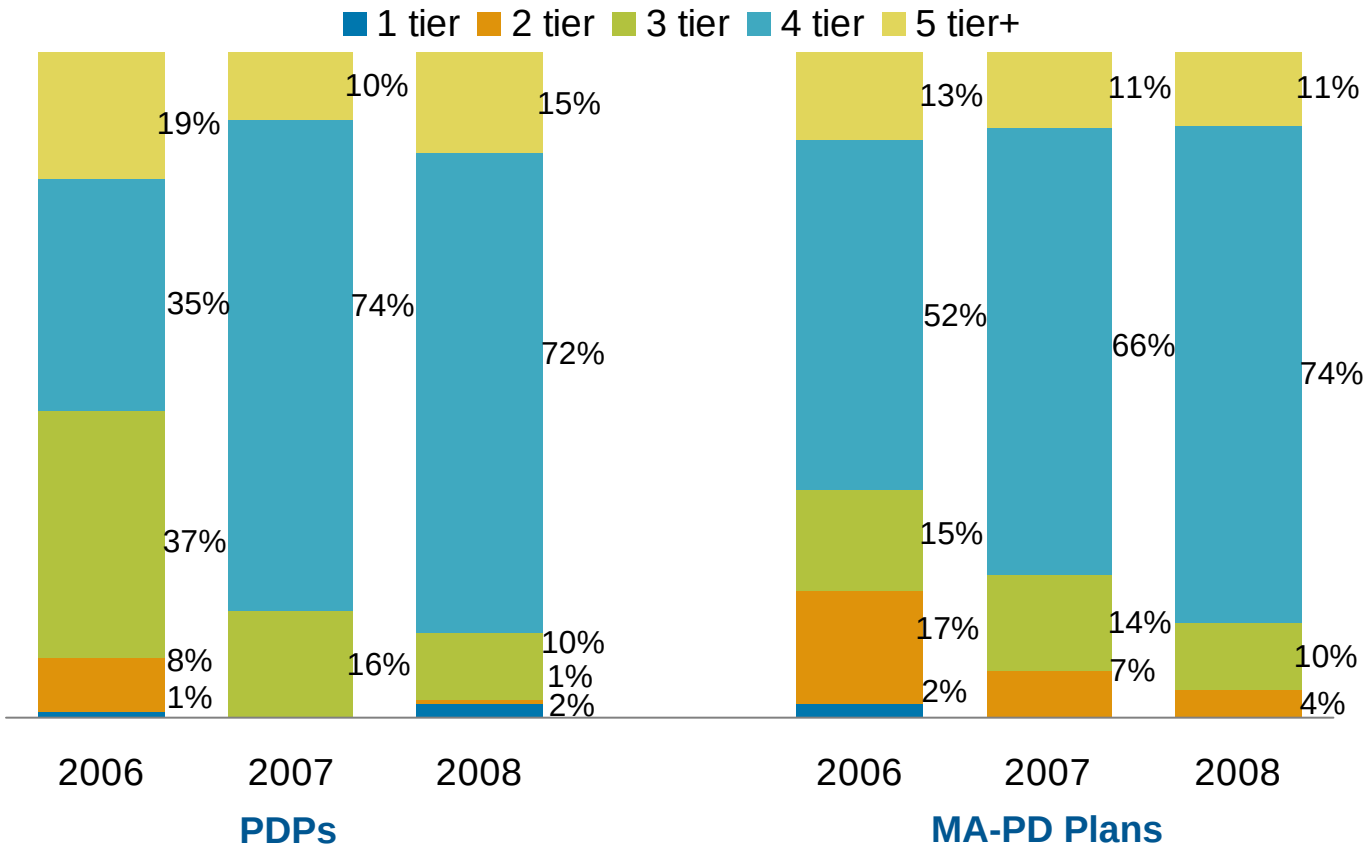
- Tools found in the commercial marketplace used to control utilization
  - » Prior authorization (PA)
  - » Quantity limits (QL)
  - » Step therapy (ST)
- Pioneered creation of specialty tiers
- More aggressive in managing utilization than Part B

MA plans looking to migrate Part B drugs into Part D to control utilization

*Healthcare Common Procedure Coding System

Tiering in Part D is More Aggressive than in Private Sector

Percent of Part D Plans by Tiering Structures



Four-tier plans typically use the following structure:

Tier 1 - Generic

Tier 2 - Preferred Brand

Tier 3 - Non-preferred Brand

Tier 4 - Specialty Drugs

Source: Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. 2008 data from November 2007; 2007 data from November 2006; 2006 data from July 2006.

Most Top Part D Plans Employ a Specialty Tier

PDP Offering	Specialty Tier in 2007 (Y/N)	Specialty Tier in 2008 (Y/N)	Tier Number of Specialty Tier	Cost-sharing on Specialty Tier	Number of Drugs on Specialty Tier
AARP MedicareRx Preferred	Y	Y	4	33%	253
Humana PDP Standard	N	Y	4	25%	244
Humana PDP Enhanced	Y	Y	4	25%	244
Community Care Rx Basic	N	N	n/a	n/a	n/a
AARP MedicareRx Saver	Y	Y	4	25%	237
WellCare Signature	Y	Y	4	33%	72
MedicareRx Rewards Value	Y	Y	5	33%	228
UnitedHealth Rx Basic	Y	Y	4	33%	237
Prescription Pathway Bronze	N	Y	3	33%	85
SilverScript	Y	Y	4	33%	99

Source: Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features.

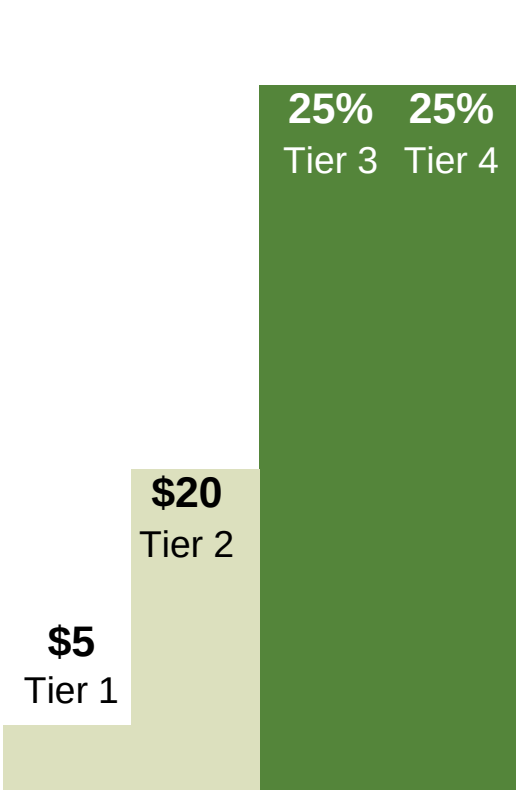
Top 20 Drugs Found on Part D Plans' 2007 Specialty Tiers

Drug	Indication	% of Specialty Tiers
1. Intron-A	Hepatitis C	98
2. Betaseron	Multiple Sclerosis	97
3. Neupogen*	Cancer	97
4. Avonex	Multiple Sclerosis	96
5. Actimmune	Chronic Granulatamous Disease	96
6. Fabrazyme	Enzyme Replacement Therapy	95
7. Remicade*	Rheumatoid Arthritis	94
8. Intron-A w/ Diluent	Hepatitis C	94
9. Copaxone	Multiple Sclerosis	94
10. Procrit	Anemia	92

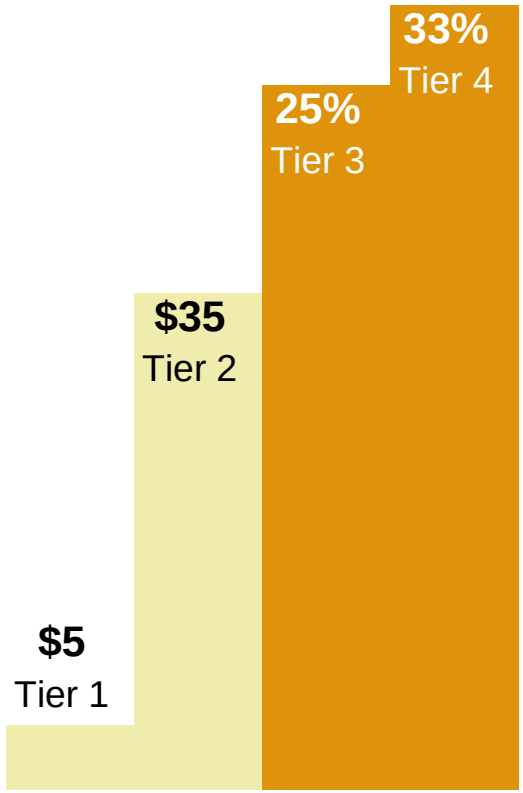
Drug	Indication	% of Specialty Tiers
11. Humira*	Rheumatoid Arthritis	92
12. Cerezyme	Enyzme Replacement Therapy	92
13. Fuzeon*	HIV/AIDS	91
14. Enbrel*	Rheumatoid Arthritis	91
15. Aranesp	Anemia	90
16. Roferon-A	Hepatitis C	89
17. Pegasys	Hepatitis C	86
18. Peg-Intron	Hepatitis C	85
19. Norditropin Nordiflex	Growth Hormone Deficiency	85
20. Rebif	Multiple Sclerosis	84

Source: Avalere Health analysis using DataFrame, a proprietary database of Medicare Part D plan features. Data from November 2006.
*Drug found in a protected class

Varying Cost Sharing Structures in PDPs and Commercial Plans; Coinsurance More Common in PDPs



2007 PDPs



2008 PDPs

2007 Commercial Plans

*Graphics for PDPs display the most-frequently-occurring number of tiers used by plans in each year. Cost sharing values represent the most-frequently-occurring value among plans with the most-frequently-occurring number of tiers. 'Most common' for commercial plans refers to the average cost-sharing for the most-frequently-occurring number of tiers in the commercial market. Source: Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. 2008 data from November 2007; 2007 data from November 2006; 2006 data from July 2006. Commercial plan data from Kaiser Family Foundation Employer Health Benefits, 2007 Annual Survey.

Higher Rates* of Utilization Management in 2008 Part D Plans

		All Part D Plans			PDPs			MA-PD Plans		
		2006**	2007	2008	2006**	2007	2008	2006**	2007	2008
Prior Authorization	Total	8.9%	9.1%	12.2%	9.8%	10.2%	12.4%	7.9%	8.1%	12.0%
	Brand	*n/a*	*13.3%*	*16.5%*	*n/a*	*14.6%*	*16.8%*	*n/a*	*12.2%*	*16.3%*
	Generic	*n/a*	*4.8%*	*6.3%*	*n/a*	*5.8%*	*6.7%*	*n/a*	*4.0%*	*6.1%*
Quantity Limits	Total	8.9%	8.0%	12.0%	10.6%	8.1%	11.8%	7.4%	7.9%	12.1%
	Brand	*n/a*	*11.7%*	*15.8%*	*n/a*	*11.7%*	*15.7%*	*n/a*	*11.6%*	*15.9%*
	Generic	*n/a*	*4.4%*	*6.8%*	*n/a*	*4.5%*	*6.8%*	*n/a*	*4.2%*	*6.8%*
Step Therapy	Total	0.8%	0.9%	1.7%	0.6%	0.9%	1.7%	0.6%	0.9%	1.7%
	Brand	*n/a*	*1.7%*	*2..8%*	*n/a*	*1.7%*	*2.8%*	*n/a*	*1.7%*	*2.9%*
	Generic	*n/a*	*0.1%*	*0.1%*	*n/a*	*0.1%*	*0.1%*	*n/a*	*0.1%*	*0.1%*

Source: Avalere Health analysis using DataFrame®, a proprietary database of Medicare Part D plan features. 2008 data from November 2007; 2007 data from November 2006; 2006 data from July 2006.
*Unweighted averages **Data for utilization management by brand and generic were not available for 2006 Part D plans

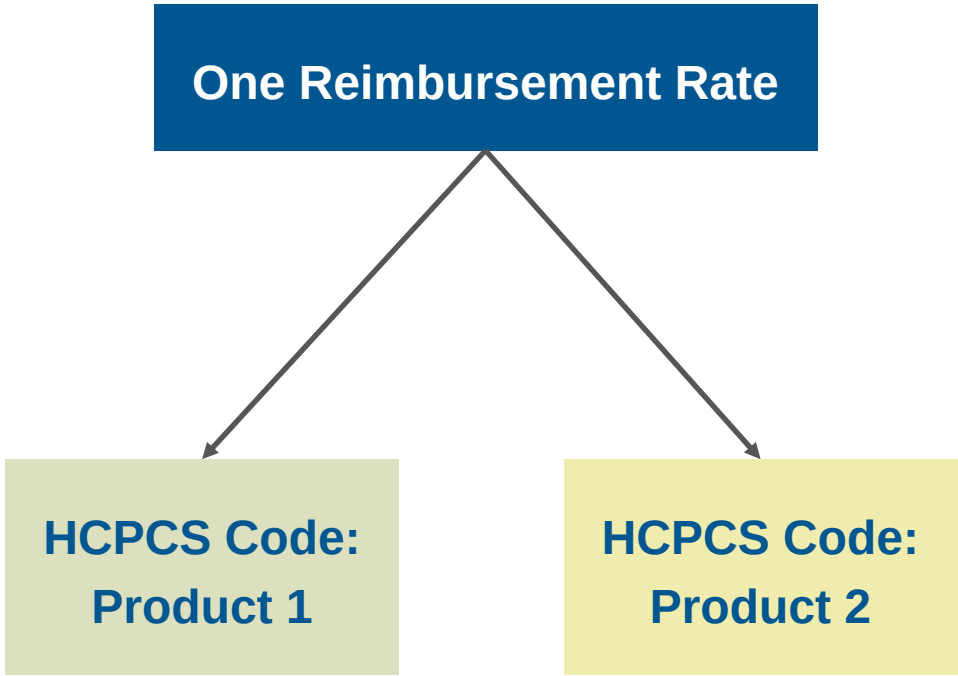
Medicare Can Limit Payment Through HCPCS Decisions

J-code	Drug	Dosage	Manufacturer
J1234	Drug X	25 mg	Company A
	Drug X	50 mg	Company A
	Drug Y	25 mg	Company B

J-code	Drug	Dosage	Manufacturer
J1234	Drug X	25 mg	Company A
J1235	Drug Y	50 mg	Company B
J1236	Drug Z	70 mg	Company C

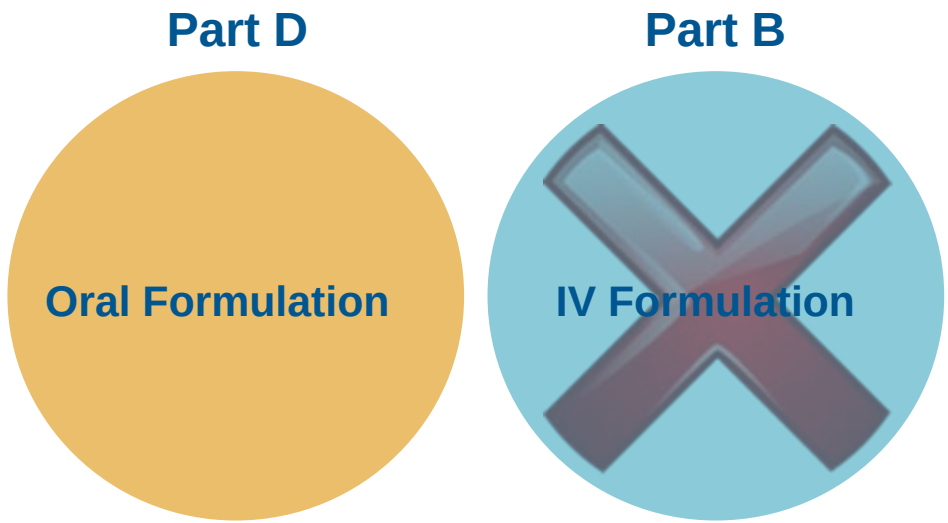
- **Unique codes allow for payment based upon individual drug prices**
- **Sharing codes blends the prices to create one reimbursement rate**
- **Utilization rates affected by whether a product has a unique HCPCS code**
- **CMS has tried aggressive approach, but faced congressional opposition**

LCA Can Limit Payment Under Part B



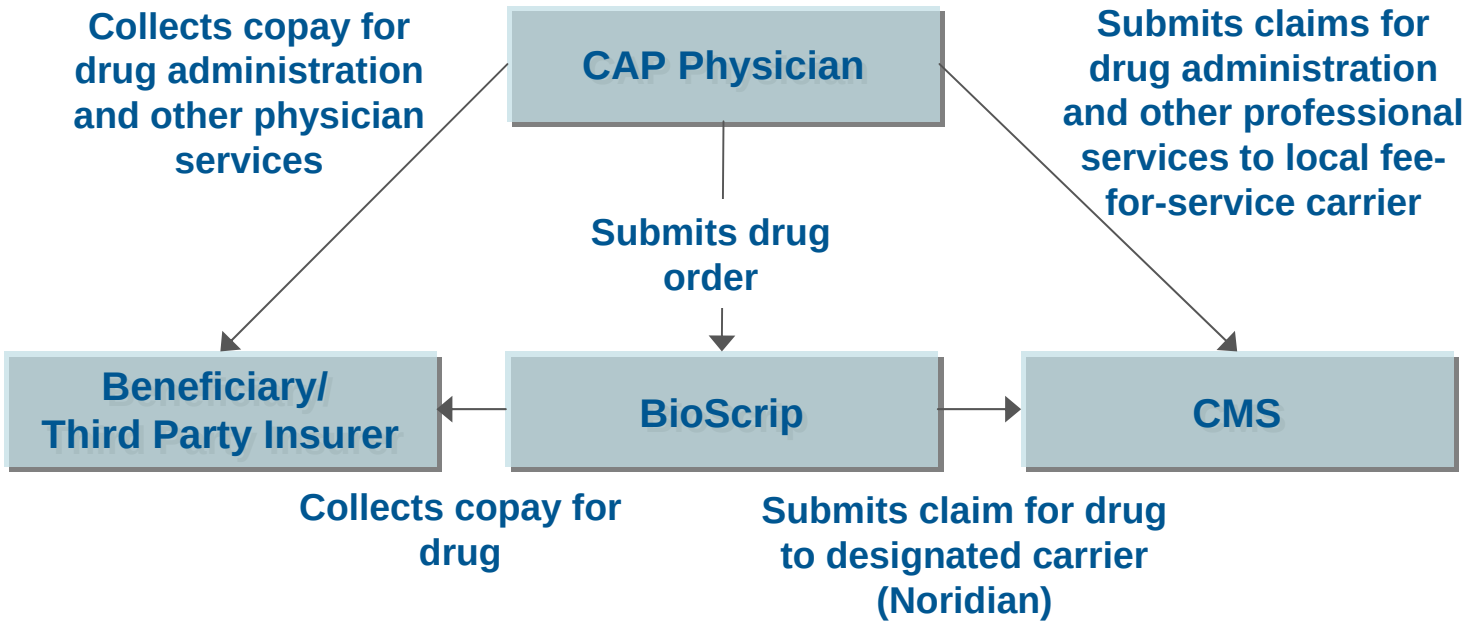
- LCA and shared HCPCS codes both result in the same outcome
- Application limited to one class to date: prostate cancer drugs
- CMS national reticent to apply more broadly

Part B Can Deny for Traditionally Covered Formulations



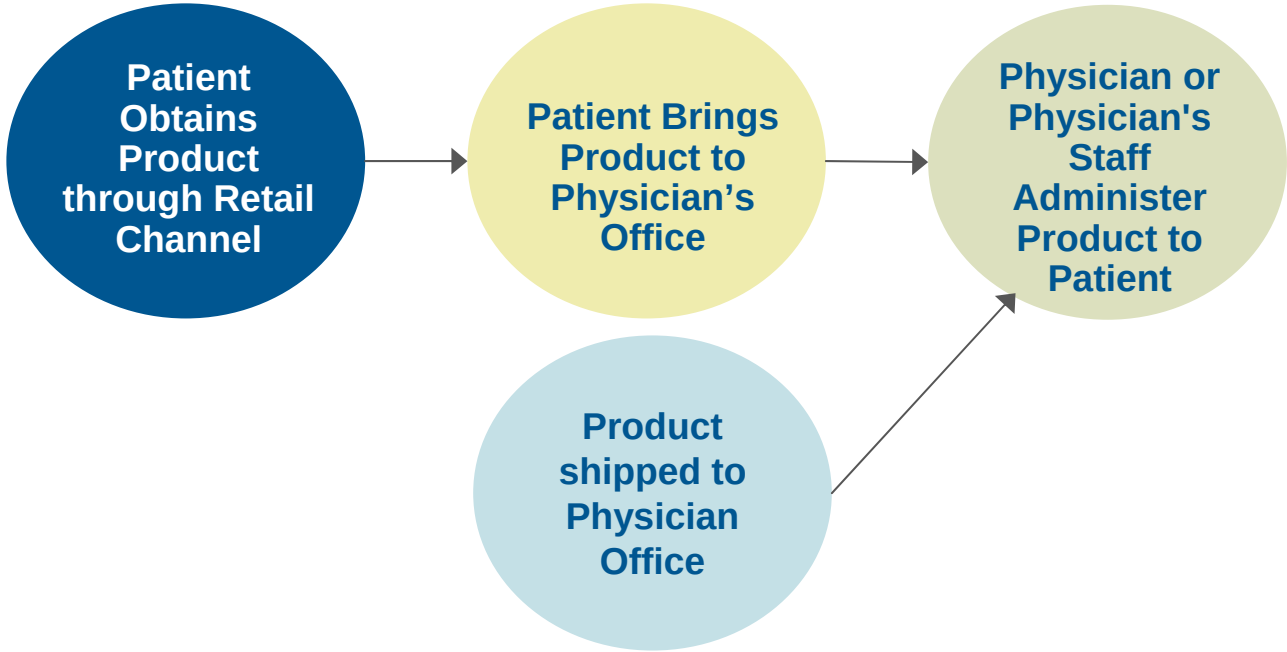
- Typically IV formulations are covered by Part B
- However, contractors may deny Part B coverage if a self-administrable formulation is available
- Such decisions may increase given availability of Part D coverage

CAP Has Limited Ability to Control Utilization



- CAP is an optional program
- Limited provider enrollment to date (~4,000 Medicare providers)
- CAP does not establish a formulary, thus does not control utilization
- Cannot be used to move drugs from one benefit category to another

“Brown Bagging” Increasing; Poses Safety and Policy Issues



- “Brown bagging” results in shift of products across benefit categories
- To date limited policies on brown bagging, however program incentives may cause practice to increase
- Policies could be developed to define if/when it is appropriate

Summary: Medicare Today

- Current system is based on statutory evolution
- Some regulatory flexibility exists and will be used more often
- Brown bagging and lack of utilization controls will increase scrutiny
- Serious change in approach would require legislation

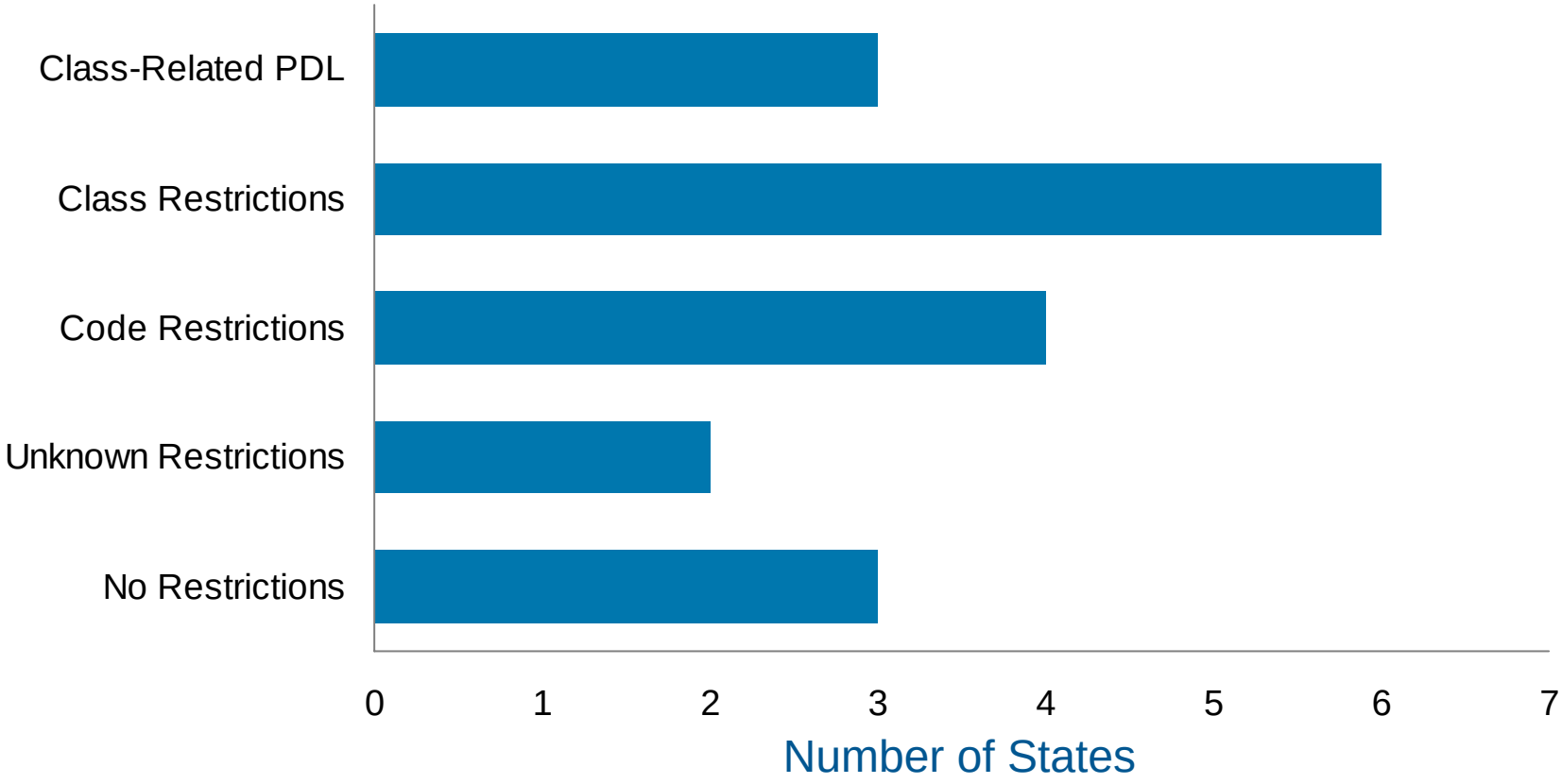
Medical Benefit:
- IV and Injectable products
- Little to no utilization management
- Controls on off-label use

Pharmacy Benefit:
- Oral and injectables
- Tight utilization controls
- Few off-label control

Specialty Pharmacy:
- Any product
- Utilization management
- Controls on off-label use
- Provider/patient administers drug

Medicaid is Managing Specialty Drugs as Well

- Avalere: 53% of surveyed states have restrictions based on therapeutic class and additional states have restrictions on particular codes



Based on 17 respondents, combined analysis of medical and pharmacy benefits.

Medicaid Experimenting with Specialty Pharmacy

- Most states do not have any relationships with specialty pharmacies
  - » Pennsylvania and Washington have early-stage or pilot programs
  - » Missouri has an existing program
- Some Medicaid programs have specialty pharmacy initiatives
  - » Plans under discussion in Massachusetts, Mississippi, Wyoming, and Virginia
  - » Alabama, Utah, and West Virginia all have many injectables on prior authorization, but do not currently work with specialty pharmacies
- Maine recently announced plans to develop a specialty pharmacy program

Medicaid Collecting Rebates for Specialty Drugs

- Deficit Reduction Act (DRA) requires states to collect Medicaid rebates on certain drugs*
- Historically, challenges existed in collecting such rebates (data, systems)
- Operational improvements allow for rebate collection
- Rebates can be collected retrospectively

Example of a HCPCS-NDC Code Crosswalk: Drugs From Several Manufacturers May Be Mapped to the Same J-Code

J-code	Drug	Dosage	Manufacturer	NDC Code
J1234	Drug X	25 mg	Company A	00015-0503-02
	Drug X	50 mg	Company A	00015-0503-01
	Drug Y	25 mg	Company B	00015-0504-01
	Drug Y	50 mg	Company B	00054-4130-25
	Drug Z	25 mg	Company C	00054-8130-25
	Drug Z	50 mg	Company C	00054-4129-25

Manufacturers must plan for Medicaid rebates for specialty, physician-administered drugs.

* States must collect rebates on single source and the top 20 multiple source product administered in the physician office or in hospital outpatient settings

Future of Specialty in Public Programs: Policy Debates

- Cost / Access / Quality Issues
  - » Appropriateness of formularies for specialty products
  - » Appropriateness of other utilization controls (e.g., step edits)
  - » Pricing of specialty drugs to patient
  - » Quality Focus (nurse education, compliance, adherence, P4P)
- Programmatic Items
  - » Biases in playing field between orals and IV (B vs. D)
  - » Feasibility of the CAP systems
  - » Economic incentives facing physicians
  - » Role of Part D plans in managing injected products
  - » Expectations of MA plans in cost / access / quality