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Minding the Guarantee Gap

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Agenda

Common Rebate Exclusions

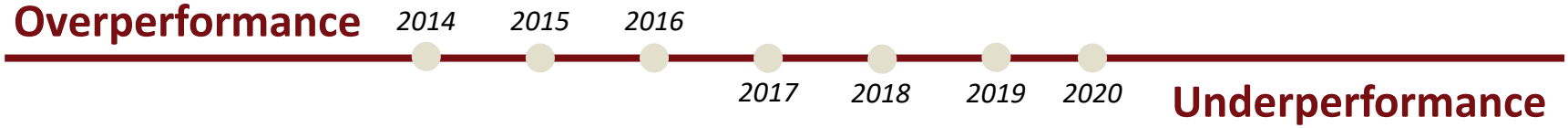
- **Limited Distribution Drugs**
- **Biosimilars**
- **340B Claims**

1. Discuss definitions for these categories of drugs
2. Discuss industry trends for these products
3. Surface recommendations for PBM contracting best practices

Rebate Guarantees: Mechanics

What a Plan Sponsor Gets Paid by Pharmacy Benefits Manager (PBM):

X% of Rebate **OR**
X% of Rebate, minus Administrative Fee **OR**
X% of Rebate, but narrow scope of what constitutes "Rebate"



What Plan Sponsor Gets Paid by Pharmacy Benefits Manager (PBM):

$$\frac{\text{\$X Guaranteed}}{\text{Brand Rx}} * \text{\# of Brand Rx}$$ **OR** $$\frac{\text{\$X Guaranteed}}{\text{Brand Rx}} * \text{\# of Brand Rx}$$ *(minus exclusions)*

Rebate Guarantees: Mechanics

Rebate Projection A

$\frac{\$200 \text{ Guaranteed}}{\text{Brand Rx}}$ * (100 Brand Rx – **10 Excluded Rx**) = **$18,000** Rebate Yield

Utilization of Excluded Products Increases 20%

2% Shortfall in Projected Rebates

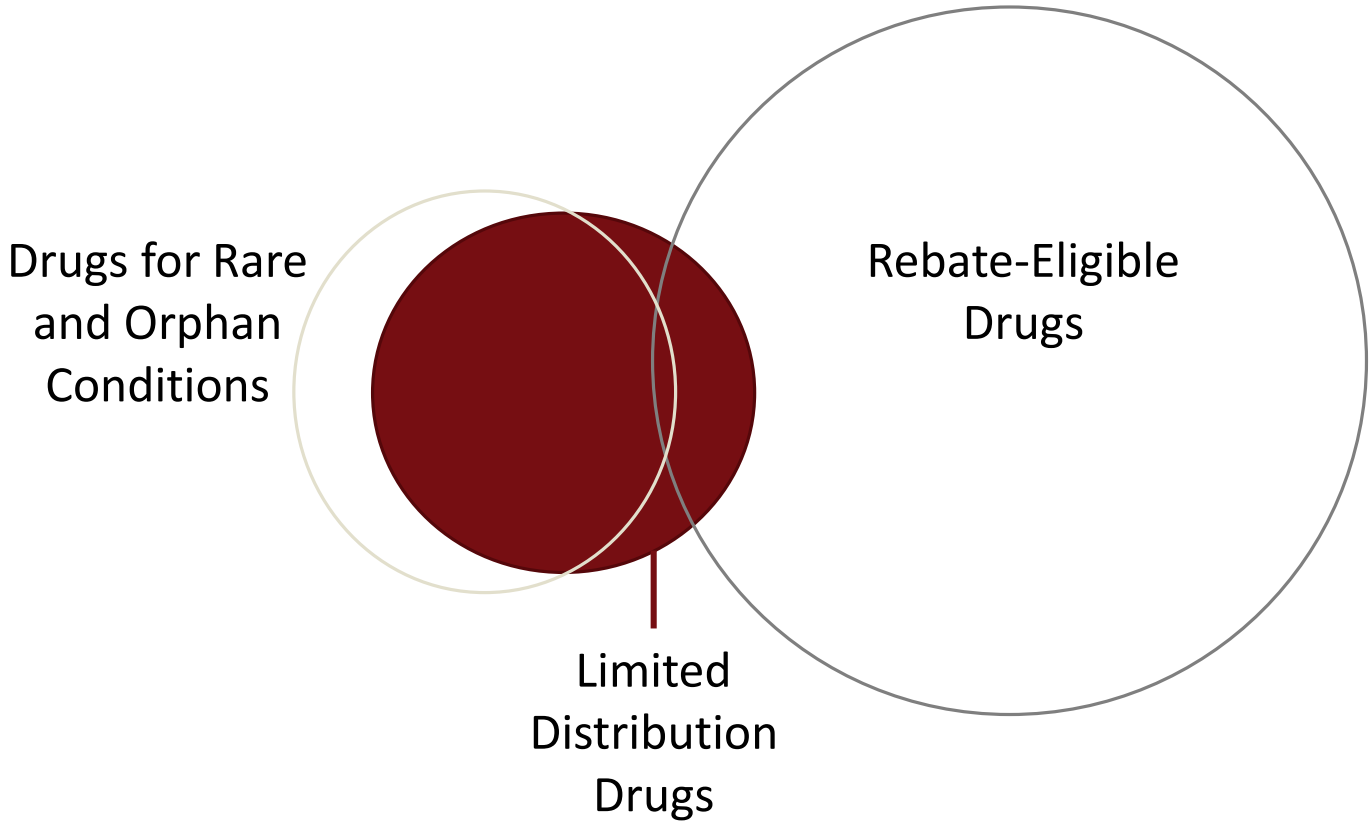
Rebate Projection B

$\frac{\$200 \text{ Guaranteed}}{\text{Brand Rx}}$ * (100 Brand Rx – **12 Excluded Rx**) = **$17,600** Rebate Yield

When products excluded from rebates increase in script count, shortfall from projected rebate could result

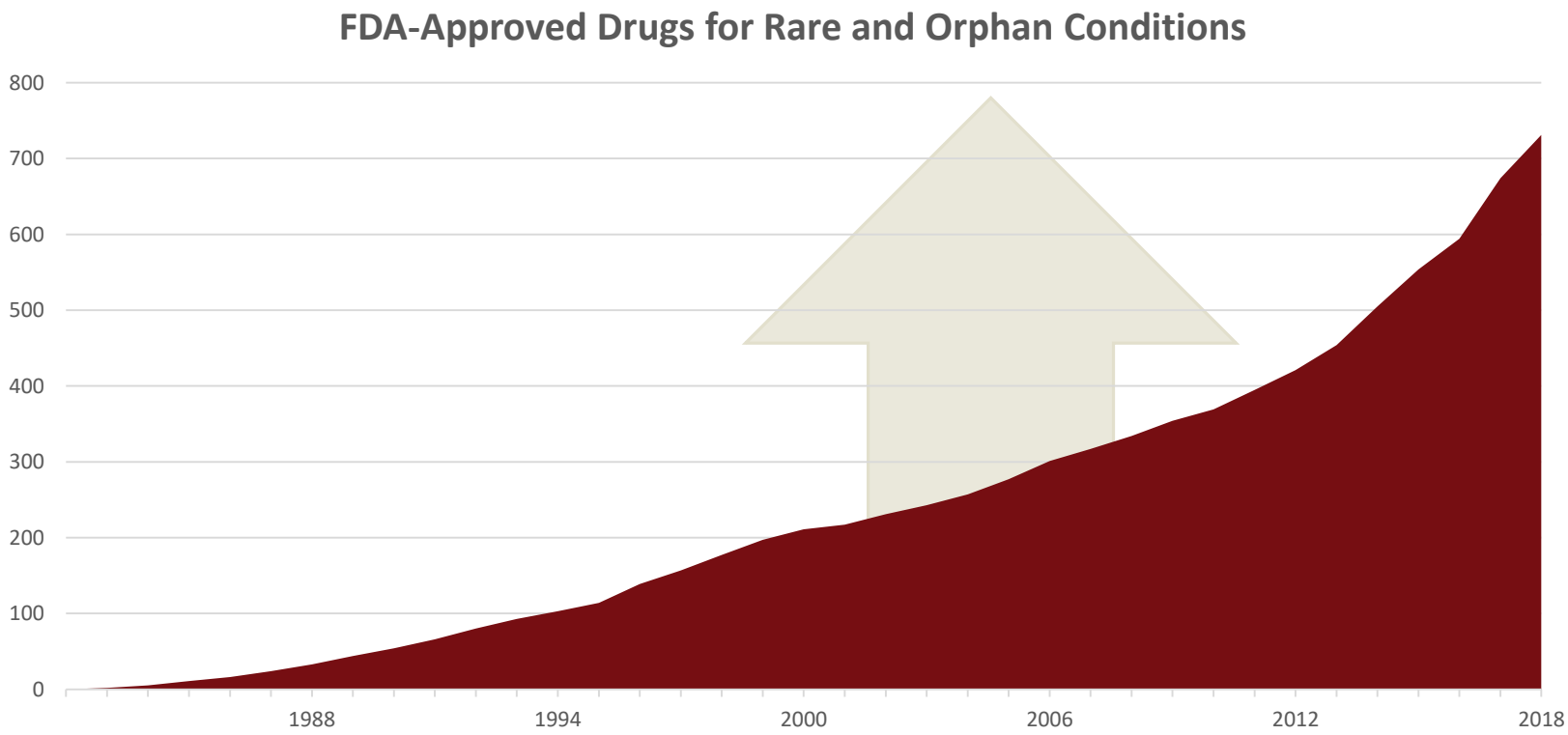
Limited Distribution Drugs: Definitions

- Products available for dispensing at a limited number of pharmacies
- Many treat rare and orphan conditions
- Some are rebate-eligible, where multiple products to treat a condition are available



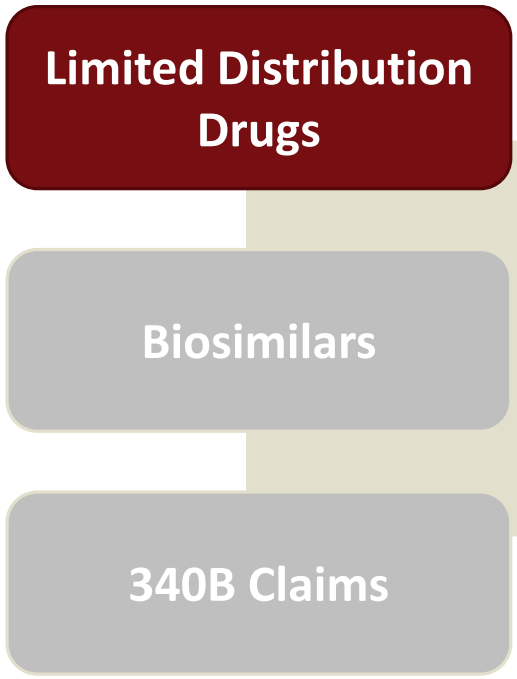
Limited Distribution Drug: Trends

Continued growth in rare and orphan disease treatments, likely to continue increasing number of Limited Distribution Drugs



Limited Distribution: Best Practices

Common Rebate Exclusions



1. Define which drugs are categorized as “Limited Distribution” at the time of an RFP
2. Regularly get copies of the specialty list, including LDD designation from PBM
3. Where possible, avoid language that excludes LDD products from rebate guarantees

Biosimilars: Definitions

Large and complex molecules, produced from living organisms, carefully monitored to ensure consistent quality; demonstrated to not be clinically different from originator in purity, molecular structure, bioactivity, pharmacokinetics, or immunogenicity

FDA Approval Pathways

New Drug Application (NDA) 505(b)2

Sunsets March 2020

Biologics Licensing Application (BLA) 351(k)

MediSpan/First Databank Coding

Launch as Brand Products

Different GPI or GSN than originator

Biosimilars: Trends

	2016-2019	2020-2025
Site-of-Care	Mostly on medical benefit (e.g. cancer therapies, blood modifiers)	Growth in biosimilars managed on pharmacy benefit (Humira, Revlimid, insulins)
Rebate Strategy	Limited rebate availability	Potential for rebates to compete with originator products
Formulary Status	Rebate and/or low net cost strategies drive share to originator products	Media pressures on gross-to-net bubble encourage biosimilars on formulary
Patient/Prescriber Comfort Level on Interchangeability	Hesitation to try something new	Increasing comfort with switching

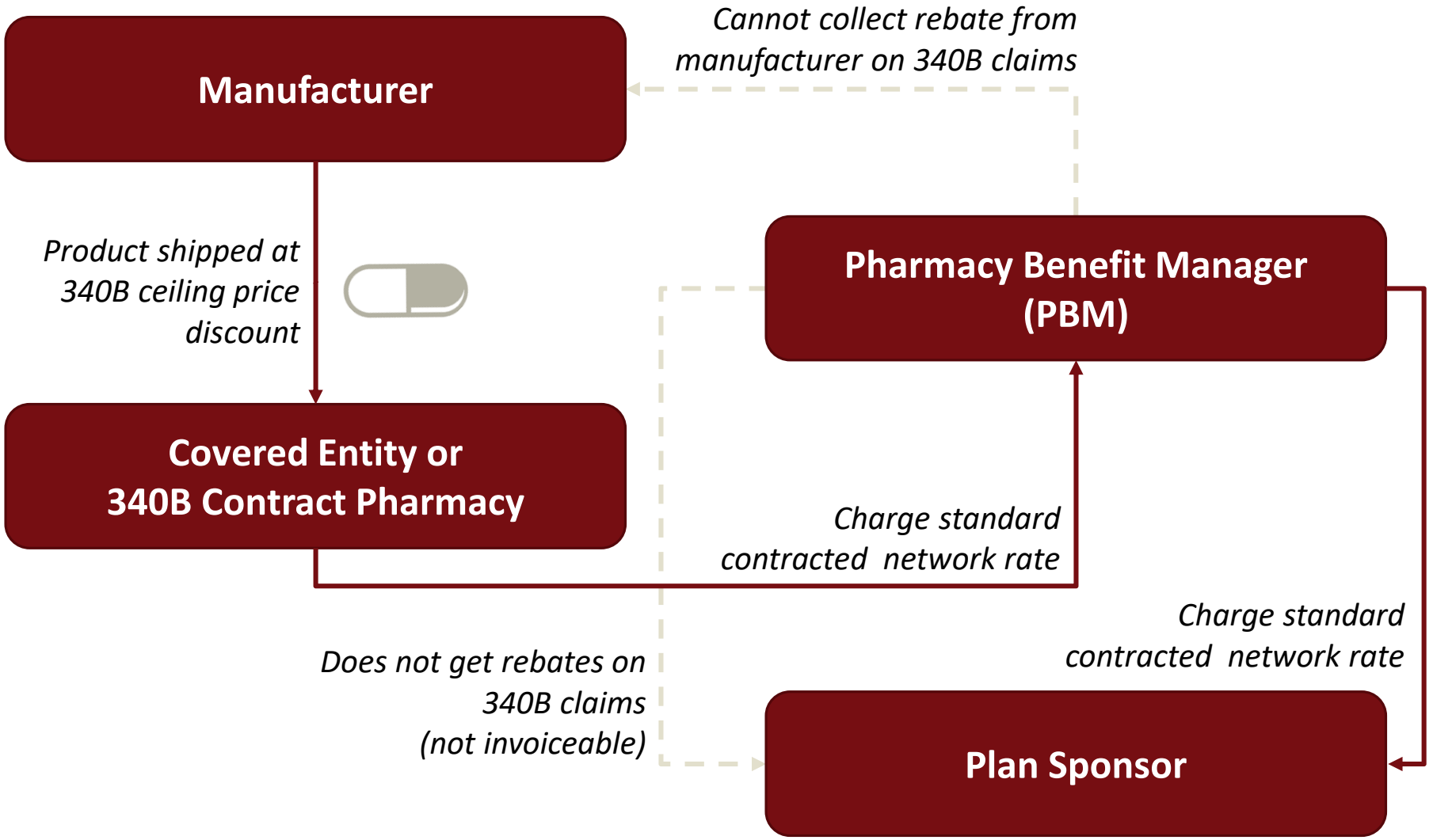
Biosimilars: Best Practices

Common Rebate Exclusions

- Limited Distribution Drugs
- **Biosimilars**
- 340B Claims

1. Define Biosimilars, in reference to BLA 351(k) approval pathway
2. Where possible, avoid exclusion of Biosimilars from rebate guarantees
3. Where exclusions persist, forecast based on futuristic projections, rather than current utilization

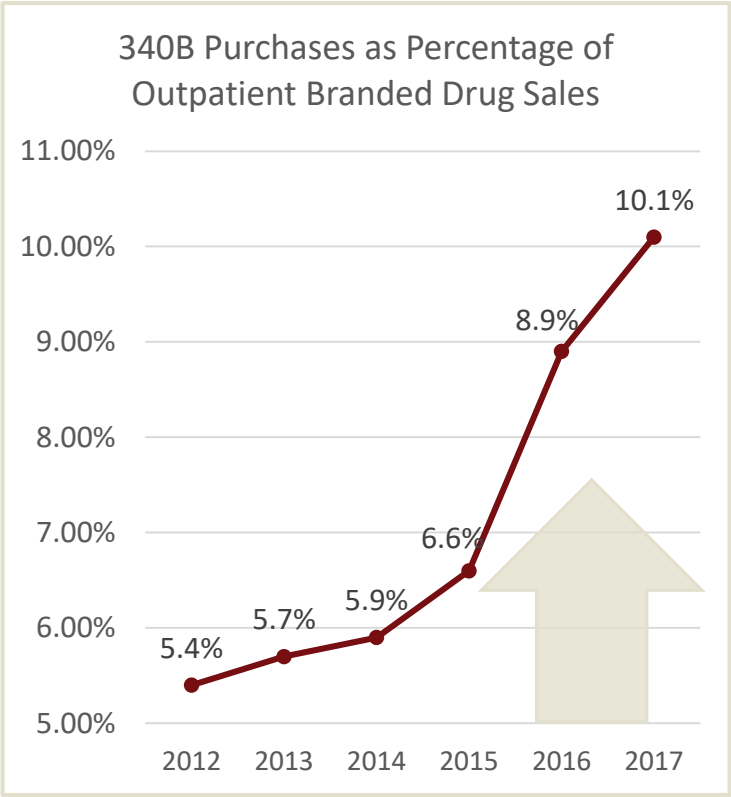
340B Claims: Definitions



For purposes of simplicity, this slide negates role of wholesalers, 340B split-billing vendors, and the relationship between covered entity and contract pharmacy (where applicable)

340B Claims: Trends

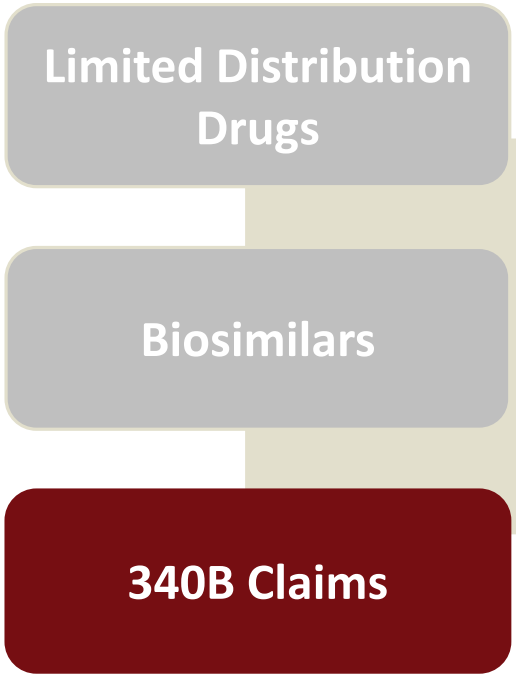
Volume of Specialty Brand Claims from 340B-eligible pharmacies can represent a meaningful portion of specialty claims; excluding claims filled at 340B-eligible pharmacy artificially inflates specialty rebate/rx figures.



Measuring the Relative Size of the 340B Program: 2017 Update. Berkely Research Group. Published July 2018. http://340breform.org/wp-content/uploads/2018/07/Vandervelde_Measuring340Bsize-July-2018_WEB_Draft-43.pdf

340B: Best Practices

Common Rebate Exclusions



1. Narrow definition of "340B Claims" to only those specific claims dispensed through the 340B program
2. Where excluded claims scope extends to "340B pharmacies," base projections on anticipated program growth

Recommendation

Common Rebate Exclusions

- **Limited Distribution Drugs**
- **Biosimilars**
- **340B Claims**

Recommendation:

- Be specific, when creating definitions for contracting purposes
- Avoid exclusions in drug categories
  1) For which rebates are invoiced
  2) With likely future increases in utilization
- Forecast based on future trends, rather than current use patterns

Open Questions & Our Contacts

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