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# 340B Update: Meeting Specialty Pharmacy Challenges and Moving Forward

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# Disclosure

**The following individuals report having no relevant conflicts of interest:**

- Chris Hatwig
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# Learning Objectives

1. Describe how the 340B Program has become a vital program and key driver for growth of health system specialty pharmacies
2. Discuss the challenges of covered entity specialty pharmacies gaining access to restricted distribution specialty medications, including the impact of the GPO and orphan drug rules
3. Discuss implications of recent 340B events, including restrictions on use of contract pharmacies, vertical payor and PBM alignment, and network restrictions affecting reimbursement and calls for 340B Program revisions and transparency

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# 340B Program Overview

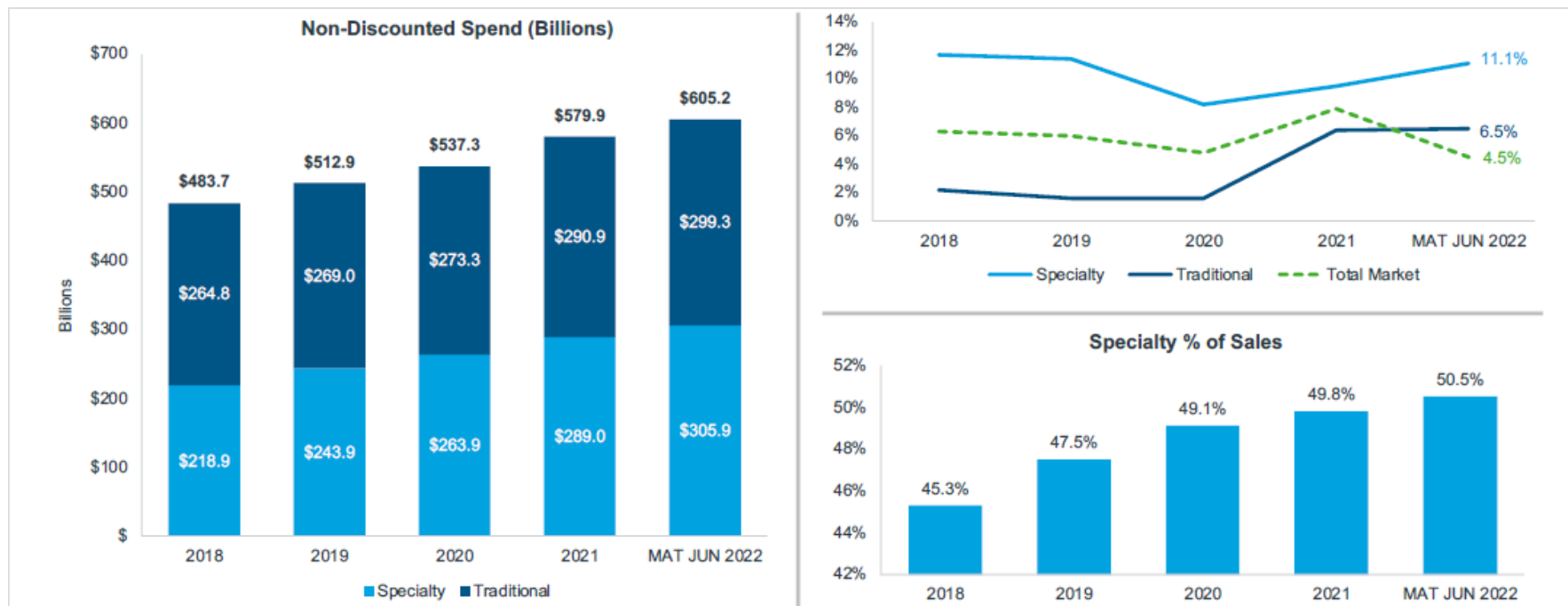
## Relevancy to Health System Specialty Pharmacy

- **Vital program for covered entities**
- **Many diverse program stakeholders**
- **Specialty pharmacy is a major contributor to many health systems' financial performance**
- **Key drivers of specialty pharmacy growth and drug movement to limited distribution channels**
  - Traditional wholesaler agreements' fee costs
  - 340B price exposure and growth of the program
  - ASP price protections
- **Specialty drug spending is outpacing traditional drug spending**



# For the total market, specialty growth is outpacing traditional growth and now has ~50% share of total non-discounted spend

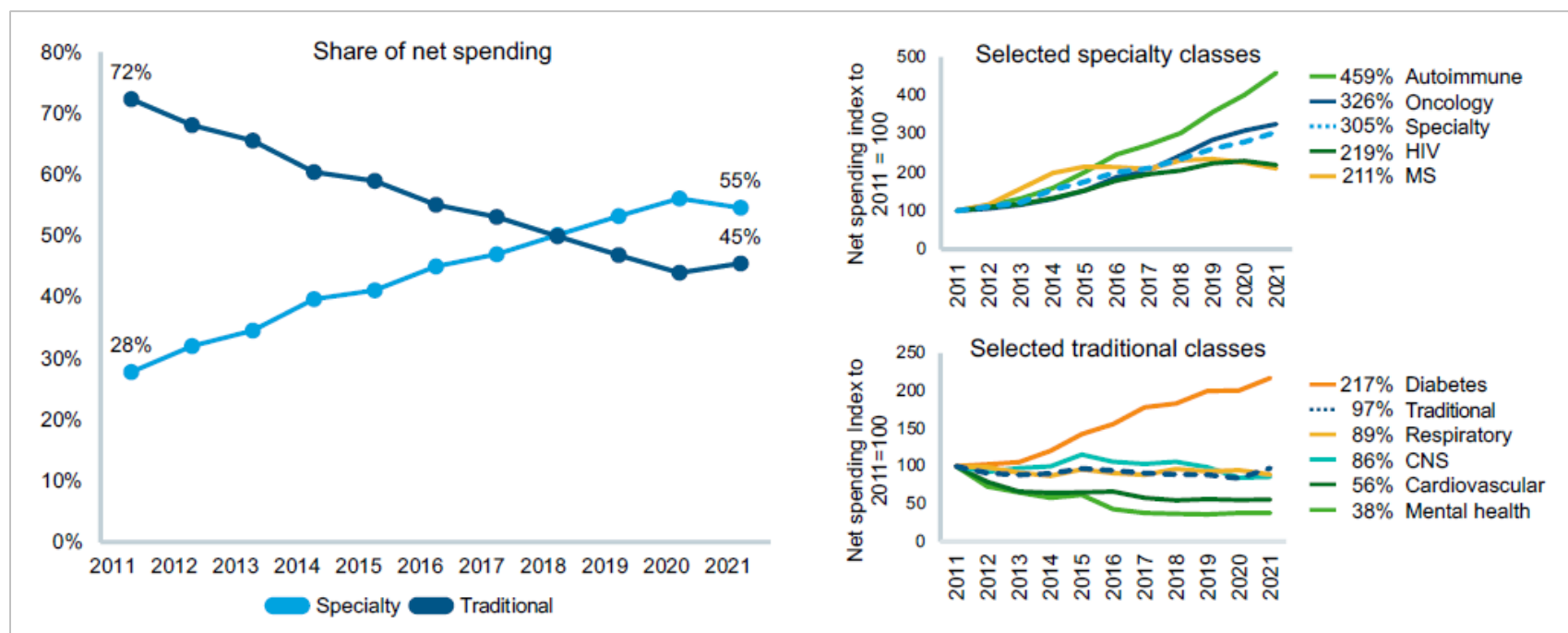
In MAT June 2022, specialty spending grew by 11.1% while traditional spending grew 6.5%



Source: IQVIA, National Sales Perspectives, June 2022  
MAT = Moving Annual Total (rolling 12 months)

# Specialty medicines now account for 55% of net spending, up from 28% in 2011, driven by growth in autoimmune and oncology

Share of spending at estimated net manufacturer prices

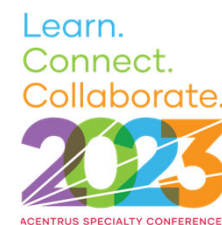


Source: IQVIA Institute, Mar 2022.

The Use of Medicines in the U.S.: Usage and Spending Trends and Outlook to 2026. Report by the IQVIA Institute for Human Data Science.



# Hot Topics with 340B



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# What is the impact of manufacturer restrictions on use of contract pharmacies?

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# 340B Contract Pharmacy Arrangements

## Challenges and Implications

- **Multiple manufacturers revising sales policies**
  - Restricting sales to 340B contract pharmacies
  - Requiring submission of data via 340B ESP or submission directly to the manufacturer
  - Enrollment difficulties, staff required for managing, monitoring and reporting, company roll-offs
  - HIPAA implications and concerns
- **Federal appeal courts cases with rulings pending**
  - One federal appeal court ruled in favor of manufacturers; other cases pending
- **Affecting operations of health system specialty pharmacies (HSSPs)**
  - Affecting access to traditional and specialty drugs
- **Restructuring ownership of retail and specialty pharmacies under the health system umbrella, i.e., system-owned contract pharmacy versus ship-to/bill-to of the covered entity**



# Can anything be done to improve LDD access for 340B drugs?

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# LDD Access

**For a manufacturer, whose specialty drug is in the 340B Program, can HRSA require the manufacturer to sell the outpatient covered drug (e.g., BMS and Revlimid) directly to covered entities?**

- **Many factors to consider**
  - Did manufacturer sign pharmacy participation agreement with CMS?
  - REMS drug?
  - Is the 340B drug available through any mechanism, e.g., closed network?
  - Are covered entities held to different requirements for drug access than non-covered entities?
- **HRSA authority is restricted to what is granted by the 340B statute**

# WAC Access for 340B Drugs

Our specialty pharmacy can obtain some specialty drugs via our 340B account, but not on our WAC account. Can HRSA require manufacturers to allow WAC purchases so covered entities subject to the GPO requirement can first establish a neutral inventory?

- HRSA does not have authority beyond the 340B statute and thus cannot regulate WAC sales
- Acentrus assists members with specialty distributors and manufacturers



# Will HRSA continue to do 340B Program audits?

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# 340B Program Audits

## Manufacturer Audits Increasing

- **HRSA audits covered entities; currently audits 200 covered entities annually**
- **HRSA audits manufacturers; meeting program requirements and providing drugs at 340B prices**
- **Manufacturers may audit covered entities with HRSA approval**  
Limited to auditing for compliance on the issues of patient definition and duplicate discounts
- **Manufacturer inquiries and audits are increasing**
  - Can be challenging and time consuming
  - Burdensome for covered entities, especially staffing issues
  - Specialty pharmacy may be a focus due to dispensing of high-cost drugs

**With rapid growth of specialty pharmacy, how do we address staffing issues and ensure 340B compliance?**

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# Workforce Issues

## Staffing Needs in Specialty Pharmacies

- **Specialty pharmacies continue to grow rapidly**  
Professional and technical staff shortages: 20–30% shortages of technical staff
- **Complex programs require specialized knowledge**
  - Difficult to find qualified people
  - In-house training requires extensive time
  - Staff shortages create burden on existing staff, increasing turnover
- **Training, cross-training, and retraining necessary**
- **340B Program compliance**
  - Adequate staffing is essential to ensure compliance
  - Compliance is essential to ensure 340B Program sustainability
  - Addressing the interplay of 340B Program requirements and unique specialty pharmacy issues is critical
  - Important to access 340B PVP educational programs to maintain 340B Program awareness

With so much focus  
on 340B, will there  
be congressional  
action?

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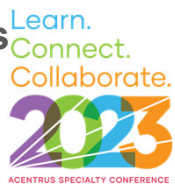
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# Congressional Action

## Spotlight on the 340B Program

- **Considerations:**
  - 340B Program value to covered entities → continued program growth → increased manufacturer drug price discounts → increased total 340B drug spending
  - Innovative drugs for rare and common diseases → higher drug costs → increased 340B drug spending
  - Evolution of health care delivery and technology → increased complexity and delivery of care → 340B drug savings increasingly important to covered entities' sustainability
  - Increased 340B Program value in dollars → outspoken critics and calls for program revision
- **Feds and states addressing, or proposing to address, various elements of the 340B Program**
- **HRSA would like more authority to administer the 340B Program**
- **Congress likely to hold more hearings; call for more program transparency; courts' actions may push Congress and administration to make changes; split Congress will affect results**



# 340B Program Future

**Can we count on the 340B Program to continue? Without the revenue margins on specialty drugs, our specialty pharmacy program would not survive, and our patients would suffer.**

- 340B is critical and will likely continue in some form
- More audits and more required transparency are possible
- Important to document how savings are being used and be able to communicate this to the public and lawmakers

# How can we protect the image of the 340B Program?

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# Image of the 340B Program

## Sustainability of This Fragile and Controversial Program

- Reliance of hospitals, health systems, and specialty pharmacies on 340B
- Commit to compliance and ensure compliance at the organizational level
  - Allocate the staffing and time required
  - Acquire the technology systems needed
  - Don't be "penny wise and pound foolish" with providing required resources
- Leverage your program to support your mission
- Work with 340B Program stakeholders to address areas of concern
- Know how to tell your story
- Tell it!



# Take-Home Thoughts

- **Purchasing and distribution models have changed; limited distribution channels will continue to expand; data is important; greater transparency is desired, and Acentrus is expanding data capabilities**
- **Acentrus will support clients through leveraging data to open drug access and to break down payer barriers**
- **It is important to effectively manage all elements of the specialty pharmacy program, including 340B compliance and 340B Program opportunities; and the Acentrus network supports health system specialty pharmacies in these efforts.**

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# Questions



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