Specialty Pharmacy: 5 Ways to Maximize Your 340B Program

Callie Lyons, Pharm.D.

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Virginia Society of Health System Pharmacists 2017 Spring Seminar

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Title of Activity: VSHP 2017 Spring Seminar
Date of Activity: April 7-8, 2017

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Second, describe what you or your spouse/partner received (ex: salary, honorarium etc). VSHP does NOT want to know how much you received.

Third, describe your role.

<table>
<thead>
<tr>
<th>Nature of Relevant Financial Relationship</th>
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<tr>
<td>Commercial Interest</td>
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<td>What was received</td>
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<td>For What Role?</td>
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<td>Example: Company 'X'</td>
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<td>Salary</td>
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<td>Employment</td>
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I do not have any relevant financial relationships with any commercial interests.

Y

Please indicate whether the presentation will be evidence-based (place a yes or no in the box)

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Example terminology:
- What was received: Salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stock, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit.
- For what role: Employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on committees or review panels, board membership, and other activities (please specify).

Glossary of Terms

Commercial Interest
The ACCME defines a "commercial interest" as any proprietary entity producing health care goods or services, with the exception of non-profit or government organizations and non-health care related companies.

Financial Relationships
Financial relationships are those relationships in which the individual benefits by receiving a salary, royalty, intellectual property rights, consulting fee, honoraria, ownership interest (e.g., stocks, stock options or other ownership interest, excluding diversified mutual funds), or other financial benefit. Financial benefits are usually associated with roles such as employment, management position, independent contractor (including contracted research), consulting, speaking and teaching, membership on advisory committees or review panels, board membership, and other activities from which remuneration is received or expected. ACCME considers
By the end of this presentation, the audience should be able to:

• Understand how the recent and anticipated growth of specialty pharmacy necessitates adding specialty pharmacy to your existing pharmacy services.

• Gain tactical knowledge to help health systems build successful specialty programs, while coordinating with payers and improving patient care.

• Gain familiarity with best practices that ensure 340B program compliance.

• Strengthen your understanding of the impact of incorporating specialty medications into hospital 340B programs.
Understand how recent and anticipated growth of specialty pharmacy necessitates adding specialty pharmacy to your existing pharmacy services
What is a Specialty Drug?

- No true consensus
- IMS Health: Drug meets 5 of 8 factors:
  - Biotech product
  - Injectable formulation
  - Risk Evaluation and Mitigation Strategy (REMS) requirement
  - Indicated for chronic condition
  - Specialist-initiated
  - Requires special handling (e.g., cold chain)
  - Costs >$6,000 per year
  - Limited distribution network
### What is a Specialty Pharmacy?

<table>
<thead>
<tr>
<th>Channel</th>
<th>Inventory Access</th>
<th>Trained Pharmacists</th>
<th>Adherence Monitoring</th>
<th>Nursing Support Services</th>
<th>Therapy Mgmt. Services</th>
<th>Home Nursing Coordinator</th>
<th>Pharmacy and Medical Billing</th>
<th>Formulary Mgmt. Services</th>
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<tbody>
<tr>
<td>Retail Pharmacy</td>
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<td></td>
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<td>Outpatient Clinic</td>
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<td>✗</td>
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<tr>
<td>Home Infusion</td>
<td>✗</td>
<td>✗</td>
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<td>✗</td>
<td>✗</td>
<td></td>
<td>✗</td>
</tr>
</tbody>
</table>
Specialty Pharmacy Services

In addition to dispensing, specialty pharmacies provide complex care:

- Disease specific patient education
- Patient therapy management
  - Supporting adherence and side effect counseling
- Ready telephone access to nurse/pharmacist
- Prior authorization management and third party eligibility coordination
- Information exchange between pharmacy and HCP

Specialty drug spending on a net price basis reached $121 billion in 2015, up more than 15% from 2014, and is expected to reach over $400 billion by 2020, and $1.7 trillion by 2030.

- Specialty spending doubled in the last five years, contributing 70% of overall medicine spending growth between 2010 and 2015.
- Increased specialty spending was driven primarily by treatments for hepatitis, autoimmune diseases, and oncology which accounted for $19.3Bn in increased spending.
- Specialty drug pipeline has nearly 700 specialty products currently in development.

US specialty drug spending will quadruple by 2020
Projected specialty drug spending from 2012 to 2020

Spending amounts in US$ billions

- 2012: $87.1
- 2016: $192.2
- 2020: $401.7

Increase from 2012: 121% (2012-2016) 109% (2016-2020)

Spending on Medicines in 2015 Increased 8.5% to $309.5B

- Spending grew 8.5% net of off-invoice discounts and rebates, driven above the levels of the last ten years primarily by a wave of innovative new medicines.

The 2015 late phase pipeline includes 2,320 novel products, an increase of 9% from the 2014 pipeline analysis.

A quarter of the pipeline is comprised of oncology drugs, of which 25% are indicated for blood cancers.

<table>
<thead>
<tr>
<th>Selected Diseases</th>
<th>Medicines in Development*</th>
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<tbody>
<tr>
<td>Cancers</td>
<td>1,813</td>
</tr>
<tr>
<td>Cardiovascular disorders</td>
<td>599</td>
</tr>
<tr>
<td>Diabetes</td>
<td>475</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>159</td>
</tr>
<tr>
<td>Immunological disorders</td>
<td>1,120</td>
</tr>
<tr>
<td>Infectious diseases</td>
<td>1,256</td>
</tr>
<tr>
<td>Mental health disorders</td>
<td>511</td>
</tr>
<tr>
<td>Neurological disorders</td>
<td>1,329</td>
</tr>
</tbody>
</table>

1. 2015 Profile: Biopharmaceutical Research Industry, PhRMA, April 2015
### Exhibit 31: Top 10 Specialty Therapy Categories and Average Prescription Cost, 2014

<table>
<thead>
<tr>
<th>Therapy Class</th>
<th>% of Pharmacy Benefit Spending</th>
<th>Average Cost Per Prescription*</th>
<th>Representative Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inflammatory Conditions</td>
<td>8.2%</td>
<td>$2,913</td>
<td>Humira, Enbrel, Stelara</td>
</tr>
<tr>
<td>Multiple Sclerosis</td>
<td>5.3%</td>
<td>$4,510</td>
<td>Copaxone, Tecfidera, Avonex</td>
</tr>
<tr>
<td>Cancer</td>
<td>4.2%</td>
<td>$6,191</td>
<td>Gleevec, Revlimid, Lupron Depot</td>
</tr>
<tr>
<td>Hepatitis C</td>
<td>3.9%</td>
<td>$16,373</td>
<td>Sovaldi, ribavirin, Olysio</td>
</tr>
<tr>
<td>HIV</td>
<td>2.8%</td>
<td>$1,138</td>
<td>Atripla, Truvada, Norvir</td>
</tr>
<tr>
<td>Misc. Specialty Disorders</td>
<td>1.1%</td>
<td>$4,540</td>
<td>Botox, Xyrem, Arestin</td>
</tr>
<tr>
<td>Growth Deficiency</td>
<td>1.0%</td>
<td>$3,853</td>
<td>Norditropin FlexPro, Genotropin, Humatrope</td>
</tr>
<tr>
<td>Hemophilia</td>
<td>0.6%</td>
<td>$7,519</td>
<td>Desmopressin, Advate</td>
</tr>
<tr>
<td>Pulmonary Arterial Hypertension</td>
<td>0.6%</td>
<td>$4,023</td>
<td>sildenafil, Adcirca, Tracleer</td>
</tr>
<tr>
<td>Transplant</td>
<td>0.5%</td>
<td>$208</td>
<td>azathioprine, mycophenolate, tacrolimus</td>
</tr>
<tr>
<td>Other</td>
<td>3.5%</td>
<td>n.a.</td>
<td></td>
</tr>
</tbody>
</table>

1. Average cost per prescription excludes payer rebates.  
Gain tactical knowledge to help health systems build successful specialty programs, while coordinating with payers and improving patient care.
Health systems want to develop specialty pharmacy services
  • Understand the potential for 340B impact
Most lack product access, payer contracts
  • Even their own employee benefit programs
Health systems want a partner that is not going to take over
Additional specialty volume will drive down operating costs (on a per-unit basis)
Network Considerations

Manufacturer Considerations

- Ability of specialty pharmacy provider to:
  - Engage patients effectively
  - Collect clinical and patient feedback to meet quality reporting requirements of new payment and care delivery models
  - Help patients and providers understand the implications of specific medication use throughout the care continuum

Payer Considerations

- Ability of specialty pharmacy provider to:
  - Reduce inappropriate utilization
  - Ensure appropriate dose of medication
  - Reduce drug acquisition cost
  - Coordinate reimbursement and eligibility
  - Improve compliance and persistency

Consolidation has created large pharmacies

- Express Scripts/Medco: Accredo (mail order)
- CVS/Caremark (mail order and retail)
- Walgreens (mail order and retail)
- These 3 companies generate 65% of the revenues from pharmacy-dispensed specialty drugs

Other pharmacies continue to grow

- Avella, Diplomat, Orchard, BriovaRx, Onco360, Aureus, Modern Health

Participation in 340B contract pharmacy programs is growing

### Specialty Pharmacy Relationships

<table>
<thead>
<tr>
<th>Ownership</th>
<th>Examples</th>
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<tbody>
<tr>
<td>Pharmacy Benefit Managers (PBM)</td>
<td>accredo</td>
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<tr>
<td></td>
<td>CVS</td>
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<td>PRIME THERAPEUTICS</td>
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<td>Retail Chains</td>
<td>Walgreens</td>
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<td>AIUM</td>
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<tr>
<td>Independent Specialty Pharmacies</td>
<td>DIPLOMAT</td>
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<tr>
<td></td>
<td>Avella</td>
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<tr>
<td>Health Insurer with a PBM</td>
<td>OPTUMRx</td>
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<td>Cigna</td>
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<td>Wholesalers</td>
<td>US Bioservices</td>
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<td></td>
<td>CardinalHealth™</td>
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<td>OncologyRx Care Advantage</td>
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<td>Physician Practices</td>
<td>RX TO GO</td>
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<td></td>
<td>RainTree</td>
</tr>
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<td></td>
<td>TEXAS CONCANCER</td>
</tr>
<tr>
<td>Hospital Systems and Group Purchasing Organizations</td>
<td>FAIRVIEW</td>
</tr>
<tr>
<td></td>
<td>COMMCARE SPECIALTY PHARMACY</td>
</tr>
<tr>
<td></td>
<td>excelera</td>
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</tbody>
</table>

Source: Pembroke Consulting research

Dedicated and specialized infrastructure support including:

- Marketing and sales
- Information systems and technologies
- Pharmaceutical purchasing
- Payer contracting

URAC Accreditation

- Becoming a *de facto* standard and requirement for payer contracts
- Assesses a pharmacy’s (1) organization and administration (2) pharmacy operations (3) clinical management, and (4) quality reporting and improvement

Ability to manage key points in the process:

- Prior authorization
- REMS support, including data collection and reporting
- Timely, efficient distribution
- Inventory management and control
- Patient assistance programs
- Billing, collections and claims denial management
- Data warehousing, analytics, integration and reporting
- Audit readiness and prevention strategies
  - Regulatory and commercial
Gain familiarity with best practices that ensure 340B program compliance.
340B Drug Pricing Program

- Established by section 340B of the Public Health Service Act of 1992
- Enables “covered entities” to receive discounts on drug purchases
- Requires drug manufacturers to provide outpatient drug discounts to certain covered entities and to participate in other government programs such as Medicare/Medicaid
- Not subsidized by the federal government
340B Covered Entity Types

**Initial legislation:**
- Disproportionate share hospitals ("DSHs")
- Federally-qualified health centers ("FQHCs") or look-alikes ("FQHCLAs")
- Family planning clinics ("FPs")
- State-run AIDS drug assistance programs ("ADAPs")
- Early intervention programs for HIV ("HVs") or certain Ryan White Care Act grantees ("RWs")
- Black lung clinics ("BLs")
- Comprehensive hemophilia treatment programs ("HMs")
- Urban Indian organizations ("UIs") and Native Hawaiian ("HIs") health centers
- Certified STD ("STDs") or tuberculosis treatment centers ("TBs")

**Affordable Care Act added:**
- Critical Access Hospitals ("CAHs"): no DS% required
- Sole Community Hospitals ("SCHs"): DS% >8%
- Rural Referral Centers ("RRCs"): DS% >8%
- Free-standing Children’s Hospitals ("PEDs"): DS% >11.75%
- Free-standing Cancer Hospitals ("CANs"): DS% >11.75%

All of these organizations are referred to in the legislation as: **340B Covered Entities**
340B DSH Entity Requirements

- Eligible hospitals must have a high share of Medicaid or low-income Medicare patients, or serve isolated rural areas (11.75% disproportionate share).
- Must be public or nonprofit.
- 340B Hospitals serve low-income patients:
  - 340B hospitals are responsible for 60% of all uncompensated care provided by hospitals.
  - 340B low income patient loads are nearly twice as large as non-340B hospitals.
  - 340B hospitals are significantly more likely to offer specialized services that are financially draining for the hospital.
Prescriptions qualify for 340B, not prescribers or patients

To qualify for 340B, a prescription must meet the following criteria:

1. Care is provided by a health care professional who is either employed by or under contract to the covered entity or has some other arrangement (e.g. referral for consultation)

2. Care is provided in a clinic or department on the Medicare cost report (above line 118)

3. Covered entity maintains a record of care and has responsibility for patient care

4. Prescription is filled at a contract pharmacy or ship-to location
340B Pricing Guidelines

- Requires manufacturers participating in Medicaid rebate programs to pass on similar discounts to qualified Entities
- 340B prices are ceiling prices, equivalent to Medicaid prices after rebates
- Discounts apply only to outpatient drugs
- Certain covered entities may not participate in other group purchasing organizations (GPOs) for outpatient drugs
- Drugs purchased under 340B contracts can be used for all qualified patients, including those covered by commercial insurance, Medicare or Medicaid Managed Care
340B Covered Outpatient Drugs

- Vaccines
- Inpatient Drugs
- Drugs not directly reimbursed
- Drugs for which FDA does not require and NDC

- Outpatient Prescription Drugs
- Over-the-counter drugs (with a prescription)
- Clinic administered drugs
- Biologics
- Insulin
Strengthen your understanding of the impact of incorporating specialty medications into hospital 340B programs.
Outsourced: Health system allows another pharmacy to handle it all on their behalf
  • Walgreens model

Insourced: Health system develops complete solution in-house
  • UHC, Excelera, Premier, other consulting firms offering assistance with this approach (consortium model)
  • Must carefully look at financial and operational capabilities and objectives

Hybrid: Health system builds out some capabilities, backed up by outsource provider
  • System does RA, MS, first-line HIV and other retail-oriented diseases
  • Partner does oncology, transplant, Hep C, CF, second-line HIV/AIDS, hemophilia and other complicated conditions
  • Split could also be dictated by payer or drug access
  • Could be implemented in a staged fashion
Some pharmacy companies will put up on-site operations to capture specialty prescriptions

- Walgreens
- Diplomat
- Aureus (focused on FQHCs/ASOs)
- Cardinal (focused on FQHCs/ASOs)
- Independents

Hospitals give up some amount of patient/customer experience, EMR integration
The Consortium Model

Outsource Partner

- Local payer contracts
- Rx distribution
- Clinical services

Network Member A

- Program management
- Standards setting
- National payer contracts
- Supplier contracts
- National distribution
- Platform
- Central customer service center
- Central MTM center
- Payer audit support
- Revenue cycle management services
- Marketing/Communications services
- Training services
- Data collection and reporting

Network Member B

- Local payer contracts
- Rx distribution
- Clinical services

Network Member C

- Local payer contracts
- Rx distribution
- Clinical services
Health systems need to capture every possible patient interaction
  • ACO and case-rate payment structures require comprehensive patient management
  • Patient data needs to be integrated to track health and financial outcomes and performance
  • Point of care training and education on first-fills will improve patient education and outcomes
  • Profitable revenues are good!

Health systems need to leverage current assets
  • Maximize volumes to reduce per-unit costs
  • Optimize investments in clinical staff and programs
  • Add new sources of revenue and margin, including 340B savings

Health systems need to use best practices to optimize clinical and financial performance
Health System Advantages for Having a Specialty Pharmacy

- Local provider
  - Same-day delivery – key differentiator for new and repeat therapies

- Access to providers and medical record
  - Including collaborative practice agreements, allowing pharmacists to make therapeutic changes

- Payer leverage
  - Hospitals can leverage inpatient rates against specialty pharmacy participation
Building In-house Capability Helps Meet Health Systems’ Objectives

- Capture and Retain Revenue
- Leverage Assets
- Access All Products and Therapies
- Gain Positive Returns on Capital Investments
- Optimize Clinical Performance
The Hybrid Model

- Program assistance
- National payer contracts
- Limited Distribution Drug access
- National distribution platform
- Central customer service center

- Focus on “easy” drugs and conditions
- Local payer contracts
- Rx distribution
- Local clinical services
- Local customer service
Under a contract pharmacy arrangement, the covered entity retains legal title to all drugs purchased under 340B.

The covered entity must pay for all 340B drugs, but a “ship to-bill to” arrangement may be used, where the drug is directly shipped to the pharmacy.

The contract pharmacy is subject to audits to identify and prevent diversion and/or duplicate discount.

As of 2010, covered entities can contract with multiple pharmacies.
◆ One third of all hospitals are participating in the 340B program
◆ DSH hospitals increased from 185 entities in 2003 to approximately 970 entities by 2013
◆ In 2014, almost two-thirds of all DSH hospitals participated in contract pharmacy arrangements
  • 90% DSH participation expected by 2019
  • Majority have anywhere from 5 to 50 contracted pharmacies
Include specialty pharmacies in your contract pharmacy network
  • Be mindful of their ties to health plans, PBMS, or wholesalers

Work through third party administrator (TPA)
  • Essential to maintaining compliance and program integrity for larger programs

Align with specialty pharmacy partner
  • High standards for patient care
  • Where are your patients already going?

Build capability in-house
  • Several factors to consider
Highly dependent on the health plans

May require several pharmacies to capture majority of prescriptions
  • Limited distribution networks, payer lockouts

Dispensing fees are high on a dollar basis, within market on a % basis
  • Consider high cost of specialty medications and special handling required
# Specialty Pharmacies in 340B

<table>
<thead>
<tr>
<th>Model</th>
<th>Companies</th>
<th>Marketed As</th>
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<tbody>
<tr>
<td><strong>Pure-play</strong></td>
<td><strong>Aureus Health Services</strong>&lt;br&gt;&lt;br&gt;<strong>Avella Specialty Pharmacy</strong>&lt;br&gt;<strong>BioPlus Specialty Pharmacy</strong>&lt;br&gt;<strong>Diplomat Specialty Pharmacy</strong>&lt;br&gt;<strong>Transcript Pharmacy</strong></td>
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<tr>
<td><strong>Infusion</strong></td>
<td><strong>Ambient Healthcare</strong>&lt;br&gt;<strong>AxelaCare</strong>&lt;br&gt;<strong>BioScrip</strong>&lt;br&gt;<strong>HomeSolutions</strong>&lt;br&gt;<strong>Onco360</strong>&lt;br&gt;<strong>US Bioservices</strong></td>
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</tr>
<tr>
<td><strong>PBM-affiliated</strong></td>
<td><strong>Caremark</strong>&lt;br&gt;<strong>Catamaran</strong>&lt;br&gt;<strong>Express Scripts / Medco</strong>&lt;br&gt;<strong>Catamaran</strong>&lt;br&gt;<strong>OptumRx</strong></td>
<td><strong>Caremark Specialty (few)</strong>&lt;br&gt;<strong>Briova Rx</strong>&lt;br&gt;<strong>Accredo (few)</strong>&lt;br&gt;<strong>BriovaRx</strong>&lt;br&gt;<strong>OptumRx Specialty Pharmacy</strong></td>
</tr>
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<table>
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<th>Model</th>
<th>Companies</th>
<th>Marketed As</th>
</tr>
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<td><strong>Distributor-affiliated</strong></td>
<td>AmerisourceBergen, Cardinal, McKesson</td>
<td>AmerisourceBergen Specialty Group, Cardinal Specialty Pharmacy, McKesson Specialty</td>
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<tr>
<td><strong>Retail-affiliated</strong></td>
<td>CVS, Hyvee, Kroger, Walgreens</td>
<td>ProCare, Amber Pharmacy, Axium Healthcare Pharmacy, Walgreens Specialty Pharmacy</td>
</tr>
<tr>
<td><strong>MCO-affiliated</strong></td>
<td>Aetna, Cigna, Centene, United Healthcare</td>
<td>Aetna Specialty, Cigna Specialty Pharmacy Services, Acaria Health, Optum Rx</td>
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</table>
Discuss the possible implications of the recent Mega Guidance on specialty pharmacy, and how this could affect your 340B program.
Specialty Pharmacy is definitely a growth opportunity, but requires firm commitment to long-term strategy
- Opportunity is especially strong for 340-eligible hospitals and systems

Successful programs, starting now, probably require partnerships
- Consortia, hybrid models

Don’t lose sight of seemingly simple things
- Customer service, billing support, disaster recovery

Bottom Line: The 340B program will remain vitally important for safety-net providers and their patients because expensive specialty drugs are a quickly growing share of the pharmaceutical market
A specialty drug is characterized by which of the following:

A. Specialist-initiated
B. Requires complex handling (e.g., cold chain)
C. Cost >$6,000 per year
D. All of the above
A specialty drug is characterized by which of the following:

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Question Two

Which covered entity type accounts for the largest portion of contract pharmacy arrangements?

A. Consolidated Community Health Centers (CHC)
B. Rural Referral Centers (RRC)
C. Disproportionate Share Hospital (DSH)
D. Free Standing Cancer Hospital (CAN)
Question Two

Which covered entity type accounts for the largest portion of contract pharmacy arrangements?

A. Consolidated Community Health Centers (CHC)
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C. Disproportionate Share Hospital (DSH)
D. Free Standing Cancer Hospital (CAN)
The relationship between Accredo Specialty Pharmacy and Express Scripts represents which of the following types of specialty pharmacy business models:

A. Pure-Play
B. PBM-Affiliated
C. Distributor-Affiliated
D. Retail-Affiliated
Question Three

The relationship between Accredo Specialty Pharmacy and Express Scripts represents which of the following types of specialty pharmacy business models:

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B. **PBM-Affiliated**
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D. Retail-Affiliated
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