Specialty Pharmacy: Optimizing Value for Better Outcomes

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Disclosures

• JoAnn Stubbings has no disclosures to report.

• Jerry Buller
  • Is the current Chief Pharmacy Officer for Trellis Rx a company that partners with health systems to build and develop in-house specialty pharmacies.
CPE Information

• Target Audience: Pharmacists
• ACPE#: 0202-0000-19-061-L04-P
• Activity Type: Knowledge-based
Learning Objectives

At the completion of this knowledge-based activity, participants will be able to:

• Explain the importance of clinical outcomes from the perspective of a payer and specialty pharmacy provider.
• Discuss strategies on how to effectively collect, synthesize, and manage patient data.
• Identify clinical and cost considerations payers face when covering specialty medications.
• Discuss strategies and challenges associated with operating a specialty pharmacy, including accreditation, administrative requirements, and access to limited distribution drugs.
1. Specialty drug expenditures are predicted by many to be ___% of total payer drug spend by 2020?

A. 3%
B. Approximately 25%
C. Approximately 50%
D. Greater than 75% for the first time in history.
2. Which of the following would NOT be considered to be a “good” clinical outcome?

A. A disease cure  
B. Increased survival  
C. Minimize Active Disease  
D. Patient out of pocket expenses <$50
3. Payers optimize the value of specialty medications by balancing which of the following:

A. Annual budget and federal regulations
B. Cost and clinical outcomes
C. Cost and rebates
D. Duration of treatment and patient population
4. Specialty pharmacy accreditation offers what advantage to a specialty pharmacy?
   A. Allows the pharmacy to reduce staff
   B. Guarantees access to limited payer or drug distribution networks
   C. Provides lower rebates
   D. Serves as a blueprint for building and managing a specialty pharmacy
1. Importance of clinical outcomes from the perspective of a payer and specialty pharmacy

NO OUTCOME → NO INCOME

C. Wright Pinson, CEO of the Vanderbilt Health System
Some projections suggest specialty drug costs could account for ~50% of all drug spending by 2020.

The Managed Care Payer

Source: EMD Serono Specialty Digest 2018. Managed Care Strategies for Specialty Pharmaceuticals. Represents a survey of 59 commercial health plans covering more than 76 million covered lives.

Specialty products are 3% of population and can be targeted and managed by plan sponsors

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<tr>
<th>Generics</th>
<th>Brands</th>
<th>Specialty</th>
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<tr>
<td>84% of Rx Volume</td>
<td>13% of Rx volume</td>
<td>3% of Rx volume</td>
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<tr>
<td>15% of dollar volume</td>
<td>35% of dollar volume</td>
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- **Units**: Primary Care Pharmacy Benefit
- **Dollars**: Specialty Pharmacy Benefit
- **Gatekeeper**: PBM (AWP-18%)
- **Reimbursement**: PBM (AWP-20%)
What is a good clinical outcome?

- A cure
- Survival
- Minimize Active Disease
- Reduced “Flares” Relapses

Other Outcomes
  - Patient Experience
  - Customer Satisfaction
    - Net Promoter Score (NPS)

Reduced Costs

- Hospitalizations ↓
- Readmissions ↓
- Transplants ↓
What are we measuring today?

Most specialty outcomes have focused on what we can measure, from a Pharmacy point of view (MPR*, TAT** etc.) Can we begin to leverage a “connected” model to demonstrate a “Real Outcome”?

**Good Outcome**

- Cure
- Reduction of
  - Strokes
  - Cardiac Events
  - Fractures
  - ED Visits
  - MS Flares
- Reduced Overall COSTS

**Typical/Surrogate Measures**

- Adherence (MPR/PDC)
- Speed to Therapy
- Abandonment rate
- Reduced Copays

*MPR=Medication Possession Ratio
**TAT=Turn Around Time
Specialty Pharmacy care has been shown to produce positive outcomes in certain disease states

Specialty pharmacy care is associated with a significantly lower risk for disease relapse in patients with MS (specifically the first relapse) and fewer relapses compared with usual community pharmacy care.

High touch management of HCV Patient Population in a clinic setting

**VANDERBILT SPECIALTY PHARMACY**

Real World Assessment of All-Oral, Sofosbuvir-Based, Hepatitis C Therapy at an Academic Integrated Specialty Pharmacy Services

_Cori Nielsen, PharmD, BCPS, Alicia Carter, PharmD, BCPS_

**BACKGROUND**

- The discovery of orally administered, direct acting antivirals (DAAs) therapies redefined the treatment of hepatitis C virus (HCV).
- Clinical trials report superior durability, response rates, 12 week on-treatment SVR12 rates of over 90%, with these newer agents comparable to SVR12 rates of over 85%, with the previously monotherapy-based standard of care.
- In addition to better efficacy, these new therapies also have limited side effects profile, which, in turn, improves therapy completion rates.
- However, the study controlled environment does not translate into real world settings where patient adherence and completion are a challenge.

**PURPOSE**

- To evaluate patient outcomes to all oral, fixed-dose combination (FDC) based, HCV antiviral regimens in the real world setting and assess the impact of an integrated specialty pharmacy on treatment completion rates.

**METHODS**

- MEDS approved, retrospective chart review.
- Protocol approval.

**ENDPOINTS**

- SVR12 rates stratified by drug regimen
- Adverse event rate
- Therapy discontinuation rate
- Patient adherence
- Clinical trial vs. real world
- SVR12 rates stratified by drug regimen
- Out-of-pocket prescription costs utilizing VSP

**RESULTS**

- SVR12 Rates (%)
  - L/S-R: 92%
  - L/S: 92%
  - S+S: 92%
  - Clinical Trials: 92%
  - Real World: 92%

- Early Discontinuations:
  - All: 6%
  - Noncompliance: 3%
  - Death: 3%
  - Poor Tolerance: 2%
  - Other: 2%

- Therapy Discontinuations:
  - Clinical Trials: 2.4%
  - Real World: 2.4%

- Total:
  - Clinical Trials: 1.1%
  - Real World: 1.1%

**Adverse Events**

- L/S: 31 (29.5%)
- L/S-R: 20 (20.5%)
- S+S: 27 (29%)
- S/R: 14 (19.6%)

**VSP Medication Access**

- New Prescription Received: 79%
- PA Approval: 75%
- PA Denial: 20%
- Second Level Approval: 12%
- Second Level Approval: 10%

- Manufacturer Assistance Approval: 81%

- **PAP Completion Rates Statistically Better**
  - 2% vs National Average of 30%

**Key Points**

- 717 Patients Referred
- 717 (100%) Patients Started Therapy
- Response Rates Comparable to Clinical Trials

**VSP Completion Rates Statistically Better**

- PAP Required 2% vs National Average of 30%

*Opportunity for Community Pharmacy*

*PAP=Patient Assistance Program*
Goal is to capture patients at risk for “falling off” after initial diagnosis as well as identifying patients with clinical markers that have yet to be diagnosed.

Key Points
- Captive Populations
  - Health Plans
  - IDN
- Known Clinical Triggers
- Health Information Exchange/EMR
- Natural Language Processing

IDN=Integrated Delivery Network
EMR=Electronic Medical Record
IBD=Inflammatory Bowel Disease
2. Strategies on how to effectively collect, synthesize, and manage patient data

“Data”
The 4-Legged Stool
Understanding the types of data available and the associated data stakeholders/customers are key

**Business**
- Opportunity Management (How Successful Are We?)
- Patient Eligibility (Who Can Fill With Us)
- Market Share & Conversion
- Segmenting Opportunity
- LDD & Payer Targets

**Stakeholders**
- Performance Metrics (Turn Around Times, Call Center)
- Adherence Metrics (PDC, MPR)

**Accrediting Bodies**
- Performance Metrics

**Clinical Outcomes**
- Adherence
- Hospitalizations, Disease-Specific Metrics

*PDC=Proportion of Days Covered
**MPR=Medication Possession Ratio
Can we demonstrate an impact to overall patient survival, disease progression or quality of life?

Success Measures
- Rheumatology
  - Quality of Life Measures
- Oncology
  - ↓ Admissions & ED* Visits
- PAH*
  - ↓ Admissions & ED* Visits
  - ↑ 6 Min Walk

*Requires Integration with Provider

*PAH=Pulmonary Arterial Hypertension
**ED=Emergency Department
Interoperability Operations, Clinical and Outcomes

• Collecting Meaningful Patient Outcomes Data Requires
  • A Referral Management System
    • ScriptMed, Atlas Rx, TCMS, Caret, Therigy, Asembia-1, etc.
  • Integrated Model With A Provider Or Referral Source
    • Collaborative Practice? Maybe But Not Necessary
  • Access To Provider Or Health System EMR (Ideal)
    • Requires BAA
    • Must Be Able To Articulate Value Proposition To Provider
  • Dedicated Resources
    • Pull All Of Data Together And Submit Manuscript (Can Outsource)
    • A Good Lawyer 😊
Build it and they will come

• Create Product
  • Have Poster, Paper, Charts In A Presentable & Digestible Form
  • Can Utilize Partner Health System Resources (Provide Them Authorship)

• Present Product
  • National Meetings (NASP, APhA, AMCP etc.)
  • Engage Local Payers
  • Plan Sponsors
    • Local Employers
    • Self Funded

*NASP=National Association of Specialty Pharmacy
**APhA=American Pharmacists Association
***AMCP=Academy of Managed Care Pharmacy
Future is Outcomes Based Contracting

• Manufacturers Are Your Friend
  • Payers are assigning more risk to manufacturers to ensure their product meets the same clinical trials efficacy
  • Manufacturers will start to dictate which specialty Pharmacies they want to work with
  • Your pharmacy could be one of the “preferred” for a manufacturer

• You And The Manufacturer Are Very Aligned
  • Want patient to have good outcome
  • Want to dispense more drug (if appropriate)
  • Values the patient journey
3. Identify clinical and cost considerations payers face when covering specialty medications

- Private/commercial
- Medicare/Medicaid

"If you’re not at the table, you’re on the menu."
Anonymous (in reference to Washington DC politics, but could refer to specialty pharmacy networks)

Determining the value of specialty drugs and managing oncology drugs and services were the #1 challenge for 44% of respondents in 2017.

Source: EMD Serono Specialty Digest 2018. Managed Care Strategies for Specialty Pharmaceuticals. Represents a survey of 59 commercial health plans covering more than 76 million covered lives.
All payers share the same concerns: Specialty drugs make up a growing part of their budgets

- Specialty medicines are rapidly approaching half of medicine spending, driven by innovators.
- Two-thirds of new medicines approved in the last five years have been specialty drugs.

How payers are responding

- Vertical integration
- Limit specialty pharmacy networks
- Formulary and utilization management
- Cost shifting and takebacks
  - Copay accumulator and copay block programs
  - Direct and indirect remuneration (DIR) fees
Vertical integration – bigger is not always better

• CVS Pharmacy + CVS Caremark + Aetna
• UnitedHealthcare + OptumRx + Briova + Cigna + Catamaran
• Express Scripts + Accredo
• Blue Cross Blue Shield + Prime Therapeutics + Walgreens

https://www.drugchannels.net/2018/03/cigna-express-scripts-vertical.html
Limited specialty pharmacy networks - increase revenues to payer-owned specialty pharmacies

- Your pharmacy may have the following payer restrictions:
  - Out of network
  - In network but with copay penalties for filling at your pharmacy (non-preferred pharmacy)
  - First fill only (grace fills)
  - In network with pharmacy benefit manager (PBM) but sponsor (employer) locks out your specialty pharmacy

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<tr>
<th>Patient case: Penalty for filling at in-network non-preferred pharmacy</th>
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<tr>
<td>Ingredient cost + dispensing fee</td>
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<tr>
<td>Deductible</td>
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<td>Amount attributed to deductible</td>
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<tr>
<td>Amount attributed to provider network selection</td>
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<td>Patient pay amount</td>
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Formulary and utilization management for specialty drugs - varies widely by payer

• Formulary management
  • Study of 3,417 health plan coverage decisions with 302 specialty drug-indication pairs
  • 84% of the 302 pairs had some differences in coverage across health plans
  • In 38% of cases, health plans did not cover drugs or they covered drugs more restrictively than the Food and Drug Administration (FDA) indication.
  • Reasons: negotiated rebates, discounts, uncertainty in the marketplace, lack of transparency

• Utilization management
  • Prior authorization (PA) is the most common
  • Clinical consideration: PA is meant to ensure the medication dispensed is appropriate based on approved clinical guidelines
  • PBMs get higher rebates from manufacturers if their approval rates are higher

Specialty drug formulary exclusions are growing

- Proposed expansion to Medicare Part D protected drug classes
  - Antidepressants
  - Antipsychotics
  - Anticonvulsants
  - Immunosuppressants
  - Antiretrovirals
  - Antineoplastics

Sources:
Cost shifting and takebacks - can impact the patient’s ability to afford medication and on a pharmacy’s bottom line

- High deductible plans
  - 39% of beneficiaries in employer-based plans
- Copayments
- Coinsurance
- Copay accumulator programs
- DIR fees

**Patient case: High deductible plan**

| Ingredient cost + dispensing fee | $6,000 |
| Deductible                      | $45,000 |
| Amount attributed to deductible | $6,000  |
| Patient pay amount              | $6,000  |
Copay accumulator programs – a form of cost shifting to the consumer to reduce payer net spending on specialty drugs

• Definition: copay accumulator programs are offered by commercial payers and PBMs to ensure that manufacturer contribution no longer counts toward a patient’s deductible or out-of-pocket maximum.

• Currently impact about 25% of commercially insured lives

• Eventually copay accumulator programs will apply to 100% of benefit designs

Copay accumulator update: Widespread adoption as manufacturers and maximizers limit patient impact. Available at: https://www.drugchannels.net/2018/09/copay-accumulator-update-widespread.html?m=1#more

In 2017, manufacturer coupon usage reached 18% of all branded prescriptions filled under commercial plans and 42% of specialty prescriptions.
How do copay accumulator programs work?

Patient case:
- Specialty medication with a monthly cost of $10,000
- Coinsurance 25% ($2500)
- Copay assistance brings copay down to $25 (maximum on card $10000)
- Patient annual out-of-pocket limit $6000

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<tr>
<td>Payer pays</td>
<td>$114,000</td>
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The copay card covers copayment and patient annual out-of-pocket limit

The copay card covers copayment but NOT the patient annual out-of-pocket limit
# How do copay accumulator programs work? - DETAIL

**Patient case:**
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- Patient annual out-of-pocket limit $6000 (see arrows)

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<th>May</th>
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<td>40,000</td>
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DIR Fees – does the patient benefit?

- Point-of-sale or post point-of-sale (clawbacks)
- Claim to be performance based - Shift the risk for Part D quality performance from plan sponsor/PBM to the pharmacy provider. However, pharmacies do not benefit from star rating incentives.
- DIR fees may create losses in revenue that may result in negative gross margins.
- In specialty pharmacy, DIR fees calculated as a % of the price of the drug result in higher fees for more expensive drugs.
- According to the Centers for Medicare and Medicaid Services (CMS), DIR fees serve to reduce the cost of drugs under Medicare Part D.
  - Change the final price of the drug retroactively
  - Beneficiaries face higher cost-sharing at point of sale


Behind Diplomat Pharmacy’s plunge: A primer on DIR fees in Medicare Part D. Drug Channels, November 8, 2016. Available at: https://www.drugchannels.net/2016/11/behind-diplomat-pharmacies-plunge-primer.html
Manufacturer response

• Do payers adequately balance clinical and cost considerations to offer patients the best value?
• Evaluate potential impact of payer programs on their market share
• Lower prices so patients pay lower coinsurance
• Future of rebates/DIR?
• Favor innovative patient support solutions that can adjudicate at the switch or reimburse patient directly
• Contracting that excludes copay accumulator or DIR programs
In summary

• Payers attempt to balance clinical and cost outcomes to optimize the value of specialty medications.

• All payers are concerned about specialty medications consuming a growing portion of their drug budget.

• In response, payers are vertically integrating, establishing limited networks, implementing formulary and utilization management programs, and cost shifting to patients and taking back from pharmacies.
4. Discuss strategies and challenges associated with operating a specialty pharmacy, including accreditation, administrative requirements and access to limited distribution drugs

Do you still want to build or grow a specialty pharmacy?
What is the role of specialty pharmacy accreditation?

- It serves as a blueprint for building and managing a specialty pharmacy
- It fulfills the requirements for access to specialty pharmacy payer networks and limited drug distribution networks
- However, accreditation is costly, time consuming, and requires dedicated staff
Questions to consider before seeking accreditation

- Should we hire a consultant?
- Who will manage the project?
- How will tasks be allocated to team members?
- How many staff will be allocated in the scope of the accreditation?
- Which model will be pursued: accredit then build or build then accredit?
- Which therapeutic categories will be included?

Administrative requirements for launching a specialty pharmacy

1. Establish goals, mission, and vision
2. Develop a financial pro forma
3. Identify product opportunities
4. Define customer opportunities
5. Investigate payer opportunities
6. Develop a prescription capture model
7. Consider infrastructure and long term growth
8. Monitor safety and outcomes
9. Manage and utilize data
10. Develop management guidelines

“The ultimate goal of implementing a specialty pharmacy is to increase patient access to medications.”

Source: Stubbings JA. Top 10 checklist for launching a specialty pharmacy. 12(3):1; March 2015. Available at: https://www.pppmag.com/article/1787/?search=specialty%20pharmacy%20accreditation
Building a specialty pharmacy requires more space and services

- Staffing
- Space
- Can retail and specialty coexist?
- Walk up or closed door?
- Call center
- Cold chain distribution

Access to limited distribution drugs

• Focus on the low hanging fruit, depending on your location and relationships with clinics
  • Oral oncology
  • Human immunodeficiency virus (HIV)
  • Hepatitis C
  • Immunosuppressants
  • Autoimmune
  • Multiple sclerosis
  • Fertility
  • Migraine
  • PCSK9 inhibitors
  • ‘Tweeners’

• Focus on payer access
• Then tackle the limited distribution drugs
• In specialty pharmacy, “no outcomes lead to no income.” A connected model between process and outcomes can leverage good clinical outcomes.

• Collecting meaningful outcomes data requires an understanding of the types of data required, the customers, and stakeholders.

• Payers are responding to the specialty market dynamics with a variety of strategies, some of which are challenging for providers and pharmacies.

• There are still many opportunities to build or grow a specialty pharmacy, but the barriers to entry are steep. Specialty pharmacy requires space, staffing, contracts, accreditation, and other changes to the business model.

• Specialty pharmacy is a growing opportunity for pharmacy practice!
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