Specialty Pharmacy: What Now and What’s Next?
Dan Steiber RPh

Principal
• Registered Pharmacist
• Washington State University College of Pharmacy
• Harvard and Northwestern Executive Programs
• Committee Member various organizations including National Association of Chain Drug Stores, Health Care Distributors Marketing Association, Winner of Innovation for Success Award
• Adjunct Professor at University of Pacific College of Pharmacy

Worked in Sr. Management Positions at:
– Longs Drug Stores / Eli Lilly and Company
– Integrated Health Concepts-Founding Member (now RxAmerica)
– Numerous Vice President positions at Bergen Brunswig/ Amerisource Bergen
– General Manager/ VP Integrated Commercialization Solutions (ABSG 3PL)

Consultation:
– Academic: Washington State University, USC, UOP, UCSF
– Pharma: 60+ Companies

• Editor in Chief Specialty Pharmacy Times
# D2 Focus Areas

## Pharma: Supply Chain
- Strategic Planning
- Supply Chain: USA
  - 3PL
  - Wholesale
  - Pharmacies
  - GPO, Reimbursement HUBS etc
- Supply Chain: Global
  - Puerto Rico
  - Canada
  - 20 European
  - East: Korea, Japan
- State Licensing
- Fair Market Analysis
- Listing Agency Representation
- Market Research
- Operations/ Infrastructure Development: REMS
- Contracted Sales: Trade/ GPO Account Management

## Pharma: Managed Care
- Strategic Targeting
- Market Research
- Contracted Managed Care Field Sales Force
  - Payors
  - Commercial
  - Employer
  - PBMs
  - Govt
  - Medicaid
  - VA/ DOD
- Advisory Boards

## Financial
- Diligence/ M&A Evaluation:
  - Service Providers
  - Preparation
  - Financial
  - Capital Groups
  - Analysis
  - Targeting
  - Ops
  - Financial
  - Strategic /Tactical Planning
- Pharma
- Product Brokering
- Market Research
- Financial Analysis
- Commercialization Modeling

## Service Provider
- Education
- Operational Support:
  - Facility Planning/ Build-out
  - IT Infrastructure, Automation
  - Data Collection and Reporting
  - REMS Preparation & Execution
  - Development of Solutions by Product, Device, or Disease
  - Development of Ancillary services: PAP, CoPay, GAP, Sampling, HUB, 3PL, SD, Adherence, Clinical, other
- Contracting:
  - Regulatory and Process Best Practices
- Fair Market Analysis:
  - Benchmarking, Analysis, Levers
- Growth Strategies:
  - Financial Analysis & Planning
  - Network Strategies
  - Strategic Partnerships
SPECIALTY PHARMACY

• Provide High End Direct to Patient Services
• Works Directly with Manufacturers, Patients, MD’s, Hospitals, Payors, other
Specialty Product Defined

- Typically small populations, rare and chronic diseases
- High cost per unit products for high cost diseases (1k-45k month)
- Require special handling and services (frig, hazmat, frozen, other)
- Multiple dosages forms – no longer just injectables
- Reimbursement Challenges (Prior Authorizations, Step Edits, etc)
- Distributed through multiple pharmacy models
- Complex large molecule and biologic drugs
SP Flow of Activities

- Filled GAPS
- Increase Care
- Stakeholder Ease
- Control Costs

New Responsibilities:
- Enhanced Data
- REMS Mgmt
- Inventory Mgmt
- Coordination of Care
- Testing Mgmt

- Hemophilia/ VonWillebrands
- Gaucher’s Disease
- Growth Hormone Deficiencies
- Multiple Sclerosis
- Hepatitis C,B,A
- Pulmonary Hypertension

- Cystic Fibrosis
- Fertility/ Hormone Therapies
- Immune Disorders: IVIG
- Respiratory Syncytial Virus
- Hemopoietics/ Colony Stimulating Factors

- Rheumatoid/ Osteoarthritis
- AIDS/ HIV
- Transplant
- Oncology
- Dermatology/ Psoriasis
- Devices/ Testing
Specialty Pharmaceutical Market, 2011

$227.3

Source: Company reports, IMS Health, and J.P. Morgan estimates.
# 2011 Top 20 Specialty Drugs, based on IMS Sales Data

<table>
<thead>
<tr>
<th>Product</th>
<th>Sales ($B)</th>
<th>Indication</th>
<th>2011 Rank</th>
<th>2010 Rank</th>
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<tbody>
<tr>
<td>Humira</td>
<td>$3.53</td>
<td>Rheumatoid Arthritis, Crohn's Disease</td>
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<td>Enbrel</td>
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<td>Remicade</td>
<td>$3.47</td>
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<td>Neulasta</td>
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<td>Rituxan</td>
<td>$3.00</td>
<td>Rheumatoid Arthritis; Oncology</td>
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<td>Copaxone</td>
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<td>Multiple Sclerosis</td>
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<td>Epogen</td>
<td>$2.77</td>
<td>Anemia</td>
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<td>Avastin</td>
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<td>8</td>
<td>4</td>
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<td>Atripla</td>
<td>$2.57</td>
<td>HIV/AIDS</td>
<td>9</td>
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<td>Truvada</td>
<td>$1.91</td>
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<td>Revlimid</td>
<td>$1.83</td>
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<td>Lucentis</td>
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<td>Avonex</td>
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<td>Gleevac</td>
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<td>Enoxaparin</td>
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<td>anti-clotting</td>
<td>16</td>
<td>NM</td>
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<tr>
<td>Procrit</td>
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<td>Oncology</td>
<td>17</td>
<td>NM</td>
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<td>Eloxatin</td>
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<td>Oncology</td>
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<td>NM</td>
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<td>Lovenox</td>
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<td>anti-clotting</td>
<td>19</td>
<td>16</td>
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<tr>
<td>Rebif</td>
<td>$1.06</td>
<td>Multiple Sclerosis</td>
<td>20</td>
<td>9</td>
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</table>

Source: Company reports, IMS Health, J.P. Morgan estimates.

Table 3: 2011 Top 20 Specialty Drugs, based on IMS Sales Data
### U.S. Specialty and Overall Market Growth Rates (2008-2011)

<table>
<thead>
<tr>
<th></th>
<th>2008</th>
<th>2009</th>
<th>% Chg Yr/yr</th>
<th>2010</th>
<th>% Chg Yr/yr</th>
<th>2011</th>
<th>% Chg Yr/yr</th>
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<tbody>
<tr>
<td>Specialty</td>
<td>$75.6</td>
<td>$81.0</td>
<td>7.1%</td>
<td>$85.8</td>
<td>5.9%</td>
<td>$92.5</td>
<td>7.9%</td>
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<tr>
<td>'Traditional' (Non-Specialty)</td>
<td>$210.1</td>
<td>$219.7</td>
<td>4.6%</td>
<td>$222.8</td>
<td>1.4%</td>
<td>$227.4</td>
<td>2.0%</td>
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<tr>
<td>Total U.S. Market</td>
<td>$285.7</td>
<td>$300.7</td>
<td>5.3%</td>
<td>$308.6</td>
<td>2.6%</td>
<td>$319.9</td>
<td>3.7%</td>
</tr>
</tbody>
</table>

*Source: IMS Health, J.P. Morgan estimates*
2011 IMS Sales By Therapeutic Area ($ bil)

- Oncologics: $23
- Respiratory Agents: $21
- Lipid Regulators: $20
- Antidiabetes: $20
- Antipsychotics: $18
- Autoimmune: $12
- Antidepressants: $11
- ADHD: $10
- Anti-Ulcerants: $10
- Narcotic analgesics: $8
- Angiotension II: $8
- Multiple Sclerosis: $8
- Vaccines: $6
- Anti-epileptics: $6
- Erythropoietins: $5
- Immunostimulating Agents: $5
- Hormonal Contraceptives: $5
- Antivirals (ex-HIV): $4

Source: IMS Health
2011 IMS Sales By Therapeutic Area (% Chg. Yr/Yr)

- Multiple Sclerosis: 24.6%
- Antidiabetes: 16.0%
- Antivirals (ex-HIV): 15.6%
- Autoimmune: 13.2%
- Antipsychotics: 13.0%
- HIV: 12.0%
- Vaccines: 10.5%
- Antiplatelets: 9.9%
- ADHD: 9.7%
- Respiratory Agents: 8.8%
- Hormonal Contraceptives: 7.1%
- Lipid Regulators: 6.9%
- Anti-epileptics: 5.4%
- Oncologics: 4.0%
- Narcotic analgesics: (1.2%)
- Antidepressants: (5.2%)
- Angiotension II: (12.6%)
- Erythropoietins: (14.8%)
- Anti-Ulcerants: (15.1%)
- Immunostimulating Agents: (16.4%)

Source: IMS Health
Biotechnology Drugs Currently in Development

- Cancer/Related Conditions: 352
- Infectious Diseases: 188
- Autoimmune Disorders: 69
- Cardiovascular Disease: 59
- Neurologic Disorders: 44
- Respiratory Disorders: 40
- HIV Infection: 39
- Blood Disorders: 32
- Skin Disorders: 28
- Digestive Disorders: 27
- Diabetes/Related Conditions: 24
- Musculoskeletal Disorders: 22
- Eye Conditions: 20
- Generic Disorders: 19
- Transplantation: 18
- Growth Disorders: 5
- Other Diseases: 36

Source: PhRMA. Note: Data from October 2011.
## Selected Specialty Drugs in Development

<table>
<thead>
<tr>
<th>Name</th>
<th>Indication</th>
<th>Innovator</th>
<th>Event / Stage</th>
<th>Est. Timing</th>
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<tbody>
<tr>
<td>Bronchitol</td>
<td>Cystic Fibrosis</td>
<td>Pharmaxis</td>
<td>NDA/BLA</td>
<td>1H12</td>
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<td>Vyndaqel</td>
<td>transthyretin familial amyloid polyneuropathy</td>
<td>Pfizer</td>
<td>FDA panel</td>
<td>May-12</td>
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<td>BG-12</td>
<td>Multiple Sclerosis</td>
<td>Biogen</td>
<td>NDA</td>
<td>May-12</td>
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<tr>
<td>MDV3100</td>
<td>oncology: prostate cancer (post-chemo)</td>
<td>Medivation</td>
<td>NDA</td>
<td>2Q12</td>
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<td>PD-1</td>
<td>oncology</td>
<td>Bristol</td>
<td>clinical data</td>
<td>June 2012</td>
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<tr>
<td>Regorafenib</td>
<td>oncology: colorectal cancer</td>
<td>Bayer</td>
<td>NDA/BLA</td>
<td>June 2012</td>
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<tr>
<td>tivozanib</td>
<td>oncology: renal cell carcinoma</td>
<td>Aveo</td>
<td>Phase III results</td>
<td>June 2012</td>
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<tr>
<td>carfilzomib</td>
<td>oncology: multiple myeloma</td>
<td>Onyx</td>
<td>PDUFA</td>
<td>July 2012</td>
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<td>tofacitinib</td>
<td>Rheumatoid Arthritis</td>
<td>Pfizer</td>
<td>PDUFA</td>
<td>Aug 2012</td>
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<td>QUAD</td>
<td>HIV</td>
<td>Gilead</td>
<td>PDUFA</td>
<td>Aug 2012</td>
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<td>Zaltrap</td>
<td>oncology: metastatic colorectal cancer</td>
<td>Regeneron</td>
<td>PDUFA</td>
<td>Aug 2012</td>
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<td>bapineuzumab</td>
<td>Alzheimer's</td>
<td>Pfizer</td>
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<td>2012</td>
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<td>solanezumab</td>
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<td>Lilly</td>
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<td>2H12</td>
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<td>Phase III data</td>
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<td>Amigal</td>
<td>Fabry</td>
<td>Amicus</td>
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<td>dexamprimpexole</td>
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<td>Biogen</td>
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<td>2H12</td>
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<td>Factor IX/Factor VIII</td>
<td>hemophilia</td>
<td>Biogen</td>
<td>Phase III data</td>
<td>2H12</td>
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</table>

Source: Company reports and J.P. Morgan Biotechnology team.
Great Sources of Data
Specialty Pharmacy Times

New Frontiers in Retail

Opportunities and Challenges:
- Launching a New Specialty Product?
- Entering the Specialty Pharmacy Market?
- Growing a Specialty Pharmacy Business

PLUS
- Compliance Corner: What Keeps You Up at Night?
- Specialty Pharmacy: An Industry at Warp Speed
- The Remaking of Specialty Pharmacy
Specialty Pharmacy in Community Pharmacy: The Time is Now and How!

Dan Steiber, R.Ph
Dean P. Erhardt, M.B.A.

D2 Pharma Consulting LLC

Prepared on behalf of the NACDS Pharmacy Industry Council Supply Chain Committee
Evolution in Specialty Pharmacy

- Many new “entrants” to the specialty arena
  - Retail Chains
  - Infusion Providers/ Networks
  - HUB’s
  - GPO’s on behalf of membership
- New models focusing on “local” service vs National
- REMS dynamic is affecting all aspects of the supply chain and solutions have emerged to meet the new requirements
- Payors are revisiting “local” specialty solutions for available products
Specialty Mail Pharmacy Market Share, 2011

Total Addressable Market = $48.2 billion

- Express Scripts: 28%
- CVS Caremark: 17%
- Walgreens: 8%
- Diplomat: 2%
- Omnicare: 1%
- Total other: 44%

Source: Company reports, J.P. Morgan estimates. Note: Express Scripts includes Medco and Walgreens includes BioScrip assets.
Industry Specialty Pharmacies......today

<table>
<thead>
<tr>
<th>WHOLESALER OWNED</th>
<th>PBM OWNED</th>
<th>RETAIL OWNED</th>
<th>MANAGED CARE HYBRID</th>
<th>ONCOLOGY FOCUS</th>
<th>NICHE</th>
<th>INDEPENDENT</th>
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<td>AmerisourceBergen</td>
<td>Express Scripts</td>
<td>CVS/ Caremark</td>
<td>Wellpoint</td>
<td>OncoMed</td>
<td>Centric</td>
<td>Acaria Health</td>
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<td>US Bioservices SP</td>
<td>CuraScript SP</td>
<td>Caremark SP</td>
<td>PrecisionRx</td>
<td>Biologics</td>
<td>Foundation Care</td>
<td>Amber</td>
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<td>ICS (3PL)</td>
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<td>Caremark PBM</td>
<td>Aetna</td>
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<td>Axium HC</td>
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<td>Caremark SD</td>
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<td>BioPlus</td>
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<td>HealthBridge (HUB)</td>
<td>Proherant (HUB)</td>
<td>Cigna</td>
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<td>Coram Rx</td>
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<td>Value Drug</td>
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<td>Value SP</td>
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</tbody>
</table>

... Many others
Model # 1: Exception / Central Fill

THE CHAIN WILL HAVE A FULLY OWNED CENTRAL FILL SP PHARMACY (HUB) THAT IS TIED TO THE PHARMACY DISPENSING PLATFORM. THE HUB WILL PROVIDE SERVICES TO THE RETAIL SITES AND TO THE PATIENTS.

**PROS**
- POSITIVE Sell to Pharma, Payors
- Good Control
- Best Data
- Consistency of Services (at HUB)
- Easier Contracting vs Trad Retail
- Good Patient Options/ Customer Svc

**CONS**
- Pt Home Delivery Decreases Store Sales
- State Regulations may Prohibit
- Service Issues/ Resolution Difficult
- RPH Training and Education

**MODEL THAT IS GAINING TRACTION**
ONLY WHEN CONTROLS ARE TANGIBLE
Model # 2: Exception / BOSP

**THE CHAIN WILL HAVE AN OUTSOURCED BACK-OFFICE SERVICE PROVIDER**
**THAT WILL PROVIDE EXPERTISE IN:**
Benefits Investigation, Compliance, Education, Medical Billing, and 24/7 Availability

**PROS**
- Experts Doing BI = Lower A/R Risk
- Less Employee Overhead
- No IT Build-out Needed
- Consistency of Services (at BOSP)
- Compliance Services Pay for Itself
- Good Patient Customer Service: 24/7

**CONS**
- Pts Must Opt IN
- HIPAA concerns
- Service Issues/ Resolution Difficult
- RPH Training and Education
Model #3: WHOLESALE COOP - BOSPSP

NON-COMPETITIVE ENVIRONMENT CREATES EFFICIENCIES

→ BOSPSP – Back Office Specialty Pharmacy AND Service Provider

PROS
- Lower A/R Risk
- Less Employee Overhead
- No IT Build-out Needed
- Consistency of Services (at BOSP)
- Competitive Pricing to Payers
- Good Customer Service: 24/7

CONS
- STATE REGS ON RX DELIVERY
- HIPAA concerns
- Service Issues/Resolution Difficult
- MANY OWNERS

INDEPENDENT COOP MEMBER WINS

VALUE DRUG COMPANY

ELSEVIER
Model # 4: GPO- BOSPSP

THE GPO-BOSPSP OFFERS “OPTIONS” FOR HOSPITALS BASED UPON CAPABILITIES

BOSPSP – Back Office Specialty Pharmacy AND Service Provider

**PROS**
- CAN SEND ALL RXS TO GPO-BOSPSP
- CAN SEND 1st FILL TO GPO-BOSPSP
- CAN SEND SELECTED RX / PRODUCT TO GPO-BOSPSP
- PHARMACIES PROVIDED LIST OF SP PRODUCTS & DISEASE CATEGORIES
- INSTRUCTIONS TO “ENROLL” PT IN SERVICE
- OUTSOURCED BENEFITS INVESTIGATION TRIAGE TO GPO-BOSPSP
- OUTSOURCED PT EDUCATION: 24 / 7 / 365 AVAILABILITY AT GPO-BOSPSP
- OUTSOURCED COMPLIANCE PROGRAM VIA GPO-BOSPSP
- INVENTORY PROCUREMENT VIA PHARMACY IF ELIGIBLE w/ BOSPSP ASSISTANCE
- PROVIDES SHARPS CONTAINERS, SYRINGES, Etc.
- PROVIDES SOME EDUCATIONAL MATERIALS/ OTHER PROVIDED BY BOSPSP
- DATA OWNED BY PHARMACIES BUT AGGREGATED BY BOSPSP

**CONS**
- Pts Must Opt IN
- HIPAA concerns/ Data Aggregation
- Service Issues/ Resolution Difficult
- RPH Training and Education

**GOOD PHARMA VALUE PROP**
- Experts Doing BI = Lower A/R Risk
- Less Employee Overhead
- No IT Build-out Needed
- Consistency of Services
- Allows Hosp to “Keep” Pt (lab, infu, )
- Good Patient Customer Service: 24/7
Model # 5: Retail/Infusion BOSP

**PROS**
- Good Payor Option
- Experts Doing BI = Lower A/R Risk
- Less Employee Overhead
- Minimal Franchise Cost
- Ongoing Ops Support
- Sales & Marketing Included
- Multiple NABP #, Class of Trade

**CONS**
- Franchise Participation in Offerings
- HIPAA Concerns
- Service Issues/Resolution Difficult
- RPH Training and Education
- Consistency of Services

**ALLOWS INDEPENDENT BUSINESS EXTENSION WITH MINIMAL INVESTMENT**

**PREPARES FOR FUTURE:**
THE BLUR OF SP AND Infusion Pharmacy

Vital Care©
Home Infusion Services
Specialty Trends Summarized

- Supply Chain efficiency trends will continue and thus influence access to products across all stakeholder channels.

- Consolidation will continue: Regional Pharmacies, Infusion Pharmacies, Service Providers in the specialty space.

- REMS requirements will be required for 40% of new products and thus influence access to products across all stakeholder channels.

- New Specialty Models are emerging/taking hold:
  - Retail - Central Fill models (owned or subcontracted)
  - Regional Niche SP’s

- SP’s look to diversify portfolio/offers:
  - To drive additional revenue and provide solutions to Pharma: 3PL, Wholesale/SD, Infusion, LTC, Transportation, HUB, PAP, Devices, etc.
Specialty Trends Summarized

- **Compliance & Persistency/Adherence / MPR**
  - Vital to the success of SP’s longevity
  - Cost to start a patient increasing: Copay, increasing PA’s, REMS, data capture requirements complexities
  - Most SP’s break even on first fill or lose money

- **Pharma seeking more customized solutions: SPP’s responding**
  - To meet FDA control requirements
  - Desire for “higher touch services” (overall)
  - Desire for “higher touch services” at a local level (if measureable and easy)
  - “Minute Clinic Solutions”: injection training, education, infusions, DME

- **Local Payor solutions starting to gain traction**
  - Payers opening up local specialty providers
  - Employers looking to keep in state providers
  - New products require local urgent services
How a manufacturer Selects an SP

BEST PRACTICE
Launching a New Specialty Product? How to Select a Specialty Pharmacy

Dan Steiber, RPh

One of several decisions a manufacturer must make when launching a new product is its distribution strategy. Specialty pharmacy offers a greater level of complexity and a longer time frame. Typically, a manufacturer contemplating a distribution strategy for the launch of a new product should be in the planning phase no sooner than 24 months from its launch date. A number of critical variables need to be weighed when selecting a strategy and the manufacturer’s team should be evaluating these often, led by the supply chain team. If a manufacturer does not have a team in place, there are a handful of experienced consultants that can drive the process of strategy, selection, and implementation.

IS IT SPECIALTY?

Specialty pharmaceuticals are generally defined as products used to treat chronic, high-cost, or rare diseases and can be injectable, inhaled, oral, or inhaled medications. Specialty pharmaceuticals tend to be more complex to maintain, administer, and monitor than traditional drugs; therefore they require closer supervision and monitoring of a patient’s overall therapy. Key characteristics include:

- Frequent dosage adjustments
- Dosage administration of injectable and infusible product
- More severe side effects than traditional drugs
- Special storage, handling, and/or administration
- Narrow therapeutic range
- Periodic laboratory or diagnostic testing
- Higher costs than “traditional” products ($10,000 to $100,000 annually)
- Target small numbers of patients (5000 to 10,000)

Other specialty pharmaceuticals can be broken down into 4 distinct categories. They are commonly defined and/or classified by the method of administration and these often drive a plan around the use of specialty pharmacy:

- Office-administered injectable products
- Self-administered injectable products
- Clinic/office-administered infusible products
- Select oral agents

Newer criteria around the need for specialty pharmacy have also emerged, including:

- Enhanced data
- REMS management
- Inventory management
- Coordination of care
- Testing management
- Reimbursement handling and patient assistance
- White and brown tagging needs

IS SPECIALTY PHARMACY THE RIGHT CHANNEL FOR YOUR PRODUCT?

Specialty pharmacy is defined as the service created to manage the handling and service requirements of specialty pharmaceuticals including dispensing, distribution, reimbursement, case management, and other services specific to patients involved with rare or chronic diseases. Specialty pharmacy, therefore, is a service that endeavors to provide 2 key deliverables: 1) A mechanism to manage the cost of specialty pharmaceuticals for the patient; and 2) An opportunity to save money for the benefit sponsor compared with traditional models in which products are delivered through less efficient means, primarily the hospital or physician offices.

A critical step in the selection process is the development of a Request for Proposal (RFP). As we’ve seen, specialty pharmacy offers a menu of services, therefore determining which services best fit your product’s needs is crucial.

Since specialty pharmacies usually fill a prescription on the day it is received, products are generally distributed by third-party carriers such as FedEx or UPS. Typically, products are delivered the next day to the patient, or in the case of “White tagging,” to the caregiver.

Specialized handling is often required for controlled products and cold chain products, for example, biotech injectables and other similar products. One key shipping requirement is that products must be maintained at the proper temperature levels. Products remain refrigerated while in the pharmacy’s inventory and are shipped to patients in special packaging, typically containing refrigerated gel packs.

“Kitting” or providing the patient/caregiver all of the essentials is done to assure that the patient/caregiver has all the necessary equipment to reconstitute and administer the product, and also dispose of any waste, including needles, vials, syringes, infusion pumps, puncture-resistant containers, etc. Pharmacies work with patients to set up inventory management programs, utilizing just-in-time delivery processes that eliminate the need to maintain a large inventory, ensuring the stability of the product on hand.

REIMBURSEMENT CHALLENGES

Reimbursement for specialty drugs can be extremely challenging, mainly due to product costs and the duration of therapy. Often specialty pharmacies take on the assignment of benefits or take on the burden of obtaining reimbursement by billing the insurance companies directly. Patients benefit by eliminating the claims process and the associated risk of nonreimbursement, as so many of these product have complex reimbursement and high product costs.

Additionally, specialty pharmacies will verify insurance coverage on the assignment of patients, eliminating potential challenges.

Specialty pharmacy provides a high-touch environment for better patient care and adherence. For example, patient hot-
Distribution Scenarios for Biotech Products

What has the market taught us to date?

Open/Retail

Specialty/Open

Hybrid

Specialty/Limited

Specialty/Exclusive
Therefore often look to outsource:

🌟 • Logistics
🌟 • Packaging and Labeling
🌟 • Customer Service
🌟 • Account Management (AP/AR)
🌟 • Reimbursement Support
🌟 • REMS/ Registry Programs
  • Product Allocation Programs
  • Patient Assistance Programs
🌟 • Sampling
🌟 • Field Sales
🌟 • Clinical Support to Patient
🌟 • Medical Affairs
  • Marketing Development
  • Literature Fulfillment
  • Contract Sales and Marketing
  • Other, Starter Kits, Gap

🌟 = SP (‘s) with other Pharma Services can provide assistance or manage
Recommended Approach use and RFP

Pharma SHOULD utilize RFP process for:

- Documentation of company “viability”
- Education and documentation of capabilities (internally)
- Departmental inquiries/ focus areas
- Documentation for FDA/ REMS submissions
- Verification of pricing methodology
- Pricing for services/ benchmarking
- Future reference at manufacturer – sets best demonstrated practice
RFP Categories

- Pricing/ Methodology
- General Information
- Operations/ Reimbursement
- Accreditation (URAC)
- Inventory Management
- REMS
- Quality: Metrics, SOPs
- Clinical
- Sales
  - Payor
  - Pharma: act mgmt
  - Field
  - Telephone
- 24/7/365 services
- Web
  - MD Portal
  - Pharma Portal
  - Payor Portal
  - Patient Portal
  - Information
- Data capture and reporting
  - Aggregators (IMS)
  - Direct to Pharma
  - Direct to HUBS
  - Other
- Customer Service Metrics
Specialty Contracting Trends

- Previously focus was up-front discount, rebates for market share and volume discounts/rebates
- Shift towards performance based bona fide services
- Most new contracts are fee for service at fair market value
- Old established contracts slowly converting to FFS at FMV
- May take years for full Manufacturer conversion
- Some Manufacturers resistant to methodology change
Fair Market Value, Part 2: Embracing the Practice

David M. Suchanek, RPh

In our last article, “Navigating the Perils of Fair Market Value” (Specialty Pharmacy Times, October 2010), we reviewed and defined Fair Market Value (FMV), bona fide services, and how organizations can establish a process and create a benchmark of their service offerings. The overall intent of the FMV contracting methodology is to bring clarity and transparency to the financial relationship between 2 contracted organizations. This sounds easy in principle, but the reality is that due to the wide variety and complexities of products and their required services, it is not so black and white. So how can a pharmacy or pharmaceutical manufacturer put policies in place to adhere to the interpretation of the law?

The first step for a pharmacy is to embrace the contracting practice and methodology of Fee For Services (FFS) at FMV. This can be difficult for pharmacies to fully execute as some pharmaceutical manufacturers have not yet transitioned or are partially transitioned to FFS contracts, but the trend is certainly shifting towards more transparent and benchmarked processes. Many manufacturers over the past 18 to 24 months have been steadily researching ways to properly transition contracting methodologies, and are also evaluating services and their associated fee structures. This is partially due to general awareness of these trends, but more recently there has been a dramatic shift and urgency to the process.

Why? There is a perception that this is partially due to the awareness of “new” government practices. Numerous articles have discussed how the government is now enforcing the practice of holding pharmaceutical manufacturer executives accountable for “misbehavior” on their watch. This bold step has direct repercussions for the manufacturer and all of its vendors down the entire supply chain.

If a manufacturer is held accountable for violations of health care laws, the organization or executives could be excluded from participation in any federal health-related programs—meaning Medicaid, Medicare, and an extensive list of other federally sponsored programs. As such, anything that touches a government program is being re-reviewed internally at most manufacturers. With state, federal, and employer budget shortfalls continuing, pharmaceuticals prices/contracts and related services are targets of focus. When audits occur, any participant in the supply chain can be impacted.

Many manufacturers over the past 18 to 24 months have been steadily researching ways to properly transition contracting methodologies.

The second step for a pharmacy is:

1. Identify current services offered to the marketplace
2. Stratify/break down services into basic (offered to everyone), enhanced, and custom
3. Investigate the internal cost of each service
   • This will serve as your internal benchmark for the low end of your organization’s FMV range
4. Make sure no fees are for referrals or the marketing/promotion of the product
5. Make sure services are bona fide and have a commercial need
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THANK YOU...
Fair Market Value: Why?

- Fair market value is a business valuation concept that has **significant implications** for transactions involving health care providers. The definition of fair market value for general business valuation purposes is considered the price at which property would change hands between a hypothetical willing and able buyer and a hypothetical willing and able seller, acting at arms-length in an open and unrestricted market, when neither is under compulsion to buy or sell and when both have reasonable knowledge of the relevant facts.

- Nearly every health care business transaction must be **based on some measure of fair market value**. Setting a transaction at fair market value attempts to ensure the price paid will be comparable to that which would typically be paid by unaffiliated third parties. The need to set a health care transaction at fair market value can come from a number of sources. Fair market value can be defined and measured in a number of ways. Federal fraud and abuse laws, such as the **Stark law and Anti-Kickback statute**, generally require contract terms to be set at fair market value if referrals occur between the contracting parties for services reimbursed by federal health care programs. Fair market value issues also arise in transactions involving tax exempt entities.