

What's So Special About Specialty Pharmacies? Overview and Role of Pharmacists and Pharmacy Technicians

Implementation of a Specialty Pharmacy Program


NISHP Meeting
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The speaker has no conflicts to disclose.
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Overall Learning Objectives


For Pharmacists and Pharmacy Technicians:

1. Describe the function of a specialty pharmacy
2. Outline the impact of specialty pharmacies on patient care
3. Explain the role of a pharmacist and technician in a specialty pharmacy.


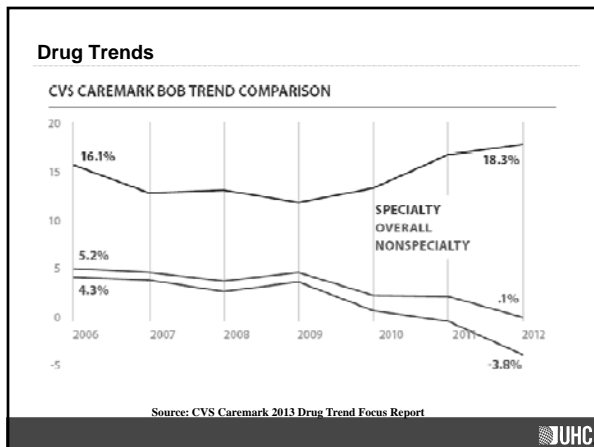



Specialty Pharmacy Marketplace Overview

How large is the specialty pharmaceutical market?



- \$92.2B in 2013 according to IMS
- 27.6% of the US pharmaceutical market
- Anticipate SP > 30% of market in 2014 with Solvaldi/Olysio Hep C sales of \$6.15B through Q2
- 80,000 of 3.5M Hep C patients treated – 2015??

Top specialty classes dollar sales - 2013

	Sales (\$MN)	Share	Growth
U.S. Specialty Market	92,216	100.0%	7.6%
Oncology	27,878	30.2%	9.2%
Autoimmune	17,861	19.4%	18.0%
HIV Antivirals	12,365	13.4%	10.0%
Multiple Sclerosis	9,683	10.5%	10.6%
Hematopoietic Growth Factors	4,714	5.1%	3.2%
Erythropoietin Products	4,151	4.5%	-0.6%
Other Immunosuppressants	2,320	2.5%	3.3%
Viral Hepatitis Products	1,936	2.1%	-33.5%
Polyval immunoglobulins IV IM	1,894	2.1%	-3.0%
Growth Hormones	1,618	1.8%	5.8%
Top 10	84,421	91.5%	8.2%

Source: IMS Health, National Sales Perspectives, Jan 2014




Breakthrough pharmaceuticals with limited distribution supply channels is growing

July 2013



Specialty Pharmacy Drug List

Providing one of the broadest offerings of specialty pharmaceuticals in the industry

If you are a plan member or health care provider, please contact Specialty Customer Care toll free at 1-800-237-2787 or visit www.cvs-caremark-specialty.com

With nearly 25 years of experience, CVS Caremark Specialty Pharmacy provides quality care and service. We have a network of pharmacies which includes those with Joint Commission and URAC accreditation. The Joint Commission and URAC are nationally recognized symbols of quality which reflects an organization's commitment to meet high standards of quality and safety.

ADRENAL ACTONIS (ACTO) (SARIGOSTATIN) Sandostatin LAR Somatropin Depot Somavert	DUPYRRENE CONTRACEPTIVE Xelara Xelara	HEMOPHILIA, acute Kogenate FS Atonase Atonase Novoclenet Pralfiumin SD Pralofer 1 Pralofer 2 Hematec Hematec Zimelis Zimelis	HIV MEDICATIONS Abacavir (Abi) (ABICAVIR) Atrinis Atrinis Combiata Crixivan Dolutegravir (VIVEN) VIVENECY	HORMONAL THERAPIES Ciglit Arimidex aromatase inhibitor (LUPRON) Lupron Depot Suprovis LA Tostol Vantas Vantas Zoladex Zoladex
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Summary: 290 → 353 products – 84 → 114 LD 29 → 32% LD



Access to Specialty Drugs

Oral Therapies

Gilotrif \$5500	Zydelig \$7200 LD	Tafinar \$7600 LD	Imbruvica \$8200 LD	Mekinst \$8700 LD	Polamyst \$10,500 LD	Keytruda \$12,500 LD	Zykadia \$13,200 LD
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Injectable Therapies

Beleodaq Not on market yet	Gazyva \$6880	Sylvant \$7250	Kadcyla \$9800	Cyramza \$13,000
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What are the top specialty drug categories?

- A. Limited Distribution Specialty Pharmaceuticals
- B. Biosimilars
- C. Oncology, Multiple Sclerosis, Autoimmune, HIV and HCV therapies
- A. Immune Globulin, Growth Hormone, & Insulin

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Specialty Pharmacy Vertical Alignment

Payer	PBM	Provider	Wholesaler	Retail	Independent
Aetna	acredo	Wake Forest Baptist Health	AmersourceBergen	CVS	Avelta
Aetna Health	briova	Shields	Cardinal Health	CVS	Biologics
Blue Cross of Michigan	CVS CAREMARK	PARSONS BRINCKERHOFF	Cardinal Health	CVS	ACS
Blue Cross of Michigan	CVS CAREMARK	KENTUCKY ALCALOID	Cardinal Health	CVS	BioPlus
Blue Cross of Michigan	CVS CAREMARK	CVS	Cardinal Health	CVS	Amber Pharmacy
HUMANA	CVS CAREMARK	CVS	Cardinal Health	CVS	COHAMIX
OptumRx	CVS CAREMARK	CVS	Cardinal Health	CVS	Diabetes
OptumRx	CVS CAREMARK	CVS	Cardinal Health	CVS	Onco360
OptumRx	CVS CAREMARK	CVS	Cardinal Health	CVS	Overstock
OptumRx	CVS CAREMARK	CVS	Cardinal Health	CVS	OncoSource Rx
OptumRx	CVS CAREMARK	CVS	Cardinal Health	CVS	SALVEO

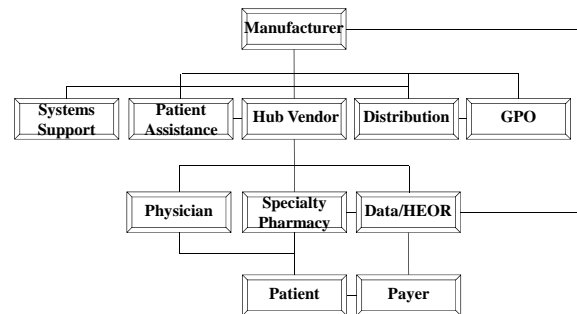
Why manufacturers and insurers choose Specialty Pharmacy providers

- Eliminate distribution costs
- Access to data
- REMS
- Integration with a reimbursement hub
- Training patients on how to self-administer drugs
- Advising health plan providers on how to manage and implement access to new pharmaceutical products as they enter the marketplace
- Finding co-payment assistance or alternative coverage for the patient
- Perception of increased quality of patient management

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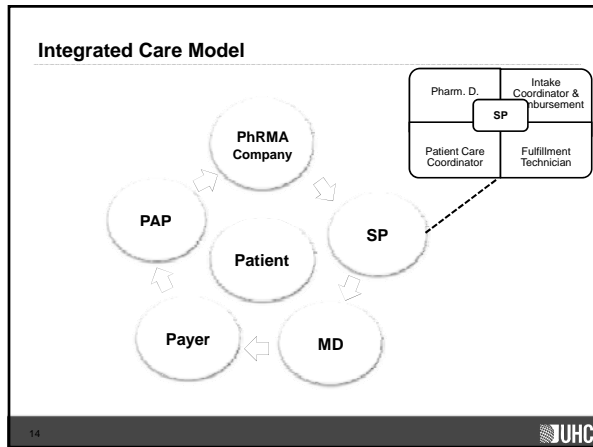
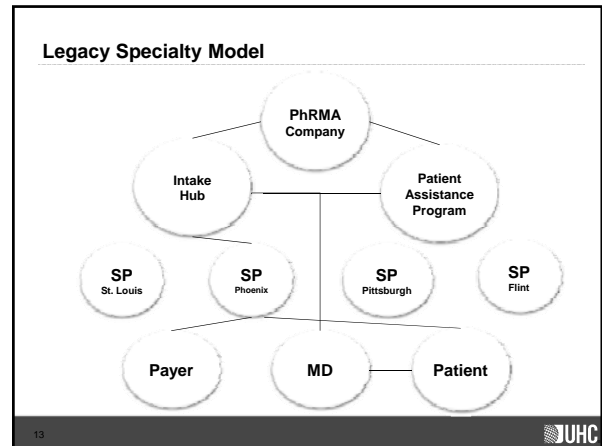
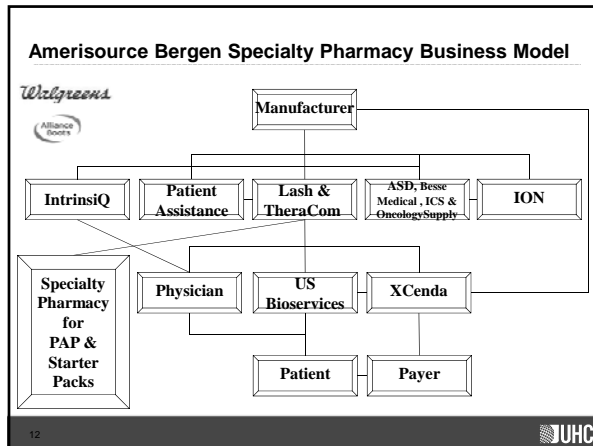


Specialty Pharmacy Business Model



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Motives for AMC's to establish Specialty Pharmacy Programs

- Eliminate care fragmentation & improve the patient experience
- Excel at complex care management
- Push to initiate outpatient therapy during an inpatient stay due to delays in the current system
- Quality improvement

Improvement in Safety Monitoring of Biologic Response Modifiers After the Implementation of Clinical Care Guidelines by a Specialty Pharmacy Service in an Academic Health System

Rebekah L. Hansen, PharmD, BCPE, BCAGP; Michael J. Cannon, BS; Nichole Khanna, PharmD; Michael Rizzo, PharmD, MSc; PDC; Alexander M. Cho, PharmD; and John Huddings, BS Pharm, MHA

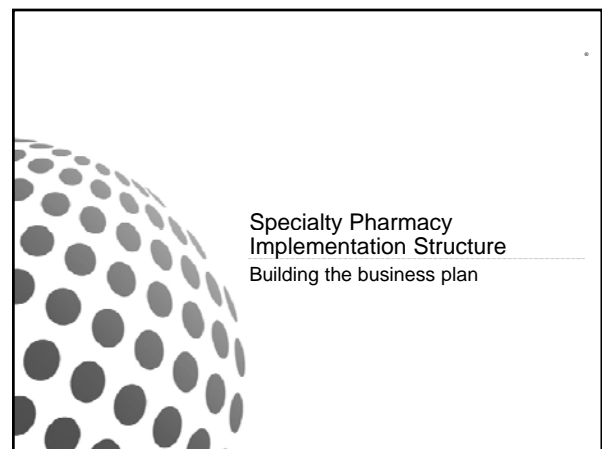
ABSTRACT: [Small text describing the study's purpose and findings]

BACKGROUND: [Small text describing the clinical context]

CONCLUSIONS: [Small text summarizing the study's conclusions]

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- ### What are the primary functions of a specialty pharmacy?
- Fill mail order prescriptions and provide patient counseling
 - Provide a supply channel that reduces distribution costs for manufacturers and reduces 340B exposure
 - Reduce fragmentation of care, assist patients with access and affordability, and provide ongoing clinical management
 - Provide another source of profitability for the health system
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Planning Infrastructure

Step 1: Establish the Business Planning Committee

- Include administrative sponsor, pharmacy leadership, key specialty medical staff leadership, contracting and finance

Step 2: Perform an internal and external situational analysis

- Visit other programs
- Meet with oncology, GI, rheumatology, neurology, hepatology & other clinic staff to determine current hub & referral systems being utilized and the unmet need for coordinated care
- Meet with contracting department to determine price pressure placed by payers on clinic administered drugs & specialty pharmaceuticals

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Planning Infrastructure

Step 3: Determine your current state and any additional revenue opportunities

- Determine the number of Rx's generated and estimate the revenue impact
 - Consultants are available to assist – Visante, Therigy, D2 Consulting
- Perform an analysis of 340B impact
 - Review number of clinics listed as child sites for 340B
- Perform an analysis of payer mix in each clinic

Payer	Percent Payer Mix(%)										
	MS	Rheum	GI	Hep	SOT	ONC	HW/ID	CF	Endocrin	Neph	PH
BCBS	42.6	28.3	29.2	15.9	20.0	30.6	22.1	22.2	24.9	12.7	32.6
Commercial	1.7	0.4	0.5	0.7	0.8	0.8	2.1	0.4	0.8	0.6	0.7
HMO/PPO	21.8	15.0	18.9	8.9	8.0	11.2	13.8	13.0	12.9	7.4	19.3
Medicaid	8.9	16.2	10.1	30.2	20.2	15.9	28.0	16.5	15.6	12.8	7.3
Medicare	23.3	36.2	34.5	38.3	48.7	38.7	31.0	44.1	40.6	57.0	32.2
Self Pay	1.7	3.9	6.8	6.0	2.3	2.8	3.0	3.8	5.2	9.5	7.9

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Planning Infrastructure

Step 4: Determine what is required to establish a SP program in your institution

- Current retail pharmacy structure & services
 - Prepare a list of support services (benefits investigation, PA, PAP, billing & collection, call center, and case management)
 - Prepare a list of fulfillment services (drug access, payer contracts, marketing materials, care coordination, delivery, REMS, prescription renewal)
 - Determine if information systems and facilities are adequate
- Explore accreditation requirements for managed care contracting
- Determine if you have adequate management, clinical & support personnel

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Planning Infrastructure

Step 5: Develop a Marketing Plan

- Define your target market
 - Orals and self-administered injectables vs. infusion
 - Medicare Part D open access
 - Medicaid
 - Access PSAO contracts
- Determine top insurers & assess specialty network (Chicago)
 - PPO market – BCBS (80%) & Aetna (11%)
 - HMO market – BCBS (88%) & Humana (8%)
 - POS market – United Healthcare (64%) & Cigna (35%)
- Determine key employers (Chicago & Suburbs)
 - US Government
 - Chicago Public Schools & City of Chicago
 - Cook County
 - Advocate healthcare
 - Archers Daniel Midland
 - Boeing
 - Walgreen Co.
 - Caterpillar

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Planning Infrastructure

Step 6: Develop a Financial Proforma

- Gross profit analysis by clinic
 - Investigate Hep C opportunity

Preliminary Three Year Growth Model: Annual Revenue & Expense FY18 - FY16 Medicare & Medicaid Market Share 15-55% Capture				
	FY18	FY19	FY20	FY21
Revenue				
Gross Revenue - Rheumatology/GI	\$ 4,009,000	\$ 4,614,270	\$ 5,174,000	\$ 5,774,000
Gross Revenue - Multiple Myeloma	\$ 1,033,750	\$ 4,182,360	\$ 1,188,000	\$ 1,188,000
Gross Revenue - GI/Hepatology	\$ 303,100	\$ 1,108,180	\$ 1,351,250	\$ 1,351,250
Gross Revenue - Non Oncology	\$ -	\$ 492,400	\$ 492,400	\$ 492,400
Gross Revenue - Solid Organ Transplant	\$ -	\$ 432,000	\$ -	\$ 432,000
Gross Revenue - HIV	\$ -	\$ -	\$ 1,512,000	\$ 1,512,000
Gross Revenue - Case Management Fees	\$ 198,300	\$ 79,400	\$ 79,400	\$ 79,400
Net Revenue	\$ 5,642,150	\$ 10,996,610	\$ 10,189,050	\$ 10,189,050
Total Payers	\$ 5,642,150	\$ 10,996,610	\$ 10,189,050	\$ 10,189,050
Expenses				
Salaries and Benefits	\$ 3,000,000	\$ 3,000,000	\$ 3,000,000	\$ 3,000,000
Other Expenses	\$ 1,000,000	\$ 1,000,000	\$ 1,000,000	\$ 1,000,000
Total Direct and Indirect Expenses	\$ 4,000,000	\$ 4,000,000	\$ 4,000,000	\$ 4,000,000
NET OPERATING INCOME	\$ 1,642,150	\$ 6,996,610	\$ 6,189,050	\$ 6,189,050
FINANCIAL CASH FLOW OPERATIONS	\$ 1,642,150	\$ 6,996,610	\$ 6,189,050	\$ 6,189,050
Operating	\$ 1,642,150	\$ 6,996,610	\$ 6,189,050	\$ 6,189,050

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Planning Infrastructure

Step 7: Initiate program

- Determine scope - # of specialty clinics included
- Allocate space & equipment
- Determine if start-up consulting is needed
- Hire manager, clinical & support staff
- Determine what additional IT support systems are needed
- Send staff for training to another specialty program
- Prepare policies & procedures
- Develop case management protocols
- Meet with PhRMA – learn about programs & hub requirements for patient assistance programs
- Kick off meetings with specialty clinic business staff, nursing & medical staff leadership – determine workflow in the clinic & how pharmacy will fit in.

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Systems Infrastructure Required



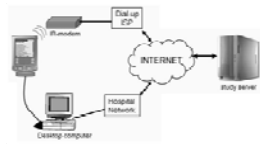
Call Center



Specialty Rx, Clinical Staff & Mail Order Services



Case Management System



Data Transmission to MFT

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Which of the following systems infrastructure is not to operate a specialty pharmacy?

- A. Case Management System
- B. Separate retail facility
- C. Clinical Staff
- D. Call Center

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Summary

- Determine what is the single most important aspect of your business plan
- Identify members of your organization that will need to be convinced – seek alignment of stakeholders
- Ask finance to prepare the financials in the manner they are accustomed to using.
- If a quick start is needed, consider consultants
- Hire a manager with ambulatory care and contracting experience
- Place clinical staff in the clinics to capture referrals.

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What's So *Special* About Specialty Pharmacies?

Overview and role of pharmacists and pharmacy technicians

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Clinical Pharmacy Specialist
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Disclosure

- I have no conflict of interest in relation to this activity.

Objective

- Explain the role of a pharmacist and pharmacy technician in specialty pharmacy.

Specialty Pharmacy Mission

- To provide medication management services to patients with chronic diseases
- To provide patient case management and high touch services to patients requiring complex therapies

The Players

- Patient
- Provider
- Payors
- Pharmacists
- Pharmacy technicians

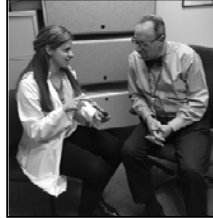
Core services - Pharmacist

- Clinical assessments
 - Order accuracy
 - Baseline labs
 - Drug-drug interactions
 - Drug-disease interactions



Core services - Pharmacist

- Benefits investigation
 - Ensure access
 - Prior authorizations
 - Medical necessity letters
 - Peer to peer reviews
- Patient education
 - Injection training
 - Medication education
 - Disease state education



Core services - Pharmacist

- Ongoing assessments
 - Adverse effect management
 - Therapy adjustment
 - Medication adherence
 - Re-education

Audience Question

Which of the following does NOT describe a potential role of a specialty pharmacist?

- A. Recommending the titration of an interferon to minimize flu-like symptoms.
- B. Completing a peer-to-peer review to resolve the denial of a medication.
- C. Treating active tuberculosis prior to initiation of a TNF-alpha blocker.
- D. Recommending influenza vaccination prior to initiation of TNF-alpha blocker.

Core services – Pharmacy Tech

- New patient enrollment
 - Patient entry
- Benefits Investigation
 - Perform insurance verification
 - Initiate prior authorizations
 - Obtain financial assistance
 - Patient assistance programs

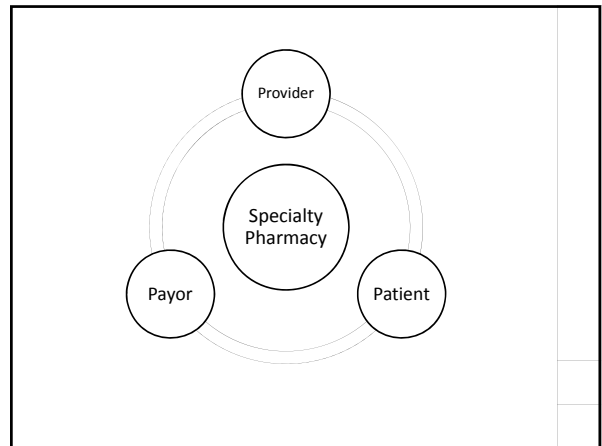
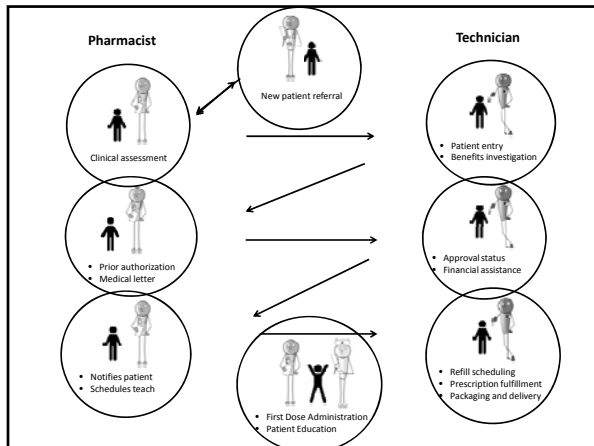
Core services – Pharmacy Tech

- Prescription management
 - Order Processing
 - Packaging
 - Delivery
- Refill Management
 - Manage calendars
 - Reminder calls



Patient Case

Ashley is a 29 year old female with a PMH of Crohn's Disease. Based on her risk factors for a severe disease course, it is decided to start biologic therapy with Humira® (adalimumab).



Questions?

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