Changes in Pharmaceutical and Healthcare Environment
William Roth, Blue Fin Group

www.ncpanet.org/multiplelocations

Disclosure

William Roth is the Founding Partner of Blue Fin Group. The conflict of interest was resolved by peer review of the slide content.

Learning Objectives

- Review key legislative issues facing community pharmacy.
- Discuss global issues that are affecting community pharmacy long-term.
- Evaluate the reimbursement picture changes that are developing for pharmacy.
- Discuss the movement toward enhanced services for pharmacy and how this is growing and developing.

Discussion Topics

- Pharmaceutical Ecosystem
  - Overview of the system and macro-situations
- Sourcing The New Mix and channel dynamics
  - Scramble to sustain profit margin – musical chairs
- Reimbursement and payer dynamics
  - Pharmacy and Medical Benefit converging
- Pharmacy Business Model Evolution

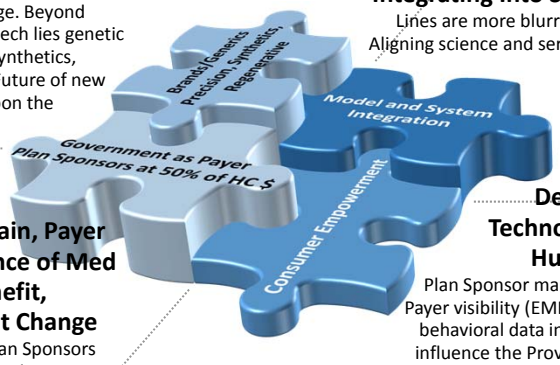
Industry Macros At A Glance

Key Message	Strategic Implication
CMS has a "linked" view of the HC Ecosystem	HC spend $3.2 (growing at 7%) assumed holistic view of the flow of the discounts down to the provider and pharmacy (squeeze out inefficiency)
Reimbursement primary agent of change	Government and Employers dealing with exponentials. Pressuring the economics drives horizontal and vertical consolidation.
Product mix already is driving change	Decline of small molecule, the rise and fall of generics, the explosion of specialty, and the slow adoption of biosimilars – long term stakeholders struggled to evolve
New HC service models and their effort for HC effectiveness	As accountability for science and how it's delivered intensifies, manufacturers take a much more active role in ensuring optimal provider and patient journeys
New models will emerge for sites of care	It's a great big game of musical chairs. IHNs create pharmacies. Providers create ITPs. GPOs go to payers and become distributors. Specialty channels emerge. Integration occurs. Channels become providers.
Status quo is being rethought	From patient and provider engagement, to channel relationships, to benefit constructs, and account management – there are no sacred cows - all is on the table

Industry Trends and Impacts 2016-2020

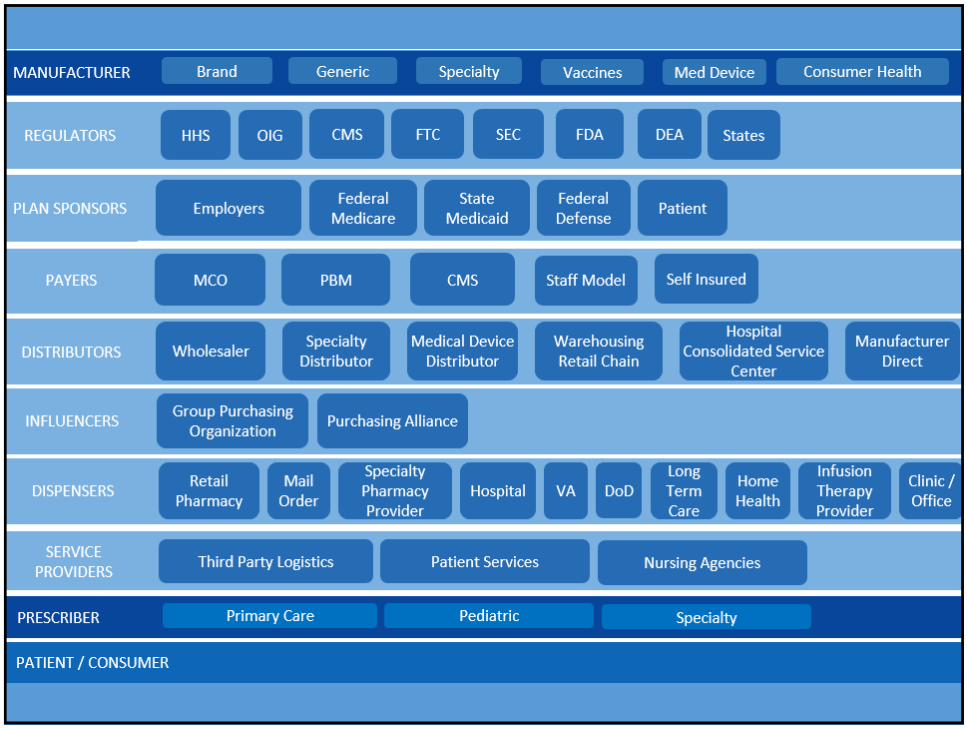
Product Mix & Innovation
The shift in mix and the associated economics will drive immediate and profound change. Beyond brand, generic, biotech lies genetic testing, precision, synthetics, regenerative, etc. Future of new science depends upon the commercial model.

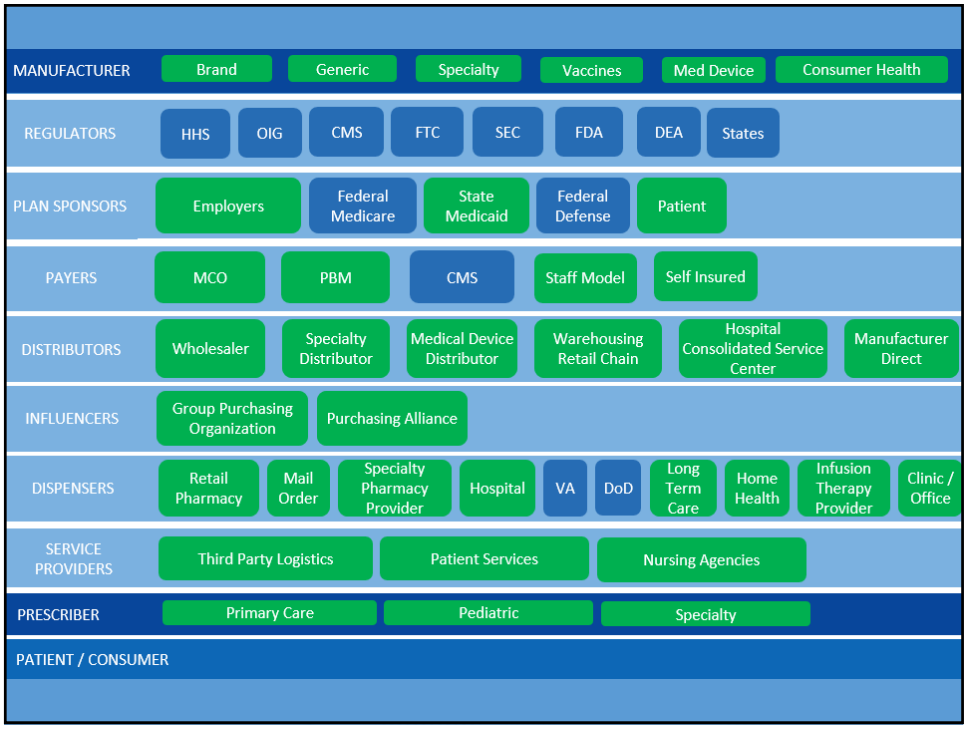
Payers, Delivery Systems, Providers, & Channels Are Integrating Into Something New
Lines are more blurred then ever before. Aligning science and service to create value.



Plan Sponsor Pain, Payer Mix, Convergence of Med and Pharm Benefit, Reimbursement Change
Governments and Plan Sponsors objective is cost control. A tipping point is here/fast approaching. Fragmented application of science.

Democratization, Technology, Data and Human Longevity
Plan Sponsor mandates coupled with Payer visibility (EMR, etc), Genetics and behavioral data increase the ability to influence the Provider and the Patient Both can be monitored and managed, to see the decline of paternalism and the rise of the empowered patient

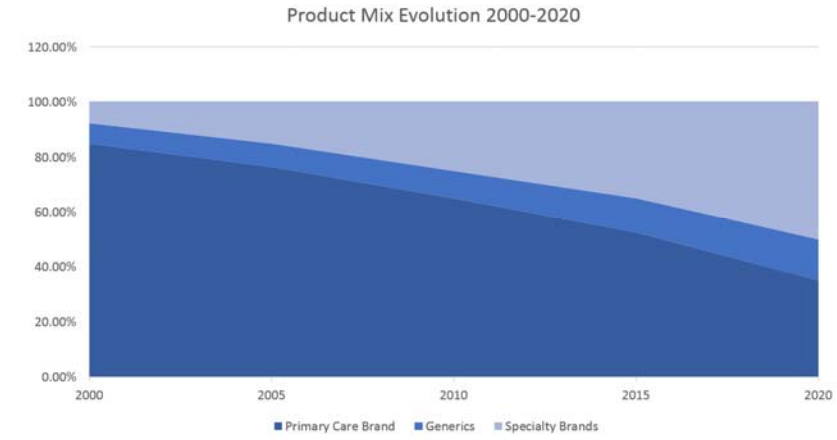

MANUFACTURER
Brand
Generic
Specialty
Vaccines
Med Device
Consumer Health
REGULATORS
HHS
OIG
CMS
FTC
SEC
FDA
DEA
States
PLAN SPONSORS
Employers
Federal Medicare
State Medicaid
Federal Defense
Patient
PAYERS
MCO
PBM
CMS
Staff Model
Self Insured
DISTRIBUTORS
Wholesaler
Specialty Distributor
Medical Device Distributor
Warehousing Retail Chain
Hospital Consolidated Service Center
Manufacturer Direct
INFLUENCERS
Group Purchasing Organization
Purchasing Alliance
DISPENSERS
Retail Pharmacy
Mail Order
Specialty Pharmacy Provider
Hospital
VA
DoD
Long Term Care
Home Health
Infusion Therapy Provider
Clinic / Office
SERVICE PROVIDERS
Third Party Logistics
Patient Services
Nursing Agencies
PRESCRIBER
Primary Care
Pediatric
Specialty
PATIENT / CONSUMER


MANUFACTURER
Brand
Generic
Specialty
Vaccines
Med Device
Consumer Health
REGULATORS
HHS
OIG
CMS
FTC
SEC
FDA
DEA
States
PLAN SPONSORS
Employers
Federal Medicare
State Medicaid
Federal Defense
Patient
PAYERS
MCO
PBM
CMS
Staff Model
Self Insured
DISTRIBUTORS
Wholesaler
Specialty Distributor
Medical Device Distributor
Warehousing Retail Chain
Hospital Consolidated Service Center
Manufacturer Direct
INFLUENCERS
Group Purchasing Organization
Purchasing Alliance
DISPENSERS
Retail Pharmacy
Mail Order
Specialty Pharmacy Provider
Hospital
VA
DoD
Long Term Care
Home Health
Infusion Therapy Provider
Clinic / Office
SERVICE PROVIDERS
Third Party Logistics
Patient Services
Nursing Agencies
PRESCRIBER
Primary Care
Pediatric
Specialty
PATIENT / CONSUMER

Products – Understanding Differences In Commercial Models

	Brand	Generic	Specialty	Biosimilar	Orphan	Precision
Cost	Low	Very Low	High	High	Very High	Very High
Patient Base	Very large	Very large	Small to Medium	Small to Medium	Very Small	Very Small
Payer Barriers	Low	Very Low	High	High	Very High	Uber High
Complexities	Rare	Very rare	PA, Step Edit, Benefit Design, Reimbursement, Storage, Admin	PA, Step Edit, Benefit Design, Reimbursement, Storage, Admin	Find patient, PA, Step Edit, Benefit Design, Reimbursement, Storage, Admin	Qualify patient, PA, Step Edit, Benefit Design, Reimbursement, Storage, Admin

Change In Product Mix Drives Significant Change



* Intervening years' share removed for clarity. Source: Simplified BFG estimates based upon IMS data and BFG Research

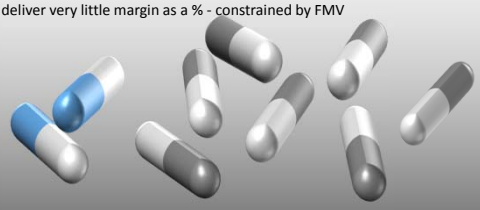
Letting It All Spill Out – 2017 will Not A Good Year For Intermediaries

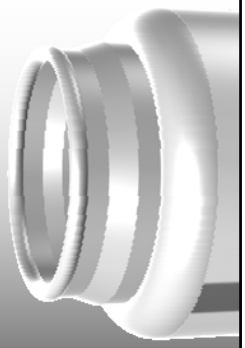
In the News

- Price increases reduced, lack of generic price increases, massive layoffs, hits to stock, generic company changes, price increases to pharmacies, weak margins

Happening Or About to Happen

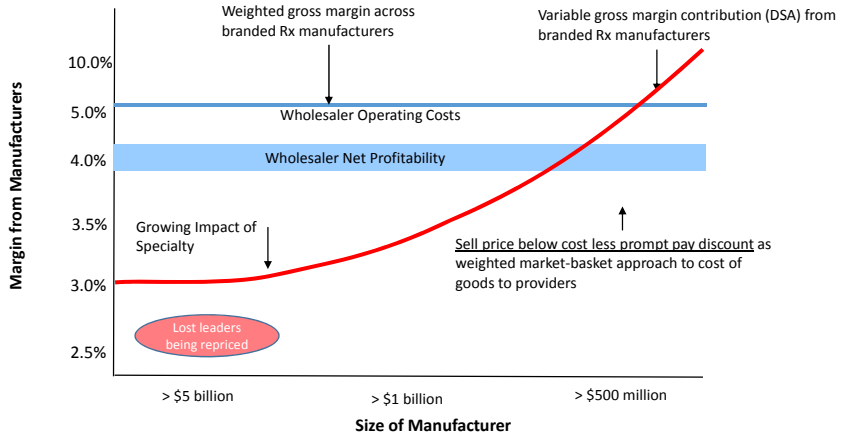
- Fragmentation of the prime vendor model
- Buy-and-bill Med Benefit products have been going "around" full line wholesale for 13 years now – since 2003 – passage of MMA
- Specialty Products deliver very little margin as a % - constrained by FMV





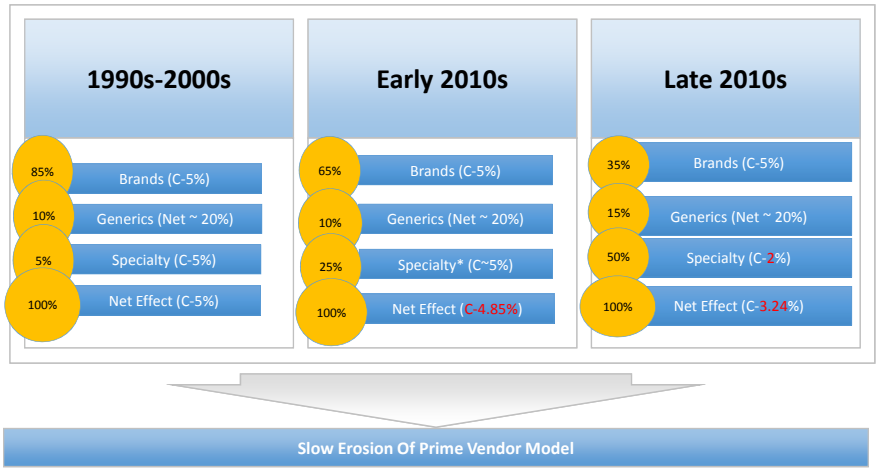
- 70% of wholesalers' profits from Generics
- Generic Wave Machine stops in 2017
- Biosimilars are not the channels' savior as originally hoped – lower priced brands (less money)
- Reimbursement pressure will continue because Plan Sponsors are hemorrhaging
- Threat of removal of 11-20 million covered lives on top of all of this – ACA repeal

BRX Economics On Wholesale Distribution



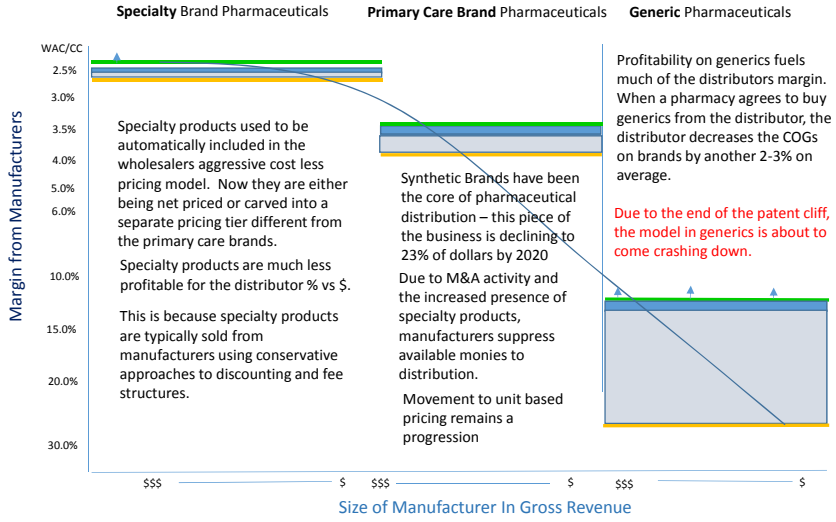
Inclusive of prompt pay discount
Graph does not introduce complexities of variable cost of goods across provider type and size

Evolution Of New Wholesaler Pricing Model

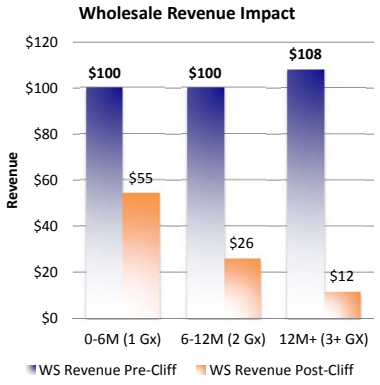


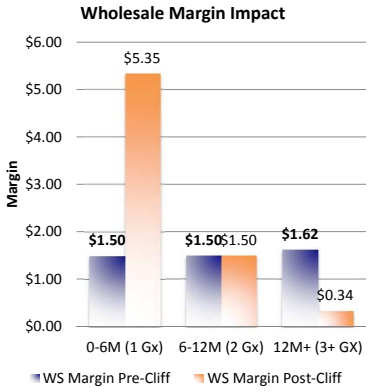
*Began carving out RA, Hep C, and others

Economics Of Wholesale Distribution – Fragmenting Bundle



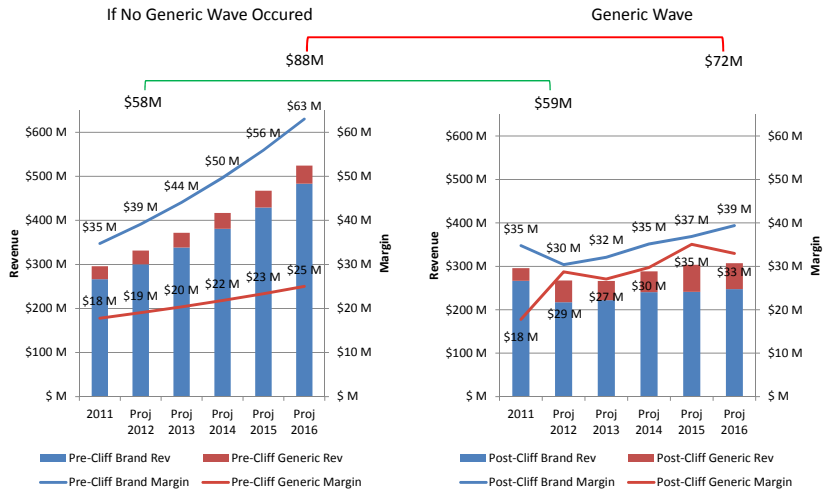
Distributor Impact From Generic Wave





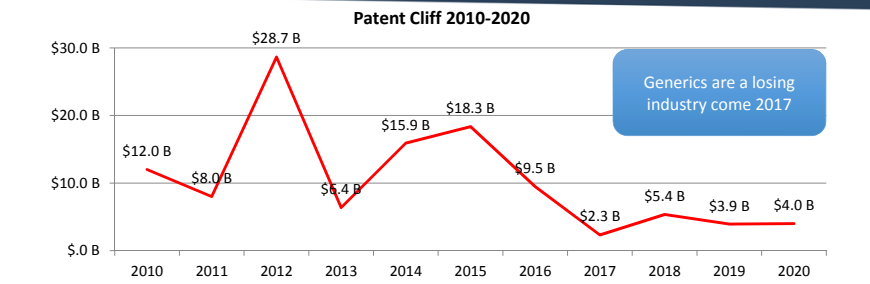
Source: BFG analysis from industry insider interviews. Based on $100 Branded drug with annual 8% price increase. Assumes introduction of exclusive generic for first 180 days, 2nd generic at 6months and 3rd at 12 months with generic at 55%, 26%, 12% of Branded WAC, at 0-6, 6-12, 12+ months respectively. Assumes wholesaler margin on Generics at 10-30% and brand margin assumed at 1.5%

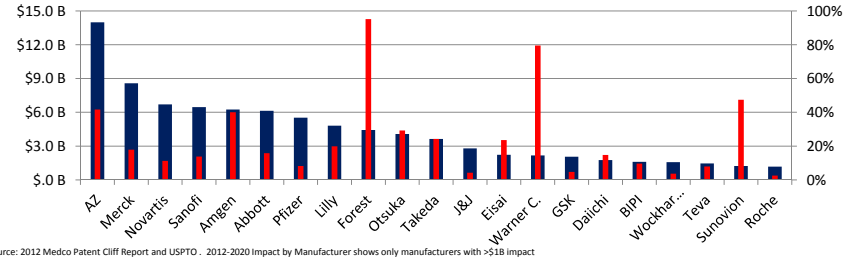
Retailers Impact From Generic Wave



Source: BFG analysis from 2012 $250M Pharmacy Margin Analysis Project

The Ocean Becomes A Quiet Lake (What's Left Are BLAS)





Source: 2012 Medco Patent Cliff Report and USPTO . 2012-2020 Impact by Manufacturer shows only manufacturers with >$1B impact

Intermediaries Are Scrambling To Weather The Hits

Which Models Are Impacted By These Changes And What Are They Doing?

Wholesale Distributors	IHN GPOs	Retailers	PBMs
Diversifying businesses, creating alliances, reducing costs, raising prices to downstream buyers, focusing on Specialty	Consolidating, diversifying, data business, services to downstream members, vertically integrating	Diversifying businesses, creating alliances, pursuing networks, reducing costs, focusing on Specialty, IHN integration	Diversifying businesses, consolidating, creating alliances, reducing costs, focusing on Specialty, MCO integration

Consider how this would affect your business – do not think in the past

Evolving Pharmacy Model

1. Patient presents in a Specialty Area

2. HCP prescribes a self-administrated product – leaves with an Rx

Retail Pharmacy

3. No support for BI/BV, copay, no re-education and no adherence support
+ 50% abandonment issue
- 25% adherence issue

Specialty Pharmacy

4. If economical for SPP, basic support for BI/BV, copay, minimal re-education and some adherence support
+ 40% abandonment issue
- 20% adherence issue

Mfgr Patient Services

5. If made aware of PS, support for BI/BV, copay, re-education and no adherence support
+ 10% abandonment issue
- 10% adherence issue

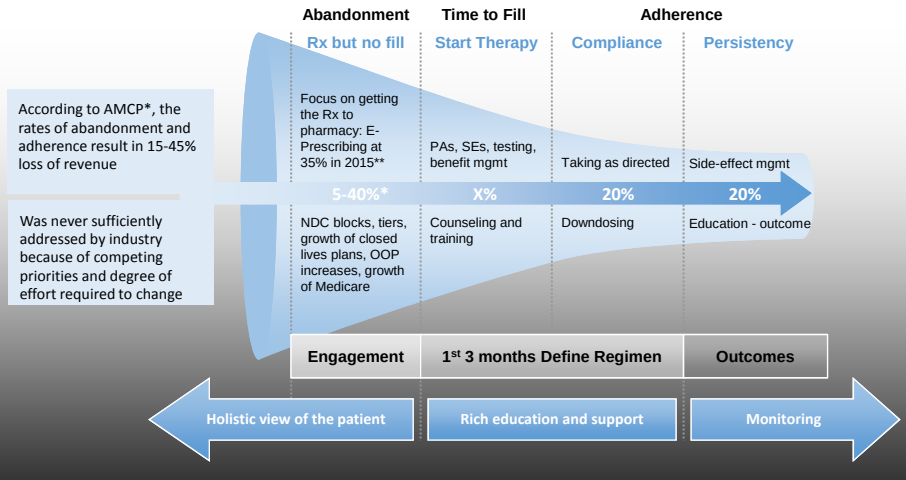
IDN/Ambulatory Specialty Pharmacy

6. IF ambulatory services, support for BI/BV, copay, no re-education and no adherence support
+ 5% abandonment issue
0% adherence issue

7. Problem for the IDN
- Lost revenue $$$ Value to external pharmacy
- Risk for IDN – if patient cannot gain access or be compliant – readmitted – lowering reimbursement rates

8. Problem for Others
- Providers – losing all value and increasing the risk
- Patients – do not realize the care they expect from IDN
- Manufacturers – loss of revenue and drug viewed as either troublesome to Rx or doesn't work
- Payers – really Plan Sponsors – higher overall cost of care

Optimize The Patient Journey
Inclusion is about solving this puzzle

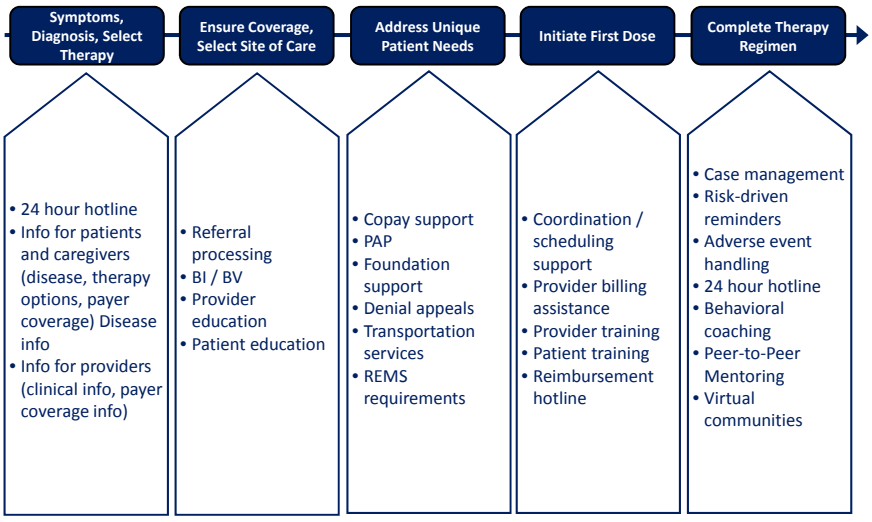


* AMCP JMCP 2015 adherence reports
** Surescript article August 2016

If Not, Manufacturers And MDs Will Solve It

Attract Patients (Identify)	Easy access to passionate people and high quality information on disease, therapy, payer coverage and service model
Acquire Patients (Access)	Overall service model that supports provider confidence in ability to initiate therapy and get reimbursed
Convert Patients (Start)	Services that support provider reimbursement, patient payment, training and first dose coordination
Support Adherence (Regimen)	Services that support, engage and empower patient and caregivers
Retain Patient (Brand Loyalty)	Communication about alternate therapies in manufacturer disease state portfolio, initiated by signal of risk to switch or discontinue

Patient Services – Optimizing the Patient Journey



Specialty Pharmacy has Taught What is Possible

Clinical	Hotline Support	Reimbursement	Data Analytics	Pharmacy
• Clinical Trial Conversion • Compliance / Adherence Support • Nurse Training & Coordination of Patient Training • Linkages to Outcomes, ACOs, PCMHs • Role of Pharmacy integrated with collaborative care • Recommending alternative therapies for holistic pharmacoeconomic reasons	• Call Center Scripting • Call Center Management • Call Triage • Billing and Coding • Sales Rep Support • Market Preparation Support	• Benefit Verification • Prior Authorization • Pre-certification • Medical Appeals • Financial Appeals • Co-Pay Assistance • Alternative Funding • Medicare Part D • Patient Assistance Program Management	• Weekly, Monthly, and Quarterly Reporting • Hotline Metrics • Service Metrics • Reimbursement Metrics • Compliance Metrics • Reimbursement Service Metrics • Web Based Sales Tracker Utility • Physician Web Portal • Data Aggregation Services	• Patient Referrals • Pick, pack and shipment of drug to patient / site of care • Collection of patient co-pay • Submit claims to payers • Receive reimbursement from payers • Switching of patients to alternative therapies for economic reasons • Inventory Management

Direction of Retail Pharmacy

Current View of Retail Pharmacy

IDN/HMO To Become The New Model (Delivery of Care At the Right Cost)

Accountable Care Organizations Model Principles

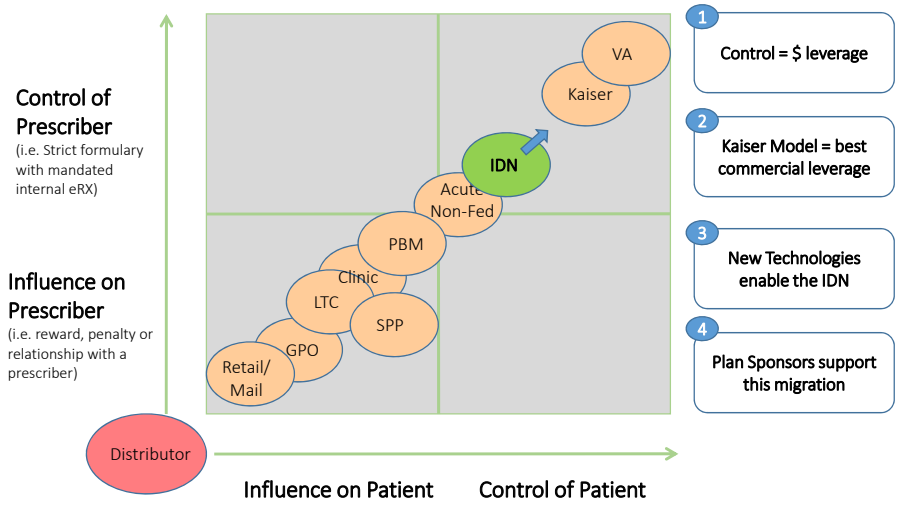
Key Principles for Formation of an ACO

Local Accountability	Shared Savings	Performance Measurement
ACOs will consist of locally based providers. Benchmarks for ACO spending are based on historical spending patterns and risk-adjusted based on patient mix. The local ACO is accountable for costs, quality, and capacity.	Reimbursement model for ACOs is termed "Shared Savings." Shared savings combine fee-for-service with cost savings.	"You can't manage what you don't measure. " ACOs will provide metrics on clinical process, outcome measures, and the patient experience.

ACOAdvantage©

Source: "The Promise ACOs." *Accountable Care Organization Learning Network*. The Engelberg Center for Health Care Reform at Brookings and the Dartmouth Institute for Health Policy & Clinical Practice , n.d. Web. 18 Apr 2011. <http://www.acolearningnetwork.org/who-we-are/about-the-network>.

Why? IDNs Gaining Influence And Control



Every IDN Is Different – Choose Carefully

IDN w/ limited ambulatory	IDN w/ small ambulatory No systems/data	IDN w/ ambulatory Basic systems/data	IDN w/SP Intermediate systems/data	IDN w/ large SP Advanced systems/data
Capital constrained Struggling with priorities	Capital pressured Resource constrained Struggling with priorities	Capital limited Resource limited Systems multi-focused Struggling with priorities	Capital for strategic use Resources to allocate Retail pharmacy skill Payer access improved Struggling with priorities	Capital empowered Resources to allocate Retail pharmacy skill Payer access enhanced Struggling with priorities
Relies on other SPs	Supports some Specialty Relies on other SPs	Building functions Building technology Building data Focused TA build-out Operationally focused Relies on other SPs	Enhancing functions Enhancing technology Enhancing data Focused TA build-out Performance focused	Innovating functions Innovating technology Innovating data Full TA build-out Integrated Care

IDN Pharmacy Will Take Time To Mature: Stages of Excellence

101 Rx Journey (Adjudication)	201 Enhanced Rx Journey (Case Management)	301 Care Journey (Medical Intelligence)	401 Outcomes Journey (Patient Reported Outcomes)
Varies by TA Prescriber data Patient (de-identified) Patient attempts therapy Insurance benefits (time) Prior Authorization Step Edits Tier status Prescription overview Prescribed supply Dispensed as Written Electronically subscribed Patient Out of Pocket Assistance amount Assistance program Status (time to fill) Abandonment Shipping details	Facility type Basic Patient Data Smoker, pregnant, weight, height ICD9 code (I,II,III) Prior diagnosis (I,II,III) Prior treatment Combo-therapy Source of patient Invention date/method Test conducted Last surgery date Line of therapy Educational intervention Adherence/abandonment Rx History Patient histology	Socioeconomics Weight trend Blood pressure trend Liver enzyme trend Cholesterol trend Current/previous disease CT Scan results Genetic predispositions Care history Spirometry test Sputum test Biopsy results Behavioral data Dates of behavior change Drug interaction risks Drug/treatment response	Physical well-being Social/family well-being Relationship with doctor Emotional well-being Functional well-being Treatment response Duration of response Progression free survival Disease free survival Mass size Behavioral changes

How Network Partners Are Chosen

Channel Access To Drug → Level of Control

Open	Preferred	Limited	Exclusive
• > 100k patients • Low control • Low touch service • No data visibility • No limit on access	• 100k – 20k patients • ⇧ control • Low touch service • ⇧ data visibility • No limit on access; list of preferred partners	• 20k – 5k patients • ⇧ control • Medium touch service • ⇧ data visibility • 1 SPP/$1,000 drug cost • 1 SPP/100 patients/month	• < 5k patients • High control • High touch service • High data visibility • 1 SPP

These networks can vary by drug AND by type of site of care

View Of Manufacturer Networks

	Open	Preferred	Limited	Exclusive
Benefits	•Serves large patient populations (>500k+) •$ and care poorest •Little effort and cost for the manufacturer •Product available for all sites of care •Market dynamics dictate care	•Serves large patient populations (<500k) •$ and care enhanced •Contracts pharmacy for data/services •Product available for all sites of care •80/20 rule serviced	•Serves large patient populations (<100k) $ and care enhanced •Manufacturer Patient Journey requirements now influence care •(REMS)	•Serves large patient populations (<10k) •$ and care optimized •Manufacturer Patient Journey requirements now influence care •Every patient intervention point managed – no leaks
Challenges	•No visibility to patient journey – high rates of abandonment – poor adherence •Less connection with sites of care •Discount impacts •Patient services is an afterthought	•80/20 visibility to patient journey – modest improvements on abandonment and adherence •Still no payer data •Discount impacts •Patient services is a back-up plan	•More effort and cost for the manufacturer •Must direct provider and patient •Payer mandates •MCO/PBM SPs •IDNs/Clinics typically omitted	•Significantly more effort and cost for the manufacturer •Must direct provider and patient •Payer network coordination •MCO/PBM SPs •IDNs/Clinics typically omitted

IDNs have access to products in several classes
Strategy is to get the limited and exclusive products to chase the IDN Network

Understanding Flow Of The Dollar By Product Type And Benefit Type

Product type and Reimbursement	Primary Care Pharmacy Benefit	Specialty Pharmacy Benefit	Specialty Medical Benefit
Ultimate Economic buyer *Focus on high spend and low patient counts*	Plan Sponsor 23% of spend*	Plan Sponsor 35% of spend*	Plan Sponsor 35% of spend*
Economic Gatekeeper *Real motives are roughly 5% profit on total volume*	PBM Blocks and tiers/copay Push product to cash	PBM PAs and Step Edits Patient hits deductible fast	MCO PAs and Step Edits Patient hits deductible fast
Economic Administrator *Real motives are roughly profit on total volume*	Pharmacy AWP – 18% Low cost to serve	Pharmacy AWP - 20% Low $ to high cost to serve	Provider ASP + 4.3% Office visit and admin $
Economic Consumer Increasing ownership for economics – poor knowledge of access and C&P	Patient (low OOP, no deductible impact, potential for blocks)	Patient (high OOP, hit deductible fast, need for support)	Patient (low OOP, hit deductible fast, physician supports)
Non-economic buyer	Provider Access support is cost	Provider Access support is cost	n/a ROI for access support
Business Model	Large # patient, low dollar, low abandonment, high adherence, directional 3rd party data	Small # patient, high dollar, high abandonment, low adherence, actionable direct data	Small # patient, high dollar, high abandonment, low adherence, mix of actionable direct data

*Percentage Mix by 2020

Growing Concern of Pharmacy Profitability

	AWP -15%	AWP-17%	AWP-20%
Wholesale Acquisition Cost	$5,950	$5,950	$5,950
Average Wholesale Price (AWP = WAC + 20%)	$7,140	$7,140	$7,140
Reimbursement from Payer (AWP-x%)	$6,069	$5,926	$5,783
Purchase Price from Manufacturer or Wholesaler (WAC-5%)	($5,653)	($5,653)	($5,653)
Reimbursement - Purchase	**$417**	**$274**	**$130**
Manufacturer Service Fees (2% of WAC)	$119	$119	$119
Gross Margin	**$536**	**$393**	**$249**
Gross (% of WAC)	**9.0%**	**6.6%**	**4.2%**
Reimbursement BI/BV Cost/Rx	($42)	($42)	($42)
Patient Services Cost/Rx	($10)	($10)	($10)
Pick/pack/ship Costs/Rx	($25)	($25)	($25)
Net Profit $/Rx	**$459**	**$316**	**$172**
% of WAC	**8.1%**	**5.5%**	**3%**

Service Fees/Rebates from manufacturers vary based on multitude of factors. Evaluation as bona fide service and FMV to be determined

SPPs seek 5-6% gross profit to offset 2-3% operating expenses

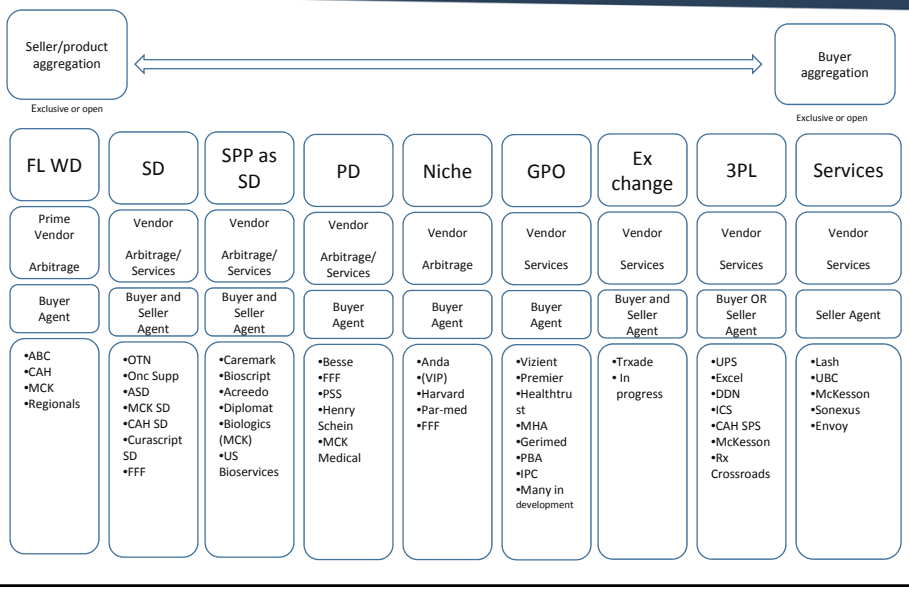
Reimbursement (BI/BV) cost assumes 30 mins/Rx @$60/hr; and 30 mins for PA on 50% of Rxs

Patient services cost assumes 15 mins/Rx at $40/hr

Pick/pack/ship cost /Rx assumes $15 per shipment

SPP' s profitability drivers: product acquisition cost; revenue from manufacturer contracts (service fee/discount/rebate); reimbursement from payers; and SPP operating costs.

Sourcing Will Need to Be Reconsidered



In Summary

- $3.2T at a CAGR of 7% is unsustainable
  - 7.6% of average employers' opex is healthcare
- Plan Sponsors want to condense the Ecosystem
- Payers cannot allow diverged Med and Rx
- Changes in Product Mix drive significant change
  - Scramble to sustain profit margin – musical chairs
- Channels will have to vertically integrate
- Sourcing is fragmenting and will need to be reconsidered

William Roth
Founding Partner
wroth@consultbfg.com
678.522.3728
@rxchangeagent
www.linkedin.com/in/williamroth

www.consultbfg.com

BLUE FIN GROUP

34

NCPA
NATIONAL COMMUNITY
PHARMACISTS ASSOCIATION
www.ncpanet.org/multiplelocations