Purchaser's Guide

Minnesota Health Action Group™
Innovating, Leading, Engaging

Spotlight on: Specialty Pharmacy (Phase I)

Shining the light on purchaser cost and value expectations

Identifying Challenges

Becoming Informed

Understanding Distribution and Reimbursement

Defining Action Steps

Influencing the Marketplace

NOTE TO READERS:

This document contains a number of words that are highlighted in red. These words link to the corresponding entry in the Glossary of Terms.

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About the Minnesota Health Action Group Care Delivery Learning Network

The Minnesota Health Action Group is the only Minnesota organization whose sole purpose is to represent the collective voice of those who pay the bill for health care—employers, public purchasers, and individuals. Through its Care Delivery Learning Networks, all Action Group employer members are invited to take a deep dive on how to increase the value of health care goods and services that are subject to high cost, variability, and overuse or inappropriate use. Each Learning Network typically occurs over a six-month period, with monthly meetings that explore various facets of the topic at hand. The resulting Employer Purchaser's Guides help members shape their benefit strategies and influence essential marketplace change to help ensure the economic vitality of all Minnesota communities.

The collective purchaser voice does what no single purchaser can do as effectively on their own:

- Sends a strong, clear and consistent signal to providers, vendors and health plans about care delivery cost and quality expectations.
- Eliminates redundant initiatives of multiple employers, thus diminishing the impact of disparate efforts on a single provider, vendor or health plan.
- Yields greater leverage in discussions and negotiations with providers, vendors, health plans, and lawmakers.

About the Specialty Pharmacy Care Delivery Learning Networks

Background/Overview

There are more participants in the Specialty Pharmacy Care Delivery Learning Network than ever before, including 3M; Best Buy; Blue Cross and Blue Shield of Minnesota; Carlson Companies; Emerson; HealthPartners/Park Nicollet; Hennepin County; Land O' Lakes; Mills Fleet Farm; Minnesota Management & Budget – SEGIP & PEIP; SUPERVALU; Thrifty White; University of Minnesota; U.S. Bank; and Wells Fargo.

This fourth Learning Network kicked off in October 2014, in response to the prediction that costs for specialty medications are projected to quadruple between 2012 and 2020, in part because the current pipeline includes over 900 new drugs. Specialty pharmacy has been called "the new gold rush," due to the large number of new drugs and the high demand for them, coupled with the fact that no one is responsible for holding drug makers accountable to rational pricing practices. The pharmaceutical market is not economically sound: There is no relationship between price and value. Further complicating matters, each vendor determines its own definition and list of drugs and can change them at will, which accounts for differences in reporting trends and other significant inconsistencies.

Defining Specialty Pharmaceuticals

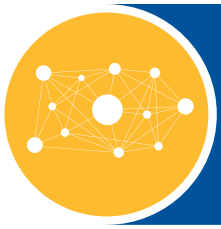
- Prescribed for individuals with complex, chronic, and/or rare medical conditions.
- Have a cost of at least $600 (per Medicare's definition) for a 30-day supply; up to $12,000-$400,000/year.
- Originally included only infused or injected drugs, but now include self-injectables, oral and inhaled medications.
- Made from proteins, nucleic acids, living organisms (biologic).
- Available through limited distribution channels and not typically stocked at retail pharmacies.
- Administered by physicians and often purchased through "buy and bill."
- Difficult, unusual process of delivery to the patient/provider such as preparation, handling, storage, inventory, distribution.
- Involve complex patient care that often requires intensive clinical monitoring and frequent dosing changes.
- Require enhanced patient education, management, or support often needed for adherence and effective treatment.
- Covered in both medical (53%) and pharmacy (47%)* benefits:
  - "Medical side" drugs administered by providers who "buy and bill" through health plan.
  - "Pharmacy side" includes a prescription and is dispensed by pharmacy (usually mail) to patients.
- Common conditions today—hepatitis C, oncology, arthritis, multiple sclerosis; future conditions—cystic fibrosis, oral oncology, others.

**Milliman: Evaluation of Medical Specialty Medications, April 8, 2014.*
Specialty pharmaceutical definition courtesy of Dr. Stephen Schondelmeyer.

Identifying the Challenges

Specialty drug trends are rising sharply, in part because new high-cost specialty drugs are being approved for higher prevalence diseases and conditions (e.g., high cholesterol, asthma), and manufacturers are focusing on developing these extremely high-margin drugs (well over 900 are in the pipeline).

There is a lack of transparency about the actual cost of drugs, financial incentives, distribution channels, and how industry players are maximizing profits.



The complexity of this enormous and powerful industry is growing organically and exponentially due to vertical expansion with wholesalers, providers, and retail and pharmacy benefit managers (PBMs) owning hubs and other emerging businesses/systems. There are also continuous consolidation activities as the players look for ways to expand their role in specialty pharmacy.

Drugs are covered under both the pharmacy and medical benefit, and the diversity of payment and dispensing options makes it hard for payers to get full visibility on specialty drug spending or manage drug utilization effectively.

For patients and their caregivers, low health literacy, challenges that come with managing complex conditions, overwhelming administrative challenges, and troublesome side effects, means they often are not prepared or able to be active and informed members of their care teams.

Payers and policymakers have been unwilling to undertake significant cost controls on prescription pricing.

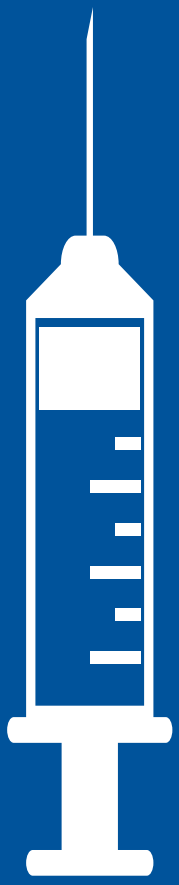
By **KIM PETERSON** / **MONEYWATCH** / *April 3, 2014, 8:27 AM*

$1,000-a-day miracle drug shocks U.S. health care system

"Sovaldi, a new hepatitis C treatment, can cure up to 90 percent of patients within three months. There's just one problem: The drug costs $1,000 a day. That price tag has thrown the biotechnology world into turmoil, as lawmakers and insurance companies complain that Sovaldi's maker is trying to milk desperate patients."

- CBS MONEYWATCH, April 3, 2014

Specialty Drug Fast Facts



+50% of specialty drugs are covered under the medical benefit.

8/10 of the top drugs will be specialty products by 2016.

27.7% of PBM managed drug spend in 2013 was in Specialty.

24% expected annual increase in spend for cancer medications in 2015 and 2016.

1/3 of the products in the pipeline will require professional administration.

$100-$200 billion added annual cost of specialty drugs due to the introduction of cholesterol-lowering PCSK9 inhibitors. These are expected to be approved by the FDA in mid-2015. Because about 15 million Americans have high cholesterol, these will likely be the highest selling class of medications in history. (For comparison: The annual estimate to treat hepatitis C patients is $15 billion.)

Source: Health Affairs, October 2014, Vol. 33 No. 10

Hepatitis C

- At least three million Americans are infected.
- Less than one-quarter of them have been diagnosed.
- New therapies cost at least $85K per patient.

Source: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention Fact Sheet (2015)

Examples of New Therapies and Their Cost Per Episode

- Nivolumab - $143K per cancer patient
- Sovaldi - $85K per hepatitis C patient
- Xalkori - $67K per lung cancer patient
- Yervoy – $120K per metastatic melanoma patient

Source: Health Affairs, October 2014, Vol. 33 No. 10

Employer Roundtable Discussion

The Action Group kicked off the Learning Network by hosting an employer roundtable featuring speaker Sara Drake, R.Ph, M.P.H., M.B.A., Pharmacy Program Manager for the Minnesota Department of Human Services. In her presentation, Drake discussed the advantages and disadvantages of a specialty pharmacy model, as well as the distribution of public and private prescription drug payers, and how specialty drugs are accounting for an increasingly higher portion of drug spending for Minnesota Health Care Programs (MHCP).

Potential Advantages of Specialty Pharmacy Model (i.e., PBM moves drugs from the medical benefit to the pharmacy benefit)

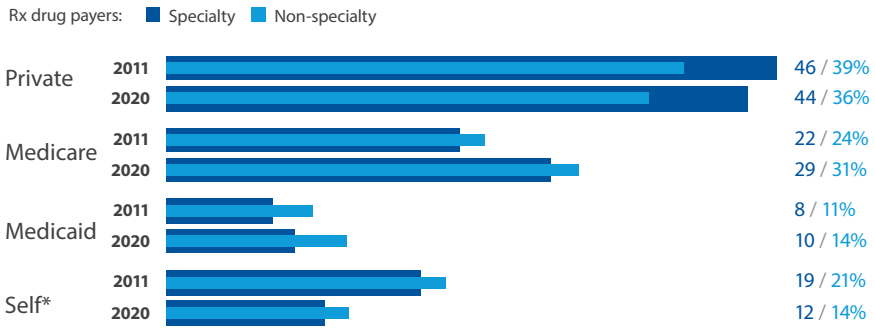
- Streamlined prior authorization processes
- Improved utilization management and drug utilization review (DUR)
- More opportunity for pharmacist review
- Less financial risk to the prescriber
- Eliminates mark-up revenue for prescriber (may reduce incentive to prescribe high-margin items)

Disadvantages to Specialty Pharmacy Model

- Significant potential for waste
  - Recent report found 20 percent of drugs shipped to physicians office are ultimately not used*
- Additional administrative burden on providers
  - Patient-specific drugs require special storage and handling
- Drug ingredient cost may be higher
  - More discounts available to clinics/outpatient hospitals

Who pays for specialty drugs now, and later?

Private payers will likely continue to be the largest purchaser of specialty drugs. But public payers, such as Medicare and Medicaid, are expected to see their cost burden increase through 2020. Consumers may pay for a smaller portion of specialty drug costs than traditional drugs.



*The Self category captures out-of-pocket spending by patients across all sources of insurance and the uninsured. The Self category declines from 2011 to 2020 largely due to legislative changes, such as many uninsured people gaining coverage through Medicaid and health insurance exchanges.

Source: PwC's Health Research Institute analysis of data from the Medical Expenditures Panel Survey (MEPS), Evaluate Pharma, National Health Expenditure Survey.

Key Learning Network goals that came out of the participant discussion following Drake's presentation included:

- Becoming smarter about how specialty pharmacy benefits are delivered, administered and managed.
- Being able to ask important questions of consultants, health plans, and PBMs—and understand the answers.
- Having information and questions to include in requests for proposals (RFPs).
- Understanding the implications of new drugs, developments, and industry changes as they unfold.
- Learning about actions that may be taken to reduce costs and improve outcomes.
- Exploring collective actions that may be discovered through collaborative learning.

* ICORE 2012 Medical Pharmacy and Oncology Trend Report

About the Phase I Specialty Pharmacy Learning Network

The Specialty Pharmacy Learning Network is considerably more complicated than past Learning Networks for many reasons explored in this Purchaser's Guide. As the group neared the end of its key informant meetings, participants unanimously agreed that they had only scratched the surface of specialty pharmacy issues facing employers. As such, this Learning Network has been granted an extension of six months, with Purchaser's Guides being divided into Phase I and Phase II. Phase I is the discovery phase; Phase II focuses on understanding what is and isn't within the employers' control, and where they can effectively collaborate to drive meaningful change in the marketplace.

The key steps followed in Phase I enabled Learning Network participants to address the unique nature of this complex and rapidly evolving area of study, as shown below.

Phase I

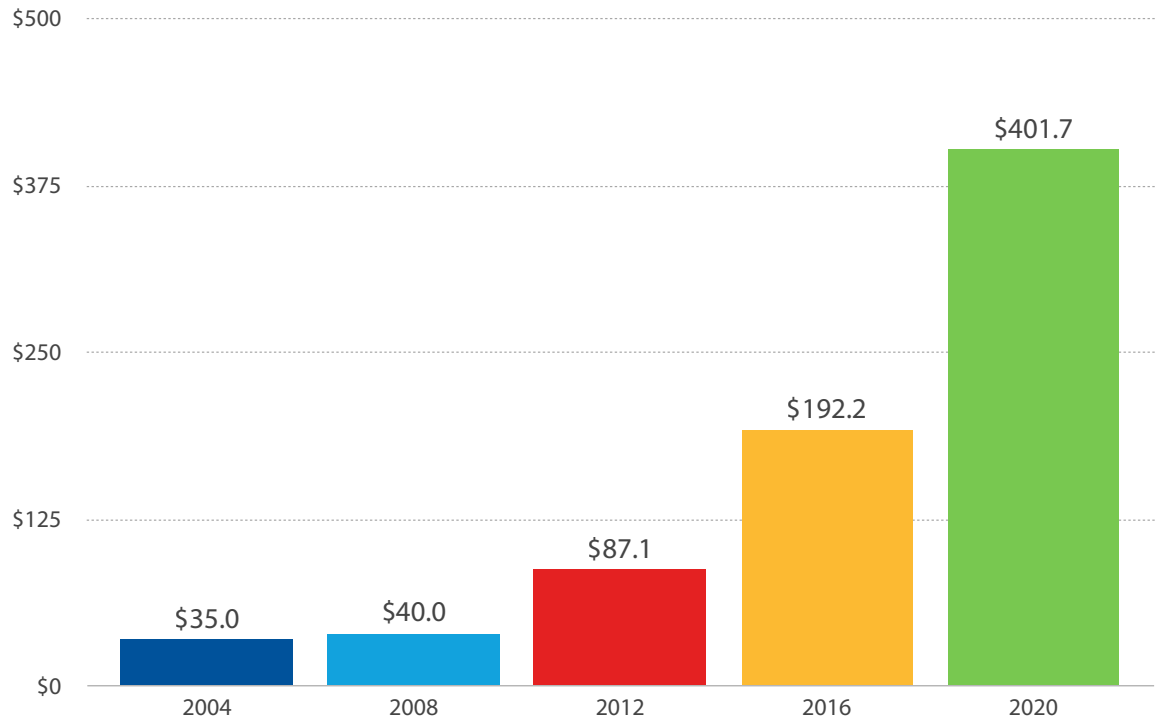
Phase II

Key Informant Meetings

To better understand the positions of various stakeholders, in Phase I we held a record number of key informant meetings featuring thought leaders from universities, health plans, care systems, specialty pharmacies, and consultancies. We also invited Dr. Schondelmeyer, Pharm.D., Ph.D., to serve as senior advisor to the Specialty Pharmacy Care Delivery Learning Network. Dr. Schondelmeyer is a professor of Pharmaceutical Economics in the College of Pharmacy at the University of Minnesota where he holds the Century Mortar Club Endowed Chair in Pharmaceutical Management and Economics. He is also the Director of the PRIME Institute, which focuses on pharmaceutical research related to management and economics, and serves as Head of the Department of Pharmaceutical Care and Health Systems. Dr. Schondelmeyer is an internationally renowned expert with a unique understanding of the complex and technical issues that have led to dramatic changes in the pharmaceutical marketplace. Not only did he kick off the Learning Network meetings, he also attended all meetings to facilitate discussions between employers and key informants.

Meeting One:
During the first Learning Network meeting, Dr. Schondelmeyer provided a crash course on the specialty pharmacy industry. Here are some highlights:

Specialty Drug Spend: 2004-2020



Courtesy of Dr. Stephen Schondelmeyer

"It is currently the wild, wild west in drug pricing. I believe in markets, but this market is broken; it's failing. Even for generics, the trend is going up rather than down, as we'd expect, and not just two or five percent, but by hundreds or even thousands of percent."

Dr. Stephen Schondelmeyer

$ SPECIALTY DRUG SPEND

$87 Billion

Specialty drug spend in 2012.

22%

The percentage specialty drugs contributed to total drug spend in 2013.

30%-60%

of specialty spend is in the pharmacy benefit.

40%-70%

of specialty spend is in the medical benefit.

SPECIALTY DRUG TREND

15%-35%

annual growth rate

2x

the growth rate of regular drug trend

Growth is being driven by price, utilization and new products.

Specialty drugs were

25%

of total drug growth trend in 2006.

They will be

> 50%

of total drug spend by 2018.

Courtesy of Dr. Stephen Schondelmeyer

The Specialty Drug Boom

As baby boomers age, and as chronic, high-cost conditions continue to plague the population, more complex, longer-term, and rigid controls around administration and monitoring have become essential components of responsible patient care. Although the number of patients being treated with specialty drugs, to date, makes up only a small sliver of those receiving treatment, this group accounts for more than a quarter of employers' overall medical costs.

As the specialty pharmacy marketplace has evolved and profit margins have soared, a complex web of providers, administrators and vendors has emerged. What's more, these groups are distinguishing themselves by building in attractive features like 24/7 hotlines, reimbursement and administration support, home health coordination, and patient outreach for medication renewal.

Over the coming months and years, employers should anticipate more specialized players entering the field, each with competitive selling points, as well as greater movement by traditional sources (e.g., community pharmacies) into this space. Time will tell the extent to which more sophisticated medical management may translate into greater cost management and improved patient outcomes.

U.S. spending on specialty prescription drugs—those used to treat chronic, complex diseases such as cancer, multiple sclerosis, and rheumatoid arthritis—is projected to increase 67 percent by the end of 2015.

Specialty Drug Trend

Therapy Class	2013	2014	2015	3-Year Compound Total
Inflammatory Conditions	25.1%	17.2%	17.4%	72.2%
Multiple Sclerosis	19.8%	18.5%	16.8%	65.6%
Cancer	21.3%	20.9%	21.0%	77.4%
HIV	9.2%	9.6%	9.4%	30.9%
Hepatitis C	33.0%	58.5%	168.4%	465.8%
Growth Deficiency	6.2%	5.9%	6.5%	19.9%
Anticoagulant	-0.3%	-0.2%	0.0%	-0.6%
Pulmonary Hypertension	11.0%	11.1%	10.5%	-14.2%
Respiratory Conditions	24.8%	29.5%	27.9%	36.3%
Transplant	-2.2%	1.0%	-1.2%	-2.4%
Overall Specialty	**17.8%**	**19.6%**	**18.4%**	**66.8%**

Source: Express Scripts Drug Trend Report

According to the forecast, overall spending on traditional prescription drugs—mostly pills used to treat common conditions such as high cholesterol and depression—will decline four percent by the end of 2015, largely because of the availability of generic medications. Only two of the top 10 traditional therapy classes, diabetes and attention disorders, are likely to have spending increases over the next three years, but those increases will be significant.

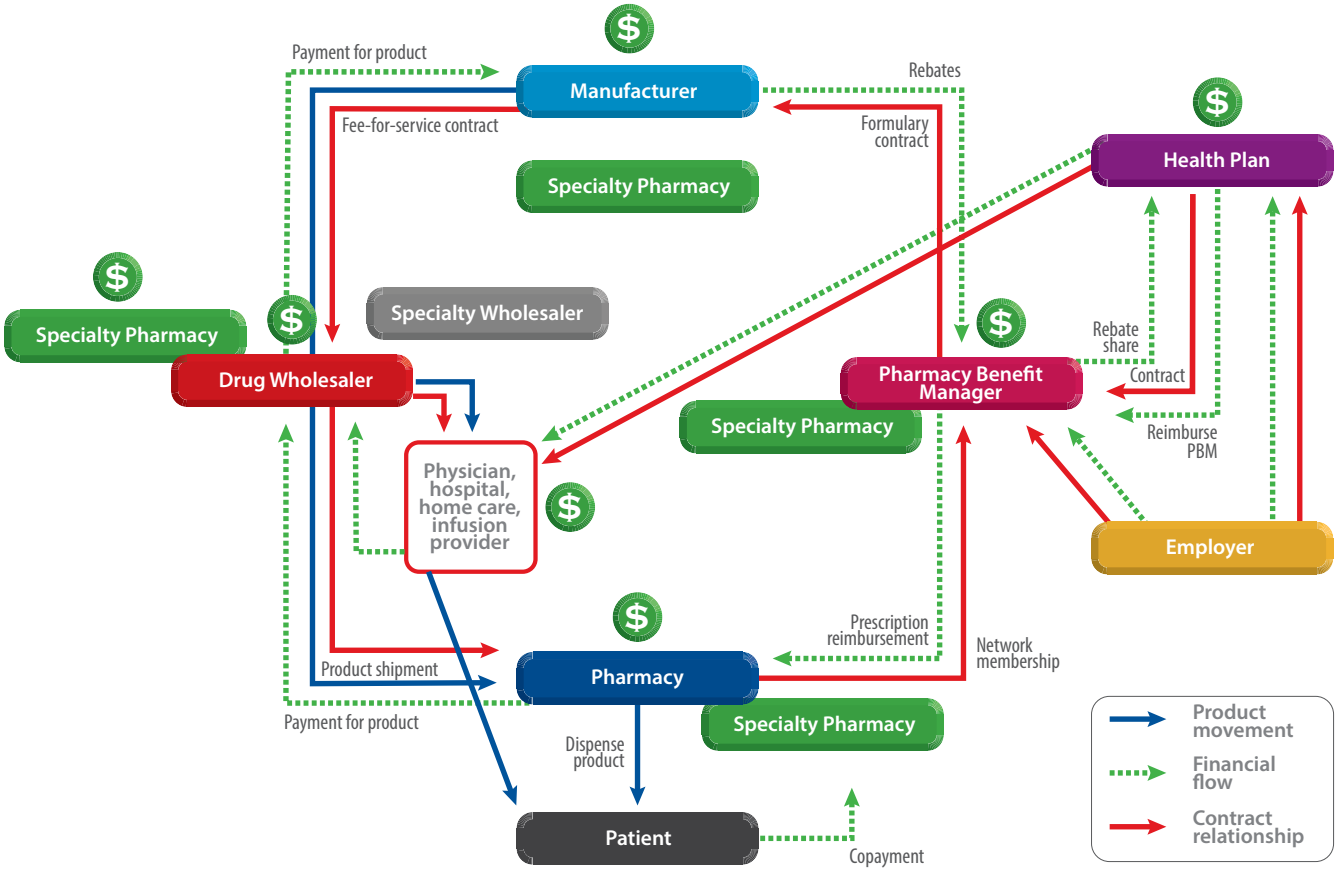
Traditional Drug Trend

Therapy Class	2013	2014	2015	3-Year Compound Total
Diabetes	8.9%	6.8%	6.7%	24.1%
High Cholesterol	-6.9%	-4.0%	-5.3%	-15.4%
High Blood Pressure/Heart Disease	-7.2%	-5.9%	-6.0%	-17.9%
Asthma	-7.3%	0.8%	1.3%	-5.4%
Ulcer Disease	-5.6%	-6.4%	-13.2%	-23.3%
Depression	-4.7%	-8.7%	-6.5%	-18.6%
Attention Disorders	4.4%	10.0%	8.6%	24.8%
Mental/Neurological Disorders	-7.4%	-1.8%	-5.7%	-14.2%
Pain	-3.3%	-4.5%	-4.2%	-11.6%
Infections	-6.9%	-6.8%	-6.0%	-18.4%
Overall Traditional	**-1.0%**	**-1.7%**	**-1.4%**	**-4.1%**

Source: Express Scripts Drug Trend Report

Distribution and Reimbursement

Never before have we seen such complexity in the distribution channels for prescription drugs. Every additional touch point adds cost, confusion and complexity.



Adapted from Fein, Adam J., 2014-15, Economic Report on Retail, Mail and Specialty Pharmacies; Drug Channels Institute, January 2015

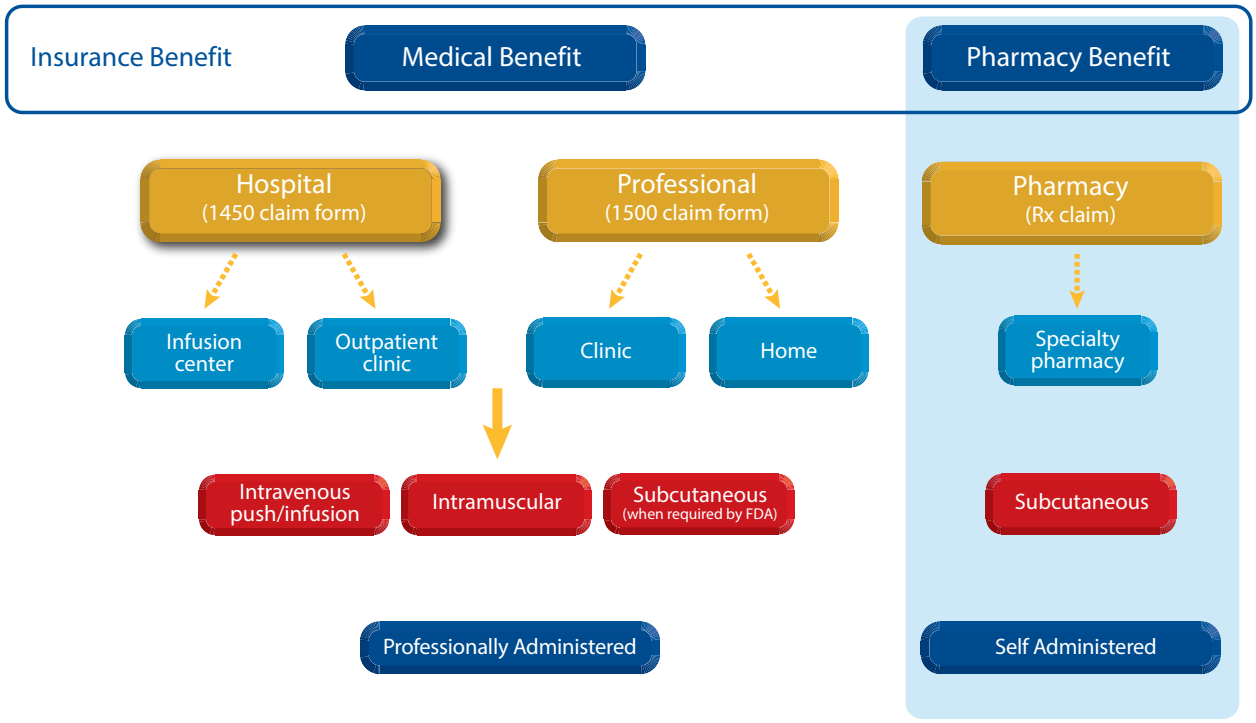
The "eye popping" cost of cancer drugs

OCTOBER 5, 2014, 7:00 PM | Lesley Stahl tells 60 Minutes Overtime about another "devastating" side effect of cancer: the bill.

"I was asked to report on the backbreaking cost of cancer drugs by a friend of mine who has cancer. He told me that it's going to bankrupt him to get treatment. Just for him to get started, you're talking about a quarter-million dollars. The whole system is off-kilter. It's really heartbreaking."

Lesley Stahl, 60 Minutes, October 5, 2014

Specialty Drugs: Insurance Coverage and Distribution



Courtesy of HealthPartners

Specialty Drug Coverage: Why it Matters

Coverage Issue

- Prescriptions
- Transaction record
- Drugs identified
- Drug cost
- Drug volume
- Hidden incentives
- Timely claims
- Utilization management
- Case management
- Drug use data
- Drug cost

Medical Benefit

- Not always written
- Buried in office visit claim
- J Codes used, at best
- Drug cost part of total visit
- Drug manufacturer and dose uncertain
- Provider discount unknown
- Claims processed (days-months)
- Retrospective DUR (at best)
- Poor information (not possible, not available, not included)
- 20% to 30% > Pharmacy benefit

Pharmacy Benefit

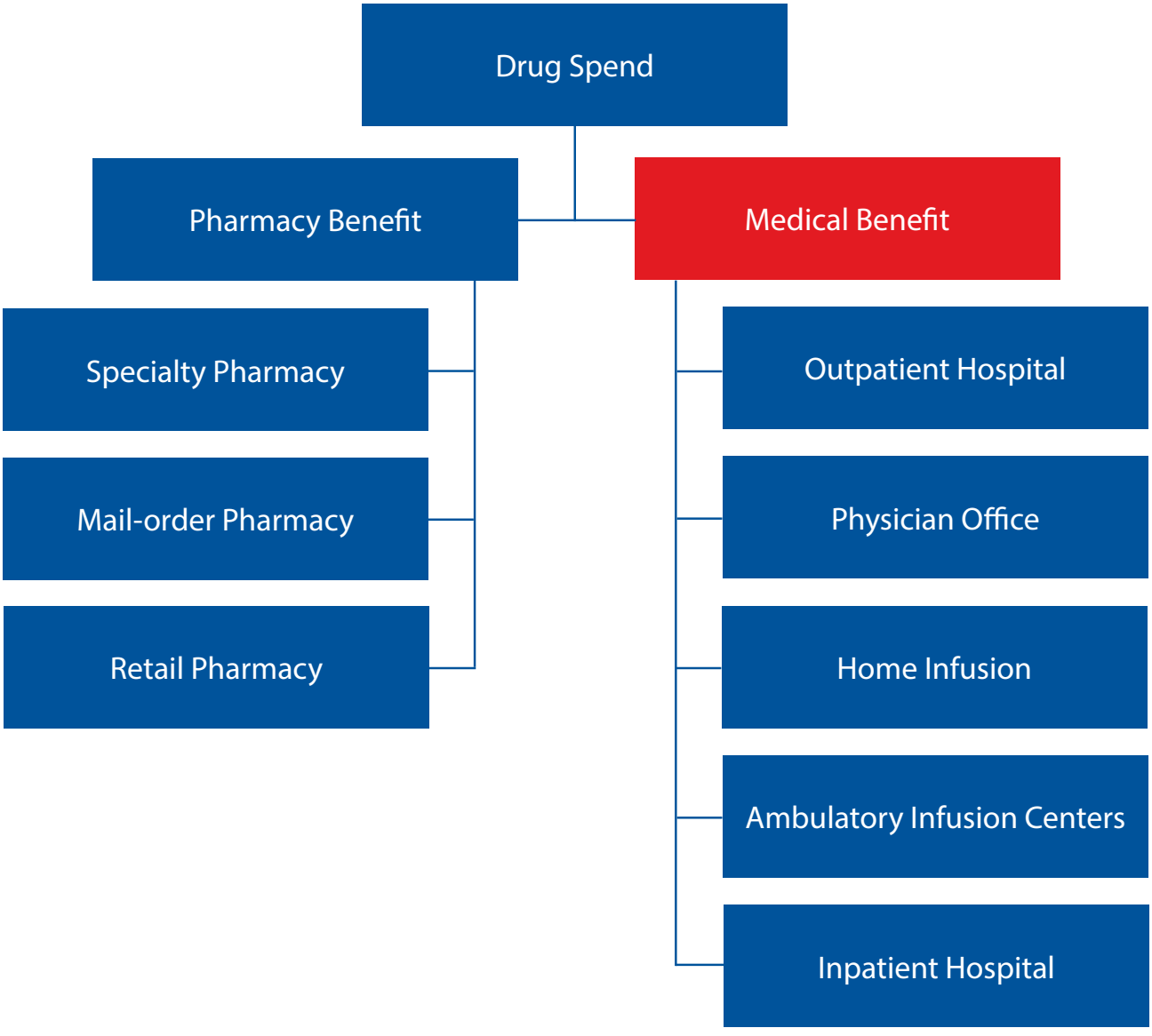
- Based on prescriptions
- Claim for each prescription
- NDC # for each drug
- Drug cost is known
- Drug manufacturer and dose known
- Pharmacy price known
- Claims processed (real time)
- Concurrent DUR
- Good information, easily done
- Readily available
- Cost less than medical benefit

Courtesy of Dr. Stephen Schondelmeyer

Meeting Two:

- **Business and medical ethics considerations:**
  - The entire Medicaid drug budget would be spent if all eligible patients with hepatitis C received treatment at the current price point, so should all who are eligible receive it?
  - There are three values to balance in resource allocation: autonomy, beneficence, and fairness.
  - There is no quantifiable value on what drugs deliver to people (e.g., if a drug costs 20 percent more, the patient generally doesn't get 20 percent better).
  - Patients will accept limitations more readily if procedures are transparent.
  - Quality Adjusted Life Years (QALYS) can quantify value and potentially defuse emotion; measure individual QALYS by patient.
  - We do not "die gracefully" in the U.S., but insist on heroic measures, even when quantity or quality of life is not improved.
- **Understanding specialty pharmacy spending through data analysis:**
  - Medical specialty pharmacy data is difficult, but not impossible, to analyze and evaluate. If NDCs (National Drug Code) are used, they should be captured in both data warehouses (health plans' and employers').
  - There are four key areas of cost savings in order of amount: Site of care; clinical management (e.g., step therapy); reimbursement (quantity) management; benefit design (copay assistance).

Specialty Drugs: Covered Under Both the Pharmacy and Medical Benefit

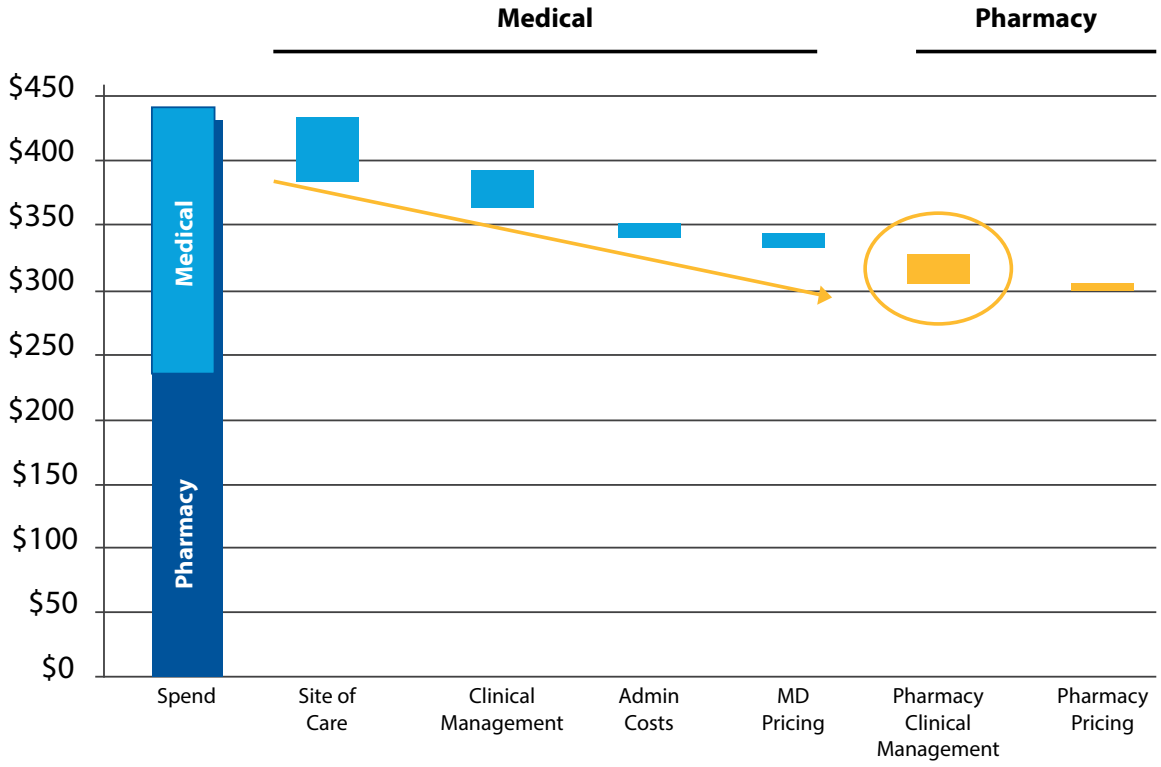


Courtesy of Artemetrx

Savings Opportunity Summary, Employer Example

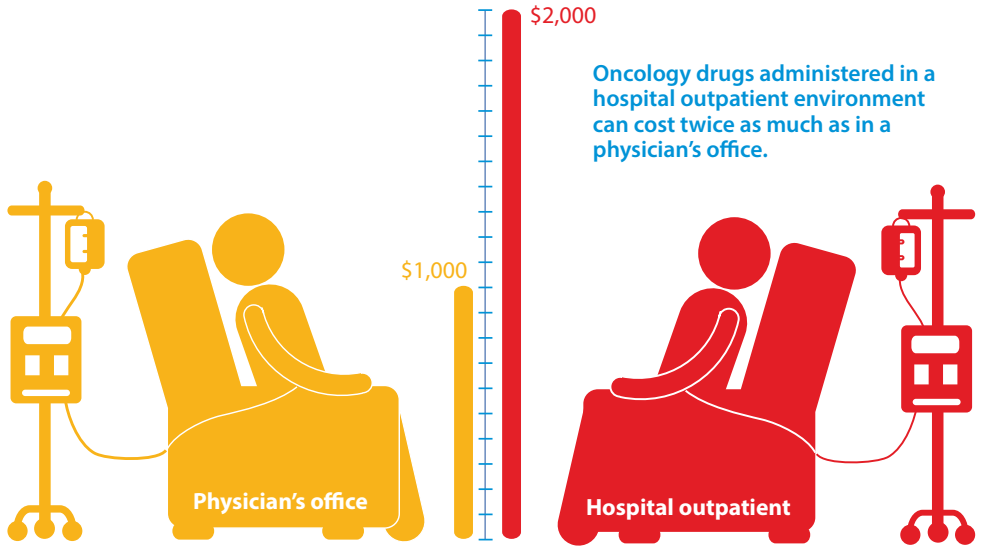
Courtesy of Artemetrx

Specialty Drug Savings Opportunity



Courtesy of Artemetrx

Oncology drug costs can double when administered in a hospital outpatient department

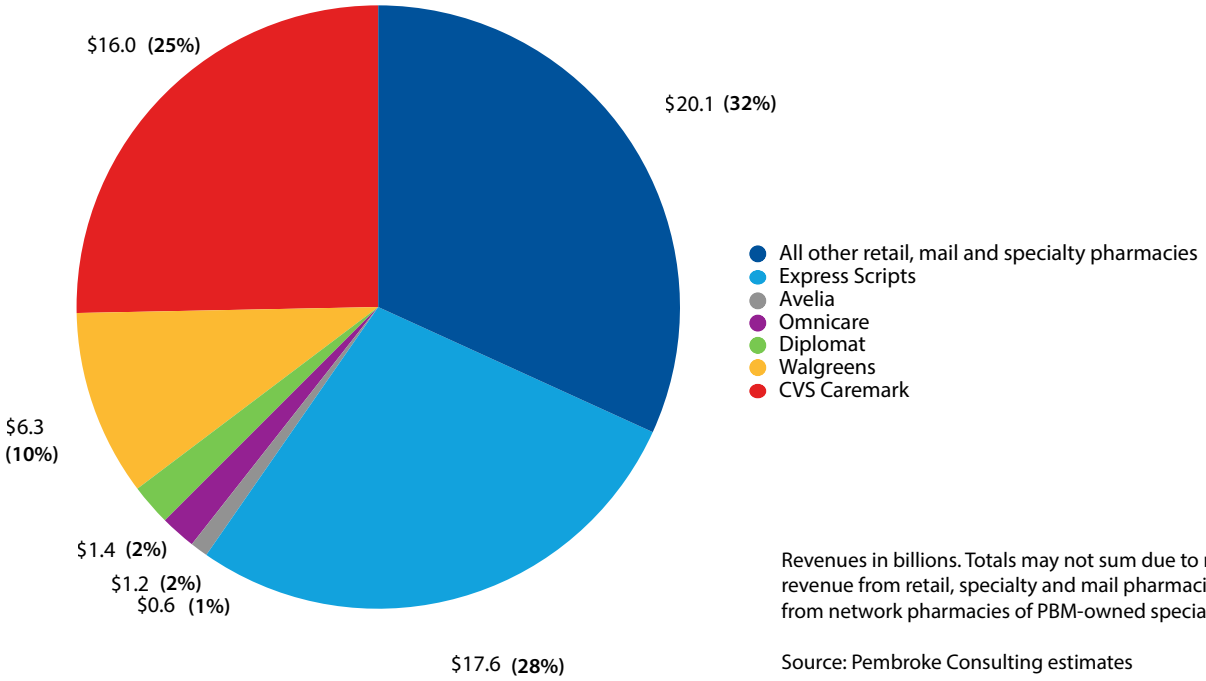


Example: oncology drugs
Total payment $ per claim

	Physician's office	% difference	Hospital outpatient
Alimta	$5,460	78%	$9,710
Herceptin	$2,740	95%	$5.350
Avastin	$6,620	113%	$14,100

Source: PwC Health Research Institute analysis based on 2012 Truven claims data

Specialty Pharmacy Market Share by Company 2013



Revenues in billions. Totals may not sum due to rounding. Includes revenue from retail, specialty and mail pharmacies. Excludes revenues from network pharmacies of PBM-owned specialty pharmacies.

Source: Pembroke Consulting estimates

Meeting Three: Four different models of specialty pharmacies:

- Financial arrangements and incentives between manufacturers, PBMs, specialty pharmacies, and hubs are not transparent to employers and they have not typically been involved in any decisions related to these entities.
- Employers heard from four specialty pharmacies. Prime Specialty and Lumicera are subsidiaries of PBMs, Prime Therapeutics and Navitus, respectively. Prime Specialty's goals include meeting the needs of its health plan owners, while Lumicera's goals include the needs of its PBM owner and clients. AmerisourceBergen, a pharmaceutical distributor, owns USBioservices, and Fairview Specialty is owned by a locally based provider delivery system.
- Specialty pharmacies evolved originally from pharmaceutical manufacturers, then wholesalers, PBMs, and delivery systems. Some independent specialty pharmacies also exist and the field continues to evolve.
- No single specialty pharmacy has access to all "limited access drugs," so PBMs and/or specialty pharmacies make arrangements to work with several.
- All the players perform the same functions including acquisition, distribution, and physician and patient support, however, each has different strengths and weaknesses, skills, information and goals, based on ownership and financial incentives.
- Several players are involved in helping physicians and patients obtain access to specialty medications, including entities called hubs. Hubs are funded by manufacturers and strive to get patients on specific drugs as soon as possible. They often replicate the work of specialty pharmacies by assisting in completing steps necessary for prior authorization and obtaining financial assistance for patients. (See sidebar.)

Meeting Four: Pharmacy program consultant observations and general recommendations:

- It's time for health plans to get in the game, for physicians to be held accountable for shared decision-making, and for patients to be held accountable for medication adherence.
- Good news: we're treating diseases that were formerly untreatable. Bad news: we're in an ethical conundrum about access and cost.
- There is good ROI for using drug therapies v. surgery and ongoing treatment (e.g., Sovaldi is priced below liver transplants—but why is it $84,000 in the U.S. and $2,000 in 80 other countries?).
- Why allow PBMs to provide prior authorization when they are paid by drug manufacturers for providing it ("Is there a fox in the henhouse?")?
- Just 12 nations drive 66 percent of prescription drug spend, and the U.S. spends 40 percent more on prescriptions than the next highest country. It's a price, rather than utilization, issue.

Meeting Five: The role of health plans in managing specialty pharmacy:

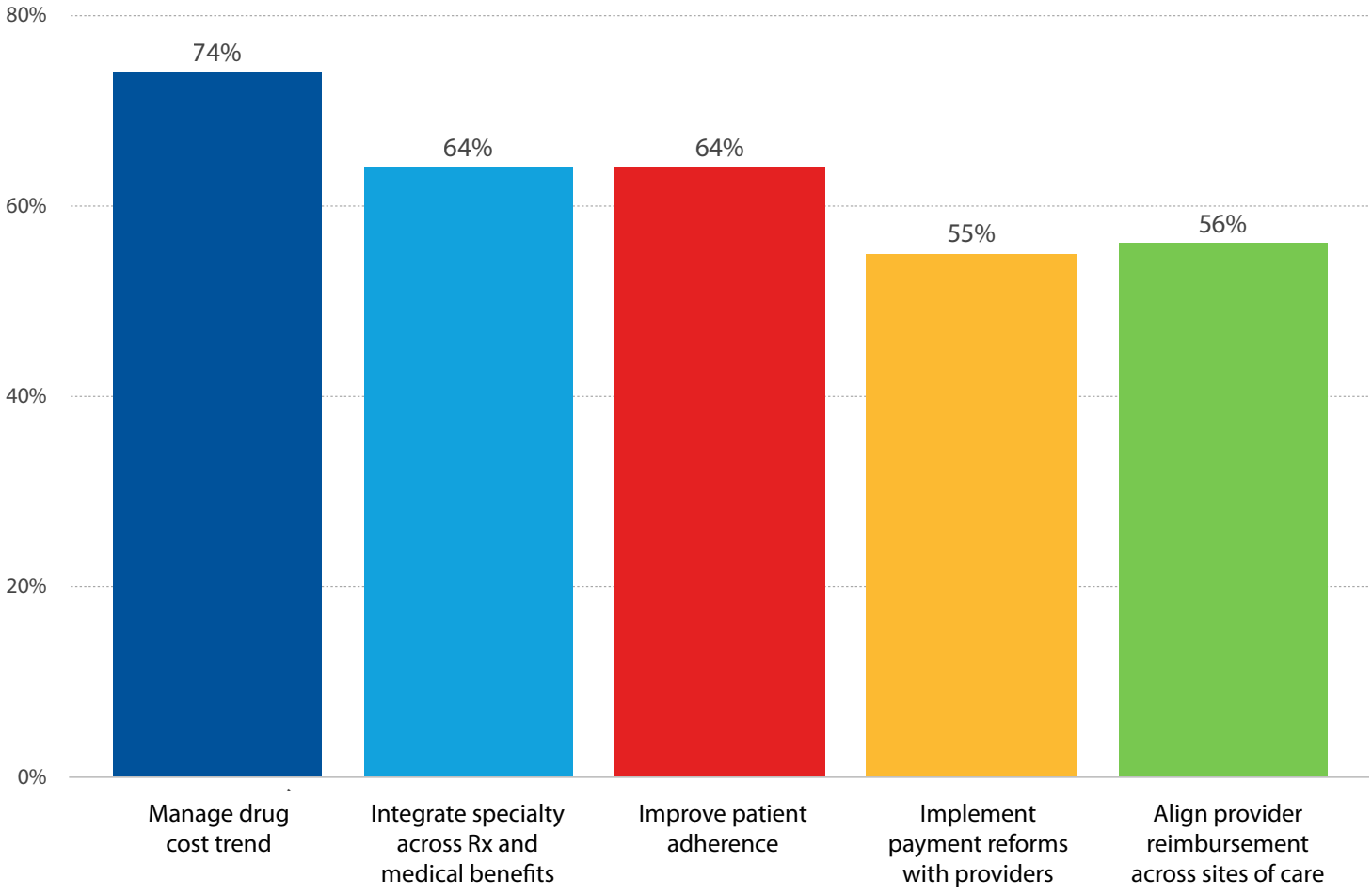
- Pharmacy and medical benefits need to be much more closely aligned.
- Plans are considering more aggressive prior authorization requirements to identify members early in their course of treatment. Employers need to help with employee communication and education about the importance of prior authorization.
- Behavior and medication adherence are affected by out-of-pocket costs.
- Health plans need to use prior authorization as an expense, utilization, and clinical quality management tool. The Care Delivery Learning Network was advised of current legislative action challenging prior authorization and responded immediately with letters to lawmakers. Click here to see a sample letter.
- Some suggested linking NDC and J codes, but consensus is that we really need to get to an NDC-specific system.

Cancer specialists slam high cost of drugs

"Treating cancer is expensive. …Some of the world's top cancer specialists took an extraordinary step on behalf of their patients. They demanded that drug companies roll back their prices."

CBS Evening News, July 25, 2013

Top Five Specialty Drug Management Goals for Payers



Courtesy of PSG

Meeting Six: National thought leader, Dr. Brian Klepper, president and CEO of the National Business Coalition on Health

- "Culture of Health" is a big movement, but lifestyle is not what's causing health care costs to explode. It's because everybody in the industry has found ways to extract more money than they are entitled to.
- The specialty drug problem is like having a stone in your shoe: It's not going to go away unless you do something about it. Taking action in this area could serve as a pathway to address other excesses in the system.
- Purchasers must collaborate. That's where the power and strength to make change happen lies.
- Specialty drugs are the "poster child" for what's wrong with the health care industry. Pricing is not tethered to anything—there is no reason we should be paying double what other countries are paying for the same medications.
- According to a 2010 Rand study, 79 percent of the growth in household income is being absorbed by health care. Health care is undermining our ability to have a sustainable society.

Specialty Pharmacies and Hubs: Comprehensive or Duplicative Patient Support Services?

A key part of the Specialty Pharmacy Learning Network includes hearing from key informants, organizations and entities employers typically don't work with directly. One session included presentations by representatives from four specialty pharmacies.

In addition to dispensing drugs, employers heard about other services specialty pharmacies offer patients and physicians. Several presenters introduced the term "hubs," a new term to most employers. It became clear that hubs offer many of the same services as specialty pharmacies, except they are paid by manufacturers to get patients on drugs as soon as possible.

Marketplace Confusion

There is conflict between those who want patients to get their prescriptions as soon as possible (e.g., hubs), and those who want to manage the cost, appropriateness and effectiveness of those drugs (e.g., payers, PBMs).

Specialty pharmacies are paid by PBMs whose goals are to assure appropriate and effective use of the drugs by requiring prior authorization and setting benefit plan designs to include cost sharing.

Hubs are paid by manufacturers to support physicians in getting prior authorization from the PBM; find financial support for the patient, if needed; and help the patient with drug therapy adherence. Hub advisors have even been known to arrange for prescriptions to be delivered to patients in advance of prior authorization.

Hubs originated as drug manufacturer "financial hubs" to assist patients in getting coverage for early biotech products. They have evolved to offer ongoing patient services, gather data, develop information technology and mobile applications, and more. They have also evolved to become subsidiaries of wholesalers (e.g., AmerisourceBergen's Lash Group), PBMs (e.g., Express Scripts' HealthBridge), retail pharmacies (e.g., Walgreens' CareMetx), as well as stand-alone operations.

As more doctors move toward an e-prescribing model and opt for specialty drugs to treat chronic and expensive conditions, many in the pharmacy industry anticipate a shift from traditional, one-off dispensing models toward emerging, innovative solutions such as specialty pharmacy hubs.

As with most evolving approaches, prescription hubs hold promise, yet also present unique challenges.

Pros

- Help physicians find the best coverage for patients—which drugs are most affordable, what discounts or copayment offsets may be available, what alternatives are possible, and which appeals may provide coverage for drugs otherwise not accessible.
- Capture data on trends in enrollment, prior authorizations, missing information, and patient copays, which benefits current and future patients.
- Convenience: many hubs offer 24/7/365 access.
- Extensive educational support for patients.

Cons

- Services may be duplicative of those offered by specialty pharmacies, PBMs, health plans, and other vendors, increasing costs and confusion.
- Some have a vested interest in helping drug manufacturers increase market share.
- Do not actively dispense medications.
- Lack the "high-touch" personal connection available through local pharmacists and other health care professionals.
- May involve lockouts by exclusive payer networks.
- May be harder to resolve service and support issues because of the remoteness of the hub from the patient.

Hub vendors serve as a central interface between the manufacturer and other players in prescription delivery. In many cases, the hub is internal to a specialty pharmacy, or even the manufacturer. By connecting all parties to provide more comprehensive and effective care for patients, the goal is better outcomes, lower health care costs, and better quality of life.

What Employers Can Be Doing

HEALTH PLAN	PBM	SPECIALTY PHARMACY	INDIVIDUAL EMPLOYER TIPS AND ACTION ITEMS
			ACCURATE AND COMPLETE REPORTING
X	X		Establish a ***complete and accurate baseline*** of total specialty pharmacy costs for both medical and pharmacy benefits to track trend and changes over time.
X	X		Require ***cost projections*** for the following year including anticipated FDA approvals, e.g., cystic fibrosis, familial hypercholesterolemia, specific to your population.
X			***Do not accept*** imputed NDC numbers artificially assigned by ***HCPCS-NDC crosswalks*** since these are not as specific as NDCs and insufficient for determining provider costs and payment.
	X		Require reports on drug spend to ***break out costs by specialty, retail and mail order*** pharmacies to understand any variation over time.
	X		Require reports that evaluate the ***impact*** of specialty prior authorizations and step therapy protocols (i.e., % approvals/denials, appeals, cost per claim).
			UTILIZATION AND CLINICAL MANAGEMENT
X	X		Conduct an ***independent audit of prior authorization and step therapy criteria, procedures and utilization measures*** to assure safety, effectiveness and appropriateness (evidence-based) for specialty meds under both the pharmacy and the medical benefit.
X	X		Require prior authorization and ***step therapy criteria are transparent*** to providers and patients.
X	X		Require that ***preferred products are based on clincal evidence.***
X	X		Review ***clinical management*** programs for effectiveness, safety and appropriateness (***evidence-based***) for top drugs; ask for information on provider conformance to guidelines, use of appropriate dosages, need for genetic testing, off-label use, patient engagement and compliance, and other evidence.
X	X		Require appropriate adherence (or compliance) under both the pharmacy and the medical benefits through effective management practices.
X			Require health plan reports on costs including ***expenditures for all four sites of care.*** (1. hospital outpatient, 2. freestanding infusion, 3. home infusion and, 4. physician office.)
X			Require reports on ***provider-specific variation in costs for conditions with high specialty pharmacy utilization***, e.g., psoriasis, MS, colitis, oncology, to understand variation in provider practice patterns.
			Require health plans/medical providers to ***report payments made by a manufacturer's patient assistance program or copay coupon program.***
X	X		Require that ***preferred products are based on clinical evidence.***
X	X		Review information on provider conformance to guidelines including use of appropriate dosages, need for genetic testing, off-label use, patient engagement and compliance, and other evidence.
	X		Select a PBM that will support and implement ***employer-specific criteria*** for specialty drug utilization management such as prior authorization, step therapy, quantity limits, drug or NDC exclusions, split fills, copay and coinsurance policies, and others.
	X		Select a PBM that will provide ***value-based assessments of new drug (and biological) products*** in relationship to alternate therapies at the time the new product is initially considered for coverage in the health benefit.
		X	Require information on, and reporting of ***results from, specific care management programs*** for patients on specialty meds including 1. how delivered, 2. who provides the care management, 3. which patients receive care management, 4. how the care management is coordinated with medical providers, 5. patient satisfaction with the experience, and 6. cost of the care management program.
		X	Require the ***specialty pharmacy to support utilization management tools*** to manage specialty meds including but not limited to 1. split fills, 2. custom reports on compliance by therapeutic category, 3. specialty care management services and support, 4. high-risk member targeting for adherence program, and 5. access to patient assistance programs and coupons that provide an overall benefit to the patient (combined effect of out-of-pocket amounts and premium contribution impact).
			BENEFIT PLAN DESIGN
X	X		Implement ***similar coverage and payment policies*** for specialty meds under both the pharmacy and the medical benefits (e.g., eliminate incentives for patients to use the most expensive providers).
X	X		Require value-based therapy coverage (covered and non-covered drugs are evidence-based and most cost effective).
X	X		Consider "floating" (copays/coinsurance) member cost sharing for specific drugs with generous ***manufacturer patient assistance programs*** and coupons to optimize their payments and mininize total expenditures by patients and employers.
X	X		Review and revise employer's "summary plan description" (SPD) for issues related to specialty drug coverage and management, e.g., ***optimizing biosimilars.***
X	X		Implement deductible polices so payments from manufacturer coupons and ***patient assistance programs do not count toward patient out-of-pocket deductibles.***

HEALTH PLAN	PBM	SPECIALTY PHARMACY	INDIVIDUAL EMPLOYER TIPS AND ACTION ITEMS
			CONTRACTUAL TERMS
X	X		Do not agree to an "exclusive specialty pharmacy" contract without complete ***transparency of economic transactions*** including rebates and other real or potential financial conflicts of interest.
X	X		Determine and negotiate employer rebate goals, strategies and agreements for specialty pharmacy specifically with both health plan and PBM.
X	X		Assure all summary plan descriptions include terms that optimize use of biosimilars.
	X		Require ***PBMs to serve as a fiduciary agent*** for the health benefit program and to be transparent by reporting all revenue streams actually or potentially affecting specialty use and spending (including rebates and any other forms of economic consideration).
		X	Review ***specialty pharmacy contracts with PBMs***, or directly with a specialty pharmacy/ies, to support value-based use and management of specialty meds.
		X	Require that patients receive specialty medication management from an independent party or, if provided by the specialty pharmacy, require that ***oversight be from an independent source*** (consultant) to assure appropriate clinical and value-based use of specialty meds including prior authorization, step therapy, biosimilar interchange, and net cost impact to both patient and plan.
		X	Require that oral specialty meds be provided by ***PBM-owned specialty pharmacy at the same reimbursement rate as a retail pharmacy*** providing the same prescription to a plan member.
		X	Review PBM-owned specialty pharmacy periodically by an independent auditor/consultant to assure that contract terms, as well as potential and real ***conflicts of financial interest***, have not adversely affected the employer or the covered members.
			PREPARE FOR FUTURE
X	X		***Raise awareness*** of senior corporate executives, unions, and other key stakeholders about the growing use and expenditures for specialty meds and the cost implications for employees and their health care costs.
X	X		Require reports on ***projected costs*** for the following year including anticipated FDA approvals, e.g., drugs for cystic fibrosis, familial hypercholesterolemia, specific to your population.
HEALTH PLAN	PBM	SPECIALTY PHARMACY	COLLECTIVE EMPLOYER ACTION
			ACCURATE AND COMPLETE REPORTING
X			Require health plans to ***report the specific NDC numbe***r for the drug product administered including the dosage form, strength, package type, and manufacturer.
X			Require health plans to ***break out drug-specific costs*** on each claim (and EOB for patient information) from the facility fees and professional charges for drug administration.
X			Require health plans/medical providers to collect and ***report rebates at the NDC level***, if they are or are not collected by the health plan,, to provide detailed reports that are sufficient to enable the employer or their PBM (preferable) to negotiate and collect rebates on specialty meds.
			PROVIDER CONTRACTING
X			Require health plan to equalize reimbursement for providers regardless of site-of-care to steer patients to the most cost-effective site of care.

Food for Thought From Dr. Schondelmeyer

- Drug spend is the iceberg in your benefits.
- Pharmaceutical Research and Manufacturers of America (PhRMA), a lobbying organization, is going after specialty because that's where the money is; specialty pharmacy is their new blank check.
- Pharmas play on employer fears of disrupting the sickest patients—they know employers won't say no.
- Rebates do not equal discounts. We should outlaw rebates like they have done in Massachusetts.
- The pipeline for traditional drugs is withering and dying.
- The FDA can't evaluate the economics of drugs, so who does?
- There are reverse, perverse incentives for medical providers that you don't know about.
- Pharma outsources R&D to companies backed with venture capital, they don't spend it themselves.
- We need a global approach to pricing; just going to one country like Canada won't work; pharma will just raise their prices.

The Importance of Engaging Consumers

The High Cost of Low Health Literacy and Poor Patient Engagement

For patients and their caregivers, low health literacy, challenges that come with managing complex conditions, troublesome side effects, and overwhelming administrative details means they often are not prepared to be active and informed members of their care teams.

Just 12 percent of adults have "proficient health literacy," according to the National Assessment of Adult Literacy. In other words, nearly 9 out of 10 adults—or over 91 million Americans—may lack the skills needed to manage their health and prevent disease. About 14 percent of adults (30 million people) have "below basic" health literacy. These adults are more likely to report their health as poor (42 percent) than adults with "proficient" health literacy.

Low health literacy leads to patients and caregivers who are not able to follow treatment compliance guidelines, express their wishes, or question the appropriateness of care. Further, it has been linked to poor health outcomes such as higher rates of hospitalization, a lower ability to comply with treatment regimens, and less frequent use of preventive services. These outcomes are associated with significantly higher health care costs.

There are many ways employers can assist employees in becoming well informed about their benefits, their health care, and their options.

> Low health literacy is a major source of inefficiency in the U.S. health care system. Estimates of the cost of low health literacy to the U.S. economy range from $106 to $236 billion annually. That's enough to insure about 47 million uninsured Americans.
>
> *School of Public Health & Health Services*
> *The George Washington University*

Beyond Basic Literacy: Six Steps

1. **Programs put employees first.** Unsuccessful health and benefits education programs focus on what's in it for the company. Effective efforts hone in on issues most important to employees like family, good health, security and opportunity.
2. **Leadership walks the talk.** In organizations with effective health care and benefits communications, leaders play an active and visible role. A study by HR consulting firm Mercer finds that 66 percent of employers with strong leadership support of benefits/wellness programs report a reduction in health risks, compared to just 26 percent of those with little or no management support.
3. **Health and benefits literacy is integrated into business strategy.** A positive corporate culture treats benefits, health and wellness matters not as an HR "project," but as a business imperative, linked to broader organization goals.
4. **No "off-the-shelf" solutions.** Many employers turn to health benefit providers for the bulk of communication materials. Although some of these resources can be valuable, they fail to capture the unique aspects and expectations of individual employers. A branded, customized approach greatly increases the odds employees will pay attention.
5. **Tie the communication strategy to the long-term vision.** Effective health and benefits education efforts take the long view. They recognize that employees may be resistant to change, and that support systems need time to evolve.
6. **Use formal and informal channels.** Thriving health and benefits programs use not only formal channels of communication such as benefits guides, newsletters, and email blasts, but also informal, interactive, employee-focused channels, including social media.

Fast Facts About Medication Adherence

Up to 30% of prescriptions are never filled.

Up to 50% of medications are not taken as prescribed.

125,000 deaths per year due to failure to take medications as prescribed, which also causes up to 10 percent of hospitalizations.

$100-$289 billion Medication non-adherence is estimated to cost the U.S. health care system $100 billion to $289 billion annually.

Source: Annals of Internal Medicine

Emerging Knowledge on Improving Adherence

Factors affecting adherence and persistency to therapy regimen				
Social and Economic Conditions	Health Care Team/ System	Characteristics of the Disease	Disease Therapies	Patient Characteristics
• Poor socio-economic status • Illiteracy • Unstable living conditions • Cost of medications • Cultural beliefs • Family dysfunction	• Poor patient-provider relationship • Poor medication distribution systems • Overworked health care provider • Lack of providers • Lack of knowledge on managing adherence	• Level of disability • Severity of symptoms • Rate of progression and severity of the disease • Comorbidities	• Complexity of regimen • Duration of therapy • Previous treatment failures • Side effects • Injection anxiety	• Forgetfulness • Treatment anxiety • Low motivation • Lack of understanding of health risk • Disbelief in diagnosis and/or treatment

Source: EMD Serono Digest

End-of-life Care

End-of-life care continues to be characterized by aggressive medical intervention and runaway costs, some of which are driven by the high cost of specialty and experimental medications. The number of patients and associated costs in critical care involving chronic disease and multi-organ failure—often the elderly and catastrophically ill—are remarkably high. In fact, the top five percent of these patients account for nearly half of spending (more than $600 billion a year), and the cost per capita of one percent of such patients is $90,000, compared with $236 per capita of the bottom 50 percent.

"We simply do not know how to die gracefully here in the U.S.," says Dr. Don Brunnquell, director of the Office of Ethics at Children's Hospitals and Clinics and a Specialty Pharmacy Learning Network key informant. "We seem to have a terrible time accepting the inevitable, grasping at every opportunity to prolong life, whether or not it improves the quality of life."

Honoring Choices Minnesota is one organization that strives to inspire and support many community-based conversations regarding end-of-life care planning by urging Minnesotans seeking to start such conversations in their family, faith, cultural or community groups. The organization offers many resources for employers to share with employees to help them broach this extremely sensitive subject.

Additional resources of interest:

- Honoring Choices Minnesota resources
- *Having Your Own Say* by Kent Wilson
- *Being Mortal: Medicine and What Matters in the End* by Atul Gawande
- *Cutting the High Cost of End-of-life Care* by Penelope Wang
- Judge Dismisses Assisted Suicide Case Against Pennsylvania Nurse
- The Cost of Cancer Drugs

- Studies by the Agency for Healthcare Research and Quality show that 65 percent to 76 percent of doctors whose patients had documents outlining end-of-life wishes weren't aware they existed.
- A recent study in the *New England Journal of Medicine* found that nearly 70 percent of patients with advanced lung cancer and 81 percent of those with late-stage colon cancer did not understand that chemotherapy was unlikely to cure them.
- A 2010 study in the journal *Cancer* found that one out of three physicians wouldn't discuss the prognosis with a cancer patient who has four to six months to live and is still feeling well. Instead, the doctors would wait for symptoms to appear or until there are no more treatments to offer.
- Duke University researchers report hospice use cuts Medicare spending in the last year of life by an average $2,300 per beneficiary and up to $7,000 for cancer patients.

The Upshot
THE NEW HEALTH CARE

$1,000 Hepatitis Pill Shows Why Fixing Health Costs Is So Hard

"A new drug for the liver disease hepatitis C is scaring people. Not because the drug is dangerous—it's generally heralded as a genuine medical breakthrough — but because it costs $1,000 a pill and about $84,000 for a typical person's total treatment."

New York Times, August 2, 2014

Blockbuster Hepatitis C Drug Shatters Previous Cost and Use Records

At $1,000/pill and $85,000 for a full 12-week course of treatment, the blockbuster hepatitis C drug, Sovaldi, is at the center of a hot debate over drug prices. Drug maker Gilead Sciences sold $10.3 billion of Sovaldi in 2014, bringing it close to becoming the best-selling drug in the world after its first year on the market.

The sudden huge increase in spending on Sovaldi is seriously stressing the budgets of payers, health plans, state Medicaid programs, and prison systems. But with a higher cure rate, fewer side effects, and a shorter treatment time, the drug is a godsend for hepatitis C patients.

What is Hepatitis C?

Hepatitis C is a contagious liver disease that ranges in severity from a mild illness lasting a few weeks to a serious, lifelong illness that attacks the liver. Toxins, certain drugs, some diseases, illicit use of IV drugs and sharing of needles, sexual contact with an infected person, heavy alcohol use, and bacterial and viral infections can all cause hepatitis C. It results from infection with the hepatitis C virus (HCV), which is spread primarily through contact with the blood of an infected person. It can be either "acute" (sudden onset) or "chronic" (ongoing and persistent).

What is the current trend in the U.S.?

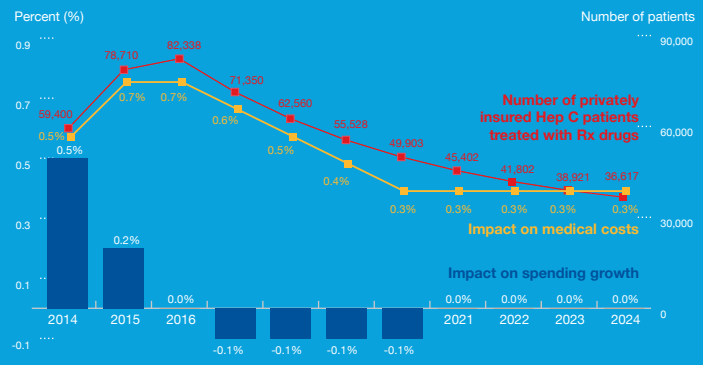
There were an estimated 21,870 cases of acute hepatitis C virus infections reported in the U.S. in 2012. Another estimated 3.2 million people in the U.S. have a chronic hepatitis C virus infection, most of whom do not know they are infected. The CDC estimates that only about 22 percent of people with the disease have been diagnosed.

How likely is it that acute hepatitis C will become chronic?

Approximately 75 percent to 85 percent of people who become infected with hepatitis C virus develop chronic infection.

Hepatitis C is different: Cures disease, affects large numbers

2015-2016 is the highest cumulative impact on benefit costs for employer plans



Source: PwC Health Research Institute estimate based on National Health and Nutrition Examination Survey and 2012 Truven claims data from employers

Why is incidence increasing?

Hepatitis C is most prevalent among those born between 1945–1965, the majority of whom were likely infected during the 1970s and 1980s when rates were highest. The American Liver Foundation suggests that everyone born between 1945 and 1965 be tested for the virus.

What is being done?

- Research into the development of a vaccine is under way (vaccines are available only for hepatitis A and hepatitis B).
- The CDC Foundation has established the Viral Hepatitis Action Coalition (VHAC), which is a public-private partnership developed to accelerate the CDC's efforts to prevent, control and ultimately eliminate viral hepatitis. The VHAC expands the capacity of the Foundation to launch new projects that are critically important to successfully prevent disease and deaths from viral hepatitis.
- The American Liver Foundation, a member of the World Hepatitis Alliance, provides a wealth of educational information and support for patients and health care providers.
- The World Hepatitis Alliance is a patient-led, patient-driven, not-for-profit international umbrella Non-Governmental Organization. Membership is composed of over 180 organizations that work in the field of viral hepatitis, representing every region of the world. The focus is on improving awareness, prevention, care, support and access to treatment.

What are the challenges and opportunities?

- The industry is rapidly changing, making it very difficult for industry outsiders to keep up.
- PBMs are telling employers what to do, without providing any type of opt-out.
- Discounts are not up front; they're given through rebates which leads to complexity and confusion.
- As the industry evolves at a rapid pace, purchasers need to do all they can to stay current. Some are doing so through the Specialty Pharmacy Learning Network.
- Purchasers can work collaboratively with PBMs to make sure cost and clinical quality are appropriately balanced and managed.
- Purchasers can require specialized reporting to better understand the flow of discounts, rebates and coupons.

Helpful Resources for Purchasers

By working collaboratively, purchasers can increase the value of high-cost, supply sensitive, health care services. Employers have an opportunity to increase value by clearly articulating goals, establishing tangible ways of evaluating whether these goals have been met, insisting on incentives for value in payment models and benefit plans, and working collectively with providers and/or health plans to achieve specific goals.

Additional Resources:

- 2014-2015 Economic Report on Retail, Mail and Specialty Pharmacies by Adam J Fein, Ph.D., Pembroke Consulting
- AHIP Issue Brief Specialty Drugs - Issues and Challenges, June 2014
- Elsevier Clinical Decision Support, SpecialtyPharmacy: What Now and What's Next?
- EMD Serono Specialty Digest, 10th Edition (2014)
- Health Affairs, October 2014, Issue
- PBMI Pharmacy Benefit Management Institute 2014 Specialty Drug Benefit Report (Sponsored by Walgreens)
- Specialty Tier Pharmacy Benefit Designs in Commercial Insurance Policies: Issues and Considerations, State Health Reform Assistance Network, a national program of the Robert Wood Johnson Foundation
- Express Scripts 2014 Drug Trend Report
- CVS Insights Report: Specialty Drive Trend Report
- The Growth of Specialty Pharmacy Issue Brief; UnitedHealth Center for Health Reform & Modernization
- Improving Print Communication to Promote Health Literacy

Glossary of Terms

- **Actual Acquisition Cost (AAC)**: Dollar amount paid by a pharmacy or other health care provider after all discounts, rebates and other price concessions have been deducted.
- **Adherence**: Degree to which a patient takes their medication or follow a treatment protocol according to the directions for which it was prescribed. It is a patient taking the prescribed dose of medication, at the prescribed frequency, for the prescribed length of time. Also referred to as compliance.
- **Ambulatory Infusion Center**: An alternative to home health care or inpatient hospitalization for patients who require administration of treatments such as chemotherapy and immunosuppressive specialty medications. Administration may include Intravenous (IV) infusions, IV, intramuscular or subcutaneous injections.
- **Average Manufacturer Price (AMP)**: Average dollar amount a wholesaler pays a manufacturer for a medication minus prompt-pay discounts. AMP is a benchmark created by the U.S. Congress in 1990 to calculate rebates owed Medicaid by drug manufacturers.
- **Average Sale Price (ASP)**: Also known as the average selling price, a weighted average of the dollar amount paid for a medication in all non-federal sales by drug manufacturers after deducting discounts, rebates, charge-backs, and free goods tied to a drug purchase. Medicare pays for the majority of Part B-covered drugs using ASP.
- **Average Wholesale Price (AWP)**: Published national average of list prices that pharmacies pay wholesalers for a medication. The AWP is specific to a drug strength, dosage form, package, size, and manufacturer or labeler.
- **Biologic**: Complex molecules produced from a variety of natural resources (human, animal and microorganisms). Biological products include a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins.
- **Biosimilar**: A biological product that is "highly similar" to an FDA-approved "reference" biological product, without regard to minor differences in clinically inactive components. There must also be no clinically significant difference in safety, purity and potency between the biosimilar and the original, approved biological product. Biosimilars are not generics and require separate contractual and regulatory considerations.
- **Brown bagging**: Refers to a specialty medication dispensed directly to patients who then carry the product to a physician's office to have it administered.
- **Buy and bill**: A reimbursement process where a health care provider (e.g., physician, clinic) purchases medicine to be administered by a physician or clinician. Once administered, medications are billed to the patient or payer for the cost of the drug plus a markup fee.
- **Compliance**: The degree to which a patient faithfully complies with administration instructions as specified by the prescribing physician consistent with the FDA-approved label. Also called adherence. Compliance is often measured by PBMs with claims data with medication possession ratio (MPR).
- **Copay offset/assistance/coupon programs**: Drug manufacturers sometimes offer copay assistance or coupons to patients, for their costs, who would otherwise be unable to afford costly medications and adhere to recommended treatment regimens.
- **Clinical case management**: The process of leading and directing patient care to assure that it is well coordinated, especially for those with chronic and serious health conditions, serious mental illness, and chemical dependency issues. Examples of a case manager's duties include regular telephone interventions to monitor treatment adherence, discharge planning from a medical facility, and monitoring for avoidable events.
- **CMS 1500 claim form**: Although most billing claim forms are completed online, paper claims are still being used in a large number of medical offices. The paper claim filing form is known as the CMS (Centers for Medicare and Medicaid Services) 1500. This is a universal form used by health care providers (professionals, not facilities) to submit their claims and invoices to insurance companies and carriers.
- **Destination pharmacy programs**: Similar to so-called medical tourism, there is a growing trend among U.S. patients who are in need of costly specialty pharmaceuticals to travel to other countries to obtain medication therapy at considerably reduced costs.
- **Drug administration costs**: Costs charged by providers for administering drugs in a professional setting, e.g., intravenous administration in an office or outpatient hospital

- **Experimental drug**: A substance that has been tested in the laboratory and received FDA approval for testing in humans. A drug may be approved for use in treating one disease or condition, but be considered experimental in treating other diseases or conditions.
- **Fail-first Therapy**: See "Step therapy."
- **HCPCS or "hick picks" (Healthcare Common Procedure Coding System)**: Codes developed to help ensure that claims are processed in a consistent and simplified way.
  - **J-Codes**: Used to report injectable drugs that ordinarily cannot be self-administered such as chemotherapy and immunosuppressive drugs. Drugs and biologicals are usually covered by Medicare if they cannot be self-administered, are reasonable and customary for a specific diagnosis or treatment of the illness or injury for which they are administered, and have not been determined by the FDA to be less than effective.
  - **Q-Codes**: Temporary codes used when a permanent code is not assigned. If a permanent code is subsequently assigned (J-Code), the Q-Code is deleted and cross-referenced.
- **Health Literacy**: Health Literacy is defined in the Institute of Medicine report, Health Literacy: A Prescription to End Confusion, as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions." Other definitions focus on specific skills needed to navigate the health care system and the importance of clear, two-way communications between health care providers and patients. Health literacy is not simply the ability to read. It requires a complex group of reading, listening, analytical, and decision-making skills, and the ability to apply these skills to health situations (e.g., the ability to understand instructions on prescription drug bottles, appointment slips, medical education brochures, doctor's directions and consent forms, and negotiate complex health care systems).
- **Hub**: Pharmaceutical manufacturers contract with hub providers to support physicians and their patients as they navigate complex access, adherence and reimbursement issues. Sometimes referred to as reimbursement hubs, they provide many more services such as copay program administration, patient assistance programs, home care coordination, injection site coordination, and patient education. Hubs also deal with such things as therapy management (e.g., step edits/fair-first policies), prior authorizations, medical necessity documentation, contracted/preferred/mandated pharmacies, and much more. Whether the drug comes through a specialty pharmacy, retails pharmacy, or buy and bill, the hub is responsible for operational excellence and timely delivery.
- **Home Infusion**: The process of infusing a medication via intravenous (IV) or other means of administration under the supervision of a professional, licensed clinician.
- **Interchangeable Biological**: A biosimilar to an FDA- approved reference product that has met additional standards for interchangeability. An interchangeable biological product may be substituted for the reference product by a pharmacist without the intervention of the health care provider who prescribed the reference product.
- **Limited distribution drug**: Medications that have special dosing requirements or lab monitoring that need to be followed very closely. Because of this, the manufacturer sometimes chooses to limit the distribution of their drug to only a few pharmacies, or, as part of the drug approval process, the Food and Drug Administration (FDA) may recommend this type of distribution in order for the drug to be approved. This type of restricted distribution helps the manufacturer keep track of the inventory of the drug, educate the dispensing pharmacists about the monitoring required, and ensure that risks associated with the medication are minimized.
- **Medical benefit**: Medical benefits help cover all medically necessary inpatient hospital care and outpatient services to promote, preserve and restore health. Examples include pharmacy, surgery, critical care, mental health, orthopedics, preventive care, and rehabilitative services.
- **Medication adherence/compliance**: Taking medications as prescribed and according to evidence-based protocols, often measured in medication possession or persistence ratio
- **NDC (National Drug Code)**: A unique 10-digit, 3-segment number that is a universal product identifier for human drugs in the United States. The code is present on all nonprescription (OTC) and prescription packages and inserts in the U.S. The first set of numbers in the NDC identifies the labeler (manufacturer, repackager, or distributer). The second set of numbers is the product code, which identifies the specific strength, form (i.e, capsule, tablet, liquid), and formulation of a drug for a specific manufacturer. The third set is the package code, which identifies package sizes and types. The labeler code is assigned by the FDA, while the product and package code are assigned by the labeler. NDC codes provide more specific information about the specific drug, its dosage and form than HCPC, J codes and revenue codes and are preferable when analyzing claims data to identify costs and patterns in specialty pharmacy use.
- **Non-responder:** According to the Hepatitis B Foundation, a "vaccine non-responder" is a person who does not develop protective surface antibodies after completing two full series of the hepatitis B vaccine and for whom an acute or chronic hepatitis B infection has been ruled out. Although the majority of people vaccinated against hepatitis B successfully respond, an estimated five to 15 percent may not. It is possible that a person who does not respond to the vaccine may already be infected with hepatitis B. Testing for the presence of the virus (HBsAg) is recommended before diagnosing a person as a "vaccine non-responder."
- **Off-label use**: When a medication is being used in a manner not specified in the FDA's approved packaging label, or insert, it is called off-label use. Every prescription drug marketed in the U.S. carries an individual, FDA-approved label. This label is a written report that provides detailed instructions regarding the approved uses and doses, which are based on the results of clinical studies that the drug maker submitted to the FDA. The FDA regulates drug approval, but not drug prescribing, so doctors are free to prescribe a drug for any reason.
- **Orphan Drug**: A pharmaceutical agent developed to treat a rare medical condition, referred to as an orphan disease. The U.S. Department of Health & Human Services' Orphan Drug Designation Program provides orphan status to drugs and biologics that are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases and disorders affecting fewer than 200,000 people in the U.S., or that affect more than 200,000 but are not expected to recover the costs of developing and marketing a drug.
- **Pharmacoeconomics**: Field of study that compares the value of different drug therapies with respect to both the financial and quality-of-life outcomes. The three most common types of analysis are cost-benefit, cost-effectiveness, and cost-minimization. Other forms of analysis include cost-utility, cost-avoidance, and cost-consequence.
- **Pharmacy benefit**: Medications prescribed by physicians are normally covered under a pharmacy benefit. Many employers "carve out" the pharmacy benefit of their health plans to a pharmacy benefit manager (PBM), which focuses solely on managing prescription drug costs which represent a disproportionate share of health care spending.

- **Pharmacy Benefit Manager (PBM)**: A company that administers a pharmacy benefit program for plan sponsors, insurers and health plans, often a third-party administrator (TPA). PBMs typically develop drug formularies, contract with pharmacies, negotiate discounts and rebates with drug manufacturers, and provide mail-order fulfillment services.
- **Price Transparency**: The disclosure of cost-related information by an organization to those outside of the organization. There is an increasing demand for transparency because there is concern that too much revenue is flowing from pharmaceutical companies to PBMs, and too little flowing to plan sponsors. In a transparent model, discounts, rebates, incentives and other benefits earned on behalf of the plan sponsor are passed along to plan sponsors and members.
- **Prior Authorization**: A check run by insurance companies or third-party payors before they will agree to cover certain prescribed medications or medical procedures. The process is intended to improve patient safety and reduce costs. Failure to obtain prior authorization when required most often results in claim denials by insurance providers.
- **Purchasing Coalition**: Individuals or organizations that join together to capitalize on their collective buying power to negotiate for goods or services. Prescription drug benefits are an increasingly popular service provided by purchasing coalitions.
- **Quality Adjusted Life Year (QALY)**: A year of life adjusted for its quality and quantity. A year in perfect health is equal to 1.0 QALY, while a year bedridden might have a value equal to 0.5 QALY. It is a widely used measure of health improvement used to guide health care resource allocations. The QALY is based on the number of years of life that would be added by an intervention.
- **Rebates (medical specialty pharmacy)**: Rebates offered by manufacturers for specialty drugs administered under the medical benefit.
- **Risk Evaluation and Mitigation Strategy (REMS)**: FDA designation for specific drugs that have serious risks; limited distribution through specially trained pharmacies is one tactic to manage these risks (see limited distribution drugs).
- **Site of Care**: A facility where a patient receives treatment or testing such as a doctor's office, clinic, hospital, laboratory, ambulatory infusion center, radiology center, etc. A pharmacy can also be a site of care if a drug is administered on premises.
- **Specialty Pharmaceuticals**: Drugs that treat complex, chronic conditions and often require special administration, handling, and care management. Terms sometimes used interchangeably with specialty pharmaceuticals include biotech drugs, injectables, biopharmaceuticals, biological, and large molecule agents. While there is no federal statutory definition of specialty drugs, they are defined by various features:
  - How they are made (biological process)
  - How they are approved by the FDA (Biologics License Application)
  - Conditions they treat (chronic, complex, genes)
  - How they are used (injected, special administration)
  - Special features (safety, monitoring, storage, etc.)
- **Specialty pharmacy**: Specialty pharmacies fill prescriptions for complex medications for complex health conditions and provide high-touch services to help patients manage their health and adhere to prescribing guidelines to improve clinical and economic outcomes. In addition to drug dispensing, they provide services similar to a hub. PBMs and health plans often contract directly with independent specialty pharmacies, and with employers that carve out specialty pharmacy services from their existing pharmacy benefit.
- **Step therapy**: An approach to prescriptions intended to control costs and risks posed by some prescription drugs. The practice begins medication for a medical condition with the most cost-effective, safest drug therapy first, and progresses to more costly or risky therapies only if necessary. Also referred to as step protocol or a fail-first requirement.
- **Suggested Wholesale Price (SWP)**: Dollar amount manufacturers recommend wholesalers use when selling a drug to customers. Wholesalers are not obligated to sell a medication at this price.
- **UB 92 Form**: Uniform/Universal 92 is the official HCFA/CMS form used by hospitals and health care centers when submitting bills to Medicare and third-party payors for reimbursement.
- **White bagging**: A shipment of a medication to a physician or other licensed practitioner in response to a patient-specific prescription.
- **Wholesale acquisition cost (WAC)**: Manufacturers develop prices for wholesalers and distributors and submit their WAC prices for commercial publication in the Pharmaceutical Pricing Compendium that details product pricing and reimbursement. WAC does not represent actual sales prices and does not include any discounts, rebates or price reductions.

Appendix

Key Informants

Phase I of the Specialty Pharmacy Care Delivery Learning Network would not have been possible without the contributions of our key informants. The Action Group is grateful for the contributions of the following people:

- **Specialty Pharmacy Care Delivery Learning Network special advisors:**
  - Stephen Schondelmeyer, Pharm.D., Ph.D., professor of pharmaceutical economics in the College of Pharmacy at the University of Minnesota-director of PRIME Institute
  - Bithia Firku, Pharm.D., M.P.A., research analyst, University of Minnesota College of Pharmacy-PRIME Institute, Department of Pharmaceutical Care and Health Systems
- **Ethical perspectives from outside the industry:**
  - Don Brunnquell, Ph.D., Director, Office of Ethics, Children's Hospitals and Clinics
  - Katherina Glac, Ph.D., Associate Professor, Ethics, University of St. Thomas
- **Deep health care data analysis and specialty drug solutions:**
  - Shannon Ambrose, Vice President, Product Development and Management, Artemetrx
  - Corey Belkin, Vice President, Business Development, Artemetrx

- **Behind the scenes with specialty pharmacies (PBMs are usually the intermediary):**
  - Pete Wickersham, M.S.E., Senior Vice President, Integrated Care and Specialty, Prime Therapeutics
  - Lisa Schissel, Regional Vice President, Client Engagement, Prime Therapeutics
  - Tim Affeldt, Pharm.D., Director, Specialty/Infusion Operations, Fairview Pharmacy Services
  - Daniel Jude, Pharm.D., Manager, Specialty Clinical Services, Fairview Pharmacy Services
  - Ann McNamara, Pharm.D., Clinical Development Management, Fairview Specialty Pharmacy
  - Alan Van Amber, Vice President, Pharmacy Network Development, Navitus/Lumicera
  - Tom Radloff, R.Ph., Senior Director, Clinical Client Services, Navitus/Lumicera
  - Tammy Tarzynski, Regional Vice President, Sales, Navitus/Lumicera
  - Kevin James, M.B.A., Vice President, Payer Strategy, US Bioservices
- **Suggested vendor conversations from independent employer consultants:**
  - Brian Bullock, Founder and CEO, The Burchfield Group
  - Shawn Patterson, M.B.A., Pharmaceutical Benefits Consultant, The Burchfield Group
  - Kevin Host, Pharm.D., President, Pharmaceutical Strategies Group (PSG)
- **Health plan role assessment:**
  - Charlie Fazio, M.D., Medical Director, HealthPartners
  - Rick Bruzek, Pharm,D., Vice President, Pharmacy, HealthPartners
  - Jana Johnson, M.B.A., Senior Vice President, Health and Provider Services, Medica
  - Jim Hartert, M.D., Senior Medical Director, Medica
  - William Gerardi, M.D., Senior Vice President Health Management, Chief Medical Officer, Blue Cross and Blue Shield of Minnesota
  - Howard Epstein, M.D., Executive Vice President, Chief Medical Officer, PreferredOne
  - Alan Heaton, Pharm.D., Director of Pharmacy, PreferredOne
- **National employer perspective, wrap up, preparation for Phase II:**
  - Brian Klepper, Ph.D.: Dr. Klepper is a health care analyst, commentator and entrepreneur. He is CEO of National Business Coalition on Health (NBCH), representing 55 regional business health coalitions, about 4,500 employer and union health benefits purchasers, and some 35 million people. He is also principal and chief development officer for WeCare TLC, LLC, a worksite primary care clinic and medical management firm based in Lake Mary, FL.

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