Purchaser's Guide

Minnesota Health Action Group™
Innovating, Leading, Engaging

Spotlight on: Specialty Pharmacy (Phase II)

Turning Knowledge Into Action

Exploring Challenges

Becoming Informed

Defining Action Steps

Influencing the Marketplace

NOTE TO READERS:

This document contains a number of words that may be unfamiliar to some readers. A comprehensive Glossary of Terms can be found in the Phase I Purchaser's Guide; newly identified terms can be found on page 24 of this Guide.

Table of Contents

Special Features

Appendix

About the Minnesota Health Action Group Care Delivery Learning Networks

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 into how to increase the value of health care goods and services that are subject to high cost, variability, and overuse or inappropriate use. The resulting Employer Purchaser's Guides enable members to shape their benefit strategies and influence 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:

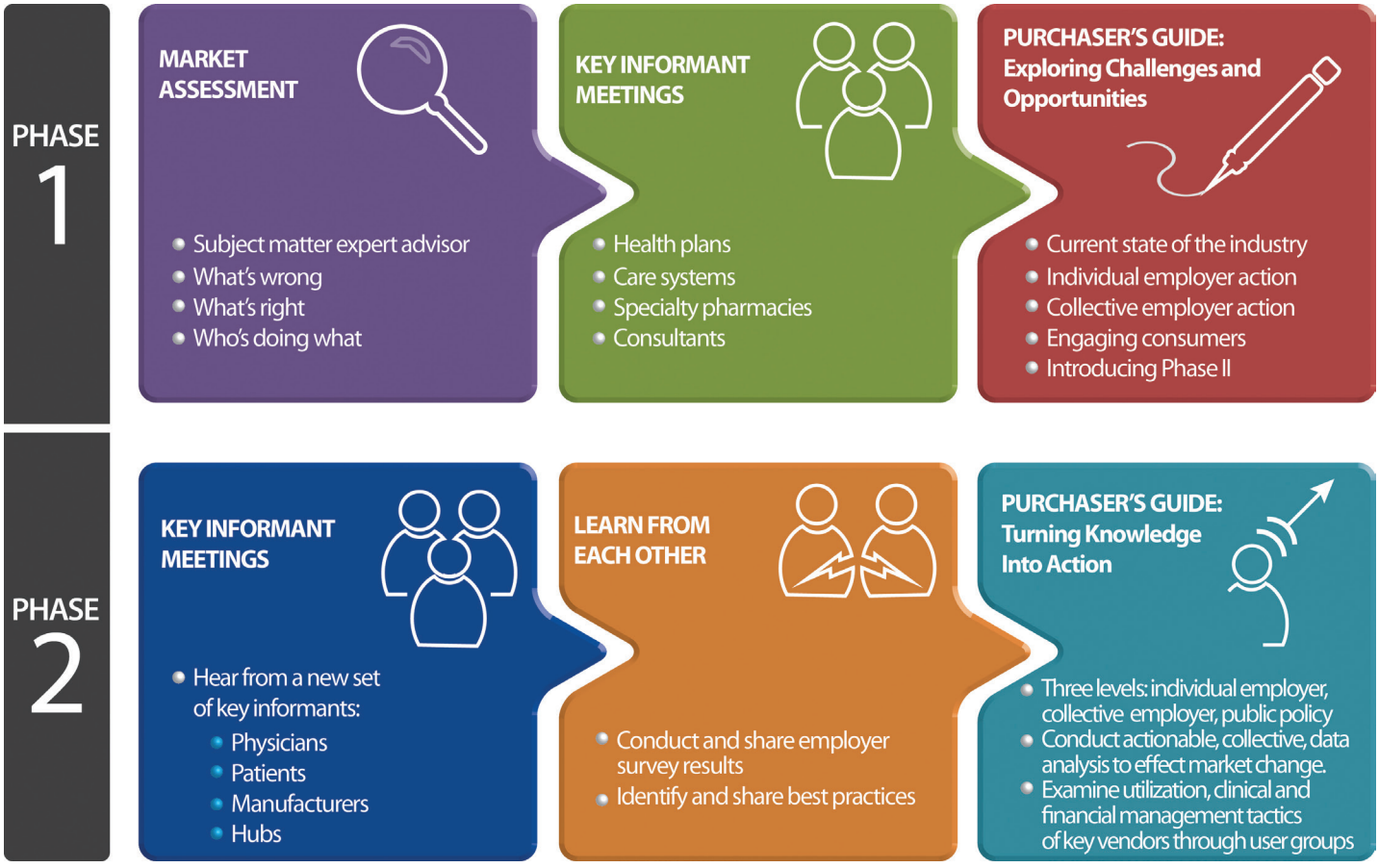
- Sends a strong, clear and consistent signal to providers, vendors and health plans about care delivery cost and quality expectations.
- Eliminates redundant efforts of multiple employers, thus diminishing the impact of disparate efforts on a single provider, vendor or health plan.
- Yields greater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

About the Specialty Pharmacy Care Delivery Learning Networks

Background/Overview

The Specialty Pharmacy Care Delivery Learning Network for Phase I and Phase II includes 3M; Best Buy; Blue Cross and Blue Shield of Minnesota; Carlson; Emerson-Rosemount; 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.

As participants in the Specialty Pharmacy Learning Network neared the end of the first six months of key informant meetings, they agreed to extend their investigation for at least six months. Phase I — Shining the Light on Purchaser Cost and Value Expectations — kicked off in October 2014 and concluded in March 2015. Phase II — Turning Knowledge Into Action — kicked off in May 2015 and concluded in December 2015. This Purchaser's Guide is designed to be used in conjunction with the Phase I edition, which identifies the serious challenges facing employers as they strive to gain control over the high cost of specialty drugs.



Specialty Pharmacy Purchaser's Guide (Phase I)

The following information can be found in the Phase I Purchaser's Guide:

- Definition of specialty pharmaceuticals.
- Identification of the main challenges employers face in trying to manage specialty pharmacy costs.
- Graphic showing the complex distribution and reimbursement channels for prescription drugs.
- Summaries of the initial employer roundtable discussion and all key informant meetings.
- Special features:
  - Individual and Collective Employer Action (Table)
  - The Specialty Pharmacy Boom: Why Now?
  - Understanding Specialty Pharmacy Hubs
  - Why Blockbuster Hepatitis C Drugs Have Shattered Previous Cost and Use Records
  - Glossary of Terms

Summary of Phase I Specialty Pharmacy Purchaser's Guide: Key Informant Meetings

Employer Roundtable Discussion. The Learning Network began with an employer roundtable featuring Sara Drake, R.Ph., M.P.H., M.B.A., Deputy Director, Health Care Purchasing and Service Delivery for the Minnesota Department of Human Services. She discussed the advantages and disadvantages of a specialty pharmacy model, 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). From this discussion emerged key Learning Network goals.

Key Informant Meetings. Featuring thought leaders from universities, health plans, care systems, specialty pharmacies, PBMs, and consultancies, key informant meetings helped members better understand the positions of various stakeholders:

- **Meeting one:** A crash course on the specialty pharmacy industry.
- **Meeting two:** Business and medical ethics considerations and understanding specialty pharmacy spending through data analysis.
- **Meeting three:** Four different models of specialty pharmacies.
- **Meeting four:** Pharmacy program consultant observations and general recommendations.
- **Meeting five:** The role of health plans in managing specialty pharmacy.
- **Meeting six:** The importance of employer collaboration in driving marketplace change.

Specialty Pharmacy Learning Network Employer Goals:

- Become smarter about how specialty pharmacy benefits are delivered, administered and managed.
- Be able to ask important questions of consultants, health plans, and PBMs.
- Have information and questions to include in requests for proposals (RFPs).
- Understand the implications of new drugs, developments, and changes in the industry as they unfold.
- Know key actions to take to reduce costs and improve outcomes.
- Explore collective actions that may be discovered through collaborative learning.

A SPECIAL THANK YOU TO

Dr. Stephen Schondelmeyer

Stephen Schondelmeyer, Pharm.D., Ph.D., has served as senior advisor to the Specialty Pharmacy Care Delivery Learning Network from the beginning. Not only does he assist in planning the key informant meetings, he also is a frequent presenter, and attends every session, generously donating his time. 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. He advises the University of Minnesota Employee Benefits Department on strategy and key decisions, which gives him insight into the unique challenges employers are facing today. 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. We are truly grateful for his leadership, vision and willingness to advise employer members about how they can work together to bring about needed change.

Carolyn Pare

President and CEO

How the Specialty Pharmacy Learning Network is Unique

- Dr. Stephen Schondelmeyer has served as the Learning Network's senior advisor from the beginning (see sidebar).
- Public and private sectors are well represented.
- It is the largest Learning Network to date, with 17 employers, most of whom attended every meeting.
- Stakeholders from care systems, specialty pharmacies, pharmacy benefit managers (PBMs), health systems, and benefits consulting firms presented to the group.
- Pharmaceutical companies were not involved during Phase I and Phase II, enabling participants to focus on learning about the marketplace and formulating a plan for gaining some control over specialty pharmacy spending.
- Participants collaborated to write and deploy Purchaser Value Statements on National Drug Codes (NDCs) and the cost of site of care. They are also investigating the possibility of defining a new "centers of excellence" model for certain high-cost specialty drugs.
- The collective impact of employers emerged as the only way to make a substantive difference in the rapidly evolving marketplace.
- Due to conflicts of interest, employers are learning they can no longer rely solely on their vendors to be stewards of their health care dollars.

NDC Codes: 11 digits specific for drug name, manufacturer, form, strength, and container or vial size.

The Action Group has been gaining local and national attention for its specialty pharmacy thought leadership:

- The Institute for HealthCare Consumerism: "Specialty Rx: What's an Employer to do?"
- Benefitspro: Rising Cost of Specialty Drugs Concerns Employers
- *Star Tribune:* Specialty Drugs: What Good is a Treatment if it's Out of Reach?
- *Star Tribune:* Employers Should Prepare for Surge in Specialty Drug Costs

KEY INFORMANT MEETINGS

Key informant meetings feature thought leaders from universities, health plans, care systems, specialty pharmacies, PBMs, and consultancies. Following is a summary of these meetings:

MEETING ONE, MAY 27, 2015

Background Information: Annual Action Group Employer Benefits Survey Summary

- The vast majority of respondents use their health plans to administer prescription drug benefits.
- Specialty pharmacy is the biggest concern, with a trend rate of 30 percent.
- Many respondents will put more management strategies into their drug programs (e.g., narrow networks, guarantees for medication adherence).
- About 85 percent of respondents offer prescription drug pricing tiers (i.e., generic, preferred, non-preferred), but less than half report offering brand and specialty categories.
- The most common health plan data reporting gaps are prior authorization, step therapy performance, and itemized rebates.
- The most common PBM data reporting gaps are performance on specialty pharmacy quality and service outcomes.
- The top steps respondents will take to manage cost and use in the short term are:
  - Require detailed health plan reporting
  - Ensure prior authorization and step therapy are employed
  - Set the expectation for better site-of-care management
  - Redesign the pharmacy benefit plan

Specialty Pharmacy Learning Network Survey

A specialty pharmacy survey was conducted mid-year. The employers' lack of response on many questions, along with their verbal responses, indicated a lack of clarity about what vendors — both PBMs and health plans — were actually doing on their behalf, and the need for increased knowledge of vendor activities and results. Generally, PBMs were more specific in their activities related to clinical and utilization management and reporting. Health plans were less specific in explaining clinical and utilization management; reporting was very limited.

Data analysis priorities: Questions and considerations about data, information and knowledge

The first meeting of Phase II included a review of reporting and analysis capabilities of two vendors with expertise in specialty pharmacy. The goal was to increase employer understanding of current vendor reports. Questions employers should ask about existing reports include:

- Is the information actionable, comparable, complete, valid and relevant to employers?
- Will the data help individual employers:
  - Understand vendor performance and results?
  - Identify savings opportunities from clinical and utilization management?
  - Identify savings opportunities from price and reimbursement?

The group explored how aggregating data from all the Learning Network participants might help the collective employer group:

- Shape the market and compare vendors, providers and employers.
- Inform conversations in vendor user groups.
- Inform policy positions.
- Achieve sustainable costs.

The group identified aggregating data as an opportunity for future collaboration and action.

All decisions should be based on accurate, complete, comparable, and timely data that can be organized to provide actionable information. The lack of NDC codes on medical specialty claims poses a fundamental barrier to understanding costs and utilization on the medical side.

MEETING TWO, JUNE 24, 2015

The group first reviewed specialty pharmacy reporting, including examples from two organizations. Advantages and challenges of collectively requiring NDCs on medical claims were explored. Also discussed were pipeline management options for PCSK9 cholesterol drugs (see PCSK9 sidebar on page 14).

NDC market strategy and tactics

- Having NDC codes on medical specialty pharmacy claims will be a necessary foundation for conducting clinical management, revealing price transparency, increasing provider and health plan accountability, and understanding and reviewing manufacturer rebates.
- Audits are needed to determine whether billing from providers is sloppy or fraudulent; purchasers should require plans to validate high-cost medical specialty claims.
- Health plans and providers will need to re-contract to incorporate NDC coding expectations. Purchasers will need to support health plans as they convince larger health systems to use NDCs and negotiate reasonable prices.

What to expect from health plan reporting

- Health plan reporting to employers on medical specialty pharmacy is very limited and not actionable. For example, one health plan provides data on trends, top therapeutic classes, and conditions, but does not compare provider costs or practices.
- When NDC codes are included on medical claims, they are not used for analysis to compare costs, utilization or outcomes. They are used to identify drug name, manufacturer, form, strength, and container or vial size.

Pipeline Management – PCSK9s

- New drug pipeline management is increasingly important for employers. They need to require information from, and input on, coverage decisions related to new drugs from both health plans and PBMs.
- Decisions about PCSK9 management are urgent given impending FDA approval. Employers were given a list of questions to ask PBMs related to their plans for managing these new drugs once they are approved and FDA labeling is established.

Collective Purchaser Voice

- Purchasers need to create and communicate their positions on a number of specialty pharmacy-related topics, including NDCs, drug prices, patient accountability, provider site-of-care practices, and other issues.
- The existing business, process and supply chain models are not working for employers or consumers. New models, capabilities and players are needed in the specialty pharmacy market and supply chain to manage current and future challenges, including integrating medical and pharmacy data and care, measuring, and patient-reported outcomes.

Employers were surveyed on current practices and vendors. Results were compared, revealing that employers have many questions about services provided by their vendors to manage costs and value, especially for health plans that manage medical specialty pharmacy costs.

New Class of Cholesterol Drugs Should Cost Much Less, Report Says

Peter Loftus of the Wall Street Journal discusses ICER's latest report on PCSK9 inhibitors for treatment of high cholesterol.

"Cholesterol-lowering Praluent and Repatha cost more than $14,000 a year per patient, but would be cost effective at $2,180, according to researchers."

ICER Review, September 8, 2015

MEETING THREE, JULY 22, 2015

Employers' Expectations for Cost Transparency on Drugs (see page 28 for full document)

- Employers will advocate for transparent, high-quality data on specialty drugs by appealing to policy makers, providers, health plans, and others to ensure NDC codes are used for all drugs and providers.
- Employers will work collaboratively to encourage mutually aligned goals of better information for better management.

Ongoing employer pipeline management

- Understand vendors' (both health plans and PBMs) internal processes for pipeline and clinical management.
- Expect health plan providers to be as skilled and knowledgeable about new drugs in the pipeline that will be paid through medical claims as PBMs are about pipeline drugs distributed through pharmacies.
- Learn why FDA drugs matter, especially REM (Risk Evaluation and Mitigation Strategies) drugs (i.e., they affect distribution channels and, potentially, pricing clout of manufacturers).
- Request important information from vendors, including, 1) the price projection for the specific drug for the upcoming year, at least three months in advance of budget decisions, and 2) the number of potential patients who could be treated with the drug given its indications so employers can predict impact on their expenses.
- Set up regularly scheduled meetings with health plans and PBMs requesting updates on priority pipeline drugs.

Clinical and utilization management

- Utilization management (UM) programs such as prior authorization (PA) and step therapy can be used to improve safety and efficacy, as well as cost-effectiveness for specialty drugs.
- Health plans, union groups, Medicaid agencies, and employers may contract with external, neutral, expert organizations to do PA for prescription and medical specialty drugs, or they may rely on PBMs to perform this function. PBMs, however, may have incentives from manufacturers to reduce UM activity to get better pricing and greater rebates.
- Patients using specialty drugs have complex conditions and care that require ongoing support and coordination beyond the PA and step therapy process.
- Goals include:
  - Understand processes, weaknesses and strengths of vendor activities.
  - Evaluate and compare vendors' performance to each other using key process and outcomes metrics.
  - Consider carving out clinical management.
  - Management methods should be used by both health plan and PBMs and include coverage determination, formulary placement, quantity limits, quantity limits, reference pricing, PA/step therapy, and adherence programs.
- Coverage decisions:
  - Determine up front who decides what is covered and what role the employer plays in these decisions. (Is it the vendor's decision, how is it made, who makes it, and how and when is the employer consulted or notified?)
  - Employers may choose to delay or deny coverage for new drugs when there are safe, effective alternatives, or if not enough is known about a new drug's effectiveness, risk and value.
  - Coverage with strict step therapy or PA on new drugs may not be possible until more is known about a drug's value and effectiveness post-FDA approval.
- Formulary placement determines member cost sharing:
  - Tiered cost sharing for specialty drugs may be explicit with PBMs; medical specialty drugs typically are not tiered.
  - Coinsurance vs. copayments impact member behavior differently; unknown out-of-pocket costs can affect medication adherence behavior.
- Quantity limits:
  - Partial orders of very expensive specialty drugs are typically dispensed to allow time to evaluate possible side effects, ineffectiveness, inability to administer, and more.
- Reference pricing:
  - Comparable drugs available at much lower prices may be offered as the only option for coverage.

Learning Network participants provide health care coverage for hundreds of thousands of people, and expect the best possible data, information and tools to manage expensive and valuable medications on behalf of employees and their family members.

The group developed "Expectations for Cost Transparency on Drugs," found on page 28.

MEETING FOUR, AUGUST 19, 2015

Health plans and PBM updates

Medica

- Magellan PA has been selected to manage medical specialty oncology drugs first. Plans are in place for expanding to other areas quickly.
- Medica has contracted directly and exclusively with Fairview Specialty Pharmacy (FVSP):
  - FVSP has relationships with prescribing physicians who have deep clinical knowledge.
  - FVSP has piloted a program where they combine and analyze data from their dispensing systems with medical data from Medica claims. They have done cost comparisons of providers and have broad variation, beginning with dermatology.

Prime Therapeutics

- Customers are viewed as the Blue Cross Blue Shield health plans that own them and not necessarily employers. Health plans determine how aggressively they manage PAs and other clinical programs.
- Prime Therapeutics is collaborating with health plans to do medical specialty PAs, support rebate negotiations, and analyze data.

HealthPartners

- All clinical management is done in-house for both pharmacy and medical specialty drugs.
- NDCs are required on some claims, and they are just beginning to use them for data analysis.
- Provider contracts do not address issues related to site-of-care administration.

CVS Health

- CVS has capabilities to analyze medical specialty data with software and change and/or report price comparisons of medical providers.
- There is no program to manage site-of-care at this time and physicians tend to choose the site based on their convenience, regardless of impact on cost to purchasers or convenience for patients.
- The effectiveness of PA processes needs to be evaluated based on the percentage of requests denied, the stated reasons for denial, the percentage overturned, and whether attestations ("the honor system") are used, rather than requiring documentation of actual evidence, e.g., genetic test results or lab results.

Employer Summary

- Overall, employers were dismayed at the number and types of decisions being made without their input.
- Employers want more consistency and scrutiny of how aggressively specialty medications are managed.

Both health plans in attendance met with the group earlier in the year and had made substantial headway in improving their services. Two PBMs that own their specialty pharmacies (SPs) also presented. The employers were concerned about the inherent conflict of interest of being both PBM and SP and about the kinds, and number, of decisions being made on their behalf without their consultation and which produced significant financial consequences.

Employer Quotes from August Learning Network

"Employers are the ultimate payers, and they are too often left out of the equation."

"We expect gas to cost roughly the same from station to station; why do we allow such huge variability in drug prices from site to site?"

"We need commodity pricing. It shouldn't vary from hospital to hospital or clinic to clinic."

"Specialty pharmacy costs are crushing and unsustainable."

"Where is the balance between 'wonder drugs' and drugs that do not prolong life significantly or improve the quality of life?"

MEETING FIVE, SEPTEMBER 15, 2015

Provider perspective and input — physician interviews

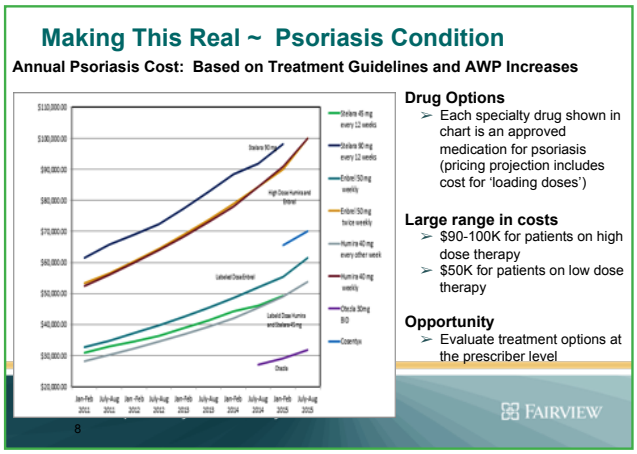
- Specialty physicians were interviewed, including rheumatologists, neurologists, gastroenterologists, oncologists, and primary care physicians.
- There is little appreciation that employers are paying the bills; health plans are viewed as the payers.
- Most doctors don't know the cost of drugs, or how their practice patterns compare to others with similar practices.
- Doctors are not convinced they could affect manufacturer pricing as a collective group.

University of Minnesota Physicians Oncology

- Between 15,000-20,000 patients are seen each year.
- There is an unspoken rule about not making treatment decisions based on cost.
- Most doctors are not aware of the cost of drugs (and most patients don't know their copayment until they get to the pharmacy or receive a bill after an infusion).
- It is very difficult to report on outcomes because of the complexity of each cancer case, although there are several thousand standard treatment protocols in accordance with national guidelines that are designed to aid decision-making.
- End-of-life decisions are part of the pathway, but it's very hard for treating physicians to bring up the topic when ending treatment is the best option.
- There is promising work in genetic mapping that may improve treatment accuracy, but we're not there yet.
- Palliative care is not a well-rewarded practice, and there is a shortage of providers; incentives lie in curative treatments.
- A better system would need to involve more transparency, recognizing a total package of care where everything is under one medical record-keeping system.
- Centers of excellence for specialty pharmacy were discussed, based on a case study illustrating the dramatic variation in cost-of-care for psoriasis by dermatology practice.

Opportunities for a new model (Fairview Specialty Pharmacy)

- The goal is to achieve optimal outcomes at the optimal price by optimizing the value of drug therapy.
- PBM strategies include:
  - Assure competitive pricing
  - Offer an effective distribution network
  - Limit distribution, drug access
  - Ensure therapy management programs and protocols are followed
  - Deliver on pipeline monitoring and reporting
  - Provide data management and reporting



- Fairview strategies include:
  - Manage drug waste and abuse (e.g., split fills, step therapy)
  - Monitor and manage patient compliance
  - Manage the "whole patient" (i.e., mental, physical, spiritual)
  - Develop pipeline projections (e.g., how many MS patients are in a particular employee population?)
  - Collect and report patient outcomes
  - Provide feedback on physician performance
- Some plan designs make it impossible for patients to adhere to their drug therapies (e.g., a plan may not allow patient assistance programs; or a 20 percent copayment on a $100,000 drug is cost-prohibitive for most).
- What can we do to manage costs on the medical side?
  - Design protocols and pathways.
  - Drive more from the medical side to the pharmacy side (although getting the necessary data is often difficult).
  - Identify outlier clinics and physicians and help them understand their practices relative to their peers. (See Psoriasis Condition chart above for an example).

Rheumatologists, neurologists, gastroenterologists, oncologists and primary care physicians were interviewed in an effort to learn more about their prescribing patterns and their understanding of the specialty pharmacy marketplace. Most were not aware of the cost of drugs, did not know that employers are payers, and had no idea how their prescribing patterns compared to their peers.

MEETING SIX, OCTOBER 28, 2015

National Coalition on Health Care (NCHC): Actions and employer collaboration (John Rother, President and CEO; former vice president of policy for AARP)

- Representing over 100 million Americans, NCHC was formed more than two decades ago to help achieve comprehensive health system change.
- Because high-cost prescription drugs are putting a strain on the entire health care system and threatening innovation, NCHC is sponsoring "The Campaign for Sustainable Rx Pricing." The first focus of the Campaign is Sovaldi®, due to "the abuse of market power and egregious overpricing."
- Three guiding principles:
  - Greater transparency (what is the justification for price in terms of value?)
  - Evening purchasing power between buyers and sellers
  - Paying for value
- Pay-for-performance needs to be applied to pharmaceuticals so we're paying for value.
- It has been a challenge to get political leadership to focus on the issue, but it's now a hot issue on the presidential campaign trail. Candidates on both sides are talking about the harmful impact specialty pharmacy price tags have on Americans. The country has turned a corner on pharmaceutical pricing, primarily because people are paying more and more out of their own pockets. It's become a serious economic issue at the household level.
- The missing voice so far has been the business community. Employer coalitions will need to represent the voice of the business community, since individual employers cannot easily come forward and speak out about this issue.
- We've prohibited the market from working because we do not have a standardized disclosure process on pricing. Price justification at the time a drug is introduced is critically important.
- To make good purchasing decisions, we need good information, which is currently elusive.
- Exorbitant drug prices deny patients access to life-enhancing medicines and result in higher out-of-pocket costs, premiums and taxes. To prevent our health care system from going bankrupt, we need to establish a drug pricing structure based on value- and data-driven evidence, and balance between the interests of innovative drug manufacturers and those of society and our health care system.

State collective policy action in Minnesota: Prior authorization bill

Discussion of policy action items:

- Federal- and state-level action items were prioritized based on impact and feasibility.
- Pricing drugs based on the value they deliver to the patient, similar to models in Western European countries and England, was a top priority.
- Accelerating development, approval and distribution of lower-cost alternatives, e.g., reducing the generic drug backlog and approving bio-similars, took priority.
- Public awareness and pressure on policy makers is necessary for political action.

Policy actions on the federal and state levels are desperately needed to rein in costs. During this meeting, policy decisions were discussed and prioritized (see page 20 for recommendations).

"We need identifiable business support and representation to drive this issue politically."

— John Rother

MEETING SEVEN, DECEMBER 2, 2015

Quotes from KARE11 story featuring Dr. Stephen Schondelmeyer

- Ordering specialty prescription drugs by mail through an insurance plan often costs patients more than simply walking into a corner drug store and buying the same drug without insurance.
- Pricing practices are a "shell game;" a "dirty little secret" in the prescription drug business.
- PBMs promise employers they will save them money by managing their specialty prescription drug claims and negotiating discounts. In return, PBMs become the exclusive specialty prescription provider for people in the company's insurance plan, in effect creating a mini-monopoly.
- PBMs have shut other people out. And they've done so in a way that you don't really know and can't find the prices.
- PBMs tell employers they can save them money by handling specialty prescription claims more efficiently and by negotiating volume discounts. The problem is, they aren't required to disclose the prices they've negotiated, leaving the door open for PBMs to quietly raise prices for their captive customers instead of lowering them.

KARE 11

"It's getting harder to follow the money because the supply chain is extremely convoluted. At the end of the day, every consumer pays for unrestrained costs. This isn't something that's going away on its own. All of us are feeling the pinch."

– Carolyn Pare
Minnesota Health Action Group
President and CEO (In a follow-up to the original KARE11 investigative report)

BUSINESS DAY

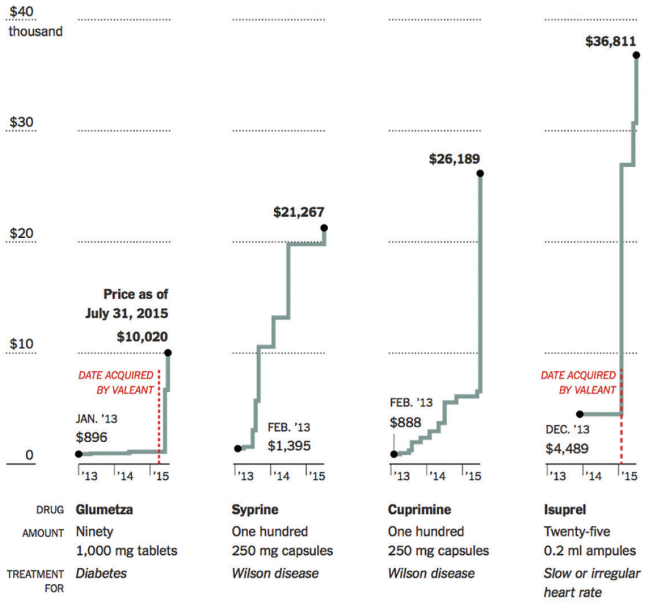
Valeant's Drug Price Strategy Enriches It, but Infuriates Patients and Lawmakers

By ANDREW POLLACK and SABRINA TAVERNISE OCT. 4, 2015

"Valeant drug prices are spiking, devastating patients while becoming one of Wall Street's most popular health stocks."

New York Times, October 4, 2015

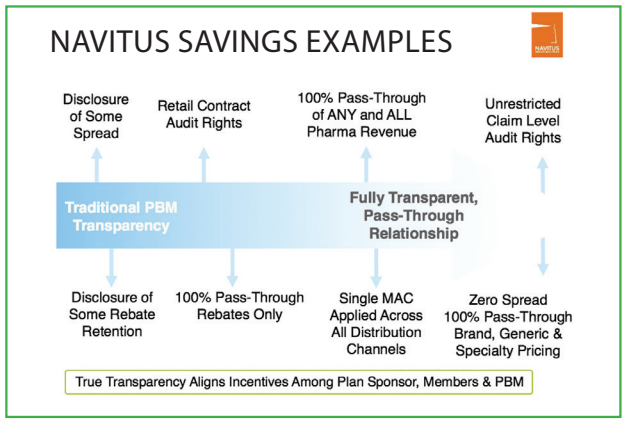
List prices for some of Valeant's prescription drugs



Navitus Health Solutions and PreferredOne

Navitus Health Solutions:

- Navitus is a full-service, national PBM with over four million members, including over 140,000 from SEGIP and 15,000 from Hennepin County.
- The focus is on delivering lowest-net-cost performance with clinical excellence and outstanding service.
- True transparency aligns incentives among plan sponsors, members and the PBM.



- The Navitus business model and expert consultation ensures:
  - Aligned goals and accountability;
  - Drug trend management for optimum cost control, including immediate pass-through of all manufacturer rebate and pharmacy discount improvements relating to each client's plan; and
  - Flexible solutions to meet the unique goals of each plan sponsor, allowing them to determine how involved they want to be in managing their pharmacy benefit plan.

PreferredOne:

- The definition for specialty drugs varies widely among PBMs. For reporting purposes, they use the Centers for Medicare & Medicaid Services (CMS) definition.
- NDCs on 87 percent of all medical drug claims and 93 percent of specialty drugs were collected.
- Disease surveillance reporting (e.g., PCSK9 drugs) is another tool to aid in specialty forecasting and coverage decisions.
- Prior authorization is limited to true medical necessity review: Currently, <1% claims, but nearly 100 percent of high-cost specialty.
- Medication utilization management (MUM) is similar for all drugs.
- A "specialty bypass program" or "notification" is used for selected, credentialed providers (they have used the Minnesota Uniform PA for years, and 23 percent of PA requests are online).
- Rebate arrangements vary from client to client.
- Provider contracting varies by site of service, using a discounted, defined fee schedule.
- Oncology bundling is currently in process.
- Customized member adherence initiatives are essential.
- Steering toward high-value providers is a priority.

Navitus Savings Examples:

Intervention	Description	Outcome	Monthly Savings	Annual Savings
Cost savings, dose change	Patient was prescribed Actemra once weekly. After asking the patient her weight (170 lbs.), I noted that the dose was written for a weight of >220 lbs. Called the M.D., verified the weight, and requested the change to every other week dosing as appropriate.	New prescription received every other week	$1,361.30	$16,335.60
Cost savings	Patient was taking 5-100 mg tablets. Upon consultation, discovered her dose had changed to 40 mg daily. Change from 5-100 mg Gleevec tablets to 1-400 mg tablet.	New prescription	$3,450	$41,400
Cost savings, dose change	Patient was receiving 45 mg of Stelara. We received a new prescription for 90 mg Stelara. Called the M.D. to verify the patient's weight (since Stelara is weight-based dosing), discovering the patient should still be on the 45 mg dose.	New prescription for the 45 mg dose. (Savings do not reflect possible cost avoidance due to over dosing.)	$2,467.65	$29,611.76

Employer Reactions to the Specialty Pharmacy Learning Network Phase II

What we heard!

I missed the magnitude of the pharmacy spending that was coming through on the medical side.

It was eye opening when the doctors came in: They had no idea what drugs cost, and no idea that employers are footing the bill.

I'm learning to ask better, smarter questions so I can help employees understand what things really cost.

It's been invaluable to have questions to ask PBMs, and to be able to ask others who have the same vendors if they are getting what I'm getting.

I was in la-la land. We have very high generic and formulary utilization, so I thought we didn't have a problem.

We've begun to make some progress in pushing the health plans to improve transparency on the medical side.

I really don't want to be the expert, but I've learned that I have to be with my vendors. I've actually had to educate some of my consultants about what they should be asking on our behalf.

Learning what other employers are getting from their vendors has been especially helpful.

We've set new expectations for our health plans. They know they need to report on numbers every time we meet.

I've learned that the savings from our PBM are often artificial; they're just bumping up the price and giving us bigger discounts. We make sure they know we're watching them.

We've stated our expectations about NDC codes to our health plans. We wouldn't have had that dialogue if we hadn't been part of this group.

Our approach to covering PCSK9s changed because of this group. We are dramatically restricting access.

Although pressure is mounting in this marketplace, there doesn't seem to be much action.

Too many health care professionals no longer look at patients as someone who needs to be helped — they look at patients in terms of dollar signs. Improving health is no longer the number one priority — money is. Optimizing profits trumps patient care.

We will be taking everything we learned through the Learning Network and including it in our RFPs going forward.

I didn't realize how huge the learning curve is on this topic. I feel like we've barely scratched the surface.

I plan on doing some employee communication workshops so they know to advocate for themselves, like the subject in the KARE11 story did. Consumers need to understand how the costs are affecting them — and what they can do about it.

PCSK9s: Illustrating How High Cost, Variability and Overuse Threaten Employer and Employee Wellbeing

While there is no shortage of drugs causing profit margins to soar across the pharmaceutical industry, a new class of medications to treat high cholesterol hit the market in 2015, pushing the U.S. one step closer to a future where health care costs bankrupt the system.

While very effective at lowering cholesterol, PCSK9s are not meant for everyone — and they are very expensive. These new drugs will cost as much as $14,600 per patient per year (compared to about $1,000 per year for conventional cholesterol medications), possibly for the lifetime of the patients who take them. These PCSK9 medications could easily cost the U.S. $100-$200 billion per year, which represents three percent of all health care spending in the country.

The complication with these medications is that recent research does not prove that lowering cholesterol in the blood actually reduces plaque in the blood vessels — the primary cause of heart attacks and strokes (see sidebar). If these drugs do not reduce plaque and reduce heart attacks and strokes, are they worth 10 times the cost of current medications? There won't be studies of this until 2018. And, since these drugs are biological agents, there will not be cheaper generics for 10-15 years.

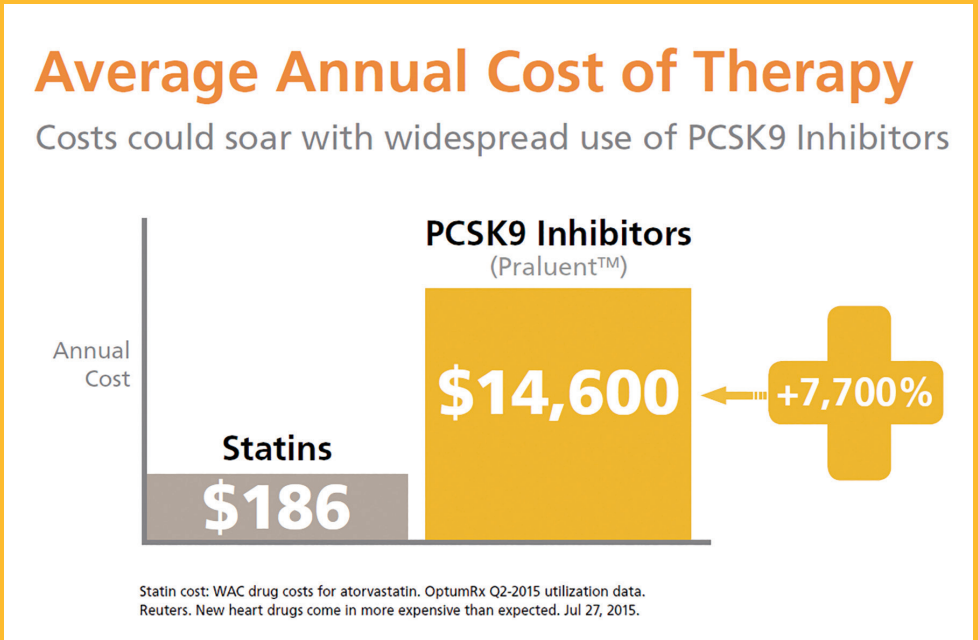
Lowering cholesterol may not have much of a medical value for most, yet the pharmaceutical advertising machine will be churning to convince millions that they need this drug. But who would really benefit from PCSK9s? They work for people who have already had heart attacks to prevent more heart attacks or death. And they work slightly for middle-aged men who have many risk factors for heart disease like high blood pressure, obesity or diabetes.

In those at high risk for heart disease, about 50 people would need to be treated for five years to reduce one cardiovascular event. To put this in perspective: If a drug works, it has a very low NTT (number needed to treat). For example, if you have a urine infection and take an antibiotic, you will get near a 100 percent benefit. The number needed to treat is "1." So, if you have an NTT of 50 — like statins do for preventing heart disease in 75 percent of the people who take them — it is basically a crap shoot. And 268 people without heart disease would have to take a statin for five years for one person to be saved from a stroke.

If an employer with about 2,000 employees uses these new drugs to treat 50 patients in its plan x $10,000 per year x 5 years, it will spend $2.5 million to prevent one cardiovascular event. A typical cardiovascular event costs $25,000-$35,000 to treat. Is spending $2.5 million to prevent one $35,000 event a prudent use of limited health care dollars? The answer depends on whether you are one of the 50 people who want to use the drug, or if you are one of the other 1,999 people paying the bill. The prevention of this one event will cost each

Recent research on lowering cholesterol shows:

- 75% of people who have heart attacks have normal cholesterol.
- Older patients with lower cholesterol have higher risks of death than those with higher cholesterol.
- Countries such as Switzerland and Spain have higher average cholesterol than Americans, but less heart disease.



PCSK9 inhibitors are not intended for the ordinary person with high cholesterol. The vast majority of people should continue to be managed with generic statins — without the addition of a PCSK9 inhibitor.

employee in the medical plan $2,500 over that five-year period ($19.23 per pay period, with $6.41 paid by the employee and $12.82 paid by the employer).

And, for self-insured employers, the company pays for every dollar of health care expenses, resulting in higher costs to employers and employees. This, in turn, can affect things like shareholder value, bonuses, and employee stock ownership plans.

What's an employer to do?

Employers will need to keep their eye on the specialty pharmacy pipeline to see which specialty drugs are on their way to market, so they can work with their health plans and PBMs in advance to determine how they will respond and communicate decisions to employees. Step therapy, prior authorization, clinical reviews, delaying payment until more evidence demonstrates the effectiveness, value and risks of drugs (when used in the general population, not just clinical trials), and genetic testing can be used to ensure these new drugs are used appropriately and under clinical guidelines.

What's an employee to do?

Employees can help control costs by learning to ask their doctors questions about their condition and options for care — including non-pharmaceutical interventions such as lifestyle changes. Patients requiring an infused drug should ask to have it administered in the doctor's office and billed through them, rather than through a hospital. Hospitals often charge twice as much for the same drug, and may add on an administrative (e.g., "chair and pole") fee of up to $1,000 per treatment.

References

Reuters. New heart drugs come in more expensive than expected. Jul 27, 2015. Accessed at: http://www.reuters.com/article/2015/07/27/us-pharmaceuticals-heart-idUSKCN0Q10YS20150727 on 07.28.2015.

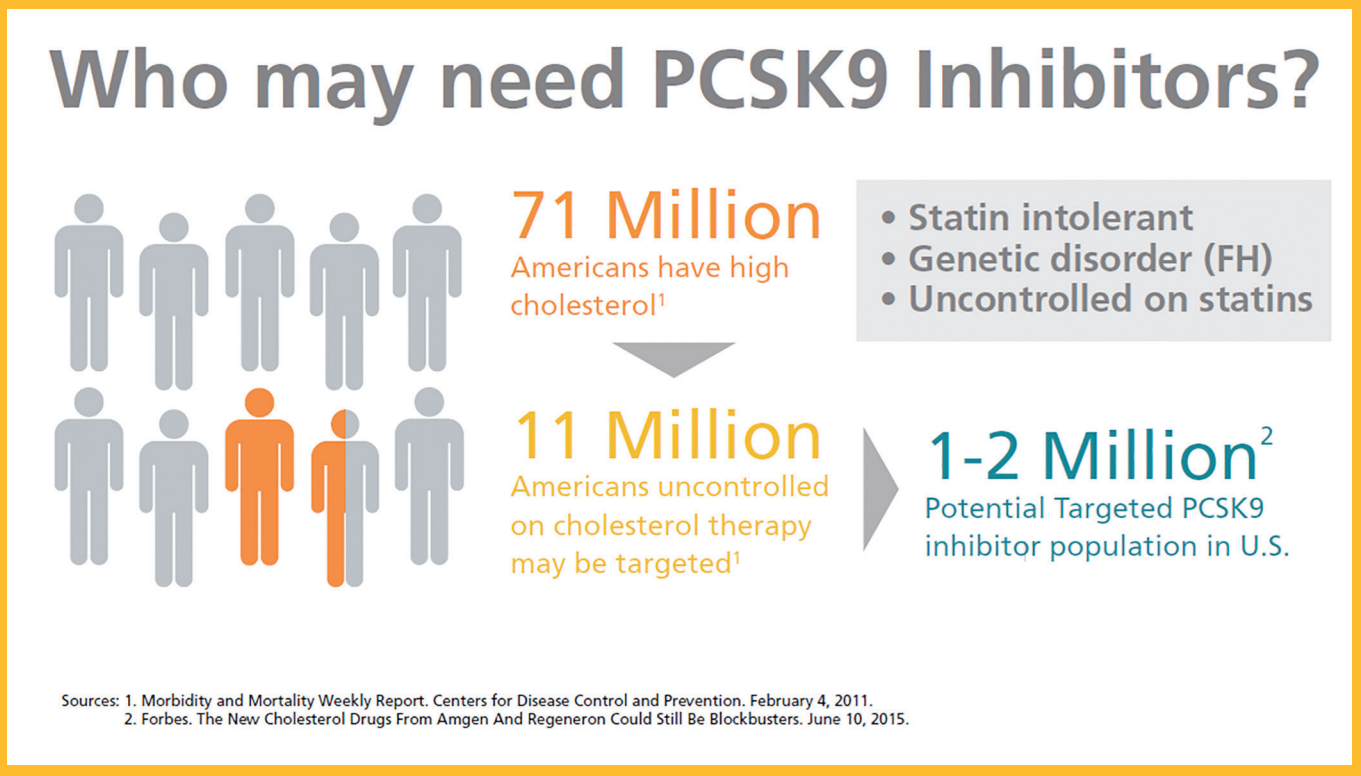
New York Times. Federal Panel Backs Approval of New Drug to Fight Heart Attacks. June 9, 2015. Accessed at: http://www.nytimes.com/2015/06/10/health/cholesterol-levels-ldl-drugs-heart-attacks-fda-panel.html on 07.16.2015.

Optum. High-cost Cholesterol Drugs are Here: Are you Ready? August 13, 2015. Accessed at: https://www.optum.com/thought-leadership/highcostcholesteroldrugs.html.

"The Hepatitis C drug, Sovaldi® made headlines last year when a course of treatment was pegged at $84,000 in the U.S., crushing previous cost and use records. The same drug is priced at $900 in Egypt and $51,000 in France. U.S. costs for powerful new cholesterol management drugs, PCSK9 inhibitors, are expected to be $7,000-$12,000 per patient per year, compared with about $1,000 on average for conventional drug therapies. Given the number of patients who might benefit, the market for this one drug could easily reach $100 billion/year, or about 1/33 of what we currently spend on all U.S. health care. And, of course, this is not a cure but a maintenance drug, with annual, lifelong, recurring costs."

From "What Good is Health Care if it's Out of Reach?" editorial by:

Carolyn Pare and Brian Klepper



Searching for Solutions: The High Cost of Cancer Drugs*

It's no secret that the increasing cost of cancer drugs is affecting patient care in the U.S. and the American health care system overall, according to the authors of a special article published in the May 2015 issue of the journal Mayo Clinic Proceedings.

"Americans with cancer pay 50 to 100 percent more for the same patented drug than patients in other countries," said co-author S. Vincent Rajkumar, M.D., a hematologist at the Mayo Clinic Cancer Center. "As oncologists, we have a moral obligation to advocate for affordable cancer drugs for our patients."

Before 2000, the average cost of a cancer drug for a year of therapy ranged from $5,000 to $10,000 in the U.S. By 2012, the average annual cost had increased to more than $100,000. Over the same period, the average household income in the U.S. decreased by about eight percent.

The article also explores other reasons for the high cost of cancer drugs, including legislation that prevents Medicare from being able to negotiate drug prices and a lack of value-based pricing, which ties the cost of a drug to its relative effectiveness compared with other drugs.

Solutions that could help control the cost of cancer drugs could include:

- Allowing Medicare to negotiate drug prices.
- Developing cancer treatment pathways and guidelines that incorporate the cost and benefit of cancer drugs.
- Allowing the U.S. Food and Drug Administration or physician panels to recommend target prices based on a drug's magnitude of benefit (value-based pricing).
- Eliminating pay-for-delay strategies (where a pharmaceutical company with a brand-name drug shares profits on that drug with a generic drug manufacturer for the remainder of a patent period, effectively eliminating a patent challenge and competition).
- Allowing the importation of drugs from abroad for personal use.
- Allowing cancer advocacy groups to consider cost in their cancer care recommendations.
- Creating patient-driven grassroots movements and organizations to advocate effectively for the interests of patients with cancer to balance advocacy efforts of pharmaceutical companies, insurance companies, PBMs, and hospitals.

** The full article may be found here: http://www.mayoclinicproceedings.org/article/S0025-6196%2815%2900101-9/pdf*

Exclusive - Transatlantic divide: how U.S. pays three times more for drugs

LONDON | BY BEN HIRSCHLER

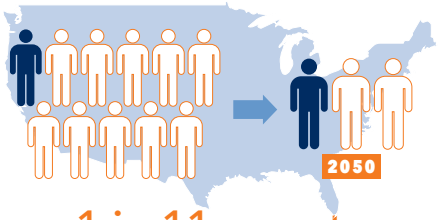
"U.S. prices for the world's 20 top-selling medicines that are, on average, three times higher than in Britain. The finding underscores a transatlantic gulf between the price of treatments for a range of diseases and follows demands for lower drug costs in America."

Reuters, October 12, 2015

The Spike in Drug Costs: Diabetes

Advancements in pharmaceuticals can result in drugs that offer fewer side effects, improve a patient's quality of life and save lives, but what if not everyone can afford them?

GENERAL STATISTICS...



1 in 11 people in the U.S. has diagnosed or undiagnosed diabetes.[1] This is expected to increase to **1 in 3 people by 2050.**[2]

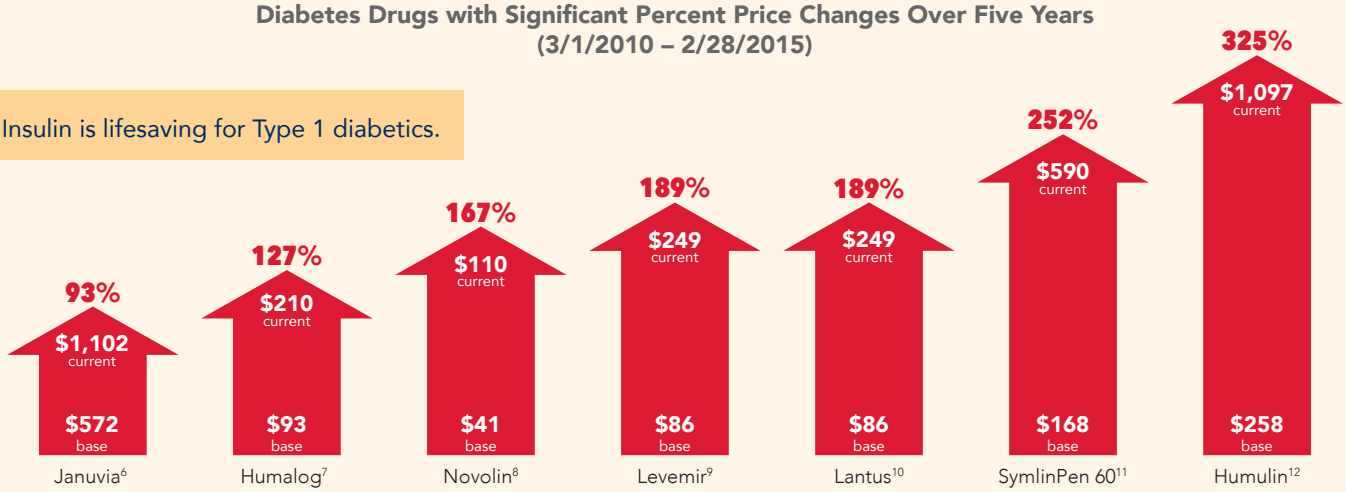
The cost of diagnosed diabetes in 2012 was **$245 billion.**[3]

Primarily because of escalating drug costs, spending on insulin and other diabetes medications is expected to rise **18.3 percent over the next three years,**[4] a rate of increase **60 times greater than the recent income growth** average of just 0.3 percent across all households.[5]

DRUG PRICES ARE RISING AT AN UNSUSTAINABLE AND SEEMINGLY IRRATIONAL RATE.

Diabetes Drugs with Significant Percent Price Changes Over Five Years (3/1/2010 – 2/28/2015)

Insulin is lifesaving for Type 1 diabetics.



Source: *Medi-Span® Price Rx®*. Figures reflect wholesale acquisition cost.

High costs affect both brand-name and generic drugs and span therapeutic areas. This graphic focuses on brand-name diabetes drugs, with no generic options yet available for insulin in the U.S.

THERE'S ENORMOUS PRESSURE ON...

Consumers and their families, who may be faced with the difficult choice between paying for diabetes medications and other necessities.

Employers, who may be forced to make cuts to their overall benefits package in order to fund rising drug costs.

Health care providers, who treat an increase in uncontrolled diabetes & disease-related complications due in part to non-adherence to costly medications.

Health plans and other payers, who want to ensure the right people get the right drugs, yet whose budgets cannot finance the high cost of drugs.

Federal government, which is bearing an ever-growing share of the costs of these drugs, placing increasing pressure on the federal budget.

ACHP
ALLIANCE OF COMMUNITY HEALTH PLANS

MINNESOTA HEALTH ACTION GROUP SPECIALTY PHARMACY LEARNING NETWORK
INDIVIDUAL EMPLOYER ACTIONS - DECEMBER 2, 2015

A Employer Benefit Design and Clinical/Utilization Management – Health Plan and PBM

	Action	Explanation
1	Utilization reporting	Overall specialty expenditures, both medical and pharmacy benefits, including expenditures by site of care, specific drug classes, patient support program funding, provider comparisons, actionable information
2	Prior authorization and step therapy	Assure safe, effective, appropriate use, transparent, evidence-based (not rebate negotiated) criteria, reports on performance including denials, appeals, overturned denials, level of evidence required (honor system)
3	Medication management	Implement support services to assure safe, effective, appropriate use including adherence and discontinuation
4	Drug pricing transparency	Drug costs are value-based compared to alternative therapies, transparent and readily available to physicians at the point of care, consumers at the point of purchase, and employers through reporting
5	Formulary and rebates	Formulary decisions of P&T committees, their processes, and rationale are transparent to employers when they are decided
6	Benefit plan design and SPDs	Health plan and pharmacy benefits and summary plan descriptions (SPDs) are aligned to support most cost effective drug, site of care, and that optimize manufacturer patient support programs*
7	Pipeline management	Communicate expectations that pipeline drug expenditures will be anticipated and coverage decisions, for all possible label indications, made by employers before FDA approval
8	Vendor contracting	Review and revise both health plan and PBM contracts to enable customization, employer input on key decisions, and that support value-based purchasing*
9	Communications	Raise awareness of senior management and employees about the growing use and expenditure and implication for future benefit decisions and other actions*
10	Procurement/RFP	Optimize procurement/RFP process to communicate expectations, shape offerings, obtain key information about performance, relationships, processes, and include consultation with employers about key decisions

B Health Plan/Medical Provider Reporting and Analysis

	Action	Explanation
1	NDC requirement	Require all providers to submit appropriate NDCs and number of units for all provider administered drugs in order to report utilization, rebates, compare performance, pricing, providers
2	Site of care	Implement reference-based pricing or other contractual terms to assure provider administered drugs and associated services are charged at lowest cost site of care and incentives are aligned with value-based purchasing
3	Reporting	Reporting includes actionable information on site of care, patient assistance, utilization, pricing, rebates by NDC, provider comparison of costs, and quality by condition
4	Transparency	Information on contractual relationships with provider systems, financial incentives, performance on clinical/utilization management*

C PBM Requirements for Reporting and Analysis

	Action	Explanation
1	Fiduciary	Require PBM to act as fiduciary (mutually agreed upon definition)
2	Transparency	Reporting and information on rebates, prices, formulary, patient support/assistance programs
3	Clinical/UM oversight	Transparent criteria for PA and step therapy, performance reporting, including denials, appeals, overturned appeals, customizable by employer
4	Specialty pharmacy	Information about relationships with all specialty pharmacies including financial, contractual, performance requirements, ownership and exclusivity

D Specialty Pharmacy

	Action	Explanation
1	Identify conflicts of interest	If owned by PBM, require direct relationship with client, reporting on performance*, periodic audits by outside entity
2	Performance	Require value-based use of specialty meds through PA, step therapy, biosimilar interchange, split fills, other UM tools; require prices be no more than retail price if available at retail
3	Reporting	Performance reporting including adherence, patient satisfaction, and patient support/assistance program use

E Communications

1	Sr. management, employees, unions	Communicate current and future cost issues and implications to support management strategies and tactics

* Specific deliverables and tools forthcoming in 2016 Action Network

MINNESOTA HEALTH ACTION GROUP SPECIALTY PHARMACY LEARNING NETWORK
COLLECTIVE EMPLOYER ACTIONS - DECEMBER 2, 2015

F All Vendors

1	Procurement	Optimize procurement process to communicate collective voice of employers*
2	Explore new opportunities	Evaluate offerings by existing vendors that optimize value including optimizing patient support programs that benefit employers, e.g., SaveonSP, vendors that carve out clinical management, e.g., RxResults, HID
3	Cost/Comparative effectiveness research (CER)	Require drug pricing for both medical and pharmacy benefit management be consistent with available cost and comparative effectiveness evaluations
4	Reporting	Integrated (medical and PBM) reporting by condition comparing employers, site of care, drug class, provider performance on cost, quality and outcomes
5	Pipeline management	Communicate expectations that pipeline drug expenditures will be anticipated and coverage decisions, for all possible label indications, made by employers before FDA approval
6	Explore new models	Explore new models of care, payment, and administration of specialty pharmacy that integrate and align incentives with purchasers and consumers goals
7	Common list of specialty drugs	Develop a common list of specialty drugs across vendors serving employers in the Minnesota market

G Health Plan/Medical Provider

	Action	**Explanation**
1	Require NDCs	Communicate expectations that NDCs be required of all providers for all drugs to payers and providers locally and nationally
2	Site of care	Communicate expectation that site of care will be managed by pricing of services rather than changing locations of care delivery
3	Centers of Excellence	Explore models of care, payment and administration that provide incentives for patients to select high-performing providers who agree to terms that enhance and advance value for patients and purchasers

H PBM

	Action	**Explanation**
1	Consistent definition of specialty drugs	Because there are multiple definitions in the markeplace, adopt a single version (the Learning Network version is in the Phase I Purchaser's Guide)
2	Specialty pharmacy relationship	Information about selection, role with hubs and manufacturers, transparent financial, operational, performance requirements

I Manufacturer

	Action	**Explanation**
1	Comparative effectiveness research (CER)	Communicate expectation that drug prices will be based on value
2	Price disclosure	Negotiated drug prices with PBMs and providers are publicly available to consumers and purchasers
3	Guarantees	Negotiate drug effectiveness guarantees and methods for measuring failure and paying back refunds

J Specialty Pharmacy

	Action	**Explanation**
1	PBM conflict of interest	Require oversight if owned by PBM, plus disclosure of financial, operational, contractual relationships with all specialty pharmacies

K Providers

	Action	**Explanation**
1	NDC submission	Require submission of NDCs for all drugs, from all providers, at all sites of service
2	Drug price disclosure	Implement method to inform providers of drug costs (benchmark pricing) at point of prescribing
3	Cost of site of care	Implement price parity for services and drugs across all sites of care
4	Prior authorization	Improve efficiency of PA processes through use of technology and transparency of criteria

* Specific deliverables and tools forthcoming in 2016 Action Network

MINNESOTA HEALTH ACTION GROUP SPECIALTY PHARMACY LEARNING NETWORK PRIORITY NATIONAL POLICY ACTIONS – OCTOBER 28, 2015		
	Topic	**Explanation**
1	Comparative effectiveness research (CER) & pricing	Establish an independent entity and/or process to assess comparative effectiveness and relative value of drugs, recommend reasonable prices, update CER with new evidence over time; authorize public and private purchasers to establish coverage based on reasonable prices
2	Price justification	Require manufacturers to disclose drug prices including prices in other countries, report development costs including R&D, marketing, and other costs, profits, and sales information
3	Price disclosure	Manufacturers and PBMs must disclose prices and economic transactions to payers and public
4	Biosimilar access	Advocate FDA regulations and policies that support accelerated approval of appropriate and economical biosimilar products; limit exclusivity period to 5-8 years rather than 12 years
5	Generic drug approval	Appropriately fund the FDA's Office of Generic Drugs to reduce approval time for Abbreviated New Drug Application (ANDA) and facilitate, in other ways, the rapid approval of generic drug applications
6	Prohibit pay for delay*	Prohibit anti-competitive arrangements between brand and generic drug makers where brand-name drug manufacturer pays generic manufacturer to delay bringing their generic alternative to market
7	Remove importation barriers*	Allow importation of high-quality drugs from multiple countries including Canada, the European Union, and Australia
8	Medicare negotiations*	Require CMS to negotiate drug prices on behalf of Medicare Part D programs or require Medicaid level rebates be applied to Part D
9	Find and join other aligned organizations	Support and coordinate with other organizations with similar positions, e.g., AARP, AHIP, NCHC, grass roots consumer groups, et. al., on establishing sustainable drug market
10	Meet with Minnesota Congressional delegation	Educate and advocate on payer, employer, and consumer perspectives related to specialty medications, biosimilar interchange, and other policies
11	Importation from Canada	Single country importation may create artificial pricing and shortages
12	Individual out-of-pocket spending caps	Limiting individual spending will not address overall pricing issues; in fact, may exacerbate irrational pricing and continue to increase insurance premiums
Priority Minnesota Policy Actions		
1	Prior Authorization (PA)	Support actions that reduce administrative burden and improve PA efficiency; do not limit ability to use PAs as an appropriate utilization management tool; increase benefit transparency; explore alternative models to PA that ensure appropriate utilization of drugs
2	Biosimilar interchange	Enable appropriate, economically effective, interchange of FDA approved biosimilar drugs in Minnesota
3	NDC coding	Require health plans to use NDC codes (and require submission by providers) on all medical claims that include prescription drugs
4	Meet with Minnesota Legislators	Educate and advocate on payer, employer and consumer perspectives related to specialty medications, biosimilar interchange, and other policies

*Proposals have been in place many years with no evidence of movement in Congress - unlikely to change.

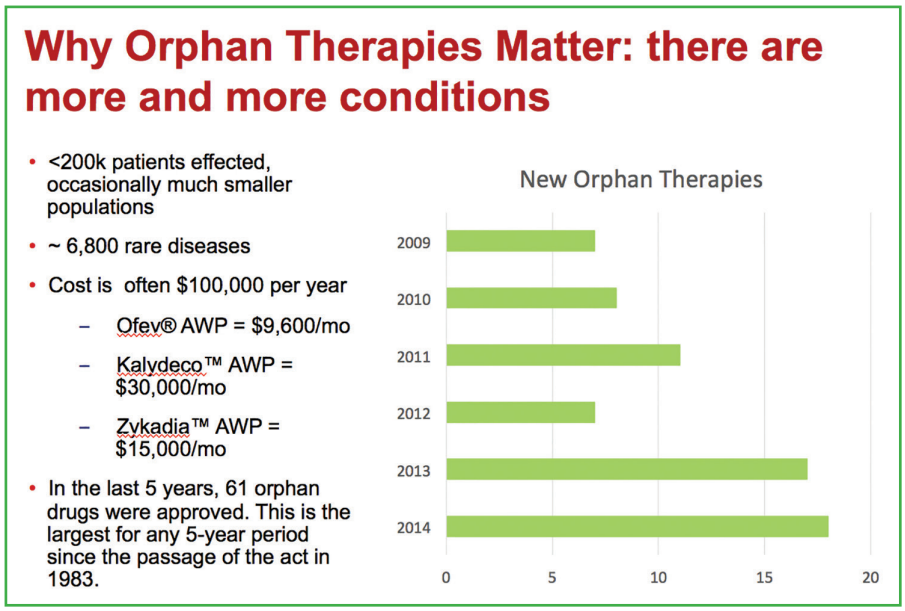
Priority actions Desired but unlikely Problematic actions

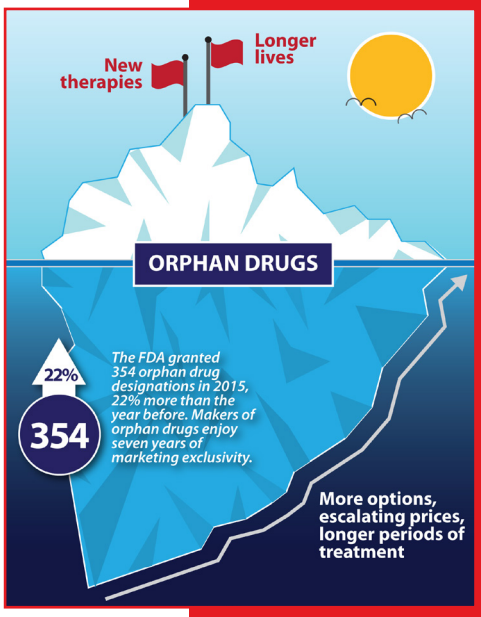
"I'm learning from this group, too. Because employers have such a wide variety of benefit plan designs, it's not possible to fit the same contracts and tools to all of them. Someone with a $10 copayment will behave much differently than someone with a high-deductible plan. Having complex and varied benefits designs seriously compromises the ability to manage specialty pharmacy costs."

— Dr. Stephen Schondelmeyer

Orphan Drugs

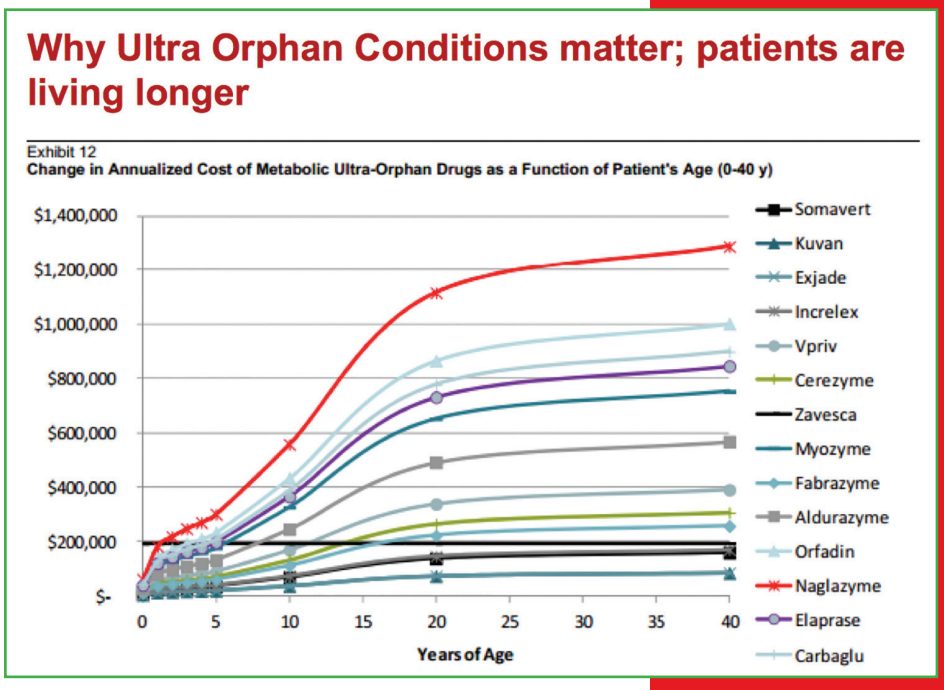
Orphan drugs are used for the treatment of rare diseases or conditions. As an increasing number of orphan conditions are identified, more patients are living longer — and requiring lifelong treatment. The FDA granted 354 orphan drug designations in 2015, 22 percent more than the year before. Congress has given the makers of orphan drugs seven years of marketing exclusivity.





IMS Institute for Healthcare Informatics. (2014). Medicine use and shifting costs of healthcare: a review of the use of medicines in the United States in 2013. Parsippany, NJ: M. Aitken, M. Kleinrock, J. Lyle & L. Caskey.

Red Book 2015: 2015 Report of the Committee on Infectious Diseases. (2015). DW Kimberlin, SS Long, MT Brady, MA Jackson.



Forbes: The First Drug With A $1 Million Price Tag May Already Be On The Market, 5/01/2012

Top 2015 Specialty Pharmacy News

December 9:

The Senate Special Committee on Aging convened for its first hearing in an investigation of drug companies that raised the prices of off-patent drugs.

November 17:

The American Medical Association calls for a ban on advertising prescription drugs and medical devices directly to consumers, saying the ads drive patients to demand expensive treatments over less costly ones that are also effective.

Dec 1:

In this KARE11 exposé, Dr. Stephen Schondelmeyer describes the "dirty little secret" in the prescription drug business: PBMs that are essentially "playing a shell game" by quietly raising unreported drug costs instead of lowering them.

October 20:

Reuters says drug companies are charging up to 600 times what medicine costs to make, making prescription drug pricing the new media focus, and capturing political center stage, according to *Employee Benefit News.*

September 28:

The FDA approves the diabetes drug Tresiba, enabling the drugmaker to prepare its largest ever drug launch. Analysts expect annual sales to hit $2.4 billion by 2020.

September 8:

The *Wall Street Journal* cites higher drug costs as consumers' biggest worry.

August 18:

The FDA approves flibanserin (Addyi), the first treatment for female sexual dysfunction.

August 15:

Turing Pharmaceuticals bought the 62-year-old drug called Daraprim, quickly raising the price of one pill from $13.50 to $750, at an average per-patient cost of $63,000 — up from $1,130 (a 5,000 percent increase).

July 21:

Express Scripts releases a white paper estimating that more than half of patients are non-adherent to their medication therapies, resulting in an estimated $337 billion in direct and indirect costs.

July 20:

With the FDA approving PCSK9 inhibitors in June, The Institute for Clinical and Economic Review came out with a report saying the cost should be about 85 percent less than it currently is.

July 1:

The global market for biosimilars could hit $20 billion by the end of the year and may reach $55 billion by the end of the decade, according to new analysis from business intelligence provider GBI Research.

June 22:

Alarmed by the rapid escalation in the price of cancer drugs, the American Society of Clinical Oncology unveiled a new way for doctors and patients to evaluate different treatments — one that includes a medicine's cost as well as its effectiveness and side effects.

June 16:

Kaiser Health Tracking Poll reveals drug costs have dislodged Obamacare as GOP voters' top health care concern. Nearly three-quarters of the American public think the cost of prescription drugs is unreasonable, placing much of the blame on drug companies' drive for profits.

March 29:

Medicare announces Medicare's spending on drugs to treat hepatitis C soared more than 15 fold — to $4.5 billion — from 2013 to 2014 as new breakthroughs came to the market.

March 4:

Action Group President and CEO, Carolyn Pare, sends letters to lawmakers describing the looming specialty pharmacy crisis facing purchasers and the merits of prior authorization (PA). Government officials were asked to intercede on behalf of all Minnesota employers to retain PA as "the most effective tool in managing use of complex and expensive drugs."

January 13:

After igniting a price war over hepatitis C medicine that agitated the pharmaceutical industry, Express Scripts Holding Co. announces it is looking to reap savings from expensive new treatments for cancer and high cholesterol (e.g., PCSK9 inhibitors).

(Phase II only; please refer to the Phase I Employer Purchaser's Guide for the full Glossary)

- **Bundled codes:** Bundling is when an insurance carrier combines two or more CPT codes, substituting one overarching code.
- **Induced demand:** The phenomenon where, after supply is increased, more of a good is consumed (e.g., PCSK9s – on page 14).
- **Moral hazard:** A term describing how behavior changes when people are insured against losses (e.g., people who have good health insurance are less likely to avoid health risks, and more likely to use medical services without regard to cost, safety and efficacy).
- **Partial fill:** An order that is not completely executed. With a partial fill, a certain portion of the order has been completed and a portion remains in the system as an open order. For example, partially filling a costly cancer drug enables patients and doctors to determine whether the drug will be tolerated and effective before the cost of a total order is incurred.
- **Pay-for-delay:** Deals in which pharmaceutical manufacturers with patents that are nearing expiration pay companies to delay the introduction of a generic version.
- **Reference-based pricing:** A reimbursement mechanism where payers set a ceiling price for medications that share similar therapeutic benefits. Cost savings are achieved by promoting alternatives to expensive, brand-name drugs.

Rx Price Watch

Specialty Prescription Drug Prices Continue to Climb

Stephen W. Schondelmeyer
Prime Institute, University of Minnesota

Leigh Purvis
AARP Public Policy Institute

In 2013, retail prices for 115 widely used specialty prescription drugs increased by an average of 10.6 percent. In contrast, the general inflation rate was 1.5 percent over the same period.

The average annual price of therapy for specialty prescription drugs was 18 times higher than the average annual price of therapy for brand-name prescription drugs and 189 times higher than the average annual price of therapy for generic prescription drugs.

The average annual cost for one specialty medication used on a chronic basis was more than $53,000 in 2013. This cost was:

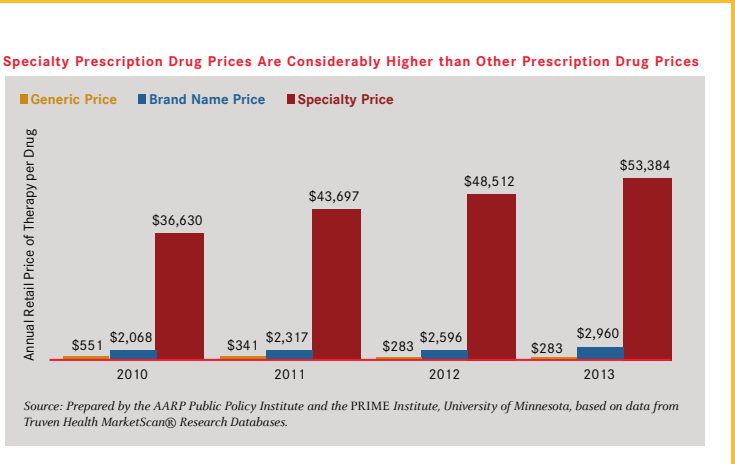
- Greater than the median U.S. household income ($52,250),
- More than twice the median income for Medicare beneficiaries ($23,500), and
- Almost three and a half times higher than the average Social Security retirement benefit ($15,526).

Prescription drug price increases also affect employers, private insurers, and taxpayer-funded programs like Medicare and Medicaid. Spending increases driven by high and growing drug prices will eventually affect all Americans in some way.

Those with private health insurance will pay higher premiums and cost sharing for their health care coverage. Over time, it could also lead to higher taxes and/or cuts to public programs to accommodate increased government spending.

If these trends continue, older Americans will be unable to afford the specialty prescription drugs that they need, leading to poorer health outcomes and higher health care costs in the future.

Policy makers interested in reducing the impact of prescription drug prices should focus on options that support innovation while also protecting the health and financial security of consumers and taxpayer-funded programs like Medicare and Medicaid.



KEY INFORMANTS (Appendix)

Phase II 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 Fikru, Pharm.D., M.P.A., Ph.D. candidate, research analyst, University of Minnesota College of Pharmacy-PRIME Institute, Department of Pharmaceutical Care and Health Systems

MEETING ONE (May 27, 2015):

Shannon Ambrose, Vice President Product Development, Artemetrx

Corey Belken, Pharm.D., Vice President Business Development, Artemetrx

Brenda Motheral, Ph.D., President, Artemetrx

Brian Bullock, R.Ph., Founder and CEO, The Burchfield Group

Shawn Patterson, (formerly) Sales and Client Management Leader, The Burchfield Group

MEETING TWO (June 24, 2015):

Sara Drake, R.Ph., M.P.H., M.B.A., Deputy Director, Health Care Purchasing and Service Delivery, Minnesota Department of Human Services

Rick Bruzek, Vice President Pharmacy Services, HealthPartners

Christine Strahl, Specialty Pharmacy Manager, HealthPartners

MEETING THREE (July 22, 2015):

Bithia Fikru, Pharm.D., M.P.A., Ph.D. candidate, research analyst, University of Minnesota College of Pharmacy-PRIME Institute, Department of Pharmaceutical Care and Health Systems

MEETING FOUR (August 19, 2015):

Rick Bruzek, Vice President Pharmacy Services, HealthPartners

Jim Hartert, M.D., M.S., FACP, Senior Medical Director, Medica

Jana Johnson, Senior Vice President, Health and Provider Services, Medica

Rae McMahan, Vice President, Specialty Pharmacy Programs, Prime Therapeutics

Eric Schupp, Vice President, Enterprise Specialty, Prime Therapeutics

Kevin Ronneberg, M.D., Vice President and Associate Medical Director, Health Initiatives, HealthPartners

Surya Singh, M.D., Vice President, Specialty Medical Pharmacy Management, CVS

MEETING FIVE (September 15, 2015):

Marie Brown, M.H.A., Oncology Service Line Executive, University of Minnesota Physicians

Ed Greeno, M.D., Oncologist, University of Minnesota Physicians

Kyle Skiermont, Vice President Operations, Fairview Pharmacy Services

MEETING SIX (October 28, 2015):

John Rother, J.D., President and CEO, National Coalition on Health Care

Samantha Mills, Field Representative, Office of U.S. Senator Alan Franken

Megan Sharp, Outreach Director, Office of U.S. Senator Amy Klobuchar

Randy Chun, Legislative Analyst – Research Department, Minnesota House of Representatives

Holly Iverson, Committee Administrator, Minnesota House of Representatives

MEETING SEVEN (December 2, 2015)

Stephen Schondelmeyer, Pharm.D., Ph.D., professor of pharmaceutical economics in the College of Pharmacy at the University of Minnesota, director of PRIME Institute

SPECIAL MEETING (December 7, 2015)

Laura Jester, Pharm.D., Specialty Pharmacy Programs, Navitus Health Solutions

Alan Van Amber, Vice President, Pharmacy Network Development, Navitus Health Solutions

Howard Epstein, M.D., Executive Vice President and Chief Medical Officer, PreferredOne

Al Heaton, Pharmacy Director, PreferredOne

Specialty Pharmacy Action Network 2016: Goals and Deliverables

Goals and Deliverables

Members of The Action Group's Specialty Pharmacy Learning Network have met monthly for over 12 months and are now ready to turn this learning into action with specific goals and objectives. The following is a high-level description of seven goals with key activities and objectives necessary to effect change. It also describes why this is important to employers.

1. **National Drug Codes (NDC Codes) on Medical Claims:** Employers collectively expect and require goals stated in the NDC Value Statement:
   - Communicate goals to key players, including health plans and providers.
   - Promote and support organizations that move toward our goal:
     - Encourage players to share best practices
     - Encourage analysis of data using NDC codes
   - Develop language for requests for approval (RFPs) and health plan contracts that require implementation.

Why is this important for employers?

NDCs are used to identify specific drugs, dosages and packaging, and are tied to specific prices on pharmacy claims. They are not routinely submitted on claims for drugs administered by providers and paid for by health plans on medical claims. This level of specificity is necessary for employers to identify specific drugs, quantities and charges for these drug costs. NDCs are also necessary for accurate prior authorization requirements, rebate contracting and payment, as well as quality improvement. They have been required for Medicaid claims for several years.

2. **Site-of-Care Management:** Employers collectively change how providers are reimbursed — either with a reference-based model, or parity by site of care — for medical specialty pharmacy services and drugs, regardless of site of care to remove incentives to shift care to more expensive outpatient hospital settings:
   - Communicate goals to key players, including health plans and providers.
   - Develop language for Request for Proposals (RFPs) and health plan contracts that require implementation.

Why is this important for employers?

- *Infused drugs can be administered at a variety of locations, including physician offices, hospitals (outpatient), patient homes, and freestanding infusion centers. Hospital settings are much more expensive than the other options, and coding on facility claims are much less specific. Therefore, providers have an incentive to move patients to outpatient hospital settings.*
- *Rather than dictate where infusions occur, require patients to change locations, and providers to recommend alternate infusion sites. Provider contracts should not vary between sites of care for the same drug and services. Health plans should negotiate with providers accordingly.*

3. **Pipeline Management:** Employers develop plans and communicate actions to vendors related to new drug approvals:
   - Monitor pipeline drugs before they are approved; gather information to predict impact.
   - Develop questions to ask vendors about benefits and clinical management before FDA approval.
   - Develop recommendations on what, when, how and why to cover new drugs.

Why is this important for employers?

- *The current drug pipeline includes many high-cost specialty drugs that, cumulatively, will greatly impact employer costs.*
- *Employers can make proactive decisions about coverage if they are aware of specific drug approval dates, costs, less-costly alternatives, and potential utilization by their populations. Having this information enables them to discuss options with the vendor who will be administering the benefit (PBM or health plan).*

4. **Establish Standard Collective Approach, Vendor (PBM and health plan) Expectations, and Language; give employers access to independent experts to analyze, evaluate and develop:**
   - Actionable reports on utilization, rebates, clinical and utilization management.
   - RFPs that include questions related to collective employer expectations.
   - Contracts that redefine vendor framework and employers' role (proactive).
   - Summary plan description (SPD) language and benefit plan design that anticipate specialty pharmacy impact and implications.
   - Clinical and utilization management reporting, processes, evaluation.
   - Questions and areas of focus for periodic vendor meetings, including pipeline management.

Why is this important for employers?

- *Employers will learn from others going through the procurement process, share best practices, and have the insight of experts from the University of Minnesota School of Pharmacy throughout the year.*

- *Vendors will be more likely to respond positively to a collective of employers who are part of the Action Network and who know they are not "the only employer" asking for a specific contractual requirement, revision or performance expectation.*
- *Employers who are part of the Action Network will be more prepared for new developments and vendor offerings, informed about financial relationships between parties in the supply chain, conflicts of interests, and incentives.*

5. Senior Management and Employee Communications: Employers will increase public awareness of specialty drug market dysfunction including pricing by:

- Developing communications strategy, key messages, tactics, and activities.
- Developing materials and communications to educate senior management, unions (if applicable), and consumers on specialty drug market dysfunction.
- Arranging for c-suite/senior management briefings with Dr. Steve Schondelmeyer to update on the state of the industry and prepare for future implications.

Why is this important for employers?

- *Senior management may be more amenable to more restrictive changes to benefit plans and vendor contracts as they understand future cost implications.*
- *Employees may be more accepting of more restrictive changes in benefits if they understand future cost implications.*

6. Policy Actions: Employers will collaborate with other aligned organizations to affect policy at a national and state level:

- National
  - Support organizations and activities that establish drug prices based on value.
  - Educate policy makers on employer positions related to accelerating lower-cost alternative drugs including generics and bio-similars.
- State
  - Support legislation related to requiring providers and health plans to submit NDCs for medical claims.
  - Support streamlined prior authorization processes without limiting the ability to manage drug costs.
  - Support bio-similar interchange.

Why is this important for employers?

- *The purchasers' voice is absent in current policy discussions while they pay over half the costs of private insured individuals and experience cost shifting from public programs.*
- *Sustainable pricing is necessary for public and private purchasers for a sustainable economy.*

7. New Model Development: Employers will have information about and input into new specialty pharmacy care and market models

- Explore alternatives to existing processes and organizations; carved out specialty pharmacies from PBMs.
- Communicate and evaluate alternative, disruptive models (e.g., SaveonSP).
- Support new, value-added programs and activities that support new models (e.g., Fairview comparisons psoriasis providers, measuring patient-reported outcomes).
- Work collaboratively with outside organizations that offer services and models that benefit employers and consumers (e.g., Magellan's prior authorization of medical specialty claims).

Why is this important for employers?

- *No single vendor provides all the services, expertise and knowledge necessary to manage these costs and improve value today.*
- *Employers have not had a voice in developing solutions or systems to manage specialty pharmacy costs; today's model is shaped by the industry suppliers.*

2016 Action Network Deliverables

Tools

- Checklists and guides for vendors including:
  - RFPs
  - Vendor contracts with definitions and terms
  - SPDs

Assessment and Evaluation

- Drug price transparency tools with suggested action steps
- Pipeline management, decision support, and budget implications

Initiatives

- Communications on NDCs and site-of-care expectations to health plans and providers
- Collective specialty pharmacy carve-out
- Identify new care models
- Implement new savings opportunities — SaveonSP patient-support program

Employer role

- Six employer meetings to evaluate deliverables, review progress on action items
- 1:1 calls/meetings to prepare for vendor meetings, pharmacy fee schedules, vendor selection, and negotiations
- C-suite/senior management "State of the Industry" briefing with Dr. Stephen Schondelmeyer

(Appendix)

Expectations for Cost Transparency on Drugs

Employers' Expectations

Our companies, as purchasers of health care, are responsible for providing health care coverage to hundreds of thousands of people every year. Specialty drug costs are one of the biggest drivers of health care inflation and expenditures today. Therefore, we expect the best possible data, information and tools to manage these valuable, yet very expensive, medications.

It's time for all Minnesota medical providers to standardize their billing processes for specialty drugs, and to produce medical claims data that are at least as specific and accurate as are pharmacy claims data. We expect:

1. *All providers to submit National Drug Codes (NDC), units and quantity (standard claim fields) on all drug-related claims, to all payers, just as they do today for Medicaid claims.*
2. *The reporting of NDCs, units and quantity on medical drug claims will begin as soon as is possible for the Top 10 medical specialty drugs (see list provided), but no later than January 1, 2016.*
3. *After January 1, 2016, NDC codes, units and quantities shall be provided on all claims for all new medical specialty drugs not yet assigned a specific Healthcare Common Procedure Coding System (HCPCS) code.*
4. *Beginning July 1, 2016, NDC codes and NDC quantities will be provided on all drug-related medical claims for all drugs in all settings.*

The use of these codes will provide more specific, accurate and relevant information so all purchasers, including employers, can have better information to manage the safety, cost, quality and utilization of this rapidly exploding expense.

Background

- Half of specialty pharmacy costs are submitted for payment from medical providers including doctors' offices, home health care agencies, free-standing infusion centers, and outpatient hospital centers; the other half are submitted for payment by pharmacies including retail, mail order, and specialty pharmacies.
- Billing systems for drugs delivered by medical providers differ from pharmacy systems.
  - Medical providers use HCPCS codes that were designed to provide general information on equipment and supplies, and often don't identify a manufacturer's product, specific drug, strength, dosage form, or dose given.
  - Pharmacies and pharmacy claims routinely use NDC codes, units, and quantities that are designed to provide this level of detailed information.
- NDC codes are currently being used for medical specialty claims:
  - Medicaid has required NDC codes for specialty pharmacy claims from medical providers since 2008, in order to allow Medicaid to negotiate and collect rebates.
  - Some providers submit NDC codes, units and quantities, and find value in this level of detail as they evaluate their total cost of care and quality metrics.
- By creating a synchronized market-wide change to use of NDC codes, we expect providers and health plans will achieve efficiencies and coordinate implementation of these changes.

Rationale: NDCs

- Provide specific information on manufacturer, drug name, packaging, strength and dose form.
- Enable more specific pricing and more accurate payment for drugs.
- Enable more specific identification of newly approved drugs not yet assigned HCPCS codes.
- Enable purchasers and their health plans to negotiate drug-specific rebates with manufacturers.
- Provide uniform dosing information to assure appropriate amounts of drugs are used.
- Improve accuracy and efficiency of prior authorization and step therapy processes.
- Improve information given to providers to better manage their total cost of care, safety and quality.
- Enable health plans to provide drug price and quantity information to patients on their Explanation of Benefits (EOBs).
- Improve transparency of costs, utilization, safety and quality on regular reports to purchasers.

Next Steps

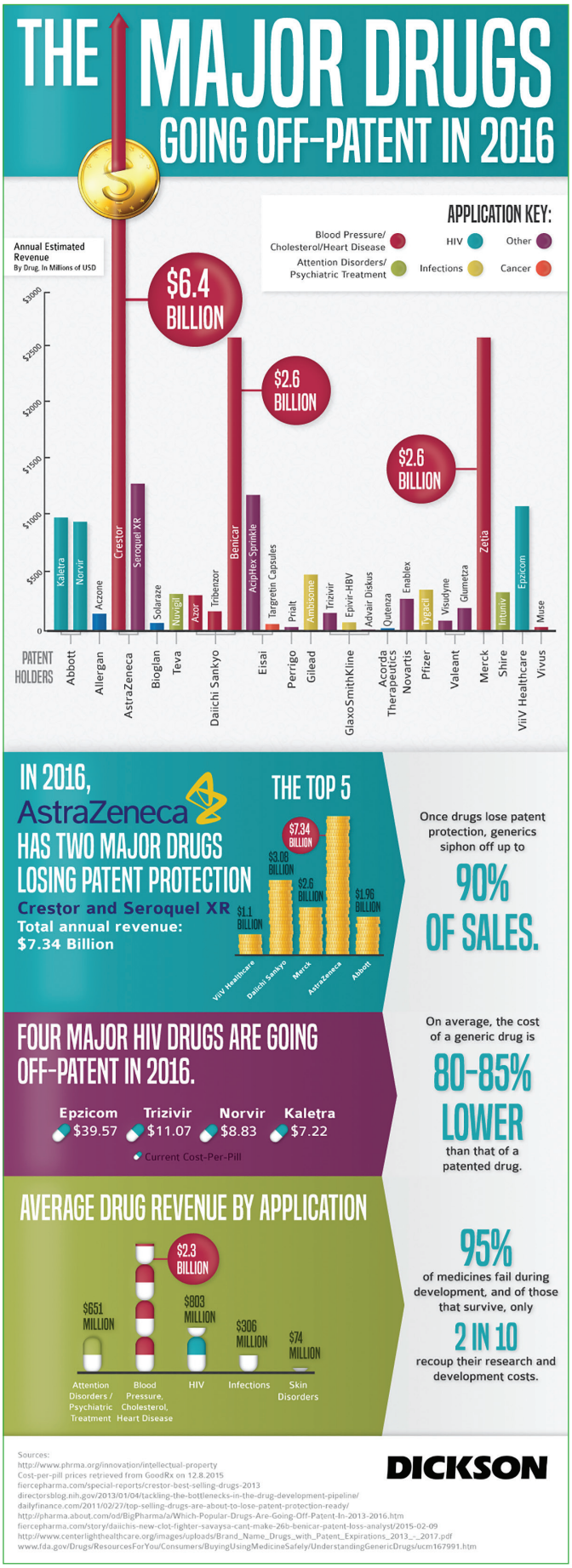
We will be advocating for this change immediately to policy makers, providers, health plans, and others involved in implementing this change.

Top 10 2015 Commercial Medical Specialty Drugs

1. Remicade
2. Neulasta
3. Avastin
4. Rituxan
5. Herceptin
6. Advate/Helixate/Kogenate/Recombinate
7. Gammagard Liquid
8. Gamunex-C/Gammaked
9. Tysabri
10. Eloxatin

Forecast: Top 20 2020 Drugs

1. Humira
2. Revlimid
3. Opdivo
4. Harvoni
5. Prevnar 13
6. Avastin
7. Herceptin
8. Soliris
9. Tecfidera
10. Orkambi
11. Entresto
12. Rituxan
13. Enbrel
14. Remicade
15. Xtandi
16. Januvia
17. Keytruda
18. Eliquis
19. Eylea
20. Triumeq



Funding for this project was provided by

3M, Best Buy, Blue Cross and Blue Shield of Minnesota, Carlson, Emerson-Rosemount, 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.

PURCHASER'S GUIDES
are published by the
Minnesota Health Action Group

7900 International Drive
Suite 1080
Bloomington, MN 55425
www.mnhealthactiongroup.org

March 2016