Specialty Drug Employer PLAYBOOK

Minnesota Health Action Group™
Innovating, Leading, Engaging

Taking action to ensure stakeholders are measuring progress and achieving goals

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Introduction

Specialty Drug Employer Playbook: Stabilizing a broken system

Over 40 Minnesota Health Action Group Specialty Drug Guiding Coalition members from more than 20 organizations collaborated for nearly two years to uncover solutions to the specialty drug challenges affecting employers and their workforces. Representatives from employers, health plans, pharmacy benefit managers, specialty pharmacies, provider organizations, and drug manufacturers set aside their differences to, ultimately, develop this Playbook.

In addition to effective management of specialty drug benefits provided to their employees, public and private purchasers can use the Playbook to amplify their collective voice to drive efficiency and transparency in the marketplace. Further, through a disciplined purchasing process, employers can ensure shared accountability for change in Minnesota and beyond.

The Action Group has received national attention for this leading-edge work, and the framework has been adapted by the National Alliance of Healthcare Purchaser Coalitions and is available to over 50 of its member coalitions throughout the United States.

Fast Facts on Specialty Drugs:

- For some chronic conditions, a year of treatment with a specialty drug can exceed $100,000. In 2015, only one to two percent of the American public used specialty drugs, yet they accounted for approximately 38 percent of total drug expenditure, according to a *Health Affairs* Report.
    - The cost of Bavencio, a new drug approved in 2018, is about $156,000 per year, per patient.
    - Sarepta came on the market for the treatment of Duchenne muscular dystrophy in late 2017 – at a cost of $300,000 per year, per patient.
    - In 2016, the FDA approved Tecentriq, a bladder cancer treatment that costs $150,000 per year, per patient.
    - Even the four-decade-old EpiPen, a lifesaving allergy medication, has seen a price hike of 500 percent since 2007.
- Related analysis in *Health Affairs* modeled the impact of a hypothetical specialty drug that costs $100,000 per patient. Its use would increase total health care costs by $250 for every 0.25 percent of the population using the drug. Under this model, such a specialty drug used by just five percent of the population would lead to an almost 15 percent increase in premiums.
- The AARP reports that the average cost of treatment with a single specialty drug was $52,486 in 2015. This cost is three times higher than the average Social Security retirement, which is $16,101, and twice the income for a Medicare beneficiary, which is $25,150. Notably, the average cost for a specialty drug used to treat a chronic condition increased by nearly $35,000 between 2006 and 2015.

"With the Playbook, employers will now be better equipped to gain more control over specialty drug use and spend on behalf of their employees which, in turn, will contribute to stabilizing a very broken system."

Carolyn Pare, Action Group President and CEO

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Getting the 5 Rights, Right
Right drug, right price, right place, right support, right data

Health Plans

- Require submission of actual National Drug Codes (NDCs), in addition to Healthcare Common Procedure Codes (HCPCs), units, quantity and day's supply by all providers, in all settings; use NDCs for prior authorization, utilization management, payment, collection of rebates, claim-level reporting, data analysis, provider contracts, and patient outcomes.
- Contract with providers to assure cost parity of all sites of care for the same drugs and services.
- Align total cost of care (TCOC) and accountable care organization (ACO) provider contracts so practitioners select and/or administer high-value drugs.
- Involve employers in key decisions* that affect their overall health care costs.

Specialty drug costs affect Minnesota city, county, state budgets, global competitiveness, and overall vitality of the state and U.S. economy.

** Additions to the specialty drug list, pre-FDA approval pipeline management, dramatic drug price increases (for under-the-radar drugs), excluded drugs, UM/PA criteria, formulary designation, etc.*

From 2012-2020, spending on specialty drugs is expected to increase 361%.

Source: PwC Health Research Institute: Behind the Numbers 2015 and analysis of CVS Caremark Data.

Provider Organizations

- Include actual NDCs (in addition to HCPCs), units, quantity and day's supply by all providers in all settings; use NDCs for prior authorization, utilization management, payment, collection of rebates, claim-level reporting, data analysis, provider contracts, and patient outcomes.
- Include cost parity across all sites of care for the same drugs and services in all contracts.
- Align TCOC/ACO contracts to include drugs so practitioners select and/or administer high-value drugs.
- Ensure practitioners know drug prices (what employers and consumers pay) at the point of care to support use of high-value drugs.

Pharmacy Benefit Managers (PBMs)

- Accept fiduciary responsibility (ERISA definition).
- Ensure a level of financial transparency, so purchasers know exactly how their money is being spent.
- Provide complete claim-level reporting, including all data fields, for employer ad hoc analysis.
- Involve employers in key decisions* that affect their overall health costs.

Normally, prices go down as more competitors enter the market.
What happened when multiple therapies became available for multiple sclerosis patients?
The annual cost increased 500% in just 10 years.

Source: The cost of multiple sclerosis drugs in the U.S. and the pharmaceutical industry: Too big to fail? Neurology, 84, May 26, 2015, pp.1-8

Specialty Pharmacies

- Ensure a level of financial transparency, so purchasers know exactly how their money is being spent.
- Make operational processes and decisions on behalf of the purchaser, independent of the specialty pharmacy parent organization's financial interests.
- Ensure that high-level, timely clinical expertise supports provider decisions to use high-value drugs and achieve optimal outcomes.
- Provide patient education and support that includes timely instruction on drug administration and emotional and social support to increase adherence and improve outcomes.

Our ultimate goal:
All stakeholders develop solutions together, holding one another accountable for getting the 5 rights, right.

Manufacturers

- Ensure that price increases over time do not exceed the Consumer Price Index (CPI).
- Create a model of financial transparency that will assist purchasers in making value-based decisions.
- Develop and implement value-/performance-based pricing (to be defined).
- Discontinue consumer coupon programs that encourage use of low-value, high-cost drugs in place of therapeutically equivalent generics.

The Action Group convenes a multi-stakeholder workgroup to determine specific action items, deliverables and a multi-year timeline. For more information, visit mnhealthactiongroup.org.

About the Minnesota Health Action Group

The Minnesota Health Action Group is a coalition of public and private purchasers whose sole purpose is to represent the collective voice of those who write the checks for health care in Minnesota. Action Group members collaborate with community stakeholders to drive innovations that support high quality health care, create engaged consumers, and ensure the economic vitality of all Minnesota communities. Based in Bloomington, Minn., the Minnesota Health Action Group was formed in 1988 as the Buyers Health Care Action Group. To learn more, visit www.mnhealthactiongroup.org. Follow on LinkedIn and Twitter: @actiongroupmn.

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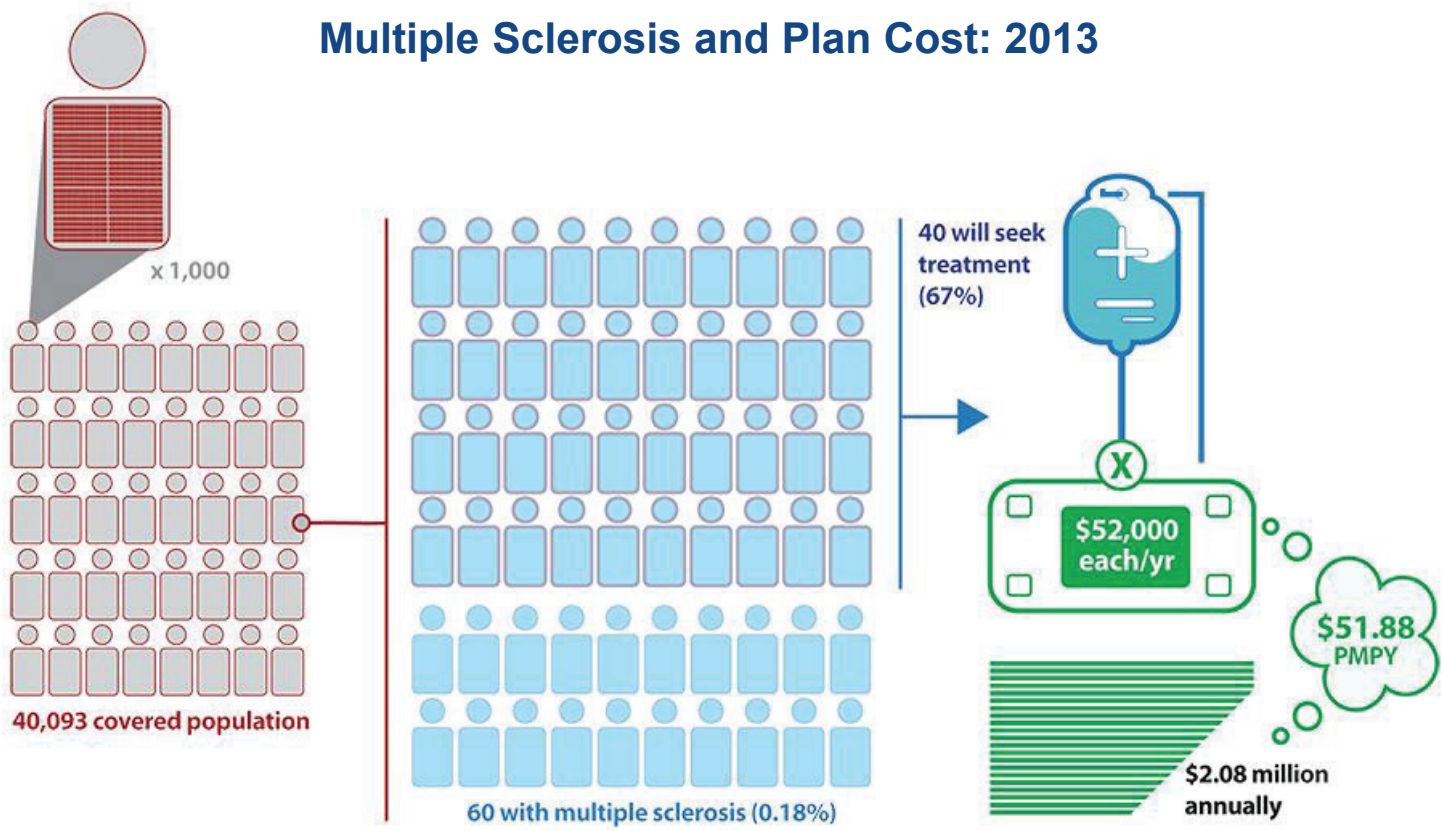
Why Getting the 5 Rights, Right Matters:

The example below shows just *one condition at one Minnesota employer*, illustrating why it's so important to get the 5 rights, right. With MS therapy costs increasing 500% in a decade, just 40 patients cause costs to increase by $51.88 *per health plan member, per year, or $2.08 million per year*. Now multiply this by countless other conditions requiring lifelong drug therapies.



Minnesota Health Action Group

Taking Action EXPRESS

September 14, 2017

INNOVATION UPDATE: SPECIALTY DRUG GUIDING COALITION

The Action Group convenes employers, health plans, provider organizations, pharmacy benefit managers, specialty pharmacies, and manufacturers in its Specialty Drug Guiding Coalition to identify real opportunities to collaborate for positive change in the specialty drug marketplace.

When it comes to specialty drug affordability and access challenges, the blame game is alive and well. But over 40 Specialty Drug Guiding Coalition members from more than 20 organizations have been working together since February, putting a stop to the blame game, and elevating the discussion to find solutions that work for all.

As one coalition member said, "We're sharing our ideas and expertise – essentially, our secret sauce – which is only possible because of a real feeling of camaraderie and trust, and a commitment to making things better."

As a bonus, Dr. Stephen Schondelmeyer, renowned pharmacy economics expert from the University of Minnesota and long-time advisor to The Action Group attends the Guiding Coalition meetings. He offers insights into complex topics such as class of trade, which enables pharmaceutical manufacturers to vary the price of their products, depending on the type of customer, or the channel products flow.

Because of the specialty drug market complexities, there will be no quick fix to ensuring we get the Five Rights Right: Right Drug, Right Price, Right Place, Right Support, Right Data. This is why The Action Group is convening key stakeholders who have each made a commitment to meeting mutually agreed-upon goals for 2017 and 2018. These goals can be found on the following pages.

Class of Trade: Why Employers Should Care

The class of trade concept is important for employers to understand and discuss with their vendors when considering the variables, incentives and implications of various distribution channels. For example, physicians and hospitals typically get the lowest price when purchasing drugs, and retail and mail order pharmacies typically pay the most. Drug price transparency is based on understanding the difference between acquisition cost and what the purchaser or consumer is charged.

Action Group @ Work!

Even with the climate of uncertainty about the future of health care in America, on one thing we can all agree: Everyone deserves to live the healthiest life possible. That's why the nonpartisan Action Group unites the public and private sectors, fostering partnerships that lead to proactive, collaborative strategies focused on a common end point: Better, more affordable health care solutions for all. To learn more, please visit mnhealthactiongroup.org.

2017 Goals: Setting the Stage for Success

During our first meeting, we began working on action plans to enable each of the five stakeholders to achieve four goals, developing report cards with scoring criteria to measure progress. It quickly became clear, however, that addressing 20 goals in a single year was overly ambitious. As such, each stakeholder is now responsible for delivering on two goals per year in 2017 and 2018.

Key initiatives for 2017 include (these are summarized; click here to view full text):

HEALTH PLANS:
- Require the submission of actual National Drug Codes (NDCs), in addition to Healthcare Common Procedure Codes (HCPCs), units, quantity and day's supply by all providers in all settings.
- Contract with providers to assure cost parity of all sites of care for the same drugs and services.

PROVIDER ORGANIZATIONS:
- Include actual NDCs (in addition to HCPCs), units, quantity and day's supply by all providers in all settings; use NDCs for prior authorization, utilization management, payment, collection of rebates, claim-level reporting, data analysis, provider contracts, and patient outcomes.
- Include cost parity across all sites of care for the same drugs and services in all contracts.

PHARMACY BENEFIT MANAGERS (PBMs):
- Accept fiduciary responsibility (ERISA definition).
- Ensure a level of financial transparency, so purchasers know exactly how their money is being spent.

SPECIALTY PHARMACIES:
- Ensure a level of financial transparency for purchasers.
- Ensure that high-level, timely clinical expertise supports provider decisions to use high-value drugs with the goal of achieving optimal outcomes.

MANUFACTURERS:
- Create a model of financial transparency that will assist purchasers in making value-based decisions.
- Discontinue consumer coupon programs that encourage use of low-value, high-cost drugs in place of therapeutically equivalent generics.

THE VOICE OF SPECIALTY DRUG GUIDING COALITION MEMBERS:

Following each Specialty Drug Guiding Coalition meeting, we gather feedback to ensure we are advancing toward our goals, and meeting expectations. Here are some highlights:

"We are really digging into understanding the scorecard, and figuring out ways to move it forward." ~ *Provider Organization*

"Small group discussion allows the various stakeholders to articulate the influences and impacts within their organizations." ~*Employer*

"It has helped to understand the difficult decisions employers face when deciding what to cover." ~*PBM*

"I have gained a better understanding of the challenges each of us faces from day to day." ~*Manufacturer*

"The expertise Steve Schondelmeyer brings to the table is absolutely invaluable." ~*Specialty Pharmacy*

"Hearing the perspectives of employer groups has really opened my eyes to the difficult choices they make every day on behalf of their employees." ~ *Health Plan*

2018 Goals: Building on Our Momentum

As the group continues to gel and momentum grows, members of the Specialty Drug Guiding Coalition will be tackling the remaining goals in 2018. Additionally, we will be working closely with the National Alliance of Healthcare Purchaser Coalitions and its adapted "5 Rights Framework" to drive national collaboration with key stakeholders to bring a measure of control back to the specialty drug marketplace. The 10 goals for 2018 are as follows:

HEALTH PLANS:
- Align total cost of care (TCOC) and accountable care organization (ACO) provider contracts, so practitioners select and/or administer high-value drugs.
- Involve employers in key decisions that affect their overall costs.

PROVIDER ORGANIZATIONS:
- Align TCOC/ACO contracts to include drugs, so practitioners select and/or administer high-value drugs.
- Ensure practitioners better know drug prices (what employers and consumers are paying) at the point of care to support the use of high-value drugs.

PBMs:
- Provide complete claim-level reporting, including all data fields, for employer ad hoc analysis.
- Involve employers in key decisions that affect their overall costs.

SPECIALTY PHARMACIES:
- Make operational processes and decisions on behalf of the purchaser, independent of the specialty pharmacy parent organization's financial interests.
- Provide/improve patient education and support that includes timely instruction on drug administration and emotional/social support to increase adherence and improve outcomes.

MANUFACTURERS:
- Ensure that price increases over time to not exceed the Consumer Price Index (CPI).
- Develop and implement value-/performance-based pricing.

National Alliance of Healthcare Purchaser Coalitions Adapts Action Group's 5 Rights Framework

"Specialty drugs are the fastest growing area of spend for employers today. While these new drugs are truly innovative and important, the specialty drug marketplace itself is dysfunctional with high cost, high variation and high waste. We need to collaborate with stakeholders to wring out the costs of poor quality and unwarranted cost, complexity and conflicts."

~ Mike Thompson, National Alliance president and CEO

To drive collaboration to control costs, reduce waste, and maximize the effectiveness of specialty drugs, the National Alliance adapted The Action Group's stakeholder guidelines and engagement framework targeting critical issues and opportunities. To learn more about the national initiative, visit http://www.nationalalliancehealth.org/initiatives/initiatives-national/specialty-drug-marketplace.

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Health Plans

Health Plan Goals

Setting the stage for success

1. Require submission of actual NDCs and HCPCs, units, quantity and day's supply by all providers in all settings.
2. Contract with providers to assure cost parity of all sites of care for the same drugs and services.
3. Involve employers in key decisions that affect their overall costs.
4. Align TCOC and ACO provider contracts so practitioners select and/or administer high-value drugs.

NDC Codes:

Adding Clarity To Better Manage Costs

Currently, about 40 percent of specialty drug spend is under the medical benefit. Drugs reimbursed through the pharmacy benefit include an NDC code, identifying the specific brand, dosage, and number of units administered. Drugs reimbursed through the medical benefit include HCPCS codes, which are less specific and may include multiple products under a single code. Additionally, there is often a lag in assigning HCPCS codes, so newer drugs may have an unclassified or unlisted designation making it even harder for employers to manage specialty drug benefits.

Health Plan Tips and Actions

Baseline Expectations

- 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 drugs under both the pharmacy and the medical benefit.
- Require prior authorization and ***step therapy criteria*** *are transparent* to providers and patients.
- Require ***preferred products to be based on clinical evidence.***
- 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.
- Require appropriate adherence (or compliance) under both the pharmacy and the medical benefit through effective management practices.
- Require health plans/medical providers to ***report payments made by a manufacturer's patient assistance program or copay coupon program.***
- Require that ***preferred products are based on clinical evidence.***
- 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.
- Require appropriate adherence (or compliance) under both the pharmacy and the medical benefit through effective management practices.
- Require ***preferred products to be based on clinical evidence.***
- 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.
- Implement ***similar coverage and payment policies*** for specialty drugs under both the pharmacy and the medical benefits, e.g., eliminate incentives for patients to use the most expensive providers.
- Require value-based therapy coverage (covered and non-covered drugs are evidence-based and most cost effective).
- Consider "floating" (copays/coinsurance) member cost-sharing for specific drugs with generous ***manufacturer patient assistance programs*** and coupons to optimize their payments and minimize total expenditures by patients and employers.
- Review and revise employer's summary plan description (SPD) for issues related to specialty drug coverage and management, e.g., ***optimizing biosimilars.***
- Implement deductible policies so payments from manufacturer coupons and ***patient assistance programs do not count toward patient out-of-pocket deductibles.***
- 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.
- Determine and negotiate employer rebate goals, strategies, and agreements for specialty pharmacy specifically with both health plan and PBM.
- Assure all summary plan descriptions include terms that optimize use of biosimilars.
- 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).
- Implement support services to assure safe, effective, appropriate use including adherence and discontinuation.
- 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.
- Information on contractual relationships with provider systems, financial incentives, performance on clinical/utilization management.

Health Plan Tips and Actions

Transformative Goals

NDCs and reporting	Establish a ***complete and accurate baseline*** of total specialty pharmacy costs for both medical and pharmacy benefits to track trend and changes over time.
	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.
	Do not accept imputed NDC numbers artificially assigned by ***HCPCS-NDC crosswalks*** since these are not as specific as NDCs and are insufficient for determining provider costs and payment.
	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).
	Require reports that evaluate the ***impact*** of specialty prior authorizations and step therapy protocols, i.e., % approvals/denials, appeals, cost per claim.
	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 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).
	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.***
	Require health plans to ***report the specific NDC numbe***r for the drug product administered including the dosage form, strength, package type, and manufacturer.
	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.
	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.
Cost parity across sites of care	Require health plans to equalize reimbursement for providers regardless of site-of-care to steer patients to the most cost-effective 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

Health Plan Tips and Actions

Transformative Goals

Employers at the table for key decisions	Require ***cost projections*** for the following year including anticipated FDA approvals, e.g., cystic fibrosis, familial hypercholesterolemia, specific to your population.
	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.
	Formulary decisions of P&T committees, their processes, and rationale are transparent to employers when they are decided.
	Review and revise both health plan and PBM contracts to enable customization, employer input on key decisions, and that support value-based purchasing.
TCOC/ACO provider contracts align incentives	Require (individually and collectively) that health plans align incentives within their contracts so that specialists select high value drugs.
	Require health plans to implement downside risk in TCOC contracts.
	Health plans should provide support systems that provide information on comparative effectiveness and value to providers at the point of prescribing.
	Management tools should be provided to physicians to support management of specialty drug costs.

Health Plan Goal Briefings

National Drug Codes (NDCs)

Require submission of actual National Drug Codes (NDCs), in addition to Healthcare Common Procedure Codes (HCPCs), units, quantity, and day's supply by all providers in all settings; use NDCs for prior authorization (PA), utilization management (UM), payment, collection of rebates, claim level reporting, data analysis, provider contracts, and patient outcomes.

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers
▪ Employers learned early on that medical claims, unlike PBM claims, do not include NDCs, which identify manufacturer, dosing, packaging, or unit of measure. ▪ Medical claims include HCPC codes, introduced in 1978, when the average prescription cost was $5; it was $3,500 in 2015. ▪ More specific data is needed to increase transparency and provide information to manage increasing costs today and in the future. ▪ Medicaid has required NDCs for years to collect manufacturer rebates. ▪ MN All Payer Claims Database pharmacy analysis revealed the most expensive therapeutic category for medical specialty drugs was "bundled and unknown."	▪ Knowledge of specific drug spend under the medical benefit so they "know what they are paying for." ▪ Increased transparency of price and margin, administrative fees, and areas of variation to identify cost savings opportunities. ▪ Expand use of NDCs to improve UM, identify pricing, support rebate negotiations, conduct comparative effectiveness, and other opportunities possible with additional information and granularity. ▪ Provide more specific data to health care providers to better manage cost, quality, and improve safety. ▪ Better identify and inform all cost performance components under ACO contracts.	▪ This goal includes all claims; all settings such as hospital outpatient, and all therapeutic classes, such as oncology. ▪ Claims submission should include HCPCs, NDCs, the definition of unit of measurement, the number of units, dosage, and day's supply.	▪ The MN Administrative Uniformity Committee (AUC) does not explicitly allow health plans to require provider submission of NDCs except for Medicaid products; it has challenged this goal in the past and may challenge it in the future. ▪ Drugs administered by medical providers represent a significant revenue source; they may resist exposing cost allocations and margin.	▪ Major health plans now require reporting of NDCs selectively or completely, e.g., HealthPartners, BCBSMI, HCSC, UHC, and others. ▪ The tipping point has been reached; Magellan's most recent medical specialty report states more than 64% of payers plan to capture NDCs in 2017. ▪ Providers who are at risk for the cost of drugs in TCOC/ACO contracts will benefit from more specific information to manage these drugs.

Health Plan Goal Briefings

Cost Parity

Contract with providers to assure cost parity of all sites of care for the same drugs and services.

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers
▪ Employers heard repeatedly that physician groups, acquired by hospitals, changed their billing for infusion services from physician office settings (CMS 1500 claim) to outpatient hospital (UB 04 claim) settings and claims, resulting in increased costs. ▪ Moving patients from outpatient hospital settings to home or physician office settings was proposed to solve this problem. It also created patient disruption and administrative expense.	▪ Value-based pricing that includes cost parity for the same services regardless of location or provider. ▪ Employers want to minimize patient disruption and the resulting benefit dissatisfaction.	▪ All charges including drug prices, administration and other fees should be included when comparing price parity. ▪ NDCs will support data analysis to compare providers' itemized costs and billing practices.	▪ Provider consolidation and the resulting market power will present negotiation challenges for health plans. ▪ Health plans have pressured health systems for cost parity by moving patients away from outpatient hospital settings. ▪ Some health systems have claimed lack of supply (facilities) to support increased volume in non-hospital settings. ▪ Heath systems may negotiate to be "kept whole" in exchange for cost parity.	▪ Many regional and national health plans have recently implemented PA processes that require medical necessity criteria for outpatient infusion services and have been educating and preparing providers and patients for this change. ▪ Employers can collectively send a clear, consistent message to hospital systems that they are aware of this practice and want to see a movement to value-based care.

Health Plan Goal Briefings

Involve Employers

Involve employers in key decisions that affect their overall health care costs.

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers

▪ Employers must project health care costs for future years; the costs of many new, very costly drugs, e.g., cystic fibrosis, may not be anticipated. Employers need to be involved in drug pipeline management.
▪ Employers learned there was great variation among health plans in their knowledge, focus, ability, and management of medical specialty drug costs.
▪ The largest therapeutic category for medical specialty drug costs is "unknown and bundled" demonstrating the need to require NDC submission from providers.
▪ Specialty drugs are the fastest growing area of health care benefit spend.
	▪ Increased transparency of decisions made by health plans on their behalf to manage specialty drugs.
	▪ Timely, accurate and detailed data to support health care budgeting and cost projections.
	▪ Detailed information on how medical specialty drugs are managed.
	▪ Increased focus and management of medical specialty drugs that reflects their goals, not those of providers or other players in the supply chain.
	▪ No additional costs or charges to make these decisions.
		▪ Employers should identify and clearly communicate which decisions they want to "be at the table" for, and when and how they want to weigh in.
		▪ Decisions could include:
		  ▪ which drugs require PA criteria coverage decisions:
		  ▪ excluded drugs
		  ▪ rebate payments
		  ▪ pipeline drug management
		  ▪ provider submission and health plan use of NDCs
		  ▪ how to manage variation in use of sites of care
		  ▪ utilization reporting
		  ▪ provider contracting
		  ▪ provider reporting
			▪ Employers' interest and capability to weigh in on decisions will vary.
			▪ Employers may be unprepared to make these decisions without education and guidance from experts.
			▪ They may need the expertise of consultants to inform their decisions.
			▪ Health plans are not accustomed to including employers in key decisions.
			▪ Health plans may charge for information and consultation.
				▪ Employers should discuss their goals for involvement and provide health plans with information on which specific decisions they want to be included, how they want to be involved, and when they are included.
				▪ Health plans should know which employers want to be involved in which decisions and manage accordingly.
				▪ Contracts should reflect these decisions and processes for decision making.

Health Plan Goal Briefings

Total Cost of Care (TCOC) Alignment

Align Total Cost of Care (TCOC) and Accountable Care Organization (ACO) provider contracts, so practitioners select and/or administer high-value drugs and manage utilization.

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers

▪ Health plans first implemented TCOC contracts in 2011, with the goal of bending the cost curve.
▪ TCOC contract's financial targets include specialty drugs.
▪ Employers have purchased ACO/TCOC products from health plans with the assumption they provide incentives for providers to better manage all care including specialty drugs.
▪ Payment/compensation models within care systems/ medical groups do not include incentives for those who select specialty drugs, to manage drug costs, utilization, or outcomes.
▪ Specialty providers typically administer specialty drugs, e.g., oncologists, and often do not know drug prices at the point of prescribing or administration.
	▪ Value-based purchasing should align providers and employer incentives to measure and improve outcomes at the lowest possible price, at all levels
	  ▪ payer to care system
	  ▪ care system to medical group
	  ▪ medical group to individual practitioner
	▪ All providers, including primary care physicians and specialists, have incentives, information, and tools to inform them on prices, drug value, and support the use of high-value specialty drugs.
		▪ TCOC contracts typically include upside rewards to providers for shared savings and little if any downside risk.
		▪ TCOC contracts attribute patients' costs to primary care physicians who have little or no information to guide decisions on which specialists have better outcomes or deliver more value with specialty drugs.
		▪ Primary care physicians have little if any information to decide who to refer patients to.
		▪ Specialists, not primary care physicians, typically prescribe or administer specialty drugs and have little, if any, incentive through TCOC contracts or compensation models to manage costs or quality.
			▪ Existing TCOC contracts do not provide incentives to specialists to manage specialty drugs or use high-value drugs.
			▪ Some providers may receive delayed utilization reports from health plans to help them manage specialty drugs.
			▪ Carved out PBM costs may be average estimates, not actual costs, further eroding the quality of the information to providers and their ability to manage these costs.
			▪ Many specialty providers benefit financially from infusing medical specialty drugs and have little, if any, incentive to reduce costs.
				▪ Employers should require (individually and collectively) that health plans align incentives within their contracts so that specialists select high-value drugs.
				▪ Require health plans to implement downside risk in TCOC contracts.
				▪ Support systems that provide information on comparative effectiveness and value should be provided to providers at the point of prescribing.
				▪ Management tools should be provided to physicians to support management of specialty drug costs.

Health Plan Scoring Criteria

Goal	0	1	2	3
NDCs[1]	▪ No plan to require NDCs from providers OR ▪ Plan to collect and use (report, administer claims, other) NDCs in next 12 months	▪ Currently provides employer reports with HCPCs ▪ Requires NDCs selectively, e.g., otherwise unclassified codes OR ▪ Only providers who don't refuse OR ▪ < 50% of claims (all sites of care) OR ▪ Plan to collect and use (report, administer claims, other) with NDCs for all claims in next 6 months	▪ Requires NDCs of all providers, all drugs, all settings (home, office, OP hosp., other) AND ▪ Provides high-level analysis and reports using NDCs for employers AND ▪ Exploring other uses of NDCs	▪ Employer reports include NDCs AND ▪ > 90% claims include NDCs OR ▪ Using NDCs and dosing in PA OR ▪ Collecting and distributing rebates to employers OR ▪ Using NDCs to adjudicate claims OR ▪ Provider reports include NDCs to support Total Cost of Care (TCOC) management AND ▪ Exploring other uses

Cost parity across sites of care[2]	▪ No plans to manage cost parity by site of care	▪ Contracts with some providers with cost parity by site of care
		
		OR
		
		▪ Requiring medical necessity PA for outpatient hospital (OPH) use on < 50% claims (all sites of care)
			▪ Parity of drug costs only
			
			OR
			
			▪ Parity for limited number of providers for all costs (drug, facility, administration)
			
			OR
			
			▪ PA on > 50% (OPH) claims with drug administration and facility fees
				▪ Process for assuring parity of all costs (drugs, facility, administration, etc.) on:
				  ▪ All drugs
				  ▪ All providers
				  ▪ All sites of care

[1] Actual NDCs submitted (not imputed) in addition to HCPCs, units, quantity and day's supply
[2] Cost parity includes all charges; drugs, administration, facility fees, and others when comparing costs across sites of care

Health Plan Scoring Criteria

Goal	0	1	2	3
Employers at the table for key decisions*	▪ Employers don't communicate which decisions they wish to make ▪ Health plan informs employers of key decisions after they are implemented	▪ Employers communicate which decisions they wish to make ▪ Health plan decides if, when and which decisions employers make	▪ Employers communicate which decisions they wish to make ▪ Health plan consults with employer with adequate lead time ▪ Employer input determines some decisions	▪ Employers communicate which decisions they wish to make ▪ Health plan follows employer wishes on all key decisions ▪ Health plan contracts reflects this agreement and key decisions
TCOC/ACO provider contracts align incentives	▪ TCOC contract targets include all medical drug costs but not carved out PBM costs ▪ < 50% of provider lives included in alternative risk arrangements	▪ All medical and PBM drug costs, including all carved out contracts, included in TCOC costs and targets ▪ > 50% lives in TCOC contracts ▪ TCOC contracts include shared savings (upside risk) and downside risk	▪ All drug costs included in TCOC contract targets ▪ > 50% lives in TCOC contracts that include unlimited downside risk ▪ Data analysis and provider reporting conducted to provide feedback on drug costs and utilization by provider group	▪ All drug costs included in TCOC contracts ▪ > 70% lives in TCOC ▪ All TCOC contracts include unlimited downside risk ▪ Data analysis and provider reporting conducted to identify areas for improvement, e.g., site of care ▪ Incentives for specialty providers to select high value drugs

**Employers communicate which decisions they wish to make in writing, e.g., benefit plan design, pipeline drug management, which drugs require PA, criteria, site-of-care management, coverage decisions, exclusions…*

Required Detail Claims Data Elements

- Claim descriptor elements
  - Claim type, claim sequence, Claim ID, prescription number, refill number, date submitted, date of service, specialty prescription, specialty indicator, retail indicator, mail order indicator, pharmacy network, extended supply network, member age, gender, MTM indicator, carrier identification, carrier description, account identification, account description, group identification, group description, member identification, prescriber identification, prescriber type, prescriber type, prescriber name, prescriber specialty, prescriber city, prescriber state, prescriber ZIP code, NCPDP number, pharmacy name, pharmacy type, pharmacy city, pharmacy state, pharmacy ZIP code, year, month.

- Financial elements
  - AWP, WAC, MAC, U&C, total paid, plan paid, member paid, copay, co-insurance, ingredient cost, dispensing fee, sales tax, incentive fee, professional service fee, coordination of benefit, and net drug dollars.

- Utilization management elements
  - DAW, % DAW, formulary indicator, formulary tier, step therapy indicator, prior authorization indicator, prior authorization reason, prior authorization effective date, and prior authorization end date.

- Drug product descriptors

- NDC, brand name, generic name, generic product indicator name, product name/name extension, manufacturer abbreviated name, labeler code, dosage form, strength, strength unit of measure, generic product packaging code, packaging quantity, package quantity dispensed, product package size, package standard unit of measure, route of administration, dispensing unit, unit dose, NDC status, NDC effective date, NDC inactive date, Rx OTC indicator, trade/brand/generic code, multi-source summary code, TEE code, DEA code, DESI, labeler type, limited distribution code, repackage code, AHFS, AHFS Name, and all levels of GPI codes and GPI name (GPI14 to GPI0).

- Other data elements as requested by employer.

Total Cost of Care (TCOC)

What's Important When Considering Total Cost of Care (TCOC) Contracts and Accountability for Specialty Drug Costs

SUMMARY

The Minnesota Health Action Group's Specialty Drug initiative identified 20 key goals for five different stakeholders in the supply chain as a step to a transformed specialty drug market and delivery system. One specific goal for both health plans and providers is to align financial incentives in Total Cost of Care (TCOC)/Accountable Care Organization (ACO) contracts (providers' financial targets include all drugs) so that providers select, prescribe and administer high-value drugs — drugs that provide optimal benefit at the lowest cost.

In the process of developing scorecards to evaluate provider and health plan performance related to TCOC incentives to choose high-value drugs, providers, health plans, and employers were queried to determine the current state of TCOC contracts and specialty drugs. Costs for medical specialty drugs and carved-in pharmacy benefit manager (PBM) arrangements for insured and self-funded employers included these costs. Self-funded employers who carved-out these costs from their health plan carriers (the most common arrangement of employer members of the Minnesota Health Action Group), produced surprising findings including:

- Representatives from key stakeholders, including provider systems and health plans, did not know whether carved-out drugs were included in TCOC targets.
- Representatives from providers and health plans who stated they knew whether carved-out drugs were included or not gave conflicting answers; some said they were included, others said they were not.
- MN Community Measurement, the entity that measures and publishes TCOC costs by medical group, stated that in their calculations some health plans include specific data by medical group on carved-out prescription drugs, while others include calculated averages. In all cases, all drug costs were attributed to the specific provider system that prescribed specific drugs for their attributed patients.
- Prescribers have few, if any, tools to know the cost of drugs or to compare effectiveness at the point of prescribing.
- Various Medicare products, e.g., Medicare Advantage, Medicare NextGen ACO products, Part D Drug Coverage, and other products vary in whether providers in those products bear risk for drug costs.

The current state of drug risk attribution is varied, complicated and confusing for all stakeholders, including prescribers. No data is available on whether and what specific information prescribers have at the point of care to support selection of high-value drugs or whether they understand their incentives in TCOC contracts to support selection of high-value drugs. In conclusion:

- Employers should require their health plans to negotiate provider financial accountability at the system level and at the prescriber level for all drugs costs in all their products, especially narrow network and ACO products.
- Employers should require their carved-out PBM vendors to routinely send claims data on drug costs to their health plans and require health plans to integrate that data into their TCOC reports.
- Delivery systems should include incentives in their contracts with specialty providers, including non-owned medical groups who are most likely to prescribe specialty drugs, to choose high-value drugs.
- Delivery systems should provide tools and information to prescribers at the point of care so that they can make informed choices when prescribing drugs.
- Public programs including Medicare and Medicaid should align their Alternative Payment Models to include provider accountability for all drug costs.

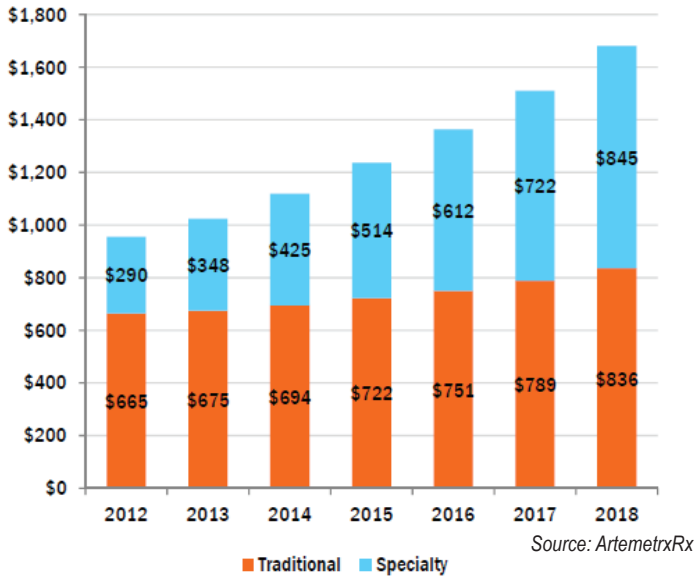
INTRODUCTION

Alternative Payment Models (APMs), models that move payment away from volume towards value, have been touted by public and private payers as the most important change needed to address health care costs and affordability, and to encourage accountability by providers for both quality and costs. TCOC contracts between providers and payers have emerged as one of these APMs for both public programs and commercial products. Minnesota was an early adopter in negotiating TCOC contracts going back as far as 2010. Eight years later, it is unclear how Minnesota compares to other parts of the country in adopting value-driven payment models.

MINNESOTA HEALTH ACTION GROUP LEARNS ABOUT SPECIALTY DRUGS

In late 2014, the Minnesota Health Action Group (The Action Group), a Minnesota-based employer coalition of health care purchasers, decided to form a learning network to increase their knowledge of how to better manage these drugs to increase their value. Employers were concerned by historical costs, projections of future prices and utilization, and their lack of knowledge of the complicated and inefficient supply chain. The chart below illustrates the dramatic increase in specialty drug costs.

FIGURE 1: FORECASTED PMPY NET DRUG SPEND ACROSS THE PHARMACY AND MEDICAL BENEFIT FOR COMMERCIAL PLAN SPONSORS



Source: ArtemetrxRx

The Action Group convened a Specialty Pharmacy Learning Network for employer members only in October 2014. Their intention was to meet for six months. They soon realized they would need much more time and continued to meet through 2016. They then formed a multi-stakeholder Specialty Drug Guiding Coalition that met with them throughout 2017 and 2018.

The focus of the Guiding Coalition was to develop scorecards for 20 priority goals. These goals addressed changes for health plans, providers, PBMs, specialty pharmacies and manufacturers in both the medical and prescription benefit supply chains. Two of the 20 goals related to incentives in payment models between health plans and providers related to managing specialty drugs:

"Align Total Cost of Care (TCOC) and Accountable Care Organization (ACO) contract incentives so practitioners select and/or administer high value (low cost/high benefit) drugs."

These score cards would include specific criteria to evaluate performance of stakeholders against these goals. The first step in developing criteria was to understand the current state of these contracts. Several key informants were tapped including:

- Employer members who had ACO products through their health plans.
- Fairview Health System, an early adopter and leader in APM contracting for both Medicare and commercial ACO contracts.
- MN Community Measurement, who measures and publicly reports TCOC by medical annually.
- HealthPartners who developed an NQF endorsed measure and, as a health plan and delivery system, has extensive experience.
- Ridgeview Health System, a locally based ACO.
- Numerous other providers, payers, and health plan representatives.

Several additional health plan and provider representatives were asked to describe their current incentive models, comment on draft criteria, and discuss their current status with ACO/TCOC contracts, but did not respond.

FINDINGS: UNKNOWN, CONFUSED, CONFLICTING

Several findings were identified through these conversations, both generally with TCOC contracts and specifically with prescription and specialty drugs including:

- Contracts have been in place since 2011, yet less than 41% of fully insured patients are included in these contracts as of 2015, according to results of research by the Minnesota Department of Health. More recent discussions with provider groups and payers confirm that while there are pockets of high ACO contracting rates, the average across Minnesota is below 50%, not enough to create a tipping point in behavior change for systems or individual providers.
- "Downside risk" is not defined consistently and less common that upside risk.
- Target rates are confidential as is provider performance against their targets. Larger systems have more leverage to negotiate greater increases in targets, therefore decreasing their incentive to reduce costs.
- Lack of transparency, complexity of payment models, and a general lack of knowledge raised more questions including:
  - How much unprotected downside risk, the most effective incentive for behavior change, is in place?
  - How specific provider systems perform against their contracted target rates?

- Whether prescription drug costs, including carved-out PBM drug costs of self-insured employers, is included in TCOC cost targets?
- Whether specialists, those players who prescribe most specialty drugs, have any accountability or risk for costs?

- Whether any supply chain players, including ACOs, medical groups, employed or contracted, specialists or primary care practitioners are incented to use high-value drugs?
- There is a wide variety of APM products and models in place today including:
  - Commercial narrow networks, ACOs, and new players with new products.
  - Medicare Advantage, NextGen ACOs, Cost Products, fee-for-service.
  - Medicaid Managed Care, Integrated Health Partnerships (IHPs) and fee for service products.

Even if providers and their systems had risk for these drugs, they have little information or tools at the point of prescribing to manage these costs. We heard from stakeholders that some specialty pharmacies inform providers of drug costs before they are filled, that some health plans inform providers of high-value drugs periodically and that some care systems may have e-prescribing technology that displays high-value drugs and suppresses low-value drugs at the point of prescribing. Drug costs seem to be an afterthought as part of TCOC even though they are the fastest growing component of health care costs.

- There is a general lack of understanding among individuals from all stakeholder groups on how incentives in TCOC contracts work, their structure, measurement specifications, contract terms and how they will manage costs.
- Health plans are inconsistent in whether and how they include or exclude prescription drugs generally, and carved-out PBM drugs costs specifically.
- Specialty groups have different risk arrangements with health plans depending on their size, use of specialty drugs and negotiating strength.
- Medicare products differ in whether drug costs are included in provider risk arrangements.

DEFINING TOTAL COST OF CARE

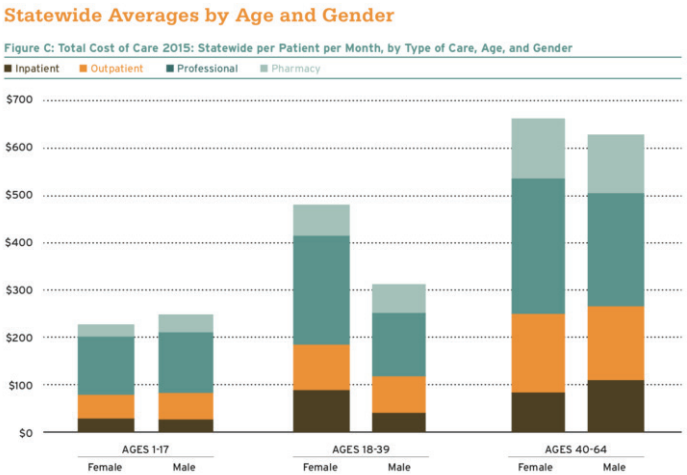
Several organizations were queried on their definition of TCOC.

The State of Washington states on its website that TCOC is a risk-adjusted payment that captures all costs of care for a defined population, including all professional, pharmacy, hospital, and ancillary care.

HealthPartners, a Minnesota-based health plan and delivery system, has developed a measure for TCOC that was endorsed by the National Quality Forum (NQF) in 2012 and again in 2017, in an effort to standardize and develop comparative data. Currently, the measure is being used in over 32 states and by over 150 providers, payers, employer consulting and other health care organizations. Their measure specifies that pharmacy costs are included in the total cost unless a providers' percentage of members with a pharmacy carve-out is high, between 70%-100%. In that case, costs are included but estimated at an average rate.

MN Community Measurement has published TCOC by medical group using the HealthPartners' measure since 2014. Their most recent report includes data on statewide averages by type of service, gender and age illustrating that pharmacy costs are a significant part of their calculations, nearing 20% of total costs.

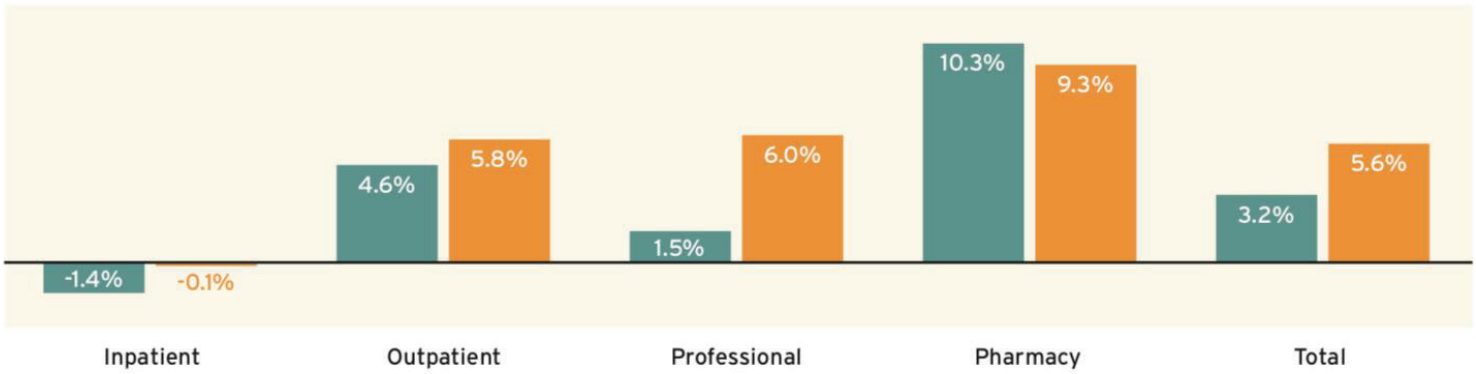
Statewide Averages by Age and Gender



They also illustrate changes in costs over the last two years with pharmacy costs showing the largest increase over time. These data illustrate the need to increase the focus on drug costs and include and strengthen incentives for all players to select and encourage use of high-value drugs.

1. *Minnesota Accountable Heath Model – SIM Minnesota, May 29, 2015 http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_FILE&RevisionSelectionMethod=LatestReleased&Rendition=Primary&allowInterrupt=1&noSaveAs=1&dDocName=dhs16_197637*

Figure A: Total Cost of Care - Changes in Total Cost of Care, MN Commercial Patients



IDEAL STATE

The Specialty Drug Guiding Coalition's goals would be met if all health plans, ACOs, and practitioners, were at risk for, and had incentives, to choose high-value drugs. This would require that:

- All health plans include carved-out PBM drug costs in their TCOC calculations;
- All providers know what they are at risk for and that they have incentives to choose high-value drugs;
- All providers have information about drug specific costs and value/benefit available at point of care to support their selection of high-value drugs;
- All health plans provide pharmacy cost and utilization information and reports to provider systems to support their management of all high-cost drugs;
- Individual providers receive information on their performance compared to their peers in order to inform and support improvement;
- All employers require their health plans to include all prescription costs in TCOC contracts and align incentives with all providers to support use of high-value drugs.

While employers are far removed from Medicaid and Medicare APMs, they can begin to shine a spotlight on their own costs related to specialty drugs in commercial products and their goals of shifting accountability for managing these costs to those who can make an impact – providers, ACOs, and health plans. Employers should send a strong message to their vendors and to providers, collectively and individually, that movement to value-based payment should accelerate dramatically, and that should include incentives aligned with their goals.

2

Provider Organizations

Provider Organization Goals

Setting the stage for success

1. Include actual NDCs and HCPCs, units, quantity and day's supply by all providers in all settings. Use NDCs for prior authorization, utilization management, payment, collection of rebates, claim level reporting, data analysis, provider contracts, and patient outcomes.

2. Include cost parity across all sites of care for the same drugs and services in all contracts.

3. Ensure practitioners better know drug prices (what employers and consumers are paying) at the point of care to support the use of high-value drugs.

4. Align TCOC and ACO provider contracts so practitioners select and/or administer high-value drugs.

Class of Trade:

Enhancing Price Transparency

Despite its complexity, the class of trade concept is important for employers to understand and discuss with their vendors when considering the variables, incentives and implications of various distribution channels. For example, physicians and hospitals typically get the lowest price when purchasing drugs, and retail and mail order pharmacies typically pay the most. Drug price transparency is based on understanding the difference between acquisition cost and what the purchaser or consumer is charged.

Provider Organization Tips and Actions

Baseline Expectations

- Require health plans/medical providers to ***report payments made by a manufacturer's patient assistance program or copay coupon program.***
- Improve efficiency of PA processes through use of technology and transparency of criteria.

Transformative Goals

NDCs	Require submission of NDCs for all drugs, from all providers, at all sites of service.
Cost parity across sites of care	Implement price parity for services and drugs across all sites of care.
Drug prices at point of care	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.
	Implement method to inform providers of drug costs (benchmark pricing) at point of prescribing.
Align TCOC	Provider systems should align incentives within their organizations and in health plan contracts so that specialists select high-value drugs.
	Assume and manage downside risk in TCOC contracts.
	Provide support systems that provide information on comparative effectiveness and value to providers at the point of prescribing.
	Management tools should be provided to physicians to support management of specialty drug costs.

Provider Organization Goal Briefings

National Drug Codes (NDCs)

Include actual National Drug Codes (NDCs), in addition to Healthcare Common Procedure Codes (HCPCs), units, quantity, and day's supply by all providers in all settings; use NDCs for prior authorization (PA), utilization management (UM), payment, collection of rebates, claim level reporting, data analysis, provider contracts, and patient outcomes.

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers
▪ Employers learned early on that medical claims, unlike PBM claims, do not include NDCs, which identify manufacturer, dosing, packaging, or unit of measure. ▪ Medical claims include HCPC codes, introduced in 1978, when the average prescription cost was $5 compared to $3,500 in 2015. ▪ Medicaid has required that providers submit NDCs since 1990 to support collection of manufacturer rebates. ▪ MN All Payer Claims Database pharmacy analysis revealed the most expensive therapeutic category for medical specialty drugs was "bundled and unknown" due to lack of specific data such as NDCs.	▪ All providers submit NDCs on all medical claims that include drugs. ▪ Knowledge of specific drug spend under the medical benefit so they "know what they are paying for." ▪ Health plans provide reports on medical drug spending including NDCs to increase transparency of top conditions, providers, drugs, trends, drug price comparisons, administration fees, and areas of variation to identify cost savings opportunities. ▪ NDCs enable health plans to enhance UM, identify drug prices, support rebate negotiations, conduct comparative effectiveness and other opportunities.	▪ This goal includes all providers, all claims and all settings (including hospital outpatient) and all conditions including oncology. Selective collection of NDCs for some drugs does not provide complete, valid, accurate, comparative data to support analysis. ▪ Claims submission should include HCPCs, NDCs, the definition of unit of measurement, the number of units, dosage, and day's supply.	▪ The MN Administrative Uniformity Committee (AUC) does not explicitly allow health plans to require provider submission of NDCs except for Medicaid products; it has challenged this goal. ▪ Some medical providers generate significant revenue and margin from administered drugs; they may resist exposing costs and potential loss of margin. In some markets, providers have refused to negotiate with payers. Employers, in turn, have resorted to reference pricing of facility and administration fees to provide incentives to members to seek lower cost settings.	▪ Major health plans now require NDC reporting selectively or completely, e.g., HealthPartners, BCBSMI, HCSC, UHC, and others. ▪ The tipping point has been reached; Magellan's 2016 medical specialty report states more than 64% of payers plan to capture NDCs in 2017. ▪ Providers who are at risk for the cost of drugs in TCOC/ACO contracts will benefit from more specific information such as NDCs to manage the cost of these drugs.

Provider Organization Goal Briefings

Cost Parity Include cost parity across all sites of care for the same drugs and services in all contracts.				
Background – Learning Network Findings	**Employers' Goals**	**Specifics**	**Feedback – Challenges**	**Feedback – Enablers**
▪ Employers heard repeatedly that physician groups acquired by hospitals changed their billing for infusion services from physician office settings (CMS 1500 claim) to outpatient hospital (UB 04 claim) settings and claims, resulting in dramatically increased costs. ▪ Moving patients from outpatient hospital settings to home or physician office settings was proposed to solve this problem. It also created patient disruption and administrative expense. ▪ Some health plans now require PA for certain infusions in hospital outpatient settings.	▪ Value-based purchasing that includes cost parity, at the lowest price, for the same services and drugs regardless of location or provider. ▪ Minimize patient disruption of changing sites for infusions and the resulting risks and dissatisfaction. ▪ Minimize administrative cost of managing changes in sites of care.	▪ All charges including drug prices, administration, and other fees should be included when comparing price parity. ▪ NDCs will support data analysis to compare providers' itemized costs including drug prices and billing practices.	▪ Provider consolidation and the resulting market imbalance will present negotiation challenges for health plans. ▪ Health plans have pressured health systems on cost parity by moving patients away from outpatient hospital settings by requiring PA for certain types of infusion. ▪ Provider systems may negotiate to be "kept whole" in exchange for lower reimbursement resulting from cost parity for administered drugs resulting in no net savings.	▪ Recognition of these billing practices has gained national attention of consultants, employers, health plans and the public resulting in numerous, varied attempts to manage these costs. ▪ Many regional and national health plans have recently implemented PA processes that require medical necessity criteria for outpatient infusion services and have been educating and preparing providers and patients for this change. ▪ Employers can collectively send a clear, consistent message to hospital systems that they are aware of this practice and want to see movement to value based care.

Provider Organization Goal Briefings

Align TCOC Contracts

Align TCOC/ACO contracts to include drugs so practitioners select and /or administer high-value drugs.

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers

▪ Providers first entered into TCOC contracts in 2011, with the goal of bending the cost curve.
▪ TCOC contract's financial targets include specialty drugs.
▪ Employers have purchased ACO/TCOC products from health plans with the assumption they provide incentives for providers to better manage all care including specialty drugs.
▪ Payment/compensation models within care systems/ medical groups do not include incentives for those who select specialty drugs, to manage drug costs, utilization, or outcomes.
▪ Specialty providers typically administer specialty drugs, e.g., oncologists, and often do not know drug prices at the point of prescribing or administration.
	▪ Value-based purchasing should align providers and employer incentives to measure and improved outcomes at the lowest possible price, at all levels
	  ▪ payer to care system
	  ▪ care system to medical group
	  ▪ medical group to individual practitioner
	▪ All providers, including primary care physicians and specialists, have incentives, information, and tools to inform them on prices, drug value, and support their use of high-value specialty drugs.
		▪ TCOC contracts typically include upside rewards to providers for shared savings and little if any downside risk.
		▪ TCOC contracts attribute patients' costs to primary care physicians who have little or no information to guide decisions on which specialists have better outcomes or deliver more value with specialty drugs.
		▪ Primary care physicians have little if any information to decide who to refer patients to.
		▪ Specialists, not primary care physicians, typically prescribe or administer specialty drugs and have little, if any, incentive through TCOC contracts or compensation models to manage costs or quality.
			▪ Existing TCOC contracts do not provide incentives to specialists to manage specialty drugs or use high-value drugs.
			▪ Some providers may receive delayed utilization reports from health plans to help them manage specialty drugs.
			▪ Carved out PBM costs may be average estimates, not actual costs, further eroding the quality of the information to providers and their ability to manage these costs.
			▪ Many specialty providers benefit financially from infusing medical specialty drugs and have little, if any, incentive to reduce costs.
				▪ Employers should require (individually and collectively) health plans, SPs, PBMs, and providers to align incentives within their systems for specialists to select high-value drugs.
				▪ Require health plans implement downside risk in TCOC contracts.
				▪ Support systems that provide information on comparative effectiveness and value should be provided to providers at the point of prescribing.
				▪ Management tools should be provided to physicians to support management of specialty drug costs.

Provider Organization Goal Briefings

Drug Costs at Point of Care

Ensure practitioners know drug prices (what employer and consumers pay at the point of care to support use of high-value drugs.

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers
▪ Specialty providers have no incentives or tools to inform selection of high-value drugs. ▪ They are often not aware of price variation among competing drugs. ▪ Some providers believe it's an ethical conflict to choose drugs based on cost. ▪ Tools are being developed to provide information to providers on patient's cost at point of care but not total plan sponsor costs.	▪ Providers have information to inform decisions to select high-value drugs. ▪ Providers have information on both patient costs and plan sponsor/ employer costs.	▪ PBMs and vendors are developing tools to provide patient cost information to providers at the point of prescribing through their EHRs. ▪ Costs are sometimes approximate costs, not actual costs.	▪ The process of providing accurate and precise information is complex due to number of drugs (thousands), numerous prices based on various players, frequent price changes, changing negotiations between players, benefit designs, coupons, rebates. ▪ Price negotiations often are "secret" and actual costs are not shared.	▪ Specialty pharmacies have cost information that could be provided to physicians on selected drugs. ▪ Employers can provide feedback and collective pressure to providers directly and through health plans to adopt tools to provide decision support and other tools that encourage selection of high-value drugs.

Provider Organization Scoring Criteria

Goal	0	1	2	3
Align TCOC/ACO contracts to include all drugs and align incentives	▪ TCOC contracts in place for < 25% lives ▪ All medical and some PBM drug costs included in targets	▪ TCOC contracts in place for > 25-50% lives ▪ Limited upside risk (shared savings) for providers ▪ All medical and all PBM drug costs included in targets ▪ Use decision support* and/or guidelines to support use of high value drugs	▪ TCOC contracts for > 50% lives ▪ Upside and downside risk* for PCPs and specialists ▪ Provider data analysis conducted on drug costs and conformance to guidelines	▪ TCOC contracts for > 70% lives ▪ Include downside risk for all providers ▪ Provider data used to manage drug costs, value, and outcomes ▪ Reporting and incentives provided to individual providers on conformance to guidelines and use of high value drugs
Prescribers know drug costs (consumer and plan sponsor) at point of prescribing	▪ Cost of drugs (consumer out of pocket and plan sponsor) are not known by prescribers at point of care (AWP not sufficient)	▪ Some consumer drug costs known through EMR/e-prescribing technology ▪ Preparing to provide plan sponsor costs in future	▪ All consumer specific costs known ▪ Some plan sponsor drug costs known, e.g., those with wide variation	▪ All consumer and plan sponsor drug costs known ▪ Individual provider incentives in place to select high value drugs
NDC submission and use to improve value	▪ Does not submit NDCs on claims (other than Medicaid) unless required by payers	▪ Submits NDCs on claims as required by Medicaid and payers and uses NDCs internally for cost and quality management	▪ Submits NDCs on more than 50% of claims that include drugs and uses NDCs internally for cost and quality management	▪ Submits NDCS on all claims that include drugs and uses internally for analysis, cost and quality management
Cost of care parity across sites of care	▪ Utilizes outpatient hospital routinely for infusions that could be done in lower cost site of care	▪ Performs infusions in lower cost sites when required by insurers AND ▪ considering contracts that include infused drug and administrative cost parity	▪ Performs infusions in lower cost sites when required by insurers AND ▪ contracts for infused drug cost parity selectively	▪ Performs infusions and contracts for cost parity regardless of site of care for all infusions where medically appropriate

**Decision-support tools provide information on drug prices, effectiveness, safety, side effects, value*

Total Cost of Care (TCOC)

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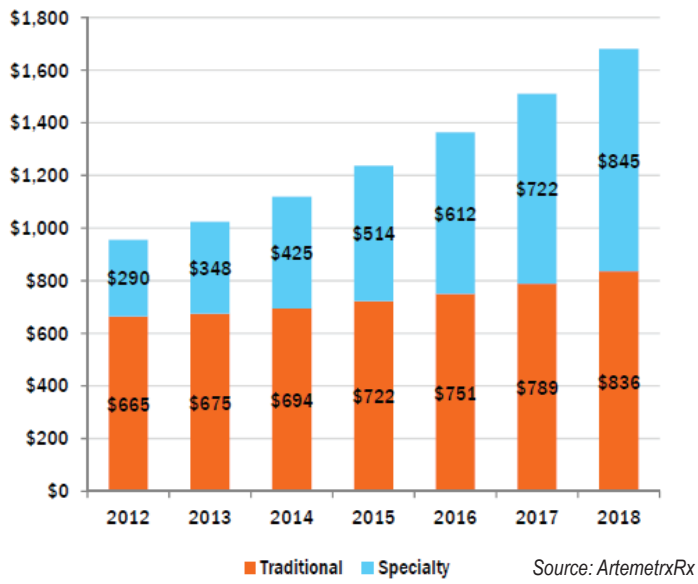
MINNESOTA HEALTH ACTION GROUP LEARNS ABOUT SPECIALTY DRUGS

In late 2014, the Minnesota Health Action Group (The Action Group), a Minnesota-based employer coalition of health care purchasers, decided to form a learning network to increase their knowledge of how to better manage these drugs to increase their value. Employers were concerned by historical costs, projections of future prices and utilization, and their lack of knowledge of the complicated and inefficient supply chain. The chart below illustrates the dramatic increase in specialty drug costs.

FIGURE 1: FORECASTED PMPY NET DRUG SPEND ACROSS THE PHARMACY AND MEDICAL BENEFIT FOR COMMERCIAL PLAN SPONSORS



Source: ArtemetrxRx

The Action Group convened a Specialty Drug Learning Network for employer members only in October 2014. Their intention was to meet for six months. They soon realized they would need much more time and continued to meet through 2016. They then formed a multi-stakeholder Specialty Drug Guiding Coalition that met with them throughout 2017 and 2018.

The focus of the Guiding Coalition was to develop scorecards for 20 priority goals. These goals addressed changes for health plans, providers, PBMs, specialty pharmacies and manufacturers in both the medical and prescription benefit supply chains. Two of the 20 goals related to incentives in payment models between health plans and providers related to managing specialty drugs:

"Align Total Cost of Care (TCOC) and Accountable Care Organization (ACO) contract incentives so practitioners select and/or administer high value (low cost/high benefit) drugs."

These score cards would include specific criteria to evaluate performance of stakeholders against these goals. The first step in developing criteria was to understand the current state of these contracts. Several key informants were tapped including:

- Employer members who had ACO products through their health plans.
- Fairview Health System, an early adopter and leader in APM contracting for both Medicare and commercial ACO contracts.
- MN Community Measurement, who measures and publicly reports TCOC by medical annually.
- HealthPartners who developed an NQF endorsed measure and, as a health plan and delivery system, has extensive experience.
- Ridgeview Health System, a locally based ACO.
- Numerous other providers, payers, and health plan representatives.

Several additional health plan and provider representatives were asked to describe their current incentive models, comment on draft criteria, and discuss their current status with ACO/TCOC contracts, but did not respond.

FINDINGS: UNKNOWN, CONFUSED, CONFLICTING

Several findings were identified through these conversations, both generally with TCOC contracts and specifically with prescription and specialty drugs including:

- Contracts have been in place since 2011, yet less than only 41% of fully insured patients are included in these contracts as of 2015, according to results of research by the Minnesota Department of Health. More recent discussions with provider groups and payers confirm that while there are pockets of high ACO contracting rates, the average across Minnesota is below 50%, not enough to create a tipping point in behavior change for systems or individual providers.
- "Downside risk" is not defined consistently and less common that upside risk.
- Target rates are confidential as is provider performance against their targets. Larger systems have more leverage to negotiate greater increases in targets, therefore decreasing their incentive to reduce costs.
- Lack of transparency, complexity of payment models, and a general lack of knowledge raised more questions including:
  - How much unprotected downside risk, the most effective incentive for behavior change, is in place?
  - How specific provider systems perform against their contracted target rates?

- Whether prescription drug costs, including carved-out PBM drug costs of self-insured employers, is included in TCOC cost targets?
- Whether specialists, those players who prescribe most specialty drugs, have any accountability or risk for costs?

- Whether any supply chain players, including ACOs, medical groups, employed or contracted, specialists or primary care practitioners are incented to use high-value drugs?
- There is a wide variety of APM products and models in place today including:
  - Commercial narrow networks, ACOs, and new players with new products.
  - Medicare Advantage, NextGen ACOs, Cost Products, fee-for-service.
  - Medicaid Managed Care, Integrated Health Partnerships (IHPs) and fee for service products.

Even if providers and their systems had risk for these drugs, they have little information or tools at the point of prescribing to manage these costs. We heard from stakeholders that some specialty pharmacies inform providers of drug costs before they are filled, that some health plans inform providers of high-value drugs periodically and that some care systems may have e-prescribing technology that displays high-value drugs and suppresses low- value drugs at the point of prescribing. Drug costs seem to be an afterthought as part of TCOC even though they are the fastest growing component of health care costs.

- There is a general lack of understanding among individuals from all stakeholder groups on how incentives in TCOC contracts work, their structure, measurement specifications, contract terms and how they will manage costs.
- Health plans are inconsistent in whether and how they include or exclude prescription drugs generally, and carved-out PBM drugs costs specifically.
- Specialty groups have different risk arrangements with health plans depending on their size, use of specialty drugs and negotiating strength.
- Medicare products differ in whether drug costs are included in provider risk arrangements.

DEFINING TOTAL COST OF CARE

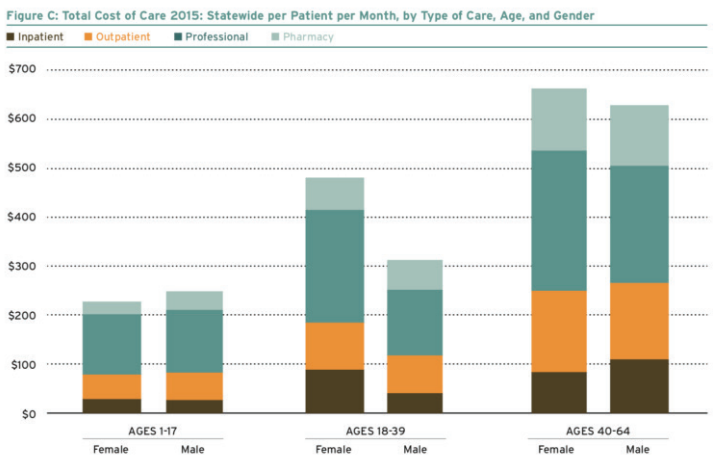
Several organizations were queried on their definition of TCOC.

The State of Washington states on its website that TCOC is a risk-adjusted payment that captures all costs of care for a defined population, including all professional, pharmacy, hospital, and ancillary care.

HealthPartners, a Minnesota-based health plan and delivery system, has developed a measure for TCOC that was endorsed by the National Quality Forum (NQF) in 2012 and again in 2017, in an effort to standardize and develop comparative data. Currently, the measure is being used in over 32 states and by over 150 providers, payers, employer consulting and other health care organizations. Their measure specifies that pharmacy costs are included in the total cost unless a providers' percentage of members with a pharmacy carve-out is high, between 70%-100%. In that case, costs are included but estimated at an average rate.

MN Community Measurement has published TCOC by medical group using the HealthPartners' measure since 2014. Their most recent report includes data on statewide averages by type of service, gender and age illustrating that pharmacy costs are a significant part of their calculations nearing 20% of total costs.

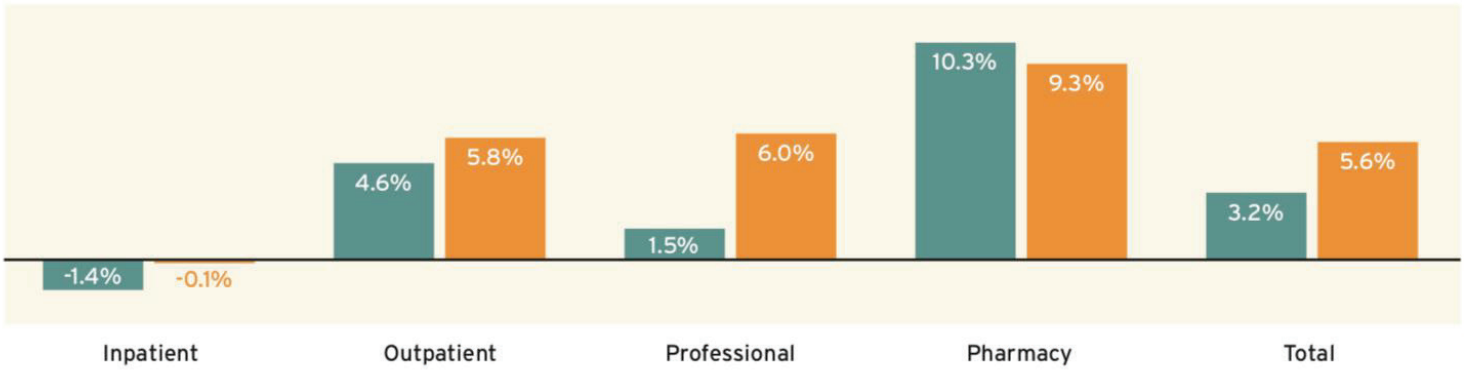
Statewide Averages by Age and Gender



They also illustrate changes in costs over the last two years with pharmacy costs showing the largest increase over time. These data illustrate the need to increase the focus on drug costs and include and strengthen incentives for all players to select and encourage use of high-value drugs.

1. *Minnesota Accountable Heath Model – SIM Minnesota, May 29, 2015 http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_FILE&RevisionSelectionMethod=LatestReleased&Rendition=Primary&allowInterrupt=1&noSaveAs=1&dDocName=dhs16_197637*

Figure A: Total Cost of Care – Changes in Total Cost of Care, MN Commercial Patients



IDEAL STATE

The Specialty Drug Guiding Coalition's goals would be met if all health plans, ACOs, and practitioners, were at risk for, and had incentives, to choose high-value drugs. This would require that:

- All health plans include carved-out PBM drug costs in their TCOC calculations;
- All providers know what they are at risk for and that they have incentives to choose high-value drugs;
- All providers have information about drug specific costs and value/benefit available at point of care to support their selection of high-value drugs;
- All health plans provide pharmacy cost and utilization information and reports to provider systems to support their management of all high-cost drugs;
- Individual providers receive information on their performance compared to their peers in order to inform and support improvement;
- All employers require their health plans to include all prescription costs in TCOC contracts and align incentives with all providers to support use of high-value drugs.

While employers are far removed from Medicaid and Medicare APMs, they can begin to shine a spotlight on their own costs related to specialty drugs in commercial products and their goals of shifting accountability for managing these costs to those who can make an impact – providers, ACOs, and health plans. Employers should send a strong message to their vendors and to providers, collectively and individually, that movement to value-based payment should accelerate dramatically, and that should include incentives aligned with their goals.

3

PBMs

PBM Goals

Setting the stage for success

1. Accept fiduciary responsibility (ERISA definition).
2. Ensure a level of financial transparency so purchasers know exactly how their money is being spent.
3. Provide claim level reporting, including all data fields, for employer ad hoc analysis.
4. Involve employers in key decisions affecting their overall cost.

Going Around PBM-Owned Specialty Pharmacies:

Independent Specialty Pharmacies May Be Cheaper

The largest specialty pharmacies are owned by PBMs. They are not the only specialty pharmacies available to purchasers, however. In many cases, health plans and union trusts deliberately purchase services from a specialty pharmacy not owned by their contracted PBM to increase transparency, eliminate inherent conflicts of interest when the PBM owns a specialty pharmacy, and to reduce their costs. One case publicized by a local Twin Cities television station found a patient whose maintenance drug had suddenly become a specialty drug, as defined by his PBM. When filled at the PBM-owned specialty pharmacy, it was more expensive, in orders of magnitude, than when it was filled at the local pharmacy used previously. It pays to comparison shop – even if you're locked into an arrangement – to prepare for future negotiations.

PBM Tips and Actions

Baseline Expectations

- 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.
- Require prior authorization and ***step therapy criteria to be transparent*** to providers and patients.
- Require that ***preferred products are based on clinical evidence.***
- 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.
- Require appropriate adherence (or compliance) under both the pharmacy and the medical benefits through effective management practices.
- Require ***preferred products to be based on clinical evidence.***
- 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.
- 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.
- 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.
- Require value-based therapy coverage (covered and non-covered drugs are evidence-based and most cost effective).
- Consider “floating” (copays/coinsurance) member cost sharing for specific drugs with generous ***manufacturer patient assistance programs and coupons*** to optimize their payments and minimize total expenditures by patients and employers.
- Review and revise employer’s summary plan description (SPD) for issues related to specialty drug coverage and management, e.g., ***optimizing biosimilars.***
- Implement deductible polices so payments from manufacturer coupons and ***patient assistance programs do not count toward patient out-of-pocket deductibles.***
- Assure all summary plan descriptions (SPDs) include terms that optimize use of biosimilars.
- 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.

Transformative Goals

Fiduciary	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).
Transparency	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.
	Transparent criteria for PA and step therapy, performance reporting, including denials, appeals, overturned appeals, customizable by employer.
	Information about relationships with all specialty pharmacies including financial, contractual, performance requirements, ownership and exclusivity.
Claim level reporting	Determine and negotiate employer rebate goals, strategies and agreements for specialty pharmacy specifically with both health plan and PBM.
	Require reports on drug spend to ***break out costs by specialty, retail and mail order*** pharmacies to understand any variation over time.
	Require reports that evaluate the ***impact*** of specialty prior authorizations and step therapy protocols (i.e., % approvals/denials, appeals, cost per claim).
Employers at the table	Require ***cost projections*** for the following year including anticipated FDA approvals, e.g., cystic fibrosis, familial hypercholesterolemia, specific to your population.
	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.
	Determine and negotiate employer rebate goals, strategies and agreements for specialty pharmacy specifically with both health plan and PBM.
	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.
	Formulary decisions of P&T committees, their processes, and rationale are transparent to employers when they are decided.
	Review and revise both health plan and PBM contracts to enable customization, employer input on key decisions, and that support value-based purchasing*.

PBM Goal Briefings

Accept Fiduciary Responsibility (ERISA definition)				
Background – Learning Network Findings	**Employers' Goals**	**Specifics**	**Feedback – Challenges**	**Feedback – Enablers**
▪ ERISA requires that persons or entities that exercise discretionary control or authority are subject to fiduciary responsibilities. ▪ Self-insured employers have a fiduciary responsibility to act in the best interest of the plan and its members. ▪ PBMs make many discretionary decisions on behalf of the plan and its members when determining formulary, administering clinical management, negotiating rebates, contracted networks, etc. ▪ PBMs have traditionally refused to act as a plan fiduciary for legal and financial reasons. ▪ Consultants may advise clients to not pursue PBM fiduciary status given their historical resistance.	▪ PBMs act in the best interest of their plan and their members. ▪ Conflicts of interest don't exist or if they do exist, are revealed and data and financial relationships are transparent.	▪ Both PBMs and employers can be fiduciaries for the same discretionary decisions; there is not a requirement that one party be a fiduciary. ▪ Fiduciaries are required to follow principles of conduct stated in ERISA; if not, they may be personally liable to restore any losses to the plan.	▪ PBMs that own pharmacies (retail, mail or specialty) have inherent conflicts of interest since they advise clients on how to manage and reduce costs yet realize increased revenue and margins if their owned pharmacies (retail, mail, specialty) increase distribution. ▪ PBMs that own pharmacies generate revenue from "spread," the difference between the price paid by their owned pharmacies (acquisition cost) and amount charged to clients/employers. ▪ PBMs may state they have "Firewalls" to eliminate these internal conflicts of interest however effectiveness is difficult to evaluate and enforce.	▪ Identify which specific decisions are to be made by PBMs, employers or both. ▪ Identify criteria processes and timing for decision making. ▪ Pass-through pricing and transparency of all transactions and costs approach, but do not entirely align interests or eliminate conflict of interest. ▪ See "Transparency Map" for specific types of information needed to assess aligned interest or conflicts.

PBM Goal Briefings

Financial Transparency

Ensure a level of financial transparency so purchasers know exactly how their money is being spent.

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers

▪ PBMs have multiple sources of revenue.
▪ PBMs that own pharmacies, (retail, mail, specialty) have inherent conflicts of interest, e.g., the more revenue generated from spread from owned pharmacies raises costs for employers.
▪ Manufacturers provide multiple, often undisclosed, sources of revenue to PBMs, not just rebates.
▪ Rebate guarantees mask specific amounts paid by manufacturers to PBMs and provide protection only from downside risk to employers, reducing transparency.
	▪ Understand all sources of revenue and the inherent incentives in their inherent financial arrangements.
	▪ Aligned interests between PBM and employers to increase value.
		▪ Revenue from manufacturers include:
		  ▪ Rebates (multiple types)
		  ▪ Data fees
		  ▪ Reporting
		  ▪ Administration
		  ▪ Clinical programs
		  ▪ Price protection
		  ▪ Switching
		  ▪ Other
		▪ Revenue from pharmacies:
		  ▪ Retail DIR fees
		  ▪ Specialty network access fees
		  ▪ Owned pharmacy profits
		  ▪ Revenue from clients:
		  ▪ Administration
		  ▪ Clinical programs
		  ▪ Reporting
			▪ Negotiating transparency with one of the large "spread model" PBMs may be challenging and costly for employers due to PBM market power.
			▪ Transparency may mean different things; the term is widely used but rarely defined precisely. See "Transparency Map" for details.
				▪ Negotiate contractual language for specific terms related to financial transparency.
				▪ Contract with pass-through model PB.

PBM Goal Briefings

Claim Level Reporting

Provide complete claim level reporting, including all data fields, for employers' ad hoc analysis.

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers
▪ Most PBMs provide summary data with no ability to customize reports or drill down to claim level information. ▪ Audits of data may be highly restricted and expensive. ▪ Employers often don't have expertise or resources to conduct analysis to understand their utilization, determine opportunities for savings or what to do to realize savings.	▪ Complete transparency of all data and transactions. ▪ Ability to manipulate and drill down into their own data. ▪ Develop ad hoc reports to inform them on specific areas of cost and savings opportunities. ▪ Expertise to analyze and recommend actions based on findings. ▪ Audits available with adequate notice and no restrictions.	▪ Require claim level reporting, all data fields reported to PBM by all pharmacies. ▪ Receive data in a format that allows employer flexibility to conduct ad hoc reporting. ▪ Reports that break out drug spend by specialty, retail and mail order pharmacies to understand variation over time. ▪ Data on impact of PA, step therapy and other utilization management interventions. ▪ Data includes claim specific drug prices, rebates, patient assistance programs.	▪ Employers' lack pharmaceutical expertise in house, analytic capability and information technology. ▪ PBMs often charge exorbitant amounts to provide data and produce ad hoc reports. ▪ Employers' data warehouse vendors may not have pharmaceutical experts in house to conduct analysis of pharmacy data. ▪ Consultants may be conflicted and not working in the clients' best interest. ▪ Contract terms may prohibit price disclosures. ▪ Contract terms may prohibit claims level data.	▪ Transparent pass through PBMs may provide claim level data more readily than traditional model PBMs. ▪ Negotiate requirement during initial contract negotiations. ▪ Conduct periodic reviews by independent consultants. ▪ Skilled, independent expertise is likely to pay back its cost in savings by multiples.

PBM Goal Briefings

Involve Employers

Involve employers in key decisions that affect their overall health costs.

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers

▪ Employers must project health care costs.
▪ PBMs may make many discretionary decisions that dramatically impact employers' cost including network contracting, formulary development, rebate negotiations, pipeline management, clinical utilization management, without employer input or consultation.
▪ Key decisions may not be transparent depending on the PBM's financial model; pass through pricing or "spread" model.
▪ Clinical management decisions are often negotiated arrangements with manufacturers and have impact on rebates and formulary placement.
▪ Newly approved drugs may dramatically increase employers' costs; employers may not be informed of these costs creating budget "surprises".
	▪ Increased transparency of decisions made by PBMs, on their behalf, to manage specialty drugs.
	▪ Many, but not all, employers want to be included in key decisions that impact their costs.
	▪ These decisions may vary by employer
	▪ Timely, accurate and detailed data to support budgeting and cost projections.
	▪ Employers want financial and clinical management decisions to reflect their goals, not those of the PBM, manufacturers or other parts of the supply chain.
	▪ No additional costs or charges to make these decisions.
		▪ Employers will vary in their interest and ability to provide input into key decisions.
		▪ Each employer should identify and clearly communicate the decisions where they want to provide input, when and how.
		▪ Decisions could include
		  ▪ PA drug list
		  ▪ PA criteria
		  ▪ coverage decisions
		  ▪ excluded drugs
		  ▪ drug pipeline management
		  ▪ detailed reporting
		  ▪ network determination and contracting including specialty pharmacies
			▪ Employers' interest and capability to weigh in on decisions will vary.
			▪ Employers may be unprepared to make these decisions without education and guidance from experts.
			▪ They may need the expertise of consultants to inform their decisions.
			▪ Many PBMs are not accustomed to including employers in key decisions.
				▪ Employers should discuss their goals for involvement and provide PBMs with information on which specific decisions they want to be included, and how and when.
				▪ PBMs should focus on involving employers in key decisions and increase knowledge of specialty drug management.
				▪ Contracts should reflect these decisions and processes for decision making.

PBM Scoring Criteria

Goal	0	1	2	3
Employers at the table for key decisions*	▪ PBM informs employers of key decisions after they are implemented ▪ Employers don't communicate which decisions they wish to make	▪ PBM decides if, when, and which decisions employers make ▪ Employers communicate which decisions they wish to make ▪ PBM provides at significant client expense	▪ PBMs consult with employers with adequate lead time ▪ Employers communicate which decisions they wish to make ▪ PBM provides at reasonable expense ▪ Employer input determines some decisions	▪ PBM works at employers' direction and in their best interests in all key decisions ▪ Employers communicate which decisions they wish to make ▪ PBM provides at no additional expense ▪ PBM contract reflects these decisions
Claim level reporting	▪ PBM provides ▪ Summary data only (may be a PDF document) ▪ Employer has no ability to customize reports or drill down ▪ No audits possible	▪ PBM provides ▪ Summary data ▪ Ad hoc standard reports provided at significant expense ▪ Allows audits with strict conditions regarding who, when, how, what	▪ PBM provides ▪ Summary data with limited claim level (NDC) reporting ▪ Timely response to requests for more information at reasonable cost ▪ Audit restrictions negotiated to mutual agreement	▪ PBM provides complete (all fields) claim and transaction data on all transactions including: ▪ Paid amounts by plan, member and total ▪ Amount paid to specific pharmacies ▪ Rebates/claim ▪ Timely response to requests for specific data ▪ No audit restrictions
Financial transparency	▪ No transparency on revenue sources, rebates, drug prices, spread, retail, mail and specialty pharmacy network contract arrangements, manufacturer arrangements ▪ Restrictions on audit and auditors	▪ Detailed rebate reports (by drug or prescription) AND ▪ Reveals revenue streams beyond rebates AND ▪ No restrictions on auditors or audit findings	▪ Provides financial information on: ▪ All revenue streams AND ▪ Contract terms with retail mail and specialty pharmacies AND ▪ Drug by drug price negotiations	▪ Total transparency ▪ Agrees to audits of all documents and data requested, client selected auditor AND ▪ Access to all information AND ▪ Pass through pricing
Fiduciary status	▪ Closed to discussing, non-negotiable	▪ Agrees to fiduciary status in principle AND ▪ Negotiates contractual terms that align financial goals of PBM, purchaser and patients	▪ Actively moving towards contractual agreement on fiduciary status with all clients ▪ Adding contractual items that align goals	▪ Contractually agrees to accept ERISA definition of fiduciary status with all clients

**Employers communicate which decisions they wish to make in writing, e.g., benefit design, PA drugs and criteria, coverage decisions, exclusions, pipeline management…*

Transparency Questions, Rationale and Action to Increase Transparency

PBM Questions

Pharmacy Benefit Manager Priority #1

What information is requested?
All revenue sources including manufacturers, pharmacy DIR fees, client administration fees, and others.

Please provide the following:
Data on the amount and percentage of your total revenue realized from:

- Manufacturers
- Retail pharmacies
- Specialty pharmacies
- Mail order pharmacies
- Any other entities

Describe the inherent incentives within PBM contracts and the entities above, e.g., higher drug spend increases PBM's revenue.

For revenue from manufacturers, break out types of rebates/financial benefits including:

- Formulary placement rebates
- Utilization rebates
- Market share rebates
- Rebated administration fees
- Any additional rebate/financial benefit related revenue

Rebate/financial benefit data related to client's claims including: 1) amount paid, and 2) number of claims for each National Drug Code (NDC) by manufacturer (not aggregated data).

Data fees

Data on revenue realized by PBM from price protection arrangements with manufacturers including duration and the difference between the PBM's contracted increased rate guarantees compared to employer/purchaser's guarantee, by claim

Why this information is needed?
Purchasers wish to understand the inherent incentives within contracts/agreements between their contracted PBMs and other entities in the supply chain to assure the PBM is acting in the purchasers' best interest and not maximizing the PBM's revenue, e.g., maximizing rebates or other fees at the expense of the purchasers' goals of reducing overall costs and maximizing value. It is also important that PBMs know that employers are aware of revenue sources and incentives.

What will purchasers do with this information?
This information will allow purchasers to have more informed and focused conversations with their PBM about key sources of revenue and inherent conflicts of interests within PBM's contracts with other entities. Purchasers may negotiate revisions to their contracts to align interests, e.g., revise formularies if drugs with the lowest net price are not preferred, or are restricted, to maximize rebates on competing, higher priced drugs. They may also choose to change vendors.

Transparency Questions, Rationale and Action to Increase Transparency

PBM Questions

Pharmacy Benefit Manager Priority #2

What information is requested?
PBM "spread" (difference between amount paid by PBM to pharmacies per claim compared to amount clients are charged for the same drug per claim).

Please provide the following:

- Claim level data of the amounts paid to pharmacies, compared to the amounts paid by purchasers for the same claim.
- Claim level data comparisons of spread by pharmacy type:
  - Preferred network
  - In-network
  - Out of network
  - PBM owned (itemized)
    - Mail
    - Specialty
    - Retail, if applicable
  - Non PBM owned

Why is this information needed?
Purchasers do not typically know the amount of revenue realized through "spread" by their PBM vendors, whether that amount is reasonable for the services provided, or if this revenue presents a conflict of interest. They also do not know how the "spread" of PBM owned pharmacies compares to non-owned pharmacies, and whether the purchaser would realize lower costs with different pharmacies. This information cannot be derived from line item claims data.

What will purchasers do with this information?
This information will allow purchasers to have more focused and informed conversations with their PBM about how much revenue their PBM is realizing from "spread" and whether the "spread" varies by type of pharmacy. They can then evaluate whether that amount is reasonable and aligns with their interests. If they choose, they may renegotiate their contracts to decrease spread, change their pharmacy network, or change their payment model to a "pass-through" model to increase transparency, align interests and reduce their costs.

Transparency Questions, Rationale and Action to Increase Transparency

PBM Questions

Pharmacy Benefit Manager Priority #3

What information is requested?
Rationale for Pharmacy & Therapeutics (P&T) Committee clinical evaluation and business decisions including formulary placement, prior authorization/utilization management (PA/UM) processes, criteria, coverage and exclusions.

Please provide the following:

- Describe how financial considerations and clinical recommendations of the P&T Committee are weighed when making decisions for the top 10 specialty drugs by spend (utilization x price) and for all newly approved drugs in advance of FDA approval.
- Include decisions related to:
  - Preferred coverage
  - Tier placement, if applicable
  - Excluded drugs
  - Whether and which PA processes are put in place
  - PA criteria and rigor of enforcement
  - Whether providers must submit source documents such as medical records or lab reports
  - Step-therapy
  - Any other utilization management procedures. Purchasers are not “at the table” when business decisions are made

Why this information is needed?
Purchasers are not “at the table” when business decisions are made related to formulary placement, UM processes, coverage or other decisions that may be driven by rebates/financial benefits rather than lowest net price and clinical evidence on safety and efficacy. These decisions should align with purchaser interest of lowest total net cost vs. maximizing rebates.

What will purchasers do with this information?
This information allows purchasers to have more informed and focused conversations with their PBMs about financial considerations and clinical evidence related to specific drug formulary placement, UM processes, and criteria. They can evaluate whether specific decisions align with their interests or if alternative drugs, UM processes, or criteria would better align with their goals. They then may renegotiate their contract to align their goals and the PBMs, determine whether and how purchasers could be included in future decisions, or they may choose to change vendors.

Transparency Questions, Rationale and Action to Increase Transparency

PBM Questions

Pharmacy Benefit Manager Priority #4

What information is requested?
Line item claims data (complete claim record) with Medi-Span or First Databank data elements and information on audit procedures.

Please provide the following:

- Detailed line item claims data for the last 24 months, periodically, and at least annually, for all drugs including all claims elements; include data on submitted amounts vs. paid amounts. Claim data elements should include, but not be limited to, data elements listed. Provide information about when and how unrestricted audit procedures may occur.

Why this information is needed?

- Detailed line item data, rather than summary data, may be analyzed by independent consultants or other purchaser representatives so they can identify key areas of concern, analyze specific related information, periodically look back over time to find utilization and cost outliers and patterns, and other information. Without line item data, PBMs determine what employers see, at their discretion. Examples of key areas include:
- Drugs with rapid and dramatic price increases
- Newly approved drugs
- Pharmacy network cost comparisons
- Comparing specialty and non-specialty drug trend over time
- PBM conformance to contract terms including PA requirements, formulary decisions

What will purchasers do with this information?
This information will inform purchasers and support focused and informed conversations with their PBM to identify variation from expected utilization and costs, prioritize areas of concern, and develop plans for further investigation and solutions.

Required Detail Claims Data Elements

- Claim descriptor elements
  - Claim type, claim sequence, Claim ID, prescription number, refill number, date submitted, date of service, specialty prescription, specialty indicator, retail indicator, mail order indicator, pharmacy network, extended supply network, member age, gender, MTM indicator, carrier identification, carrier description, account identification, account description, group identification, group description, member identification, prescriber identification, prescriber type, prescriber type, prescriber name, prescriber specialty, prescriber city, prescriber state, prescriber ZIP code, NCPDP number, pharmacy name, pharmacy type, pharmacy city, pharmacy state, pharmacy ZIP code, year, month.

- Financial elements
  - AWP, WAC, MAC, U&C, total paid, plan paid, member paid, copay, co-insurance, ingredient cost, dispensing fee, sales tax, incentive fee, professional service fee, coordination of benefit, and net drug dollars.

- Utilization management elements
  - DAW, % DAW, formulary indicator, formulary tier, step therapy indicator, prior authorization indicator, prior authorization reason, prior authorization effective date, and prior authorization end date.

- Drug product descriptors

- NDC, brand name, generic name, generic product indicator name, product name/name ext, manufacturer abbreviated name, labeler code, dosage form, strength, strength unit of measure, generic product packaging code, packaging quantity, package quantity dispensed, product package size, package standard unit of measure, route of administration, dispensing unit, unit dose, NDC status, NDC effective date, NDC inactive date, Rx OTC indicator, trade/brand/generic code, multi-source summary code, TEE code, DEA code, DESI, labeler type, limited distribution code, repackage code, AHFS, AHFS Name, and all levels of GPI codes and GPI name (GPI14 to GPI0).

- Other data elements as requested by employer.

MAKING THE CASE FOR FIDUCIARY AGREEMENTS

SEPTEMBER 8, 2017

BACKGROUND

A study of the specialty drug landscape through the MN Health Action Group's Specialty Drug Learning Network, first convened in 2014, identified the need for employers to require Pharmacy Benefit Managers (PBMs) to accept fiduciary responsibility for pharmacy benefit plan management. Historically, PBMs have rejected this request.

The following is the Department of Labor (DOL) summary definition of fiduciary from its website. The operative are words in bold:

> *The Employee Retirement Income Security Act (ERISA) protects your plan's assets by requiring that those **persons or entities** who **exercise discretionary control or authority** over plan management or plan assets, **anyone** with discretionary authority or responsibility for the administration of a plan, or **anyone** who provides investment advice to a plan for compensation or has any authority or responsibility to do so are subject to fiduciary responsibilities. **Plan fiduciaries include**, for example, **plan trustees, plan administrators, and members of a plan's investment committee.***
>
> *The primary responsibility of fiduciaries is to run the plan solely in the interest of participants and beneficiaries and for the exclusive purpose of providing benefits and paying plan expenses. Fiduciaries must act prudently and must diversify the plan's investments to minimize the risk of large losses. In addition, they must follow the terms of plan documents to the extent that the plan terms are consistent with ERISA. They also must **avoid conflicts of interest**. In other words, they **may not engage in transactions on behalf of the plan that benefit parties related to the plan, such as other fiduciaries, services providers or the plan sponsor.***
>
> *Fiduciaries who do not follow these principles of conduct may be personally liable to restore any losses to the plan, or to restore any profits made through improper use of plan assets. Courts may take whatever action is appropriate against fiduciaries who breach their duties under ERISA including their removal.*

SELF-FUNDED EMPLOYER'S RESPONSIBILITIES

Self-funded employers are obligated, as ERISA fiduciaries, to protect plan assets and act in the best interests of the plan participants, honoring the fiduciary duties of loyalty and care. Plan sponsors are legally obligated to ensure all compensation paid to PBMs is reasonable and justifiable with respect to the level of services rendered. Therefore, all forms of remuneration should be disclosed.

The ERISA definition also clearly states that ***anyone*** who makes discretionary decisions, not only the plan sponsor, should act as a fiduciary. This could include the PBM, benefit consultants, health plans, and other vendors when discretionary decisions are made. This is especially important when the plan sponsor is relying on their vendors' expertise and discretion because the plan sponsor has little or no direct expertise in specific technical areas like clinical information, formulary arrangements or prior authorization criteria.

The definition of discretion, according to Dictonary.com, is "the ability to make responsible decisions; power or right to decide or act according to one's own judgment; freedom of judgment or choice."

LEGAL AND REGULATORY ACTIONS

According to PBM Watch, a website dedicated to bringing PBMs under regulatory scrutiny, the major PBMs have faced numerous federal and multidistrict cases over allegations of various misconduct. This website lists and describes several of these cases. It also describes current legislative initiatives by state, many of them related to transparency and pricing.

As out of pocket drug costs increase for employees, and as consumer awareness of manufacturer rebates increases, consumers are beginning to take legal action against PBMs[1]. Cigna, Express Scripts, Prime Therapeutics, CVS and UnitedHealth Group have been sued for many reasons including inflating prescription costs causing consumers to pay more than they otherwise should have paid for medically necessary prescription drugs (otherwise known as "claw-backs"), "gag" rules for pharmacists, inflating prices through rebates, fixing prices for insulin, and suppressing competition from independent pharmacies for mail order pharmacy services. It's not inconceivable that employees could also initiate legal action against self-funded employers if they believe their employers are not acting in their best interests or by holding vendors accountable for adequately protecting plan assets.

WHO SHOULD ACT AS FIDUCIARIES?

Anyone, including but not limited to Plan Sponsors and PBMs, who exercises discretionary control or authority over plan management and assets, often make decisions relying on the expertise of others or as part of a negotiated agreement. All entities involved in these negotiated decisions should be fiduciaries.

In some cases, it's clear who makes which decision; employers make final decisions on vendor selection. In other cases, they often take advice from consultants and negotiate with PBMs on decisions such as benefit plan design and rebate sharing. They also often negotiate and ultimately accept the PBMs' terms regarding administrative fees, guarantees, formularies, tiers, rebates, specialty drug lists, coverage of newly approved drugs, excluded drugs, utilization management and clinical program administration, and other decisions. Fiduciary responsibility falls on the entities involved in decision making.

PBMs VARIED APPROACH TO FIDUCIARY ROLES AND RESPONSIBILITIES

Most of the longer established PBMs refuse to agree in concept or in practice to act as a fiduciary for their clients or their plan. There has been movement, however, by some PBMs to move towards transparency and fiduciary status in various ways.

The following is an abbreviated list of PBMs who provide exceptions to the rule on how to approach fiduciary roles and responsibilities. Other PBMs may be adapting their approach to shared or full fiduciary responsibility as employer pressure increases.

- **PharmAvail,** agrees to act as fiduciary[2], pass through pricing, transparency of all costs and does not own mail or specialty pharmacies,
- **Transparent RX,** claims to be a "fiduciary model" PBM[3]
- **RxAdvance** describes themselves as a transparent PBM with a pharmacy risk partnership model, implying they are willing to share risk
- **Navitus** agrees to act as a "steward" of the client's resources and act in their best interest but does not agreed to fiduciary roles and responsibilities in contracts

[1] Kimberly A. Negron V. Cigna, Case No. 3:16-cv-01701 (D. CT.), Elan and Adam Klein, Leah Weav, et. Al v. Prime Therapeutics, Express Scripts, and CVS Health, Case No 0:17-cv-01884 (D.MN.), in Re UnitedHealth Group PBM Litigation, Case No. 16-cv-3352 (D.MN)
[2] Pharmacy Benefit Management Institute (PBMI) website member directory
[3] ibid

PBMs VARIED APPROACH TO TRANSPARENCY

The PBMI website identifies "pass-through" PBMs where all costs and revenues (rebates, administrative fees, other) are passed through to the client and are fully transparent. While this doesn't substitute for agreeing to fiduciary roles and responsibilities, it does get closer to the goal of acting in the best interest of the client and its members by being transparent about revenue models, conflicts of interest and all financial arrangements.

The following list includes some PBMs that state they use "pass-through" pricing rather than the traditional PBM financial model.

- AmWINSRx
- EmpiRx
- EnvisionRx (purchased by RiteAid in 2015 and the PBM for National Prescription Coverage Coalition, founded by Linda Cahn, an attorney and PBM consultant)
- ClearScript (owned by Fairview Health Services)
- Navitus
- Veridicus Health (purchased by Magellan November 2016)

PBMs OWNED BY HEALTH PLANS

The following health plans own PBMs and take risk for medical benefits for the insured portion of their population. They also serve health plans' insured, carved-in populations.

- AmeriHealth Mercy - PerformRx
- Aetna - Aetna
- Cigna - Cigna
- Centene – Envolve
- Humana - Humana
- Cambria – Omeda
- UHC – OptumRx
- BCBS (14 plans) – Prime Therapeutics

It stands to reason that these plans may be more willing to accept fiduciary roles and responsibilities or agree to accept certain types of risk since they are required to act as fiduciary for decisions related to medical benefits for their insured populations. This concept requires further research.

WHY SHOULD EMPLOYERS REQUIRE THEIR PBM TO ACT AS FIDUCIARY?

Most large established PBMs generate revenue from several, often undisclosed, sources including manufacturers, retail pharmacies, mail order and specialty pharmacy operations, as well as multiple processes and agreements including drug price manipulation, price protection arrangements, and others. The complexity and lack of transparency of these arrangements, and incentive to maximize revenue are at the expense of, and in conflict with, their clients and members' best interest. Fiduciary roles and responsibilities align the employer's and PBM's goals contractually and, in practice, to act in the best interest of the client and members.

WHO MAKES DISCRETIONARY DECISIONS AND HOW ARE THEY MADE?

Given the information asymmetry between employers and PBMs, e.g., employers' limited expertise and knowledge of the complex clinical and technical decisions and operations of PBMs, the PBM often uses discretion to make key decisions such as formulary development and utilization management protocols (among others). Employers' expertise and resources vary. Some employers may want to be at the table for most decisions while others may want to be informed or provide input for selected decisions.

Two of the twenty Minnesota Health Action Group Guiding Coalition goals state that the employer should be "at the table" for key decisions. Employers cannot exercise discretion if they are not "at the table". PBMs are exercising discretion if they are making decisions without the employers' agreement.

Employers and PBMs must spell out which decisions are made by which party and how they are to be made in contractual language to clarify fiduciary roles and act in the best economic and clinical interest for the employer and patient.

The following chart is an example of how some key decisions may be made by PBMs and employers. Decision making will vary from employer to employer.

Decision	Employer/ Plan Sponsor	⇦ Shared ⇨	PBM
Vendor Selection	Employer chooses PBM, specialty pharmacy, mail order vendor		
Vendor Payment Amount and Method		Traditional negotiated administrative fee with PBM revenue from other sources or pass through model with all revenue from administrative fee	
Benefit Plan	Employer determines tiers, cost-sharing, deductibles, exclusions, other…		PBM advises employer on financial impact
Rebate Sharing		Negotiated	
Formulary	Employer outsources or develops in-house, e.g., Caterpillar	Employer makes exceptions to PBM formulary	P&T committee clinical recommendation; financial decisions
Newly Approved Drug Coverage	Employer decides whether and how to cover newly approved drugs	PBM and employer agree, negotiated	PBM dictates what, how
UM/Prior Authorization Criteria and Processes	Employer may outsource to external vendor, develop criteria independently	Employer reviews and approves	PBM uses standard PA
Retail Pharmacy Network Selection	Employer selects, contracts, outsources	Negotiate network configuration	Accepts PBMs network
Specialty Pharmacy Network Selection	Carves out	Negotiates additional SPs	Exclusive owned SP
Mail Order Selection/ Promotion	Carves out and determines incentives to use mail	Negotiates exceptions to standard	Accepts PBM owned and recommended incentives
Coverage Exceptions	Employer may determine exceptions and process		PBM may make final decisions
Specialty Drug List	May provide input or have final decision making	Negotiated	PBM decides
Generic Pricing		Negotiates whether MAC list/s is/are used, who determines, how and when determines	
Audit Provisions	Employer chooses who, when, what is audited	Negotiated	PBM dictates

Each employer should determine which decisions they want to make. Contractual terms should then clearly delineate the process for making decisions including timing, notifications, methods of communication, who will be involved, and how decisions will be implemented.

Contract language, however, cannot cover every possible scenario, unknown, or unexpected development. PBMs who accept the fiduciary role are obligated to operate in the best interest of the client and member regardless of unknown or unexpected possibilities. Being a fiduciary provides overarching protection and accountability. In this case, the burden is on the PBM.

If the PBM does not agree to act as fiduciary, the burden is on the employer/plan sponsor to negotiate detailed contract terms, in a piece-meal fashion. They must also identify if, and when, the plan sponsor's and patient's best interests are not being served and must act to remedy the situation.

WHAT SHOULD EMPLOYERS DO?

1. Understand your ERISA responsibilities and ensure you are meeting them
2. Understand fiduciary role and rationale
3. Talk to your vendors about their fiduciary role and responsibilities

Tips for talking to PBMs about fiduciary roles and responsibilities

- Both PBM and plan sponsor, among others, should act as fiduciaries
- The PBM must act as a fiduciary because:
    - They make discretionary decisions
    - The plan sponsor has a duty to pay reasonable fees to its vendors; the PBM's multiple revenue streams including multiple MAC lists, spread, rebate arrangement with manufacturers, incentives to maximize rebates rather than provide lowest net price, financial arrangements internal to PBM through retail, mail and specialty pharmacy operations, e.g., how much PBM profit is made from specialty pharmacy spread, revenue from network pharmacies, and other revenue conflict with that duty

If full fiduciary status is not feasible

Ask your PBM to represent they are fiduciaries for specific functions and decisions (see chart above) where the plan sponsor is relying upon their expertise.

At a minimum, your PBM contract should:

- Allow you to select your pharmacy network including retail, mail and specialty
- Provide adequate audit rights in terms of timing, auditor selection and scope. Include all records relevant to direct and indirect compensation and documents needed to assess reasonableness of PBM compensation
- NOT include language that the ERISA plan, not the PBM, maintains sole discretion and authority and that the PBM is NOT a fiduciary
- Include clear, non-ambiguous definitions for:
    - Specialty drugs and who determines changes to the specialty drug list
    - Rebates including all types
    - Generic and Brand drugs

If your current PBM does not agree to the contract terms above, talk to other PBMs who will agree to this status and consider changing vendors. Employers are liable and responsible, as fiduciaries, to act in the best interest of the plan and its covered employees. They must be prepared to the take on the risk for all the clinical and financial decisions made by the PBM, if the PBM is not willing to share that responsibility.

All employers should consult their benefits counsel for advice on their specific circumstances.

Debunking the PBM Contract

Navigating the PBM Marketplace

Chuck Gamsu, R.Ph., MBA - Principal, SkySailRx September 12, 2018

Introduction

"A guarantee is a guarantee." Or is it? The long-standing view by the PBM industry has been that employers are "sophisticated purchasers" and know exactly what they are signing. But most employers would agree that PBM contracts are too complex and lack transparency. The PBM contract not only controls what price is paid by the purchaser, it also dictates which drugs are used, where the medications are purchased (often a pharmacy owned by the PBM), and the quantity of drugs dispensed. So it is of the utmost importance that purchasers choose and agree to the contract that's right for them. The best strategy to get control of rising drug costs requires choosing experts who are working in your best interest (e.g., don't get paid by the PBM for placement), can read, write and comprehend PBM contracts, validate the plan documentation, verify the implementation, and monitor the benefit plan.

Don't Sign That Contract

Although the PBM contract is a legal document, the focus needs to be on the business terminology. When an employer or consultant allows the PBM to utilize their standard contract language and definitions, the employer/payer is typically left at a disadvantage. Key definintions can be used to inflate and obscure the true financial arrangement.

One way to inflate discounts is to manipulate the base price measurement (AWP definition) through tactics including picking different AWP sources, using different package sizes (NDC codes), and applying reference pricing at strategic times. Every term and definition in the contract matters. Contradictory terms, circular references, or even missing terms can put a payer at a disadvantage. For example, something as simple as the term "claim" can change what counts toward a fee or guarantee and what doesn't count. A "claim" can be defined as a "plan-paid claim," or it can include or exclude reversed, rejected, COB, DMR (paper submitted) and member-paid claims. A key term that can inflate the reported discount off AWP are the definitions of "brand drug" and "generic drug." By manipulating the definition of brand/generic, the contract allows the PBM to artificially inflate both the reported discounts on brands and generics simultaneously. For example, if brand drugs have an average discount of 16 percent off AWP and generic drugs have an average discount of 80 percent off AWP, what happens if we count a generic drug with a 50 percent discount as a brand? Instead of negatively impacting the average generic discount, this claim can actually positively impact the reported brand discount.

Agreements that use a referenceable third-party source, rather than a PBM's propriatry information, is preferable. Within the variety of PBM options there are two different business models to consider: Traditional "spread-pricing" and "pass-through" pricing. Business models that attempt to combine "pass-through," "transparent" and "spread" fall into the "spread pricing-based" model. Focusing on deep discounts (AWP-%) and large rebate guarantees requires the standard, spread-based PBM contract to protect the PBM from financial risk, provide caveats to the guarantees, and allow multiple revenue streams for the PBM. To achieve certain guarantees, the PBM needs to drive drug utilization toward its preferred formulary products while capturing as many prescription claims as possible within their owned pharmacies.

Some key terms that need to be addressed and clearly defined in every PBM contract include: AWP, Brand Drug, Generic Drug, Specialty Drug, Rebate and Manufacturer Derived Revenue, Claim, Data Rights, Audit Rights, Administrative Fees, Allowances and Termination Rights. References to "proprietary," "exclusive" or "mandatory" also need a high level of scrutiny. Having the ability to access your claims utilization data at any time without paying any additional fees is an absolute requirement.

Verify and Audit

Active engagement is needed to identify problematic issues with PBM performance, verify and monitor plan operation, and make adjustments throughout the year as the pharmaceutical marketplace changes. On a regular basis, an independent audit should be performed to determine if the PBM contract has any meaningful client protections. Many payers, however, don't have access to their claims data, have one-side PBM contracts that offer little protection, have no direct contract, or simply don't take the initiative to audit their PBM regularly with an independent, qualified auditor. Similarily to allowing poor contract language, clients relying on generalists or brokers to audit their plans tend to find very few issues. Sophisiticated auditors find performance problems, missing guarantees, and inappropriate plan operations virtually 100 percent of the time. Often, though, the PBM contract protects the PBM from actually paying any penalties or

providing the guaranteed pricing listed in the agreement. A common PBM contracting practice is to use “off-set” language that allows the PBM to underachieve guarantees in one or more areas while overachieving in another area. This moving target provides the client with no recourse whatsoever. The best consultants understand the PBM pricing model games — the contractual nuances that can change the reality of the agreement and are aligned with the interests of the payer.

Getting started:

- Review your PBM contract including all ammendments and exhibits.
- Review your plan design documentation.
- Ask for, receive and review your full pharmacy claims utilization data.
- Find an independent PBM expert, whose goals are aligned with yours, to review the language and determine the areas of risk as well as improvement.
- Verify the pharmacy claims utilzation data against the contract as well as the plan design on an ongoing basis.
- Audit, renegotiate or consider replacing the PBM.
-

Get Your Own PBM Contract

Steven Covey said it best: “Begin with the end in mind.” Start with your own PBM contract that is aligned with your goals and objectives rather than the PBM’s standard agreement. Know which definitions are required and maintain the ability to carve out certain functions. Make changes to the formulary, or use an independent specialty pharmacy without penalty. The further removed the payer is from its own contract, the less control they will have and the more likely that the PBM will take advantage. While using a coalition contract may seem appealing, it is not a viable alternative to having your own direct contract. Using a carved-in PBM with the medical carrier typically results in even less transparency, control and recourse. Frequent verification, validation, market checks, renegotiation, and the willingness to make a wholesale change can dramatically impact drug utilization patterns, waste reduction, overall cost trend and your members’ health.

4

Specialty Pharmacies

Specialty Pharmacy Goals

Setting the stage for success

1. Ensure a level of financial transparency for purchasers.
2. Ensure that high-level, timely clinical expertise supports provider decisions to use high-value drugs that the goal of achieving optimal outcomes.
3. Make operational processes and decisions on behalf of the purchaser, independent of the specialty pharmacy parent organization's financial interests.
4. Provide/improve patient education and support that includes timely instruction on drug administration and emotional/social support to increase adherence and improve outcomes.

Big Chains May Not Have The Cheapest Drugs:

Volume Purchasing Doesn't Always Reduce Prices

Purchasers often assume the larger pharmacy chains have more clout in negotiating drug prices with manufacturers. This may be true; however, whether these lower prices are passed along to purchasers and consumers is another matter. In an analysis of data of a large Minnesota-based employer, when costs were compared by pharmacy, the larger chains were more expensive than independent, community pharmacies. Purchasers should works with consultants and vendors to do the same comparison with their own data to verify costs by pharmacy to make sure the network includes a diverse set of pharmacies, including independents.

Specialty Pharmacy Tips and Actions

Baseline Expectations

- 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.
- 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).

Transformative Goals

Financial transparency	Require face-to-face meetings with SPs to discuss revenue sources, expenses, margin and spread.
	Require information on reporting relationships within PBM and SP.
	Require information on SP interactions with Hubs; who provides which services and volume of services provided by Hubs.
Independence from parent	Review ***specialty pharmacy contracts with PBMs***, or directly with a specialty pharmacy/pharmacies, to support value-based use and management of specialty meds.
	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.
	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.
	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.
	If owned by PBM, require direct relationship with client, reporting on performance, periodic audits by outside entity.
	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.
Clinical expertise	Require SPs to report to employers their interaction with clinicians/prescribers including number of direct interactions, type of communication vehicles, content of communications.
	Require SPs to collect, aggregate and interpret data on Patient Reported Outcomes for top 10 conditions (by spend).
Patient support	Implement support services to assure safe, effective, appropriate use including adherence and discontinuation.
	Performance reporting including adherence, patient satisfaction, and patient support/assistance program use.

Specialty Pharmacy Goal Briefings

Financial Transparency

Ensure a level of financial transparency so purchasers know exactly how their money is being spent

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers

▪ Some employers are unclear about the roles and relationship between PBMs and specialty pharmacies (SPs). PBMs developed SPs organically, when specialty drugs were less prevalent and costly; they were offered as part of their portfolio.
▪ Many employers assume their PBM's owned SP is their only option.
▪ Employers typically don't compare SP performance or have direct contacts.
▪ Many employers are unclear about their SP's revenue sources, services, expenses, margins, organizational structure, how decisions are made, how finances flow between the SP and parent, how they manage conflicts of interest and other aspects of their SP.
▪ SPs consider physicians as their customers.
▪ "Hubs", who are funded by manufacturers to expedite patients' acquisition of drugs, perform some of the same functions as SPs.
	▪ Understand the SPs revenue sources, expenses, margin, and its impact on employers' costs.
	▪ Understand the relationship between SPs and their PBM owners (if applicable), e.g., who makes which decisions and how, how finances flow, and their organizational relationship.
	▪ Receive information regarding the percentage of SP revenue that goes to its parent.
	▪ Understand the difference between drug acquisition cost and what they charge their customers.
	▪ Receive claim detail at the transactional level and/or the ability to audit data.
	▪ Be able to see alternate SP revenue sources (manufacturer, data) as a percentage of total SP prescription revenue.
		▪ Specialty pharmacies may have many and, in some cases, unknown alternate revenue sources including:
		  ▪ Care management fees
		  ▪ Data fees
		  ▪ Pharmaceutical fees
		  ▪ Margin (spread) on drugs purchased and billed this is not a revenue source
		  ▪ Rebates
		  ▪ Other
			▪ Employers believe they don't have a choice in selecting SPs.
			▪ Carving out SPs from the PBM presents complexities, an additional vendor relationship, RFP process, and ongoing management.
			▪ SPs may agree to proprietary pricing that prohibits them from revealing acquisition costs to clients.
				▪ Employers could compare PBM owned SPs practices, costs, and transparency to independent, stand-alone SPs.
				▪ Employers with more than one SP in their network could compare prices and performance and create competition for service and price.

Specialty Pharmacy Goal Briefings

Drug Value Expertise and Expert Clinical Support to Providers

Ensure that high-level, timely, clinical expertise supports provider decisions to use high-value drugs and achieve optimal outcomes.

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers
▪ Providers find prior authorization (PA) and utilization management (UM) requirements burdensome, while SPs claim to support them in this process; it is unclear how burdensome or how effective this support is. ▪ No easy way to quantify SPs clinical expertise, or ability to support provider decisions to optimize value, or act as part of the care team. ▪ Providers don't know the cost of drugs when prescribing or administering them. Providers debate whether drug selection should consider costs.	▪ Integrated, coordinated care across SPs, health plans, physicians, and other providers. ▪ Avoid duplication of services, coordinate care between multiple external organizations including SPs, hubs, manufacturers, health plans, providers, and others. ▪ Improve appropriate drug, dosing, and delivery. ▪ Reduce waste and fraud. ▪ Improve patient adherence to the most effective drugs, thereby achieving optimal health outcomes.	▪ SP relationships to physicians and their organizations vary depending on SP ownership, electronic connectivity, and access to medical data. ▪ SPs have collaborated with health plans to produce integrated data to compare physician performance by condition.	▪ SPs collect patient reported outcomes (PROs) data but don't aggregate it to compare patient outcomes or provider performance. ▪ SPs vary in their communication with providers; EMRs, portals, phone calls, faxes. ▪ Difficult to verify and compare SPs staffing levels, credentials, clinical expertise, knowledge, and responsiveness to physicians' needs.	▪ SPs could provide information to providers on PROs, drug costs, effectiveness, and other decision support. ▪ SPs provide information on changing payer or PBM UM requirements. ▪ SPs support providers' decisions for patients with unusual comorbidities or other complexities.

Specialty Pharmacy Goal Briefings

Independence from Parent Influence

Make operational processes and decisions on behalf of the purchaser independent of the specialty pharmacy (SP) parent organization's financial interests.

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers
▪ SPs may be owned by another entity in the supply chain including PBMs, providers, health plans, or they may be independent. ▪ SPs may be conflicted and act in their owner's best interest rather than their clients'. ▪ PBMs vary in their response to employer requests to carve out SPs, ranging from significant to no financial impact. ▪ PBMs decide which drugs go on the "SP drug list", require SP dispensing for coverage, and have increased the drug's price to the consumer and the employer.	▪ Confidence that their SP is working in their best interest, rather than their parent's. ▪ Clearly defined and differentiated roles of SPs and PBMs. ▪ Input into decisions that affect their costs, e.g., which drugs are on the SP list. ▪ Direct contact with their SP without their PBM involvement. ▪ Guidance from SPs on how to improve PBM performance, e.g., when PBMs are allowing drugs to "slip through" (circumvent the PA process).	▪ Employers who have carved out SP relationships receive more complete information on performance of other vendors, e.g., the SP can report on PBM performance and vice versa.	▪ Many PBMs charge clients higher fees if they carve out their SP; it is difficult for employers to predict if the price of carving out will be offset in better performance or drug pricing. ▪ Employers may not have the expertise or resources to manage an additional vendor relationship, even if it is financially worthwhile.	▪ Transparent pass-through PBMs and PBMs that don't own specialty pharmacies are examples of alternatives to the standard approach. ▪ Examples of carved out SPs exist; health plans, union groups and some employers have taken this approach.

Specialty Pharmacy Goal Briefings

Patient Support

Provide patient education and support that includes timely instruction on drug administration and emotional and social support to increase adherence and improve outcomes.

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers
▪ All SPs describe patient satisfaction scores based on self-reported data, proprietary survey tools and methods; employers have no comparable objective data to compare SPs. ▪ No aggregate PROs data to evaluate or compare SPs to each other. ▪ Manufacturer sponsored financial support/coupon programs are pervasive and their utilization unknown. These programs circumvent incentives within benefit plan designs.	▪ Integrated care across SPs, physicians, and other providers. ▪ Avoid duplication between, and coordinate care management of SPs, hubs, manufacturers, health plans, providers, and others. ▪ Improve appropriate drug, dosing, and delivery. ▪ Reduce waste and fraud. ▪ Improve patient adherence to the right drugs and therefore improved PROs. ▪ Understand the impact of financial assistance programs on utilization and cost.	▪ Patients receive calls from numerous sources including SPs, hubs, health plan, physician, and manufacturer. ▪ Unknown impact of manufacturer financial assistance programs/ coupons.	▪ No independent, comparative, evaluation of quality to compare performance; e.g., Hospital Compare. ▪ Lack of coordination among all players in reaching out to patients. ▪ Lack of knowledge regarding patient use of unrelated drugs, other medical conditions, treatments, or treating providers. ▪ Manufacturers offer independent patient support programs, usually in the form of home visits. ▪ The amount and reasons for drug waste are unknown.	▪ Manufacturers and SPs could collaborate to provide patients with social and emotional support. ▪ Most SPs collect PROs today to use for individual patient management. Information is not communicated to providers, aggregated or analyzed to compare provider performance or track drug specific outcomes.

Specialty Pharmacy Scoring Criteria

Goal	0	1	2	3
Independence from owner influence	▪ SP owned by another supply chain entity, e.g., PBM, health plan, provider, wholesaler ▪ PBM parent provides financial incentives for clients to choose owned SP exclusively ▪ PBM parent has authority to make key financial, clinical and management decisions re: specialty pharmacy ▪ Clients have no relationship with specialty pharmacy management staff	▪ Client's relationship with parent, not SP ▪ Clients not clear on roles and authority related to clinical coverage decisions and refill processes ▪ PBM makes decisions that affect SP revenue, PA criteria, auto-refills	▪ Parent neutral in client's SP selection(s) ▪ No financial consequences to client if non-owned SP/SPs selected ▪ SP offers data, direct client consultation to client ▪ SP collaborates with PBM regardless of ownership ▪ Client receives data on SP margins (acquisition cost v. charges to client)	▪ SP not owned by another supply chain entity ▪ SP suggests discontinuing ineffective drugs and use of higher value drugs to providers and PBM ▪ SP identifies opportunities to improve clinical value and effectiveness to client ▪ SP reports performance on savings, provider consultation and PROs to client ▪ Client receives data on PBM spread and SP margin
Patient support and reporting	▪ No direct patient contact before fill, refill, dispense ▪ No performance data collected or reported, e.g., satisfaction, adherence, engagement or Patient Reported Outcomes (PRO), e.g., quality of life, functional status	▪ Disease specific protocols shared with client ▪ Documents patient specific care management ▪ Reports patient satisfaction data by independent entity, engagement and adherence rates	▪ Adherence measured by proportion of days covered ▪ PROs collected using validated tools on > top 5 conditions ▪ Social/behavioral health assessment and referrals conducted	▪ PROs collected on > top 10 conditions ▪ Aggregates PRO data for internal process and patient outcome analysis and improvement ▪ Multiple patient communication channels in place ▪ Patient adherence, engagement, PROs evaluated and improved over time

Specialty Pharmacy Scoring Criteria

Goal	0	1	2	3

Financial transparency	▪ No information provided on drug prices, sources of revenue
	▪ No ability to audit
		▪ Discloses information on revenue sources
		▪ Allows audit by selected auditors
			▪ Discloses:
			  ▪ All revenue sources
			  ▪ Total and % revenue by source
			  ▪ Unrestricted audit
				▪ Discloses:
				  ▪ All revenue and expense sources and margin/spread
				  ▪ Total and % revenue to parent (if applicable)
				  ▪ "Opens books" on all requests without audit requirements
				  ▪ Provides transaction level claims data

Clinical expertise and cost information to providers (not patients)	▪ No evidence of provider communications re: clinical issues, PA guidelines, or other	▪ Provides evidence that specialty pharmacy communicates with physicians:
		  ▪ Beyond PA processing support, e.g., new guidelines, rationale, new drugs
		  ▪ Using multiple channels, e.g., web, phone, email, other upon request
			▪ Evidence of all activities in #1
			AND
			▪ Routinely advises physicians on patient specific pharmaceutical care management, e.g., patient reported outcomes (PROs), comorbidities, titration
			AND
			▪ Collects PROs on < 50% of patients
			▪ Provides drug cost information (net of rebates)
				▪ Collects, aggregates, analyzes and shares:
				▪ PROs with validate comparable tools on > 50% of patients
				▪ Compares trends, provider outcomes, drugs
				▪ Compares provider cost information
				▪ Provides feedback to providers, clients and PBMs on cost and outcomes

Transparency Questions, Rationale and Action to Increase Transparency

Specialty Pharmacy Questions

Specialty Pharmacy Priority #1

What information is requested?
All revenue sources including spread (difference between paid amount to wholesalers/distributors and charges to PBM) and all other sources.

Please provide the following:

- Data on the percentage of total revenue realized from manufacturers, PBMs, and any other entities.
- Describe the inherent incentives within these contracts. For revenue from manufacturers, break out revenue by:
  - Data fees
  - Rebates/financial benefits, if applicable
  - Care management fees
  - Other

Why this information is needed?
Purchasers are interested in the inherent incentives within contracts/agreements between specialty pharmacies and other entities in the supply chain to assure the specialty pharmacy is acting in their best interest.

What will purchasers do with this information?
This information will allow purchasers to have more informed and focused conversations with their specialty pharmacy about specialty pharmacies' key sources of revenue and potential inherent conflicts of interests within these relationships and contracts with outside entities including their owner, if applicable. Specialty pharmacies typically generate revenue from spread, the difference between their drug acquisition cost and what they bill PBMs. Therefore, the more drugs they dispense, the more spread they realize. They typically do not have incentives to prevent unnecessary or inappropriate claims. Purchasers may also choose to negotiate directly with specialty pharmacies for certain performance guarantees or outcomes.

Specialty Pharmacy Priority #2

What information is requested?
Patient reported outcomes, information gathered directly from patients through surveys, e.g., functional status, quality of life, or disease specific instruments for rheumatoid arthritis, and the impact of specific drugs on their members' functionality, outcomes, and quality of life, by condition.

Please provide the following:
Information related to the collection of patient reported outcomes including:

- Specific conditions for which outcomes data are collected
- Name of the measurement instrument/s used for each condition
- Percentage and number of patients who respond to inquiries to gather outcome information by condition
- Range and average results of responses by condition
- Describe how outcomes data are used, e.g., comparisons of outcomes by physician, drugs within therapeutic categories, reports to prescribing physicians, reports to manufacturers, other

Why this information is needed?
Employers are not aware of the impact of expensive drugs on the productivity, functionality, and quality of life of their employees and family members, whether these data are used to manage patients' care, or even if specialty pharmacies use these data. If outcomes data is collected, they are not aware of how it is used by specialty pharmacies to improve their members' health or purchaser value.

What will purchasers do with this information?
This information will allow purchasers to have more informed and focused conversations with their specialty pharmacy about the impact of specialty drugs on their population's health overall and the impact of their specialty pharmacy on improving their value by condition and drug. They will have information to evaluate their current specialty pharmacy's performance and compare to alternative specialty pharmacies. They also may negotiate terms to improve performance or add or change specialty pharmacies.

Transparency Questions, Rationale and Action to Increase Transparency

Specialty Pharmacy Questions

Specialty Pharmacy Priority #3

What information is requested?
Audit rights and claim level data to compare to PBM data.

Please provide the following:

- When and how unrestricted audits may be conducted
- Detailed claim level data (including all data fields) of all specialty drugs dispensed over last 24 months (Appendix A)

Why this information is needed?
Detailed line item data, rather than summary data, may be analyzed by independent consultants or other representatives of employers who can identify and prioritize areas of concern and then drill down further to identify causes and potential solutions. Without line-item data, employers are not able to quantify the difference between the specialty pharmacy's acquisition cost and the amount charged to the PBM (specialty pharmacy spread).

What will purchasers do with this information?
This information will allow purchasers to have more informed and focused conversations with their specialty pharmacy about potential conflicts of interest and alignment of goals with purchasers' goals.

5

Manufacturers

Manufacturer Goals

Setting the stage for success

1. Create a model of financial transparency that will assist purchasers in making value-based decisions.
2. Discontinue consumer coupon programs that encourage use of low-value, high-cost drugs in place of therapeutically equivalent generics.
3. Ensure that price increases over time do not exceed the Consumer Price Index (CPI).
4. Develop and implement value-/performance-based pricing.

DIR Fees:

Why Employers Should Care

Direct and Indirect Remuneration (DIR) Fees originated with Medicare Part D plans to give the Centers for Medicare and Medicaid Services (CMS) a tracking mechanism for total costs of Medicare Part D medications. PBMs have now expanded these fees to commercial plans and use them as a claw-back fee for a number of complicated and vague reasons including “pay-to-play” as a preferred provider, and as a way to reimburse pharmacies for meeting or failing to meet certain quality measures, among others. It impacts independent (non-PBM owned) pharmacies more directly, since they are difficult to predict or to know how they will be applied. It is unknown how or if they are applied to PBM-owned pharmacies including retail, mail or specialty. DIR Fees are another example of the lack of transparency in the supply chain and the conflict of interest inherent in PBM-owned pharmacies. Purchasers should question their PBM’s DIR practices and their impact on pharmacy competition and be aware of federal legislative actions to eliminate these fees. In the event DIR fees are revised or eliminated, they should be eliminated for commercial populations as well.

Manufacturer Tips and Actions

Baseline Expectations

- 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.
- 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.
- 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.
- 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.
- Allow importation of high-quality drugs from multiple countries including Canada, the European Union, and Australia.
- Require CMS to negotiate drug prices on behalf of Medicare Part D programs or require Medicaid level rebates be applied to Part D.

Transformative Goals

Financial transparency	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.
	Manufacturers and PBMs must disclose prices and economic transactions to payers and public.
Discontinue coupons for low-value drugs	Require PBMs to report on use of low value coupons in their owned pharmacies and/or discontinue their acceptance.
Value-based pricing	Require drug pricing for both medical and pharmacy benefit management be consistent with available cost and comparative effectiveness evaluations.
Price increases do not exceed CP	Require PBMs and health plans to track and report price increases by manufacturer that exceed CPI (all costs, not medical) and price increases that exceed public pledges made by manufacturers.

Manufacturer Goal Briefings

Transparency

Create a model of financial transparency that will assist purchasers in making value-based decisions

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers

▪ The goal was revised due to the low likelihood of making progress in overall transparency in the next year.
▪ Several states have proposed legislation mandating reporting these costs with no success to date.
▪ Manufacturers have resisted providing specific revealing information on costs, especially marketing and margin.
▪ Higher rebates, paid by manufacturers, reflect a less unique drug and less competitive market position; lower rebates reflect more unique drugs.
▪ Increased rebates increase revenue to PBMs, health plans, providers, GPOs, and others in the supply chain.
▪ Focusing on obtaining higher rebates, rather than higher value (better outcomes/ lower cost) drugs, ultimately raises overall costs.
	▪ Manufacturers report all costs including R&D, marketing, manufacturing, margin, etc. by product.
	▪ Advertising drives off-label and inappropriate use; eliminate or limit advertising.
	▪ Rebates are transparent; reported at the individual claim level.
		▪ Rebate information is not available publicly by drug but is published by manufacturer, in aggregate, from annual report disclosures.
		▪ No consistent data is available to compare manufacturers to each other.
		▪ A 2014 Credit Suisse report aggregated data from 20 companies and found that:
		  ▪ Rebates paid ranged from 6% by Regeneron to 56% by Astra Zeneca
		  ▪ Rebates increased 24% against a 7% increase in net sales.
			▪ Desire transparency of multiple transactions and relationships.
			▪ Payments to PBMs, others
			  ▪ Data
			  ▪ Services
			  ▪ Rebate administration fees
			  ▪ Administration fees
			  ▪ Clinical programs
			  ▪ Other
			▪ Rebates to
			  ▪ PBMs
			  ▪ Health plans
			  ▪ GPOs
			  ▪ Wholesalers
			  ▪ Providers
			  ▪ Specialty pharmacies
			  ▪ Other
			▪ Payments to Hubs.
			▪ Funding to support co-pay assistance programs and patient support foundations.
			▪ Manufacturer prices
			  ▪ WAC
			  ▪ 340B
				▪ Franken's "Improving Access to Affordable Prescription Drugs Act" includes drug manufacturer reporting.
				▪ Several states have proposed similar bills.
				▪ Rebate payments are reported in public documents.

Manufacturer Goal Briefings

Co-Pay/Financial Assistance Programs/Coupons

Discontinue consumer coupon programs that encourage use of low-value, high cost drugs in place of therapeutically equivalent generics

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers
▪ Numerous types of programs to assist patients in purchasing drugs including assistance for: 1. More expensive brand drugs where generic equivalents exist 2. More expensive brands where generic therapeutic equivalents exist 3. Financial assistance for patients' cost-sharing portion regardless of financial need 4. Financial assistance for patients' cost-sharing portion with qualifying criteria ▪ The number and use of these programs is increasing dramatically. ▪ Most PBMs have developed and are implementing programs that utilize the full benefit of the manufacturer patient support programs to offset patient and employer liability.	▪ Eliminate or limit coupons that encourage the use of more expensive brand drugs where generic equivalents and/or therapeutic equivalents exist. ▪ Do not apply funding for any programs to patients' deductible accumulator. ▪ Optimize funding from specialty drug programs to benefit of employer and patient. ▪ Quantify the amount of manufacturer funding going to financial assistance programs to estimate savings if applied to drug prices.	▪ There are many types of co-pay assistance programs with multiple names and definitions; it's important to be clear about the specific goals and impact of each program before proposing changes. ▪ Programs for specialty drugs differ from programs for traditional drugs; generics are less common, patients/physicians are less likely to switch drugs because of a financial assistance program. ▪ Given the price of specialty drugs, most patients qualify for one or more assistance programs available.	▪ Multiple and emerging programs create confusing terminology, understanding and impact. ▪ Rising premiums result in more low-income individuals who are unable to afford specialty drugs are enrolling in high deductible health plans. ▪ PBMs and purchasers have no "line of sight" into programs' utilization and impact on outcomes. ▪ The future of these programs is unclear if there is a sudden expansion of funds applied to employers' costs.	▪ Dispensing pharmacies have transaction and payment information; they could aggregate and report to PBMs, purchasers. ▪ Seek out other sources of information on utilization. ▪ PBMs are developing programs to apply manufacturer funding to purchasers and member costs.

Manufacturer Goal Briefings

Price Increases
Ensure that drug price increases (over time) do not exceed the Consumer Price Index (true/all CPI*)

Background – Learning Network Findings	Employers' Goals	Specifics	Feedback – Challenges	Feedback – Enablers
▪ Manufacturers' price increases don't relate to costs or increased value but what the market will bear. ▪ The U.S. pays much higher prices for drugs than other wealthy, industrialized countries. ▪ New drugs often do not create competition for lower prices, e.g., new MS drug launch prices higher than existing drugs, have risen over time. ▪ Drug prices are obfuscated by the supply chain; wholesalers, PBMs, providers, others change the price comparison points, e.g., ASP, AWP, net price after rebates. ▪ Rebates replace discounts; they are paid to PBMs and may be passed along in part or all to employers. ▪ Rebate payments are delayed, often without detailed accounting identify amounts by drug, patient or manufacturer.	▪ Drug prices should reflect their competitive value, e.g., their comparative effectiveness, side effect profile, impact on productivity and quality of life. ▪ Market forces such as competition and value should support purchasers' goals. ▪ Providers who are aware of price increases and the competing drugs' prices at the point of prescribing would support selection of high-value drugs. ▪ Drug prices should not create unsustainable costs to purchasers or consumers.	▪ Employers should ask their vendors, PBMs and health plans how they track and manage drug price increases. ▪ Employers should ask them for data on the top 20-40 specialty drugs (in spend) for both medical and PBM costs when reviewing price increases. ▪ Focus on conditions with highest spend, not therapy classes, to identify competing drug prices and specialty providers most likely to prescribe/administer high value drugs. ▪ Use List Price (from Medispan and FDA) when comparing increases. ▪ Ask vendors to alert purchasers when dramatic price increases will impact their expenses.	▪ Complexity of financial flow through drug supply chain; role of rebates, multiple class of trade prices. ▪ Lack of easily acquired, public data to compare performance of manufacturers or drug prices. ▪ "Confidentiality" of prices between manufacturers and PBMs.	▪ Information from vendors on manufacturers' intentions related to price increases. ▪ Information from vendors on historic price increases of top spend drugs.

Manufacturer Goal Briefings

Value-Based Pricing Develop and implement value/performance-based pricing (to be defined)				
Background – Learning Network Findings	**Employers' Goals**	**Specifics**	**Feedback – Challenges**	**Feedback – Enablers**
▪ Other advanced countries have systems for determining drug values, e.g., NICE in UK. ▪ ICER (Institute for Clinical and Economic Review) is an example of an effort to establish a comparative effectiveness value and price for specific drugs. ▪ PBMs and manufacturers are in the very early stages of piloting value-based pricing and purchasing efforts. ▪ Employers may not see significant progress in value-based pricing based on comparative effectiveness in the near term.	▪ Drug prices reflect the benefit derived by the patient and purchaser, not influenced, not "what the market will bear." ▪ New competing drugs, brands, biosimilars and generics, will drive down prices. ▪ Net prices will be used in negotiations rather than rebates to clarify actual prices. ▪ Too early to tell whether value base pricing will impact costs or value in the long term.	▪ Indication specific programs are being piloted by some national PBMs; results are not yet in. ▪ PBMs are also negotiating arrangements with manufacturers to guarantee results; rebates are used as "money back."	▪ Many programs are administratively complex and difficult to administer. ▪ It's "too soon to tell" in many cases with PBMs and manufacturers experimenting with numerous models. ▪ PBMs, health plans and providers have no authority to require manufacturers to adhere to recommended prices based on comparative effectiveness but may use market power, if they have it to force price concessions.	▪ ICER, the Institute for Clinical and Economic Review has begun to publish comparative effectiveness (CE) prices from analysis. ▪ CVS has launched a program to only cover new drugs that meet ICER's cost recommendations. ▪ Ask PBMs and health plans whether they have adopted ICER's recommended prices. ▪ Encourage validated, CE pricing for more drugs. ▪ Require vendors to adhere to their recommendations. ▪ Increased attention by policy leaders, Congress, others to manage drug prices.

Manufacturer Scoring Criteria

Goal	0	1	2	3

Financial transparency	▪ No information provided on drug prices, sources of revenue
	▪ No ability to audit
		▪ Discloses information on revenue sources
		▪ Allows audit by selected auditors
			▪ Discloses:
			  ▪ All revenue sources
			  ▪ Total and % revenue by source
			  ▪ Unrestricted audit
				▪ Discloses:
				  ▪ All revenue and expense sources and margin/spread
				  ▪ Total and % revenue to parent (if applicable)
				  ▪ "Opens books" on all requests without audit requirements
				  ▪ Provides transaction level claims data

Patient support and reporting	▪ No evidence of provider communications re: clinical issues, PA guidelines, or other	▪ Provides evidence that specialty pharmacy communicates with physicians:
		  ▪ Beyond PA processing support, e.g., new guidelines, rationale, new drugs
		  ▪ Using multiple channels, e.g., web, phone, email, other upon request
			▪ Evidence of all activities in #1
			
			and
			▪ Routinely advises physicians on patient specific pharmaceutical care management, e.g., patient reported outcomes (PROs), comorbidities, titration
			
			and
			▪ Collects PROs on < 50% of patients
			▪ Provides drug cost information (net of rebates)
				▪ Collects, aggregates, analyzes and shares:
				▪ PROs with validate comparable tools on > 50% of patients
				▪ Compares trends, provider outcomes, drugs
				▪ Compares provider cost information
				▪ Provides feedback to providers, clients and PBMs on cost and outcomes

Price increases over time do not exceed Consumer Price Index*	▪ Average annual price increases > 9.9% ▪ Price increases behavior reflect no relationship to value	▪ Publicly pledge single-digit annual increases ▪ Average annual price increases > 5% to 9.9%	▪ Publicly pledge single-digit annual increases ▪ Average annual price increases > 2.5% and < 5%	▪ Average price increases = or < CPI (2.5%)
Develop and implement value/ performance-based pricing (reflects the comparative effectiveness the drug)	▪ Not supportive of pricing drugs to reflect value/performance (comparative effectiveness) ▪ Actively pursues delaying introduction of competing generics and biosimilars	▪ Agrees publicly to need for value/performance-based (comparative effectiveness) pricing but taking no specific action ▪ Does not block introduction of generics and biosimilars	▪ Actively pursuing value-based pricing models and arrangements with PBMs and providers ▪ Actively pursing value/performance-based pricing with selected payers that reflect comparative effectiveness ▪ Value reflected in acquisition price, not financed through rebates	▪ All new drugs launched at value/performance-based pricing recommendations from organizations such as ICER ▪ Actively supports introduction of generics and biosimilars

**2017 CPI (Consumer Price Index-all items) = 2.5%*

Transparency Questions, Rationale and Action to Increase Transparency

Manufacturer Questions

Manufacturer Priority #1

What information is requested?
Copay assistance program descriptions including dollars paid to replace generic drugs or lower priced drugs with higher priced drugs.

Please provide the following:
Information from manufacturers on their copay assistance programs that are designed to replace generic drugs (if applicable) or lower priced drugs with higher priced drugs for the top drugs, by spend. Include copay assistance dollars paid by:

- Drug
- Claim
- Number of claims where copay assistance dollars are paid
- Cost of the drug compared to lowest cost competing drug
- Number of patients served

Why this information is needed?
This information will increase transparency of the dollars spent on these programs, the financial impact of programs designed to increase utilization of lower value drugs, the cost of these programs to employers, and the amount of subsidies to patients.

What will purchasers do with this information?
This information will allow employers to have more informed and focused conversations with their PBMs and health plans on the impact of these programs on their costs, and patients' incentives and behavior. They may encourage their vendors to negotiate changes to these programs or influence their buying decisions with manufacturers based on the impact of these programs on market dynamics.

Manufacturer Priority #2

What information is requested?
Publicly stated position and pledges on prices and price increases.

Please provide the following:
Provide information related to the publicly stated position of the top 10 manufacturers (by specialty drug spend) on pricing, price increases and rebates/financial benefits vs. discounts and any other pricing decisions.

Why this information is needed?
Manufacturers' market behavior is changing based on increased scrutiny, the threat of legislative action, and actual legislation. Some manufacturers are offering new drugs at much lower prices than competing drugs with low or no rebates, a pricing model that promotes transparency and competition. Other manufacturers have operated in ways that optimize their profits without consideration for its impact on overall market dynamics and sustainability. Information on other anti-competitive behavior, such as "pay for delay" and "product hopping" would also be useful. This information will allow purchasers to compare public relations to actual behavior of specific manufacturers as it relates to pricing behavior and market dynamics. It could also stimulate conversations between PBMs and manufacturers, as well as public positions and statements from manufacturers.

What will purchasers do with this information?
This information will allow employers to have more informed discussions with their vendors on the pricing behavior of manufacturers and determine whether and what further actions to take because of this behavior. It will also allow employers and their vendors to compare stated positions to actual behavior over time.

Transparency Questions, Rationale and Action to Increase Transparency

Manufacturer Questions

Manufacturer Priority #3

What information is requested?
Publicly stated position and pledges on prices and price increases.

Please provide the following:
Provide information related to the publicly stated position of the top 10 manufacturers (by specialty drug spend) on pricing, price increases and rebates/financial benefits vs. discounts and any other pricing decisions.

Why this information is needed?
Manufacturers' market behavior is changing based on increased scrutiny, the threat of legislative action, and actual legislation. Some manufacturers are offering new drugs at much lower prices than competing drugs with low or no rebates, a pricing model that promotes transparency and competition. Other manufacturers have operated in ways that optimize their profits without consideration for its impact on overall market dynamics and sustainability. Information on other anti-competitive behavior, such as "pay for delay" and "product hopping" would also be useful. This information will allow purchasers to compare public relations to actual behavior of specific manufacturers as it relates to pricing behavior and market dynamics. It could also stimulate conversations between PBMs and manufacturers, as well as public positions and statements from manufacturers.

What will purchasers do with this information?
This information will allow employers to have more informed discussions with their vendors on the pricing behavior of manufacturers and determine whether and what further actions to take because of this behavior. It will also allow employers and their vendors to compare stated positions to actual behavior over time.

Appendix

Minnesota Health Action Group™
Innovating, Leading, Engaging

Specialty Drug 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:** The degree to which a patient takes their medication or follows 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 intravenous (IV) treatments such as chemotherapy and immunosuppressive specialty medications.
- **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 items 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 dosing instructions as specified by the prescribing physician consistent with the FDA-approved label. Also, called adherence.
- **Co-pay offset/assistance/coupon programs:** Drug manufacturers sometimes offer co-pay assistance or coupons to patients for their costs. The offer is for patients 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 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 need 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, etc., intravenous administration in a clinic or outpatient hospital setting.

- **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 communication 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 co-pay 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, retail 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 products 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), who 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 employers and health plans, most 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 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):** The 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 payers 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.

Minnesota Health Action Group™
Innovating, Leading, Engaging

June 5, 2018

Susie Blake
Minnesota Department of Health
P.O. Box 64882
St. Paul, MN 55164-0822

Re: Proposed Changes to Minnesota Uniform Companion Guides (proposed version 13.0 rules, new Appendix D, as published in the Minnesota State Register on Monday 7 May 2018)

Dear Ms. Blake:

My name is Linda Davis. I represent members of the Minnesota Health Action Group where I have served as the Specialty Drug Project Lead for their Specialty Drug Learning Network and Guiding Coalition since October 2014.

The Minnesota Health Action Group is a coalition of public and private purchasers whose sole purpose is to represent the collective voice of those who write the checks for health care in Minnesota. Action Group members collaborate with community stakeholders to drive innovations that support high quality health care, create engaged consumers and ensure the economic vitality of all Minnesota communities. Based in Bloomington, Minnesota, the Minnesota Health Action Group was formed in 1988 as the Buyers Health Care Action Group. To learn more, visit www.mnhealthactiongroup.org.

We, as purchasers, see the lack of specific data on medically-administered prescription drugs to be a significant gap in knowledge and a barrier to improving safety, quality and increasing value for patients. **We applaud the Minnesota Department of Health's move to require National Drug Codes (NDCs) for outpatient care and highly encourage that the requirement also include NDCs for inpatient care.**

Why Require NDC Codes?

In October 2014, The Action Group convened a "Learning Network" to focus on specialty drugs, both prescription and medically administered. The Learning Network included eighteen Minnesota employers, representing an array of industries and both private and public-sector purchasers. Our goals were to:

- Better understand the multiple supply chains and relationships among the many players within those supply chains in order to identify ways to increase the value (benefit/cost) of specialty drugs; and
- Remodel the drug market to assure financial sustainability over time.

With Stephen Schondelmeyer, a professor at the University of Minnesota College of Pharmacy, as their advisor, the employers met regularly for over two years and heard from an array of key informants and market experts. In 2017, employers invited supply-chain stakeholders to come to the table to continue this important work. Today, the "Guiding Coalition" continues to meet regularly. It includes leading employers as well as representatives of health plans, care systems, pharmacy benefit managers, specialty drug pharmacies, and manufacturers working together to find solutions.

One of the earliest findings of the Learning Network was that, while most attention related to specialty drugs is focused on prescription drugs obtained through pharmacy settings such as community pharmacies, mail order pharmacies, and specialty pharmacies, **medically administered drugs represented a much larger cost than expected.** In fact, these costs were approximately equal to their specialty drug cost dispensed through the pharmacy supply chain. Closer analysis of medical claims data and Dr. Schondelmeyer's findings from the Minnesota All Payer Claims Database Drug Spending project in 2015 confirmed this fact, with over $1.1 billion spent on drugs that were "bundled and unclassified". This stark realization and the fundamental belief that purchasers are entitled to basic information on what they are paying for resulted in one of our key goals for market reform being:

> *Require submission of actual National Drug Codes (NDCs), in addition to Healthcare Common Procedure Codes (HCPCs), units, quantity and day's supply by all providers, in all settings; use NDCs for prior authorization, utilization management, payment, collection of rebates, claim-level reporting, data analysis, provider contracts and improving patient outcomes.*

More recently, data published by America's Health Insurance Plans in April 2018, confirms the importance of medically administered drugs by reporting that 23.2 cents per dollar goes to pay for prescription and medical outpatient drugs, more than any other single category. Hospital stays are 16.1 cents, doctor services are 22.2 and office and clinic visits are 20.2 cents.

In addition to increasing transparency of specific drug prices, our rationale for collecting NDCs included gaining information about:

- Manufacturer, specific drug name, packaging, strength and dose form
- Drug specific pricing and payment amounts
- Newly approved drugs not yet assigned HCPCS codes
- Potential rebates from manufacturers
- Dosing information to assure appropriate quantities
- Managing total cost of care (TCOC) contracts and quality for providers
- Costs, quality and utilization for purchasers and consumers

Having these data for specialty drugs administered in outpatient and inpatient settings will allow employers to make informed purchasing decisions. It is highly relevant to their efforts to improve safety, quality and outcomes, reduce duplication, waste, and other costs, and ultimately measure and increase value. These data are also increasingly relevant to providers as health care moves to more value-based payments and total cost of care contracts. Finally, more precise and granular data will be necessary as the market moves to predictive modeling, artificial intelligence for clinical decision support, personalized care, additional development of clinical guidelines, automated alerts and reminders, genetic testing, clinical research on disease progression, and other advances.

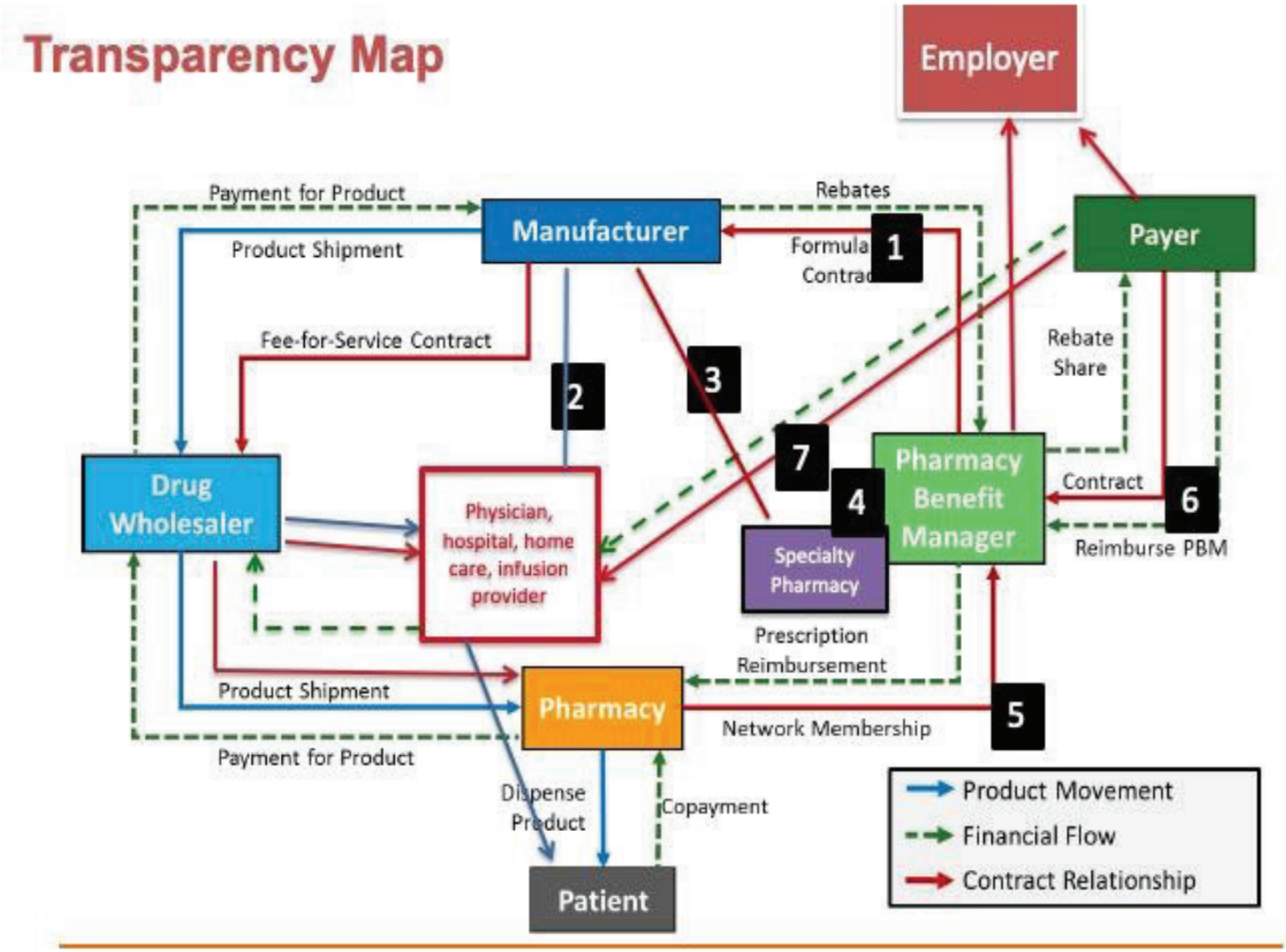
In conclusion, **we highly encourage the Minnesota Department of Health to require NDCs for all sites of care, including outpatient and inpatient sites.** Please feel free to reach out to me if it would be helpful to know more about the Minnesota Health Action Group's work and purchaser perspectives on transparency of specialty pharmacy data.

Sincerely,

Linda Davis

Linda Davis

Cc: Carolyn Pare, President and CEO, Minnesota Health Action Group



Pembroke 2013-14 Economic Report on Retail, Mail, and Specialty Pharmacies; Drug Channels Institute

Transparency – Relationships

Manufacturer with:

1. *PBM*
    - Revenue to PBM: amount and contract terms regarding rebates, data, reporting administration, clinical, price protection, other
    - Formulary placement rationale
    - UM/PA rigor by drug and client
    - Rationale for excluded drugs
    - Bundled drug arrangements (use less attractive drugs)

2. *Provider Organization*
    - 340B amounts and terms by drug, rebates, other revenue to provider

3. *Specialty Pharmacy*
    - Revenue amount and contract terms including data, rebates, other

Pharmacy Benefit Manager with:

4. *Specialty Pharmacy*
    - Difference between owned vs. independent
    - Payments to PBM: network access, other

5. *Traditional Pharmacy*
    - Fees to PBM: Direct and Indirect Remuneration (DIR), other

6. *Payer/Health Plan*
    - Health plan incentive arrangements

Payer/Health Plan with:

7. *Provider*
    - Total Cost of Care incentives for specialty drugs (medical and PBM)
    - "Spread" between acquisition cost (340B if applicable) and allowed charges to payer/purchaser
    - Site of care cost parity
    - Other

Transparency – No defined relationship or accountability

Manufacturer:

- Drug launch prices to comparable drugs (3-5 years)
- Price increases over time by drug (3-5 years) and overall (AARP reports periodically)
- Type and utilization of co-coupon/financial assistance programs
- Relationships and payments to "hubs"
- Investment in new value-based pricing models

Cost and comparative effectiveness of competing drugs:

- ICER, UM carve-out firms, other efforts to evaluate evidence and compare drugs
- Emerging companies developing tools

How to Choose a Pharmacy Benefit Consultant

Chuck Gamsu, R.Ph., MBA - Principal, SkySailRx June 29, 2018

Introduction

The most utilized, complex, and least understood health care benefit is the pharmacy benefit plan. In a constantly changing environment with rapidly escalating prices, expensive new medications, drug company advertisements, and confusing contracts, most payers value the services of a health care consultant. But how do you know if your consultant is providing independent, high-quality advice at a reasonable price?

Beyond the Spreadsheet

A simplified approach to selecting a consultant relies on five key points: Relevant experience; skill set; professionalism; methodology and tools; personality and fit. However, the pharmacy benefit supply chain and PBM industry is too complicated for most generalist benefit consultants to fully understand. Many rely on spreadsheets that focus on simplistic, quantitative comparisons and allow the PBM providers to manipulate the pricing optics to show deep discounts, large manufacturer rebates, and low or no administrative fees.

Many consultants are brokers (paid through commissions) who have aligned themselves with PBM providers. One warning sign that the consultant has a misaligned interest is the existence of a PBM coalition. These consultants often provide preferential treatment to the PBM providers represented in their coalition product in exchange for undisclosed revenues. All consultants' fees should be negotiated directly with the payer/employer not subsidized by commissions provided by PBMs. The most important result of any RFP or procurement process is the final PBM contract.

The PBM Contract

PBM contracts are deceptively complicated and can result in higher profit margins for the PBM and higher costs for the plan sponsor. The typical RFP process starts with an initial assessment of various aspects of the plan, followed by a lengthy questionnaire and concludes with a spreadsheet of discounts, rebates, fees and allowances. These are often standard, boilerplate, documents, developed by the consultant with minimal customization for the employer.

This leaves the most important part of the evaluation to the very end: The contract with the PBM. When a consultant allows the PBM to use their standard contract language and definitions, the employer/payer is typically left at a real disadvantage. Overtime, without constant diligence, pricing discounts erode, rebate yields shrink, and operational problems may be hidden for years. The "set it and forget it" consulting approach that revisits the pharmacy RFP process every two to three years benefits the PBM providers and ultimately the consultants rather than the payer clients.

An independent pharmacy benefits expert is needed to identify the employer/payer goals, develop contract terms based on their goals, and negotiate the business language with a PBM before the final determination is made \to protect the best interests of the plan sponsor. Many consultants are unaware of possible manipulations of PBMs, such as rebate guarantees or definitions of terms that can result in subtle changes to an agreement, which lead to the invalidation of pricing guarantees or the inflation of discounts and an overall misrepresentation of the contract. For example, the contract may require compliance with the PBM's formulary with no exceptions to qualify for the rebate guarantee. Any changes to the formulary may invalidate some or all of the contractual guarantees. A contract may also dictate that the employer use the PBM's mail and specialty pharmacies on an exclusive basis in order to qualify for rebates. In reality, manufacturer rebates are not contingent on the dispensing pharmacy.

Consultant Evaluation Criteria

The best consultants understand the PBM pricing model games, the contractual nuances that can change the reality of the agreement and are aligned with the interests of the payer client. They will:

- Focus on "lowest net cost" and use PMPM cost comparisons rather than rebate or discount guarantees
- Have a broad vision of the pharmaceutical marketplace along with a deep, sophisticated understanding of the PBM industry
- Review claims level data using complex data analytics and clinical expertise
- Conduct periodic reviews in order to monitor and validate the plan's performance over time
- Review utilization reports to provide actionable information on key cost drivers, new drugs to market and overall pricing trends.

A partner consultant challenges the PBM, provides collaborative input on industry trends, plan performance and proactively offers insights. Quite simply, the plan payer/employer must be engaged and in control, willing and able to question the entire process without abdicating to the PBM or to their consultant.

Overarching Themes and Opportunities for Employer Influence

Employer Expectations

- 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.
- Communicate current and future cost issues and implications to support management strategies and tactics.
- Optimize procurement/RFP process to communicate expectations, shape offerings, obtain key information about performance, relationships, processes, and include consultation with employers about key decisions.

Employers' Collective Voice

Procurement	Optimize procurement process to communicate collective voice of employers.
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.
Reporting	Integrated (medical and PBM) reporting by condition comparing employers' site of care, drug class, provider performance on cost, quality and outcomes.
Explore new models	Explore new models of care, payment, and administration of specialty pharmacy that integrate and align incentives with purchasers and consumers goals.
Common list of specialty drugs	Develop a common list of specialty drugs across vendors serving employers in the Minnesota market.
Require NDCs	Communicate expectations that NDCs be required of all providers for all drugs to payers and providers locally and nationally.
Site of care	Communicate expectation that site of care will be managed by pricing of services rather than changing locations of care delivery.
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.
Consistent definition of specialty drugs	Because there are multiple definitions in the marketplace, adopt a single version (the Learning Network version is in the Phase I Purchaser's Guide).
Specialty pharmacy relationship	Information about selection, role with hubs and manufacturers, transparent financial, operational, performance requirements.
Comparative effectiveness research (CER)	Communicate expectation that drug prices will be based on value.
Price disclosure	Negotiated drug prices with PBMs and providers are publicly available to consumers and purchasers.
Guarantees	Negotiate drug effectiveness guarantees and methods for measuring failure and paying back refunds.

This Playbook is published by:

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