CATALYST FOR PAYMENT REFORM

SPECIALTY PHARMACY

WHAT PURCHASERS NEED TO KNOW

CATALYST FOR PAYMENT REFORM

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How to Use this Guide

The information in this guide is for employers and other purchasers of health care interested in understanding more about specialty pharmacy and how best to manage their specialty pharmacy spend. This paper explores various facets of specialty pharmaceuticals and specialty pharmacy benefits; the current and potential medical benefits are enormous, but the costs are exorbitant, the pricing mechanisms and distribution channels complex, and there is variation in how drugs are handled under the pharmacy benefit versus the medical benefit. This guide outlines a variety of tactics, including payment reforms that purchasers should consider when implementing or expanding a specialty pharmacy management strategy. There is no easy solution to these complex issues, but there are various strategies purchasers can consider.

Disclaimer

Engaging in a specialty pharmacy management strategy will likely result in company- or organization-specific negotiations with various parties. CPR is not providing legal advice or direction on how to address these negotiations. The tools in this guide are for informational purposes only. Before making decisions about whether to use these tools in whole or in part and to understand the legal implications of doing so, purchasers should consult with a qualified legal professional for advice.

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I. Introduction Specialty Pharmaceuticals

Definitions and Costs

Specialty pharmacy medications are high-cost injectable, infused, oral, or inhaled medications that generally require some supervision and monitoring of the patient's therapy by a clinician. While there is no standard definition, specialty drugs generally treat chronic, complex, and/or rare conditions, are high cost (usually more than $600 per month), require special storage, handling and administration sites, and involve a great deal of patient and provider education, monitoring and management. Historically, the three chronic diseases for which specialty pharmaceuticals have been used the most are cancer, rheumatoid arthritis, and multiple sclerosis; however, specialty drugs are now available to treat Hepatitis C, hemophilia, and even high cholesterol. Specialty pharmaceuticals are typically developed through advances in biotechnology and referred to as "biologics" or "large molecules." Compared to traditional drugs, like aspirin, molecules of specialty pharmaceuticals can be over 800 times larger, giving many in this class of drugs the "large molecule" label. They are also biologically derived rather than chemically synthesized, which makes them more expensive.

Specialty Pharmacy Spending

Specialty pharmacy is the fastest growing sector of pharmacy spending today with a projected growth rate of 17 percent.[1] The number of specialty pharmaceuticals available has increased from 10 to more than 900 over the last 20 years.[2] Although less than 1 percent of the U.S. population uses specialty drugs, they account for more than 25 percent of total pharmacy spend.[3] In 2012 alone, employers paid $87 billion for specialty pharmaceuticals, comprising 25 percent of total drug spending.[4] These costs are anticipated to grow and account for at least 50 percent of drug spending nationwide by 2019.[5]

[1] "2014 Insights Report." *2014 Insights Report*. CVS Health, Fall 2014. Web. <http://www.cvshealth.com/2014-insights-report-specialty-drives-trend>.
[2] "Specialty Pharmacy." *NBCH Action Brief*. NBCH, Dec. 2013. Web. <https://www.nbch.org/nbch/files/ccLibraryFiles/Filename/000000003258/NBCH_AB_SP%20Pharmacy%20original.pdf>.
[3] Frazee, Sharon, Rochelle Henderson, Robert Nease, Steve Miller, Andy Behm, Chris Peterson, Aimee Tharaldson, and Ruth Martinez. *The Express Scripts 2011 Drug Trend Report*. Rep. Express Scripts, Apr. 2012. Web. <http://lab.express-scripts.com/drug-trend-report/previous-reports>.
[4] UnitedHealth Center for Health Reform & Modernization. "The Growth of Specialty Pharmacy, Current Trends and Future Opportunities." UnitedHealth Group, Apr. 2014. Web. <http://www.unitedhealthgroup.com/~/media/uhg/pdf/2014/unh-the-growth-of-specialty-pharmacy.ashx>.
[5] Maryland (State). House. Department of Legislative Services. *Pharmacy Benefits Managers - Specialty Drugs*. HB 875. Fiscal and Policy Note. General Assembly of Maryland, 26 Feb. 2014. Web. <http://mgaleg.maryland.gov/2014RS/fnotes/bil_0005/hb0875.pdf>.

II. Challenges in the Specialty Pharmaceutical Market

In order to address the cost of specialty drugs, it is important to understand the marketplace in which they are offered and consumed, including the perverse incentives and practices that get in the way of free market dynamics.

Patent Exclusivity

One issue with the specialty pharmaceutical market, similar to the pharmaceutical market generally, is the issue of patent exclusivity. Under current law, and upon approval from the FDA, brand-name biologic drugs have a 12-year exclusivity period, which essentially allows the manufacturer to function like a monopoly in regard to its specialty drug during this time period. The exclusivity period creates strong incentives and protections that manufacturers need in order to make the investment and take on the risk of developing this class of drugs. But from a cost perspective, this does not serve purchasers or patients well. Furthermore, due in part to these exclusivity patents, there are limited therapeutic equivalents or substitutes for specialty drugs that could provide patients with less expensive alternatives to treat their condition. However, the market for generic specialty drugs or generic biologics, known as biosimilars, is growing. These drugs are very similar to the approved brand-name biologic (referred to as the reference product) and are typically available at a much lower cost. A 2013 study found that approval of 11 biosimilars for use in the United States, which are already for sale in European and other countries, would save approximately $250 billion in U.S. health care spending from 2014 to 2024.[6] As the biosimilar market grows, there is more opportunity to control the costs of specialty drugs.

Lack of Options for "Tiering"

For traditional drugs, health plans can structure the pharmacy benefit to provide incentives for patients to select high-quality, lower-cost drugs. The best example of this strategy is the three-tier drug benefit; the tiers of generic, preferred brand, and non-preferred brand give patients access to all drugs, with the incentive to choose the higher-value option (e.g. generic tier). However, since generics or biosimilars for specialty drugs are non-existent or scarce, there is little to no opportunity to direct patients to lower-cost, high-quality alternatives. This is leading to new definitions of the plan design tiers. For example, certain targeted brand products can be found on the lowest (cheapest) tier, while some generics could be on the second or higher tier. Exclusionary formulary strategies are also emerging as a potential solution as competition between manufacturers grows. We explain this concept in more detail, later in this paper.

[6] Miller, Steve. "The $250 Billion Potential of Biosimilars." *The Lab - Express Scripts*. Express Scripts, 23 Apr. 2013. Web. <http://lab.express-scripts.com/insights/industry-updates/the-$250-billion-potential-of-biosimilars>.

Evergreening

Another challenge is the strategy of "evergreening." Manufacturers make slight modifications to a drug's chemical composition or delivery mechanism (e.g. modifying the drug from a twice per day dose to extended release), thereby technically changing the drug. These modifications to the drugs typically do not provide enhanced clinical benefits to patients, yet they extend and preserve the patent exclusivity period, allowing the manufacturer to continue to enjoy a monopoly on the market. In the end, this strategy prevents biosimilars from being developed or offered in the market as a competitive alternative.

Adding Indications

A fourth obstacle is the practice of obtaining regulatory approval to broaden the indications for an existing specialty medication, enabling it to be used to treat additional diseases -- thereby increasing utilization. While this practice can produce benefits for patients, such as new treatments or cures for particular illnesses, most expanded indications result in patients using products that are no more effective but 10 to 50 times the cost of the drugs they were using previously. But aggressive advertising campaigns funded by the manufacturers of these products urge people to adopt the more expensive treatment.

High Prices

A fifth challenge, and central to the issues surrounding specialty drugs, is the exorbitant prices for these products. Many specialty products cost over $10,000 per month, and some as much as $1 million or more in annual treatment costs. For example, a new and popular treatment for Hepatitis C called "Sovaldi" costs around $84,000 for an average treatment cycle, which equates to about $1,000 per pill.[7] Although specialty drug prices are extremely high, because patients may be protected from these prices by their insurance coverage, their incentives to be fiscally conscious may be weak and therefore not aligned with those of their plan sponsor. Due to the high price of these drugs, the patient will hit his or her annual out of pocket (OOP) maximum quickly, at which point there are no adverse cost consequences for the patient who seeks a costlier treatment. Making the end-user (the patient) – who sees the ad on TV or hears about it from his or her doctor – sensitive to the price becomes difficult.

Relative Lack of Price Regulation

Finally, while plan sponsors cannot address the macroeconomics around prescription drug pricing in the short-term -- whether specialty or non-specialty – it is important to understand them. Prescription drugs cost far more in the United States than in most other countries around the world. The previous example of Sovaldi (treatment for hepatitis C) costs $84,000 in the U.S., but only $900 in Egypt (99%

[7] "Costly Hepatitis C Drugs for Everyone?" Editorial. The New York Times 2 Sept. 2015, New York ed.: A24. Print. <http://www.nytimes.com/2015/09/02/opinion/costly-hepatitis-c-drugs-for-everyone.html?_r=0>.

less).[8] Americans utilize more prescription drugs per capita than citizens of other nations. However, it is price, not utilization that is the source of excess cost. Drugs are more costly in the U.S. because of the lack of price regulation; other countries typically regulate the prices of drugs.[9] The environment in the U.S. allows the costs of individual products to skyrocket and this pricing gap is even more accentuated for specialty products. Price regulation is beyond the scope of this paper, but it is important to understand how its relative absence affects prices in the U.S.

Together, these systemic challenges contribute to the growing costs of specialty drugs. In addressing this significant challenge, this document explores payment reform and other non-payment reform strategies.

III. Common Pricing Practices by Health Plans and Pharmacy Benefit Managers (PBMs)

The most common pricing term purchasers will encounter when discussing drug prices is Average Wholesale Price, or "AWP." There are many other terms and pricing mechanisms that purchasers will encounter, but the focus of this paper is on AWP. AWP is calculated and published regularly by companies such as Medi-Span. This published price is important to purchasers because of how it is used as a benchmark and serves as a standard unit of measurement.

At one time, the AWP was a strong estimate of the price retail pharmacies pay for drugs from their wholesale distributors. Over time, while the AWP continues to provide the standard for price benchmarking among commercial plans, the prices themselves have become outdated. The workaround has been to express contractual pricing as "AWP minus X%," which notes the discount off of the wholesale price typically applied in the market. AWP is analogous to the manufacturer suggested retail price (MSRP) for a new car, or the advertised price on the back of a hotel room door. It is not the actual price anyone will pay, but is used as the starting point for getting to the actual price. Purchasers can use the AWP to help evaluate the prices their health plan or PBM has negotiated.

A typical group insurance plan pharmacy pricing contract will include the discounts off of AWP (for drugs dispensed at retail or mail, brand drugs versus generics versus specialty), rebates earned from the manufacturer and shared in some way with the plan sponsor, and fixed costs for the plan (dispensing fees, administrative fees, etc.).

[8] Fick, Maggie, and Ben Hirschler. "Gilead Offers Egypt New Hepatitis C Drug at 99 Percent Discount." Reuters. Thomson Reuters, 21 Mar. 2014. Web. <http://www.reuters.com/article/2014/03/21/us-hepatitis-egypt-gilead-sciences-idUSBREA2K1VF20140321>.

[9] Paris, Valerie. "Why Do Americans Spend so Much on Pharmaceuticals?" PBS. NewsHour Productions LLC, 7 Feb. 2014. Web. <http://www.pbs.org/newshour/updates/americans-spend-much-pharmaceuticals/>.

Specialty drugs are sometimes listed in these pricing agreements, subject to the specified price schedule (drug A receives AWP minus 15%, drug B receives AWP minus 20%, etc.). There are other variations as well. For example, some contracts provide a fixed price for the drug, while other contracts use the stated price as a "floor guarantee." This means that if the actual earned discount on the drug is bigger than what is stated in the contract, the excess savings are "passed through" to the plan sponsor. The latter types of contracts are also referred to as "transparent contracts."

The most important considerations in negotiating a successful contract are 1) understanding the marketplace (which typically requires obtaining the support and expertise of an industry expert), and 2) leveraging economies of scale, such as through a health plan or PBM, because 100 purchasers who purchase together have more spending power than one purchaser purchasing on its own.
It is important to note that the nuances of pricing can become far more complicated than what we describe in this paper. Therefore, deep knowledge of the marketplace is critical. For example, two different contracts may both say: "Generic drugs will receive AWP minus 75%." However, one of the contracts is financially superior for the health care purchaser. How could this be the case? It is due to the definitions underlying the contract, such as what constitutes a generic drug, when the move to a generic drug will take place, how the calculation will be done to test the discount earned, etc. These underlying definitions and provisions are just as important as the pricing terms themselves.

So where is the right place to source a specialty drug - the medical plan or the pharmacy plan? The answer is "it depends." Sometimes drugs delivered through the medical plan will cost much more than the pharmacy benefit. Other times, drugs delivered through the medical plan will cost less. Plan sponsors should analyze both of these options and ask questions to understand the trade-offs. The underlying provider reimbursement structure (discussed later in this paper) is another key variable that impacts the decision about whether to source a specialty drug on the medical or pharmacy plan. The complexities of pricing and contractual terms notwithstanding, the opportunities are significant. Plan sponsors that have analyzed multiple options, optimized the delivery of the pharmacy program, and sourced the products optimally, spend far less on their pharmacy programs than average companies. The savings on specialty drug costs through a pharmacy benefit program can be as much as 15 percent.

IV. A Complicated Landscape for Purchasers

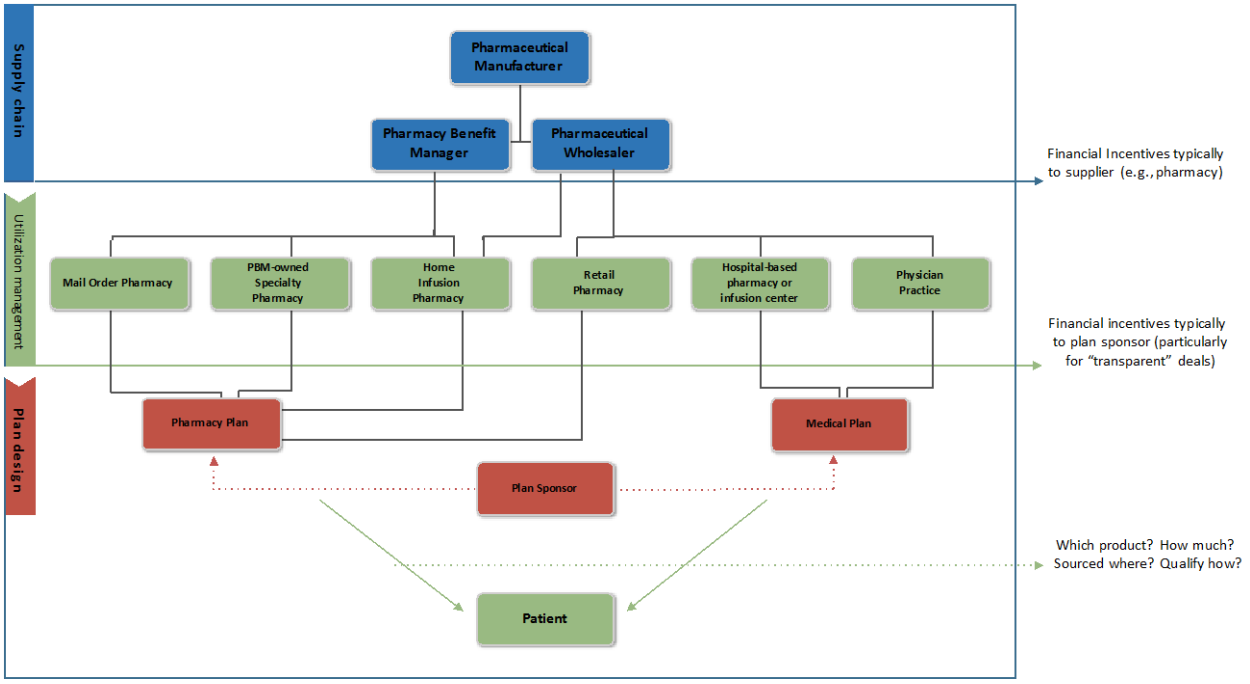
Specialty Pharmaceutical Supply Chain

As depicted in the diagram below, the flow of money through the specialty pharmaceutical supply chain is complex. The drug manufacturer typically distributes the drug through three entities: wholesale distributors, retail specialty pharmacies, and pharmacy benefit managers (PBMs). Manufacturers will

also entertain direct relationships with health care providers, offering substantial incentives to continue "buy and bill" practices where providers buy drugs directly from the manufacturer at a discount and, as

they administer them to patients, bill the insurer and patient at a margin, along with billing for the visit. Manufacturers enter into various contractual arrangements, including discounts and rebates, with all of the entities in the supply chain. Health plans and PBMs can also negotiate directly with manufacturers for discounts and rebates based on their patient volume, overall market share, and formulary placement. If a drug is administered through a specialty pharmacy, the pharmacy receives a payment from the health plan or PBM for the drugs dispensed to plan members based on a reimbursement formula agreed to by the payer and pharmacy. Providers negotiate with health plans and PBMs for payments for the drugs they administer to patients themselves. Finally, depending on how their benefits are structured, consumers will likely share in the costs (e.g. co-payments or co-insurance) either through the medical or pharmacy benefit.

The illustration below shows how specialty products flow through various supply channels, different utilization management strategies, and the benefit plan - pharmacy or medical.



Developed in collaboration with Joey M. Dizenhouse, FSA, MAAA.

Medical Benefits versus Pharmacy Benefits

Specialty pharmaceuticals are typically divided into two groups. There are specialty pharmacy medications that patients administer themselves, and there are specialty medications that require administration by a clinician. This latter category of medications is typically purchased by a health care provider and administered in a medical office or outpatient setting. Whether a drug is self-administered

or clinician-administered usually influences whether it is covered by the medical insurance benefit (typically clinician-administered) or the pharmacy insurance benefit (typically self-administered). Approximately half of all specialty pharmacy spending is funded as a pharmacy benefit, while the other half is under the medical benefit.[10]

Sometimes there are specialty drugs that could be covered either under the medical or the pharmacy benefit. Which one the purchaser should use depends entirely on the specific drug, how each program prices it and manages the care of patients needing that drug. The route that is better for the purchaser to take cannot be generalized; especially when it comes to determining which benefit will more effectively contain costs. This will be a drug-by-drug determination.

Pharmacy utilization management under the medical benefit can be subpar when compared to similar functions under the pharmacy benefit. Ensuring that patients receive the right product in the right setting is not necessarily a core utilization management function offered under the medical benefit. Utilization management requires active monitoring and oversight of prescriptions prescribed for patients and where the patients are referred to receive the treatment or acquire the drug. Specialty programs within pharmacy benefits are constantly evolving to monitor these activities, while the medical benefits may or may not perform these utilization management functions with as much rigor.

Another challenge with utilization management under the medical benefit is that it can complicate the payer-provider relationship. Payers work hard to maintain strong relationships with contracted providers as they need them in their network to be able to offer adequate access and choices to insured members. Providers, in turn, need the insured members to have sufficient patient volume and revenue. Utilization management programs can interfere with both dynamics. For example, a payer may alter the medical benefit, shifting a specialty pharmacy product over to the pharmacy benefit, thereby eliminating its administration by the provider along with the provider's revenue for this service. Providers unhappy with a particular specialty pharmacy management program may then seek to renegotiate the medical contract they have in place with the payer. Under a pharmacy benefit, such disruption is less likely as there is no direct tie to the medical contract and tried and true utilization management can be applied without bringing other contracting dynamics into play.

Whether a drug is attributed to a pharmacy benefit or medical benefit has implications for both the cost and management of the drug for the patient as well. For example, if a drug is attributed to the medical benefit, the medical benefit utilization management and financial out-of-pocket costs apply. In these circumstances, a patient might be responsible for a deductible, co-insurance related to the office visit,

[10] UnitedHealth Center for Health Reform & Modernization. "The Growth of Specialty Pharmacy, Current Trends and Future Opportunities." UnitedHealth Group, Apr. 2014. Web. <http://www.unitedhealthgroup.com/~/media/uhg/pdf/2014/unh-the-growth-of-specialty-pharmacy.ashx>.

co-insurance for the cost of the drug, etc. On the other hand, if a drug is attributed to the pharmacy benefit, the pharmacy benefits utilization management protocols and out-of-pocket costs apply. This might mean a co-pay or co-insurance for the cost of the specialty drug. Considering the extreme cost of specialty drugs, the financial implications can be significant and very different for the patient.

There are three circumstances where the patient experience can differ. First, there can be inconsistent application of the plan benefits to the patient. In some instances and for certain specialty drugs the pharmacy benefits apply, while for other specialty drugs the medical benefits apply. This can be confusing (and frustrating) to the patient who is taking multiple specialty drugs that fall into different benefit categories. Second, the patient can suffer from inconsistent and uncoordinated management due to the application of different protocols across the pharmacy and medical benefits. The first two points are of particular importance to patients with comorbidities. On the pharmacy benefit side, the patient deals primarily with a PBM and pharmacist. For drugs that are administered through the medical benefit, the patient deals with the physician, health plan, PBM, site of administration (e.g. infusion center), etc. (See diagram on page 6 for reference). Ensuring a smooth, positive experience for patients taking multiple medications administered through different benefits is important to the patient's overall satisfaction. Finally, and perhaps most importantly, the patient is likely to hit his or her annual out-of-pocket (OOP) maximum earlier in the plan year if the drug is covered under the medical benefit, rather than the pharmacy benefit. While this might be advantageous to the patient, it can be financially disadvantageous to the purchaser because the patient no longer has incentives to seek the most cost-effective care.

Payers and purchasers are experimenting with different approaches to keep patient incentives aligned both before and after the patient has reached his or her OOP maximum. Payers and purchasers can design benefits to create incentives for patients to use the lowest cost site of care without compromising the quality of their care. In these cases, reduced co-payments or co-insurance amounts can apply to patients receiving care at lower cost sites before a patient reaches his or her OOP maximum. After the patient reaches his or her OOP maximum, payers and purchasers can offer additional incentives to ensure the patient's financial interests remain aligned with that of the purchaser and payer. One way this can be achieved is to offer additional contributions to the patient's health savings account if the patient seeks care at the lowest cost site.

There are no easy answers about whether drugs should be attributed to the medical or pharmacy benefit. As a purchaser, it is important to know that under either benefit there are financial consequences for the patient, but there are also some strategies to counterbalance these financial consequences.

Finally, as we mention above, whether a drug is attributed to a pharmacy or medical benefit also creates challenges for the integration and management of a patient's care. Health plans have implemented strategies between the providers treating their members and the specialty pharmacists that have expertise in medication management. Coordinating the management of the medical and pharmacy benefit gives health plans the ability to track the usage of specialty drugs, and has the potential to lead to better patient care. However, if coordination between managing the medical and pharmacy benefit and care coordination lags, there is less ability to ensure controlled spending, and delivery of the right medicine to the right patient, at the right time and in the right setting.

V. Using Claims Experience to Assess the Opportunity

Purchasers evaluating their specialty pharmacy strategies must examine their own claims data to address priority quality improvement and cost containment needs, both generally and in any specific geographic markets of interest. Claims data analysis allows a purchaser to see spending trends and outliers that can identify areas needing intervention. Resulting interventions might include therapeutic "steps" for certain products, such as having members participate in a program, or try another product, before getting access to the expensive one. Other interventions include targeted formularies to steer utilization to the most appropriate product from a net cost perspective and focused chronic condition management initiatives spanning both the medical and pharmacy programs.

Appendix A provides a list of data to collect and analyze to assess where and under what circumstances a payment reform program or other strategies might have value. This data can be analyzed with the support of a health plan, PBM, or consultant who specializes in pharmacy analysis. Many purchasers who do not yet have high specialty pharmaceutical costs have adopted aggressive strategies as a defense mechanism, since few current employees or dependents would be impacted by the changes. For most purchasers, however, it is only a matter of time before they will need such a strategy and they do take some time to set up. The exposure faced by plan sponsors due to the upcoming 2018 Excise Tax is, alone, cause for concern.

VI. Building a Strategy: Payment Reform Opportunities for Specialty Pharmacy

Developing an effective specialty pharmacy program involves much more than providing access to drugs at a discounted rate. Changing the payment approach for specialty pharmaceuticals has the potential to improve health outcomes, while reducing overall expenditures. We recognize that the following strategies are not used in practice at this time (or are in very limited practice), but as payment reform in

the commercial sector continues to evolve, we encourage purchasers to work with their health plan or PBM, who will then work with providers, to experiment with these strategies.

Bundled Payments

A bundled payment that includes the total cost of care for a particular episode is a potential approach to aligning provider and payer incentives for specialty pharmacy. Under a bundled payment structure, the episode of care, including the cost of the drug, is defined and a price for that episode is set. Under this model, the provider does not directly bill the payer for the drug cost, mitigating the benefit to providers that currently comes from purchasing a drug and then charging payers a higher price for that drug (see reference to "buy and bill" above). A bundled payment strategy is applicable to specialty drugs covered under a purchaser's medical claims. Management of a bundled payment program requires detailed utilization data and willingness on the part of providers to accept financial risk.

UnitedHealthcare implemented and evaluated an episode payment program for oncology care. Under the pilot, United paid participating medical oncologists upfront the margin they would normally make on the drug treatment program for 19 different clinical episodes. This episode payment was frozen until evaluations were complete. The cost of the drug was reimbursed fee for service and the drugs could be changed if new evidence justified the change. Evaluation of the pilot found that the new cancer care payment model resulted in a 34 percent reduction in medical costs. The physicians received a raise equal to about one third of the savings in their next episode payments. The evaluation also found that there was no decrease in quality of care between those patients in the episode payment program vs. those not in the program.[11]

This approach will work best when there is a single entity managing the purchaser's medical and pharmacy benefit. If the pharmacy benefit is managed by a different entity than the medical benefit ("carved out"), it would be critical to define when a certain drug is subject to the bundle versus when it is not. For example, adjunctive therapy to chemotherapy, such as anti-nausea drugs, can be used for other indications and the PBM would not automatically be able to tell if the drug was part of the bundled payment.

[11] Newcomer, Lee, Bruce Gould, Ray Page, Sheila Donelan, and Monica Perkins. "Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model." *Journal of Oncology Practice* (2014): n. pag. *Journal of Oncology Practice*. American Society of Clinical Oncology, 8 July 2014. Web. <http://jop.ascopubs.org/content/early/2014/07/08/JOP.2014.001488.abstract>.

Bundled Payments Paired with Reference Pricing

A reference pricing program can be implemented simultaneously with bundled payment. Reference pricing for specialty pharmacy would establish a standard, allowed price for the prescription and any related administration by a clinician, and would require that health plan members pay any allowed

charges beyond this amount. In this scenario, payers can set a reference price for the treatment that stays the same regardless of the site of service. This would encourage providers to administer the drug in the least expensive site. The price can be based on the drug acquisition costs plus a flat fee for providers, rather than a fee based on a percentage of the drug's cost. These models require that consumers have access to accurate price and quality information so that they can seek out providers meeting or beating the reference price. In addition, purchasers would need to ensure that there are enough providers meeting the reference price to safeguard adequate access to care for their population.

Incentive Payments

Under an incentive payment structure, payers provide a financial incentive to providers to use an equally effective, but more cost-effective therapy, where one exists. Under these models, providers who adhere to evidence-based, recommended treatment plans for the patient's condition would receive a bonus payment. Due to the lack of alternatives for certain specialty drugs, this approach is limited to more mature drug groups with therapeutic equivalents. Incentive structures are frequently used in formulary management to encourage patients to use higher-value drugs.

Non-Payment Policies

A non-payment policy for inappropriate use of specialty pharmaceuticals could encourage adherence to evidence-based medical guidelines for conditions that have them. These policies can remove the incentives for health care providers to offer higher cost treatments, especially where effective, lower cost treatments exist. They can be particularly effective in addressing concerns of over utilization of higher-cost sites of service. By eliminating payment for non-authorized sites of service, these policies discourage providers from recommending medications that require administration in an inpatient setting when there is a self-administered therapeutic equivalent available. This approach can also encourage adherence by providers to clinical guidelines regarding how and when a patient is most likely to benefit from a particular specialty drug. A non-payment policy can support clinical recommendations and direct the higher cost treatments to the population most at need. Under this arrangement, it is important to prohibit a provider's ability to bill patients for the balance related unpaid claims, also known as "balance billing."

Pay for Drug Performance - Provider

This payment or reimbursement strategy works in the following way: a physician or hospital receives higher reimbursement for using a particular specialty medication in situations where the drug is highly likely to be successful. Conversely, the provider receives lower reimbursement for using the same drug in circumstances where it has not been shown to be successful. An example of this approach is a drug used for different cancer types. A specialty drug might have better outcomes or perform better with

one type of cancer, but less well with another. In this case, the reimbursement is tied to greater efficacy. The use of comparative effectiveness data is a key element in implementing this type of innovative payment arrangement. Note: this is a new strategy and based on our review, it has not yet been implemented.

Pay for Drug Performance – Manufacturer or Outcome-Based Contracting
This payment strategy is between the manufacturer and the payer. If a medication is administered and taken correctly and the desired clinical outcome is not achieved, the manufacturer is required contractually to offset some portion of the medical costs associated with the non-performance of the drug. This approach requires a clear medical outcome and data/claims to support reimbursement.

All of these payment approaches are applicable in a variety of care settings. Determining the best strategy will be on a condition- and market-specific basis.

VII. Building a Strategy: Other Opportunities for Specialty Pharmacy

Strategic Formularies
Formularies are common in pharmacy benefits and are becoming more refined with the emergence of specialty drugs. One benefit approach for specialty drugs is to develop a formulary with specialty tiers for drug categories that have therapeutic equivalents or generic biosimilar options. For example, there are multiple manufacturers with similar therapy options for Hepatitis C, such as those therapies released in late 2014 and the two recently approved cholesterol lowering specialty injections. There are a small but growing number of alternatives – as the first to market are able to command high prices, it creates an incentive for competitors to develop their own therapeutically-equivalent drugs.

Additionally, purchasers might consider offering a closed or exclusionary formulary, choosing one of two or more equivalent specialty drugs, to maximize the potential discount available through the manufacturer, when applicable.

Medical Carve Out
In the same vein as a strategic formulary, where only one drug is available on the formulary, purchasers can work with health plans to develop a medical carve-out, where all self-administered or oral specialty drugs will not be attributed to the medical benefit, rather, they will be "carved-out" to the pharmacy benefit for administration by a specialty pharmacy PBM. Such carve-out arrangements provide greater visibility into drug costs and allow for greater steerage to high-value pharmacies, including a set up under which patients obtain their medications from designated pharmacies.

Prior Authorization
Prior authorization by the health plan or PBM for medical services and certain drugs is a utilization management strategy that has been used for some time. Given the increased cost of specialty drugs

administered in a facility or office setting, purchasers should work with health plans and PBMs to require prior authorization for all in-office or facility-based administration of specialty drugs.

Site of Care

Where a specialty drug is administered can drastically change the price the purchaser pays for the drug. Like the prior authorization strategy, purchasers can work with their health plans and PBMs to determine if there is a preferred site of service for a specific set of drugs. If there is, the benefit could be modified so that claims for these defined specialty drugs, when not administered in the preferred site of service, are not paid. But purchasers should also evaluate the prior authorization and medical policy bulletins from their health plans and PBMs to understand members' responsibility if they do not obtain prior authorization. Some health plans, for example, state that the patient member is held without fault if the provider is a network provider and fails to obtain, or disregards, prior authorization for those specialty medications that require it.

Step Therapy Protocols

Like formularies and prior authorization, step therapy protocols have been used for some time in pharmacy benefits. This approach can be applied to specialty drugs as well. Under the protocol, patients would begin therapy for a medical condition with drugs considered first-line (the therapy accepted as the best treatment) for safety and cost-effectiveness, then progressing as necessary to other drugs that may have more side effects, risks to the patient, or are more costly. The step therapy requirements are based on FDA recommendations, nationally recognized treatment guidelines, medical studies, information from the drug manufacturer, and the relative cost of treatment for a condition. Specialty drugs are sometimes excluded from the general step therapy programs for traditional drugs, so purchasers need to ask whether their current step therapy program applies to specialty medications. This approach can be foundational to managing specialty drug costs and not all purchasers currently use it.

Additional Tactical Alternatives

Group Purchasing: For a purchaser, the strategy of combining forces with other purchasers (or group plans) can be an effective way to drive down unit costs. There are many models available around the country offered by consulting firms and entities such as Group Purchasing Organizations (GPOs). A GPO's business model is to aggregate the health care spending across all of the purchasers to use as leverage to negotiate better deals. The rules and terms of these arrangements vary, but ideally, a purchaser should seek out a GPO that:

1. Permits autonomy in design of plans, networks, and clinical programs;
2. Offers support in benefit design and utilization management, where required; and
3. Provides full transparency on fees and compensation arrangements.

Sole Source PBM Services: While specialty pharmacy can be sourced on its own and separately from the rest of the PBM benefit, this can lead to less efficient purchasing and higher unit costs.

Generally speaking, a PBM manages multiple types of products: specialty drugs, retail pharmacy dispensed drugs, mail order drugs, physician or hospital-administered drugs, etc. Using a combined effort to source and deliver these products has the potential for not just obtaining a lower unit cost (similar to the concept of group purchasing above), but also more integrated management of the tools available to control the total amount of spending on pharmaceuticals.

There is an age-old argument when it comes to sourcing strategies: Does one combine multiple purchasing areas (specialty drugs, retail drugs, mail order drugs, etc.) and source the needs to one partner, or is it more effective to use a "best-in-class" approach by sourcing each individual purchasing area? In the case of specialty pharmacy, it is likely more advantageous to consolidate to a single partner and leverage the greatest purchasing power.

VIII. Contracting with Your Health Plan

Purchasers can use **CPR's Model Contract Language** to send the message to health plans regarding priority payment and other reforms. The model contract language will be updated in early 2016 with language specific to specialty pharmacy. The model contract will outline expectations for the health plan to improve the delivery and management of specialty pharmacy, including by implementing significant changes in existing payment structures and methodologies.

IX. Monitoring the Progress and Impact of Your Program

Regardless of the method of implementing a specialty pharmacy management program, all purchasers should evaluate **the impact on** patient outcomes, utilization, cost trends, and costs or savings. Purchasers should seek evaluation results on a semi-annual basis to track progress against expectations. At a minimum, the purchaser should require that the PBM or administrator report the following purchaser-specific information:

1. A comparison of costs by drug by examining both the allowed and billed costs per unit. Note: medical claims will likely be ambiguous regarding units (e.g. milliliters (mL), milligrams (mg), tablet (ea or tab)), and quantity (number of units dispensed).

2. Prescribing patterns of individual physicians or physician practices to the plan's preferred sites of care.
    - Understanding the impact individual physicians or practices have on plan spending can inform future decisions such as covered products, negotiated terms for the covered products, and network design.
3. Use of retail pharmacy versus mail-order pharmacy or other sources for patient acquisition.
    - Key metrics include the patient count, days' supply, cost per day, participation in utilization management strategy.
4. Additional reports, such as PBM utilization management statistics, including:
    - Results of prior authorizations (e.g. number applied, impact on utilization).
    - Number of unique patients where step therapy was applied, use of generics and preferred brand products versus non-preferred products.
    - Compliance measures (e.g. off-label use of individual products, use of "dispense as written" notations from physicians).
    - Impact of utilization management programs and the associated return on investment to the plan.

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Appendix A: Claims Evaluation Checklist

Assemble paid specialty pharmacy medical and pharmacy claims data for the last 3 years

- Claims data should include the complete claims paid and run out – a six-month look back is suggested at a minimum.

Organize data set by patient and by NDC, CPT, J-Codes, and ICD procedure codes to include:

- Dates of services for the procedure: group claims for not less than 90 days following the end date of service field. Example: Discharge date is 1/30/2015; gather all claims for that patient through 4/30/2015.
- Physician identification number and name, as well as all professional services tied to that procedure (often aggregated by date of service).
- Hospital or outpatient facility claims, including MS-DRG classification.
- It can be very helpful to work with an analyst familiar with claims data and merging data sets (e.g. combining medical and pharmacy data, which are often from different data sources and need to be merged into a single file).

Organize the cleaned and grouped data to understand the following (minimum suggested):

- Total number of unique patients with a diagnosis code that can be treated by a specialty pharmaceutical.
- Total number of unique patients treated with a specialty pharmaceutical and amount paid per patient by year.
- Highest cost drug categories and highest cost areas of overall spend (accounting for both prevalence and cost).
- Cost differences by place of service (e.g. hospital, outpatient setting, free-standing facilities, infusion sites, etc.).
- Which drugs are covered under both the pharmacy and medical benefit.
- Cost differences between therapeutically equivalent drugs being used to treat a condition.
- Allowed and billed cost per unit by drug. Note: medical claims will likely be ambiguous regarding units (e.g. milliliters (mL), milligrams (mg), tablet (ea or tab)), and quantity (number of units dispensed).
- Prescribing patterns of individual physicians or physician practices.
- Use of retail pharmacy versus mail-order pharmacy or other settings for patient acquisition.
- Changes in key statistics from last period to current period (to evaluate trends). Note: Must ask for two periods of data. For initial review and analysis, the recommended period to examine is the last two years of data, if available. For ongoing reporting, the recommended time to review is every six months.
- Additional reports, such as PBM utilization management statistics.