

PHARMACY OUTCOME-BASED CONTRACTING

HOW DOES IT WORK AND WHOM DOES IT IMPACT?



OUTCOME-BASED CONTRACTING: A FUNDAMENTAL SHIFT IN CONTRACTING

Outcome-based contracts are a relatively new contracting methodology focused on shifting reimbursement from volume to value (similar to the medical contracting transition from fee-for-service to pay-for-performance, risk/gain share and bundled payments). The contracts are between a health plan and manufacturer where reimbursement is dependent on pre-defined outcome metrics focused on improving patient responses/health. Outcome metrics include patient access values, adherence/compliance improvements, cost-of-care reductions and medical resource utilization increases. Manufacturer drugs are administered to plan members, data is tracked for a determined time frame (historically one to three years) and results identify whether the drug achieved desired results. Rewards or penalties are then collected on top of fixed payments paid at the beginning of the contract. This contracting methodology is typically used when a new, more expensive drug—shown to be more efficacious than existing treatments—enters a therapeutic class as a way for manufacturers to gain formulary coverage for sharing in the financial risk with the plan.

As treatments for certain disease states become more costly, an increasing number of plans are looking towards outcome-based contracting as a vehicle to share risk with the life sciences manufacturers. This trend originated with payers looking to change the financial flow and risk for reimbursement.

Some early examples of outcome-based contracting arrangements include:

- The National Institute of Health and Care Excellence (NICE) in the United Kingdom contracted with Johnson & Johnson for myeloma patients that included a refund for patient relapses.
- CIGNA contracted with Merck in 2009 for brand drugs Januvia and Janumet to lower blood pressure and improve adherence.¹
- CIGNA also contracted with EMD Serono in 2015 for multiple sclerosis (MS) drug Rebif to prevent relapses in MS patients.

From the studies listed above, the CIGNA and Merck outcome-based contracting published a press release in 2010 that showed positive outcomes:¹

- Blood sugar levels improved by more than 5 percent.
- Individuals who participated actively in CIGNA's diabetes support program were more likely to control their blood sugar than those not in the program.
- 87 percent of people taking Merck's Januvia and Janumet took their medications correctly.
- Savings could be as much as \$8,000 per person when medications were taken properly.

As noted above, early results of outcome-based contracting are positive and lead to the potential for significant savings and improved health—a win-win situation.

Why This Change? The Driving Forces

The main driving force behind outcome-based contracting is the rising price of specialty drugs and the need for plans to justify these costs with clinical outcomes that improve member health and potentially avoid other more costly forms of treatment. Globally, payers have identified this as an opportunity to share risk with manufacturers and regulatory agencies; other government institutions are incentivizing the industry to move in this direction. A 2015 Journal of Clinical Pathways article notes that at least 20 documented risk-sharing agreements (RSAs) have been executed in the U.S. and hints that many more may have been contracted confidentially.² Much of the industry, including the “Private Sector Risk-Sharing Agreements in the U.S.: Trends, Barriers and Prospects,” published by the American Journal of Managed Care, expects this number to continue to grow as technology progresses toward the sophistication necessary for outcome-based contracting.³ Some of the specific drivers include:

ACA Incentives: The Affordable Care Act (ACA) implemented new initiatives aimed at improving the quality of care for members. Proposals included penalties for hospital readmissions and value-based purchasing programs. The Centers for Medicare & Medicaid Services (CMS) also set a goal in 2015 that 30 percent of Medicare payments would be tied to an alternative payment model (APM), one of which is outcome-based contracting, and it has already achieved that goal this year.

1. Shearer, L. (2010, October 28). CIGNA and Merck Help Customers Better Manage Diabetes. Retrieved July 11, 2016, from <http://www.fiercehealthcare.com/healthcare/cigna-and-merck-help-customers-better-manage-diabetes>

2. Bastian, A., Dua, D., & Mirzahosseini, S. (2015, September/October). The Use of Risk-Sharing Agreements to Manage Costs, Mitigate Risk, and Improve Value for Pharmaceutical Products. *Journal of Clinical Pathways*. Retrieved from <http://www.journalofclinicalpathways.com/use-risk-sharing-agreements-manage-costs-mitigate-risk-and-improve-value-pharmaceutical-products>

3. Garrison, L. P., Jr, PhD. (2015, September 15). Private Sector Risk-Sharing Agreements in the U.S.: Trends, Barriers and Prospects. *American Journal of Managed Care*, 21(9), 632-640. Retrieved July 11, 2016, from <http://www.ajmc.com/journals/issue/2015/2015-vol21-n9/private-sector-risk-sharing-agreements-in-the-united-states-trends-barriers-and-prospects>

According to a thinc.org article, “Beginning in 2012, Medicare reduced payments to hospitals with higher than expected readmission rates for heart failure, heart attacks and pneumonia. The rate reduction was 1 percent in 2012, 2 percent in 2013 and 3 percent in 2014.” The ACA also allowed CMS to utilize savings from DRG (diagnosis-related group, a classification of hospital cases by a “product” such as an appendectomy) payments to fund a bonus pool that rewards hospitals that perform above average on a variety of performance measures or show significant performance improvement from previous years.⁴ These incentives are driving providers towards plans that have implemented value-based actions like outcome-based contracts.

Drug Validation (Health Plans and Manufacturers):

Generic drug use continues to dominate the industry and therapeutic classes have become more competitive. As a result, brand drugs need to differentiate themselves more than ever through creative partnerships focused on quality of care with risk sharing regarding efficacy. Outcome-based contracting allows manufacturers to enter into transparent arrangements, demonstrating to the industry the advantages of their drugs. Comparative metrics of existing treatments provide members evidence for drug choices and details a clear framework for achievable health gains and reduced side effects from adhering to drug schedules.

Total Cost of Care Reduction: Ultimately, health plans are looking for ways to reduce member costs. Between the state exchange costs greatly exceeding projections, the aging American population, the unhealthy lifestyles of the population, and expensive new medical services/ technologies, plans need to find revenue-saving initiatives while maintaining positive member experiences.

It Sounds Positive but Barriers Exist

Barriers still exist and delay increased usage of outcome-based contracts. Stakeholders across the pharmacy system envision major roadblocks, driving them to choose the status quo rather than undertaking “risky” outcome-based contracts.

Structural Barriers: A fragmented delivery system in the U.S. healthcare system obstructs the ability of stakeholders to implement outcome-based contracts. Accountable care organizations are a step towards consolidation but, as the system currently stands, coordinating data collection, negotiating contracts between payers, pharmacy benefit managers (PBMs), and manufacturers, and internal separations between clinical and pharmacy benefits worry the industry.

Unclear Performance Indicators: Determining performance indicators that providers, manufacturers, and payers all agree properly measure drug effectiveness is a troubling endeavor. Furthermore, differentiating the impact the drug has on the ultimate outcome of members as opposed to supplementary outside factors must be determined. How will stakeholders account for poor medication adherence, modified member lifestyles, unrelated health issues, and “random noise”?

Contracting/Accounting Difficulties: Determining accurate average sales (ASP) prices for drugs utilized in outcome-based contracting requires precise forecasting analytics in an attempt to match future reward/rebate payments. Inaccurate ASP results in impactful reconciliations and can seriously influence stakeholder financials. However, realizing that members may choose to switch plans in the middle of outcome-based contracts and therefore need to be excluded from a future reconciliation complicates this process. Therefore, health plans with shorter member lifecycles (industry average is 2.6 years) may need to avoid outcome-based contracting or solely focus on drugs where effectiveness can be determined in shorter time frames. Using depression as an example: the STAR trail demonstrated that approximately 50 percent of the population does not respond well to current treatments and, for those who do respond, the timeframe to see efficacy is weeks to months and is based upon non-objective scoring metrics such as HAM-D.⁵ Certain disease states may not be candidates for outcome-based contracting.

4. Hastings, D. A., & Lutes, M. E. (2011, October 25). Building ACOs and Outcome-based contracting in the Commercial Market: Provider and Payor Perspectives, for THINC: Taconic Health Information Network and Community. Retrieved July 11, 2016, from <http://www.ebglaw.com/value-based-purchasing-and-accountable-care/news/building-acos-and-outcome-based-contracting-in-the-commercial-market-provider-and-payor-perspectives-for-thinc-taconic-health-information-network-and-community/>

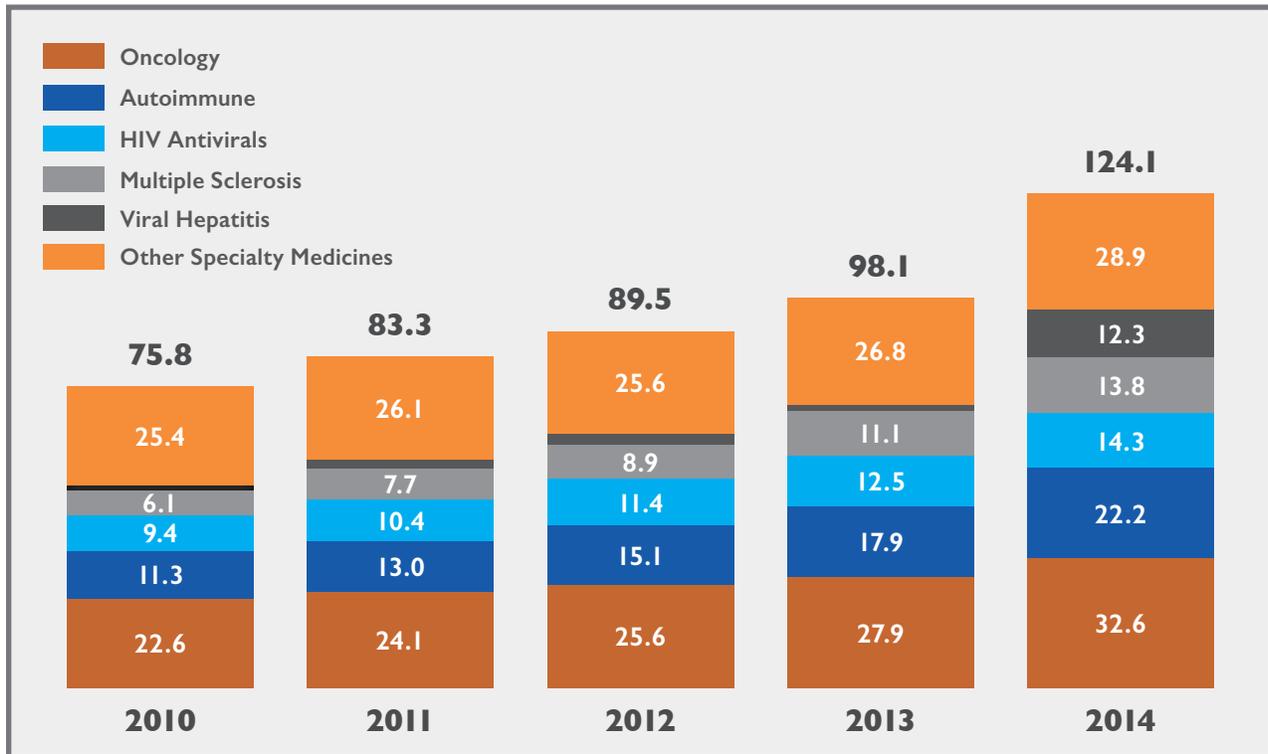
5. Huynh, N. N., & McIntyre, R. S. (2008). What Are the Implications of the STAR*D Trial for Primary Care? *Prim. Care Companion J. Clin. Psychiatry The Primary Care Companion to The Journal of Clinical Psychiatry*, 10(02), 91-96. doi:10.4088/pcc.v10n0201

CURRENT STATE OF PHARMACY FINANCIALS

Pharmacy drug prices continue to skyrocket and key stakeholders are unsure of how to rectify the issue. Free market ideologies that impact U.S. drug pricing result in a government with a hands-off approach for setting costs, driving the average price of new specialty drugs to exceed the median U.S. annual income. PhRMA (the industry's policing arm) generally monitors manufacturers to ensure that average price increases net out to around 3 percent, or close to CPI. There are exceptions but the industry does try to reign in price gouging. In the U.S., drugs are priced significantly higher than elsewhere due to the fact that most countries (EU, Japan) have price controls and formulas for calculating the selling price. While the notion

of new drug development being impacted by limiting costs is valid, the result on the rest of the pharmacy ecosystem is becoming too much to handle. Drugs are priced in the U.S. at extreme multiples when compared to more highly regulated countries (i.e., Lipitor costs 15 times more than in New Zealand; Sovaldi costs 90 times more than in Egypt). As a result, health plans are brainstorming new ways to reduce costs, such as denying treatment to members, limiting access by only offering specialty drugs in high copay tiers, and limiting prescriptions to members in advanced stages of the disease. This causes costs to continue to rise and beneficial drugs to go unused.

SPENDING ON SPECIALTY MEDICINES US\$Bn



Source: IMS Health, National Sales Perspectives, Dec 2014

The tense relationship this causes between health plans and manufacturers hurts drug development and weakens the quality of care available to members. To continue innovative pharmacy growth, stakeholders need to determine opportunities beneficial to all parties. One direction the industry is trending is entering into outcome-based contracting.

WHO ARE THE KEY PLAYERS?

Major stakeholders of outcome-based contracting include the pharmacy manufacturers, PBM, and payers including health plans. Each stakeholder is impacted differently in relation to benefits, barriers and provider/member impacts.

Manufacturers

Manufacturers assume the most risk in outcome-based contracting but are also afforded new opportunities for their drugs. Potential risks associated with outcome-based contracting include:

- Loss of revenue
- Loss of brand reputation in failing scenarios
- Repayments or balloon payments to payers for outcomes failures
- Less advantageous formulary placement
- Outright exclusion when outcomes not realized

Due to these risks, pharmaceutical manufacturers must agree to publish outcomes regardless of trial success.

The benefits for manufacturers is an increased ability to quantify advantages and further differentiate proprietary drugs from generics/competitors. The necessity for member adherence increases drug usage, resulting in higher upfront revenue from distribution. This revenue can be redistributed into research and development for other drugs. Since outcomes require a longer contracting period to measure outcomes, manufacturers get security from extended contracts.

With the rising price of pharmaceuticals and the industry trending towards these types of arrangements, Optimty recommends manufacturers consider entering into these types of arrangements with payers. Manufacturers that have a newer, more efficacious drug entering an existing class with competition should use this as part of the strategy to gain broader formulary coverage across the market.

Pharmacy Benefit Managers (PBMs)

Pharmacy benefit managers operate as the middle-man in the pharmacy distribution and reimbursement system connecting health plans and manufacturers. In this capacity, PBMs will have unique roles and responsibilities

when transitioning into outcome-based contracting models. PBMs will be required to negotiate contracts and determine appropriate reward metrics with drug manufacturers. This can prove difficult since the majority of manufacturers have not participated in these value-based engagements. PBMs will be required to actively promote patient care management activities which help to measure drug outcomes. This new core functionality requirement may necessitate a redesigning of departmental roles and responsibilities with costly associated training and onboarding.

PBMs also see unique opportunities with this new model. The complexities involved in outcome-based contracting solidifies a health plan's needs for PBMs. PBMs will act as the source of truth for pharmacy claims data throughout measurement activities and will develop industry-leading operational capabilities in data and analytics functions. Negotiating and executing outcome-based contracts with manufacturers provides a reputational advantage that can be leveraged when trying to contract with new plans.

Creating expertise in this area will help validate PBMs as a necessary part of the pharmacy process instead of a traditional "middle-man" engaging in "pass-through pricing". As the healthcare industry continues to move towards consolidation, this will be a valuable ideological shift for PBMs to impress on other stakeholders within the distribution process. It will bring increased value to their clients and continue to show that PBMs are an essential part of creating new financial arrangements that adapt to market changes and develop enhanced ways for payers and pharmaceutical companies to conduct business.

Payers

Health plans, similar to drug manufacturers, have financial, reputational, and operational risks associated with transitioning to outcome-based contracting. Contrary to popular belief, payment to manufacturers for successfully hitting metrics does not have a negative financial impact. The increased payment to manufacturers is offset by the decreased medical costs after improving a member's health. On the other hand,

failing outcome-based contracting scenarios can potentially cause a loss of membership, which significantly impacts financials. Members faced with a formulary that includes a drug proven to be ineffective will begin searching for other plan options. Health plans will also need to devote resources to work with providers and PBMs to incentivize data collection and determine appropriate populations/ drugs for pilots. Data and analytics departments will require enough sophistication to aggregate medical data housed by the plan and determine outcome success for piloted drugs.

The plan's main influencer towards transitioning to outcome-based contracting is the opportunity to better tie drug prices to outcomes. For too long, manufacturers determined the price of their drugs by providing qualitative and some quantitative data on effectiveness from clinical trials. A health plan's ability to take ownership of this function and drive the market in the future is an opportunity worth seizing.

CONCLUSION

Optimty sees value-based contracting and, in the pharmacy area, outcome-based contracting, becoming more prevalent to counteract rising prices in healthcare and pharmaceuticals. Our team has extensive experience across the spectrum of players: life sciences manufacturers, payers, and PBMs. Bringing our understanding of the evolving financial arrangements between these players, clinical expertise, and analytics experts, we can help structure these agreements so they hold each party accountable for successful and desired outcomes and, ultimately, an improved patient experience while reducing overall costs. This approach brings a cross-section of our business, clinical, and analytics teams and typically consist of three phases:

Planning

Develop a set of criteria that determine therapies and drugs that are candidates for outcome-based contracting. This process is conducted through collaboration across the healthcare spectrum (payers, PBMs, and life sciences manufacturers), and the clinical, operations, business, and analytics experts to determine which drugs fit best into the outcome-based contracting model. The typical inputs include price point, length of treatment, dosing regimen, clinical outcome measurements, competition, and time on market

amongst others. Once an appropriate modality is identified, several different financial outcomes can be modeled to determine the impact of the contract methodology on financial outcomes. This exercise can be conducted for payers and PBMs across the entire pharmacy spend and at the life sciences manufacturer across the entire book of assets or for a specific product. At the end of the planning phase, the product(s) that best fit this model can be considered for outcome-based contracting.

Contracting

Once the recommended list of drugs is agreed upon, the parties can identify clinical measures, outcomes, and other key performance indicators as variables. Through a collaborative effort, the payer and life sciences manufacturer can begin with a very broad list of measurements then narrow the focus through iterations and analytics to identify the specific metrics and measures that are most critical and impactful with respect to outcomes and overall cost. This information and background can then be utilized in the partnership between the payer, PBM, and life sciences manufacturer. This information can inform the negotiations and modeling of the impact of different scenarios and outcomes to show the benefits and risks of different arrangements. Throughout the process, we can also determine the measurements that can be tracked and reported based on existing operational capabilities and new capabilities that can be put in place.

Outcomes Tracking

Once the contracting is complete, it is important to design and implement the analytics needed to properly track and report the outcomes. In addition to core analytical tracking, each party should provide various alternative scenarios for forecasting purposes, determining payments, penalties, and other assessments over the life of the contract. This ongoing analytical tracking of key metrics can also be used to make increasingly more informed decisions in future outcome-based contracting arrangements with other life sciences manufacturers or payers.

ABOUT OPTIMITY ADVISORS

Optim�ity Advisors is a rapidly growing, multi-industry strategy, operations, and information technology advisory firm with multiple locations throughout the United States, United Kingdom and Europe. We specialize in the critical set of services that sit between high-level strategy and delivery and execution. We provide a strategic outlook through proven methodology, knowledge, and instinct, helping to craft an actionable future vision that aligns with your long-term goals and objectives. We bring an end-to-end industry understanding to help you rise above the day-to-day, focus on the opportunities ahead, and align your organization for success.

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