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Managing Medicaid Spend through Supplemental Rebates

Riparian White Paper

For:
Clients and Friends of Riparian, LLC

Leadership

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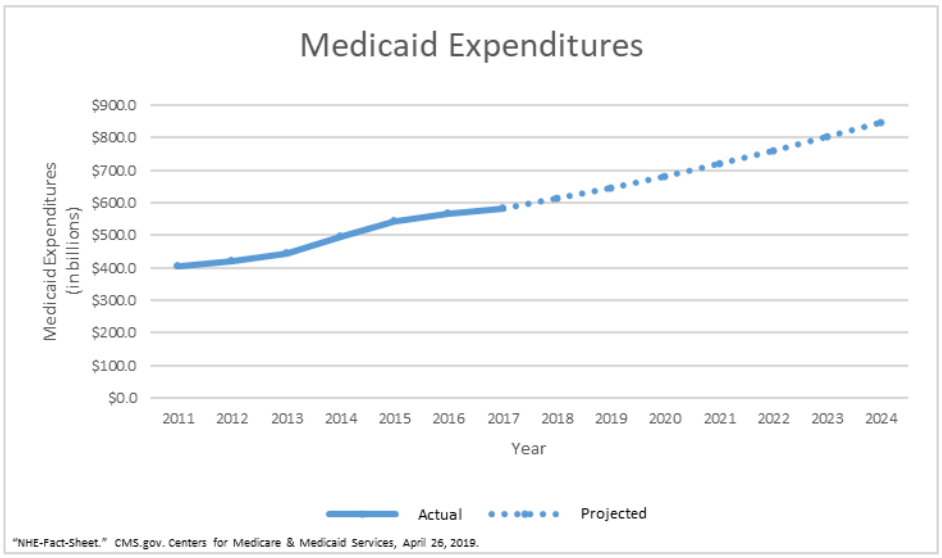
1.0 Overview

Medicaid expenditures have increased significantly over the last decade and states are looking for novel approaches to help control costs while maintaining access to drugs. In 2017, Medicaid spending was $581.9 billion, an increase of 2.9% from 2016 and 43% since 2011.[i] CMS projects that average annual spending will continue to grow by 5.5% per year from 2018 through 2027.[i] The cost increases have correlated to the rise of specialty drugs and are expected to increase even further as gene therapies and orphan drugs continue to enter the market.



Gene therapies are expected to become more prevalent as technology and research advance. Based on current therapies that have been released, these treatments can be expected to cost between $1-$2 million per patient.[ii] With estimates of 25 – 30 million Americans having a rare genetic disorder,[ii] there is a potential for significant budget impacts to the health care system. In addition, with the unique mechanism of action for each therapy, it can be difficult to capture the long-term safety and efficacy results from typical clinical trial periods[ii] which adds additional risk for payers with limited budgets, such as Medicaid.

Due to these high costs and uncertain long-term efficacy, it is likely state Medicaid programs will have to restrict access through prior authorizations, step therapies, and other methods as a cost and risk saving measure. There have been examples of this with specialty drugs, such as Medicaid programs restricting the use of certain Hepatitis C drugs until patients' fibrosis scores have worsened[iii] or step therapies requiring use of older drugs to fail before taking newer and more expensive drugs.[iv] These types of restrictions significantly limit access to therapies and potential cures for Medicaid populations.

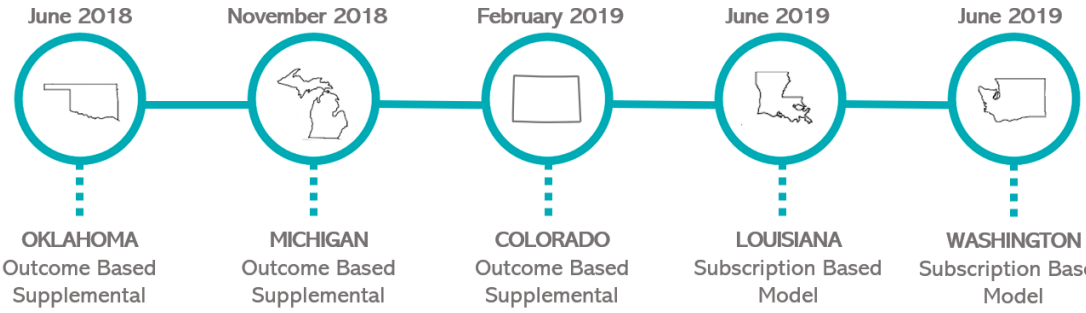
2.0 Medicaid and Legislative Response

In response to these rising costs, uncertain risks, and restricted access, state Medicaid programs and Congress have been looking for strategies to stabilize budgets and expand access to medication. Since 2018, several state Medicaid programs have begun looking into alternative payment models and CMS has approved several state plan amendments ("SPAs") for risk-sharing value-based contracting to be allowed. These contract terms fall primarily under two categories: outcomes based contracting and subscription based contracting. Outcomes based contracts allow states to contract supplemental rebates based on efficacy or similar performance metrics which is ideal for expensive cutting-edge therapies. Subscription based contracts allow states to spread a fixed dollar amount for drug utilization over a predetermined length of time which provides states with predictable costs.

More recently, the Prescription Drug Pricing Reduction Act of 2019, which was introduced into the Senate on July 23, 2019, also includes a provision setting guidelines for and expediting the implementation of risk-sharing value-based contracting in Medicaid.[v] Section 208 of the bill includes a provision where states can negotiate risk-sharing value-based contracts for gene therapies for "treatment of a serious or life-threatening disease or condition, [if it] is expected to cure or reduce the symptoms of the disease after not more than three administrations."[vi] This provision, if passed, proactively provides a way for state Medicaid programs to enter risk-sharing contracts with manufacturers.

3.0 Risk-Sharing Contracting Strategies

CMS APROVALS OF VALUE BASED AND RISK SHARING CONTRACTS



Outcomes Based Contracts

Outcomes based contracts are a type of risk-sharing contract where a part of the rebate owed to the payer, which in this is case are the states, is "tied to future measures of clinical or intermediate endpoints ultimately related to patient quality or quantity of life."[vii] The manufacturer and the payer define the metric that will be tracked and the terms of the rebate associated. Generally, the payer is responsible for tracking the metric and providing the results to the manufacturer. Based on these results, the manufacturer may have to pay additional rebates based on the reported utilization. In some cases, this could result in the manufacturer reimbursing 100% of drug spend to Medicaid due to failed therapy.

The primary advantage of this type of contracting is that it could potentially prevent Medicaid from expending resources on drugs or gene therapies where clinical trials were performed on a highly selective population but is not as effective in a real population,[viii] or the long term success of certain therapies are not captured in clinical trials. As such, outcomes based contracting can act as a safeguard when expanding access to a drug or therapy by sharing the risk and cost of unsuccessful treatment courses with the manufacturer.

The most difficult part of administering outcomes based terms is choosing the outcome to tie the rebate to and collecting the necessary data. While the outcome that is tracked should ideally be tied to the efficacy of a drug, the data needed might not be easily accessible or available within the timeframe of the contract. Therefore, in many cases, a secondary outcome is tracked. For example, for oncology drugs, tumor shrinkage rates are used as a measure instead of the more ideal cancer survival rates.[viii]

In June 2018, Oklahoma was the first to receive CMS approval for an outcomes based contract and a Best Price waiver, which would ensure additional rebates paid by manufacturers would not impact their Best Price.[ix] They also went on to contract outcomes based terms with manufacturers within the past year.[x] Michigan would follow and receive CMS approval in November 2018[xi] and Colorado received approval in February 2019.[xii]

Subscription Based Contracts

Subscription based models are a more recent type of contract where the state pays a fixed amount per year for a supply of the contracted drug.[xiii] In this scenario, the state contracts directly with a manufacturer to cap total costs over a length of time regardless of utilization level. Louisiana is one state to employ a subscription based contracting model such that the contract leverages a supplemental rebate to the manufacturer in order to prevent triggering Medicaid best price regulations.[xiv]

The advantage of this type of contracting is that Medicaid programs can expand access to drugs and therapies to their patient population with reduced or no restrictions. In addition, state budgets can be stabilized with predictable expenses for high cost drugs and therapies. Currently, only Hepatitis C cures are currently contracted under these subscription based terms. This type of contracting appears best suited for cures where the initial years of the subscription see very high utilization of a drug or therapy and taper off in the later years as the patient population is cured. Under this scenario, the manufacturer may not recoup their costs until these latter years.

In June 2019, Louisiana and Washington both received CMS approval for their respective SPAs allowing them to enter into subscription based agreements with

manufacturers.[xv] [xvi] Louisiana contracted with Asegua Therapeutics, a subsidiary of Gilead Sciences, for Hepatitis C therapies.[xvii] Washington contracted with AbbVie for Hepatitis C therapies.[xviii]

RISK SHARING CONTRACTS ENACTED

State	Manufacturer	Therapy	Contract Strategy	Agreement Date*
Oklahoma	Alkermes	Injectable Antipsychotic	Outcomes Based	July 2018
Oklahoma	Melinta	IV Antibiotic	Outcomes Based	September 2018
Oklahoma	Eisai	Epilepsy	Outcomes Based	October 2018
Oklahoma	Janssen (J&J)	Injectable Antipsychotic	Outcomes Based	December 2018
Louisiana	Asegua (Gilead Sciences)	Hepatitis C Cure	Subscription Based	June 2019
Washington	Abbvie	Hepatitis C Cure	Subscription Based	July 2019

*Based on publicly available information as of 9/12/2019 [xvii] [xviii] [xix] [xx] [xxi]

4.0 Manufacturer Considerations

There is ambiguity over how states and manufacturers operationalize these types of risk-sharing agreements. Often times there is a disconnect between those developing the contractual terms and the functional contract administrative process. This results in the inability to accurately administer the contracts, as well as track contract performance. Coordination between the functional area developing and executing the contract and the functional area responsible for administrating the agreements is essential, and upfront planning when negotiating the contact terms can mitigate the risk of revenue leakage and poor contract performance in the end.

Some contract administration challenges manufacturers may consider when negotiating these agreements include:

1. Align contract performance terms to relevant data available from States and other third parties, and incorporate the data submissions as part of the terms of the agreement;

2. Perform financial impact on government and commercial contracts and adjust Gross-To-Net forecast models to account for varying reimbursement/ payment scenarios;
3. Establish a clear understanding of the monthly/quarterly/annual contract administration process in place to measure contract performance and compliance;
4. Develop and implement procedures to assess the accuracy, completeness and validity of the data being used to administer the agreement. This could include exercising contract audit clauses or verifying through third party data sources;
5. Maintain periodic (quarterly/semi-annual/annual) analysis and procedures designed to measure the contract's actual to forecasted performance. These processes should activate contractual termination clauses and/or amendment to the original contract terms to minimize losses timely.

Understanding that not all contract risk can be completely mitigated, manufacturers should be incorporating input from various functional areas (contract administration (both government and commercial), IT, finance, legal, supply chain, etc.) to assist with identifying, developing and implementing revenue risk mitigation plans before executing these agreements. In addition, once a contract is executed it should be continually evaluated at all levels during the contract term to ensure this is meeting the expectations of both the Medicaid State Agency and the manufacturer.

References

[i] "NHE-Fact-Sheet." CMS.gov. Centers for Medicare & Medicaid Services, April 26, 2019. https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nhe-fact-sheet.html

[ii] Hampson, Grace, Adrian Towse, Steven D Pearson, William B Dreitlein, and Chris Henshall. "Gene Therapy: Evidence, Value and Affordability in the US Health Care System." Journal of Comparative Effectiveness Research 7, no. 1 (November 16, 2017): 15–28. https://doi.org/10.2217/cer-2017-0068

[iii] Kim, Morris M, and Keanan M McGonigle. "Restricted Access and Delays to HCV Treatment Among Medicaid Patients in Louisiana." Journal of Health Disparities Research and Practice 12, no. 1 (2019). https://digitalscholarship.unlv.edu/jhdrp/vol12/iss1/8

[iv] Barlas, Stephen. "States Try to Control Medicaid Pharmaceutical Costs: Numerous, Diverse Cost Pressures Force Myriad Reform Efforts." Pharmacy and Therapeutics 40, no. 4 (April 2015): 260–62. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4378518/

[v] "Grassley, Wyden Introduce Major Prescription Drug Pricing Reform to Lower Costs for Americans." United States Senate Committee On Finance, July 23, 2019. https://www.finance.senate.gov/chairmans-news/grassley-wyden-introduce-major-prescription-drug-pricing-reform-to-lower-costs-for-americans

[vi] "Description of the Chairman's Mark The Prescription Drug Pricing Reduction Act (PDPRA) of 2019." Description of the Chairman's Mark The Prescription Drug Pricing Reduction Act (PDPRA) of 2019. Senate Committee on Finance, July 23, 2019. https://www.finance.senate.gov/imo/media/doc/FINAL%20Description%20of%20the%20Chairman's%20Mark%20for%20the%20Prescription%20Drug%20Pricing%20Reduction%20Act%20of%202019.pdf

[vii] Carlson, Josh J., Sean D. Sullivan, Louis P. Garrison, Peter J. Neumann, and David L. Veenstra. "Linking Payment to Health Outcomes: A Taxonomy and Examination of Performance-Based Reimbursement Schemes between Healthcare Payers and Manufacturers." Health Policy 96, no. 3 (March 11, 2010): 179–90. https://pdfs.semanticscholar.org/a51b/26afc64147f9cb01cc5580b87fe12b9da362.pdf

[viii] Seeley, Elizabeth, and Aaron S Kesselheim. "Outcomes-Based Pharmaceutical Contracts: An Answer to High U.S. Drug Spending?" Outcomes-Based Pharmaceutical Contracts: An Answer to High U.S. Drug Spending? The Commonwealth Fund, September 2017. https://pdfs.semanticscholar.org/591a/b421f7dfd318d51d05408d4b51313efdc4bd.pdf

[ix] "CMS Approves State Proposal to Advance Specific Medicaid Value-Based Arrangements with Drug Makers." CMS. Centers for Medicare & Medicaid Services, June 27, 2018. https://www.cms.gov/newsroom/press-releases/cms-approves-state-proposal-advance-specific-medicaid-value-based-arrangements-drug-makers

[x] Reck, Jennifer Cothran, Burl Cothran Beasley, Terry Cothran Knoth, and Russell Cothran undefined. "Medicaid Alternative Payment Models for Prescription Drugs: Do They Add Value for States?" National Academy For State Health Policy. December 12, 2018. https://nashp.org/wp-content/uploads/2018/11/NASHP-APM-Webinar-Slides-12.12.18.pdf

[xi] "MI-18-0009 Outcomes-Based Contract Arrangements with Drug Manufacturers." MI-18-0009 Outcomes-Based Contract Arrangements with Drug Manufacturers. Medicaid.gov, November 14, 2018. https://www.medicaid.gov/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/MI/MI-18-0009.pdf

[xii] "CMS Approves Colorado Medicaid Plan for Value-Based Pharmaceutical Contracts." Colorado Department of Health Care Policy and Financing, February 26, 2019. https://www.colorado.gov/pacific/hcpf/news/cms-approves-colorado-medicaid-plan-value-based-pharmaceutical-contracts

[xiii] "Solicitation for Offers for Pharmaceutical Manufacturer(s) to Enter Into Contract Negotiations to Implement Hepatitis C Subscription Model." Louisiana Department of Health, January 10, 2019. http://ldh.la.gov/assets/oph/SFO/LDH_Hep_C_SFO.pdf

[xiv] Dunn, Andrew. "Unblinded: Rebekah Gee's Drug Pricing Experiment in Louisiana." BioPharma Dive, August 28, 2019. https://www.biopharmadive.com/news/unblinded-rebekah-gee-drug-pricing-experiment-louisiana/559543/

[xv] "CMS Approves Louisiana State Plan Amendment for Supplemental Rebate Agreements Using a Modified Subscription Model for Hepatitis C Therapies in Medicaid." CMS, June 26, 2019. https://www.cms.gov/newsroom/press-releases/cms-approves-louisiana-state-plan-amendment-supplemental-rebate-agreements-using-modified

[xvi] "CMS Approves Washington State Plan Amendment Proposal to Allow Supplemental Rebates Involving a 'Subscription' Model for Prescription Drug Payment in Medicaid." CMS, June 12, 2019. https://www.cms.gov/newsroom/press-releases/cms-approves-washington-state-plan-amendment-proposal-allow-supplemental-rebates-involving

[xvii] "Louisiana Launches Hepatitis C Innovative Payment Model with Asegua Therapeutics, Aiming to Eliminate the Disease." Louisiana Office of the Governor, June 26, 2019. http://gov.louisiana.gov/index.cfm/newsroom/detail/2031

[xviii] "HCA Finalizes Contract with AbbVie to Eliminate HCV in Washington State." Washington State Health Care Authority, July 1, 2019. https://www.hca.wa.gov/about-hca/hca-finalizes-contract-abbvie-eliminate-hcv-washington-state

[xix] "Oklahoma Signs the Nation's First State Medicaid Value-Based Contracts for Rx Drugs." NASHP. National Academy for State Health Policy, September 25, 2018. https://nashp.org/oklahoma-signs-first-medicaid-value-based-contracts-for-rx-drugs/

[xx] "Eisai and Oklahoma Health Care Authority Enter Value-Based Agreement for FYCOMPA." Press Releases. Eisai Co. Ltd, October 24, 2018. http://eisai.mediaroom.com/2018-10-24-Eisai-and-Oklahoma-Health-Care-Authority-Enter-Value-Based-Agreement-for-FYCOMPA

[xxi] "Janssen Signs Results-Based Contract with Oklahoma Health Care Authority (OHCA) for Its Long-Acting Injectable Schizophrenia Medicines." Janssen Pharmaceuticals, Inc., December 13, 2018. https://www.janssen.com/janssen-signs-results-based-contract-oklahoma-health-care-authority-ohca-its-long-acting-injectable

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